Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fischers Lane, Room 1061
Rockville, MD 20852

Docket # FDA-2010-N-0237

July 23, 2010

Dear Members of the Council on Medical Device Innovation:

On behalf of the mHealth Regulatory Coalition I am pleased to submit these comments in response to the Council's request for industry perspectives in the notice of public meeting titled, "Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development." mHealth Regulatory Coalition appreciates the opportunity to provide comments on this topic of significant importance to the public health.

The mHealth Regulatory Coalition represents a broad cross section of critical technology providers and other stakeholders in the rapidly growing sector of mobile healthcare. The coalition was formed to proactively engage with the Agency to help clarify and form regulatory policy that accounts for the convergence of cellular, wireless, and mobile applications for healthcare use. FDA policy decisions regarding the regulation of these technologies, commonly referred to in the industry as "mHealth" will significantly impact the diverse members of the coalition whose technologies enable the delivery of wireless and mobile networking services and software. With barriers to innovation reduced, coalition members' technologies have the potential to dramatically improve the efficiency and effectiveness of our healthcare system.

Rather than engaging as distinct business entities or industry sectors, mHealth Regulatory Coalition members have joined together to promote their common interests in facilitating the expansion of mHealth technologies to improve patient care and reduce costs. Coalition members represent a diverse array of stakeholders, including 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 development and adoption of regulatory policy that accounts for the inclusion of mHealth technology. The coalition is also intended to provide a convenient forum for FDA to work with a broad representation of industry stakeholders on what constitutes appropriate mHealth technology regulatory policy that both enables innovation while protecting the public health. The Coalition offers the following comments on the two important questions raised by the Council at the June 24th, 2010 public meeting.

1. **Areas of unmet public health need that may be addressed by the development of new, or the redesign of existing, medical devices.**

The healthcare system in the United States is faced with conflicting pressures to provide increased access to care, while dramatically reducing the total cost burden delivering this care imposes on society and individual consumers. This must be done even as the demand for health services grows with the aging of the population and the number of patients with chronic disease conditions such as diabetes, cancer, asthma, COPD, obesity, or heart disease.

The challenge of meeting the surge in demand for increased healthcare services and the decline in resources and staffing may be addressed, in part, by the increased use of mHealth technologies. Innovations in medical device technologies offer ways to better, faster, and less intrusively diagnose, treat and monitor a variety of disease conditions. The benefits of these sophisticated technologies are nearly universally amplified by connecting them to wireless networks that enable the information to be shared between patients, health care providers, and caregivers. The ability of mHealth technologies to easily and quickly make data available to a patient's health care provider will make continuous monitoring and remote treatment a reality. Further, healthcare can be more effective if it reaches patients where they are and is continuously applied to help support healthy lifestyle patterns and behaviors in a way that is not possible with the intermittent service models of the past. The Coalition has identified three examples of unmet public health need that may be addressed by the design or redesign of mHealth medical device technologies.

a. **Improving treatment and monitoring of major chronic disease conditions.** Studies by organizations such as AHRQ indicate that nearly 75% of U.S. healthcare spending can be attributed to patients that have one or more chronic conditions. Chronic disease care could benefit from continuous rather than interval based monitoring, given that a patient's condition can fluctuate throughout the day and is highly influenced by behavior, environment, and even the time of day. mHealth enabled technology can deliver data to care providers and feedback to the patient, effectively enabling better self-care and non-intrusive professional clinician notification if problems arise. This helps avoid unnecessary trips to the emergency department, enhances treatment adherence, and improves quality of life.

b. **Enabling care of elderly patients in the comfort of their homes.**

Demographic trends point to the increased aging of the population of the United States. This trend that will only continue as the 78 million people that are part of the Baby Boom generation, defined by the Census Bureau as those citizens born between 1946 and 1964, begin to reach retirement age. AHRQ reported in a 2006 study that the elderly (65 or older) in the US represented approximately 15% of

the total population, yet consumed 36% of the nation's healthcare spending. These numbers will almost assuredly increase as the largest generation in US History has already started to reach the age of 65 and begun to qualify for Medicare coverage. mHealth technologies can alleviate the burden on healthcare providers, facilities, and family caregivers by extending the monitoring and treatment of conditions to the patient's home. Many of the top chronic diseases discussed in the first unmet need frequently begin to appear as part of the aging process, but the benefits of mHealth for the elderly population also include care targeted at other more age specific diseases, such as Alzheimer's. The greater likelihood of multiple chronic illnesses in later stages of life lead to more frequent hospitalization and greater cost burdens, due to the lack of ability to continuously monitor those conditions through traditional episodic interactions.

c. **Reducing the number of unnecessary hospital readmissions due to lack of discharged patient monitoring**

According to a 2009 study conducted by the New England Journal of Medicine, about 20% of hospitalized Medicare patients are readmitted within 30 days of original discharge. In 50% of these cases, the patient did not see a doctor between the initial stay and the readmission. The estimated cost to Medicare associated with this lack of follow up is $17B per year, according to this study. mHealth technologies can provide a means for overburdened primary care physicians and nursing staff to remotely monitor a patient's condition, including for the first time new measurements such as movement and mobility. Though movement is not recognized as a clinical body vital sign today, many physicians see its potential to serve as a valuable "leading indicator" of a patient's vitality and condition ahead of a drop in blood pressure or other physiological measurement.

All three of these areas are significant contributors to the cost burden of the current health system and the consumption of its constrained resources, and many of the mobile healthcare technologies in development are focused on specifically addressing these unmet needs. The Coalition believes that technologies offering the dual benefits of improved care and reduced cost should be among the Council's highest priorities. Therefore, the Coalition urges the Council to look both for ways to ease the path towards combining the available wireless mobile technology infrastructure with existing medical device technology, clinical software, and to encourage and support the development of new device design concepts including network connectivity, smart sensors, and innovative materials in their product design specifications at concept inception.

2. **Barriers to development and/or redesign of medical devices.**

The primary barrier to mHealth innovation that the Coalition would ask the Council to consider is the uncertainty regarding FDA regulatory oversight of enabling mHealth technologies such as Web infrastructure, storage and software, mobile devices, and cellular networks. There is a great deal of concern that the perceived costs and risk of FDA regulation, especially in light of the proposed changes to the 510(k) process, will negatively impact non-health related revenue sources and business operations for the providers of these technologies. The uncertainty of how interconnected technologies that support mobile healthcare delivery will be regulated is considered one of the largest barriers to innovation by members of the Coalition. This uncertainty affects the entire mHealth system, including existing medical device manufacturers, who also desire to leverage the existing shared network infrastructure to enhance the value of their therapeutic and diagnostic devices by extending them to the patient's mobile phone or home.

The Coalition encourages the Council to work to remove or reduce these barriers to the adoption of secure networking technologies, which can bring substantial medical or wellness benefits to the public without increased risk to the patient. Removing the perceived or actual barriers to mHealth technology innovation would provide the industry the incentive and ability to redirect a greater proportion of creative and intellectual capital towards healthcare, rather than towards the entertainment, media, or other less regulated industries consuming the majority of industry resources and attention today. We encourage the Council to work with industry to find ways to facilitate and promote the increased use of valuable mainstream mobile technologies, such as mobile location based services, for healthcare applications. By improving the flow of private capital to these technologies, the government can reduce costs and improve care without the expenditure of additional federal funds. The reduction of actual and perceived regulatory barriers will permit the more rapid adoption of emerging technologies for medical or wellness uses.

The true measure of appropriate regulation of any product or commercial activity is its beneficial protection of the public interest from unnecessary risk and its associated harmful consequences. Viewed from a risk management perspective, including both the likelihood of risk occurrence and the impact of an occurrence, the Council should seek to identify and reduce areas of regulation that are out of proportion to what is warranted by the public need. We encourage the Council to avoid unnecessary regulation of the many technologies and suppliers that collectively comprise the nation's communications and technology infrastructure, shared across many uses, solely because these technologies are employed in the use of a mobile health device. Regulation of these technologies should be narrowly targeted to address clearly identified areas of risk sufficient to warrant regulation of the technology as a medical device.

Lastly, the recently launched initiative to review and potentially revise the medical device 510(k) approval process could itself have lasting impact on successful deployment of mobile health

technologies. Telecommunications, information technology, and consumer electronics companies, large and small, are investing significant resources in the development of mobile technology for health care uses; in many instances this will mean they will be experiencing potential interaction with the FDA for the very first time. At the same time, the existing 510(k) process for submissions could be subject to substantial changes. The mHealth Regulatory Coalition urges the Council to work with industry to ensure that any changes to the 510(k) process recognize and avoid the creation of new barriers to entry for these important new contributors to the public health.

In closing, the mHealth Regulatory Coalition appreciates the Council's recognition of the importance of enabling technology innovation to more quickly meet the needs of society. We are glad to have the opportunity to provide the perspective of a broad coalition of companies that are interested in applying the intellectual property and energy they have invested in technology development to the unmet needs of mobile health care. We appreciate the Council's consideration of our comments and welcome the opportunity to engage in additional dialogue with the Council in an ongoing collaborative effort to improve the public health through the use of information and communication technologies.

Sincerely,

Dane Stout
Executive Director
The mHealth Regulatory Coalition
dstout@ansongroup.com
317.569.9500 ext. 115
www.mhealthregulatorycoalition.org