

FDA Should Publish Its Final Guidance on Mobile Medical Apps As Soon as the Agency Can

Industry has been awaiting FDA’s final guidance on mobile medical apps for nearly two years. There has been some discussion recently regarding whether FDA should delay the release of the final guidance until after the Secretary of the Health and Human Services (“HHS”) develops its comprehensive regulatory strategy for all health IT as required by The Food and Drug Administration Safety and Innovation Act (“FDASIA”) of July 9, 2012. We disagree with that view.

Indeed, this argument was made once before and rejected by Congress. In addition, as recently as March 2013, industry and several members of Congress strongly urged FDA to release its final guidance as soon as possible.

The mHealth Regulatory Coalition (MRC) opposes any delay in the issuance of the final guidance and believes the immediate release of final guidance will benefit industry, enable more predictable investment in innovative mHealth technologies, and help ensure patient safety.

1. Benefits industry through deregulation

The draft guidance is deregulatory in nature. The draft guidance identifies those low risk mobile medical apps that the Agency does not intend to actively regulate at this time. It is incredibly important for companies to understand if their app will not be regulated. The final guidance will particularly benefit those early stage companies with limited resources. This clarity will enable developers of those low risk apps to create products without the burden of complying with FDA requirements. As we understand it, the guidance will prove useful to the FDA review divisions that need to understand what they should and should not regulate. In that sense, the guidance is instruction from senior FDA management to its staff.

2. Enables more predictable investment in mHealth technologies

The draft guidance also identifies those higher risk mobile medical apps that the Agency will actively regulate. Right now, many companies are sitting on the sidelines and not developing higher risk apps because the rules are unclear. They do not want to invest in developing a quality system, taking the time to develop evidence, and submitting that evidence to FDA as needed, if their competition is going to be able to undercut them by not investing in FDA compliance. The final guidance will clarify those higher risk apps that are subject to FDA regulation and help level the playing field for companies in that segment.

3. Helps ensure patient safety

Many companies new to the FDA regulatory environment mistakenly believe that mobile medical apps will not be regulated until the final guidance is issued. Hence, they are taking a “wait and see” approach to FDA compliance and releasing products that, in many cases, have not met basic requirements for quality and patient safety. In fact, according to a recent study by the University of Pittsburgh, smartphone applications used to detect melanoma are inaccurate in diagnosing deadly skin cancer. Although these apps include disclaimers stating

- Agamatrix
- Anson Group
- AT&T
- Continua Health Alliance
- Great Call
- Ideal Life Online
- OmniScience Mobile
- Partners Healthcare System
- Center for Connected Health
- Philips
- Qualcomm
- Roche
- Samsung
- Underwriters Labs
- Vasoptic Medical
- Verizon
- View720.com
- Voxiva
- WellDoc
- Wireless Life Sciences Alliance

they are providing information for educational purposes only, the apps are intended to help users decide, using a digital image for analysis, whether or not their skin lesions are potential melanomas or otherwise concerning, or if they likely are benign.¹ Another study of asthma-related apps has shown errors in predicted peak flow calculators, symptom score diaries with little basis on validated research or expert opinion². These types of errors could cause significant safety issues for patients diagnosed or at risk for these conditions. Issuance of the final guidance will eliminate any confusion underlying this misperception and help ensure that the apps that are regulated are being developed in a manner that helps ensure patient safety.

4. Does not overlap with the work of the Secretary

The Health IT regulatory strategy required by FDASIA will not provide the level of detail needed by the industry and included in the FDA guidance. To delay the release until after the comprehensive Health IT strategy is finalized would only perpetuate the confusion that plagues the mHealth industry today without providing the clarity and direction to enable and accelerate mHealth innovation.

The FDA's guidance, in contrast, covers largely uncontroversial topics in that it simply explains what the existing FDA statutory authority means. Unless and until Congress revises FDA's statutory authority, this guidance will be useful.

5. Broad consensus on need for final FDA guidance

As mentioned above, delaying the release of the final guidance was proposed previously and rejected. In May 2012, the Bennett-Hatch Amendment to the Medical Device User Fee Amendments (MDUFA III) legislation proposed a moratorium on the final guidance until September 30, 2013. The proposed amendment never became law. Legislators rejected the proposed moratorium, and FDASIA does not contain any provisions to delay the final guidance. Members of Congress further reiterated this position in March 2013 when it held three days of hearings on FDA regulation of mobile medical apps. During those hearings, Congress and the majority of those who testified called upon FDA to publish the final guidance.

Conclusion

The Secretary's objectives are different from the FDA regulatory framework on mobile medical apps. The Secretary is charged with making broad policy recommendations on a comprehensive strategy for all Health IT. FDA's guidance, on the other hand, is focused on providing specific details of whether different mobile medical apps will be regulated or not – this is the level of regulatory detail app developers need now.

¹ *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, JAMA Dermatology, Jan. 16, 2013

² *Currently available smartphone apps for asthma have worrying deficiencies*, Evidence-Based Medicine, Feb. 2013