August 16, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fischers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2010-N-0291/ FCC Docket No. ET 10-120: Converged Communications and Health Care Devices Impact on Regulation; Public Meeting; Request for Comments

Dear Sir/Madam:

The mHealth Regulatory Coalition is pleased to submit the following comments in response to the notice of public meeting and request for comments referenced above. We also appreciated the opportunity to briefly share our views during the oral comment period on the first day of the meeting jointly sponsored by the Federal Communications Commission and the Food & Drug Administration, and wish to supplement those oral comments with this written statement.

Background and Purpose of the mHealth Regulatory Coalition

The mHealth Regulatory Coalition (MRC) was formed in May of 2010 to bring mobile healthcare technology stakeholders together to collaborate and develop an honest, realistic, and thoughtful regulatory policy perspective, representing a broad, industry-wide view, to present to FDA. The consensus policy opinions formed by the MRC would be presented in a format appropriate for consideration and use as content for a draft Guidance Document from the agency.

Rather than engaging as distinct business entities or industry sectors, mHealth Regulatory Coalition members have joined together to promote their common interests in facilitating the expansion of mHealth technologies to improve patient care and reduce costs. Coalition 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 goal of promoting, and the adoption of, mHealth aware regulatory policy. Finally, the coalition is intended to provide a convenient forum for FDA to work with industry stakeholders on the topic of mHealth technology regulatory policy.

The MRC recognizes the need for FDA regulatory oversight of mobile healthcare technology medical claims, medical technology product safety and effectiveness, adherence by medical devices manufacturers to the intended use statements, and appropriate labeling for medical device products that may take advantage of mHealth communication technologies. However, the MRC emphasizes that FDA 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 Coalition is committed to providing specific industry feedback for the agency to consider as it formulates a balanced policy guidance it will supply to mobile and wireless healthcare technology companies. The Coalition intends to serve as a representative voice for the entire mHealth industry for this important issue.

Consistent with the MRC's focus, the MRC offers the following comments in response to the request for feedback regarding FDA requirements for mHealth technologies.

The FCC and FDA MOU Will Accelerate the Advancement of mHealth Technologies

The MRC applauds the formalization of the FCC and FDA joint effort to make the expansion of mHealth a reality through the execution of an MOU at July's public meeting. The MOU provides clear evidence that the federal government considers mHealth a vitally important contributor to the reengineering of the US healthcare delivery system, with the potential to provide improved cost efficiency and better quality of care.

Worthy ambitions are never easy, and the MRC recognizes the significant challenges the FCC and FDA will face as they begin to work together to development consistent and coordinated policies between their two areas of respective jurisdiction. The coalition appreciates the proactive effort by the agencies to collaborate with each other as they face these respective challenges, managing both the rapidly expanding and changing wireless infrastructure and the medical technology that will be connected to it.

Role of the FCC

Ensuring the integrity and reliability of the public communication spectra, particularly for wireless use, is a critical role of the FCC. Through the management of electromagnetic compatibility and appropriate testing and certification of devices within the various bands of communication spectrum involved, the FCC ensures the foundation for multi-purpose public communication infrastructure will work as designed, preventing cross signal contamination and minimizing the risk of data transmission errors and wireless network outages due to interference. As the number of general and special purpose devices rapidly grows into billions of connections, managing wireless communication traffic has become a top priority.

Role of the FDA

Meanwhile, the FDA is tasked with ensuring that medical devices that are connected to the wireless public communication infrastructure are safe and effective, that they comply with all of the necessary regulatory requirements established for medical devices, and that there is sufficient evidence supporting the claims about these products. The agency has adapted to many technology advances over the past thirty years since medical device oversight was added to its responsibility, but connectivity of medical devices to mobile and wireless networks represents one of its most significant challenges yet.

The mHealth Regulatory Coalition Contribution for Enabling the Convergence of Communication and Medical Systems: Focused on FDA Regulatory Policy Clarity

During the Public Meeting on July 26 and 27, many challenges to the development and deployment of mHealth technologies were identified and discussed throughout the sessions. These challenges included information security, reimbursement, interoperability, alignment with clinical workflow and practice, quality of service requirements for mobile networks, and electromagnetic compatibility. These are all vitally important issues, and many organizations will be working diligently on addressing them in the coming months, as will the FCC and FDA. However, an overriding theme repeated frequently throughout the two day meeting was the need for regulatory clarity, which is precisely where the MRC is focusing its energy and attention.

The MRC advocates the expansion of FDA's current risk-based approach to the regulation of medical devices to mHealth technologies. The MRC can agree that FDA regulation of the most critical and higher risk uses of mHealth technologies should be subject to FDA regulatory oversight. Distinct consideration should be given, however, to the lower risk uses of these technologies, such as connecting non-life critical medical devices to mobile phones. Reducing unnecessary regulatory burdens to providers of lower risk technologies would permit more rapid growth and expansion of these technologies to streamline healthcare delivery and benefit patients.

In response to the need for clarity regarding which aspects of mHealth technology FDA will regulate, the MRC has identified three primary considerations that we believe will bring significant clarity to this issue:

1. **Define the regulatory boundary between medical and health and wellness use**.

   The shared purpose mobile networks in place today provide a wide range of different content types and functions. Likewise, many mHealth technologies can be used for both medical care and general health and wellness applications, using the same technology product or platform. For example, a digital weight scale connected through Bluetooth IEEE 802.15.1 wireless networking technology to a mobile phone or wireless gateway could be used as part of a treatment protocol for obesity or cardiology care, with the data uploaded to an electronic health record at the physician's office. The exact same technology could also be used by people who are tracking their body weight and BMI, and simply want to upload that information to a personal health record to monitor their progress towards a health goal. MRC believes that the intended use of a device for general wellness rather than medical care purposes is an important consideration that should be addressed in FDA's regulatory oversight strategy. We seek to work with FDA to reconcile both medical and wellness intended uses for a given connected device when determining the regulatory requirements applicable to the device and to the mHealth technologies involved in the capture and transmission of health information from the device.

2. **Address the challenges of the medical device accessory rule for mHealth.**

   The medical device accessory rule adopted by FDA was logical and fairly easy to understand when medical devices were mainly standalone pieces of equipment and the rule applied to products that end users of the device would physically connect to the primary medical device. Under these circumstances, the application of the regulatory requirements of the parent device to the attached accessory was simple. In the mHealth context, however, traditional medical devices are connected to other devices and systems through a network, intended for a variety of general communications purposes. Many of these systems and software are necessary for the connected use of the device, but are not, of themselves, medical devices. Rather these system components are broadly used for multiple communication applications. In this context, the beginning and end of the regulated medical device is unclear. FDA regulatory strategy for mHealth technologies will need to address the application of the accessory rule to the reality that network connectivity will be built into almost every medical device going forward. MRC believes that a policy that considers, for example, a carrier's mobile network as an accessory to a given device would be an untenable policy to apply and would unnecessarily limit the advancements in healthcare delivery offered by mHealth technologies.

3. **Addressing software that is not directly involved with the operation of a medical device.**

   When medical devices are connected to mobile networks, there often is a considerable number of supporting software systems that enable healthcare providers to use their mobile devices to help them diagnose, treat, or monitor a remote patient. MRC acknowledges that FDA has been working on this issue for some time, including in the draft Medical Device Data Systems (MDDS) proposal that was published in March of 2008 but never finalized. The MRC intends to present to FDA the industry perspective on possible approaches to the regulation of software that plays important, but reasonably unregulated, behind-the scenes roles to enable mHealth networks. Here, too, the MRC advocates a risk-based approach to the application of FDA's regulatory oversight.

Summary

It is the intent of the MRC to utilize a model of collaboration, enlisting a broad set of stakeholders focused on a single important goal, to effectively break down complex problems to deliver meaningful, actionable proposals to FDA. The FCC-FDA Public meeting highlighted many of the obstacles that stand in the way of widespread deployment of mHealth, but we are confident that with focus, effort, and cooperation between public and private sector stakeholders, these challenges will be overcome and mHealth will be able to deliver the benefits and meet the high expectations that all involved have for its contributions to improving our nation's healthcare system.

The MRC looks forward to engaging with FDA on the specific challenges it faces as mobile and wirelessly connected medical devices become increasingly commonplace and reliable contributors to the nation's health and well being.

Respectfully submitted on behalf of the mHealth Regulatory Coalition members:

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