



July 3, 2014

Leslie Kux, Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: FDASIA Health IT Report Docket No. FDA-2014-N-0339

Dear Ms. Kux:

Thank you for the opportunity to provide comments on the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Risk Based Regulatory Framework (the “FDASIA Report”). The mHealth Regulatory Coalition (“MRC”) is appreciative of the tremendous amount of time and efforts the Food and Drug Administration (“FDA” or “Agency”), the Office of The National Coordinator (“ONC”), the Federal Communications Commission (“FCC”) and other government, public and industry stakeholders have put into FDASIA Report. We applaud all those involved for the progress made by the FDASIA Report and wish to offer our opinions and some constructive comments on the FDASIA Report and the regulation of health information technology (“health IT”) generally. These are critical issues and industry, providers and patients are anxiously awaiting clear and detailed guidance.

The MRC is a diverse group of mobile healthcare technology stakeholders focused on promoting the development of an open, realistic, and thoughtful regulatory policy perspective on mobile health technologies. The MRC members include 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 promoting a balanced approach between regulatory policies that protect the public and insure patient safety, and the need for innovation and getting new products to the market for patients’ best interests.

We advocated strongly for the publication of FDA Final Guidance on mobile medical apps to ensure that the industry had the clarity it needed to drive innovation. MRC members and leaders also testified at congressional hearings related to mobile apps and health IT in March 2013. Further, five MRC members served on FDA Safety and Innovation Working Group (the

“Working Group”), helping to define the Working Group’s recommendations to FDA, ONC and FCC on a comprehensive health IT regulatory framework. The MRC wishes to continue its involvement in the development of a health IT framework by providing the Agency with these comments on FDASIA report.

Our goals with this commentary are to:

- Identify those aspects of FDASIA Report which we agree with,
- Address our conceptual concerns with a three-tier system for regulating health IT,
- Provide feedback on a few specific issues and ambiguities raised by the FDASIA Report, and
- Propose some ‘next steps’ for FDA in the regulation of health IT.

In addition to this commentary, we have also included several appendices which address aspects of health IT regulation which merit further explanation. Appendix A will address our comments on the FDASIA Report’s proposed three-tier structure in detail, Appendix B contains a policy paper drafted by the coalition on FDA’s Accessory rule and its applicability to health IT and Appendix C addresses the use of health management health IT by consumers.

Finally, we end with a brief reminder to the Agency regarding the importance of issuing well-balanced guidance on health IT in a timely manner and the impact the lack of regulatory clarity has on the health IT industry. We must emphasize the importance of providing clear guidance to industry as soon as possible. Much of industry and the investment community has been waiting for a detailed understanding of the regulatory framework before devoting time and money to new technologies. Clear and specific guidance is urgently needed to enable and accelerate innovation.

I. Where the FDASIA Report Succeeds

We would like to begin by congratulating FDA and the other agencies involved on several aspects of FDASIA Report. It is the MRC’s opinion that many of the concepts and suggestions proposed in FDASIA Report are on point and will be important to adhere to in the development of a regulatory framework.

First and foremost among these is the clarity the FDASIA Report provides about the role that FDA will play in health IT regulation. The report clearly and repeatedly says that FDA will not expand its regulatory scope. We believe it is very important for FDA to go on record as making that broad commitment, but we were also interested in specific limitations the Agency agreed to:

- The FDA says that it does not plan to “focus its oversight on” the middle category, the health management health IT functionality.¹ The MRC agrees that FDA should limit its authority over health IT, but we are concerned that the broad definition of health management health IT functionality could be problematic as explained further on in this commentary.
- FDA reiterates statements that it made in its final mobile medical app guidance issued in September 2013 that the Agency does not plan to regulate cell phones and cell phone manufacturers simply because an end user can operate a mobile medical app on one.²
- FDA also suggests that if a piece of software constitutes health management health IT and happens to meet the statutory definition of a medical device, but does not include higher risk device functionality, then the Agency does not intend to require facility registration or product listing.³

Second, ONC will play the central role in overseeing the middle category, the health management health IT functionality. The MRC agrees that a singular entity needs to take the lead in developing policy with regard to health management health IT, and that it is a very wise idea for the three agencies involved to decide that ONC will carry that ball. In the same vein, while ONC will exert leadership, it will not regulate health management health IT. The MRC agrees that such software should not be subject to regulation and instead, concerns about safety and efficacy should be addressed by voluntary standards, certification and other private sector tools.

Third, adverse event reporting is important and should be improved, and can be improved by the creation of the Health IT Safety Center, as proposed in the FDASIA Report. We request that FDA and the agencies involve provide additional clarity on how the Health IT Safety Center would function, but we support the effort to improve the collection of data about health IT safety. Many of the members of the Working Group believed that there were gaps in our knowledge that could be addressed through better data collection and sharing.

Finally, the FDASIA Report recommends taking numerous steps to facilitate the interoperability of medical devices and health IT used in systems. Interoperability is an important aspect that has been missing from some other health IT policy initiatives. The FDASIA Report expressly uses the word “functionality” to make clear that the regulatory divisions proposed have nothing to do with where a given program might reside. Considerable work needs to be done to determine how to regulate health IT which functions in a system and

¹ See page 4 (upper left hand corner) of the FDASIA Report.

² See page 6 of the FDASIA Report.

³ See page 23 (lower right hand corner) of the FDASIA Report.

especially the interoperability issues, but the FDASIA Report rightly identifies these issues as needing attention.

II. Concerns with a Three-Tier Regulatory Framework for health IT

The MRC is extremely concerned with the feasibility of a three category system under which all health IT will be regulated. A simplistic approach like that assumes an ability to draw black and white lines between the different categories. Rather, the lines between different types of health IT are grey at best and a three category approach also ignores important risk factors. Additionally, this approach ultimately misinterprets the direction in which medical device technology and health IT is heading. In particular, the FDASIA Report's proposal does not address complex systems that could include all three categories proposed and also integrate traditional medical devices. We have attached as Appendix A our detailed analysis of a three-category system which we hope the FDA will review and consider.

III. The FDA Accessory Rule, and Wellness vs. Disease

We want to highlight two important concepts discussed in the report which the three agencies need to address when developing a health IT regulatory framework: (i) the FDA accessory rule; and (ii) wellness vs. disease. A traditional application of the FDA accessory rule to health IT products will frustrate the rule's purposes and could lead to the unnecessary regulation of low risk products. The MRC makes several recommendations below on how the accessory rule should be tailored with respect to health IT. Wellness management is a modern concept that does not fit neatly into a scheme that is focused on regulation of devices that diagnose or treat diseases. The application of FDA's authority to health IT focused on wellness should be limited in consideration of the low risk nature of such software. The MRC also makes several recommendations below on an appropriate regulatory framework for wellness based health IT.

A. Clarifying the accessory rule is extremely important

- *A Technology Trend.* The future belongs to sharing medical device data among various technology platforms and mobile devices. Everything that produces or receives medical device data, whether therapeutic or diagnostic, will likely be connected to a network. So, for example, a blood glucose meter will be connected to a cell phone, which will connect to a cell tower, which will connect to a local area network, which will connect to a server, which will dump data in an electronic medical record (EMR), which a physician will view on a tablet or smartphone. The traditional approach to regulating products connected to medical devices is outdated in today's environment where a web of medical and non-medical products interconnect. The old approach results in over-

regulation of many health IT products - products that simply do not involve sufficient risk to warrant regulatory oversight.

- *Historical FDA Policy.* FDA has generally regulated products that connect to medical devices by placing them in the same regulatory classification as the “parent” medical device. FDA considers these connected products to be accessories to the “parent” device.
- *The Challenge:* This approach would seem to regulate accessories once removed, twice removed—indeed, the whole family tree – at the same level as the “parent” device. The Agency’s theory was simply: if an accessory breaks, the risk to the patient would be the same as if the parent medical device broke. However, that does not always make sense. Consider the example of a simple USB cable that can be purchased off the shelf at any electronics store to connect a smart phone to a computer. If that USB cable is intended and marketed to be used with a glucose meter to enable the download of data from the glucose meter to a smart phone, that USB plug would be considered an accessory to the glucose meter and would be regulated the same way as the blood glucose meter - as a Class II device. This results in regulatory overkill, as harmless widgets get heightened regulatory scrutiny just because they help transfer data from a Class II or Class III medical device.

MRC Recommendation: We recommend the Agency take the critical steps below to provide clarity with respect to the treatment of accessories, avoid unnecessary up-regulation and overly burdensome requirements and protect patient safety by assuring appropriately substantiated claims of compatibility.

1. Clearly define what is and is not an accessory.
2. Regulate an accessory under the same classification as the parent device only if the accessory does not fall within an existing classification or a newly created accessory enforcement discretion category.
3. Avoid overly narrow interpretations of existing classification regulations and establish additional classification regulations for common mHealth accessories based upon the accessory’s risk.
4. Clearly articulate the application of the accessory rule to general purpose platforms, complex systems and interoperable products.

5. Provide guidance regarding de novo submission requirements for mHealth products and streamline the de novo process.
6. Document its use of any enforcement discretion in a way that can be consistently and confidently relied upon by industry.
7. Ensure accessory claims of compatibility with a parent device are appropriately validated through FDA's post market inspection processes.

B. Importance of Guidance on Wellness Focused Software

- *A Trend of Managing Health through Lifestyle Choices.* Today, we are more aware of how lifestyle choices can impact our health generally and affect certain diseases and conditions more specifically. We also have access to mobile technologies that provide information about an individual's health or condition in their daily environment. Much of this information was not previously available outside of the traditional healthcare setting, but can be used today by patients and consumers to inform lifestyle decisions. As a result, individuals are able to more actively manage their overall health. This engagement has the potential to not only benefit the individual but also public health at large.
- *Historical FDA Policy.* FDA regulates products that are intended for use in the diagnosis, treatment, or prevention of disease or a medical condition. Intended use is determined, in part, by the claims a manufacturer makes about its product.
- *The Challenge.* The Food, Drug and Cosmetic Act was written in a different era—where disease was the doctor's domain and the impact of lifestyle choices was not well-understood. The traditional approach to regulate products is outdated in today's environment where patients and consumers use technology to engage and invest in their wellness as a way to improve their overall health. The line between treating a disease and maintaining a healthy lifestyle is blurred and so is the line between regulated and unregulated claims. Without further clarity, many health IT products could become over-regulated based on their claims even though they present virtually no or low risk to patients. This will have the further adverse effect of stifling innovation in an area that has the potential to radically improve public health and wellness.

Take, for example, the developer of a mobile app that monitors and tracks a user's daily exercise. This developer might claim that using the app can reduce the risk of heart disease or diabetes or help treat obesity. That same developer may claim that its app can be used to monitor daily activity, manage your heart health, or improve the user's physical condition.

Which of these claims would make this app a regulated medical device? The ambiguity in the definition of a medical device and/or the words in the claims themselves results in a lack of regulatory clarity and predictability for many of these health IT products.

MRC Recommendation. FDA must provide a predictable, risk-based regulatory framework which excludes low risk products that benefit consumer engagement and public health from active regulation. As detailed in Appendix C, MRC specifically recommends FDA take the following actions:

1. Define a new category of diagnostics for managing wellness that is intended to be used by asymptomatic individuals, who may be at risk for a certain disease or condition, to trend and track their health data over time to manage their health.
2. Clarify that such managing wellness products would be subject to enforcement discretion.

IV. Specific Concerns Regarding the FDASIA Report and Ambiguities to be Addressed

In addition to our broader comments regarding a risk-based regulatory framework and the regulation of health IT generally, the MRC also wishes to pose a few questions and address specific concerns we had with the FDASIA Report. We hope that the questions to the Agency below will help to define the aspects of the proposals in the FDASIA Report which need to be further addressed.

A. Role of the FDA

FDA indicates that it does not intend to focus its oversight on software in the health management health IT category, even though the software may meet the definition of a medical device. The problem is that FDA does not indicate how they might react if a health management health IT application begins to introduce harm to users or patients. Will these products be monitored? What would push a product from one category to another? Does functionality need to change for this to occur or will healthcare practices play a role?

B. Function vs. Platform

The report states the focus is on the function and not the platform. However, there is not a clear indication of whether or how marketing claims may influence the decision. For example, if a cell phone manufacturer states that their phone is great for running mobile medical apps. In this case, the phone manufacturer is not developing the app, that is the 'function', but claiming use for their 'platform' with these types of apps.

C. Regulation of Electronic Health Records (EHR)

In both the FDASIA Report and several FDA town hall meetings, the FDA has stated that they do not intend to focus oversight on EHRs. However, if a function inside an EHR meets the definition of medical device health IT, then FDA will regulate the medical device health IT functionality. From an operational standpoint, how will the FDA regulate such functionality without regulating the EHR as whole? What information is and is not included in an associated design history file for such embedded medical device health IT functionality? In a filing? What is the scope of risk management expected for the EHR as whole? What evidence is sufficient to define the boundary between the regulated and non-regulated software if the regulated module is operating inside the non-medical software (of which I also have design control over)?

D. Practicality of Industry led Approach for Health Management Health IT

Activities associated with the health management health IT software in the report include: (a) promote use of quality management principles; (b) identify, develop, and adopt standards and best practices; (c) leverage conformity assessment tools; and (d) create an environment of learning and continual improvement. Participation and incorporation of these various concepts are voluntary as ONC has no enforcement powers. For companies creating or using software from the health management health IT category, what is the incentive to participate in the proposed self-regulation? For example, why would a manufacturer spend resources to participate in the Health IT Safety Center? If a consumer, say a hospital, already expends a great deal for meaningful use under HITECH; why would that consumer volunteer to be part of the Health IT Safety Center work? There do not appear to be compliance or financial incentives to drive involvement. Without incentives, the agencies are unlikely to influence entities to participate.

V. Proposed path forward

The FDASIA process, as authorized by Congress and pursued by FDA, ONC and FCC, involved the creation a federal advisory committee. This FDASIA committee worked throughout the summer of 2013, met over 30 times and ultimately produced a report that was communicated to the three agencies above in September 2013. The MRC participated in that committee and our natural assumption was that the three agencies would use what the advisory committee recommended as a starting point for developing its proposed regulatory framework. Of course the three agencies would be entitled to accept, reject or modify any of the recommendations from the federal advisory committee.

A. Issues with the Execution of the FDASIA Process

Unfortunately, something was lost in the process. The federal advisory committee addressed many important issues in its recommendations that were simply left unaddressed by the three agencies and the FDASIA Report. For example, in the PowerPoint presentation that constituted the advisory committee's recommendations, the advisory committee specifically recommended that the three agencies:

- Develop a detailed, flexible taxonomy for health IT that would allow the appropriate risk classification of specific items of health IT. Instead, in the FDASIA Report, the three agencies take a giant step backward to simply say that all health IT should be sorted into three buckets, with very little guidance as to how exactly that is supposed to be done.⁴
- Building on that taxonomy, the advisory committee recommended specific risk factors the three agencies ought to consider as they try to stratify health IT for regulatory purposes.⁵ In FDASIA report that the three agencies released, there is not one whisper or hint regarding how the Agency's view those risk factors, and whether they can be used to parse health IT either into the three buckets suggested by the agencies, or within those buckets for specific regulatory purposes.
- The advisory committee recommended that the agencies develop a plan for addressing weaknesses within the regulatory programs of the three agencies.⁶ For some reason, the three agencies omitted any discussion of these issues. That could not be simply because the issues were agency specific. The report does recite the areas where clarity is needed in FDA regulation based on slide 35 of the advisory committee report. The advisory committee spent numerous hours developing and refining these recommendations about needed improvements, directly responsive to the request of Congress in Section 618 of FDASIA. It is incomprehensible why the three agencies would simply ignore these aspects than in their report to Congress. Frankly, it should not matter that some issues were specifically addressed to individual agencies. Section 618 of FDASIA did not authorize the FDA, ONC or FCC to ignore an issue simply because it resides within a single agency.

Overall, the three agencies resolved fewer issues than the list recommended to it by its advisory committee. To help health IT developers innovate the agencies need to develop clear policies in a more timely way. Regrettably, the agencies are failing to do the very thing industry needs most, which is to make a decision.

⁴ See slides 12 through 15 of the FDASIA federal advisory committee PowerPoint Presentation.

⁵ See Slides 16 through 29 of the FDASIA federal advisory committee PowerPoint Presentation.

⁶ See Slides 36 through 39 of the FDASIA federal advisory committee PowerPoint Presentation.

In December 2010, the mHealth Regulatory Coalition issued a report entitled “A Call for Clarity: Open Questions on the Scope of FDA Regulation of mHealth.” In that 61 page report, we provided in detail numerous questions regarding the scope of FDA regulation that needed to be addressed so that companies wishing to develop mobile apps could do so with a clear understanding of whether FDA regulated those apps or not. Ever since then, now coming up on four years, we have been asking FDA such things as:

- Exactly when does a piece of hardware or software become an accessory to a parent medical device (and thus regulated with the medical device)?
- Where exactly is the dividing line between unregulated claims related to wellness and regulated claims related to disease?
- Exactly which types of clinical decision support software does FDA regulate and which do they not?
- How does FDA treat software modules that may be unregulated individually but are combined ultimately to form a regulated piece of software?

The mobile medical app guidance from September 2013 answered some of the frankly easier questions. But the more difficult questions listed above have remain unanswered for years now. We were hoping that the FDASIA Report would take us at least partway down that road. It is a report to Congress, so we understand that it must be at a high level, but at the same time we were expecting more detail than was provided and more answers to our repeatedly asked questions.

B. The MRC’s Approach – What would we have done differently?

First, we would have proposed a more nuanced explanation for how a software developer could determine into which of the three buckets outlined in the FDASIA Report a given piece of software falls. Last summer our general counsel, Bradley Thompson, served on the Working Group that offered input to the three agencies in advance of this report. In fact, he co-chaired the regulations subgroup. As a part of that input, in the Working Group’s final presentation to the agencies, the Working Group outlined about a dozen factors that could be used to discern high from low risk health IT.⁷ Those factors include things like the intended use of the software, the knowledge and experience level of the intended user, the seriousness of the disease being diagnosed or treated, the transparency with which the software operates and so forth. In the FDASIA Report, we were really hoping to see the agencies’ assessment of those factors: (1) do they agree with them, disagree, or are they unsure and need additional input; and (2) do the recommended factors help put a given piece of software into the correct bucket? Unfortunately, we received none of that clarity, but were instead given three simplistic buckets

⁷ See slide 20 of the FDASIA federal advisory committee PowerPoint Presentation.

with no real words of wisdom to discern how a given piece of software might be placed in the correct bucket. The MRC and the health IT industry want and need more.

Second, we were hoping the FDASIA Report would explain in more detail the future process for tackling the issues that remain. We understood that the FDASIA Report would not answer all questions. Frankly, no one who appreciates our political process would expect that type of a result. The agencies expectedly stated that they would be publishing Federal Register notices that would establish a 90 day comment period as well as the dates for a public workshop to discuss these issues. But what happens after those 90 days? We really have very little idea, other than FDA's regulatory agenda written last fall which included the development of several guidance documents of interest. The health IT industry needs to know if that is still the FDA's plan. We also need to know when those documents will be released. If past experience with the FDA on this topic is any indicator, presumably we would just see proposed documents without a time frame for making them final. We were looking for more substance with regard to the future plans of the agencies to tackle these issues.

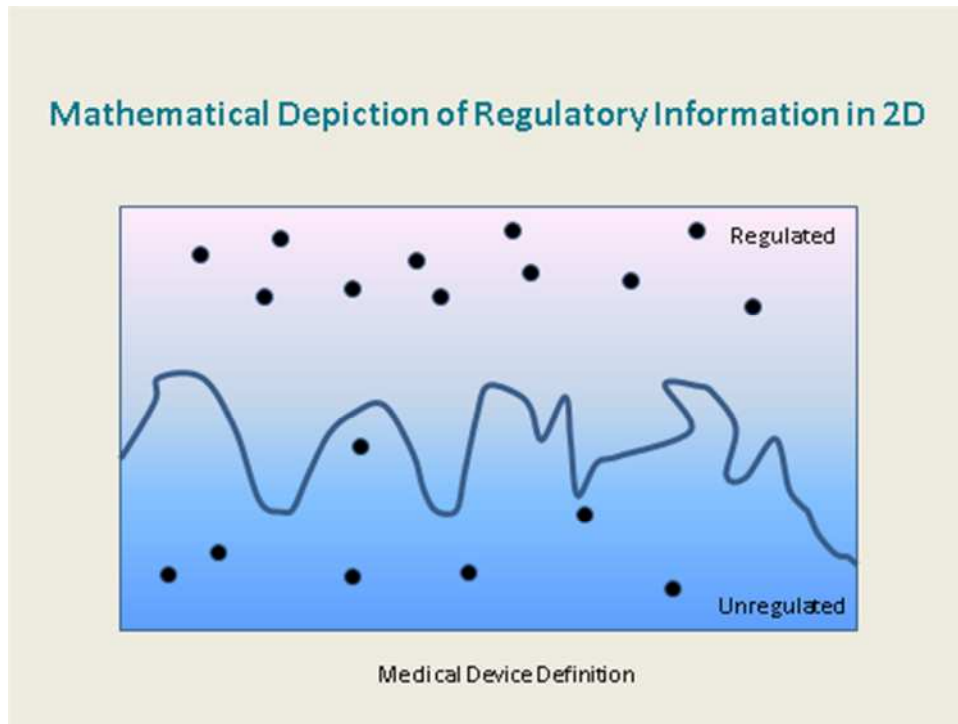
Ultimately, important substantive questions remain about FDA's oversight of software that constitutes a medical device. Until these questions are truly answered, companies must make investment decisions every day about whether to develop a high-value mobile app that may or may not be FDA regulated. That makes it very difficult to do business and consequently stifles innovation.

C. The Desired Shape of the Ultimate Work Product

One of the more interesting aspects of the FDASIA Report was its discussion of clinical decision support software, or "CDS." The report provided about a dozen examples of CDS that FDA would not regulate, and about a half-dozen examples of CDS that FDA would regulate. That was helpful, although quite honestly most of those examples were already known. Even with these examples, however, the FDASIA Report fall short of providing the level of clarity the health IT industry requires.

The fundamental problem is that the examples the FDA provides are no substitute for understanding the rule that separates the regulated from the unregulated. To borrow a principle from geometry, points are not lines. The MRC and the health IT industry need lines. We need to see the general rules that define the scope of FDA regulation. Unfortunately, the CDS examples the FDASIA Report provides have limited value because they are not even near the borderline. Instead, they are the outliers. So they do not help us understand or discern the line that defines the boundaries of FDA jurisdiction.

Simply put, points cannot define the jurisdictional line as illustrated in the following chart:



We need to define the line as well, and use the examples to illustrate points on either side.

The MRC appreciates that the line between regulated and unregulated CDS specifically, and health IT generally, is extremely difficult to draw, and the devil is very much in the details. In fact, we are not talking about two-dimensional geometry but rather a multivariate system, and the true line that defines FDA jurisdiction is not even close to straight. It cannot be so. Technology and medicine both are simply too complicated for the line that defines the risk associated with the intersection of those two disciplines to be simple and straight. If there were a straight and simple line, someone would have thought of it by now and suggested it. Unfortunately, no one has come up with that Holy Grail of health IT regulation and we should abandon the possibility of a simple solution.

Speaking more practically, the final work product actually needs to be a detailed articulation of the lines (as complex as they may be), but also must include numerous example points. Those two techniques working together will be necessary to convey a full understanding such that technology developers can appreciate where their new technologies, not even on the drawing board right now, will fit in the future.

VI. Conclusion

We would like to work collaboratively with the three agencies to devise a more sustainable solution to the complex problem posed by health IT. We hope that this commentary and our

supporting documentation will aid FDA, ONC and FCC in the daunting task they have been assigned. Furthermore, we are well underway in developing a regulatory paradigm that includes a nuanced classification process and a regulatory scheme based on some best practices we have seen work well in the European Union. In particular, in this area of lower risk medical technology, we have seen certifying bodies provide both significant confidence in the safety of products as well as a quicker pathway to market. We would like to work collaboratively and expeditiously with the agencies to lay out some options that would ensure appropriate oversight at a systems level as well as at the level of individual components, all the while allowing innovation to flourish. We appreciate the opportunity to submit these comments, and look forward to being a constructive participant in the process.

Very truly yours,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson". The signature is fluid and cursive, with the first name "Bradley" being the most prominent.

Bradley Merrill Thompson

Appendix A

Comments on the FDASIA Report's Three-Tier Regulatory Framework for health IT

The MRC firmly believes that the fundamental design of the proposed regulatory system, that is parsing health IT into three separate categories – medical device, health management and administrative health IT software – is misdirected. We do not see a clear, conceptual distinction between medical device software and health management software that will last into the future. This Appendix (i) explores the issues with a three-tier categorization and (ii) suggests changes to the three-tier approach by analyzing systems level regulation and component classification.

I. Issues with a three-tier categorization of health IT

There are three primary reasons the proposed categorization does not work.

A. The proposed system does not address health and wellness software

FDASIA section 618 directs that this report address “health information technology, including mobile medical applications.” A rather large part of the mobile medical applications available today address health and wellness. Examples include:

- Apps for self-diagnosis, treatment and chronic disease management
 - Symptom checker
 - Physical therapy
- Apps for reminders
 - Prescription management
 - Appointment reminders
- Apps for healthy living
 - Pregnancy and baby development
 - Diet and healthy eating
 - Exercise and fitness

But apps in these various categories do not fit neatly into any of the three buckets that the FDASIA report identifies. This is because the FDASIA report focuses on software used by healthcare professionals, typically in a healthcare setting. Many health and wellness mobile apps do not have medical device functionality. The apps listed above by category also do not fit the administrative category because they have nothing to do with professional healthcare administration. Likewise the Health Management category seems focused on professional tools that potentially engender some risk, and therefore in the proposal are targeted for ONC oversight. But many of the health and wellness mobile apps would not seem to have the same

risk profile. Basically it seems to us as though the agencies did not consider health and wellness mobile apps intended for consumer use when they designed their three categories system.

B. The proposed three-part distinction ignores important risk factors.

The impracticality of the FDASIA Report's use of only three categories comes in part from the fact that the risk profiles of software vary greatly even within a single functionality. In its September 2013 report, FDASIA advisory committee provided a comprehensive assessment of the issues to be addressed in parsing the categories of software, and the risk factors that impact safety. We highly recommend that the FDA review the work of that federal advisory committee on this point. Distilling the issues down greatly, we offer the following examples of a few of the drivers of risk in health IT:

- Clinical decision support software as a functional category ranges from highly risky software used, for example, to spot potential tumors in radiological images to low risk software that might simply add 5 numbers to calculate an APGAR score.
- Some software operates transparently so the user can understand and challenge the software, while other software might be designed to function as a black box, offering the user a take it or leave it conclusion.
- The care settings and clinical uses can vary greatly, with some software merely transmitting information on a patient's diet to a doctor, while other software might alert an anesthesiologist to critical information during a delicate surgery.

Health IT does not come in merely two or even three flavors. The FDASIA advisory committee does a thorough job of explaining the complexities involved.

C. The Report's distinction is outdated because medical device and health management software are converging, forming systems, and blurring the lines between them.

Organizationally, our healthcare system has been highly fragmented, and many people have spent the last couple decades trying to bring it together. In parallel, from a technology standpoint, we are seeing the same trend. Previously siloed technology is being interconnected to improve patient care. And it is health IT that is stitching together that previously fragmented technology. Now, instead of lone medical devices doing their individual thing, we are seeing systems of care, where medical devices, electronic health records and a lot of health IT in between are being developed to improve the quality and coordination of care.

It seems to us that the categorization offered by the FDASIA Report between medical device software and clinical software is an idea borrowed from the days of yore, and rapidly becoming

extinct. Today hundreds of organizations are working to enhance the interoperability of technology to create powerful systems that better ensure the quality, safety, effectiveness and efficiency of care. And the health IT they are developing does not fit neatly into those old buckets.

II. Changes Needed to the proposed three-part approach

At a high level, for the proposed framework to be workable, we see the need for two structural changes:

- Systems Level Regulation. To embrace the future, we need a regulatory paradigm that recognizes the growing importance of systems. In particular, we need a more comprehensive regulatory scheme that helps to manage risk at a system-level, while not interfering with the practice of medicine.
- Component Classification. Likewise, when we look at the components of those systems, we need a more nuanced classification scheme that takes into account the different risk factors that characterize the components. Thus, rather than trying to separate all health IT into three buckets and regulate health IT based on those three buckets, we need a classification scheme that takes into account, for example, how transparently the health IT operates and the specific clinical uses of the health IT.

Systems are complex technologically and also organizationally. But legislating as though the complexities are not present would not produce a good long-term solution. In this Appendix, we describe some of the healthcare and technology drivers toward systems that we are seeing.

A. The Drive toward Systems and Interoperability

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. This was a substantial topic for discussion among FDASIA advisory committee, and we recommend the committee's September 2013 report for further background on this issue.

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.

To understand this trend, it is important to consider the various technology, healthcare and organizational drivers propelling it forward.

B. Safety and Economic Drivers

Future innovations toward interoperability are expected to 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 (2013), the ECRI Institute listed medical device and Electronic Health Record (EHR) interoperability as fifth in its list of top health technology hazards for 2013.
- Similarly, in a 2012 survey conducted by the Association for the Advancement of Medical Instrumentation (AAMI) of healthcare technology management professionals in 1900 different US hospitals, interoperability placed first and second in the top 10 list of medical device challenges. More specifically, those challenges included:
 - Medical devices and systems on the IT network-- cited by 72% of respondents
 - Integrating device data into EHR – cited by 65% of respondents

There is growing recognition that interoperability and the convergence of technology can substantially improve outcomes, both health and economic.

C. Organizational Drivers

i. Government

Given these opportunities, the government has been looking for ways to accelerate progress. FDA has dived in on the technical standard side, and the ONC has been working to ensure that its meaningful use program encourages interoperability. These issues are set to take on much greater prominence during stage 3 of the meaningful use program.

ii. Standards Bodies

While the push toward interoperability has been ongoing for decades, consider the standards activities of just the last few years:

- 2005—IHE starts work on data transmission and point-of-care devices to EMR connectivity.
- 2006—The International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) propose the standard IEC 80001 to define how to

address new problems in connecting medical devices to a network. The standard was published by AAMI in 2010 and two companion additions were published by AAMI in 2012.

- 2009—The ASTM F2761 standard is published, “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE),” providing a high-level system architecture for medical device interoperability.
- 2012—AAMI Ad Hoc Group on Health Information Technology and Interoperability (health ITI) releases white paper on interoperability envisioning “an entire family of clinically-based, systems-level standards, each targeted at specific important clinical scenarios.”
- 2012—AAMI and Underwriters Laboratories (UL) sign a memorandum of understanding to develop a suite of medical device-related interoperability standards with a focus on patient safety.

Momentum is clearly gaining.

iii. Healthcare Think Tanks

The challenge is well-recognized, and many of the finest minds in healthcare are focused on solving the problem. For example, West Health Institute in San Diego is hot on the trail of interoperability. The West Health Institute explains that it is “exploring means of enabling and accelerating interoperability through the acceptance and implementation of standardized communication protocols. This would reduce the costs of operating medical devices, and facilitate more efficient, accurate and timely transmission of patient data between devices and across health system networks.”⁸

In Boston, the Medical Device “Plug-and-Play” Interoperability Program is 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.”⁹

And the circle of interested groups is growing. In October 2012, in a meeting organized by FDA and AAMI, over 260 people converged to discuss how to enhance the interoperability of medical devices, EHR’s and other forms of clinical software. The organizations supporting the

⁸ West Health Institute - <http://www.westhealth.org/institute/our-priorities/medical-device-interoperability>

⁹ MD PnP - <http://www.mdppn.org/>

event included: American College of Clinical Engineering (ACCE), American Society for Healthcare Engineering (ASHE), Anesthesia Patient Safety Foundation (APSF), Center for Integration of Medicine and Innovative Technology (CIMIT), Continua Health Alliance, ECRI Institute, Healthcare Information and Management Systems Society (HIMSS), Healthcare Technology Foundation (HTF), Integrating the Healthcare Enterprise (IHE), International Council on Systems Engineering (INCOSE), The Joint Commission, National Institute of Standards and Technology (NIST), UL (Underwriters Laboratories), and West Health. We talk more about the output of that meeting below.

iv. Provider Drivers

Hospitals and other healthcare providers are beginning to demand that their technology vendors supply interoperable hardware and software. To coordinate that initiative, the Continua Health Alliance, a non-profit, open industry organization of healthcare and technology companies, is leading the collaboration to improve the quality of personal healthcare. With more than 200 member companies around the world, many of them the largest organizations in their space, Continua is dedicated to establishing a system of interoperable personal connected health solutions. Through this effort, providers are demanding that suppliers obtain certification from Continua to assure interoperability based on agreed upon standards.

v. Consumers as Drivers

Beyond provider-lead initiatives, consumers are driving the bus. The Deloitte Center for Health Solutions (2011) reports that 61% of consumers are interested in using a medical device that would enable them to check their conditions and send that information to their doctors electronically. These consumers are insisting that the previously fragmented healthcare system come together electronically, through software. Those demands will only grow as consumers become more attached to their cell phones.

Convergence of medical devices, EHR's and other forms of clinical software is going to happen; it's only a question of when it will be complete. The technology obstacles are frankly very modest. Instead, stakeholders are working to navigate the human and organizational challenges. But success will come.

D. Examples of the Technology Convergence

Describing the change in technology as an evolution would be a bit misleading. The change has been more abrupt, radical and disruptive than that. The following are examples of converging technologies driven by the desire to improve care. Consider:

- Medical device hospital beds becoming electronic hubs into which all of the various patient monitors and therapeutic devices such as insulin pumps are connected and coordinated, and through which data are collected for deposit into the EHR.
- Medical devices being electronically networked together to directly coordinate the delivery of specific types of care, for example an oxygen monitoring device might tell an intravenous device to stop delivering narcotics if hypoxemia is detected.
- Enhancements coming from the EHR side, including middleware to directly connect the EHR to medical devices so the data might be transferred automatically.
- With the growth of EHRs and the collection of all that data, attention is naturally turning to clinical decision support software to analyze the data, so the software can help guide the clinician in decision-making. Indeed, clinical decision support software is the focus of the next round of meaningful use adoption.
- In the later part of the 20th century, professional care basically stopped when the patient went home. Now we are seeing a whole slew of technologies that allow for connected health. These include cell phone apps that might extract data from a pacemaker or defibrillator and send it back to a cardiologist, as well as home-based hubs to which all sorts of medical devices might be connected, and the data ultimately relayed to a doctor and into an EHR.
- Laboratory testing was one of the first areas to connect to the doctor. Testing on large analyzers conducted at clinical labs has been connected for many years through middleware directly to caregivers and EHRs. Beyond that, point of care testing is following suit. There is a cell phone app that uses the camera to measure color changes in a test strip for urinalysis.
- Medical imaging has gone digital, with ultrasound and other clinical images being transmitted to tablets and cell phones that the doctor can use at the bedside, or even at the doctor's home. It seems reasonable to expect that these mobile monitors will get more sophisticated, and begin to apply computer aided diagnostic software to the images.
- Orthopedic implants can now have sensors attached that allow doctors to remotely monitor the wear and tear on the implant. All of this data then gets stored and trended in an EHR, and analyzed by software.

- Sensors can even be used preventatively, for example monitoring the environment for allergens and alerting a patient with asthma or his caregiver to potential danger. This data can all get stored and analyzed in the EHR.

All of this is exciting, but it points to the fact that technology of all sorts -- drugs, medical devices and health IT -- is being combined into powerful systems that improve the quality of care delivered.

E. The Need for System-Level Regulation

According to a 2012 AAMI report on *Medical Device Interoperability: A Safer Path Forward*:

Safety is a system-level property,” said Nancy Leveson, a professor at Massachusetts Institute of Technology (MIT), and author of *Engineering in a Safer World: Systems Thinking Applied to Safety*. “It must be designed top-down and include the entire sociotechnical system” — meaning the people who interact with the connected health IT. “A device or network of devices that is safe in one system may not be safe in another.”

Leveson further explained, “The compilation of safe components doesn’t necessarily add up to a safe system.” The old paradigm of simply regulating individual drugs and medical devices, without contemplating how they might be stitched together into a system, fails to manage the risk effectively.

Further, knowing that individual pieces of software and hardware will be combined into a system that is as of yet unspecified makes it very difficult to assess even the safety and effectiveness of the individual components. The safety of health related products depends on their intended use, and an open-ended intended use means that regulators need to take a different approach to evaluating the safety and effectiveness of the individual product as well as the system it will join.

III. Conclusion

Technology can be complex. Unfortunately, this means that policy, if it is going to be sensitive to the technology drivers, needs to be nuanced. Three categories will not capture the broad spectrum, graduated differentiation and networked complexity of today’s health IT. We urge the FDA, ONC and FCC to carefully map out the technology that exists today and where it is likely to go tomorrow, before developing its policy solutions. Trying to fit something as vast and differentiated as all of the health IT products and networks into three simple buckets may easily produce a federal regulatory scheme that neither protects patients, nor gives developers of health IT the clarity needed to innovate in the future. Developers will be stymied trying to figure out how to fit vast complex networks into a single software category.

Appendix B

mHealth Regulatory Coalition Accessory Policy White Paper

Problem statement

Understanding the scope of FDA regulation is the first key to business planning in the mHealth space. One of the areas greatest in need of clarity is FDA's reach over accessories to medical devices.

Further, classification is the language of medical device regulation. It is the cornerstone of understanding FDA expectations for a new medical device.

Fundamentally, the problem we want to solve is getting guidance so that the industry knows:

1. When a potential accessory, by virtue of its relationship to a parent medical device, is itself a medical device, and
2. If it is an accessory, how it is classified?
3. How are claims about accessory compatibility regulated?

For ease of reference, let's refer to the two products as the "parent medical device" and the "potential accessory."

General classification rule

We propose the following approach to classifying potential accessories.

A. Definition of an accessory

A potential accessory will become an actual accessory when the following four criteria are met:

1. The intended use – as demonstrated by words and deeds (for example by promotion and design) – of the potential accessory includes use together with either:
 - a. a specific branded medical device or
 - b. a generic category of medical device.

Automatic data transfer between the devices is not required. Manual data entry can still occur as a part of the system intended to be used together.

2. The intended use is not a general purpose, but specific to being used together with that medical device (below we explain how general purpose articles retain their status as general purpose articles even if a particular use is with a medical device);
3. The potential accessory is distributed to the end user without being integrated into the parent device and is “suitable for use or capable of functioning.” (A product that does not meet this criterion might instead be a component); and
4. The relationship between the potential accessory and parent medical device is such that the potential accessory is intended to enable or assist the parent device to be used in accordance with the parent’s intended use.

If those three conditions are met, then the item is an accessory and FDA regulates it.

B. Classification process

The next question, then, is how to classify the accessory. There are at least three possibilities.

1. First analyze whether the accessory fits within an existing device classification found in the regulations other than the classification for the parent medical device. If so, that classification determines the classification of the accessory. If not,
2. Second, analyze whether the accessory fits within one of the enforcement discretion accessory categories (defined below). If so, the accessory is exempt from active regulation. If not,
3. The accessory is classified in the same classification regulation as the parent medical device.

Note that if the potential accessory is excluded from accessory status because it actually changes the intended use of the parent medical device, the software or hardware would itself become a parent medical device and would need to be classified wherever it fits.

The idea here is for FDA to create explicit, new classifications for common accessories, because the default for an accessory otherwise, if there is no express classification already, is either class III or the classification of the parent device, both of which would result in overregulation of the accessory. So expressly granting lower classification to common, low risk accessories is an extremely important step for FDA to take.

Medical device accessories should not cause general purpose hardware and software to be regulated

It is already clear that where software constitutes a medical device and is intended by the software manufacturer to be used with general purpose computing or communication hardware (such as a cell phone) or software (such as an operating system or standard communication protocols), the general purpose computing or communication hardware or software (sold separately by a separate manufacturer) is not a medical device. The same would be true when a specialized accessory that itself has medical device functionality (such as a blood glucose test strip reader) is intended to be used with a general purpose computing or communication product (sold separately by a separate manufacturer).

We propose that FDA go a step further and clarify that the general purpose hardware or software does not need to be sold separately by a separate manufacturer. Further, FDA should clarify that the general purpose computing or communication hardware or software remains unregulated even when the manufacturer of the general purpose hardware or software intends that the hardware is to be used with any suitable software, *and in its promotion specifically includes medical device software*. In other words, the fact that a general hardware or software company explicitly identifies a specific piece of medical software, among others, that can be used with its product should not cause the general article to become regulated. For example, a general purpose cell phone should remain unregulated even when it is specifically promoted for use with a medical device app, is sold preloaded with the medical device app or contains general purpose communication protocols that meet the needs of medical apps.

Of course, if the manufacturer of the general purpose computing or communications equipment adds specific hardware or software functionality that serves a medical device functionality and adds material risk, that functionality would be regulated. Taking a risk-based approach, there are functionalities that FDA should permit without regulation such as an app that retrieves, stores and forwards data, using standard communication protocols, from a medical device to a mobile medical app to enable the mobile medical app to apply algorithms to/manipulate the forwarded data for use in a non-acute situation.

Application of accessory rules to systems

One of the areas most in need of guidance is the application of the accessory rules to systems. Systems can be quite complex, such that items might be an accessory to an accessory to an accessory of a medical device. We need some clarity from FDA regarding at which point that article no longer would be viewed as an accessory to the medical device.

We propose that each link in the system be examined using the approach outlined in the first section, that is applying the five criteria to the article to see if it is an accessory *to an article that would be considered a freestanding medical device*. The analysis should always focus on the relationship between the potential accessory and the parent medical device. This is instead of

considering whether an accessory somehow supports another accessory, which is too attenuated to declare a product regulated.

Further, the guidance should consider software modules or software add-ons to the parent software device. FDA also should address system testing and the separation of modules/units that is required before such modules might be treated differently for regulatory purposes. It is typically difficult to draw regulatory lines between two connected software modules. In a separate position paper, we will recommend a specific approach to drawing lines between modules.

Claims of interoperability

A claim that an accessory meets certain standards that are recognized as relevant to medical device functionality does not automatically mean the product is a regulated accessory. For example, the claim that an accessory is interoperable and/or compatible with a particular type piece of medical device software or hardware does not make the accessory any less of a general use item. Claims of interoperability and compatibility are commonly used to describe complex systems and underlying platforms. Because something is compatible or interoperable does not necessarily mean it has been optimized for use solely with medical devices and thus it can retain its general use status and should not be regulated. Only items of software or hardware that add or mitigate material risk and for which the seller makes medical device claims should be regulated.

Freestanding regulatory device classifications

FDA already has a few classifications in its regulations for products that can serve an accessory function. Examples include:

1. 862.2100 Calculator/data processing module for clinical use
2. 864.4010 General purpose reagent
3. 890.3710 Powered communication system
4. 892.2050 Picture archiving and communications system

With regard to these existing classifications, we would like to see four improvements in FDA's approach.

1. When interpreting the scope of those classification regulations, FDA should not be unduly narrow in its interpretation and should not, for example, exclude new products that reasonably fit within those classifications on the basis of the so-called "8xx.9 regulations." FDA should not use those 8xx.9 regulations to exclude products from the classification simply because the new product connects to another medical device or the

new product has novel features that do not impact risk. For example, we think the regulations should be revised to make clear that SaMD, as that term has been defined by IMDRF, should not be excluded from a 510(k) exemption on the basis of the 8xx.9 regulations just because it uses data from an in vitro diagnostic device. The classification should be based upon the function of the SaMD (what is done with the data), not the data source. This is consistent with the FDA Mobile Medical Application Guidance and the Food and Drug Administration Safety and Innovation Act Health IT Report where there is a clear focus on the health IT functionality and not the platform(s) on which such functionality resides or the product name/description of which it is a part.

2. FDA also should establish additional classification regulations that define and characterize the risk associated with the most common mHealth accessories that it intends to regulate. The purpose here would be to establish more appropriate, risk-based classifications specific to the accessories. We have included some specific classifications we would propose in Attachment 1. We believe that FDA should leverage FDA's recently proposed revised reclassification procedures, in accordance with FDASIA, to facilitate the creation of these new classifications.
3. FDA should document its use of enforcement discretion in a manner that can be consistently and confidently relied upon by industry. For example, FDA recently made the decision to deregulate diabetes data management software products. We think that's a good decision, as such systems are so safe and so well characterized that there was no benefit to subjecting them to regulation. We were pleased that FDA publicly announced that on the agency's website in a manner that all could see. We would like to see FDA use that same transparency for other categories that the agency has decided not to regulate.
4. And finally, we would like to see FDA make greater use of the de novo reclassification process for novel mHealth technologies that plainly do not create undue risk. We would like to see greater flexibility by the agency for assembling the necessary information for a de novo submission, and we would also like to see clearer guidance on applying the de novo process to mHealth technologies, and an expedited process.

Enforcement discretion accessory categories

Knowing which accessory categories FDA agrees are general purpose enough and low risk enough to be not regulated would greatly help industry innovate in this space. We would like to see FDA spell out in a guidance document some of the more important and common categories of accessories that the agency agrees are either not medical devices, or if they technically meet

the definition, are categories where FDA has no intention to regulate. We have assembled a preliminary list of these categories in the attached Attachment 2.

Regulatory requirements applicable to accessories

Regardless of the classification of an accessory, the following rules would apply to any intended use as an accessory.

1. Claims that certain products are compatible or interoperable with a medical device must be adequately substantiated and
2. The company making the claim must assure the claim remains accurate as the accessory or parent medical device changes over time.

So for accessories that are in fact regulated medical devices, instead of up classifying accessories, we recommend FDA use its authority under the general controls to assure that companies are adequately validating accessory type claims. Thus, instead of premarket review, we are proposing that FDA use the agency's inspection powers to make sure that the validation has been done.

Conclusion

Our goal in providing this comprehensive assessment of how accessories should be regulated is the acknowledgment that accessories often should be regulated independently of the medical devices they accessorize. If an accessory fits into its own classification regulation, or fits into one of the enforcement discretion categories, it should be regulated independently and not as part of a particular system or configuration. This has tremendous practical consequences, not the least of which is that these accessories would not need to be included in premarket notifications for the parent device. Instead, as just explained, they would have their own classification status and claims of compatibility would be addressed under the quality system, and not through premarket notification.

We include in Attachment 3 examples of accessories in the market today which demonstrate the issues identified above.

Attachment 1—Proposed New Regulatory Classifications for mHealth Accessories

Data aggregators
and report
generators

A data aggregator and report generator is a hardware or software device intended to produce an electronic report of health-related and/or medical device data generated from one or more sources connected via an mHealth system. An example of a data aggregator and report generator is a software device that electronically generates a report of data collected from a weight scale, blood pressure cuff, and a proprietary device that manually prompts the user to respond to predetermined, health-related questions.

Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Attachment 2—Proposed Unregulated, mHealth Accessory Categories

Description	Definition
General Purpose communication equipment labeled or promoted for a specific medical use	General Purpose communication equipment labeled or promoted for general use but including an explicit, specific medical use consists of products that are used for telecommunications purposes to transmit data in an mHealth system and that comply with applicable standards for such products. These include wireless routers, modems, switches, Bluetooth transmitters/receivers, cables, connectors, adaptors, and any other similar product used for basic connectivity purposes, as well as equipment used to support, test, and maintain such equipment.
Device controllers for Class I exempt devices	A device controller (for Class I exempt devices) is a hardware or software device used to electronically control the functionality of a Class I device exempt from premarket notification requirements that is part of an mHealth system. An example of a device controller is a software device that electronically triggers a sensor device in an mHealth system to perform a task (e.g., to collect health-related information, or to notify the user to respond to predetermined, health-related questions).
Adapted general purpose communication software	<p>Software allows consumer to enter vital sign and other data, or retrieves data from a medical or fitness device via standard wireless communication in lieu of manual entry of the vital sign data. This software may temporarily store data on mobile device; use standard SSL, encrypt data; and, using a standard mobile data connection, transmit data at a scheduled time to a secure data center. This software does not issue real-time alerts to healthcare providers and is not intended for individuals in acute care facility, or high-risk individuals requiring active, real time monitoring by a healthcare provider.</p> <p>This software may deliver to the consumer certain content (may be educational, motivational or instructional) that is configured for the consumer by separate software domiciled at the data center (that may be regulated) and transmitted to the mobile device for display.</p> <p>May or may not have the same brand name as one of the regulated devices or software with which it communicates.</p>
Secondary display hardware and software	In certain care settings, caregivers and patients find it convenient to use a secondary display for collected data, sometimes to simultaneously display data taken from multiple sources. Secondary displays include any hardware or software intended for displaying health or medical device data where the user has reasonable access

to another, primary display. This does not change the regulatory classification of that primary display.

Attachment 3—Examples of Accessories in the Market Today

mHealth Accessory Issue	Example	Current regulatory treatment
General purpose hardware and software used with a medical device	A Patient Management system allows implanted defibrillator data to be recorded and forwarded via Plain Old Telephone System (POTS) to a Webserver that is manufactured by the Implant Defibrillator manufacturer.	When sold by a class III manufacturer, the Web server is treated as an accessory and classified in class III. Indeed the entire Web server system including power cords and disk drives are treated in class III. This is over regulation.
General purpose hardware and software used with a medical device	A standard cell phone may well in the future be sold with a mobile medical app, regulated by FDA, preinstalled.	FDA likely would treat the cell phone as a medical device but choose not to regulate it under enforcement discretion. More accurately, the cell phone should not be considered a medical device at all.
Application of accessory rule to systems	An in-home device capable of reading implant data can then send the data to a physician. The data is non-urgent and having the home monitor is primarily for convenience. The in-home device has no decision making capability and does not close any therapy loop by reprogramming settings. The in-home device functionality could be alternatively accomplished with a standard cell phone and custom interrogation interface to collect the data. The data would flow from the implant to a custom telemetry device via a Bluetooth connection to a cell phone.	Under current regulatory approaches that FDA, any of these in-home devices would be class III. This is over regulation.

Appendix C

An mHealth Regulatory Coalition White Paper: Consumer Medical Devices Used To Manage Health

The mHealth Regulatory Coalition urges FDA to develop and issue a new guidance document explaining the difference between disease-related claims that the agency regulates under its medical device authorities, and wellness related claims that the agency does not regulate. This paper is intended to provide our proposed framework for such a guidance.

Background: What is the issue?

In the old days, we lived under the fiction that taking care of health was dichotomous:

1. Doctors managed the diagnosis and treatment of disease and they did so largely in doctors' offices or hospitals.
2. Consumers generally understood that certain things like a well-rounded diet and exercise were good for us, and we managed that in our home by ourselves.

In that scenario FDA's responsibilities were relatively clear. FDA focused on the tools used by doctors in a healthcare setting to manage disease. According to the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (section 201(h)), medical devices include those products "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." The central thrust of that definition is that the product is used in connection with disease or other conditions, the word conditions being added to address such things as pregnancy. Thus, in the early days of the 1976 amendments, the definition was relatively clear in that it referred to products used in the domain of healthcare institutions to diagnose or treat disease or such conditions as pregnancy.

Today those activities are not so neatly separated. We have a much more sophisticated understanding with regard to how daily activities influence the likelihood of disease or other adverse health conditions. So consumers are taking proactive steps in their homes to better manage their health and ward off disease. Based on newly available genetic information, for example, consumers have a better understanding of where they may be at risk for disease, which in turn allows them to manage much more carefully the elements of their daily lives that constitute risk factors for that disease.

Old approach: assessing disease

The broad category of diagnostics was broken down into three subcategories.

Subcategory	Defining Characteristics Of The Subcategory
Screening	This is when a testing product is used on an asymptomatic individual. At the same time, these products might be used on individuals who are in some manner deemed higher risk of a disease, for example testing for hepatitis among individuals struggling with substance abuse. If a screening test produces a positive result, the individual is often referred for diagnosis.
Diagnosis	This is when a testing product is used on a symptomatic individual to assess and confirm a diagnosis. So these products might be used, for example, when an adult presents an emergency room with shortness of breath, dizziness and nausea to assess for a myocardial infarction. If an individual is diagnosed with a certain disease or condition, depending on the disease, the physician may need to monitor that individual's health status relative to the disease.
Monitoring	This is when a testing product is used on a patient who has a confirmed diagnosis, for the purpose of assessing health status in order to manage treatment over time. A common monitoring system is a blood glucose test strip and reader used to measure blood glucose levels in a patient with diabetes. One of the differences between this category and the other two is that this category of testing is done as a part of therapy management, where the other two are done as a part of determining whether therapy is needed.

New approach: managing wellness

To that list of subcategories we propose to add the following 4th subcategory.

Managing wellness	This new category combines elements of screening and monitoring.
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	<ul style="list-style-type: none"> • Like screening, these testing products would be used on asymptomatic individuals where there may be some indication that the individual is at risk for a particular disease, for example because of family history, genetic makeup and other risk factors. • But like monitoring, these tests would involve tracking information over time as an aid to long-term health management. For example, regular use of a weight scale when dieting.
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Emerging clinical evidence

There is a growing body of clinical evidence around preventive health and a consumer's ability to effectively ward off disease by better general health management based on information collected over time. That research focuses on areas such as the following:

Use case 1. Reducing the risk of diabetes.

- Target consumer example: A person at risk of diabetes because of family history and weight. But presently the person does not have the symptoms of diabetes.
- The CDC observes that people with prediabetes who lose 5%–7% of body weight and get at least 150 minutes a week of moderate physical activity can reduce the risk of developing type 2 diabetes by 58%.
- Product – an app that helps them manage their calorie intake, exercise level, and other factors known to reduce the risk of diabetes.

Use case 2. Reducing the risk of heart disease.

- Target consumer example: A person at risk of heart disease because of family history, sedentary lifestyle, smoking and poor eating habits. But presently the person does not have the symptoms of heart disease.
- The American Heart Association recommends a diet low in fat, particularly saturated and trans fats, enriched in fruits, vegetables, whole grains, and fish, and low in added sugar and salt. The AHA also recommends against smoking. Smoking cessation may have beneficial effects on the lipid profile by increasing HDL-C (mean, 4 mg/dL).

Exercise, physical activity, and weight loss may also increase HDL-C and lower triglyceride levels. The AHA recommends 30 minutes of moderate-intensity aerobic exercise on most days of the week.

- Product: an app designed specifically to track the elements of dietary intake related to the risk of heart disease, particularly fat and cholesterol levels. The app could also help implement elements of a smoking cessation program, and track physical activity, for example, by connecting to a pedometer.

The bottom line is that we as a society need to be encouraging use of products that help people live healthier lives. The further bottom line is that these apps do not engender any material risk, and therefore do not merit FDA regulation even though they mention disease.

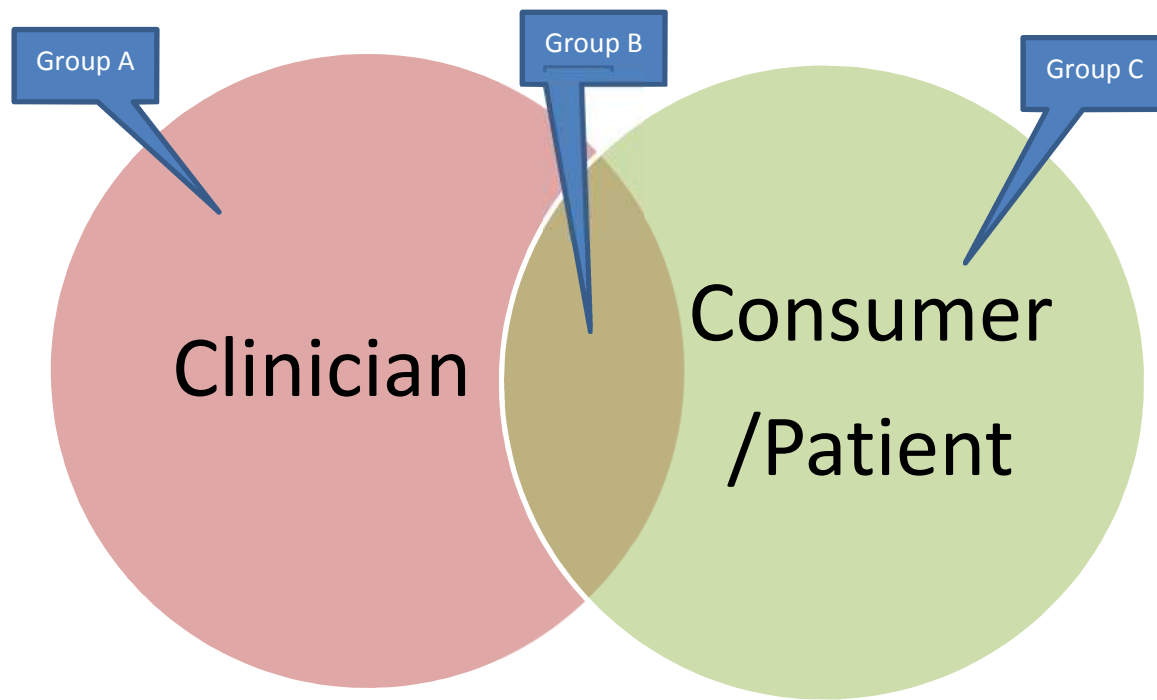
Scope: What are the defining characteristics of products in this category?

In each of the three categories below, we are focusing solely on products used by consumers outside of a healthcare institution to measure information about their bodies. These categories include any specialized software or hardware, or combination of the two, that serve these purposes.

From a big picture perspective, we divide these products into three different groups based on the roles of the doctors and patients/consumers. We explained more below, but at a high level:

1. Group A includes those products that produce information that is really only meaningful to the doctor or other caregiver, because interpreting the information requires specialized expertise. Think about interpreting an EKG.
2. Group B includes those products that produce information that is meaningful to both the doctor and the patient. While this may be result of training that the doctor gives to the patient, nonetheless the information is meaningful to the patient. Think about a blood glucose meter that people with diabetes use to manage their diabetes and report the results to the doctor. Products in this category really rely on collaboration between caregiver and care receiver.
3. Group C includes those products that produce information that is used by consumers alone without a doctor's oversight. Think about weight scales and mobile apps that allow the consumer to track and trend his or her weight to avoid future health problems.

Visually, the groups can be viewed through the following Venn diagram:

Responsibility for Interpreting the InformationGroup A – Doctor- Directed Disease Assessment Devices

The essence of this category is devices/SaMD designed to produce information that doctors are trained to interpret and understand, and consumers are not, but that are destined for consumer hands with the goal of feeding the information back to the doctor on some periodic basis. Devices in this category are easy to spot because there are existing FDA device classifications for the associated functionality, such as urine analysis for occult blood and so forth. The common thread that runs through all of these measuring devices is higher-risk disease states or conditions, with an imperative need for accuracy in either diagnosis of the disease or monitoring in the case of a chronic disease. Further, the devices will be available through prescription because it will be necessary to involve a doctor in the interpretation of the information.

Obviously if devices are intended for use by doctors on patients, they too will be in this category.

FDA regulates this category. While many devices in this category will be in class II, some devices will be regulated as class I devices (or class II exempt from premarket notification) because the technology is so well characterized that FDA premarket review is not necessary.

Group B –Disease Assessment Devices used Collaboratively by Doctor and Patient

The defining characteristic of devices in this category is that consumers are fully capable of interpreting the information produced by these devices, but at the same time a health professional should be involved. It's important to understand that there can be a natural evolution of disease assessment tests from physician-directed (Group A) to consumer-directed (Group B) as companies innovate with new ways to make the information more meaningful to people without a medical background. So long as the information is truly understandable by consumers without special medical training, assessing disease can include:

1. Screening
2. Diagnosis
3. Monitoring of a serious disease that requires reporting to a healthcare professional

As already explained, products in this group are also characterized by the need for the patient to collaborate with his or her physician. The diseases or condition is serious enough, and the measurements important enough, for the doctor to be kept at least generally informed in the case of monitoring, or consulted in the case of screening or diagnosis.

There are two different roles these products might play:

1. Devices that measure

FDA regulates the tools used for measuring in this category, and any associated accessories (see separate policy position on the scope of accessory classification). Most of these devices should be in class I, not subject to FDA review, except those new technologies that are not well enough characterized to produce reliable results, where inaccurate results could substantially jeopardize the safety of the consumer. This latter category should be in class II.

2. Devices that do not measure

If a product is not a tool used for measuring, nor an accessory of such a product, the product does not fall within FDA regulation. Examples of this would include mobile apps and other software that are merely intended to record and analyze health data for consumers.

Group C –Health and Wellness Managing Devices

The defining characteristics of devices in this category are:

1. Intended for use by consumers who

- a. Are well--
 - i. Experiencing no meaningful symptoms of the disease at issue
 - ii. But may or may not have risk factors of concern, including family history or genetic makeup; or
 - b. Have been or may still be sick, (i.e. has been diagnosed and treated), but--
 - i. live outside of a healthcare facility,
 - ii. without a healthcare professional monitoring the disease or condition, just the consumer himself and/or perhaps his family members to ensure he is following instructions;
2. Repeated use over time for the purpose of tracking and trending health information;
 3. For the purpose of influencing lifestyle decisions to reduce the future risk of disease or other conditions, or managing health issues without active health professional oversight; and
 4. Are not invasive.

The essence of this category is disease avoidance and/or health maintenance. So long as those four conditions are met, it is permissible for the labeling for these products to mention the diseases the products are intended to help the consumer avoid or manage without triggering FDA regulation.

A couple of examples may make this more concrete.

- A fitness/wellness app that uses body sensors to detect the user's bio signals for purposes such as measuring body fat to support general conditioning.
- Also to support a consumer's general fitness and wellness goals, an app that uses sophisticated analytics to review and analyze data generated from unregulated products that detect such things as heart rate or body fat.

Those products should remain unregulated even if the manufacturer chooses to educate consumers regarding general risk factors for specific diseases, and encourages the consumers to use these products to track and trend information over time so that the consumer can live a healthier life and avoid those diseases or other conditions.

FDA should not regulate this category. All of the devices in this category either are not medical devices or if they technically meet the definition of medical device, are so low risk they should be subject to enforcement discretion.¹⁰

To further explain the three groupings, we are including as attachment one a list of some of the available mobile apps that fit into these groupings.

A footnote on off label use

As with all FDA regulation of medical devices, these categories are based on the manufacturer's intended use for the product. And as with all medical devices, there is a chance that purchasers will use the product in a way different than was intended. That is unavoidable. But at the same time, FDA should not permit a sham intended use. An intended use will not be deemed a sham if there is in fact a substantial market for use of the product precisely as the manufacturer has intended.

¹⁰ This conclusion lines up with the FDA's statement in its Mobile Medical Application Guidance on certain types of applications, including wellness management applications: "Some mobile apps in the above categories and listed below may be considered mobile medical apps, and others might not. For those mobile apps listed below that are devices, FDA intends to exercise enforcement discretion because they pose a low risk to patients." (FDA Mobile Medical Application Guidance, MMA-1741, Page 16, September 25, 2013)

Attachment 1

Examples of Apps That Fall Into These Groups

Each of the following examples is presently on the market, without any apparent compliance with FDA requirements. We urge FDA to issue a guidance document to clarify the dichotomy between regulated disease claims (Group A and Group B) and unregulated health and wellness claims (Group C) so that the marketplace can come into compliance more effectively. The text that describes each app is taken from the official description of the app in iTunes and/or the company website.

Proposed Grouping	Existing App Available In The United States
Group A	<p>Sleep Aid</p> <p>By Remote Analysis</p> <p>Description</p> <p>“As a long-time iPhone user I was enthusiastic to be the medical advisor for the team to develop this application. Sleep apnea is a common sleep disorder and our aim was to create a tool that enables anyone easily detect the need for a further sleep study. Sleep Aid does not substitute a diagnosis made by your doctor but may give an alarm that one should see a doctor to find out how to sleep better. Remember that snoring may compromise the quality of your sleep. Consult your ENT-specialist to get treatment for your snoring.”</p> <p>Miikka Peltomaa, MD, PhD</p> <p>Otolaryngology, Head and Neck Surgery</p> <p>ENT Center Aino</p> <p>Jarvenpaa, Finland</p> <p>“Sleep Aid is a smart application for anyone who suspects s/he may suffer from a sleep disorder. Especially sleep apnea is a severe and insidious disease that – if not treated – may cause a number of other conditions and can in the worst case lead to death. If you find signs of sleep apnea in your recording, always consult</p>

Proposed Grouping	Existing App Available In The United States
	<p>your doctor.”</p> <p>Heikki Lehti, MD, PhD</p> <p>Pulmonology</p> <p>Kerava, Finland</p> <p>SLEEP APNEA</p> <p>Sleep apnea is characterized by recurrent episodes of airway obstructions and corresponding cessations of airflow and breathing. A cessation in breathing is called an apnea.</p> <p>The most common reason for an apnea is a physical block to airflow when the tissues in the throat prevent normal breathing. This is especially common among overweight people but individuals with normal weight may suffer from it as well.</p> <p>Sleep Aid makes it easy for you to determine whether you suffer from sleep apnea and should consult a doctor. The application records eventual snoring sounds and creates an easy-to-read graph. By examining the graph, you can find out your snoring. You can also listen to your breathing and snoring pattern.</p> <p>SLEEP AID</p> <p>Sleep Aid includes samples of typical snoring and sleep apnea events. You can compare your own recording with the provided samples to determine whether there are symptoms or signs of sleep apnea. Remember, however, that only a</p>

Proposed Grouping	Existing App Available In The United States
	<p>doctor can make the diagnosis. Always consult a physician when you think you may suffer from a medical condition.</p> <p>FEATURES</p> <ul style="list-style-type: none"> • Recording your snoring sounds • Easy-to-read graph of your snoring • Listening to your snoring • Snore and sleep apnea samples • Useful information about sleep apnea
Group A	<p>MaculaTester</p> <p>By Sabina Technology, LLP</p> <p>Description</p> <p>The MaculaTester® - A New Way to Monitor Visual Function!</p> <p>Diseases that affect the macula (the center of the retina) including macular degeneration and diabetic retinopathy are the main causes of blindness worldwide. The best defense against these macular diseases is early detection.</p> <p>This simple test of your vision can alert you to early changes that may indicate a problem with your macula caused by diabetes or macular degeneration.</p> <p>The MaculaTester (Pat. No. 8,047,652), is an INTERACTIVE version of the Amsler Grid - the standard test used by eye doctors to test macular function for over 50</p>

Proposed Grouping	Existing App Available In The United States
	<p>years.</p> <p>Image distortion is often the first visual change that patients notice when the condition is starting or advancing. Since the distortion can be subtle and difficult to notice at first, the Amsler Grid is used to help detect it as early as possible - while it is still treatable.</p> <p>Most doctors give their patients a card with an Amsler Grid to test themselves at home between eye exams. Unfortunately, many patients loose it or forget to use it.</p> <p>The MaculaTester performs the same function as the Amsler Grid but with several distinct advantages:</p> <ol style="list-style-type: none"> 1) It is interactive - allowing you to record the area of distortion by touching the screen. The recorded image is saved with date and time so you can show it to your doctor, as well as compare to previous images to look for any changes. 2) It resides on your iPhone/iPod Touch - so you won't lose it. 3) Our free "push notification" feature reminds you to perform the test at regular intervals - so you won't forget to use it. <p>-CHECK OUT THE VIDEO DEMONSTRATION ON OUR WEBSITE - www.maculatester.com.</p>

<p>Proposed Grouping</p>	<p>Existing App Available In The United States</p>
	<p>- This app is intended for use only as an early screening test for macular dysfunction. It is not designed or intended to be used as a tool to diagnose macular degeneration, diabetic retinopathy or any other disease process. This test is not a substitute for an examination by a qualified eye care professional.</p>
<p>Group B</p>	<p>Cardiograph: Heart Rate Pulse Measurement using your iPhone & iPad Camera - Track the Cardio Fitness of your Friends and Family</p> <p>By MacroPinch Ltd.</p> <p>Description</p> <p>Cardiograph is an application which measures your heart rate. You can save your results for future reference, keep track of multiple people with individual profiles, add notes and locations, and even print out your measurements for sharing or safe keeping.</p> <p>Cardiograph uses your device's built-in camera to take pictures of your fingertip and calculate your heart's rhythm - the same approach used by professional medical equipment!</p> <p>"I know you have the disclaimer on the screen but I don't care, Cardiograph saved my life. Your app was key to understanding what was going on and help the doctors understand too."</p> <p>Bob Spadafora - *****</p> <p>"After having two heart valve replacements and a by-pass, I feel it is not only smart - but also necessary - to have such a reliable heart rate monitor with me everywhere I go."</p> <p>Dantv – *****</p>

Proposed Grouping	Existing App Available In The United States
	<p>"I am an EMT and it helps me actually see what is going on. It is by no means definitive like a monitor but it is a great indicator of problems I would not see otherwise."</p> <p>Granniem – ****</p> <p>"I had a pulse oximeter on one hand, medical quality, and my iPhone app in the other and the app was dead-on accurate."</p> <p>Like it but hate it – *****</p>
<p>Group C</p>	<p>Stress Check is the most innovative tool available for quantifying your level of psychological or physical stress. By measuring your heart rate through the camera and light features on your iPhone, Stress Check can estimate your level of stress in real time.</p> <p>Using Stress Check by Azumio you will be able to:</p> <ul style="list-style-type: none"> • Quantify your level of stress • Determine the effects of different stressors • Control stress and observe progress • Reduce chances of certain chronic diseases known to be correlated with stress <p>Everyone has experienced changes in heart rate before taking an exam, giving a public speech, or when exercising. In fact, not only does your heart rate increase, but the time variations between consecutive heart beats become more random and scattered as well. By analyzing this factor of heart rate variability (HRV), it is possible to estimate your level of stress wherever you are, with no additional hardware.</p> <p>Analysis of HRV requires heart pulse data to be measured continuously for a certain period of time. The more you use Stress Check, the better the app gets to</p>

Proposed Grouping	Existing App Available In The United States
	<p>know you and your heart.</p> <p>Algorithms used to analyze HRV follow recommendations of European Society of Cardiology (ESC) and the North American Society of Pacing and Electrophysiology (NASPE).</p>
Group C	<p>HeartWise Blood Pressure Tracker</p> <p>By SwEng L.L.C.</p> <p>Description</p> <p>There is a reason our software is one of the highest-rated Apps on the App Store - with more than 1,000 ratings and reviews, our customers have been quite clear: HeartWise is the easiest-to-use application for quickly recording and keeping track of your blood pressure, resting heart rate, and weight. Our trend-setting visualization quickly shows you trends, detailed analysis, statistics that tell you how your blood pressure fluctuates on a daily basis and over time. Our powerful statistics and charts are unmatched and give you unprecedented visualization.</p> <p>HeartWise features:</p> <ul style="list-style-type: none"> - An elegant data entry screen that is seamlessly intuitive. - Tracks systolic and diastolic blood pressure, resting heart rate (Pulse), and weight. - Automatically calculates mean arterial pressure, pulse pressure, and body mass index. - Export your data by email as a fully formatted report, in spreadsheet format, or as plain text. - Easily import existing records or data from other applications. - Configure Reminders to alert your when it's time to take a measurement or your medication. - News and Announcements - Detailed statistics reporting shows how your blood pressure and other measurements change over time. - Support for weight in Imperial units (pounds) or metric (kilograms). - Clear, crisp charts with a quick "camera" feature to save high-resolution copies to your photo library! <p>HeartWise has a simple, streamlined interface that lets you input data in seconds. The touch of a button gives you detailed charts and statistical reports that show trends visually and how your blood pressure - and your health - changes over time.</p>

Proposed Grouping	Existing App Available In The United States
	<p>HeartWise has a fully capable export feature that allows you to send your data as a fully formatted report, as a spreadsheet, or as plain text directly from your phone. You can send your blood pressure, pulse, and weight history to yourself - or even your doctor. Similarly, existing data or measurements from other applications can be easily opened and imported into HeartWise.</p>
Group C	<p>Nutrition Menu - Calorie, Exercise, Weight & Water Tracking</p> <p>By Shroomies</p> <p>Advance your diet by having nutritional information for over 100,000 food items right at your fingertips! Whether you go out to eat or cook at home, Nutrition Menu takes the guesswork out of choosing healthy meals and even includes a calculator to compute your Food Score. Have the peace of mind knowing that your meal fits within your dietary allowance. You can then track from meal to meal insuring a higher weight loss by keeping a journal of what you have consumed. Whether you are counting carbs, watching calories, or have diabetes, Nutrition Menu makes it easy for anyone who needs to track what they eat.</p> <p>"The mother of all iPhone calorie counters" - Fitness Magazine</p> <p>FOOD FEATURES:</p> <ul style="list-style-type: none"> ✓ Over 49,000 restaurant menu items of 360 USA and some Canadian restaurants (see website for list) ✓ Over 51,000 entries for common foods like apples, meat, frozen meals, etc ✓ Shows Points Plus and Points Classic numbers ✓ No Internet communication means fast access to information ✓ Nutrition info includes calories, fat, carbs, fiber, serving size, protein, cholesterol, sodium, and sugars ✓ Add your own custom foods ✓ Put your popular foods in the Favorites ✓ Search feature ✓ Updates nutritional values when you change quantity <p>EXERCISE FEATURES:</p> <ul style="list-style-type: none"> ✓ 149 built-in exercises ✓ Add your own custom exercises ✓ Activity Score Calculator ✓ Put your custom exercises in the Favorites

Proposed Grouping	Existing App Available In The United States
	<ul style="list-style-type: none"> ✓ Calculate calories burned by exercising based on your weight <p>JOURNAL FEATURES:</p> <ul style="list-style-type: none"> ✓ Shows daily summary with progress bars ✓ Breaks down calories in a pie chart ✓ Shows all foods and exercises for a day ✓ Supports extra Food Scores for the week ✓ Write daily notes ✓ Email the Journal and import into a spreadsheet ✓ App icon on the Home Screen shows today's total Food Score <p>WEIGHT TRACKING FEATURES:</p> <ul style="list-style-type: none"> ✓ Weight tracking with graph ✓ Use pounds or kg ✓ Change time range of weight graph <p>WATER FEATURES:</p> <ul style="list-style-type: none"> ✓ Use cups, oz, or mL ✓ Set your personal goal