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May 17, 2012

VIA HAND DELIVERY AND ELECTRONIC MAIL

Senator Tom Harkin
Chairman, Committee on Health, Education, Labor
and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Senator Michael B. Enzi
Committee on Health, Education, Labor and
Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Re: Bennet-Hatch Amendment to MDUFA Legislation: Opposition to the Proposed Moratorium on the Publication of the FDA's Guidance on Mobile Medical Applications

Dear Senators Harkin and Enzi:

On behalf of the mHealth Regulatory Coalition ("MRC"), I am writing to express opposition to the recently proposed Bennet-Hatch Amendment to the MDUFA legislation because it effectively establishes a moratorium on the publication of the U.S. Food & Drug Administration's ("FDA") guidance on mobile medical applications. Indeed, we encourage FDA to publish guidance that describes a clear, predictable, and robust regulatory framework for these and other mobile health ("mHealth") technologies. While we recognize the need to enhance the draft guidance and support mechanisms for public input, we seek to continue dialogue and engagement on these issues directly with the Agency, rather than through legislation at this time. We believe the proposed amendment will hinder innovation and job creation in the rapidly growing mHealth ecosystem because it will extend the period of regulatory confusion and lead to over-regulation during the moratorium.

To provide some background, the MRC—which formed in July 2010—represents the heterogeneity of the stakeholders in the mHealth ecosystem, consisting of non-governmental, industry representatives; nonprofit associations; 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.

Our membership includes, among others, the following organizations:

AgaMatrix	Great Call (pka Jitterbug)	Qualcomm Inc.
Alternative Universe	Massive Health	Roche Diagnostics
Technologies	MedApps	Verizon Wireless
AT&T	Medical Graphics Corp.	View720.com
Boston Scientific Corp.	OmniScience Mobile	Voxiva, Inc.
Continua Health Alliance	Partners/Ctr. for Connected Health	WellDoc, Inc.
IDEAL LIFE	Philips	Wireless-Life Sciences Alliance

The mission of the MRC is to propose a means by which FDA can tailor and apply its existing regulatory framework to mHealth technologies. To achieve this goal, the MRC has spent the last two years identifying the challenges with the existing regulatory scheme and developing a proposed guidance document describing the approach that FDA should take in defining what types of mHealth products should be regulated and at what classification. In October 2011, we submitted our proposal to FDA in response to the draft guidance on mobile medical applications.[1] Throughout this process, FDA has engaged in dialogue with numerous stakeholders in various forums, including hosting a 2-day public workshop and accepting more than 550 pages of recommendations from over 100 different commentators on the draft guidance. We applaud the Agency's continued and consistent efforts to educate the public and to take into consideration the concerns of industry and other stakeholders as it finalizes its guidance document.

However, we recognize and call attention to the need for FDA to improve the current approach to regulation of mHealth technologies, beyond simply focusing on mobile medical applications. To be sure, the MRC believes the guidance on mobile medical applications is a significant step toward the appropriate regulation of these technologies. Indeed, the guidance provides much needed clarity in some areas, limiting regulatory oversight for certain low-risk products. Yet, the final guidance must go further. Gaps in the regulatory framework must be addressed in order to provide the predictability and robustness that investors and innovators require to further growth in an industry that promises to revolutionize healthcare in the United States. A moratorium on the publication of the guidance on mobile medical applications will only serve to delay this important, initial step toward a comprehensive regulatory scheme.

Therefore, we join other public calls for FDA to publish a final guidance that describes a clear, predictable, and robust regulatory framework. We respectfully request that you oppose any proposal that would effectively delay the publication of the FDA's guidance on mobile medical applications. If you have any questions or would like to discuss this further, do not hesitate to contact me.

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[1] *See* Letter from Bradley Merrill Thompson on behalf of the mHealth Regulatory Coalition to Bakul Patel, Policy Advisor, U.S. Food & Drug Admin. (Oct. 19, 2011), *available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/MRC-Comments-on-FDA-Draft-MMA-Guidance.pdf.

Very truly yours,

Bradley Merrill Thompson
On Behalf of the mHealth Regulatory Coalition

Cc: Dan Smith, Majority Staff Director, Senate Committee on Health, Education, Labor and Pensions
Bill McConagha, Health Policy Advisor, Senate Committee on Health, Education, Labor and Pensions
Katy Spangler, Deputy Health Policy Director, Senate Committee on Health, Education, Labor and Pensions