



July 12, 2013

**VIA US MAIL**

**The Honorable Marsha Blackburn**  
U.S. House of Representatives  
217 Cannon House Office Building  
Washington, D.C. 20515

**Re: Proposed Draft Bill to Amend Section 201 of the Federal Food,  
Drug, and Cosmetic Act (21 U.S.C. 321)**

Dear Representative Blackburn:

As members of the mHealth Regulatory Coalition, we thank you for your commitment to health information technologies and mobile medical applications and for seeking stakeholders' comments on the Proposed Draft bill to amend Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). We appreciate your interest, and we are likewise interested in ensuring that FDA regulatory oversight in the area of medical technology is appropriately balanced to promote innovation while protecting patient safety. We would like, however, to raise a number of questions and important concerns with the proposed approach and the use of new terminology.

**Background and Purpose of the mHealth Regulatory Coalition**

The mHealth Regulatory Coalition ("MRC") is a diverse group of mobile healthcare technology stakeholders focused on promoting the development of an open, realistic, and thoughtful regulatory policy perspective on mobile health technologies. The MRC members include medical device manufacturers, smartphone healthcare application developers, cellular handset manufacturers, network operators, and back end software services and data storage providers, as well as representatives of provider organizations, clinicians, healthcare researchers, and other industry and trade associations. Our members share the common goal of promoting a balanced approach between regulatory policies, and the need for innovation and getting new products to the market for patients' best interests.

With that background in mind, the MRC offers the following comments regarding the Proposed Draft.

1. **FDA has made it clear that through its upcoming Mobile Medical App Guidance, it is deregulating certain mobile medical apps and clarifying the existing regulation of others**

The MRC has published a position paper, "FDA Should Publish Its Final Guidance on Mobile Medical Apps As Soon as the Agency Can", and we enclose it with this letter. We believe the final guidance will

benefit the industry through deregulation. FDA indicated in its draft guidance on mobile medical apps that it will identify those low risk mobile medical apps that the Agency does not intend to actively regulate at this time. This clarity will enable developers of those low risk apps to create products without the burden of complying with FDA requirements. In that sense, FDA is moving in a direction that will enable the industry to more easily bring to market low risk products that contribute to better health care.

Further, the final guidance will enable more predictable investment in mHealth technologies. Currently, 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 that those higher risk apps that are subject to FDA regulation and help level the playing field for companies.

Many companies new to the FDA regulatory environment mistakenly believe that mobile medical apps are somehow not 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. Issuance of the final guidance will help ensure that the apps that are regulated are being developed in a manner that helps ensure patient safety.

FDA’s efforts with regard to mobile medical apps are at least partly deregulatory in nature. Frankly, we think Capitol Hill can take some credit for its efforts over the years to make sure that FDA does not try to expand its jurisdiction. Specifically, we believe FDA’s efforts to deregulate certain mobile medical apps are directly responsive to congressional influence.

Our comments here are specific to the FDA’s planned mobile medical app guidance. If FDA radically departed from the deregulatory approach outlined in the draft guidance, that would be a problem. Further, our remarks here are limited to the mobile medical app guidance because that is what we are familiar with and it already exists in proposed form. We don’t know much about FDA’s plans with regard to other types of software such as clinical decision support, so we express no opinion on those.

## **2. The Proposed Terminology Creates Confusion Because It Introduces Undefined Terms**

The proposed language will cause confusion and further delay for industry. Many of its terms are not defined or commonly understood by industry or regulators. It will take a significant amount of time and effort to determine how these terms should be interpreted and ensure they are consistently applied across the range of applicable products. This will only perpetuate uncertainty, continue to stall development of new technologies and hurt industry which has been waiting for clarity. We provide a few examples of the new terms that create ambiguity in the implementation of the proposed language below.

- a. The proposed language creates a new category of “medical health technology.” However, products within that new category are subject to the same FDA regulation as medical devices. In the definition of medical health technology, certain items are excluded from that definition. However nothing in the draft bill would cause items excluded from the definition of “medical health technology” to be automatically excluded from the definition of a medical device. Yes, medical health technology is excluded from the medical device definition, but that doesn’t mean that items excluded from the medical health technology definition are likewise excluded from the medical device definition.
- b. “Medical health technology” includes products “integral to the functioning of a drug or device.” It is unclear what the term “integral” means. Does it include software that is used to analyze the data that comes from a medical device? To some extent this would create a circular definition

where one would refer to the definition of a medical device to understand mobile health technology that would be regulated as medical devices. If today many mobile medical apps are medical devices, it is a bit confusing to say that medical health technology would include something integral to a mobile medical app.

- c. The definition of “medical health technology” refers to hardware and software. We believe that these terms are too generic to meaningfully distinguish “medical health technology” from traditional medical devices. A pacemaker is hardware, and software includes firmware that resides in the pacemaker. It would not be logical for a pacemaker or firmware within a pacemaker to now be reclassified as “medical health technology.”
- d. The Draft references products that would “change an individual’s physiology.” It is unclear what products or functionality the Draft is attempting to capture with this new terminology or how hardware and software ever change an individual’s physiology.
- e. The Draft excludes from “medical health technology” hardware or software that has the “capacity to collect user generated or user entered data.” This category would seem to be overly broad. There are products where data collection might be one among many functions the product performs. The issue will be particularly confusing where software goes beyond collecting data to do something else such as transmit or analyze it.
- f. The definition of “medical health technology” excludes hardware or software whose “primary purpose” is to change data from its original format. It is unclear what a “primary” purpose means. For example, if software performs several functionalities such as collecting, storing, transferring, interpreting data, and changing data format is one of these functionalities, does this mean that the whole software package that includes many modules falls outside of the definition of “medical health technology?” We think it would be very important to reconcile this concept with the existing regulatory principles in the FDA’s medical device data system regulation. That regulation specifically addresses changes to the format.
- g. The Draft references products “intended to be marketed for use by a health care provider in a health care setting.” The concept of “intended use” is well established and understood by industry and regulators. The meaning of “intended to be marketed” is unclear. How does this differ from the “intended use” of a product and what is the rationale for introducing this new term? Further, how, if at all, would this be applied in a setting where a hospital, for example, developed its own software? Does one department within the hospital “market” the software to another?

We share the same objective, which is a combination of (1) as little regulation as is necessary to ensure safety, (2) communicated in a clear fashion. Our concern is that this legislation would take an area of the law which is reasonably well settled, and would actually interject into it quite a bit of uncertainty. A better approach would be to work with FDA to develop guidance that adds clarity without regulating what doesn’t need to be regulated. The problem is the need for narrowly tailored FDA guidance and regulations that establish certainty for the marketplace. Congress can, as it did with the draft mobile medical apps guidance, influence the development of FDA guidance and regulations without passing legislation.

### **3. The Draft Is Inconsistent with Congress’s Intent in FDASIA**

In 2012, Congress enacted the Food Drug Administration Safety and Innovation Act (“FDASIA”) calling upon the Secretary of the Health and Human Services (HHS) through FDA, the Federal Communications Commission (“FCC”) and the Office of the National Coordinator for Health Information Technology (“ONC”) to develop a strategy and recommendation for Health IT, including mobile health technologies by January 2014 (“Section 618 Report”). If Congress were to adopt new legislation before the publication of the Section 618 Report, Congress would be acting inconsistent with its own directives.

Further, it would thwart the efforts of the federal agencies currently in process to propose and implement a consensus-based regulatory framework.

**4. If the Draft is Directed at the Medical Device Tax, It Would Not Bring any Clarity**

We should state up front that we certainly oppose the medical device tax. It is a tax on innovation, and in our opinion it needs to be revoked. But this approach of creating a new category, partly to avoid the tax, would seem to do more harm than good because it creates all of the ambiguities outlined above.

During the March 2013 hearings held by the House Energy and Commerce Committee, some members of Congress raised concerns that the medical device tax would apply to mobile apps, and thus stifle mHealth innovation. The medical device tax, however, does not apply to the vast majority of mobile apps and other health information technologies that are sold in the consumer market. It would appear that the Draft is attempting to shield health information technologies from the medical device tax by changing certain health information technology from the medical device category into the medical health technology category.

Ambiguity is one of the biggest barriers to innovation. Our concern is that this legislation adds ambiguity, thereby frustrating innovation. While we support any effort to repeal the tax, the approach of creating a whole new category would again be the wrong solution to the problem. The MRC believes that the tax is the problem and must go. Trying to avoid it through a new category that incidentally creates ambiguity only creates new problems.

**5. Congress should wait at least until the International Medical Device Regulators Forum has addressed this issue**

During the coming months, the International Medical Device Regulators Forum will be considering the topic of standalone software and creating certain harmonized definitions and regulatory approaches that would encompass the major regions of the world. Harmonizing the approaches to health information technology internationally would produce real benefit for American companies wanting to sell software overseas. We highly recommend that Congress wait to see what that process produces before proceeding in a way that might be inconsistent with the international approach.

**6. The cover email to the Draft bill expressed a deregulatory purpose but evidences some factual misunderstanding about FDA law and practice**

We also were concerned that the email message transmitting the bill suggested that data are never a medical device. Actually, in some cases, they are the sole factor in determining if a system is regulated. For example, a system that merely transmits data that come from a medical device is regulated as a medical device data system. And that makes intuitive sense, since the safety of a medical device is highly dependent on the data from that device being accurately presented. The cover email also stated that the draft legislation deregulates data and wireless communications. FDA regulates medical device data systems, and data can be integral to Agency's core mission to protect patient safety. FDA does not directly regulate wireless communications as FCC has jurisdiction over wireless communications. FDA does regulate medical devices that may transmit information and provide service wirelessly. We support the need to maintain the line between FDA and FCC jurisdiction.

Conclusion

Since FDA is poised to both clarify and deregulate mobile health, and since Congress in FDASIA Section 618 gave the agencies the task of developing a report that Congress will receive in January 2014, Congress should step back and let the agencies do their best to complete their statutorily mandated duties

over the next six months to see the nature of their proposals. Congress can then get involved in specific measures that it or other stakeholders find objectionable.

The MRC would appreciate an opportunity to meet with you to better understand your objectives and provide you with additional information related to health information technology and medical devices so that efforts to ensure continued technological innovation and advances in patient care are not hampered by the unintended consequences of a burdensome and duplicative regulatory framework.

If you have any questions or would like to discuss any issues further, please do not hesitate to contact me.

Very truly yours,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson", is centered on the page. The signature is fluid and cursive.

Bradley Merrill Thompson  
On Behalf of the mHealth Regulatory Coalition

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

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

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

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.<sup>1</sup> 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 opinion<sup>2</sup>. 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.

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

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