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January 20, 2012

VIA EMAIL

Mr. Bakul Patel
Policy Advisor
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 5456
Silver Spring, MD 20993-0002

Re: Request to Delay the Issuance of FDA's Final Guidance on Mobile Medical Applications: Docket No. FDA-2011-D-0530

Dear Bakul:

Thanks to your great efforts for transparency and cooperation with industry in the development of guidance on mobile medical applications, the FDA received more than 500 pages of feedback related to the above proceeding from nearly 100 different interested stakeholders. The comments from the mHealth Regulatory Coalition (MRC)[1] alone accounted for over 200 pages and were supported in whole or in part by a significant number of other commenters. After reviewing the comments, the MRC strongly believes that the Agency would need to make significant changes to adequately address the concerns that commenters raised in the proceeding. As the Agency proceeds with the guidance, the MRC respectfully requests that the Agency re-propose the guidance before issuing it as a final document. This course will give the public a meaningful opportunity to review and fully comment on the required changes. Below, we have laid out our reasoning for this request.

There are a number of commonalities in the comments. Although a handful of individuals suggest that the FDA should not regulate mobile medical apps, the vast majority indicate that some level of regulation of such devices is appropriate. The most frequent comment is that the complexity and lack of clarity on how

[1] The MRC, which formed in July 2010, is a diverse group of mHealth non-governmental representatives, non-profit associations, patient advocacy organizations, healthcare payors, and individual as well as integrated healthcare providers. Industry members include traditional medical device manufacturers, mobile app developers, online marketplaces for mobile apps, mobile platform manufacturers, telecommunications service providers, and information and communications technology companies.

the Agency intends to regulate, and the resultant cost, pose significant barriers to investment and development of new mHealth technologies. This underscores the importance of incorporating a clear and thorough regulatory framework into the final guidance. Anything short of this would fail to stimulate the innovation the healthcare community requires. A document that is ambiguous, high-level, or omits important aspects of the regulatory framework will leave mHealth technology developers scratching their heads and will do little to encourage them to pursue the research and development projects that are crucial to improving healthcare in the United States.

In addition to this broad request for clarity, the body of comments demonstrates the meticulous effort on the part of the public to review and suggest changes to the draft guidance. These comments warrant an equally thorough review and proper consideration by the FDA. In general, it is possible to divide the individual observations or requests into three different broad categories. Those categories generally include requests to supplement, reduce, or modify the guidance document.

As the agency thinks about how to respond, and its options going forward, it is important to understand how the comments fall into those three buckets. Rather than lay that out in this letter, we propose to discuss the issues more fully when we meet with you and other officials on February 1, 2012.

Some of the common recommendations contained in the comment letters include:

- Focus on regulation of mobile medical apps that involve high-risk, clearly defining what constitutes high-risk;

- Define important terms, including electronic health records, personal health records, general health, and wellness;

- Describe the premarket notification or approval process for mobile medical apps and the information the Agency expects to see in a submission;

- Clarify the regulatory approach for accessories;

- Clarify the Agency's expectations for distributors and platform manufacturers;

- Remove clinical decision support software from this guidance and describe the Agency's approach in separate guidance; and

- Expand the Agency's regulation of mHealth technologies consistent with the recommended approach of the MRC.

FDA is currently in an interesting situation due to the nature of these and other comments. On the one hand, if the Agency updates the guidance based on these recommendations, the final guidance will involve substantial changes that warrant public review and an opportunity to comment. Indeed, that's what the MRC recommends. On the other hand, if the Agency were to choose to scale back the guidance for purposes of expedience and wait until a later date to address controversial elements, very little of the guidance will remain. For example, the comments recommended several different approaches to regulation of accessories. If the Agency embraces a particular approach, the public should have an additional opportunity to comment prior to the approach becoming final. If, however, the FDA chooses to remove accessory regulation from the final guidance, the resulting policy will be fragmented and incomplete. Such core elements cannot simply be cleaved off. If the Agency pursues this route, the final guidance will be too high-level to meet the needs of its audience and would lack core elements of the

regulatory framework that are essential to ensure its clarity and predictability. Indeed, it would fail to assure patient safety.

In our view, there is a much bigger issue at stake here than only mobile health. At stake is how FDA interacts with the public. In just 2011, FDA published numerous proposed guidance documents on medical devices, requesting public comment on each one of them. We believe the FDA would better support its own transparency effort and concern for the public trust if the Agency meticulously considers and integrates the many carefully crafted comments that patient safety groups, trade associations, companies, and the general public spent significant time developing. Indeed the integrity of the guidance system requires that FDA give public comments serious, mature consideration and respond with appropriate modifications, not just promises of future action. Without preserving the integrity of the system, the Agency will likely have difficulty soliciting public participation in future proceedings.

Furthermore, regulation of the mHealth industry differs significantly from much of the FDA's other work. Many of the developers of mobile medical apps are not traditional medical device companies and are unfamiliar with FDA regulations. Accordingly, one of the primary objectives of this guidance document is to educate the community of mobile medical apps developers who are new to the world of medical device regulation. FDA should encourage a deeper collaborative approach to reach this atypical audience.

In summary, the MRC believes that the FDA should re-propose the draft guidance, incorporating the Agency's changes and allowing the public a reasonable opportunity to comment before the issuance of a final document. We want to be clear: we are not advocating for significant delay in finalizing the guidance. Prolonged use of vague enforcement discretion will perpetuate an uneven playing field, stifle innovation, and suppress development where manufacturers who make an effort to comply with regulations are disadvantaged while others go to market in ignorance of the regulations. Hence, the MRC encourages the FDA to move quickly, but not hastily, toward a re-proposal, then to final guidance. The Agency should publish the second draft guidance as soon as possible to prevent continued uncertainty and unpredictability in the regulatory approach to mHealth technologies.

We applaud the FDA for its deliberate and transparent approach to the regulation of mHealth products. We encourage the agency to continue to work toward an appropriately-tailored regulatory framework for mHealth products that balances the industry's need for clarity and predictability with the common goal of ensuring patient safety.

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