FDA Regulation of mHealth Updates

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At the Food Drug and Law Institute’s annual conference on April 21, 2015, Bakul Patel, Associate Director for Digital Health, Office of Center Director, Center for Devices and Radiological Health (CDRH), held a discussion of “FDA Regulation of Mobile Health/Medical Applications.” There have already been several important developments in FDA regulation of mHealth products this year. Patel stated that FDA recognizes the importance of digital health, and its potential to drive better health outcomes and promote patient engagement. Patel discussed two recently released draft guidances that impact FDA regulation of mHealth, the draft General Wellness Guidance and the draft Accessories Guidance, and highlighted that FDA continues to work promote innovation while at the same time protecting patient safety. The public comment period for these guidances ended on April 20th, and Patel noted that CDRH did not receive many comments. Finally, Patel emphasized that industry can continue to reach out to FDA with questions about mobile health at mobilemedicalapps@fda.hhs.gov or digital health at digitalhealth@fda.hhs.gov.

The discussion draft of the 21st Century Cures Act includes sections that would exclude “health software” from regulation as a medical device, and would require FDA to promulgate regulations to establish standards and procedures for regulating “medical software.” New 21st Century Cures language may be released by the end of this month. We will be watching closely to see if there are any changes to the software language.

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