Congress of the United States
Washington, DC 20515

April 3, 2012

Commissioner Margaret Hamburg
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Chairman Julius Genachowski
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Dear Commissioner Hamburg and Chairman Genachowski:

Innovative wireless medical devices play a vital role in addressing our nation's unsustainable health care costs. These technologies enable physicians to know that a patient's condition is worsening before the patient feels any symptoms, and provide treatment to keep the patient from having a health crisis that results in a trip to the emergency department. Additionally, the popularity of mobile medical applications reflects the desire of many Americans to use technology to actively engage in their own health. The abilities of smartphones and wireless devices to perform complex health and medical functions are increasing and the use of mobile medical applications is becoming more common. As policy makers, we must ensure a regulatory framework that encourages innovation while increasing access to care, protecting patient safety and lowering costs.

However, these new technologies increasingly cross two regulatory structures - the Food and Drug Administration (FDA) and the Federal Communications Commission (FCC). For example, mobile cardiac outpatient telemetry (MCOT) that uses peel-and-stick, band aid-like wireless sensors; real-time glucose monitors that wirelessly transmit data to wearable insulin pumps; and, wireless thermometers. It is critical that the two agencies act in concert to provide regulatory predictability, consistency, and swiftness so that needed innovation in wireless medical technology may thrive. We were pleased that both agencies recognized this necessity and began to formally address it in July 2010. The execution of a Memorandum of Understanding (MOU) between the FDA Center for Devices and Radiological Health and the FCC, the issuance of a Joint Statement on Wireless Medical Devices, and the hosting of an exploratory public meeting were important steps.

We hope that the momentum generated by those actions continues and that collaboration between the agencies remains a priority. Between 2010 and 2011 the number of medical applications (apps) available in the iTunes App Store subject to FDA evaluation under the draft guidance increased by 250 percent. The technology is changing rapidly. We are concerned that applying a complex regulatory framework could inhibit future growth and innovation in this promising market and could preclude tools that help patients better manage their care and allow the health system, as a whole, reduce costs and improve quality. More so, we fear that despite initial enthusiasm, the daily work of expeditiously

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these valuable solutions has slowed at a time when they are most needed. To that end, we request an update on coordinated FDA and FCC activities to find innovative solutions to America's health care challenges.

As Members of Congress, we understand the importance for developing public policy that addresses new emerging health technologies while ensuring patient safety. We ask that you provide a unified response to the following questions in writing within 14 days so that we can better understand the progress FDA and FCC have made to date, future steps planned by the agencies, and how we may best assist the agencies' efforts.

1. What specific joint actions have your agencies undertaken to date to implement the Memorandum of Understanding? Please include public meetings, inter-agency meetings, data sharing, publication of and/or consultation on guidance documents and reports, and other activities relevant to implementation of the MOU.

2. Who oversees each agency's policy development (including regulations, guidance, etc.) for wireless health devices and their supporting infrastructure, and how do the agencies coordinate their respective policy measures with each other, as well as the Office of the National Coordinator for Health IT (ONC) given ONC's responsibility for ensuring the certification process for electronic health records and EHR modules used in the Meaningful Use program?

3. What primary activities related to wireless health devices are underway at each agency? Please include efforts that are conducted independently and jointly, as well as those in conjunction with ONC.

4. We envision device to EHR or EHR module interoperability in the near future. What communication or coordination activities have taken place between FDA, FCC and ONC and what plans do your agencies have to coordinate regulatory requirements across the Agencies?

5. What efforts have been undertaken or are being planned to better leverage staff expertise relative to wireless medical devices and supporting infrastructure across the agencies?

6. Both FDA and FCC have publicly discussed efforts to make possible wireless "testbeds" for the important purpose of better understanding how wireless health devices coexist in health care settings and advancing medical device interoperability. Please provide an update on these efforts, including each agency's role in the development of wireless "testbeds" and the promotion of interoperability.

7. How are FDA and FCC coordinating review processes for devices that may be subject to regulation by each agency? Please include mechanisms that are in place or are being planned to prepare for the increasing application of wireless technologies in medical device innovation.

8. How are FDA and FCC approaching regulation of wireless network infrastructure, both internal and external to health care facilities, relative to its role in enabling transmission of health care data? Please include current or planned efforts to help various stakeholders understand jurisdictional delineation and agency approaches to related concerns such as transmission security and integrity.

9. Please provide a single point of contact with whom we might engage to support FDA and FCC in their coordinated efforts.

Thank you in advance for your attention in this matter. We look forward to working with FDA and FCC on responsibly fostering wireless medical device innovation. Please do not hesitate to contact Keith Studdard (keith.studdard@mail.house.gov) on my staff if you need any further explanation.

We look for forward to your response.

Sincerely,

Marsha Blackburn
Member of Congress

Joseph Pitts
Member of Congress

Greg Walden
Member of Congress

Brian Bilbray
Member of Congress

Michael Burgess, MD
Member of Congress

Phil Gingrey, MD
Member of Congress

Cc: Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201