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VIA US MAIL

Representative Mike Honda

1713 Longworth House Office Building
Washington, D.C. 20515

Re: Healthcare Innovation and Marketplace Technologies Act of 2012

Dear Representative Honda:

On behalf of the s members of the mHealth Regulatory Coalition, I thank you for your commitment to mobile health technologies and applications by introducing the Healthcare Innovation and Marketplace Technologies Act of 2012 ("HIMTA" or the "bill"). This bill would help create a sensible and predictable regulatory pathway for mobile health development.

Among other things, the current FDA proposed guidance on mobile health does not address the variety of existing technologies and applications. The lack of clear and consistent guidance has resulted in overregulation of some mobile technologies such as applications intended to assist and empower individuals to enhance their own wellness. By recommending the creation of an Office to coordinate efforts and foster consistent and appropriate guidance on mHealth regulation, the bill represents an important step toward ensuring the industry receives clear guidance on issues unique to mobile health.

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 honest, realistic, and thoughtful regulatory policy perspective on mobile health technologies. 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 patient's best interests. The MRC provides a convenient forum for FDA to work with industry stakeholders regarding mHealth regulatory policy.

With that background in mind, the MRC offers the following comments regarding HIMTA in hopes that you will take them under advisement. While the bill addresses several issues, we will focus on the creation of an Office for mobile health.

1. **Creation of an Office of Wireless Health Technology**

Section 5 of the bill recommends the creation of an Office of Wireless Health Technology within the FDA Office of the Commissioner (the "Office"). The MRC supports the concept of establishing an Office within FDA that focuses primarily on mobile health technologies, and more broadly on wireless health and health IT. To adequately address issues that are unique to the mobile health industry, the Office must have wireless technology expertise in addition to FDA regulatory experience. The MRC recommends that the mission of the Office be to: i) ensure patient safety; ii) promote innovation; and iii) develop a cohesive mHealth policy that is informed by relevant stakeholders and addresses the unique aspects of mHealth.

2. **Office Will Not Create New Regulations**

The bill provides that the Director of the Office will communicate with industry thought leaders, and receive recommendations on how to make existing regulations regarding wireless health technology "more reasonable and predictable, including ways that such regulations could be clarified and simplified." The bill should clarify that this Office will not create new regulations but help to streamline application of existing regulations to wireless products in a manner that is appropriate for the technology. In addition, the Office should ensure that there is consistent regulatory treatment of products, when appropriate, by various offices within the Agency. The MRC would oppose any structure that imposes additional levels of regulatory bureaucracy or that would otherwise slow the regulatory or policymaking process.

3. **Office Would Play Educational Role**

The bill provides that the Office will provide information to developers of wireless health technology on how to design, produce, or disseminate their products. The MRC recommends that the Office play an educational role both externally and internally. The Office must play an educational role for wireless industry members who are new entrants to the FDA-regulated environment. We also recommend that this Office be a resource within the agency to inform and educate relevant agency personnel.

4. **Office Recommendations on Wireless Technologies to Include mHealth**

The bill provides that the Office will make specific recommendations on how FDA should improve its approach regarding wireless health technology in a manner that ensures consistency without compromising patient safety or privacy. The MRC recommends that wireless health technology be clearly defined to include mHealth. The bill should clearly define whether the Office would make recommendations with respect to privacy issues, to ensure the Office does not overlap the jurisdiction of other agencies such as the Office of the National Coordinator—who has already undertaken initiatives to define privacy risks regarding mobile technologies.

5. <u>The Office Should Maintain an Open Dialogue with the Industry</u>

The bill provides that in carrying out his or her duties, the Director of the Office shall consult with any working group convened under section 618(b)(1) of the Food and Drug Administration Safety and Innovation Act, and may consult with any federal commission. The MRC recommends that independent of any section 618 working group, the Office actively solicit feedback from interested stakeholders to ensure policies and recommendations reflect stakeholders' practical experience, address concerns and remain current with wireless technology advancements.

The mobile health sector is rapidly evolving. In light of the technological progress, initiatives such as HIMTA demonstrate an understanding of the need to accelerate the dialogue among the relevant stakeholders, and to develop a consensus around a flexible regulatory framework that reflects the rapidly changing and unique nature of this new marketplace.

The MRC would be happy to provide additional feedback. If you have any questions or would like to discuss any issues further, please do not hesitate to contact me.

Very truly yours,

Bradley Merrill Thompson
On Behalf of the mHealth Regulatory Coalition