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April 26, 2012

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments to FDA's Draft Guidance on the 510(k) Program: Docket No. FDA-2011-D-0652

Dear Sir or Madam:

The members of the mHealth Regulatory Coalition ("MRC" or "Coalition") thank you for the opportunity to comment on *Draft Guidance for Industry and Food and Drug Administration Staff; The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* ("Draft Guidance"),[1] published by the U.S. Food & Drug Administration ("FDA" or "Agency") on December 28, 2011.[2] This letter details the Coalition's comments.

In short, the Coalition believes that the Draft Guidance is a significant step toward clarifying the 510(k) Program. However, there are a number of areas that need clarification to produce a clear, predictable, and

[1] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF—THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)] (2011), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

[2] Draft Guidance for Industry and Food and Drug Administration Staff; the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]; Availability, 76 Fed. Reg. 81,510 (Dec. 28, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-12-28/pdf/2011-33232.pdf.

narrowly-tailored regulatory framework that promotes patient safety and innovation in mobile health ("mHealth").[3] Specifically, the FDA should:

- Take into consideration the unique nature of the mHealth ecosystem when finalizing the Draft Guidance (referred to hereafter as the "Final Guidance") and further developing its regulatory framework for mHealth technologies;
- Be sensitive to the mHealth community, using the Final Guidance as a launching point from which to educate this new audience;
- Provide a comprehensive review of the 510(k) Program and clarify concepts like *intended use*, *predicate devices*, and *accessory regulation* (among others) in the mHealth context, ensuring that the current predicate approach, whereby a manufacturer may use multiple predicates to support a substantial equivalence claim, remains intact;
- Describe the practical implications of compliance with FDA regulations;
- Clarify the roles and responsibilities of the stakeholders involved in an mHealth ecosystem; and
- Ensure that the Final Guidance does not result in over-regulation of mHealth technologies to prevent unintended consequences on the industry.

Indeed, the FDA should avoid regulatory schemes that impose costly compliance requirements as this will hinder development in the mHealth community. Many of the developers in this nascent industry are start-up companies—organizations that are highly susceptible to cost pressures. Even in large organizations, the current economic climate combined with the unpredictability of and unfamiliarity with FDA regulations can result in the cancellation of innovative mHealth projects. Ultimately, the consumer, patients, caregivers, healthcare providers, job seekers, and the public health in general will miss the benefits that this industry can offer. Therefore, the Coalition believes that the Agency should focus its regulatory reach on moderate- to high-risk mHealth products to promote patient choice, engender innovation, and drive down the cost of healthcare through competitive efficiencies in the market.

The mHealth Regulatory Coalition

The MRC represents the heterogeneity of the stakeholders in the mHealth ecosystem, 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	• Great Call (pka Jitterbug)	• Philips
• Alternative Universe Technologies	• Kaiser Permanente	• Qualcomm Inc.
• AT&T	• Massive Health	• Roche Diagnostics
• Boston Scientific Corp.	• MedApps	• Verizon Wireless
• Continua Health Alliance	• Medical Graphics Corp.	• View720.com
• IDEAL LIFE	• OmniScience Mobile	• Voxiva, Inc.
	• Partners/Ctr. for Connected Health	• WellDoc, Inc.

[3] The *m* in *mHealth* is an abbreviation for *mobile* to recognize the integration of mobile technology in healthcare today. The technologies that fall within the scope of the mHealth space include hardware and software products in the traditional medical device realm as well as products that would otherwise be viewed as general purpose products (e.g., consumer products or IT devices). For additional information on the scope of mHealth technologies, see BRADLEY MERRILL THOMPSON ET AL., A CALL FOR CLARITY: OPEN QUESTIONS ON THE SCOPE OF FDA REGULATION OF MHEALTH (2010), *available at* http://mhealthregulatorycoalition.org/wp-content/uploads/2010/12/mrcwhitefinal122210.pdf.

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

The purpose of the Coalition 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 has spent the last two years identifying the challenges with the existing regulatory scheme and developing a proposed guidance document describing the approach that FDA should take in defining what types of mHealth products should be regulated and at what classification.[5]

Despite the heterogeneity of the industry, the members of the MRC share a unified view that patient safety must never be compromised. We recognize and respect the Agency's mission to ensure that medical devices marketed in the United States meet a high standard of safety and effectiveness. We believe this mission can be achieved while remaining consistent with the Obama Administration's call to eliminate duplicative or unnecessary regulations.[6] In this regard, we highlight the need to narrowly tailor FDA's regulatory framework for mHealth products to prevent unnecessary regulation and to promote innovation through clarity and predictability.[7] Since many regulated mHealth products may be subject to the 510(k) process, it is imperative that the Agency consider these technologies as it finalizes the Draft Guidance.

Comments on the Draft Guidance

The Coalition applauds the FDA's effort to update and clarify the 510(k) Program. We believe the Draft Guidance, when final, will play a vital role in communicating the Agency's expectations and process for determining substantial equivalence for medical devices under the 510(k) Program. Despite the significant improvement of the Draft Guidance over the existing patchwork of guidance, the Coalition has a number of comments that we believe are essential to prevent unnecessary barriers to entry for mHealth product developers and to ensure the Final Guidance will endure as mHealth technologies evolve going forward.

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[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/#!documentDetail;D=FDA-2011-D-0530-0082 and http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0530-0083.

[6] Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf. The general principle established in this presidential order is described as the following:

> Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.

Id.

[7] FDA Commissioner, Dr. Margaret Hamburg, has agreed with this principle. In a joint statement on wireless medical devices, Dr. Hamburg and FCC Chairman Julius Genachowski stated the following:

> The American public—including industry, providers, patients, and other interested stakeholders—should have clear regulatory pathways, processes, and standards to bring broadband and wireless-enabled medical devices to market. This includes clarity regarding each agency's scope of authority with respect to these devices, predictability regarding regulatory pathways, and streamlining the application process, as appropriate, to facilitate innovation while protecting patients.

U.S. FOOD & DRUG ADMIN. & FED. COMMC'NS COMM'N, JOINT STATEMENT ON WIRELESS MEDICAL DEVICES (2010), *available at* http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-300200A1.pdf.

To put our comments into perspective, consider a hypothetical mHealth ecosystem (depicted visually in Appendix A) that includes the following:

- A generic **weight scale** with standard wireless connectivity for data transmission;
- A wireless **blood pressure cuff**;
- A **non-invasive cardiac monitor** for the detection of heart disease;
- A **mobile application** that resides on a **mobile device** (e.g., smartphone or tablet) that collects and transmits data from each of these devices to **a proprietary database** on a **cloud server network**;
- A **web application server** for hosting a **website** that allows a user, caregiver, or healthcare provider to access the patient data;
- A **mobile application** and various **web application access devices** (e.g., computer, smartphone, or tablet) for allowing a user, caregiver, or healthcare provider to access the data and, depending on user access rights, to program alert notification settings, and/or to control device functions; and
- An **electronic health record** (EHR) for storage, retrieval, display, and analysis of health information from any combination of the products in the ecosystem.

Traditionally, this example would be treated as a "system" developed by a single manufacturer who designed and controlled each element. In today's mHealth world, however, there may be several manufacturers working independently and/or in concert to create the various elements. These manufacturers may or may not intend for their products to work together. In fact, some of these products (e.g., computer, smartphone, or tablet) may not be designed for use in this ecosystem but may simply become part of the ecosystem by virtue of their capacity for interconnectivity and widespread use. This decentralization of control creates challenges when applying the traditional 510(k) Program that should be addressed in the Final Guidance.

1. *Educating a New Audience*

First and foremost, it is important to acknowledge that the mHealth ecosystem is made of a heterogeneous group of stakeholders ranging from the small mobile app developer, to large IT and telecommunications companies, to integrated healthcare provider systems, to traditional medical device manufacturers, among others. Most of these stakeholders have historically not been subject to FDA regulation and, therefore, are not conversant in the FDA's language or its regulatory requirements. Indeed, many struggle to understand whether and how the regulations apply to them. The FDA should strive to educate this new audience beyond the typical approaches historically taken to communicate regulatory policy. A new approach is necessary because, unlike in the past, the Agency's audience is not limited to the traditional medical device community.

For example, the Agency has previously indicated that manufacturers of general IT infrastructure are typically not subject to FDA regulation.[8] The Agency has further clarified that mobile platform (e.g., smartphone) manufacturers would not be regulated unless the manufacturer intends the platform to be used as a medical device.[9] In order to make this determination, the manufacturer must understand the

[8] Medical Devices; Medical Device Data Systems, 76 Fed. Reg. 8637, 8643 (Feb. 15, 2011) (to be codified at 21 C.F.R. § 880.6310), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-02-15/pdf/2011-3321.pdf ("By themselves, any system, or component of a system, that is solely intended for use as general IT equipment (and that is not intended for a device use under section 201(h) of the FD&C Act), would not be considered a medical device.").

[9] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: MOBILE MEDICAL

FDA's concept of *intended use*. While the Draft Guidance provides a high-level summary, the Agency relies on guidance documents that were drafted a decade or more ago to communicate this fundamental concept.[10] Neither these referenced guidance documents nor the Draft Guidance incorporates mHealth-specific examples that would provide a stakeholder in this new industry (e.g., a mobile platform manufacturer) with the tools necessary to determine whether their product is subject to FDA regulation.

A failure to educate this diverse group of mHealth stakeholders will result in confusion and uncertainty that could hinder this rapidly growing industry. The Final Guidance is an excellent forum in which to communicate a detailed, comprehensive description of the 510(k) Program. We describe in more detail below our recommendations for the Final Guidance to facilitate this important mission.

2. *Clarifying the 510(k) Program*

In the Final Guidance, the FDA should clarify a number of aspects of the 510(k) Program to help the mHealth community understand its applicability. For example, the Draft Guidance does not adequately communicate the full landscape of the 510(k) Program. More specifically, the Final Guidance should identify other guidance documents that are fundamental to the 510(k) Program and briefly describe how those documents fit within the overall scheme. Although we recognize the need for brevity, at a minimum, the Final Guidance should discuss the following:

- *Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device*;[11]
- *Guidance for Industry: Frequently Asked Questions on the New 510(K) Paradigm*;[12]
- *Guidance for Industry and FDA Staff—FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment*;[13]
- *FDA Memorandum: 510(k) Refuse to Accept Procedures #K94-1*;[14]

APPLICATIONS 10 (2011), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf [hereinafter MMA DRAFT GUIDANCE].

[10] *See* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., DETERMINATION OF INTENDED USE FOR 510(K) DEVICES; GUIDANCE FOR CDRH STAFF (UPDATE TO K98-1) (2002), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082166.pdf; CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GENERAL/SPECIFIC INTENDED USE (1998), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073945.pdf.

[11] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF—510(K) DEVICE MODIFICATIONS: DECIDING WHEN TO SUBMIT A 510(K) FOR A CHANGE TO AN EXISTING DEVICE (2011), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM265349.pdf.

[12] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: FREQUENTLY ASKED QUESTIONS ON THE NEW 510(K) PARADIGM (1998), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073948.pdf.

[13] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF—FDA AND INDUSTRY ACTIONS ON PREMARKET NOTIFICATION (510(K)) SUBMISSIONS: EFFECT ON FDA REVIEW CLOCK AND PERFORMANCE ASSESSMENT (2004), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089738.pdf.

[14] Memorandum from Susan Alpert, Acting Director, Office of Device Evaluation, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin. (May 20, 1994), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081022.htm.

- *Guidance for Industry and Food and Drug Administration Staff—Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications*;[15]
- *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s*;[16]
- *Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements*;[17]
- *Deciding When To Submit A 510(k) For A Change To An Existing Wireless Telemetry Medical Device: Final Guidance for FDA Reviewers and Industry*;[18] and
- *Draft Guidance for Industry and Food and Drug Administration Staff—Mobile Medical Applications*.[19]

More importantly, the Agency should incorporate into the Final Guidance a flowchart or other visual schematic that describes the relationship with the above guidance documents. Where appropriate, the FDA should endeavor to update these guidance documents to address the challenges presented by these new mHealth technologies and to prevent any inconsistency.

Beyond providing a high-level description of the 510(k) guidance landscape, there are a number of specific aspects of FDA regulation that need clarification.

a. Clarifying the *Intended Use* Concept

As noted above, the Draft Guidance does not adequately describe the FDA's concept of *intended use* as it relates to mHealth technologies. Furthermore, the Agency should clarify the difference between intended use and indications for use, with particular examples that demonstrate each concept in the mHealth context. For example, it is unclear what types of changes in an mHealth ecosystem would impact the indications for use and the intended use. Take the hypothetical described above; the following questions, among others, perplex many in the mHealth community and need clarification:

- If the weight scale is a stand-alone product for general use, would its incorporation into the mHealth ecosystem create a medical intended use? If the scale was originally intended for medical purposes, does incorporation into the mHealth ecosystem change the intended use and/or indications for use?

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[15] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF—FACTORS TO CONSIDER WHEN MAKING BENEFIT-RISK DETERMINATIONS IN MEDICAL DEVICE PREMARKET APPROVALS AND DE NOVO CLASSIFICATIONS (2012), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM296379.pdf.

[16] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF: FORMAT FOR TRADITIONAL AND ABBREVIATED 510(K)S (2005), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084396.pdf.

[17] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF: INTERACTIVE REVIEW FOR MEDICAL DEVICE SUBMISSIONS: 510(K)S, ORIGINAL PMAS, PMA SUPPLEMENTS, ORIGINAL BLAS, AND BLA SUPPLEMENTS (2008), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089425.pdf.

[18] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., DECIDING WHEN TO SUBMIT A 510(K) FOR A CHANGE TO AN EXISTING WIRELESS TELEMETRY MEDICAL DEVICE: FINAL GUIDANCE FOR FDA REVIEWERS AND INDUSTRY (2000), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073658.pdf.

[19] MMA DRAFT GUIDANCE, *supra* note 9.

- If a blood glucose meter is added to the ecosystem, would the intended use and/or the indications for use of the other products change?
- What is the impact on intended use and/or indications for use if the manufacturers of the medical device and non-medical products adopt an interoperability standard to enable the various elements of the ecosystem to communicate? What is the impact if a particular product changes from a non-interoperable device to an interoperable one?
- Does a claim of compatibility with another device in the ecosystem constitute a new, expanded, or more specific patient population or indication for use warranting a new 510(k)? Would a design change for compliance with an interoperability standard constitute a major change on this basis?
- If a change allows a hospital-based device to connect to a home-use device, does the change affect the intended use and/or indications for use of either product?
- Although FDA has indicated that EHRs are not regulated, does including it into an mHealth ecosystem affect the intended use of the products in the ecosystem or the EHR itself? Does the answer depend on the significance of the integration and interoperability between the EHR and the other products of the ecosystem? How does the Agency define EHR?

b. Regulating Accessories in mHealth

As the hypothetical and the questions above demonstrate, mHealth technologies are unique in that they inherently involve interoperability and interconnectivity among a chain or web of products, some of which may be regulated while others are not. Historically, when two or more devices interconnect, the Agency has regulated the devices as a system, treating the device in the highest regulatory classification as the "parent" and regulating the other "accessories" in the same classification.[20] When applying this concept to the mHealth ecosystem, products that simply do not involve sufficient risk to warrant regulatory oversight may become regulated. The Final Guidance should describe the FDA's regulatory approach for accessories and what the Agency expects to see in a 510(k) submission as it relates to accessories in an mHealth ecosystem. Again, the Agency should consider the following specific questions, which draw on the hypothetical described above:

- Is the general-use weight scale regulated by the existing classification for such sensors as a result of the fact that it is part of an mHealth ecosystem? Or does its "connection" with the cardiac monitor render that scale a Class II device as an accessory?
- If a device receives information from the weight scale through one or more intermediary products (e.g., a computer, smartphone, or even a medical device data system), do the intermediary products shield the scale from becoming an accessory to the cardiac monitor (or blood pressure cuff)? Would the Agency regulate intermediary products? If so, would they fall into the same classification as the parent device? Which device would be the "parent"? Would the classification apply to all products in the ecosystem, including those products that would otherwise not be classified as a medical device (e.g., a computer or smartphone)? In what situations would the infrastructure (e.g., a computer or smartphone) remain unregulated?
- To what extent is the weight scale manufacturer required to ensure the proper functionality of potential accessories and the underlying network infrastructure for each of the products in the web? For instance, if a smartphone has multiple modes of data transmission, is the smartphone

[20] FDA regulations do not provide a definition for the term *accessory*, but the Agency has described what that term means in various contexts. *See, e.g.*, U.S. Food & Drug Admin., *Medical Device Quality System Manual* (Apr. 28, 2009), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/ucm122391.htm.

an accessory such that the weight scale manufacturer must ensure proper data transmission in all possible modes of the smartphone?

- To what extent can the blood pressure cuff manufacturer claim compatibility with the other devices in the ecosystem without creating an accessory relationship? Does it matter if the claim is specific to another device or to a general type of device?
- How would human intervention at some point in the process affect the application of the accessory rule, and the resulting classification? For example, if the weight scale transmits data to a computer and the computer requires the patient to actively send the information (e.g., via email or the click of a button) to a healthcare provider, does this human interaction affect the relationship between the scale and the computer? How do the regulatory requirements change if the human interaction is not the patient but is a trained clinician (e.g., physician, nurse, or physician assistant employed by the manufacturer) other than the patient's healthcare provider?

c. Describing the Practical Implications of Compliance

Ultimately, the FDA should describe in more detail the practical implications of compliance with the 510(k) Program. The Final Guidance should describe, among other things, the process of implementing a quality system, developing a 510(k) submission, communicating with FDA during the review process, and the financial implications of each. Many of these and other concepts discussed in the Draft Guidance are completely foreign to the new mHealth audience and, thus, require a bit more explanation. For example, the Agency should provide mHealth-specific examples that demonstrate the *predicate* concept and clarify in practical terms how a manufacturer demonstrates substantial equivalence to a predicate. In so doing, the FDA should describe the difference between the *split predicate*, *multiple predicate* and *reference devices* concepts more clearly.

Importantly, the FDA should reaffirm the current predicate approach, whereby a manufacturer may use multiple predicates to support a substantial equivalence claim. In its current form, the Draft Guidance seems to suggest that manufacturers are required to find a single predicate that matches perfectly to support a substantial equivalence claim. Such an approach would force many mHealth technologies into Class III, significantly restrict innovation, and result in unintended, deleterious consequences on the advancement of health technology. Instead, the Final Guidance should simply indicate that, where a manufacturer can demonstrate equivalence with a single predicate, the Agency review may be more efficient than the review for devices that require more than one predicate. The FDA should not foreclose its existing approach to the use of multiple predicates.

d. Documenting Roles & Responsibilities

As another example of a need for clarity, the Final Guidance should describe the roles and responsibilities of the various stakeholders in a specific mHealth ecosystem as it relates to the 510(k) Program. More specifically, in the hypothetical above, the Agency should address the following:

- Who would be responsible for submitting the premarket submission? Do all stakeholders need to participate in the development of the submission?
- What types of testing would be required and who is responsible for performing the testing?
- To what extent does FDA expect stakeholders to coordinate compliance efforts?
- For devices that connect via interoperability standards, would a change in one device cause the manufacturer of another device to submit a new 510(k)? If so, what factors would trigger the new 510(k)? Does it depend on whether two Class II devices are connected versus connection to a Class I device? Would the Agency apply a "collective evaluation" concept?

- Would a new 510(k) be required for a labeling change that identifies compliance with an interoperability standard or compatibility with specific devices that comply with an interoperability standard?

e. Distinguishing 510(k) Pathways

The Draft Guidance could be improved to further understanding among mHealth stakeholders by, for example, explaining the distinctions between the Traditional, Special, and Abbreviated 510(k) pathways. Specifically, FDA should describe the practical implications, including financial considerations and impact on review timelines,[21] for each pathway and give mHealth-specific examples, including examples of device types that would meet the Abbreviated 510(k) requirements along with a list of the applicable consensus standards. For each pathway, the Agency should require 510(k) summaries that are more detailed and consistent in order to improve the process of identifying a predicate device and to create a more informed public. In an effort to promote consistency, the FDA should provide templates in Appendices B & D, including desired headings and descriptions of what is expected in each section.

We believe the above clarifications are essential to address the concerns of the mHealth community and to promote a better understanding of the 510(k) Program.

3. Developing a Least-Burdensome Approach to mHealth Regulation

Not only is there a need to educate and clarify the Draft Guidance for the mHealth community, the FDA should avoid regulatory schemes that result in costly efforts for compliance. Many of the developers in this nascent industry are start-up companies. Over-regulation in even the slightest sense can mean the difference between obtaining funding for an innovative mHealth technology and closing shop all together. Even in large organizations, the current economic climate combined with the unpredictability of and unfamiliarity with FDA regulations can result in the removal of funding for innovative mHealth projects and limit job creation. The FDA should be particularly sensitive to the cost-implications of regulation and apply a least-burdensome approach to enable the mHealth ecosystem to blossom. To that end, the Coalition believes that the Agency should focus its regulatory reach on moderate- to high-risk mHealth products.

Conclusion

As described in more detail above, the Coalition believes that the FDA should take into consideration the unique nature of the mHealth ecosystem when finalizing the Draft Guidance and further developing its regulatory framework for mHealth technologies. In particular, the Agency should be sensitive to the fact that the mHealth community includes a significant number of stakeholders who are unfamiliar with FDA regulation and, therefore, require a greater degree of education than previously required for the Agency's audience. Similarly, the FDA should update the Draft Guidance to provide a comprehensive review of the 510(k) Program and to clarify a number of points, including concepts like *intended use*, *predicate devices*, and *accessory regulation*, among others. Indeed, the FDA should reaffirm the current predicate approach, whereby a manufacturer may use multiple predicates to support a substantial equivalence claim to prevent any unintended, deleterious consequences on the mHealth industry. Finally, the Agency should ensure that the Final Guidance does not result in over-regulation of mHealth technologies, as this may have negative consequences on the industry.

[21] The description of the 510(k) pathways in the Draft Guidance suggests that the review timelines are for Special and Abbreviated 510(k) submissions are the same; however, use of the term "Abbreviated" seems to suggest that the timeline for this pathway should be truncated.

For these reasons, the Coalition believes that the issues identified in this letter must be addressed to facilitate a better understanding within the mHealth community of the roles, responsibilities, and Agency expectations with respect to the 510(k) Program.

Thank you again for the opportunity to comment on the Draft Guidance. If you have any questions or would like to discuss these comments further, do not hesitate to contact me.

Very truly yours,

Bradley Merrill Thompson
On Behalf of the mHealth Regulatory Coalition

Hypothetical mHealth Ecosystem