Williams, Letise

From: Jake Benowitz <Jake.Benowitz3@bd.com>
Sent: Thursday, November 08, 2018 4:44 PM
To: Williams, Letise
Subject: FDA Patient Engagement Advisory Committee

Letise Williams,

My sincerest apologies for the late email. I have now been confirmed to attend the Patient Engagement Advisory Committee meeting next week in Gaithersburg. I see that the deadline to submit questions/comments to the committee is October 23. Would there be any possibility to allow for me to submit the following questions below:

1. **What is the Agency's opinion on medical device companies using data from nontraditional sources such as chart reviews from a single center, case studies, and social media in supporting a claim?**
2. **If a device is does not specifically have a certain clinical outcome in its label, can the manufacturer still speak about the general clinical, humanistic and economic burden of a disease or condition that the device is used in in the introduction section of HCEI materials?**
3. **How does the Agency plan to vet feedback collected through online sources (i.e. social media, patient blogs, etc.)?**

I would be very grateful. Look forward to next week.

Best,

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