mHealth Regulatory Coalition's Position on mHealth Coordinator at FDA

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There has been much discussion regarding the appropriate mechanism to oversee the regulation of mHealth technologies. Some are calling for an agency outside of the FDA. Others are proposing legislative action. Still others advocate for the office to include wireless health. The mHealth Regulatory Coalition ("MRC" or "Coalition") supports the concept of establishing an mHealth coordinator within FDA supported by a small dedicated team that focuses on mHealth policy, safety, education and program coordination. While the Coalition's focus is on mobile health technologies, we recognize there are similar issues related to wireless health and would not be opposed to broadening the scope of the coordinator to include wireless health issues.

There are several reasons why MRC supports the creation of such a role within FDA: (1) the mHealth industry is unique in several ways, and (2) it requires expertise and focus; (3) FDA is best equipped to address the different mHealth devices.

I. The mHealth industry is unique in several ways.

- Mobile health is a complex ecosystem of sophisticated technologies being used in innovative ways that do not fit neatly within the traditional FDA models. It is not atypical for an mHealth system to involve a general purpose mobile platform, a mobile medical app and a variety of different medical devices and non-medical devices all interconnected directly or indirectly through one or more mobile platforms. This interoperability issue requires a dedicated team with specialized knowledge of mHealth products and technologies.

- Many of these products cut across a broad range of device types and therapeutic areas. Unfortunately, this has resulted in an inconsistent application of the current regulatory framework to mHealth products from different offices within the Agency – without an apparent uniform methodology to consider and review these novel devices. These inconsistencies cause delays in time to market for new products and subject mHealth companies to additional user fees, delays in the filing and review of submissions, costs associated with additional filings, and in some instances, rejection of these products. Further, a predictable assessment of related device safety is needed to address risks adequately and ensure consistency, where appropriate. In order to successfully market new products, mHealth vendors need to have a predictable regulatory process and avoid unjustified inconsistencies.

- The number of innovative health IT products and converged medical devices is exploding. FDA has publicly acknowledged how rapid innovation has led to delays in approvals. Streamlining an approval process for mHealth products would only lead to more efficiency for the Agency. An efficient approval process is in the best interest of patients who can benefit from utilizing safe, innovative mHealth products.

- mHealth manufacturers are not always traditional device manufacturers and represent new entrants to the medical device industry. They are not

familiar with the FDA processes or requirements and need to be educated about how to navigate the regulatory framework to successfully and efficiently release their new mHealth products.

II. Unique mHealth industry calls for dedicated team with mHealth expertise

We envision an mHealth coordinator position as having a small, dedicated and knowledgeable staff at FDA. It would be responsible for advising and developing policies related to mHealth issues, serving as a resource for mHealth products submissions, responding to inquiries from industry, and educating industry and Agency staff, including field investigators.

The mHealth coordinator would serve three purposes:

1. Oversee policy development for mHealth issues. In developing mHealth policy issues, the coordinator would address converged medical device technologies including connected and wireless health. This position would maintain a regular dialogue with stakeholders and industry.

2. Provide education internally within the Agency and externally.

3. Function as subject matter experts within FDA to avoid unjustified inconsistent treatment of mHealth products in various therapeutic areas and device types.

III. The Office of the Commissioner

The MRC supports housing this role within FDA, as opposed to an office outside FDA. This coordination effort should be designed to consolidate mHealth efforts and have the necessary authority to effectively coordinate the various offices and divisions within the Agency on mHealth activities. Also, as mHealth products have the potential to impact both medical devices and pharmaceutical industries, the MRC believes that the Office of the Commissioner would be an appropriate setting for this position. An additional goal of this effort should be to help new non-traditional device manufacturers navigate the complex FDA regulatory environment from the perspective of converged medical devices (a function that the Division of Small Manufacturers, International and Consumer Assistance - DSMICA presently lacks).

The MRC would oppose any structure that would impose additional levels of regulatory bureaucracy or that would otherwise slow the regulatory or policy making process.

Ultimately, this mHealth coordination role must ensure patient safety, promote innovation and respect a cohesive mHealth policy that is informed by the relevant stakeholders and addresses the unique aspects of mHealth.

The Coalition believes these goals can be accomplished within the existing statute and would welcome the opportunity to review and comment on any proposed legislation addressing these issues.