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VIA US MAIL

The Honorable Kathleen Sebelius
Secretary
Department of the Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Section 618 of the Food and Drug Administration Safety and Innovation Act ("FDASIA")

Dear Secretary Sebelius:

We are writing to you on behalf of the mHealth Regulatory Coalition ("MRC") regarding the health information technology ("Health IT") report required under Section 618 of the Food and Drug Administration Safety and Innovation Act ("Section 618"). Section 618 calls upon the Department of the Health and Human Services (HHS) through the Food and Drug Administration ("FDA" or "Agency"), 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"). Consistent with the spirit of FDASIA and the mandate of Section 618, the MRC strongly supports the development of a non-duplicative, risk-based regulatory framework for mobile health technologies that promotes innovation and protects patient safety. As you may recall, the MRC wrote a letter[1] encouraging HHS to convene a working group as permitted under Section 618 to facilitate the development of the Section 618 Report. In the absence of such working group, we take this opportunity to provide feedback and recommendations on the critical issues affecting the mHealth industry that must be addressed in the Section 618 Report.

Background and Purpose of the mHealth Regulatory Coalition

[1] *Available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2012/09/2012-08-28-FDA-Safety-And-Innovation-Act-Establishing-a-Working-Group-as-Provided-by-Section-618-of-the-Act.pdf

The MRC was formed in May of 2010 to bring mobile healthcare technology stakeholders together to collaborate and develop a thoughtful, pragmatic and appropriately risk-based regulatory policy of mHealth technologies for the the FDA). MRC members represent a diverse array of stakeholders, including 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 goals of protecting patient safety and promoting a balanced approach toward regulation in order to foster innovation and get new products to the market for patient's best interests. The MRC also serves as a resource for regulators and policy makers. As the MRC is actively engaged in mHealth policy development and includes various thought leaders in the mHealth industry, we are able to provide a unique and informed perspective on the issues facing the mHealth industry today.

As such, the MRC respectively offers the following recommendations for inclusion in the Section 618 Report.

1. **<u>There Must Be Clearly Defined Jurisdiction for FDA, FCC and ONC and Effective Collaboration.</u>**

The MRC believes that coordination and collaboration among the various governmental bodies overseeing different aspects of mHealth technologies is paramount. As you know, there are a myriad of regulatory and legal issues which are implicated with the use of mHealth technologies. First, there are patient safety concerns and questions of whether certain technologies are regulated by the FDA. Equally important for those mHealth products which are regulated medical devices, are the questions of how are they regulated and what are the applicable requirements. Second, as mHealth products involve wireless communications, there are radio frequency spectrum and other issues within the FCC's purview that must be considered. Lastly, there are also privacy and security requirements that must be addressed in the transmission and access of an individual's personal health information. This is an area over which the ONC has exercised its authority.

The first step in enabling effective inter-agency coordination is to clearly define the scope of authority for each entity involved. Vague terms and unclear distinctions of the respective roles of each of these agencies will result in confusion, jurisdiction overlap, and ultimately regulatory duplication. Moreover, mobile health developers will need clear guidance as to which agency has the authority to oversee which components of mobile health products. For example, security over wireless communication devices that control pacemakers or insulin pumps potentially raises patient safety, data privacy and security, and wireless spectrum issues that span the authority of the three agencies. Therefore, the MRC strongly recommends that the Section 618 Report propose a strategy and recommendations on an appropriate, risk-based regulatory framework that delineates, with specificity, the scope of jurisdiction for the FDA, FCC and ONC on health information technology, including mobile medical applications. The Agencies should always seek to promote, innovate, protect patient safety, and avoid regulatory duplication. The report must provide clarity of relevant authorities to avoid unnecessary regulatory duplication.

The Section 618 Report must also include a mechanism to facilitate collaboration and coordination of policies. This is critical to ensure the various bodies are not independently developing policies that are overlapping and inconsistent - or worse - are impossible to comply with at the same time. We are not advocating additional bureaucracy. In fact, the MRC strongly opposes any measures that would slow the

regulatory or policy-making process or result in overly-burdensome process. However, the FDA, FCC and ONC cannot act in isolation. Given that their policies, regulations and/or requirements all impact the same products and manufacturers, there must be ongoing interaction and communication to facilitate a streamlined regulatory approach to mHealth products.

The MRC has previously proposed the concept of an mHealth coordinator within FDA to oversee policy development on mHealth issues, ensure a predictable and consistent review of mHealth products, and serve as an educational resource within the Agency *and* outside of the Agency. We provide a more detailed discussion of the concept of a mHealth coordinator in the MRC Position Paper on mHealth Coordinator,[2] and in the Letter from Bradley Merrill Thompson on behalf of the MRC to Bakul Patel, Policy Advisor, U.S. Food & Drug Admin. (Oct. 19, 2011)[3], (recommending the creation of an mHealth-specific division within FDA). However, this function could also play a key role in coordinating policy development among FDA, FCC and ONC and helping to ensure a cohesive approach to mHealth technologies.

2. The Strategy Must Include a Streamlined and Flexible Regulatory Framework.

The MRC recognizes the need for regulatory oversight of mobile healthcare technology. However, the MRC emphasizes that regulatory oversight, if too vigorously applied to an emerging industry such as mHealth, could create significant barriers to innovation that might ultimately stunt its development.

The connectivity of medical devices to mobile and wireless networks coupled with the adoption of mobile technologies that can empower the patient or consumer represents a unique regulatory challenge. The use of mHealth technologies among healthcare providers, patients and health-conscious consumers is at least as common today as is the use of the telephone, written reports or other traditional means of communication. And it is predicted that their use will exponentially increase. Moreover, the use of mobile health technologies continues to evolve, and new technologies emerge at such a rapid pace that policies and regulations issued under the traditional regulatory paradigms and timeframes will quickly be insufficient to address the current technology. In the light of the speed of technological progress, the regulatory framework for mHealth products needs to be flexible enough to adapt to the changing products and accommodate the speed, flexibility and innovation of this new marketplace.

We also encourage HHS, through FDA, FCC and ONC to maintain an open dialogue with the industry and other stakeholders to remain informed of technological trends and advancements. A true partnership in this regard can help regulators proactively address issues in a way that helps accelerate creation and adoption of new technologies.

3. FDA Must Issue Final Guidance

In addition to our general comments on the Section 618 Report, we offer the following specific recommendations with respect to FDA's mHealth regulatory policy. We appreciate the Agency's efforts in preparing the Draft Mobile Medical Apps Guidance in July 2011 ("Draft Guidance"). However, over a year later and there is still no final guidance available. The lack of clear and predictable framework of

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[2] *Available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2013/01/MRC-Policy-Position-on-mHealth-Coordinator-Jan7.pdf

[3] *Available at* http://mhealthregulatorycoalition.org/wpcontent/uploads/2010/06/MRC-Comments-on-FDA-Draft-MMA-Guidance.pdf

how these technologies will be regulated leaves both industry and investors in limbo, without the knowledge and confidence to plan their investments. This could have one of many negative consequences. First, this uncertainty could cause industry and investors to take a "wait and see" approach, which will essentially stagnate the industry and stifle innovation. Second, it could result in "over-regulation" of certain products where companies apply more stringent regulatory requirements that may be necessary due to the lack of reliable guidance. This approach likely leads to increase costs for these products and undue delays in getting the products in the hands of consumers or patients. On the other end of the spectrum, it also could enable the proliferation of mHealth products that are regulated by the FDA being provided without the applicable regulatory requirements or oversight. None of these results are acceptable. They, not only fail to promote innovation, but they also have the unintended effect of putting patient safety at risk. We call upon the FDA to issue the final Mobile Medical App Guidance without further delay.

4. FDA Should Address the Intended Use, Accessories and Software Modularization

In addition, the Draft Guidance fails to adequately address three key issues for the mHealth industry: the "accessory rule", intended use and software modularization. These concepts are central to implementing a regulatory framework that is based on the least burdensome approach. We will discuss each one at a high level below and provide a more detailed review in the MRC's proposal for FDA guidance[4].

Accessory Rule

FDA considers any product that connects to a medical device as an accessory and FDA generally regulates these accessories in the same regulatory classification as the medical devices to which they are connected. FDA's traditional approach to regulating accessories is outdated in today's technology environment, where a web of medical and non-medical products interconnect. This can result in regulatory overkill as simple widgets that do not involve a sufficient level of risk must comply with heightened regulatory requirements simply because they use or transfer data from a Class II or Class III medical device. For example, a USB cable that links a blood glucose meter to a cell phone will be classified under the same category like the blood glucose meter.

The Coalition recommends that the FDA use the statutory scheme to classify accessories as opposed to regulating them according to the classification of the device to which they connect. This will prevent inappropriate up-regulation of low risk products and apply the appropriate level of requirements based on the risk of the specific product. The MRC also recommends that the Agency embrace the notion that certain claims of interoperability will be subject to self-regulation in that the vendor making the claim will be required to have sufficient and adequate documentation to support such claims. Lastly, we strongly urge the FDA to issue guidance on when a product in the mHealth ecosystem is an accessory and the applicable requirements.

Intended Use

Medical devices are defined as products that *are intended to be used* in the diagnosis, treatment or prevention of a *disease or condition*. The FDA looks at the manufacturer's marketing claims about the product, among other things, in determining whether the product is intended to be used for a medical

[4] *Available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/MRC-Proposed-Guidance-Document-Presubmission-Draft.pdf

purpose. In today's society, consumers, patients and healthcare providers are much more aware of effects of a healthy (or unhealthy) lifestyle can have on a specific medical condition or disease. As a result, consumers and patients are much more actively engaged in managing their health and wellness than 10, 20 or 30 years ago, regardless of whether they are healthy, have a terminal illness or are managing a chronic condition. This active involvement tends to blur the line between an unregulated product being used for health and wellness and a medical device that is intended to be used to diagnosis, treat or prevent a disease. For example, a manufacturer of exercise equipment could claim that its equipment can be used to treat heart disease and obesity. That same manufacturer could claim its equipment promotes heart health and enables health care providers to monitor its patients exercise activities. Alternatively, the claims could simply be that the equipment improves overall health and physical conditioning. This range of potential claims for the same product demonstrates the need for clear guidance on when the intended use of a product crosses the line between wellness and health, and becomes a medical device. Therefore, it is essential that the FDA clearly distinguish between disease and wellness and provide guidance on if and how FDA will make enforcement discretion determinations regarding mHealth products that support active engagement of the patient or consumer for the ultimate benefit of their health.

Software Modularization

Complex mHealth products or systems are made up of a number medical and non-medical software modules, each of which has a varying degree of risk associated with it. Regulating the whole product or system in the same way may resulting in imposing overly burdensome requirements on low or no- risk modules.

We encourage FDA to adopt standard software modularization principles which allow for stratification of the modules based on the risk inherent in each module. This approach would enable the FDA to tailor the regulatory requirements based on the risk of the module and avoid overburdening low or no risk modules.

In closing, we strongly urge HHS to take affirmative steps to solicit feedback from all interested stakeholders in the development of the Section 618 Report as soon as possible. Time is of the essence and engaging the public early in the development process is critical to ensuring a regulatory strategy that comprehensively and meaningfully addresses the myriad of issues facing the Health IT industry, and mHealth industry, in particular. We appreciate the opportunity to provide feedback on the Section 618 Report and would welcome the chance to engage in a more formal dialogue about these issues through a Section 618 working group or other appropriate forum. If you have any questions or would like to discuss this further, do not hesitate to contact me.

Very truly yours,

Bradley Merrill Thompson
On Behalf of the mHealth Regulatory Coalition