MEDTECH INSIGHT
CITELINE COMMERCIAL

11 Apr 2023 | **News**

Expert: FDA's Highly Anticipated PCCP Guidance Isn't Anything Too 'Surprising'

by Hannah Daniel

The FDA's highly anticipated predetermined chance control plan (PCCP) guidance document is pretty much what the industry expected, Sidley Austin partner Deeona Gaskin told *Medtech Insight*.

Since 2019, manufacturers of medical devices with artificial intelligence and machine learning capabilities have been awaiting official guidance on submitting post-market changes to the US Food and Drug Administration.

When the Food and Drug Omnibus Reform Act of 2022 Act passed at the end of December, which gave the FDA the ability to approve Pre-Determined Change Control Plans (PCCP) as part of AI/ML medtech devices premarket submissions, industry members were pleased. The guidance, *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions)* was released on 3 April. (Also see "*Medtech Connect Episode 3: A Deep Dive Into The FDA's Cyber Reforms*" - Medtech Insight, 6 Mar, 2023.)
"I think [the guidance] was highly anticipated, and the speed at which FDA issued a draft… is great, given that FDORA passed just a couple of months ago," Deeona Gaskin, partner in Sidley Austin's Food, Drug and Medical Device group, told *Medtech Insight* in an interview.

However, the original proposal, titled *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device (SaMD)*, was issued in July 2019, and industry members have been waiting for concrete details since. (Also see "*A Brave New World: Regulatory Flexibility Key To AI Development, Stakeholders Say*" - Medtech Insight, 29 Jul, 2019.)

The Elements Of The PCCP

The approach taken by FDA is not too "surprising" given the current regulatory framework and proposals that previously articulated by the agency, Gaskin said.

PCCPs describe changes that a company plans to make post-market to "how the modifications will be assessed," the FDA wrote in the *guidance*.

DEEONA GASKIN, PARTNER IN SIDLEY'S FOOD, DRUG AND MEDICAL DEVICE GROUP

Eric Henry, senior quality systems and compliance advisor in the FDA and Life Sciences practices of at King & Spalding, outlined the three components of a PCCP in their *report*.

First, there is the modification list, which is an itemized list of each individual proposed modification, a rationale behind the change and potential labeling changes caused by the modification.

Secondly, the PCCP must include the modification protocol, which should detail how the data from the proposed modification will be collected, stored and used; how the ML software will be retrained; the updated procedures associated and how the performance of the updated device will be evaluated.

Finally, there's the impact assessment, which the King & Spalding report authors say is "unclear," due to its ambiguous relationship with a Benefit-Risk Determination, a required report under safety risk management.

The five pieces of the impact assessment include: comparison of the device before and after modification, discussion of benefits and risks of each modification, discussion of how the modifications are necessary to the safety and effectiveness of the device, how the modifications affect each other, and the holistic impact of the modifications on the device.

The Road Ahead: Potential Challenges And Opportunities

Predicting which changes will be needed post-market will be a challenge for companies, but that isn't new. Gaskin pointed out the diverse expertise needed to determine what the modifications will be and the data necessary to support them.

However, with the agency's Q-submission program, companies can go to the agency earlier in the process and "[reduce] some of that uncertainty," Gaskin said.

They can also get a sense for what the FDA "might consider very minor changes that don't even require PCCP," she explained.

Still, there's a tension between wanting to create a comprehensive PCCP to increase the speed of

post-market changes—with the desire to hit the market quickly.

"It's going to be a balancing act," Gaskin said.

Clarification Still Needed

No guidance is perfect, and Henry and his colleagues are still concerned about some of the uncertainties in the draft, including the FDA's stance on adaptive learning.

"It may be that FDA intends to be support of adaptive learning within the context of the PCCP Draft Guidance," they write, but also "encourage firms… to review the PCCP Draft Guidance carefully and consider submitting comments to FDA seeking clarity regarding the use of adaptive learning."

Comments are open under the docket *No. FDA-2022-D-2628* by 3 June.

Regardless, the "the FDA's draft guidance constitutes [one of the] the most rigorous treatment of regulating AI/ML-enabled medical devices globally," Henry and his colleagues wrote.

"Overall, I've heard positive feedback. I think most people are excited about the potential… to be able to implement innovations much more quickly," Gaskin said.