



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

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

MAY 10 2013

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the March 21, 2013, hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, entitled "Health Information Technologies: Administration Perspectives on Innovation and Regulation." This letter provides responses for the record to questions posed by certain Members of the Subcommittee, which we received on April 9, 2012.

If you have further questions, please let us know.

Sincerely,

A handwritten signature in blue ink that reads "Michele Mital".

Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

We have restated each Member's questions below in bold, followed by our responses.

The Honorable Tim Murphy

- 1. The testimony submitted by the FDA strongly states that the FDA's proposed mobile medical app policy would not apply to mobile apps that perform the functionality of an electronic health record (EHR) system or personal health record system. Has the FDA had any discussions or conducted any analysis on how this will apply to the coming health insurance exchanges that will debut on January 1, 2014 as part of the Patient Protection and Affordable Care Act? Will any mobile apps related to the exchanges be subject to this same statement?**

FDA's proposed policy would focus its regulatory oversight on only a subset of mobile medical apps that meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and are intended to be used as an accessory to a cleared/approved medical device, or to transform a mobile platform into a cleared/approved medical device. We are not aware of any mobile apps related to health insurance exchanges under the Patient Protection and Affordable Care Act that meet that definition.

- 2. During your testimony you indicated that FDA had provided technical guidance to the Internal Revenue Service to implement the Medical Device Tax created by the Patient Protection and Affordable Care Act. Please provide this for the record.**

We are in receipt of the April 9, 2013, letter to FDA on this issue from Chairman Fred Upton, House Committee on Energy and Commerce, Chairman Tim Murphy, Subcommittee on Oversight and Investigations, and Rep. Morgan Griffith. We will respond to this request under separate cover.

- 3. Both your written testimony and responses to questions at the Hearing indicated that FDA will utilize its enforcement discretion in determining whether a mobile medical app will be regulated more carefully (and ultimately become subject to the Medical Device Tax). Are there ways in which that discretion will not be necessary? If a previous or future FDA guidance indicates that manufacturers should automatically register with the FDA or otherwise notify the FDA of their intentions, could that trigger increased scrutiny? Will the use of your enforcement discretion occur on a case by case basis or will there be certain actions that guarantee a mobile medical app requires increased oversight, outside of the triggers listed in the July 2011 guidance?**

FDA's draft guidance, issued in July 2011, proposes our intent to exercise enforcement discretion for most mobile apps. As stated in our guidance, FDA is focusing its regulatory priorities on those mobile apps that meet the definition of device and are intended to (1) be used as an accessory to a cleared/approved medical device, or (2) transform a mobile platform into a cleared/approved medical device. FDA typically makes its enforcement

decisions on a case-by-case basis and these decisions will be guided by the principles set forth in the final version of this guidance.

To help clarify the Agency's policy for mobile medical apps, FDA intends to post on its website new examples of mobile apps on which FDA is focusing its priorities.

The Honorable Morgan Griffith

1. With the thousands of medical apps that are currently being developed, what plan does FDA have to approve the majority of these medical apps in a timely fashion?

FDA has been reviewing medical device software for almost as long as FDA has had premarket review authority for devices. Further, although there are thousands of mobile apps on the market, relatively few have required FDA review. FDA has reviewed approximately 100 mobile medical apps over the last decade. All of these apps have been reviewed as premarket notification (510(k)) submissions, rather than premarket approval applications (PMA).

Even with the recent increased growth and availability of these mobile apps, in the last two years FDA has received for clearance no more than 20 premarket notification (510(k)) submissions per year for mobile medical apps. 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. Under the FD&C Act, medical device 510(k) clearances are to be completed within 90 days, and our data show that the Agency is well within that time frame in reviewing mobile medical app submissions.

FDA does not anticipate a substantial increase in its premarket review workload due to an increased number of submissions for mobile medical apps. Under FDA's proposed guidance, most mobile apps will fall outside of FDA's regulatory focus. The approach proposed in the Agency's July 2011 draft guidance on mobile medical apps states that FDA's oversight will focus on a small subset of mobile apps that are similar to medical devices that are cleared/approved or that may affect the functionality of cleared/approved medical devices.

2. Has FDA considered a 3-tiered, risk-based oversight framework for health information technology, including medical apps, as discussed by McKesson in testimony before the Energy and Commerce Health Subcommittee on Wednesday, March 20, 2013 and by the Bipartisan Policy Center in a February 2013 study titled "An Oversight Framework for Assuring Patient Safety in Health Information Technology"?

As required by section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA),¹ FDA is working with the Federal Communications Commission (FCC) and the Department of Health and Human Services (HHS) Office of the National Coordinator for

¹ Public Law 112-144, 126 Stat. 992 (July 9, 2012).

Health Information Technology (ONC) to develop a report containing a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology that promotes innovation, protects patient safety, and avoids regulatory duplication.

The three agencies are convening a workgroup of external stakeholders and experts, as suggested in section 618 of FDASIA, under the Department of Health and Human Services Health Information Technology (HIT) Policy Committee. This will allow for diverse stakeholder groups to provide input to the HIT Policy Committee on the proposed strategy and recommendations for the risk-based regulatory framework for health information technology. The working group will be charged with providing input on a tiered, risk-based regulatory framework that appropriately addresses patient safety and innovation and avoids regulatory duplication. We intend to consider all suggested proposals, including the approaches that were described in the testimonies before the Health Subcommittee of the House Committee on Energy and Commerce during the March 20, 2013, hearing entitled "Health Information Technologies: How Innovation Benefits Patients."

3. If so, does the FDA need legislation to facilitate the agency's adoption and implementation of a 3-tiered, risk-based oversight framework for health information technology, including medical apps?

Please see response to Question #2 above.

The Honorable G. K. Butterfield

1. The world we live in is filled with resources for everyday folks to self-diagnose their symptoms by using popular medical advice websites, and countless medical-related apps. I am a big proponent of consumers having direct access to information, but do you have any concerns about individuals using these apps to self-diagnose and not seeing their doctor or other healthcare professional? Can you talk for a moment about the impact these medical apps have had on consumer actions?

Certain health-related mobile apps can improve the care and quality of life for many people, giving them the freedom to conveniently access health-related information that can help them make important decisions about their care. Mobile apps that motivate individuals to lead a healthy lifestyle (for example, by exercising and eating a healthy diet) by providing information and education are good examples of how mobile technology has enhanced people's lives and helped them manage their conditions. We encourage consumers of these types of apps to consult their physicians and other health care professionals before making any lifestyle changes that could potentially affect medical conditions.

For other types of mobile apps that are designed to help individuals diagnose illnesses, there is always the risk that consumers would not seek treatment when they should. We believe that consumers should make informed decisions and so instead of solely relying on

technology to diagnose a disease or health-related condition, they should also consult a licensed medical practitioner, as appropriate.

Mobile medical apps that allow consumers to self-diagnose a disease must be shown to be safe and effective so that consumers can rely on them as they would rely on a blood glucose meter or an over-the-counter blood pressure cuff.

FDA intends to focus its regulatory oversight on these types of mobile medical apps, to ensure that this technology, which enables consumers and patients to diagnose serious diseases or conditions or that may be used to make important treatment decisions, is safe and effective.

2. Many mobile applications update frequently when their creators or consumers notice problems that require correction. How will the FDA keep up with new generations of web applications and help ensure consumers are using safe and accurate mobile health applications?

FDA's proposed mobile medical apps policy would not require mobile medical app developers to seek Agency re-evaluation for minor, iterative product changes that do not significantly affect the safety and effectiveness of the mobile app. Even for the small subset of mobile medical applications that FDA would actively regulate, such changes could be made without notification to FDA, provided that the manufacturer complies with applicable Quality System requirements in making such changes.

For changes that significantly affect safety and effectiveness of the mobile medical app, FDA would take a risk-based approach that primarily relies on manufacturers to have Quality System processes in place. Significant changes made to higher-risk regulated mobile medical apps may be subject to certain additional oversight by FDA, in order to ensure that such changes do not adversely affect the safety and effectiveness of the device.

3. Certain mobile applications do not work properly with an incompatible mobile device. How can we assist in communicating to consumers which applications are appropriate for their individual mobile devices?

The mobile apps industry plays an important role in establishing standards in areas such as device compatibility. Some industry groups have already begun activities in developing open architectures and standards with regard to expectations for compatibility. FDA can also play a role, by participating with health care professionals, industry, and standard-setting organizations in standard-setting activities.