

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  
Minority (202) 225-3641

April 9, 2013

Ms. Christy Foreman  
Director, Office of Device Evaluation, Center for Devices and Radiological Health  
Food and Drug Administration  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Ms. Foreman:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, March 21, 2013, to testify at the hearing entitled "Health Information Technologies: Administration Perspectives on Innovation and Regulation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, April 23, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at [brittany.havens@mail.house.gov](mailto:brittany.havens@mail.house.gov) and mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

## Attachment—Additional Questions for the Record

### 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?
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.
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?

### 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?
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"?
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?

**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?
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?
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?