MoFo Life Sciences: Three Key Takeaways from FDLI's Panel Discussion on FDA's Digital Health Center of Excellence And Working With The FDA In The Digital Health Space

By: Stacy Cline Amin and Rachel Park

FDLI hosted a virtual conference November 9-10, 2021, titled Digital Health Technology and Regulation During COVID-19 and Beyond. One of the keynote events was the panel on **"FDA's Digital Health Center of Excellence: Working with the FDA on Digital Health."** The panel featured Bakul Patel - Director of CDRH Digital Health Center of Excellence, Zachary Henderson - Head of Legal at Levels Health, and Diane Johnson - Senior Director of Strategic Regulatory, MD&D at Johnson & Johnson. Shelby Buettner, Principal Legal Counsel at Medtronic, moderated the panel discussion.

Below are three key takeaways from the panel discussion:

1. **Intentionality of Functionality.** This is a key concept in the development of digital health products. Panelists discussed the importance of intentionality in creating and developing products in the digital health space, and the need to understand how the inclusion of or change to some functionalities may impact the level of regulatory oversight. Bakul Patel, Director of the Digital Health Center of Excellence, emphasized the importance of breaking down and parsing out the different functionalities of a digital health software product, especially in communications with FDA, to effectively evaluate if and how the product may fall within FDA's regulatory purview.

2. **Early Communications.** Panelists discussed how much information should be provided to FDA in early communications and what level of detail is actually helpful in early stages. Bakul Patel noted that manufacturers should strike a balance, providing more than just an idea but not too much information. Ideally, FDA would like companies to read the applicable FDA guidance and come to FDA with specific questions about how the guidance applies to them.

3. **Development of Guidances.** FDA has announced its intention to publish guidance on marketing submission recommendations for change control plans for AI/ML device software function in 2022. In addition, FDA's final report on the Digital Health Software Precertification Pilot Program is expected to be published soon outlining key learnings from the pilot. Examples in FDA guidance have great utility and FDA is continuing to figure out ways to craft helpful examples that provide enough detail without losing applicability across various stakeholders. FDA recognizes the usefulness of examples in guidance documents and notes that interactions with and feedback from industry stakeholders will be essential in continuing to provide detailed and meaningful guidance and examples for industry.

Morrison & Foerster's Stacy Cline Amin served on the planning committee for this conference. For questions on any of the topics discussed, please contact the authors or a member of MoFo's FDA Regulatory + Compliance practice.