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August 28, 2012

VIA EMAIL & USPS MAIL

Secretary Kathleen Sebelius
Department of Health & Human Services
Hubert H. Humphrey Building, Room 120F
200 Independence Ave. SW
Washington, DC 20201

Re: Food and Drug Administration Safety and Innovation Act – Establishing a Working Group as Provided by Section 618 of the Act

Dear Secretary Sebelius:

As you are aware, Section 618 of the Food and Drug Administration Safety and Innovation Act[1] directs you through the Commissioner of Food and Drugs, and in consultation with the National Coordinator for Health Information Technology and the Chairman of the Federal Communications Commission, to post on the Internet Web sites of the FDA, the FCC, and the ONC, "a report that contains a proposed strategy and recommendation on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[2] In furtherance of this effort, under the Act you "may convene a working group of external stakeholders and experts to provide appropriate input on the strategy and recommendations required for the report . . . ."[3] We are writing on behalf of the mHealth Regulatory Coalition ("MRC") and the CDS Coalition to strongly encourage that you convene this working group as soon as practicable to ensure the speedy development of an appropriately tailored regulatory framework for mobile health ("mHealth") technologies and clinical decision support ("CDS") software. We believe that dialogue among the agencies and interested stakeholders is paramount and that the working group is an excellent means to facilitate such a dialogue.

To put into context the reason for this correspondence, let us begin by introducing you to the MRC and CDS Coalition. The MRC represents the heterogeneity of the stakeholders in the mHealth ecosystem,

[1] Pub. L. No. 112-144.
[2] *Id.* § 618(a).
[3] *Id.* § 618(b).

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, such as:[4]

- AgaMatrix
- AT&T
- Continua Health Alliance
- Ideal Life Online
- Great Call (pka Jitterbug)
- Massive Health
- MedApps
- Medical Graphics Corp.
- Medical Imaging & Technology Alliance (MITA)
- OmniScience Mobile
- Partners/Ctr. for Connected Health
- Philips
- Qualcomm Inc.
- Roche
- Verizon Wireless
- View720.com
- Voxiva, Inc.
- WellDoc, Inc.
- Wireless-Life Sciences Alliance

The purpose 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 spent nearly two years identifying the challenges with the existing regulatory scheme and developing a proposed guidance document—which we submitted to FDA in October 2011—that describes the approach FDA should take in defining what types of mHealth products should be regulated and at what classification.[5] Throughout the development process, the MRC has worked closely with the FDA.

The CDS Coalition is composed of an equally diverse group and shares a similar purpose—to propose an appropriately balanced and non-duplicative regulatory scheme for software that is used to support clinical decision-making. The membership, which has been working over the last eight months to develop proposal, includes:

- Aetna
- AT&T
- ALR Regulatory Consulting
- American Physical Therapy Ass'n
- American Psychosomatic Society
- Anakena Solutions
- CareFusion Corp.
- CDS Consortium
- Coalition for 21st Century Medicine
- Continua Health Alliance
- FujiFilm Medical Systems
- GE Healthcare
- Happtique, Inc.
- InfraMedix
- Intermountain Healthcare
- Isabel Healthcare Inc.
- MedApps, Inc.
- Medical Graphics Corp.
- MITA
- Medtronic, Inc.
- NuVon, Inc.
- Physician Software Systems
- Roche
- Speer Medical Devices, Inc.
- Verizon Wireless
- Voxiva, Inc.
- WellDoc Inc.
- Wireless-Life Sciences Alliance

We applaud FDA on its willingness to engage us throughout our development process, but much work remains to establish the comprehensive, predictable, regulatory scheme that is vitally important to the innovators and investors of these technologies and that fulfills the intent of Section 618. As noted above,

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[4] This list does not include the names of individual members who are not associated with a specific organization.

[5] *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://www.regulations.gov/#!document Detail;D=FDA-2011-D-0530-0082.

we believe Section 618 offers an excellent opportunity to forge ahead in the development and implementation of an appropriately balance, non-duplicative, risk-based, regulatory framework that includes mHealth technology and clinical decision support software. Indeed, the working group will bring together a diverse group of interested stakeholders that may otherwise not find an opportunity to collaborate on such important policy issues and allow them to participate at a level of granularity that is necessary to develop a meaningful regulatory strategy.

To be sure, dialogue offers significant added benefits for the federal government, industry, and the general public. We believe that the formation of the working group would be the most efficient means by which to achieve the congressional mandate. The process for developing the report as directed under Section 618 will be complex and demands consensus building from the beginning among and between the various agencies and stakeholders. Delaying involvement of the public until, for example, a draft report is published will only limit the consensus building and constrain the report-drafting process. The issues involved are simply too complicated and dynamic to be solved in isolation, without an opportunity for interested stakeholders to iteratively comment and participate throughout the process. The working group facilitates this iterative development process and allows a dialogue for all stakeholders to explore the numerous potential regulatory options for tackling such a complex problem in such a short amount of time.

What's more, an open and transparent development process will increase the perceived legitimacy of the strategy. The value of regulatory transparency is often observed, for example, during the rule-making process. The main purpose of the process of rulemaking is to increase the perceived legitimacy of the final rule. Although the report to Congress is not rulemaking, an open and public dialogue will bridge any gap between industry and government as a result of the consensus-building nature of the process. The process itself will facilitate stakeholder intellectual growth, thereby informing and improving existing product development activities. Industry will, thus, be better positioned to bring these valuable technologies to market more quickly and in compliance with government expectations, ultimately improving the health and wellness of all Americans.

In addition to the procedural aspect of involving the public in the development of the report, there are significant legal issues (e.g., matters of jurisdiction) and public policy concerns that must be considered. As you know, numerous government agencies, including FDA, FCC, and ONC, have jurisdiction over various aspects of the technologies that are the subject of the report. Furthermore, many of the public policy concerns are not entirely obvious (e.g., software development and business-related issues), demanding the expertise of those in industry, professional societies, and academia to weigh-in on the practical implications of multi-jurisdictional regulation. We believe that public input on these issues is necessary to prevent duplicative and inconsistent approaches to regulation in this rapidly developing industry.

For these reasons, we strongly encourage you to establish the Section 618 working group. Failure to seize this opportunity could have long-lasting, deleterious effects on healthcare as the continued lack of clarity and predictability in the regulation of these health technologies will stifle innovation and will jeopardize the viability of an industry that promises to revolutionize modern healthcare through improved access and quality of care at dramatically reduced cost. As Congress stated, the working group should be "geographically diverse and include[] representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and

other stakeholders with relevant expertise . . . ."[6] We believe that the mHealth Regulatory Coalition and the CDS Coalition are uniquely positioned to provide an informed, consensus perspective from across the landscape of health technology stakeholders.

Should you decide to move forward with the working group, please do not hesitate to contact us if we can be of assistance.

Sincerely,

Bradley Merrill Thompson
On Behalf of the mHealth Regulatory Coalition
and the CDS Coalition

Cc: Margaret A. Hamburg, M.D., Commissioner of Food & Drugs, U.S. Food & Drug Administration

Julius Genachowski, J.D., Chairman, Federal Communications Commission

Farzad Mostashari, M.D., ScM, National Coordinator for Health Information Technology, Office of the National Coordinator for Health Information Technology

Jeffrey Shuren, J.D., M.D., Director, Center for Devices & Radiological Health, U.S. Food & Drug Administration

Bakul Patel, Policy Advisor, Office of the Center Director, Center for Devices & Radiological Health, U.S. Food & Drug Administration

[6] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 618.