



MAR 20 2013

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter of March 1, 2013, cosigned by six of your colleagues, regarding the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) 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). Your letter poses several specific questions concerning the activities of the Food and Drug Administration (FDA or the Agency) regarding the regulation of wireless medical devices (also referred to as “mobile medical applications” or “mobile medical apps”).

We have restated your questions below in bold, followed by FDA’s responses.

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?

FDA issued a draft guidance document regarding mobile medical applications on July 21, 2011.¹ That guidance announced FDA’s intention to exercise enforcement discretion for most mobile apps. The draft guidance proposed regulatory oversight of only a small subset of mobile apps (referred to in the guidance as “mobile medical apps”) that meet the definition of a device in section 201(h) of the FD&C Act and are intended for use as either: (1) an accessory to a regulated medical device, or (2) to transform a mobile platform into a regulated medical device.

¹ FDA, “Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications” (July 21, 2011), available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm>.

FDA received more than 130 submissions to the public docket on the draft guidance. Many commenters sought additional clarity on the types of mobile apps for which FDA intends to exercise enforcement discretion. FDA will seek to provide this clarity in the final guidance.

Commenters overwhelmingly supported the narrowly tailored approach FDA described in the draft guidance. FDA has since received many more inquiries from members of industry eager to see the guidance finalized. The mobile medical apps guidance is currently in the final stages of Agency review. The Agency has previously indicated its intent to publish the final guidance this year.

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.

FDA has not analyzed the effect of the medical device tax on creators and distributors of smartphones, tablets, and similar devices but is aware of concerns about the effect on innovation if novel technologies become subject to the tax. FDA developed the Agency's draft mobile medical apps policy to protect public health and promote innovation.

Although the definition of a "taxable medical device" is tied to the FD&C Act, it is the Internal Revenue Service (IRS) and the Department of the Treasury that are responsible for the excise tax imposed on the sale of certain medical devices, not FDA. Moreover, as indicated by the IRS's definition of "taxable medical device," not all medical devices regulated by the FD&C Act are subject to the tax—only those that are required to list with FDA. Because the mobile medical app draft guidance states that the Agency intends to exercise enforcement discretion for many mobile apps with respect to applicable device requirements, including listing, FDA does not expect those devices to list.

Questions about the implementation of this policy should be directed to the IRS.

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?

The answer to both questions is no.

As stated in FDA's draft mobile medical apps guidance, FDA's mobile medical apps policy will not regulate the sale or general consumer use of smartphones, or tablets even when such sale or use is in a health care setting (e.g., in a doctor's office or hospital). FDA's proposed mobile medical apps policy does not consider entities that exclusively distribute mobile medical apps, such as the owners and operators of "iTunes store" and "Android market," to be medical device manufacturers.

Instead, FDA's draft mobile medical apps guidance focuses on the intended use of the mobile app and proposes oversight only for those mobile apps that meet the definition of a "device"

under section 201(h) of the FD&C Act, and are either intended for use as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device. This analysis is typical of how FDA has handled various products that might be devices that serve multiple purposes. FDA looks to the intended use of the product to determine whether the product is a device. The intended use of a product is typically determined by how a product is marketed; that is, by labeling, advertising, and promotional claims.

We note that products that are not intended for use in the diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, including smartphones, tablets, and apps, even when used in a health care setting, would not be considered to be medical devices.

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

It is important to note that FDA has been regulating medical device software for decades and medical device software on mobile platforms for more than 10 years. During the past 10 years, the Agency has reviewed more than 30,000 premarket medical device submissions, including approximately 100 for mobile medical apps. However, FDA traditionally has not categorized or tracked premarket submissions based on the specific underlying technology of a medical device. Rather, our systems have been focused on capturing devices that generally fall within device classifications that are grouped by medical specialties (for example, radiology; ear, nose, and throat; toxicology; dental; ophthalmic; etc.). We are currently exploring methods to better capture the number and types of mobile medical app submissions.

For 2011 and 2012, the average time for FDA review of medical device submissions that were identified as containing a mobile medical app was 67 days and the average total time from submission to FDA decision was 110 days. These numbers represent review of not only the mobile medical app, but also review of any relevant attachments or accessories included in the submission. For example, review of a submission of a glucose meter included evaluation of both the mobile medical app and the blood glucose attachment.

In general, manufacturers often voluntarily correct their products that may either be in violation of the FD&C Act or experience a malfunction that could result in serious injury or death. We are aware of one voluntary recall involving a mobile medical app that could miscalculate an insulin dose potentially resulting in dangerously low or high blood glucose levels in diabetic patients. In addition, the app was unintentionally made available in the United States by the manufacturer. The manufacturer voluntarily notified all users worldwide and removed the app from the Global App Store.

As requested in your letter, appropriate FDA representatives briefed staff of the Committee on Energy and Commerce and discussed these issues by telephone conference on Thursday, March 14, 2013.

Thank you, again, for contacting us concerning this matter. If we can be of further assistance, please let us know. The same letter has been sent to your cosigners.

Sincerely,



Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Henry A. Waxman, Ranking Member

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