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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
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March 1, 2013

Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

Pursuant to Rules X and XI of the United States House of Representatives, the Committee is examining the requirements of the Food, Drug, and Cosmetic Act (FDCA) and the Patient Protection and Affordable Care Act (PPACA), and how these laws are applied to the manufacturers of smartphones, tablets, and individualized applications (apps).

With the growth of the smartphone and tablet market in the United States, the use of applications to monitor health information on these devices has also increased. Some medical applications are used to monitor health information, like diet and fitness data. Other applications can be used to monitor chronic conditions such as diabetes or high blood pressure. One news report estimated that there are as many as 40,000 medical applications currently on the market for smartphones and tablets, and the market is growing.[1]

The U.S. Food and Drug Administration (FDA) has authority under the FDCA to regulate certain products that meet the definition of a "device". On July 19, 2011, the FDA announced that it was seeking public input on its oversight approach for regulating mobile medical apps as medical devices. This 2011 draft approach called for FDA oversight of mobile medical apps that were either (1) used as an accessory to a medical device already regulated by the FDA; or (2) transform a mobile communications device into a regulated medical device by using attachments, sensors, or other devices.[2] For the purposes of this guidance, the FDA explained that the fact that a "mobile platform" (smartphones like the iPhone or Blackberry) could be used to run a mobile medical app did not mean that the smartphone maker would be considered a

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[1] Jenny Gold, *FDA regulators face daunting task as health apps multiply*, USA Today, June 27, 2012 available at http://usatoday30.usatoday.com/news/health/story/2012-06-22/health-apps-regulation/55766260/1.
[2] FDA News Release, "FDA outlines oversight of mobile medical applications", July 19, 2011 available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263340.htm.

medical device manufacturer. The distinction would rest on whether the manufacturer was marketing the product as being intended for medical uses.[3]

Since the July 2011 guidance, the FDA has held a public workshop on mobile medical apps[4] and received many public comments[5] but has not yet issued final guidance. Although FDA's announcement on medical applications focused on the "intended use" of the application when determining whether it should be regulated as a medical device, we are concerned about the potential of "actual use" becoming a factor in the future. Last year Members on this Committee wrote to you because draft guidance issued by the FDA on Commercially Distributed in Vitro Diagnostic Products indicated that "actual use" would be a factor in your analysis of "intended use".[6] If FDA decides to take a similar approach in its final guidance with medical applications, this could affect the growth and innovation in this market. It may also have implications for the implementation of the PPACA. The PPACA as amended imposes an excise tax on medical devices that was intended to generate revenue to pay for the law. If FDA determines that certain smartphone, tablet, or mobile medical apps are devices for the purposes of the FDCA, it raises the possibility that they would also be subject to new taxes under the PPACA.

In order to clarify the uncertainty surrounding mobile medical applications, and how they will be regulated by the FDA, we ask that you provide written answers to the following questions by March 15, 2013:

1. When will the FDA issue final or updated guidance with respect to the July 19, 2011, request for input on its oversight approach for mobile medical applications designed for use on smartphones or other mobile computing devices?

2. Has the FDA discussed, prepared, or analyzed the effect of the medical device tax on smartphones (as well as tablets or similar devices) or the creators or distributors of applications for those products? If so, please provide all documents analyzing or relating to this issue.

3. Will the actual use of a smartphone, tablet, or app be a factor in whether the FDA chooses to regulate the device or app as a medical device? Has it been a factor in any analysis by FDA already completed?

4. How many mobile medical apps have sought approval from the FDA before entering the market? What was the processing time for each of these apps? How many mobile medical apps have been subject to oversight by the FDA after introduction to the market?

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[3] "For example, if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany with a medical device intended use, then BrandNameCompany would not be a medical device manufacturer." *Id.*

[4] FDA News Release, "Public Workshop – Mobile Medical Applications Draft Guidance" available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm.

[5] Available at http://federal.eregulations.us/rulemaking/docket/FDA-2011-D-0530.

[6] Letter from Chairman Joseph R. Pitts to Margaret A. Hamburg, M.D., Mar. 19, 2012.

How many apps have either been changed or removed from the market by FDA oversight, and why?

In addition to answering the questions under your respective jurisdictions, we ask that you make the appropriate representatives available to brief Committee staff and discuss these issues within the same time frame. Instructions for responding to the Committee's document requests are included as an attachment to this letter. Thank you for your prompt attention to this matter. If you have questions or with to discuss your responses or production, please contact Sean Hayes with Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

Joseph R. Pitts
Chairman
Subcommittee on Health

Greg Walden
Chairman
Subcommittee on Communications and Technology

Joe Barton
Chairman Emeritus

Marsha Blackburn
Vice Chairman

Michael C. Burgess
Vice Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigation