

Williams, Letise

From: (b)(6)
Sent: Wednesday, September 08, 2021 4:28 PM
To: Williams, Letise
Subject: [EXTERNAL] 10/6 Patient Engagement Advisory Committee Meeting

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I would like to submit the following statement for consideration at the meeting regarding the Class 1 recalls for the Emblem S-ICD

I was shocked that there was no direct patient communication from Boston Scientific (BS) regarding the battery and lead recalls. In my opinion this is completely unacceptable and BS should be required to directly contact patients when things like this occur and not leave it to the doctors, who as I and others experienced, may or may not do the appropriate patient outreach. I found it pathetic that BS posted patient communications regarding the recalls on their website so they could claim they notified us
guess it is my responsibility to periodically check for recalls/issues and then go look them up on the BS website???

Individuals are contacted directly for much more minor recalls that take place in cars and other products, so why wouldn't we be told directly about an issue with a device implanted in our bodies. When I contacted BS, they claimed that they may not have the complete and accurate contact info for patients. This should not be an excuse - they should be required to try. Plus, I was recently sent a new 4G cell adapter for my Latitude communication device from BS without asking for one/knowing it should be upgraded, so if they can contact us about that, why not a major issue like a Class 1 recall? Thank you

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