Enhancing Innovation in mHealth: A Blueprint for Regulatory Modernization
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Introduction

This white paper offers a conceptual blueprint for how the federal government can best foster innovation in the mHealth ecosystem while continuing to ensure patient safety. Doing so will require that FDA modernize its regulatory approach to embrace the fact that we are witnessing a transformation of the medical technology landscape from one shaped by individual, discrete products to a new era of complex, connected diagnostic and therapeutic systems that deliver holistic care. This technical convergence will have a profound impact on FDA regulation.

While this paper encourages the use of the existing regulatory authorities to accomplish these changes, it does not advocate the status quo. Instead, it urges FDA to adopt significant, fundamental changes to its approach to keep pace with medicine and technology, and indeed encourage innovation that can do much to enhance the quality of patient care.

We all stand on the shoulders of giants, so much of this content has been borrowed from work done previously. As I indicate below, I have drawn this content from work done by coalitions I represent, including the mHealth Regulatory Coalition, as well as from the recommendations of the federal working group organized under section 618 of the Food and Drug Administration Safety and Innovation Act of 2012, on which I served.

mHealth

NIH Consensus Group defines mHealth as “the use of mobile and wireless devices to improve health outcomes, healthcare services and health research.”¹ While accurate, that definition fails to convey the reasons for the excitement around mHealth. The possibility of treating people where they are means that no longer is healthcare limited by the infrequent opportunities for scheduled encounters between patient and caregiver in dedicated healthcare facilities. Rather, healthcare can be woven into the very fabric of daily lives.

Not only is mHealth different from traditional care from a purely clinical and patient encounter standpoint, it is also fundamentally different technologically in accomplishing connectedness. Many types of mHealth are marked by a common theme of convergence, where previously

¹ www.hrsa.gov/healthit/mhealth.html
disparate activities are now being connected through electronic networks. Software and hardware are being combined to create an endless array of systems for use in nearly every aspect of healthcare from diagnosis to treatment.

Consider, for example, the “smart pill,” a drug equipped with a digestible sensor that is activated by the patient's gastric juices. The pill's sensor sends a signal to a patch on the patient’s skin. That signal is then relayed, via cell phone, over the Internet to a physician. With this smart pill and the accountability it brings, drug adherence increases significantly, patients stay healthier and our healthcare system is markedly more cost-efficient.

Further, while historically medical devices often have not been interconnected for a variety of technical and business reasons, I believe that the future belongs to those medical devices that operate as part of systems. Groups like the Medical Device “Plug-and-Play” Interoperability Program are working on “accelerating the adoption of medical device interoperability to enable the creation of complete and accurate electronic health records and the cost-effective development of innovative third-party medical apps for diagnosis, treatment, research, safety and quality improvements, equipment management, and adverse event detection and reporting when using networked medical devices for clinical care.”

I believe that future innovations toward interoperability will dramatically improve patient outcomes and reduce the cost of providing healthcare. Opportunities for improvement abound. The lack of medical device interoperability has been flagged as a significant risk to patient care. Earlier this year, the ECRI Institute listed medical device and Electronic Health Record (EHR) interoperability as fifth in its list of top health technology hazards for 2013.

The Nature of Innovation in mHealth

As already explained, my goal is to identify the key features of research and development that support innovation in mHealth and need to be protected from over-regulation. This is necessary to ensure that patients ultimately get the benefit of the promise mHealth offers. So I studied the innovation process in mHealth, viewing it through the prism of regulation and its potential effects on that innovation. Below are the salient aspects of innovation that regulation potentially touches. I divide the universe of factors important to innovation into two broad categories, specifically (1) the act and process of innovating and (2) the business model for supporting innovation.

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2 http://www.mdpnp.org/ (accessed on July 30, 2014)
3 This section, and the one follows on Ambiguity and the Entrepreneur, are both adapted from comments I submitted on behalf of Epstein Becker & Green, P.C. on August 28, 2013 in response to the Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology, Docket No. HHS-OS-2013-0003 (hereafter “EBG Comments.”)
The Act and Process of Innovating

I have tried to collect best practices from leading companies in mHealth in order to discern how they succeed in innovation. I am sure this is only a partial list, but it represents a good start in identifying what needs to be protected and allowed to flourish.

- **Collaboration among IT technical experts, clinicians, medical device developers and scientists of many sorts.** Collaboration is the wellspring of innovation. Perhaps in some areas of technology, innovation can come from a lone, brilliant scientist tinkering late at night in his own lab. But in the area of e-health, true innovation uniformly comes from collaboration among very disparate sets of expertise. After all, given the definition above, mHealth is about connecting medical devices and other technologies into networks to create powerful systems to deliver healthcare.

- **Finding talent wherever it might be.** In a sense, this is a continuation of the collaboration need, but here I focus on the fact that the needed experts might be dispersed around the world. In other areas of technology development, it’s more traditional to bring everyone together under one roof to facilitate the development process. In IT, it’s quite common not to bring everyone together physically but to let them interact virtually throughout the United States and the world.

- **Tinkering and experimentation, with feedback loops.** Any form of engineering requires the development of prototypes, but software development in particular involves the development of beta versions that can be tested in real world situations in order to obtain feedback and strengthen the technology. Consequently, to make real progress in mHealth, there must be an assurance that tinkering and experimentation can continue in some appropriate way.

- **Major breakthroughs followed by many, many incremental improvements.** The pace of innovation is uneven. Certainly inspirations leading to new technologies or new uses for existing technology take place. But those breakthroughs typically are followed by a significant number of incremental enhancements sometimes over a prolonged period.

- **Nonlinear process.** Creative minds tend to zig and zag. If you add to that collaboration where many people are working together, innovation tends to happen here and there, not necessarily according to some linear process. Regulatory restrictions in the name of a quality system that attempt to make development a purely linear process are doomed to cause confusion and unnecessary burden.
• **Short product lifecycles.** Indeed, this is simply the other side of the coin from the rapid progress in mHealth technology. But it’s important also to understand and appreciate the cultural impact that the short lifecycles have on the developers themselves. These developers thrive in an environment in which change is constant, and progress is something that can be made virtually every day. Fundamentally changing that culture and environment by imposing regulatory obligations that would dramatically lengthen the product lifecycles would have a tremendously stifling impact on the exciting cultures that exist in these technology developers’ organizations.

• **Sensible technology standards driven by industry.** The promise of mHealth depends significantly on the interoperability of medical devices and IT systems. Thus, for mHealth to flourish, the developers of these technologies need to agree upon common standards to be used. While this in a sense constrains innovation, industry organizations are in a position to develop the standards in a way that balances the need for innovation with the need for standardization.

• **Modularization of software.** It never makes sense to reinvent the wheel. Software development is no exception. Over the past few decades, hundreds of thousands of software developers have created literally millions of software programs that accomplish a mind-boggling range of tasks. It simply doesn’t make sense to ignore those existing software modules when developing new programs. So instead, developers stitch together existing programs and then add a new innovative program to do whatever is new or different that the developer wants to accomplish. Sometimes this is done by drawing those modules together into a single program, and sometimes it is effectively accomplished by a software program being designed to interact with other software on a given platform, such as a mobile phone. A simple example is a software application on a mobile phone making use of the existing program that tracks date and time. Any regulation needs to appreciate this fundamental design dynamic.

**The Business Model for Supporting Innovation**

mHealth innovators must live in the real world, and that real world includes economic considerations, as well as technological ones. The following are at least a few of the economic factors that need to be considered in order to preserve and enhance innovation in mHealth.

• **Small companies.** Fortunately for everyone, health IT in particular is not a capital-intensive business, so small companies can engage in innovation and product development. This is good news, because it means that up the
opportunity to develop innovative products can be opened up to a broader group. The bad news is that these companies tend to have inadequate capital and also tend to need more assistance from government regulators in understanding and navigating complex regulatory systems.

- **Venture capital and angel investment.** These small companies, because they often lack sufficient capital from the founders, need to seek out and obtain venture capital and angel investments. To do so, they need to be able to put together business plans that identify clearly the regulatory demands and the timetables associated with bringing their products to market. Thus, clarity in the regulatory pathway becomes extremely important.

- **Access to markets in a reasonable time.** There’s no getting around the fact that mHealth is a business. While all developers certainly have a focus on the patient and protecting the patient, healthcare doesn’t work in this country if those engaged in it can’t make a living. Thus, when determining the appropriate level of regulation, it is important to keep in mind that the healthcare system cannot succeed in caring for patients if those working in it cannot operate a viable business and cannot bring their products to the market in a reasonable time.

- **Joint ventures and other deals between parts of the mHealth ecosystem.** When focusing on technology networks, it needs to be appreciated at the outset that this will mean many different forms of business agreements among vendors supplying various components of those systems and their customers. These deals will affect the intended use of the various components of these systems. Regulators such as FDA focus on a product’s intended use, so the regulatory framework will need to be flexible to accommodate these innovative joint ventures that will undoubtedly affect the intended use.

- **Reasonable and clear regulatory risk.** The need for a relatively clear regulatory pathway to market is discussed above, so this bullet will focus on regulatory liabilities associated with marketed products. For innovative businesses to attract capital, the regulatory risks need to be reasonable and clear. These regulatory risks include such post-market obligations as adverse event reporting and conducting recalls. In a networked environment, presently these obligations are anything but clear.

**Ambiguity and the Entrepreneur**

As noted, clarity is often desirable in regulatory requirements. But it is important to be precise in where clarity is desirable. In fact, depending on the particular regulatory requirement, ambiguity can be either good or bad in its impact on innovation.
• Ambiguity can be good when it creates the opportunity for flexibility in compliance. It is okay, therefore, for many regulatory standards to be written in a general way. The quality system regulations are written at a high level, which in a sense makes them ambiguous with regard to what they require. But that form of ambiguity is good in that it allows flexibility and innovation on the part of the manufacturer in determining how it will come into compliance.

• Ambiguity tends to be bad when it relates to the scope of a regulatory requirement. Industry needs to know whether a particular requirement applies or not. Knowing whether a given piece of software is subject to FDA regulation can make a big difference in the cost and timeline associated with bringing that software to market, so the developer of that software needs a fairly clear and certain understanding of the scope of FDA regulation. Likewise, knowing the classification of a medical device is critical to determining what types of regulatory requirements apply. Ambiguity there is not helpful.

The next section identifies specific areas of harmful ambiguity that need to be resolved so that entrepreneurs can make the business decisions they need to make.

Regulatory Requirements In Need Of A New Approach

Within current regulatory frameworks there exist mechanisms that the FDA, ONC, and FCC should use to promote innovation, protect patient safety and avoid regulatory duplication (and cost). To be sure, though, these frameworks need to be improved.

1. FDA should use the current regulatory framework to clarify ambiguities

The FDA has several existing mechanisms that could help spur innovation. The agency should:
(a) establish a policy of “Enforcement Discretion” for lowest-risk HIT, where enforcement of regulations is inappropriate; (b) exempt from pre-market notification and/or good manufacturing practices (GMP) regulation lower-risk HIT in a similar manner as most Class I devices GMP; (c) expedite needed guidance related to mhealth; and (d) proactively educate the public about how policies and regulation affect mobile medical apps. There may be a need for

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4 The recommendations in this section are all adapted from the final report of the section 618 working group authorized under FDASIA. All of the materials that constitute the final report of the working group can be found on ONC’s website at http://www.healthit.gov/FACAS/calendar/2013/09/04/hit-policy-committee, accessed on July 30, 2014 (Hereafter collectively referred to as “Section 618 Working Group Report.”)
additional funding to appropriately staff and build FDA expertise in mobile medical apps. The needed FDA guidance should address four main issues:\(^5\)

a) The borderline between a disease-related claim on the one hand, and a wellness related claim on the other hand. FDA has jurisdiction over disease-related claims, but not wellness related claims. Unfortunately, simple rules in this space sometimes lead to overregulation. For example, a very simple approach would be to say that if any advertising or labeling mentions a disease, as defined in some authoritative compendium of diseases, the product would be regulated. But the mere mention of a disease such as obesity would likely cause very low risk software used to manage weight to be FDA regulated. Further, there are many different types of claims and some might make veiled, but not specific, references to the diseases. In these circumstances how should FDA regulate the associated HIT?

b) The scope of what constitutes an accessory to a medical device. FDA’s had a long-standing rule that says that anything intended to be used as an accessory to a medical device is itself a medical device and regulated to the same level as the device it accessorizes. But there are many generic accessories that are very low risk that should not take on the regulatory classification of a product it is intended to accessorize.

c) The scope of clinical decision support software that FDA regulates. FDA has long regulated certain forms of clinical decision support software, such as computer-assisted diagnosis software (UDS) used with medical imaging. Unfortunately, FDA has never been very clear on the contours of its regulation for this broad category of software. Much of it is low risk, and indeed much of it is used in a manner that makes it highly unlikely that the patient could ever be hurt. FDA needs to clarify the scope of CDS regulation.

d) The scope of FDA regulation over software modules. The development of software involves a high degree of incorporation of existing modules into larger software programs that might have a medical purpose. But many of the individual modules are very generic and not particularly intended for medical software. Does FDA regulate the modules? What about for medical device software that is used on a platform where it incorporates other existing modules already available on that platform. Are any of those incorporated modules also regulated?

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\(^5\) These four recommended issues to be addressed are adapted from the notes of the working group that are associated with slide 35 of the final presentation found in the Section 618 Working Group Report. [http://www.healthit.gov/sites/default/files/archive/HIT%20Policy%20Committee/2013/2013-09-04/Notes_for_FDASIA_RecommendationsDraft_030913.docx](http://www.healthit.gov/sites/default/files/archive/HIT%20Policy%20Committee/2013/2013-09-04/Notes_for_FDASIA_RecommendationsDraft_030913.docx), accessed on July 30, 2014.
In guidance, FDA also should define the quality system requirements for standalone software and premarket and postmarket requirements for interoperable (and “interface-able”) devices. Traditionally, medical device manufacturers seeking FDA clearance have presented a device with a well-defined intended use, typically as a solo product. For interoperable medical devices, FDA should come up with a paradigm that informs developers of system interface components how to demonstrate their claim of substantial equivalence and how to address problems residing in a network of interfaced medical devices.

The new mHealth regulatory framework should not cause confusion. The FDA should substantially revise the Limitation of Exemptions regulation because of the high probability that this regulation and the mHealth regulatory framework and/or guidance documents will conflict. This conflict could be especially acute with diabetes management software products.

2. The three agencies should avoid regulatory duplication

The respective jurisdictions of FDA and ONC are not clearly delineated to ensure the needed oversight, while eliminating duplicity. ONC may regulate HIT/medical device interfaces, and FDA regulates medical device/medical device interfaces; but the same medical device (e.g. infusion pump) could be installed in either configuration. It is unclear who will require interoperability when products need to be interoperable to be used safely. Furthermore, the ONC certification program is a voluntary certification program in that ONC cannot compel vendors to seek certification for their products. While certifications can be revoked if developers or products do not comply with the program requirements, the program requires interagency use and coordination to exercise the full realm of enforcement authority against fraud and wrongdoing. And finally, FCC and FDA do not coordinate their review processes on converged medical devices that are brought independently before both agencies.

3. New frameworks for consideration

Transparency in adverse events reporting. Currently, it is difficult to obtain data for system performance analysis, and the reporting pathway often does not facilitate timely resolution. When medical device-mHealth “system related” adverse events occur, it is often difficult or impossible to find the root cause of the failure. Data logs may be incomplete, inaccessible, non-existent, or not in a standardized format. What is the best model for reporting and analyzing issues with systems of devices/equipment that span (multiple agency) regulated and non-regulated space? It is essential to improve adverse events reporting and to enable timely and broader public access to safety and performance data.

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6 These recommendations can be found in the “Report of the Section 618 Regulations Subgroup – Summary” associated with the Section 618 Working Group Report. I co-chaired that Regulations Subgroup.

7 Ibid.
Application of FDA rules to mobile apps. There are three principal areas where FDA regulation needs to be modernized to meet the unique needs of mobile apps:

1. The vast majority of devices subject to FDA jurisdiction must meet the requirements of the quality system. Unfortunately, though, understanding how to meet those requirements can be very difficult for standalone software. The regulation was written with physical products in mind. While the basic regulation is written broadly and can be interpreted, industry needs official guidance from FDA on how it should be interpreted for standalone software. Private standards groups such as AAMI are working on this issue and so this might be as simple as FDA officially recognizing that work.

2. Typically, when a medical device manufacturer goes to FDA seeking clearance, it is presenting a device with a very defined intended use, typically as a solo product. If, instead, the manufacturer goes to FDA with what is essentially a complement of the future, unspecified network of devices, the agency is uncertain how to gauge risk and what kind of data to expect. FDA simply needs to come up with a paradigm that informs developers of these network components how to demonstrate their claim of substantial equivalence.

3. When something goes wrong with a network of connected medical devices and mobile apps, it is often unclear where the problem resides. Indeed, the problem may in fact reside between two devices at their interface, as opposed to being the responsibility of one single component. But the laws governing FDA were written with accountability in mind, so there are post-market obligations, such as adverse event reporting and field corrective actions that are written as though it should be clear whose responsibility it is.

4. FDA lacks internal coordination on mobile medical apps policies and regulatory treatment

   - FDA should disseminate consistent regulatory treatment and information; dissemination by FDA officials, reviewers and staff to inquiries by industry and public about mobile medical apps
   - FDA should coordinate internal understanding of policy positions and regulations to maximize consistency and help eliminate ambiguity and misinformation
   - CDRH Learn, Device Advice, DSMICA should be updated with information about mobile medical apps and utilized to help raise public and industry understanding in this space

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8 The following three recommendations can be found in the notes to the Section 618 Working Group Report associated with slide 36.
9 This recommendation, including the following recommendation number five, are both derived from slide 37 of the notes to the Section 618 Working Group Report.
5. There may exist a need for additional funding to appropriately staff and build FDA expertise in mobile medical apps

FDA lacks adequate staffing resources and funding to adequately oversee HIT and mobile medical apps

In light of those identified best practices associated with bringing innovative products to the mHealth market, we would like to connect the dots to highlight FDA regulatory areas in need of modernization. The following table is designed to connect those dots.\(^\text{10}\)

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<tr>
<th>Innovation Factor</th>
<th>Regulatory Need</th>
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<tr>
<td>The need of investors to identify the cost and timelines associated with developing products in mHealth</td>
<td>FDA needs to provide clarity and predictability with regard to the types of health IT the agency regulates, and for any software that is regulated, the classification. This needs to extend to both FDA guidance, and FDA enforcement action. FDA needs to act in a way that is clear and predictable. Written FDA rules that the agency ignores destroy that predictability. The agency’s words and deeds must match.</td>
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<td>The accessibility of regulatory requirements to small business</td>
<td>FDA needs to engage in more outreach, both in the creation of useful guidance, but also in proactively educating developers, perhaps through more user-friendly web-based information but also face-to-face educational programs.</td>
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<td>The development and design of hardware and software components to be used as parts of systems.</td>
<td>This requires systems approach to regulation recognizing that each of these hardware and software components is to be used as part of a much bigger and interconnected but unknown network. More specifically, this means that regulators such as FDA, ONC and FCC need to apply a consistent and unified regulatory approach.</td>
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<td>Component type intended uses, where the full design and intended use of the system is unknown.</td>
<td>FDA has always understood that a company might develop a scalpel with a simple intended use of cutting tissue, without knowing in what surgical procedures doctors might use the scalpel. FDA needs to adopt the same approach of clearing tool type claims when it comes to</td>
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\(^\text{10}\) I first presented this table as a part of the EBG Comments, supra note 3.
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<th>Topic</th>
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<td>Collaboration among all quarters in the development of mHealth technologies, including relationships between vendors and their customers.</td>
<td>FDA needs to modernize its rules on off-label promotion to allow for closer collaboration among vendors, clinicians and other scientists. FDA needs to encourage collaboration as a business model, as opposed to limiting speech. Presently, along with others, I am working on a proposal for a very different approach to the oversight of collaboration in the healthcare industry. Before presenting it to the federal government, copies have being distributed among many stakeholders in order to improve the proposal.</td>
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<td>Practical ways to test low risk components in real world settings, for example, through the release of beta software programs</td>
<td>There needs to be clarification around the investigational device exemption rules and how they apply to common forms of regulated health IT. I keep hearing people in the health IT ecosystem asking about how they can quickly and efficiently beta-test their products to identify weaknesses. While I believe the basic regulatory system already exists through which this can be done, the agency should clarify the requirements applicable to common testing practices within health IT and examine whether a further refined risk based approach is appropriate.</td>
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<td>Frequent adoption of incremental improvements to software and hardware</td>
<td>Any premarket requirements need to be clearly defined with regard to any incremental improvements that themselves might trigger premarket requirements, and imposed with a risk-based approach. Only improvements that truly engender material risk should be subject to premarket requirements.</td>
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<td>The key role of standalone software</td>
<td>FDA requirements for standalone software, including application of the quality system regulation, need to be clarified, and more closely associated with risk-based tiers.</td>
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<td>The decentralized and virtual relationship of developers</td>
<td>FDA needs to modernize its registration and listing requirements to reflect the fact that much software is developed virtually.</td>
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<tr>
<td>Software modularization</td>
<td>FDA needs to specify how the medical device classification rules are applied in the context of modularization. This issue boils down to the definition of a product to be classified. For classification purposes, under what circumstances may a particular module be viewed in isolation, when that module connects in some fashion to other software modules? When are the boundaries of the module sufficient to limit the extent of the classification?</td>
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**Conclusion**

Innovation and patient well-being are complementary, not competing, policy objectives. Innovation offers great hope to enhance patient care through improving safety and effectiveness, improving quality and indeed even reducing cost. I believe there is actually very good alignment among regulators, patients and industry when it comes to our ultimate objectives. Products that don’t work, or even worse hurt people, are not in anyone’s best interest. But innovative products that solve a real public health need are in everyone’s interest.

I believe that updating the current FDA regulatory system to addresses the unique characteristics of mHealth is necessary. Such modernization will encourage the innovation needed to advance healthcare and ensure that patients will receive the benefits of some incredible breakthroughs in a timely way.