FDA REGULATION OF MOBILE HEALTH

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2010 REPORT

Contents

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Bradley Merrill Thompson is a shareholder in the law firm of Epstein Becker & Green, P.C. There he counsels medical device and other life science companies on a wide range of FDA regulatory, reimbursement and clinical trial issues. At the firm, Mr. Thompson leads the Medical Device Regulatory Practice, the Clinical Trials Practice and the Connected Health Practice, and serves on the firm's Health & Life Sciences Steering Committee. For trade associations, Mr. Thompson has served as counsel to AdvaMed for payment issues, as General Counsel to the Combination Products Coalition, and for 17 years as General Counsel and Secretary for the Indiana Medical Device Manufacturers Council.

Connected Health Practice: In EBG's Connected Health Practice, Mr. Thompson focuses on the federal regulatory requirements—FDA, reimbursement, privacy and others—that impact remote monitoring, mobile health, HIT and device interoperability. The firm's Connected Health Practice brings together a multidisciplinary team of attorneys and consultants trained and experienced in Medicare and private insurance payment, regulatory, scientific, IT, clinical, and security disciplines. Mr. Thompson serves as outside counsel to Continua Health Alliance, conducts educational programs on connected health regulation and blogs for Mobihealthnews.com.

Teaching, Writing and Serving: Mr. Thompson has taught food & drug law at Indiana University School of Law-Indianapolis and Columbia Law School. He also serves on the editorial boards for Medical Device & Diagnostic Industry (1993-present), Food & Drug Law Journal (2007 – present) and BNA's Medical Device Law & Industry Report (2007-present) Mr. Thompson also serves as Co-Chair of the Food & Drug Law Committee of the Administrative Law Section of the American Bar Association, and as Chair of the Medical Device Committee of FDLI. Mr. Thompson has written extensively on the topics of medical device regulation, including a book entitled FDA's Regulation of Medical Devices (Interpharm Press, 1995). He has co-authored chapters in "Off-Label Communications: A Guide to Sales and Marketing Compliance" published by FDLI (2008-2009) and in a book entitled "Guide to Medicare Coverage Decision-making and Appeals" published by the American Bar Association (2002).

Honors: Mr. Thompson was included in 100 Notable People in the Medical Device Industry (Medical Device & Diagnostics Industry, June 2004), has earned an AV rating in Martindale Hubble (its highest rating), has been named a "SuperLawyer" in Indiana, has been elected as a Fellow in the American Bar Foundation and is listed in Chambers USA: A Guide to America's Leading Business Lawyers.

Education: Mr. Thompson received his B.A. cum laude, and an M.B.A. from the University of Illinois and his J.D. cum laude from the University of Michigan Law School.

Letter from the Editor

One morning last summer I got my first email from Brad. He wrote that he and a couple of colleagues had just conducted a day-long seminar on regulatory topics for the Vancouver gathering of the Continua Health Alliance. One session was a case study of FDA regulation of a mobile health platform.

"Is that the kind of topic that interests you?" Brad had asked.

For the next year -- about every six weeks -- I would receive the latest chapter in Brad's FDA regulation series. It pulled from FDA workshop meetings, political speeches, questions posed by mHealth luminaries, and Brad's vast wealth of knowledge regarding FDA policies.

Brad's series of articles quickly proved to be the some of the most talked about features published in MobiHealthNews' weekly newsletter.

At Brad's request, and with great pleasure, we at MobiHealthnews have compiled the series on mHealth regulation into this free special report for our readers. I am confident it will quickly become a seminal text for the budding mobile health industry.

Our heartfelt thanks to Brad for taking the time to provide direction for navigating these otherwise murky regulatory waters.

Brian Dolan
Editor, MobiHealthNews

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I. FDA May Regulate Certain Mobile Phones, Accessories

It can come as a bit of a shock to people in the consumer electronics, IT and telecommunications industries that FDA might regulate certain equipment like cell phones that companies are planning to put at the center of connected health services. My goal is to outline the factors that FDA considers when deciding whether to regulate such equipment.

Defining a medical device

The natural place to start is with the definition of a medical device. Since it is so central to the analysis, I'm going to quote the statute verbatim. Section 201(h) of the Federal Food, Drug, and Cosmetic Act defines a medical device as:

"… an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is … [either] 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 … [or] intended to affect the structure or any function of the body of man or other animals."

So at a high-level, we look for two things: (1) a device with (2) a medical intended use. The first prong of the test — that there must be an actual product — means FDA doesn't regulate, for example, medical procedures. The thing in question must be a thing, and not information or something else intangible. Software can be a medical device if it's written on computer media, as opposed to printed on paper. The media with the code written on it is enough of a "thing" for FDA to regulate.

Components Vs. Accessories

In the area of mobile health technology, it's important to understand that an accessory or a component of a medical device is itself a regulated medical device. Further, the difference between an accessory and a component is who buys it. End-users buy accessories, while manufacturers buy components. Thus the exact same piece of equipment could be either an accessory or a component depending on the target purchaser.

That makes a big difference in terms of applicable regulatory requirements. Components are exempt from most FDA regulatory requirements, with the regulatory burdens being borne by the finished device manufacturer. Accessories, on the other hand, since they go right to the end user, must meet the FDA requirements before they leave the hands of the accessory manufacturer. These differences are summarized in **Figure 1** on the next page.

The level of regulation imposed by FDA on accessories and components is determined by the parent device to which they relate. So if the accessory relates to a high risk device, say an implantable cardiac defibrillator, it will be subject to a high level of regulation even if the accessory is relatively benign in and of itself.

Having decided that the product meets the "thing" test, determining the intended use of the article can be much more difficult. As a preliminary matter, in the definition above you can see that the so-called medical uses are very broad, and include some conditions people may not ordinarily consider medical. For example, equipment used for exercise could become a medical device if the claims take on more of a therapeutic nature instead of simply suggesting general fitness. So if the piece of fitness equipment is specifically advocated for use in the treatment of obesity or rehabilitation of cardiac patients, it can become a medical device. Further, the definition is not limited to disease, but also relates to articles that affect the structure or function of the body (for example, pregnancy). Moreover, devices that merely monitor a body function, with no therapeutic effect, can fall into the device category if the intended use suggests a health-related purpose.

Determining "intended use"

Figuring out the actual intended use of the article depends entirely on the facts. I teach this topic at Columbia Law School, and I generally begin the session by taking out a popsicle stick. To employ a case study, I tell the students that I'm the CEO of a company that makes these sticks, and I want to know whether I have to comply with FDA regulations. At that point I encourage them to ask questions of me in my hypothetical role as CEO, and then ultimately to advise me.

If they have done their homework, they will start to ask me how I promote the stick. In my answers, I'm pretty coy at first, simply explaining that I sell sticks and what my customers do with them is their business. I explain that my labeling for the product merely identifies the product as a stick without going into its possible uses.

Hopefully my students have read enough to know that the regulations define "intended use" as: "the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances

Figure 1. Types of Devices

	Finished Stand alone Device	Accessory	Component
Definition	A medical device in finished form, ready to use perhaps with accessories, intended for sale to the end user	An article intended for use in or with a finished medical device, intended for use by the end user	An article intended for use in or with a finished medical device, intended for use by a manufacturer
FDA Clearance required?	Yes, unless exempt	Yes, unless exempt	No
GMPs required?	Yes, unless exempt	Yes, unless exempt	No, but quality must satisfy finished device manufacturer

that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. …" So what I say in my labeling is not the last word, but ultimately what matters is the totality of what I have done to promote the article and to some extent what I know about how my customers are using it.

Eventually my students start asking me about what trade shows I attend, what types of magazines I use to advertise the sticks, what my salesmen say to customers, and what I know about the actual usages of the sticks. And it turns out, in my hypothetical, I know that many of my customers are using them as pediatric tongue depressors, I promote them in advertisements in hospital journals, and at least some of my salesmen might encourage their use as tongue depressors. So eventually my students come to the view that my simple popsicle sticks might in fact qualify as medical devices and be subject to FDA regulation.

Advice for wireless health start-ups

Companies engaged in making mobile phones (or related articles or software apps) need to go through the same analysis to figure out if they are selling medical devices. They need to look first and foremost to the labeling and other promotional materials they use, but then also consider how they promote the products. In this regard, it's important to remember that we're looking for either an intended use directly as a medical device, or an intended use as an accessory to a medical device. It's more likely a cell phone or related software might end up as a regulated accessory, than a stand alone medical device.

If it is a medical device, what next?

This analysis only answers the threshold question of whether an article is a medical device. If it turns out to be a regulated article, a second step is to figure out the degree of that regulation. A fair number of medical devices are exempt from FDA premarket clearance, and others are exempt from the obligation to employ good manufacturing practices. The risks associated with the intended use determine the level of regulatory requirements, including validation and other design rigor that FDA would require.

Not the end of the world

Merely being a medical device is by no means the end of the world, just the starting point for the analysis. Companies need to be mindful of these consequences as they develop their promotional programs for hardware and software in this mobile health space. FDA is almost certainly looking.

II. Step-by-step: FDA wireless health regulation

In the last chapter I outlined the triggers that could cause an ordinary mobile phone to become an FDA-regulated medical mobile phone. In this chapter I will outline the FDA requirements that would apply to a mobile phone that crosses that line.

To summarize the last chapter "FDA may regulate certain mobile phones, accessories", a mobile phone could become a regulated medical device if the manufacturer, through its words and deeds, conveys an intention that the phone be used in medical applications. I also pointed out that medical devices come in at least three different flavors: (1) standalone medical devices, (2) accessories and (3) components to such devices.

Premarket clearance or approval

In contrast to components that are simply sold to another manufacturer, standalone medical devices and accessories sold to end users may require some form of premarket clearance or approval. Once you know you have an FDA-regulated device or accessory, here's how you figure that out, following a five-step process.

Step one. Figure out the most appropriate classification for your product.

There is a bit of both art and science to this. FDA has published about 1700 classification regulations. Each of those regulations has a description or "identification" of the types of devices covered by that regulation. FDA has a searchable database of these regulations accessible through their website.

Some articles of hardware and software are so important that FDA has separately classified them, and you can find them directly through searching. The regulations are organized by clinical application so all of the orthopedic devices, for example, are in one part of the regulations. So you might get lucky and find one that directly describes your product. A quick search of the regulations revealed that the word "computer" appears in 225 regulations, "software" in 431 and "network" in 43. There is, for example, a classification for remote medication management systems in 21 CFR 880.6315.

But if you can't find one that directly describes your product, perhaps it's because FDA considers your product to be merely an accessory to a "parent" device. I'll give you an example. In 2009 FDA cleared an updated version of the Polytel glucose meter accessory, which is a small module that plugs into the port of a glucose meter, receives data from the meter and transfers it wirelessly to an Internet capable communication device like a cell phone or an APT. In clearing the device, FDA agreed with its classification in 21 CFR 862.1345, which covers all glucose test systems, including the "parent" glucose meters.

Step two. Read the second half of the classification regulation to see how FDA regulates that particular article.

FDA will assign each product into one of three classifications, cleverly called class I, II and III. Class I devices represent the least risk, while class III represent the greatest. Associated with those classifications are specific regulatory requirements. Many class I devices will be exempt from premarket clearance, and some products will be exempt from other regulatory requirements that I'll describe in a minute. Some class I and most class II devices require filing a premarket notification (or 510(k)) with FDA. These submissions are manageable documents that compare the new device to those lawfully on the market. The specific data requirements are discussed below.

The highest risk devices-class III-usually require premarket approval (PMA) from FDA, which can cost millions. Most IT devices can avoid that, unless they are an accessory to a high risk device. If your device is classified as an accessory, it is subject to all of the regulatory requirements applicable to the parent device.

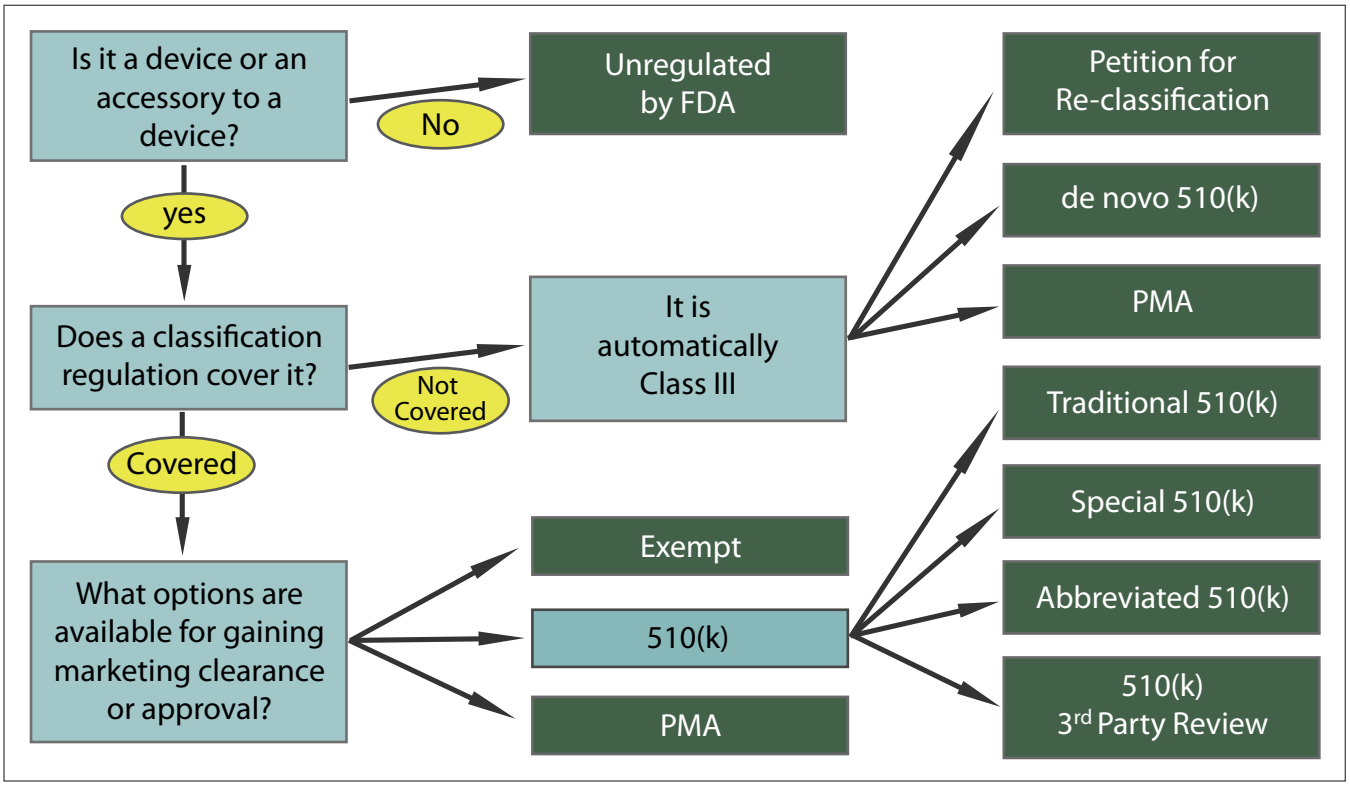
Step three. Research the requirements.

FDA has published scads of guidance documents on its website that cover many different aspects of the technologies they regulate. There are guidance documents on using wireless technologies, off-the-shelf software, and specific medical technologies such as blood glucose meters. It's important you find all of these so-called "special controls" because you'll need to make sure that your product complies with those technical standards.

Step four. Consider your options.

Even once you know how a device is classified and the specific regulatory requirements, you may well have options for how you get marketing clearance. Let's say your device is in class II, and some sort of premarket notification or so-called 510(k) is required. 510(k)s come in lots of different flavors, including traditional, special and abbreviated. For some, as an alternative to filing at the FDA, you can seek to have your device reviewed by an independent third-party who then certifies its review to the FDA. Going through each of those options is beyond the scope of this article, but it's important to understand that you have options. I have tried to illustrate the major options in **Diagram 1** below.

Diagram 1. Some Major Pathways to Market for IT Devices



Step five. Determine the type of evidence needed for FDA clearance.

Even more choices need to be made here. The amount and type of data needed to secure approval depends directly on the types of claims you want to make. In many cases, you might have the option to merely make a "tool" claim: a claim that your product simply does a specific function. In the accessory example I gave above regarding the Polytel product, the company makes a tool claim that its article merely connects one medical device to the Internet.

You might also wish to make an outcome type claim: a claim that your device will help treat or diagnose a specific disease or condition. For example: "Using this device to transmit your blood glucose readings to your physician typically allows for better control of diabetes and will help you wean yourself of dependency on insulin."

The types of data you need to provide FDA will depend on which type of claim you make and indeed on the exact wording of the claim. Typically, you could support a tool type claim with bench testing or other non-clinical evaluation. Basically you need to prove that your tool works. If you choose to make outcome-based claims, you'll need to prove that the device indeed achieves those outcomes. That's much harder, and requires testing in a clinical setting.

If you are following the 510(k) pathway, the fundamental standard is whether your device is substantially equivalent to other lawful devices. So most submissions follow a comparative format where the submitter compares his device to others in the marketplace.

In addition to the premarket clearance or approval question, devices must comply with other FDA requirements, as described in the next section.

Quality system requirements

The other big hurdle is ensuring compliance with the quality system regulations. As the name suggests, these requirements are focused on ensuring manufacturers produce quality products commensurate with the risks associated with using the device. So the exact nature of the quality system will depend on the intended use of the article. For companies that are ISO 13485 certified, becoming compliant with the quality system regulations is mostly a matter of creating documentation systems so that you can prove your compliance. More substantial changes are required if the company is only ISO 9001 certified.

These quality system regulations apply cradle-to-grave, so the minute you begin the design process, the design controls must be observed. Design Controls specify the process used and the records to be created during the design, development, and manufacturing scale-up of a device. They extend all the way to postmarket issues such as complaint handling, risk management, and failure analysis and feedback to the design and manufacturing organizations.

In the medical device world, component suppliers are exempt from these regulatory requirements (though sometimes they are contractually required).

That doesn't mean the components need not be high quality, but rather it means that the finished device manufacturer has the regulatory burden of assuring the quality of the components it uses. While this could mean incoming inspections of raw materials, components and subassemblies, it more often means that a device manufacturer must apply all necessary controls on a supplier-by-supplier basis to make sure that any controls the supplier is missing, the device manufacturer provides.

Adverse event reporting

As kind of a belt and suspenders, in addition to requiring premarket review of the product and imposing quality system requirements, FDA expects companies to be vigilant for reports of people getting hurt or products malfunctioning. In some cases those incidents might rise to the level of needing to be reported to FDA. These so-called Medical Device Reports are time sensitive (an assessment is due in a matter of days or weeks), and require the company to have in place systems for reviewing all relevant incoming information to assess the potential of each report to be categorized as an Adverse Event. If the company decides to take corrective action, in some cases the company needs to notify FDA.

Other regulatory requirements

FDA has a variety of other requirements that may apply, including such things as registering manufacturing facilities, listing the products manufactured, specific requirements for investigating the safety and effectiveness of an unapproved device, export and import restrictions, and labeling and advertising requirements. FDA also has a variety of requirements that apply to postmarket distribution to ensure that products can be identified and traced back.

From here

There is no doubt that these requirements can be quite burdensome. But to state the obvious, thousands of companies have found it possible and worthwhile to enter the medical device realm. In the coming chapters, I will explore the unique aspects of FDA regulation of software, a business assessment of whether entering the FDA-regulated realm is worthwhile, options for staying out of regulated territory, and some thoughts on where future FDA regulation could go in this space.

III. How to get FDA to clear a mobile health app

(I would like to thank John Murray of FDA, Scott Thiel of Roche Diagnostics and Russ Gray of the Anson Group for their comments on a draft of this chapter. The views expressed — right or wrong — are only the author's and should not be attributed to the commenters.)

Most people in the wireless health industry have heard by now that FDA has started to clear applications for cell phones with medical indications. A widely-reported example is AirStrip OB, cleared to deliver patient waveform data — including fetal heartbeat and maternal contraction patterns — in virtual real-time directly from the hospital labor and delivery unit to a doctor's mobile wireless device, specifically to an iPhone or a Blackberry. Other software developers are probably interested to learn when FDA clearance is required, and what it takes to accomplish that FDA clearance. In this chapter, I'll address both of those questions at a high-level.

In the first chapter I outlined the factors FDA considers generally when deciding which products need to be regulated and which fall outside of the scope of a medical device regulation. In Chapter 2, I outlined the basic steps for getting a medical device cleared by FDA. This chapter will focus on the unique aspects of those two questions in the context of mobile device apps.

Software Roles

From those two prior chapters, it's important to remember that medical devices, including software, can be divided into three categories: (1) standalone devices, (2) accessories and (3) components. Standalone are those devices that are intended to directly provide the diagnostic or treatment, while accessories are sold directly to end-users and work with standalone devices. Components, in contrast, are purchased by manufacturers of standalone or accessory devices for incorporation before sale. Mobile device (e.g. cell phone apps) can be an accessory, as opposed to a component, if they are sold or even given directly to the end-user: the patient. They can also be standalone if they do not connect physically or virtually to any device other than the mobile device platform.

Understanding that is important because determines the regulatory requirements that apply. If the app is designed, for example, to facilitate the downloading of information from a blood glucose meter, the app and maybe even the software environment are accessories and will be regulated in the same manner as the blood glucose meter. The classification and most of the requirements for the submission to FDA will be dictated by how the parent standalone device is regulated. So, the Airstrip OB app is regulated as part of a perinatal monitoring system generally, just as the sensors and other hardware that gather the information.

Some apps will not be simply enablers of transmitting data from a medical device, but will actually serve a standalone purpose. From the prior two chapters, remember that it's the claims the software developer/seller choose to make, within reason, that triggers FDA regulation in the first place, and the degree of that regulation when it comes to obtaining clearance. Once you properly figure out which of the three roles the software plays, you can figure out its regulatory status. Typically that's one of the following three choices:

- Software that does NOT meet the legal definition of a device and is not regulated by FDA.
- Software that does meet the legal definition of a device but is currently not actively regulated, and FDA is unlikely to require pre-market review.
- Software that does meet the definition of a device and FDA is actively regulating and would require a pre-market review.

Except for a few specific exempt device types identified in the classification regulations, that middle category isn't today a regulatory classification you'll find defined in any FDA records. Fortunately or unfortunately, depending on your perspective, FDA has been very reluctant over the last dozen years to define with any real precision its policy on which types of software must undergo premarket review and clearance, or even approval. The agency has held open public meetings and floated concept papers, and more recently has proposed a limited device classification for medical device data systems, but by and large has not with any certainty clarified its policy on when software trips the premarket requirement.

So the following is just my personal observations about how FDA regulates software in practice, as I can glean from watching FDA enforcement actions, podium policy, and the informal statements FDA has made in concept papers.

Unregulated Software

In its explanation surrounding the agency's proposed classification of Medical Device Data Systems published in 2008, FDA explains:

It is FDA's long-standing practice to not regulate those manual office functions that are simply automated for the ease of the user (e.g., office automation)… For example, the report-writing functions of a computer system that allow for the manual (typewriter like) input of data by practitioners would not be… [regulated] because these systems are not directly connected to a medical device. In addition, software that merely performs library functions, such as storing, indexing, and retrieving information not specific to an individual patient, is not considered to be a medical device. Examples include medical texts or the Physician's Desk Reference on CD-ROM that are indexed and cross-referenced for ease of use.

FDA goes on to say it won't regulate "software that allows a doctor to enter or store a patient's health history in a computer file." On its face, that description of unregulated software is somewhat narrowly written. That is not surprising since FDA always takes an expansive view of its jurisdiction, and is not likely to concede much ground in that regard.

Beyond that passage, I would add that there are two key features for most unregulated software.

The data are entered manually; they are not inputted directly from any machine that touches the patient

or a patient specimen. That's important to avoid becoming an accessory to a medical device.

Depending on how inputted, the output amounts simply to providing the stored data back to the patient or professional. The system does not automatically guide the diagnosis, nor does it guide any other instrument. In other words the software does not contain any algorithms that provide clinical-like functions that go beyond what FDA often refers to as library functions. It merely displays the data for the user to read and interpret.

Many mobile device apps do indeed fit this category of unregulated software. But it is important to remember to conduct an honest evaluation of the intended use of your product. The evaluation should focus on the clinical intended use of the product and less on the technical characteristics of your software or your system. In FDA's eyes, your software product does not have to provide a complete cure, mitigation, treatment, or prevention of disease to meet the legal definition of a device. If your software is intended to provide any part of cure, mitigation, treatment, or prevention of disease, FDA will probably consider it a device. Understanding the limits on the unregulated category is probably best explained, though, by looking at the other two categories.

Regulated Software Exempt from Premarket Clearance

Since the late 1980s, FDA has been publicly declaring that there exists a category of software that technically qualifies as a medical device but for which FDA has no intention of requiring the submission of a premarket notification or approval application. For those who are really interested in this topic, it probably makes the most sense to start with the "FDA Policy for the Regulation of Computer Products, 11/13/89 Draft".

In that policy, there are two categories of software products that were technically regulated but also considered exempt from the major requirements: (1) general purpose articles as defined in a regulation and (2) software that involves competent human intervention. Unfortunately FDA never got around to actually codifying the competent human intervention exemption. In its classification process, FDA has adopted certain general purpose or low risk exemptions that cover software, such as laboratory information management systems (LIMS) (21 CFR 862.2100) used as calculators or data processing modules for clinical use.

About 7 years after FDA published the 1989 draft policy, it appeared FDA was moving toward formalizing its computer product policy. In addition to publicly announcing that intention, FDA hosted a large meeting in Washington and invited many stakeholders to discuss what the policy should be. In preparing for that meeting, FDA drafted a summary of what it considered to be its then existing policy on computer products. Those workshop materials explained that much of the software the agency was seeing constituted accessories to medical devices, and the competent human intervention concept was only intended to apply to truly standalone software. The agency also argued that the concept of what constitutes competent human intervention had become increasingly complex and difficult to administer. FDA observed:

In general, to permit competent human intervention, the software decision process must be completely clear to the user, with a reasonable opportunity for challenging the results. There must also be adequate time available for reflection on the results.

But again, FDA never followed through to adopt a new regulation or policy.

In early 2008, departing somewhat from the 1989 approach, FDA proposed a new category of software that would fit within this general category of regulated software exempt from premarket clearance. They proposed to call the new category medical device data systems (MDDS), and they defined it to include:

- The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices. For example, this would include software that interrogates a ventilator every 15 minutes and transfers information about patient CO\2\ levels to a central patient data repository;
- The electronic storage and retrieval of medical device data, without altering the function or parameters of connected devices. For example, this would include software that stores historical blood pressure information for later review by a healthcare provider;
- The electronic display of medical device data, without altering the function or parameters of connected devices. For example, this would include software that displays the previously stored electrocardiogram for a particular patient;
- The electronic conversion of medical device data from one format to another format in accordance with a preset specification. For example, this would include software that converts digital data generated by a pulse oximeter into a digital format that can be printed. Examples of medical device data systems that would be used in the home are systems that periodically collect data from glucose meters or blood pressure devices for later review by a healthcare provider.

This category is only available as an exemption from premarket clearance so long as the data set is intended for professional use and does not produce irreversible data compression.

Based on the following preamble from the proposed MDDS rule, I would suggest that through this process FDA is seriously rethinking its software policy.

Since 1989, the use of computer-based products and software-based products as medical devices has grown exponentially. In addition, device interconnectivity and complexity have grown in ways that could not have been predicted in 1989. This growth and expansion have created new considerations for elements of risk that did not previously exist. FDA realized that the Draft Software Policy was not adequate to address all of the issues related to the regulation of computer based and software-based medical devices. Based on this history and the complexity and diversity of computer software, FDA decided it would be impractical to prepare one "software" or "computer" policy that would be able to address all the issues related to the regulation of computer- and software based medical devices.

While FDA has proposed the MDDS category, as of this writing the agency has not adopted it in final form. During the interim, however, it seems to be the best guidance available for deciding whether a premarket clearance is required.

Dividing Line Between Software Requiring Premarket Notification And Not

In defining medical device data systems, FDA was merely trying to define one relatively narrow, cohesive type of data set that the agency would regulate but exempt from premarket notification. However, that is

only one example, and it is not meant in any way to be the only example of software that would be treated as regulated but exempt. Indeed my understanding is that the agency plans to publish future proposals defining other regulated – exempt and nonexempt– categories.

But what are software companies supposed to do in the meantime? What else fits within this regulated but exempt category? The unfortunate answer is that this represents a huge gray area. The best anyone can do is look at a variety of risk factors to figure out which side of the premarket clearance line again a piece of software falls. Based on FDA comments and actions over the last 20 years, I would propose the following list of factors be considered:

- Whether the software is intended or designed to provide any real time, active, or online patient monitoring functions.

- The capability to display, create, or detect alarm conditions, or actually sound an alarm, or the capability to create alarms that are not already present from the connected medical devices.

- The seriousness of the particular disease or condition which the medical software device is intended to diagnose, cure, mitigate, treat or prevent and how the software contributes to the user's decision-making for diagnosis or clinical management of the patient. Example: Is it software designed to call attention to imminent hazard conditions or is it software that provides long-term storage for diagnostic information?

- The amount of time available before using the information provided by the medical software device, i.e., the time until a therapeutic or additional diagnostic intervention must be implemented by the health care provider after the results of the software have been provided. Example: Is the device an EKG reading and analysis package whose output is "SHOCK NOW" or does it provide a proposed reading with notation that the rhythm itself should be checked?

- Whether the data output is provided or manipulated in a novel or non-traditional manner, or whether decision trees within the software depart from customary use. Example: Do the system's algorithms, parameters, internal decision trees, or other output manipulations depart from customary use or traditional data presentation?

- Whether the medical software device provides individualized patient care recommendations, e.g., whether the software suggests or recommends specific treatment for a specific patient. Example: How specific is the software output with regard to particular patients? Is the software providing general advice or information, like a library, article, or textbook, or is the software designed to provide a specific recommendation for a specific patient whose individual data have been entered as input?

- Whether the mechanism by which the medical software device arrives at a decision is hidden or transparent, i.e., does the product use undisclosed parameters or internal decision trees or other mechanisms that are not available for review by the health care provider. Example: How transparent is the software manipulation to the intended user community? Included in transparency is the extent to which limitations on the process are made known to the user, such as data contraction, deletion, editing, or simplification. Also, how are comparisons made to normative databases and how are normative databases created?

Does the product provide new capabilities or intended uses for the user?

Until FDA decides to further clarify the middle category of regulated but exempt from premarket notification, a practical consideration of those factors should help the company decide whether in FDA's eyes the software is risky enough to require premarket clearance. As I said, you won't find that in any existing FDA guidance or regulation. That's just based on practical observation.

Software Requiring FDA Pre-market Clearance

In the second chapter, I outlined generally the approach for securing FDA clearance. In the case of software, the first step is identifying the most appropriate classification from among the roughly 1700 classification regulations. The word software is contained in 431 different regulations, so it's not an easy task.

Remember that software that accessorizes a medical device is classified with that medical device. So if a cell phone app allows for the downloading of blood glucose data, the app is classified with the blood glucose meter and regulated to the same degree. As another example, if the app is designed to help with medication management, there is a specific classification for such software in 21 C.F.R. § Sec. 880.6315. This can obviously get very complex in an interconnected system, perhaps on a wireless network, but that's too much for this report.

Usually in the context of clearing an app, FDA will check to ensure that the software manufacturer is complying with any published special controls. The special controls are typically stated in FDA guidance documents and include, for example:

- Guidance for Industry – Wireless Medical Telemetry Risks and Recommendations
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
- Device-specific guidance (e.g. glucose monitors)

The submission will need to be based on an appropriate level of validation for the software. If the app is an accessory, the parent device determines the level of validation required. If not an accessory, to determine the validation required, you will need to figure out whether FDA classifies the software as "major", "moderate" or "minor" "level of concern."

- It's major if the software directly affects the patient or anyone else such that a failure could result in death or serious injury
- It's moderate if the injuries would be non-serious
- An app's risk and the associated "level" determine:
  - the depth and degree of hazard analysis and mitigation that is expected
  - the depth and degree of documentation
  - what needs to be submitted vs. merely documented
  - the rigor applied to the verification and validation of the software
  - the degree to which the device manufacturer's software development process is scrutinized

And of course, before you can actually bring the product to market, you will need to make sure that your manufacturing meets the FDA requirements for quality systems. In the case of software, those requirements are acutely felt in the development stage as the software needs to be developed under special FDA design controls and in the post-launch stage as the manufacturer deals with product recalls, updates, event reporting, product lifecycle management and so forth.

Conclusion

Those are the basic FDA requirements that apply to bringing an app or other piece of software to market in the mHealth field. Undoubtedly, to those not accustomed to the FDA regulated world, those hurdles might seem high. In the next chapter, we'll tackle the benefits and burdens of going through those admittedly rigorous FDA requirements from a business standpoint. In particular we'll focus on the competitive advantages that can be derived from entering the regulated space, weighed against the cost of achieving those advantages.

IV. Should mHealth companies want FDA regulation?

(I would like to thank Dr. Deepak Ayyagari of Sharp Laboratories of America and Dane Stout of the Anson Group for their comments on a draft of this chapter. The views expressed, right or wrong, are only the author's and should not be attributed to the commenters.)

At the risk of insulting my new friends in Silicon Valley, I submit that traditionally-unregulated IT companies may want to adopt a different view of federal regulation. Over the last couple years, I've had the opportunity to observe firsthand the culture clash as free-spirited, libertarian Silicon Valley meets Rockville, Maryland, the home of the decidedly more buttoned-down U.S. Food & Drug Administration. Rather than fleeing in fear of the federal bureaucracy, I would argue that at least some IT companies should consider embracing federal regulators. Well, maybe start with at least shaking hands.

In the first chapter, I started off by explaining the scope of FDA regulation, and then in the second and third chapters explained how companies could comply with FDA regulation in the cell phone accessory and software app fields. With that basic framework behind us, in this chapter we will explore the burdens and benefits of entering FDA regulated territory. Yes, I said benefits.

It's Okay to Consider the Benefits of Federal Regulation Limiting Competition

As I've learned recently working with Silicon Valley companies, IT companies generally seem to love nothing more than a good, competitive, bare-knuckled fight with their competitors, and abhor the first hint of artificial restraints on competition, especially those from the government. In the IT industry, cooperation around the development of industry standards sets the rules of engagement for the market, and then everyone competes intensely based on those rules and execution of their business plan. Innovation can flourish, with upstarts appearing and challenging big, established companies' dominance of any particular portion of the business. The big companies accept it because they are moving aggressively too; adjacent markets can be pretty attractive if it appears there is money to be made by offering a faster, better, cheaper alternative to the current market leaders. The goal of unrestricted competition is great, and undoubtedly benefits customers in terms of producing products that they want at the best possible prices.

However, as IT companies consider entering the health market, they need to appreciate the differences. In traditional IT and telecommunications markets, if a product doesn't work, such as a server crashing, people can become really annoyed when they can't check their email from their mobile phone every second. Inconvenient and somewhat costly, for sure, but all will be forgiven once the server is back up and running. If it happens with any frequency, the company that produced the technology will get a reputation for poor reliability, and may go out of business.

But companies in the health space that produce products, using many of the same components as

what goes into the email server, face a much different problem set. If their product doesn't work consistently and reliably, they can hurt people, or even cause their deaths. So we don't, and can't, rely simply on competition to weed out the good from the bad. Instead, we regulate them.

That's more than just a legal framework: that's a philosophy for how the marketplace in health works. You can think of federal regulation as just a bunch of health and safety laws that prescriptively require that you do this and not do that, but it's more accurate to think about federal regulation as saying we only want companies willing to invest the significant resources required to get the product right the first time they enter the market, and to take the risk of failure to meet high standards of safety and effectiveness.

To put it in business school terms, federal regulation amounts to a significant barrier to entry for the health markets. And that is quite deliberate. FDA law means don't enter this business unless you're willing to do it right. And, as classic economic theory suggests, companies that are willing and able to invest the additional resources required and take greater risk get rewarded with greater return. That's as it should be, to protect the public from unsafe protects and to further the public health by encouraging companies to invest in medical innovation. In that later regard, FDA law rewards innovation in a manner similar to the patent laws. We simply do not want all companies to be able to make health care products. We choose to impose much higher standards in that field, and for companies willing and able to meet those standards we allow them to earn a potentially higher return.

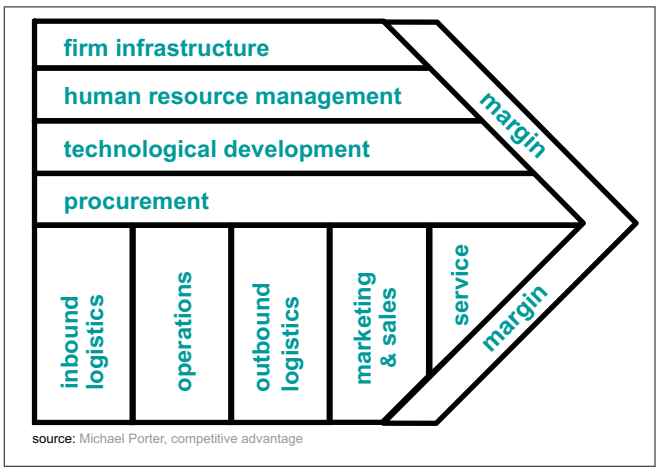
Benefits and Burdens of FDA Regulation

Let's bring it down from the 100,000 ft. view and get more specific about how entering FDA-regulated space affects both the company's cost structure and opportunities to earn a higher return. For a specific company, this would require a fairly detailed analysis, but let me provide you with an overview here.
To conduct this analysis, I've chosen the competitive strategy framework developed by Prof. Michael Porter at the Harvard Business School. It's familiar to many and reasonably well-suited to assessing the impact of a regulatory scheme on a business. In a pair of roughly 500 page books, Prof. Porter details an entire methodology for considering a company's strategic options in light of the markets and business environment in which they operate. I'll focus on two tools he uses in his analysis.

FDA Regulatory Impact on the Value Chain

In his value chain tool, Prof. Porter focuses on the individual firm, and how the firm creates value. In **Diagram 1** below, Prof. Porter shows conceptually along the bottom the sequence of steps necessary to produce a product, and in the rows at the top the overhead necessary for the firm to function.

Diagram 1. Value Chain Activities



source: Michael Porter, competitive advantage

The specific activities that the company selects to engage in directly determine its profit margin. Certain activities are high-value and produce higher margins, while others not surprisingly are lower. A firm's competitive advantage derives from its ability to select and execute the most highly value-added functions.

Much more could be said, but let's move on to look at how FDA regulation impacts the value chain. To convey this impact at a high-level, I've drawn the intensity map included as **Diagram 2** below. To understand an intensity map, think National Geographic magazine and a map showing population density through colors. I've borrowed that approach here to show the intensity of FDA regulation on each of the different elements of the value chain analysis.

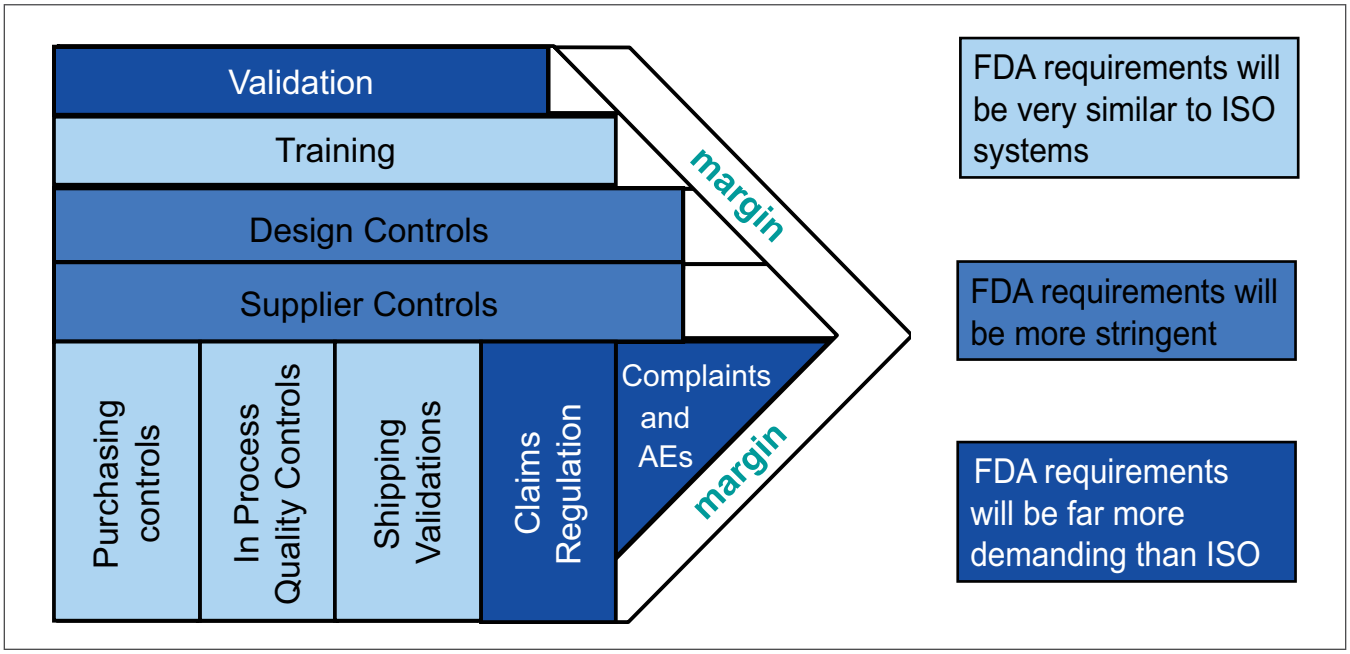
This is a bit subjective, so others might disagree. I also made an assumption that the company has a basic ISO 9001 type quality system already.

Here's how I came up with the intensities depicted.

FDA Approval. One of the most challenging steps of FDA regulation is securing premarket clearance or approval; there is no "beta testing" allowed in healthcare. You can't offer someone the chance to sign up for a discount if they help you test the product first to see if it works as you intended. For an innovative device, that requires substantial effort to design and then test the device to ensure that it meets its intended use safely and effectively, and perhaps highly regulated clinical trials. In the diagram, I suggest that the effects of this requirement are felt as a part of validation and design controls, as well as in the regulation of the claims that can be made.

Marketing regulation. In addition to FDA rules regarding securing approval of specific claims, other federal and state regulators impose stringent requirements on the marketing function. Thus federal regulation is perhaps most intensely felt in the marketing function of the company. Again, this will feel quite foreign in Silicon Valley, where battles between "Marketectures" wage almost daily. "Cloud"

Diagram 2. FDA impact on value chain activities



pitches regulated by FDA would require detailed atmospheric reporting of the composite gases in the cloud, as well as an accurate forecast of how the cloud will impact the weather, good or bad.

In the postmarket servicing function, companies in the medical device field must adopt systems designed to vigilantly watch for and report any problems, and take perhaps significant corrective action when problems arise.

In the quality system area, companies that are certified to ISO standards will have the most new work to do in the design control and validation areas.

In the modest impact category, the quality system requirements will require that the device manufacturer take greater measures to assure the quality of inputs being supplied. This will include periodic auditing of suppliers to ensure their systems are robust enough. The wide spread decision to outsource and off-shore customer service functions, prevalent in IT, would have to be considered in light of these requirements. They could still be done, but doing so could take longer, be more involved, and actually end up costing more than keeping it in-house.

The changes necessary in the actual production of the products are perhaps least burdensome for a company that is ISO compliant.

In general, all of those measures:

- Impose added cost.
- Lengthen lead times in product development.
- Add complexity.
- Can be difficult to implement from a cultural standpoint for a company unaccustomed to that environment because they require discipline and rigor.
- And of course multiply the paperwork.

In their analysis of the opportunity health markets present, many companies go no further than this. But this is exactly where some companies should persevere in their assessments, and consider the dynamics of the medical device market place.

FDA Regulatory Impact on Competitive Forces

In **Diagram 3** below, Prof. Porter depicts the five forces that in his model drive the industry dynamics. Those five forces include:

1. The threat that new companies will enter the market
2. The threat that new products will become substitutes for the marketed products
3. The bargaining power of suppliers
4. The bargaining power of customers
5. The competitive rivalry within the industry itself.

Diagram 3. Five Forces: Impact of FDA Regulation

The degrees of those threats and powers determine the ability of the company to earn a profit. With regard to the threat that new companies will enter the market, Prof. Porter identifies several barriers to entry, and one of them is government policy or regulation.

Assessing the five competitive forces, in some cases the analysis reveals some interesting opportunities. In diagram 3, again using an intensity map where darker yellow represents more competition, I suggest where I perceive the greatest sources of competition to reside for the medical device industry generally.

In the industries regulated by FDA, the greatest competition tends to be from established firms in the same industry. This is true for the simple reason that entering the regulated industry often requires a very significant investment to create the innovations and establish the manufacturing systems necessary to produce them, as well as considerable lead time to get through the FDA clearance or approval process. Thus the threat of new entrants is lower than the competition created by existing firms that have well-established systems in place for bringing new regulated products to market. Indeed a company's ability to cope with the regulated environment becomes a key asset, determining competitive advantage.

There is an important limitation to this, however. Companies that follow the premarket clearance route, if they don't have patent or other intellectual property protection for their products, might find that other established device companies can quickly follow them through the FDA clearance process. This is sometimes referred to as a first mover disadvantage. Further, the laws administered by the FDA do not create any private cause of action that an individual company can use to force competitors to abide by the law. FDA is solely responsible for enforcement of its laws, and if the agency isn't paying attention or simply doesn't have the needed resources, less reputable competitors might get away with taking shortcuts.

V. How to Avoid mHealth Regulation

Strategies for mHealth Companies Wishing to Avoid FDA Regulation

(I would like to thank Leah Kendall of EpsteinBeckerGreen and Dane Stout of the Anson Group for their comments on a draft of this chapter. The views expressed, right or wrong, are only the author's and should not be attributed to anyone else.)

Most people know the difference between tax avoidance and tax evasion. Tax avoidance is the lawful planning of such things as charitable contributions to minimize taxes, while tax evasion is the unlawful and usually deceitful actions taken to hide income. In this chapter, I will share some tips for the avoidance of FDA regulation, not the evasion of FDA regulation.

The first three chapters in this report dealt with understanding the scope and nature of FDA regulation for mHealth, and the fourth chapter advanced the notion that IT companies wanting to make money in health ought to consider entering the FDA-regulated zone. Nonetheless, subjecting your company to FDA regulation is not for everyone, so this chapter is designed to help those who have decided to stay out of the production of FDA-regulated finished medical devices. In particular, I explain four ways to connect to health markets, and the pluses and minuses of each such approach.

The Binary Misunderstanding

Some IT companies new to the health field seem to misunderstand the nature of FDA regulation, and think of it as all or nothing. In other words, a company is either a manufacturer of medical devices and subject to the full panoply of FDA requirements, or they're not and likewise are not subject to any FDA restrictions. But that's not an accurate depiction.

Instead, companies should think of FDA regulation as a continuum. **Diagram 1** on the next page illustrates the two extremes and a few of the cases in between.

On the far right side, the diagram depicts the traditional manufacturer of finished medical devices that is indeed subject to all of the FDA requirements for medical devices. Even here, though, there are different levels of FDA requirements depending on the novelty and risk associated with a particular device. As outlined in the second chapter, devices are classified into three different classifications, and the types and burdens of FDA regulations vary considerably. Class III medical devices include such things as pacemakers, embody the greatest risk and thus must meet the most demanding requirements. Class I devices include such things as tongue depressors and have very minimal FDA requirements. Indeed, most class I devices do not even need to be approved by FDA, and the quality system requirements might be very basic. Many mHealth devices might fall into class I or class II. All of this was covered in much greater detail in the second chapter in this report.

On the far left side, the diagram includes unregulated articles such as personal computers that contain no medical references at all and over which FDA has no regulatory authority. It's the stuff in the middle that is interesting for mHealth purposes.

The cases in the middle include, for example, companies that merely make components for others to use in manufacturing medical devices, distributors of finished product that have no control over the promotional claims or the design specifications of the device, and contract manufacturers that make finished medical devices at the direction of another company. These different functional responsibilities all have narrower sets of FDA requirements that apply to them, directly or indirectly. It's important to understand the range of possible relationships before talking about ways to reduce or avoid FDA requirements, and exactly what that means.

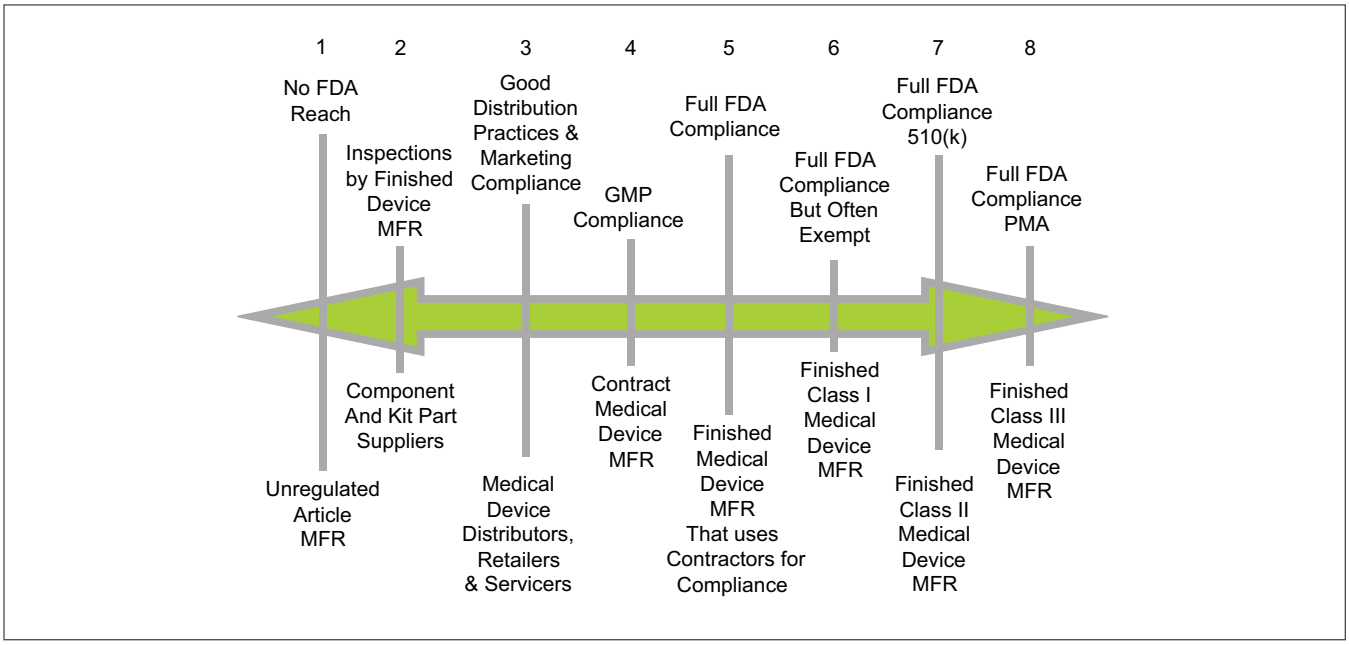
Four Ways to Connect to The Health Market While Reducing or Avoiding FDA Requirements

Before I go through the four strategies, it probably goes without saying that each one is predicated on the company fully implementing the strategy in good faith. Anything less potentially becomes FDA law evasion, rather than avoidance. Okay, so here they are:

Strategy 1: avoid medical devices and their accessories.

About now you're wondering whether this article is worth reading, but stick with me for a second, there's a more subtle and profound observation to be made. In your mind, go back to the very first chapter on the scope of FDA regulation. I went through an example of a stick, and how it could be either a popsicle stick or a pediatric tongue depressor, depending on what claims the company chooses to make. My point is that in many cases, the design of the product does not determine its regulatory status, but rather the promotional claims determine its status. So if your

Diagram 1. Continuum of Potential Involvement in the Device Industry



company can reach its commercial objectives without medical claims, and if the product has legitimate and material nonmedical uses, you might be able to avoid FDA regulation by avoiding medical claims.

A simple cell phone provides another example. A cell phone can be promoted merely as a cell phone, and no FDA compliance issues will arise. But if the manufacturer of the cell phone starts to make claims that the phone is suitable specifically for healthcare applications, the cell phone manufacturer runs the very real risk of turning its simple phone into a regulated medical device.

Remember from the first chapter that the manufacturer might get into trouble making claims that its product is specifically intended to accompany a medical device. That may very well make the product an accessory to the medical device, which makes it a regulated device. Again, claims are pivotal in determining whether something is an accessory or not.

In the last couple years as I've been watching what's coming out of Silicon Valley, I'm seeing a tremendous number of hardware and software products that probably could be sold as unregulated articles, but where the manufacturer, possibly quite inadvertently, is making claims that would cause FDA to regulate them. FDA is stretched pretty thin these days, so they aren't watching everything coming out of the IT industry, but someday I suspect FDA will get more active in this space.

There are limits to this strategy. I can't make a pacemaker, for example, and try to pass it off as a simple, generic piece of electrical equipment. In designing the pacemaker, I've done too much to make the design specific to a medical use to later disclaim that use. Remember intended use is judged by words, actions, and in some cases, inaction. If you're interested in this strategy, you ought to go back and review the first chapter of this report.

A number of startups in mHealth have come up with very innovative business plans that put them squarely in the gray area between medical and nonmedical intended uses. For example, there are companies developing strategies for remote monitoring of people, rather than their disease or condition. There are gray areas between wellness programs and disease programs where FDA needs to give industry clearer guidance. Obesity, as a disease, is often difficult to distinguish from general physical conditioning. Unfortunately, I suspect we will all need to feel our way along in the dark for the time being.

Finally, to employ this strategy, the maker of the equipment must be duly diligent in avoiding making medical claims. That means it needs to have some level of compliance and training systems in place to ensure, for example, that sales representatives do not go rogue. Even unauthorized sales activity can come back to haunt the company if the government decides that the company wasn't careful enough in managing its people.

Strategy 2: avoid controlling the product specifications or the claims made.

Most FDA requirements, including the need to obtain FDA clearance or approval, and the responsibility for reporting adverse experiences fall on the company that owns and controls the product specifications and the claims made. Because most of the risk of a medical device stems from its design and the claims made about it, whoever controls those two features has most of the FDA compliance responsibilities. So, if you don't want those responsibilities, don't own or control those two features of the device.

Some examples probably would help. In most cases, a contract manufacturer does not control the product specifications or the claims made about the product. That's true even if the contract manufacturer produces finished product and drop ships it to the ultimate

purchaser on behalf of the specification owner. In that case, FDA looks to the specification owner for compliance with most of the agency's requirements, even if the specification owner never even touches the device.

Indeed, ownership of the product and the control of the specifications and labeling determine regulatory responsibility instead of who in fact engaged in the design process or wrote the label. Companies often ask a contract manufacturer to help with the design process, or enlist the services of an engineering firm. None of that matters. The only thing that matters is who, at the end of the day, owns the product and controls the specifications and the label for the product.

This control rule is also the basis for organizations such as distributors and retailers to pass regulatory responsibility up the chain of distribution to whichever entity controls the specifications and the labeling. Although distributors and retailers have limited FDA responsibilities, the responsibilities for seeking FDA clearance and ensuring the quality of the product remain with whoever controls the specifications and labeling.

Components suppliers similarly avoid much of the onerous elements of FDA regulation. If a company makes an article that is incorporated into a finished medical device, the maker of that component is not directly subject to FDA regulatory requirements for premarket clearance or even the quality system requirements. Instead, the finished device manufacturer is obliged to have in place supplier controls sufficient to ensure the quality of the components it uses. These controls might include, for example, periodic inspections of suppliers.

Another strategy is to supply finished medical devices to a firm that will co-package its own device with yours. From a regulatory standpoint, this is essentially the same as the component supplier scenario just discussed. Even though the article is a finished one, if it is bundled together with another product before it is sold to the end user, the company that does the bundling has responsibility for ensuring that each product in the bundle has the requisite regulatory compliance. Sometimes the supplier for the article to be bundled will undertake compliance with the FDA requirements itself, and sometimes the bundler takes that job. But because the bundler is considered to own the specifications of the bundle and whatever claims are made for the bundle, it generally has the ultimate regulatory responsibility.

Let's take, for example, a common cell phone, hypothetically call it a mePhone. If the cell phone manufacturer makes no medical claims about it, the cell phone manufacturer will have no direct FDA responsibilities. But let's say a blood glucose meter manufacturer claims, in promotional materials, "our meter will pair with the mePhone to download data for analysis on our special app." Arguably the blood glucose meter manufacturer has made the mePhone and the app into components of its medical device system. So the blood glucose meter manufacturer may, for example, either need to prove through a risk assessment that mePhones available in the market place will remain suitable for that intended use, or need to enter into an agreement with the mePhone maker such that the two companies, through cooperation and control, will ensure the future compatibility of the two devices. I've kept this simple but in real life these facts are usually much more complex.

I want to underscore something I said earlier: almost none of the organizations in this section are completely outside of FDA's jurisdiction. They all have some, albeit perhaps minor, FDA responsibilities. Even distributors and retailers have to ensure their promotion remains consistent with the approved labeling, and their facilities appropriately safeguard the integrity of the products. Components suppliers, while technically exempt from the quality system

regulations, often must nonetheless ensure that they are not selling adulterated components for use in medical equipment.

Over the last several years, I have read a dizzying array of corporate agreements that provide for various kinds of collaborations like these between companies. Some of them are fashioned as supply agreements, while others look like contract manufacturing agreements, and yet others look like intellectual property license agreements.

As a regulatory lawyer, when I read these agreements, often I'm asked to make a judgment as to who has the FDA regulatory responsibilities. And sometimes, honestly, it just isn't clear. I've read agreements where all the specifications and promotional claims have to be mutually agreed upon between two parties. In other cases, one party maintains a general level of control over the specifications and claims, while the other party is able to exercise wide latitude within certain limits. In those cases, where it is genuinely unclear which party has the FDA responsibilities under the regulations, I believe FDA permits the parties to specify in the agreement who has those responsibilities, so long as that division is reasonable to resolve the gray area. So my advice: have your regulatory lawyer work closely with your corporate lawyer to make sure that your various collaboration agreements specify a reasonable – and your intended — division of labor on the regulatory compliance side.

Strategy 3: contract out the hard stuff.

Even if your company markets what is admittedly a medical device and controls the specifications and the promotional claims so that your company is clearly regulated by FDA, that doesn't mean your company itself must do the hard stuff. The regulatory work can generally be contracted out, even if the regulatory responsibility has to remain with the specification owner.

It probably won't surprise anyone to know that there are whole industries designed to conduct various responsibilities of medical device specification owners in compliance with FDA requirements. For example, there are clinical research organizations that can do all of the clinical research, soup to nuts, and one of their main selling points invariably is that they take responsibility for the FDA compliance for that function. There are regulatory consultants who can quite ably prepare premarket submissions. There are contract manufacturers who specialize in producing product under FDA quality system requirements, and there are other consultants who can help bring the specification owners' facilities up to code, so to speak. There are design organizations well-versed in conducting the design process in compliance with FDA design controls. Bottom line: if there's some feature of FDA regulatory compliance that makes you nervous, there's probably a whole industry out there quite willing to help you do it.

That said, it bears repeating that you can contract out the work but not the responsibility. If your organization is the one that controls the specifications and the labeling, your organization will bear ultimate responsibility for FDA compliance. As a practical matter, if you choose to contract out any of that work, it means you have the obligation to be duly diligent in selecting the right qualified firm to help you do the work, and providing reasonable oversight for the function. So the handoff isn't complete.

Strategy 4: sell a service or be a user, not a product producer.

This strategy is sometimes risky, but sometimes it can work. FDA's jurisdiction is very clear: the agency regulates products. In the very first article, I discussed the need for a physical product that is the subject of FDA regulation. FDA does not regulate services, nor do they regulate the practice of medicine.

That circumstance has led some professions to be able to do things that product manufacturers and sellers cannot. For example, clinical laboratories routinely develop their own clinical tests that they use with their own customers. For decades, FDA has taken a nearly hands-off approach to that practice, saying that clinical labs are sufficiently regulated under a different piece of legislation, the Clinical Laboratory Improvement Amendments of 1988. Likewise, pharmacists who are regulated under state pharmacy laws have a certain latitude to compound drugs. In these cases, FDA has decided that these are professional service businesses rather (already regulated by others) than the sellers of devices or drugs.

Conceptually, it may be possible to position certain healthcare services as services, rather than the sale of products. But be mindful that this is not simply converting outright sales to rentals. That makes no difference to FDA. Further, as you might guess, if a particular operation starts to look too much like manufacturing, FDA will regulate it. My only point is that healthcare professionals have a certain latitude to provide services to their patients without FDA intrusion. The sixth chapter in this report will discuss this latitude specifically.

The Trade-offs

As Milton Freidman observed, there ain't no such thing as a free lunch. Each of these strategies involves trade-offs, and I've tried to depict those at a high-level in **Diagram 2** below.

As with some of my other diagrams, this one reflects subjective judgments concerning the magnitude of the benefits and burdens associated with a few of the strategies. I've used blue stars to depict features where more is better, and I've used black stars to indicate attributes where less is better.

So, if we look in the column for FDA regulated articles (#8 for class III), we see my assessment that the potential profit margins are the greatest and the product life cycle length is the longest and barriers to entry are the greatest, but on the negative side internal

Diagram 2. Trade-offs

	FDA Regulated 8	Contract out tasks 5	Component supplier 2	Not regulated 1
Profit margins	★★★★★	★★★★	★★★	★★
Product life cycle length	★★★★★	★★★★★	★★★	★★
Internal over head costs	★★★★★	★★★	★★	★
Barriers to entry	★★★★★	★★★★★	★	★

overhead costs are the greatest. I chose to characterize product lifecycle length as good simply because it means the company has a longer time in which to recoup its investment. I realize some IT companies like the short product lifecycles because they consider speedy new product innovation to be a competitive advantage for the firm.

On the other end of the spectrum, I indicate that unregulated articles normally have much lower profit margins and shorter product lifecycles and fewer barriers to entry, but lower overhead costs. However, I'm sure everyone can think of examples where that's not true. In some cases companies are able to develop patent protection around truly novel technologies and earn tremendous profit margins over the full length of the patent life. Further, the development of those innovative products might be a tremendously high cost. But I'm treating those as the exception, not the rule. Perhaps I'm wrong, but in the consumer electronics area, it seems as though competition is fierce and technologies quickly become commoditized despite whatever patent protections might be available.

In the middle you find compromises between those two extremes. In scenario 5 where the company simply contracts out certain difficult tasks, the profit margins go down correspondingly as the costs of contracting go up, but the company still benefits from some barriers to entry and earns a comparatively better profit margin than the far right side of that table. Likewise, component suppliers often enjoy fewer barriers to entry and have comparably lower profit margins to the finished medical device manufacturers, but they also face a lower cost structure.

There is a quantitative basis for this judgment that bears noting. According to Thomson Reuters, medical equipment manufacturers enjoy an average five-year gross margin of 59%, compared with 45.8% for the S&P500. Recent research coming from the Deloitte Center for the Edge, which has studied the business climate for US industries over the past forty years, calculates the average return on assets (ROA) for the entire U.S. economy had fallen to almost one-quarter of its 1965 levels by 2008, while performance in the Health Care industry has run contrary to the trend. That occurred while the ROA in healthcare rose from 1.7 percent in the early 1970s to 3.8 percent in the same period, nearly doubling.

Choosing a strategy is a very complicated exercise that involves looking at these issues, plus most of the competitive issues discussed in article 4 of the series. The dynamics of the marketplace and the competitive strengths of the firm itself will play major roles in any assessment of the optimal strategy. My only point here is that each strategy has its own rewards and risks.

Conclusion

This chapter is meant to give you a high-level understanding of some broad strategies for avoiding or at least reducing your company's FDA compliance obligations. Within each of these broad strategies are multiple variations that raise complexities well beyond the scope of this chapter. The last strategy, selling services or being a user of products, is complicated enough that it deserves its own chapter. The next chapter will focus on hospitals and other providers of care that might employ their own tailored technology to diagnosing, monitoring or treating patients, and the corresponding FDA obligations that may apply.

VI. Washington signals possible FDA regulation of mHealth

"Under the Federal, Food, Drug, and Cosmetic Act, HIT software is a medical device." That's according to Dr. Jeff Shuren, the new director of the Device Center within FDA. Yikes. In February 2010 Dr. Shuren testified at a hearing of the HIT Policy Committee, Adoption/Certification Workgroup. The workgroup invited numerous speakers from different sectors to discuss the safety of HIT, and possible regulatory approaches.

Dr. Shuren's conclusion portends a new and perhaps more demanding regulatory environment for mHealth. So far in this report, I've outlined the FDA requirements that might apply, depending on the circumstances, to the hardware and software used in mHealth. Notice how I qualified that. I've suggested that manufacturers should be aware of certain nuances in FDA law related to intended use claims and other limits on the scope of FDA regulation.

But in his written statement, Dr. Shuren did not equivocate. He did not limit his conclusions, for example, depending on the specific intended uses for the HIT. He just swept it all into FDA regulation and moved on. I don't know whether Dr. Shuren and I would truly disagree on the scope of FDA regulation if we discussed it, but he seems to want to move quickly past that to talking about how FDA should regulate this area.

On the eve of the hearing, Sen. Grassley, the ranking Republican on the powerful Senate Finance Committee, sent out letters revealing his interest in FDA regulating HIT. These events are significant and I want to discuss what happened, and its implications for mHealth.

What happened?

At the hearing, after expressing his view that HIT software is a medical device, Dr. Shuren observed FDA has "largely refrained from enforcing our regulatory requirements with respect to HIT devices." That, Dr. Shuren suggests, is about to change. In explaining the change of heart, he revealed FDA has received 260 voluntary reports of HIT-related malfunctions with the potential for patient harm. Of those reports, 44 included injuries and six even reported deaths. In a table attached to his written testimony, he provided de-identified examples of these reports, several of which involved one patient's data being substituted for another's. Since FDA at this juncture only relies on voluntary reports, Dr. Shuren asserted this might be the tip of an iceberg.

In talking about how these products operate, Dr. Shuren observed that HIT software applications typically do not operate as standalone devices. Instead, they are interconnected with one another into networks of varying degrees of complexity. Sounds kinda like mHealth software.

Dr. Shuren's bottom line: while HIT software has the potential to improve patient care, given the reported safety issues, federal regulation is needed and FDA is the right agency to provide that oversight.

As to what that oversight should look like, he seemed very open to a range of possible solutions. Dr. Shuren described three different possible regulatory strategies. At the lowest level of oversight, HIT vendors could register with FDA and be required to file reports on

adverse events associated with their products. In the middle tier of oversight, on top of that FDA could require compliance with its quality system regulations. These regulations operate similar to ISO standards, but can be more demanding in that they require such things as rigorous design controls. As the highest level of possible oversight, these HIT software products could be subjected to the premarket clearance or approval scheme used for other medical devices. That approval scheme is itself a tiered approach based on risk.

Just before the hearing, anticipating FDA's testimony, Sen. Grassley sent HHS Sec. Sebelius a letter asking her to explain the Department's approach to assuring the safety of electronic health records, subsidized by the $20 billion investment in the stimulus package. He recited concerns he's heard from the public about HIT products that don't function properly, and hospital administrators and HIT vendors who turn a deaf ear to complaints. Sen. Grassley suggests FDA revisit its responsibilities in regulating HIT products.

In his letter, quoting from a 1997 article in the Journal of the American Medical Informatics Association, Sen. Grassley points out that industry groups developed a consensus approach to regulation 13 years ago. He asks what progress the Department has made in evaluating those recommendations. Those recommendations included FDA regulation of higher-risk HIT products, the adoption of industry codes to allow for self-regulation, and the use of so-called local or regional software oversight committees to provide additional protection. The article suggests these committees would be patterned after institutional review boards which monitor clinical research at hospitals and other such institutions.

Sen. Grassley, that same day, sent a letter to HIMSS, asking for the society's position on these issues. The Senator also had sent letters earlier to hospitals and others trying to gather information. He would appear to be on an earnest campaign.

What does all that mean for mHealth?

I'll offer seven observations.

First, when electronic stuff directly impacts health, the folks at White Oak get interested. It's really that simple. They take the public health very seriously, and any IT people new to the health industry need to appreciate that.

Second, when confronted by a situation such as this, FDA's natural reaction is to interpret the scope of their authority very broadly, and then propose a tiered approach based on risk. So they want everything in the tent, but once in the tent they're willing to make distinctions. A lot of people back in 2008 thought FDA's proposed regulation on Medical Device Data Systems was expansive, but Dr. Shuren's declaration that HIT software is a medical device is orders of magnitude broader in scope.

Third, FDA is not deterred simply because a regulatory task is complex or the technology is important to the point where speedy innovation is desirable. If that were the case, FDA would've abandoned regulating pacemakers long ago. Actually, high complexity and high public-health importance are archetypal circumstances for FDA to get involved.

Fourth, prior to this hearing, our orientation was to think about traditional medical devices as the stuff that touches the patient, and then to believe that the software and hardware that moves farther and farther away from that patient contact is less likely to be regulated. But the conclusion that FDA can even regulate the electronic health record (in many cases the point farthest from the patient) means that we

now need to rethink the agency's view on all the stuff that connects those two points. We must think about the various hardware and software tools used for the communication between those elements.

Fifth, from there, it is a short hop to looking at the hardware and software that typifies mHealth applications. If the sensor that collects the data from the patient is a medical device, which we always knew if the use was medical, and if the EHR that is the ultimate repository of that information might also be a regulated medical device, we need to seriously think about whether FDA intends to regulate cell phones that are anything other than generic communication instruments. In the first chapter, I described how FDA might indeed regulate cell phones based on the claims made about them. That was theory, which now seems more likely to materialize as reality. As I did in the first chapter, I would argue that a phone for which the seller makes no special medical claims is not a medical device in the hands of that seller. But any move toward suggesting that the phone is a specialized tool useful for medical communication apparently means FDA might get interested.

Sixth, frankly I interpret Dr. Shuren's comments as the beginning of a conversation. I did not hear him dogmatically say what the future will look like. Quite the opposite, I heard him reaching out to stakeholders for input. While he was fairly emphatic on the point that these software products are within their legal authority, he was expressly inviting comments on the degree of regulation required. I did hear him put a stake in the ground on the issue that something should be done, and I think industry needs to respond. The FDA public meeting on interoperability held during the last week of January similarly showed a willingness by FDA to collaboratively discuss the best approach.

And seventh, however the HIT and mHealth industries respond, as with anyone who participates in the health industry, the approach will need to meet one critical criterion. As a wise, old food and drug attorney once told me (please don't tell my Dad I called him "old"), it all starts and ends with concern for the patient. Whatever approach emerges, whether it's FDA regulation or a voluntary industry code that allows for self-regulation, it needs to have as its essence a focus on protecting the patient.

In the last chapter of this report, I will offer some views on specifically where I think the regulatory environment is going for mHealth. But before I get there, my next chapter will focus on FDA's relationship with hospitals and other users of the technology. I'll be examining what discretion users have to modify the stuff they buy. Hopefully you'll find it useful.

VII. Will the FDA regulate mHealth care providers?

(I would like to thank Tim Gee of Medical Connectivity Consulting and Mike Robkin for their comments on a draft of this chapter. The views expressed, right or wrong, are only the author's and should not be attributed to anyone else.)

At mHealth meetings, I keep hearing representatives from hospitals and other healthcare caregivers say they don't believe FDA regulations extend to them. They seem to believe that an institution must have a smokestack and an assembly line before it needs to worry about FDA regulation beyond clinical research. But that's just not true. FDA can regulate even those engaged in the practice of medicine, if they are also engaged in FDA-regulated activities.

FDA regulation covers making "devices," regardless of who engages in that activity. In this report, I've described the types of hardware and software FDA might regulate as "devices," and provided some background on what the regulatory framework looks like. In the last chapter, I noted that recent activity at FDA suggests the agency is preparing to expand its scope to most areas of HIT, and by implication into both the patient-end and the caregiver-end of mHealth. In fact, as revealed by the Huffington Post, in February of this year, FDA sent a letter to 350 hospitals inviting them to voluntarily report problems with HIT systems (including EHRs and hand-held devices), as a part of FDA's MedSun program.

In this chapter, I review examples of where FDA has regulated caregivers to identify the factors that lead the agency in that direction, and provide a high-level overview of the relevant law. With that as background, I also examine some mHealth care provider practices that might end up FDA-regulated, and offer suggestions for how care providers can avoid FDA regulation if that prospect doesn't excite them.

FDA Care Provider Regulation Examples

If, as an example, a large hospital were to buy a medical device company, FDA would not all of a sudden lose authority over the products the medical device company sells. In fact, it's actually somewhat common for FDA to regulate activities of healthcare providers and professionals who tread into product waters. I'll give four examples.

First, over the last couple of decades, in FDA's view some pharmacies went beyond the traditional practice of pharmacy services into the production of new drugs. Pharmacies have always compounded drugs, which can include mixing various ingredients to make them taste better or easier to digest. But according to FDA, in some cases pharmacies started to basically make their own versions of commercially-available drugs. Apparently some of those pharmacies also did so in advance of receiving a prescription, and in large quantities unrelated to any one patient. So FDA adopted an enforcement policy declaring those activities to be regulated drug manufacturing.

Second, some clinical laboratories develop their own chemical reagents and software for conducting tests on blood and other specimens. FDA declared it has the right to regulate those chemical products just as if they were made by commercial manufacturers. Indeed, FDA has proposed to regulate a subset of laboratory-developed tests that combine multiple variables (e.g. gender, age, and weight) using an interpretation

function (i.e. algorithm) to generate a patient specific result.

Third, physicians and other clinicians sometimes directly sell drugs to, or use medical devices on, patients. When they do so, these clinicians also might promote their services. If they promote uses the FDA has not approved for the products, FDA may enforce its regulatory requirement on the caregivers. In the 1960s and 70s, FDA took several clinics to court that were hawking various remedies for cancer and all sorts of other maladies. As recently as last year, FDA went after a clinic that was offering hyperbaric chambers to treat conditions like stroke, coma, and multiple sclerosis. When the clinicians stand to directly gain financially and use aggressive promotion beyond the cleared label, FDA tends to get involved.

Fourth, and perhaps most analogous to mHealth, FDA regulates the hospital reprocessing and reusing of "single use devices." Manufacturers of disposable products do not validate cleaning and re-sterilization of their products. So when hospitals decide, as a matter of saving money, to reuse devices intended to be thrown away, FDA says in industry guidance that the reuse is a new use beyond what the original clearance contemplated. As the promoter of the new use, the hospital needs to satisfy FDA regulatory requirements just as any other manufacturer, securing approval and following good manufacturing practices.

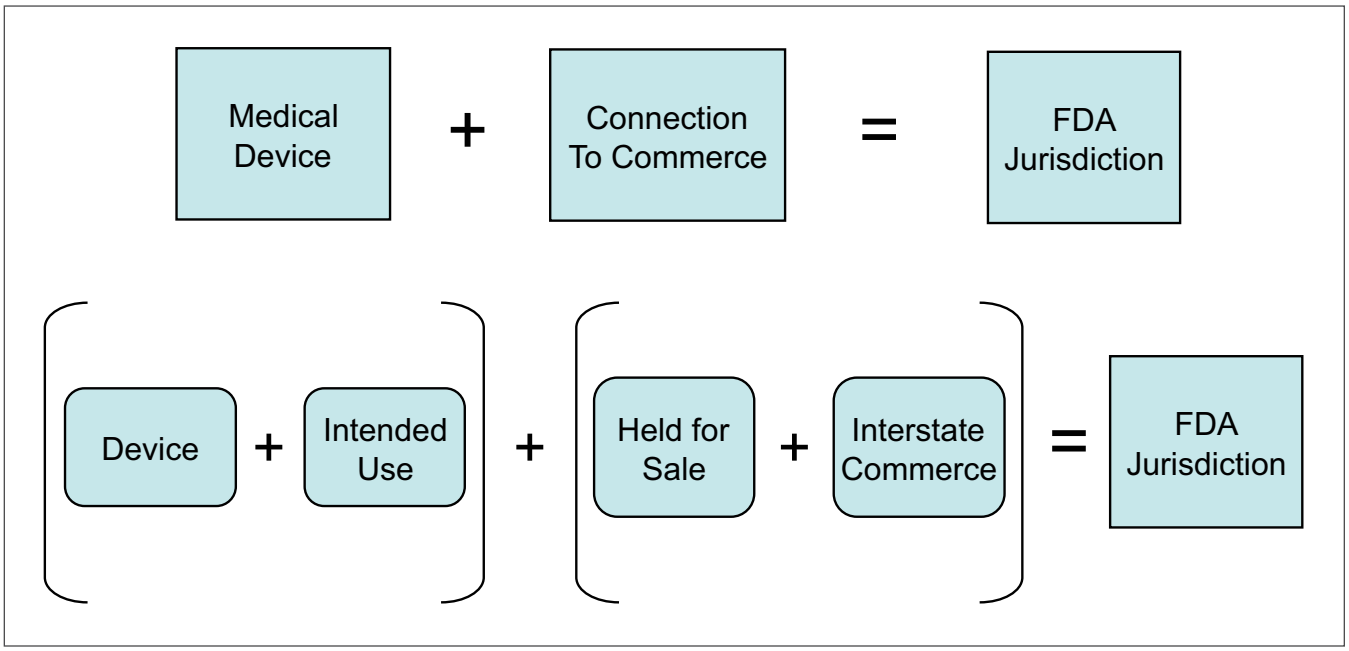
The point of these examples is FDA has shown no reluctance to impose its requirements on any type of healthcare organization that engages in what the agency believes to be manufacturing. Smokestacks are not required.

Legal Overview

A warning to lawyers: this is not a law review article. These issues are complicated, but I'd like to distill these complex laws down to an executive summary.

Being a math nut, I developed the following formula to describe how FDA jurisdiction is established:

Diagram 1. Forumla for FDA Jurisdiction



In its simplest terms, FDA regulates medical devices that have an adequate connection to commerce. As already mentioned, in the first chapter I described what it takes to be a medical device. The definition includes both a tangible device such as software and an intended use for a medical purpose. In the last chapter, I explained how FDA may be treating even the back-end HIT systems of mHealth providers as regulated articles.

So the question becomes whether these articles in the hands of hospitals and other providers satisfy the connection to commerce necessary for FDA jurisdiction. One piece of that required connection is the interstate element. While I won't bore you with a dissertation on interstate commerce, most lawyers realize that almost any commerce now is connected enough to interstate commerce to give the federal government jurisdiction. Indeed, in medical device law, that connection is presumed.

The Federal Food, Drug & Cosmetic Act says that if an organization, when holding a device for sale, does anything to cause it to be "adulterated or misbranded", including promoting for an unapproved use, the organization has committed a prohibited act. So in this case the issue really comes down to whether an article is "held for sale." Broadly speaking, there are a variety of judicial cases over the last 40 years which suggest that healthcare providers may be holding devices for sale if they resell the device to the patient, or even use the device on a patient. When enforcing this particular provision, FDA seems to look for instances where the caregiver is in the distribution chain and engaged in promotion.

Upon learning this, many doctors will quickly point out that they are engaged in the practice of medicine and section 906 of the Act says that FDA will not regulate that. That is true. But there is a line the doctors can cross leaving the practice of medicine behind and entering the business of selling devices. The statute contemplates giving freedom to those who are regulated by state boards of medicine under professional standards, with regard to the activities traditionally within that realm. The statute does not contemplate giving freedom to software engineers working away from patients, developing software and hardware configurations.

It is also true that manufacturing custom devices falls within an exemption from most FDA regulations. While the exact scope of that exemption has been the subject of much debate, most agree the custom device exemption is directed to the practice of tinkering with approved devices to make them suitable for individual patients or individual doctors or other professionals. It does not contemplate producing HIT systems used by multiple patients or multiple caregivers.

The bottom line is that the Act can quite comfortably be read as applying to hospitals and other caregivers engaged in the development and production of software and hardware configurations that support mhealth.

Implicated Hospital Activities

So what mhealth hospital activities might fall within FDA regulation? The following are just hypothetical and broad categories of activities that under certain circumstances FDA might decide to regulate.
Let's say a hospital wants to use mhealth to better manage the care of people with diabetes. Let's also say there are commercial products that allow people with diabetes to download their glucose readings into an app on their smart phones. As I've explained before, that app is quite likely to be FDA-regulated itself. Let's further say the plan is for that app to transmit the data back to a hospital.

Now here is where it gets interesting. What if the hospital wants to develop its own proprietary system that sits on its own servers to collect the data

from patients and manage a database into which physicians can tap? Let's say the hospital pursues this route because either it's simply not satisfied with the commercially-available software products, or there's some need to develop a better, more integrated approach that fits the hospital's legacy systems.

That proprietary system might be FDA-regulated. Even though the system is one-of-a-kind, in this hypothetical it is used for each and every patient enrolled in the program. If that system hiccups and switches the identities of two patients, care can be affected.

Compounding this, hospitals are apparently starting to sell access to their own HIT systems to smaller hospitals and physician practices. HealthLeadersMedia described this recent trend. In these cases, the hospitals risk even more likely becoming resellers of the software. That practice frankly makes it easier for FDA to assert jurisdiction.

Avoiding FDA Regulation of Care Providers

As before, I'm not giving advice on the evasion of detection, but rather on staying outside of the regulated territory. The following is merely my personal list of eight factors that may keep FDA from deciding to regulate a hospital's software or hardware development.

First, it would help if some regulatory authority stepped in and oversaw this area of hospital activity. In the examples above, FDA was most likely to stay away from regulating a given activity if the agency felt another agency already was doing the job. FDA avoids duplicating the efforts of the state boards of pharmacy, state boards of medicine, and federal and state regulators of clinical laboratories. If hospitals work with an accrediting organization or some other body that could oversee this activity, they may well keep FDA from getting involved. However, it's unlikely the current CCHIT certification is demanding enough to give FDA much comfort.

Second, these hospitals and clinics may wish to avoid mhealth applications that involve too much public health risk. That includes the disease or condition being treated (cancer compared to sinus infections) and the clinical role of the technology, as well as the novelty of the software applications. FDA is much less likely to regulate software applications that merely embody tried and true algorithms than those that advance novel approaches. Further, the more proactive a hospital is in conducting quality assurance of the kind a manufacturer would pursue, the less likely FDA will regulate.

Third, the hospital should stay as far away as possible from the actual parent medical device. FDA is more likely to regulate software or hardware that more directly accessorizes a blood glucose meter or other traditional medical device. Further, the less tailored the software or hardware is to the particular medical device, the less likely FDA will regulate. These factors all revolve around close functionality, not the physical proximity of the hardware or software to the medical device.

Fourth, FDA will be less likely to regulate hospitals if the hospital is filling an important void. If there are already commercially-available products and the hospital is making its own either to save money or because of some other idiosyncratic preference, FDA may view the activity as trying to skirt its authority. In a fast-moving area like mHealth, the question

is not only whether there already is a product available commercially, but whether there could be a commercial product. FDA would not want to see hospitals jump in simply because they are impatient with commercial manufacturers conducting a more diligent but time-consuming development process.

Fifth, in all of the examples above where FDA chose to regulate, the agency was responding to aggressive promotion. The more aggressive the promotion and the more outside of traditional FDA clearances, the more likely FDA is to regulate.

Sixth, scale is a big factor. In nearly all of the examples above, FDA only got interested when the practices grew big. That's a practical factor in the sense the technology starts to affect more patients, and commercial manufacturers could actually supply that need.

Seventh, sharing the hardware and software with others makes it easier for FDA to assert the hospital is in the business of reselling.

Eighth, and perhaps most obviously, if the hospital is engaged in modification of commercial systems, staying within any existing FDA clearance avoids FDA interest. Obviously "modification" can encompass a wide range of activities from life-critical changes to changes in the user interface, and configuration changes to hardware and network design and support. The regulatory risk of each type of change needs to be considered on a case-by-case basis.

Conclusions

At the end of January 2010, FDA held a public meeting on the interoperability of medical devices. At that meeting, many of the speakers talked about the need for systems integrators. The favorite analogy was the aircraft industry where two primary manufacturers are big enough to set specifications for individual component suppliers to assure interoperability. By analogy, some people at the meeting suggested hospitals and other end-users play that role with medical devices.

For mHealth, that's problematic if neither the systems integrator nor the individual component suppliers secure the necessary FDA clearance for the system as a whole. FDA regulates systems as systems. So if the individual component companies don't take on the responsibility of FDA compliance for the system, it's up to the integrator. Perhaps some hospitals want to take on that role and secure the necessary clearance from FDA. That could make some sense. But frankly it seems far more likely that an independent third party would play the systems integrator role, securing FDA clearance, and then selling that system to multiple hospitals and other caregivers. Either way, FDA will want to make sure the systems are safe and effective.

There are probably many different ways FDA can assure the safety and effectiveness of the systems. In the next chapter I'll offer some suggestions for where I personally think all of this is heading.

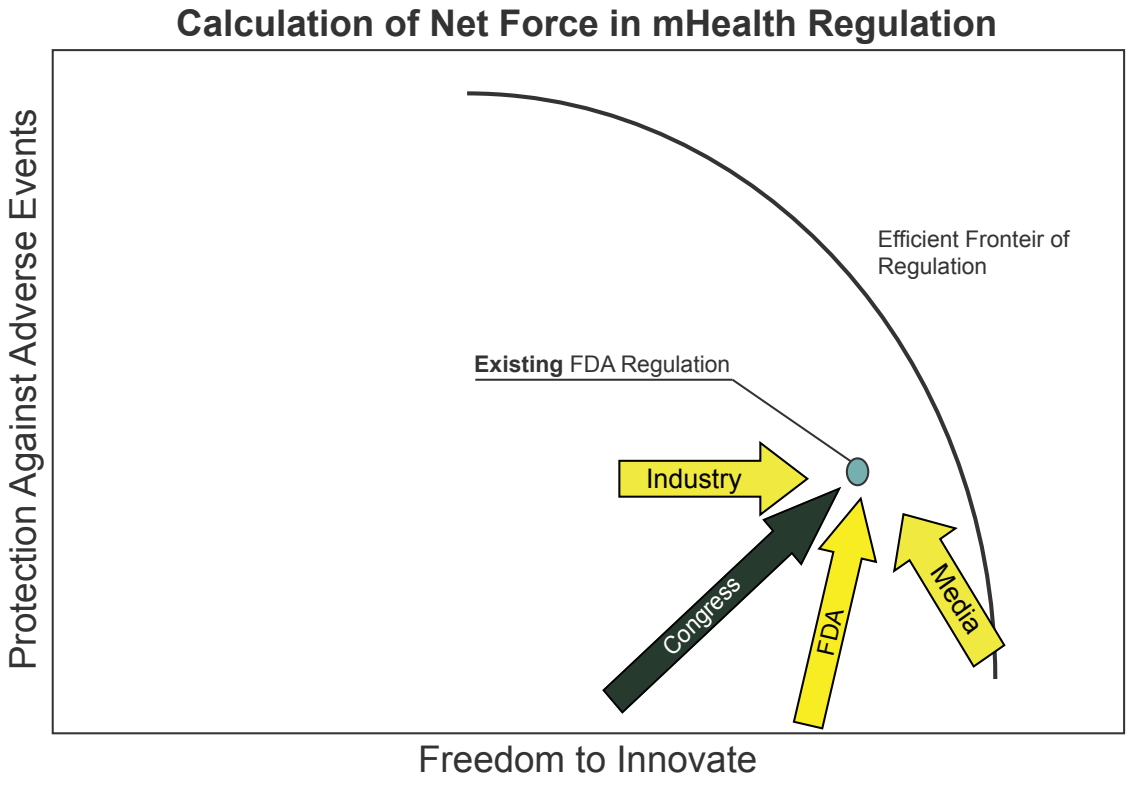
VIII. The Dynamic Future of FDA Regulation of mHealth

(Several friends commented on a draft of this chapter, and I would like to thank them.)

Warning, this chapter contains explicit and sometimes graphic depictions of possible FDA regulation.

If you've hung in until now, you know I've been leading up to this last chapter in which I offer some predictions as to where FDA regulation will end up with regard to mHealth technology. Rather than just give you my predictions, however, I'm going to show you how I arrive at them. In this chapter, as the basis for my prediction, I use the political science equivalent of Newton's second law of motion: the acceleration of an object is directly proportional to, and in a direction determined by, the net force acting on it. I also throw in a little portfolio theory, just to spice it up.

Borrowing from Newton's law, I identify the vector forces that represent each of the primary social and political constituents affecting FDA regulation. As I identify them, I estimate both the magnitude and the direction of the force. Actually it's easier to communicate this in a graph.



If that graph doesn't help you, just forget it, and go to the next section. But if you'd like to know more about how I designed it, read on. I'm a visual person, so I always try to draw myself a picture.

Innovation and protecting against adverse events can be inversely related, at least in certain instances. Requiring medical devices to go through FDA approval, for example, restricts the freedom to innovate in some measure (you can't just put a beta version out on the market and see how it does), while presumably reducing the risk of adverse events if FDA reviewers catch problems. On the other hand, there are places where regulation may actually enhance innovation by providing a framework to ensure the vigor of the analysis. Some argue that design controls lead to better, and in a sense more innovative, products. But for purposes of this analysis, let's assume that there's a trade-off between innovation and protecting against adverse events.

So basically Congress and FDA pick where on this graph they want to be in terms of that trade-off between permitting innovation and protecting against adverse events. But what determines their choices? Ideally they would like maximum innovation and maximum protection against adverse events. So they want to be at the far, upper right hand corner.

Unfortunately, it's not that easy. Their choices are constrained by reality. Perhaps limited by our collective creativity but also by the fundamental conflict between a business process that encourages creativity and innovation, on the one hand, and a business process that drives toward zero risk on the other, trade-offs are necessary. We haven't invented the perfect regulation that allows both maximums.

On the right-hand side of the graph, I depict those constraints, calling it the efficient frontier of regulation. I got kind of carried away, making an obscure reference to an economic theory developed by Nobel prize winner Harry Markowitz. In his famous graph, he shows the trade-off between risk and return from owning various bundles of stocks. His efficient frontier was a curved line representing the best trade-offs you could make in terms of risk and return. That line represented choices in the perfect market.

At my frontier, I show different best case trade-offs between levels of regulation and the associated freedom to innovate in a perfect world. In a perfect world, we have flawlessly written regulations that:

- Communicate clearly the regulatory requirements, fully answering any question you might have
- Are perfectly sensible in that they completely avoid any unnecessary impediment to innovation, always imposing the least burden to get the safety job done
- Are soundly supported by evidence
- Are clever and creative, choosing the most efficient and effective way to achieve safety, and never the product of historical anomaly or political compromise.

We don't live in that world.

That's why I have current FDA regulation inside the efficient frontier. I've done that if for no other reason than because I believe we could increase innovation, with no compromise in public health protection, if we simply clarify the regulatory scheme so that everyone understands what it is. Everyone—whether you are at

FDA or in industry—should want to move as close as possible to that line. The difficult question is, to where on that line should we aim?

Clearly I could have added another dimension in which we evaluate whether regulation advances the public health by allowing important new products onto the market. But I don't know how to draw in three dimensions, and Brian Dolan was no help.

Forces

At a high-level, this graph depicts how industry generally pushes in the direction of innovation. Many in industry don't mind at least some regulation if it keeps unscrupulous companies out. Such companies hurt the reputation of the whole industry, and drive down consumer confidence in their products.

At the other extreme, in my subjective view, the media (except Brian) often flagrantly seizes upon indications of patient risk, while not being terribly concerned about the need for innovation. FDA's mission, by statute, tends to be predominantly focused on assuring safety and effectiveness through regulation, while Congress must be concerned with jobs and assuring adequate access to the best health care (and getting elected). So the task now is to tease apart each of those forces.

Part one of this chapter will identify those existing forces at work, and part two of this chapter to be published next week will calculate the applied net force, and show at least where I think FDA regulation will likely end up.

I. Framework: Crying Wolf or Chicken Little?

Before I dive into this analysis, because portions of it are subjective, in the interests of good journalism I should disclose my own biases. I'm prompted to do this in part because of Nick Hunn's thought-provoking article on whether we should even discuss the likelihood of FDA regulation of mHealth. Nick's article advances the argument that too much talk about possible FDA regulation scares away potential entrants into the US mHealth market, those who might have allergic reactions to graphic discussions of such topics. (I tried to warn them away.) Nick's article is worth a read, and not just because he calls my article series on MobiHealthNews "excellent".

At the same time, I have to disagree with Nick's conclusions.

Over the years, I've learned that business people of all types, and particularly investors, highly value information about changes in the regulatory environment on the horizon. While Nick seems to feel discussion of FDA regulation is tantamount to fear mongering, my hope is that this information will provide the reader a rational basis for business planning.

In the end, you can decide the value of this information by whether you feel there is an objective basis for the conclusions offered. That's why I'm going to take a little bit of time to lay out my specific observations. You be the judge.

II. The Nature of FDA Regulation

I understand full well some readers will never believe FDA regulation is anything but bad news for an industry. Frankly some people (like me) simply have trouble accepting authority. So I understand they will never welcome the idea of Washington telling them what to do. They blog for a living (just kidding Nick), or only enter businesses that are largely unregulated. I honestly get that.

But throughout this report, I have advanced the idea FDA regulation can benefit the industry. At

the most fundamental level, assuring the safety of technology helps protect the image of an industry and the confidence of its customers. Beyond that, the regulatory system itself becomes a barrier to entry, and helps ensure that companies willing to make a higher investment are protected enough to earn profits proportionate to the investments they must make. The proof is in the pudding, of course. The medical device industry has been one of the healthiest industries over the last 20 or 30 years, and particularly measured by most indicators of the robustness of innovation. The industry has attracted high levels of venture capital, and has produced high numbers of patents. More anecdotally, the breakthrough technologies reaching the medical device market over the last 20 years in many cases have been breathtaking.

At the same time, it goes without saying that we can have too much regulation, and misdirected regulation can stifle innovation. The trick is to find the right balance, the sweet spot where regulation is flexible enough to allow innovation and strong enough to provide adequate protection to the public health. Abiding by that regulation constitutes the dues that any company must pay if it wants to supply medical technology that can impact the health and safety of our citizens.

III. Society and the Healthcare System

In this chapter, I'm not even going to try to analyze where the health-care system is headed. Instead, based on reading probably many of us have done, I will list the major trends (assumptions) I've factored into my analysis.

- Many U.S. citizens live in areas underserved by the health-care system. mHealth technologies, as with other remote monitoring and telehealth devices, can be used to expand access in these underserved areas.
- Healthcare costs are high, and getting higher. Throughout the last year, we've all been bombarded by stories discussing the rising cost of health care, and the need for reform. Whether or not you believe the recently enacted health-care reform will drive down costs, it's fair to say in the foreseeable future we will need to identify every possible way to reduce those costs. mHealth technologies have been touted as one possible way to treat people in lower cost care settings, and better manage chronic conditions that are driving up the cost of healthcare.
- Outside of healthcare, the world is going digital. The growth of mobile phones into a nearly ubiquitous communication tool is well-established.

So it's no great revelation to anyone reading MobiHealthNews that the societal forces driving the adoption of mHealth are strong. One way or another, society in general and our healthcare system in particular will demand access to mHealth technologies.

IV. Industry and Technology Trends

Scores of articles in MobiHealthNews describe where the industry is going. Allow me just to highlight a few trends pertinent to FDA regulation.

- The predicted growth of mHealth is enormous. Driven by the trends identified above and more, most folks in the industry expect it to grow by leaps and bounds.

- While many of the apps used in mHealth reflect nothing more than portable information sources, some are much more than that. The future is wide open to technologies that will facilitate collecting information directly from sensors on the body and transmitting the data back to caregivers for treatment decisions. In the realm of medicine, even with sophisticated caregivers such as nurses, erroneous information can affect treatment. Further, it is not hard to imagine moving beyond simply sending information from the patient to the caregiver, but actually giving some of the devices along the way an ability to make therapeutic adjustments affecting the patient. All those factors affect risk, and that draws FDA's interest.

- In terms of business and technology models, in many quarters there is a clear desire to achieve interoperability. In a perfect future world, we may well have many technologies out there that can all speak to each other in a common language, working as one integrated system to share information and potentially make machine-driven decisions. The regulatory implications of what would effectively be an open network are mind-boggling, and discussed below.

- Some hospitals and other care providers are moving in the direction of purchasing components and developing integrated care systems. Further, some of these system developers, to achieve economies of scale and efficiencies, are renting out access to their systems to smaller hospitals and care providers. The implications of this were discussed in my last article on FDA regulation of care providers.

- Traditional medical device companies are diving into the connected health arena. Seeing the benefits of having their sophisticated medical devices plugged into HIT systems, these companies are exploring ways to connect most effectively.

- Reimbursement for most areas of mHealth and indeed remote monitoring generally has been stingy. As a result, many companies exploring these markets are focusing on direct to consumer sales where the patient would pay out-of-pocket. That's important to FDA, because it directly implicates the agency's recently announced medical device home use initiative. In that initiative, FDA expresses both the positive benefits of providing better care in the home, but also questions the risks associated with untrained users trying to manage sophisticated equipment and the use of wireless communications.

Each of those trends directly affects the likelihood and possible nature of any future FDA regulation of mHealth. More on that later.

V. Political and Regulatory Trends

In chapter 6, I noted that Washington was signaling likely FDA regulation. I won't repeat that chapter here, but rather highlight a few trends in Washington.

- The most direct trend is the language coming out of FDA quite specifically suggesting they plan to regulate HIT, and presumably many of its incarnations. Dr. Jeff Shuren, the Director of the FDA's Center responsible for regulating devices, said basically that in a February speech. Part of the basis for his declaration was the injuries reported to FDA due to hiccups in HIT systems. In the early chapters of this report, I outlined the legal basis for FDA regulation of certain hardware and software involved in mHealth.

- Over the last six months, Sen. Grassley, an influential Republican, has been sending out letters expressing concern and asking questions about risks associated with HIT, and what FDA is doing about those risks. If you've read those letters, you might very well conclude the senator is not done addressing this topic.

- Early in his presidency, near the height of the recession, Pres. Obama obtained authority to invest roughly $20 billion in HIT. That's the good news. Some critics have said the investment is premature because rolling out new systems is a complicated and delicate task that will take quite a while to do safely. As a result, while the Obama Administration seems committed to proceeding with its plan, clearly they will want to do so in a way that also protects the public from weaknesses in those systems.

- With Congress and FDA focused on the safety of HIT systems, many policymakers have apparently concluded they need more data. To that end, FDA sent a letter to numerous hospitals a couple months ago asking them to more systematically and regularly report any problems associated with HIT. FDA apparently is trying to build a database on which to base future policy.

- This spring, the FCC released The National Broadband Plan: Connecting America, which included sections encouraging FDA to work with FCC to devise a coordinated regulatory approach for connected health. On the one hand, it should be welcome news that FDA and FCC would coordinate to avoid duplication and inconsistency. On the other hand, that news probably prompts the fear of the unknown, since we really do not know where the agency collaboration might lead.

- Over the last couple of months, in discussions before the HIT Policy Committee, FDA's role in regulating HIT has been actively discussed, including the testimony of Dr. Shuren mentioned above. On April 25, the HIT Policy Committee sent its recommendations to Dr. Blumenthal. With regard to FDA, after discussing the pros and cons, the committee suggested that "the ONC work with the FDA and representatives of patient, clinician, vendor, and healthcare organizations to determine the role that the FDA should play to improve the safe use of Certified EHR Technology." Wow, that's helpful. In a speech on April 29, Dr. Blumenthal is quoted as saying "although [the] advisory committee concluded that more information was necessary, he called the evidence of the reports "anecdotal and fragmented" at best. I would infer Dr. Blumenthal wants to keep FDA out of mHealth. Indeed, the committee discussed creating its own regulatory scheme that would feature adverse event reporting. Last time I checked, though, ONC doesn't tell FDA what to do.

- In a May 24 workshop on the medical device home use initiative referenced above, the FDA confirmed it was drafting a guidance document on medical device use in the home environment with a particular interest on clarifying "wireless issues" related to medical devices used in the home. It is unclear what aspects of "wireless issues" the agency hopes to focus on, how broad that focus will be and what guidance is likely to come from the agency.

- FDA has started to receive premarket notifications for new cell phone apps related to mHealth. Apparently the agency is struggling somewhat to grant clearances for new apps on the basis they lack what is referred to as a predicate device. Consider the experience of MIMvista reported earlier this year, whose iPhone app for medical imaging failed to clear FDA reportedly because there was no predicate. As explained in the third chapter on software, for a new medical device to reach the market through the clearance process, there must be an existing, substantially equivalent software device on the market. If no such substantially equivalent device exists, the manufacturer is forced to go through the much more expensive and demanding premarket approval route.

Those developments each affect the likelihood and manner of possible future FDA regulation.

VI. The Fourth Estate

That's the media. And in our political and regulatory systems, the role of the media is important. Media attention to an issue routinely spurs our elected officials and even our regulators to act. For the good of society or for profit, the media has been paying attention to the question of FDA regulation of HIT and mHealth.

- In some of the more ominous attention paid to this topic, the Huffington Post has been conducting an investigative report on injuries and other adverse effects of HIT systems. The Huffington Post has been sifting through FDA records analyzing trends associated with the use of these software-based products. Throughout this spring they have been publishing articles quite critical of the risk associated with these software products, and what they claim to be as FDA's inattention to the problem.

- Aunt Minnie's website in similar fashion has been doing investigative reporting on the need for FDA regulation of devices in this area.

- Even more mainstream publications have focused on this issue. In April, an article in Scientific American raised questions about how these important mHealth devices could escape FDA regulation.

- Those feature articles have caused a fair amount of discussion among bloggers. And before Nick says anything, this report has been educational, not critical.

So those are, in my view, the major vector forces to consider as we ponder what the future might look like for FDA regulation of mHealth. The next task is to add all those vectors up to see where they might take us. I'll do that in part two of this final chapter.

Part Two — Calculating Applied Net Force

In part one of this chapter, I described the major forces bearing on the question of if and how FDA should regulate hardware and software used in mHealth. I laid out almost a Newtonian analysis of those political science forces. In this part, I add all of those forces together to calculate (okay, guess) where FDA is going. Actually, I wish it were as simple as the diagram below.

I'm guessing you want to know a little more specifically where FDA might end up.

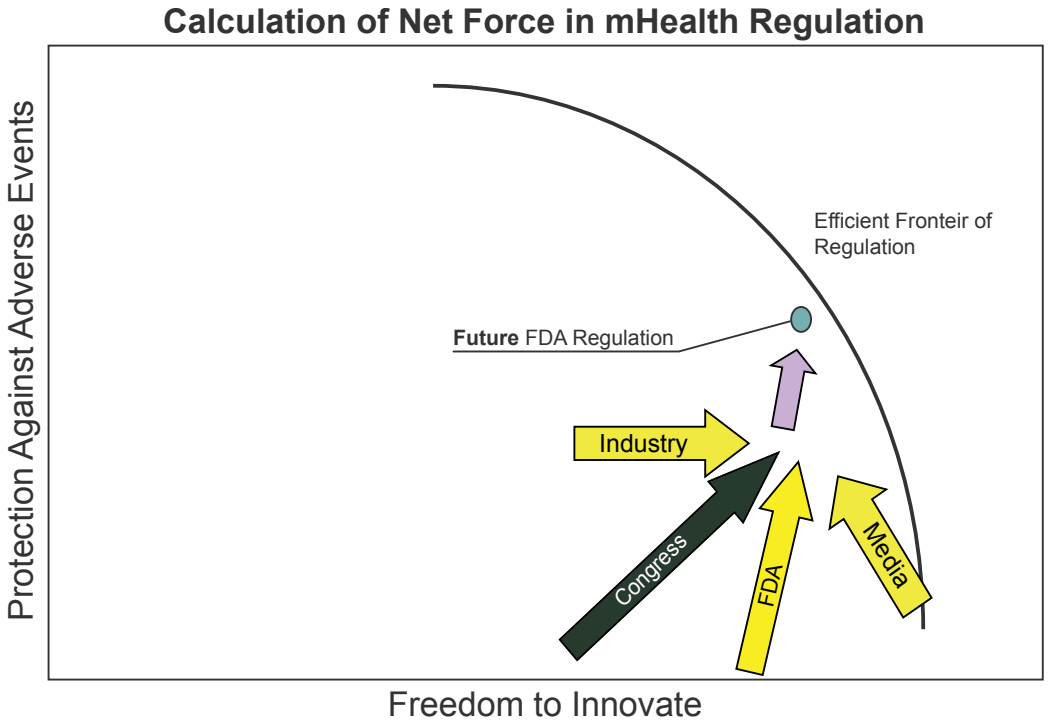
I. Where do these forces collide?

The starting point is to understand where exactly these existing forces collide. In broad terms, they collide in two areas: proactive and reactive discussions.

There currently are a half dozen forums sponsoring proactive, constructive discussion.

First, as I mentioned in Part I of this chapter, FDA has undertaken to define home use medical devices through the creation of a special initiative. Until now, FDA has not articulated a clear regulatory pathway for devices intended for home use. In order to facilitate the development of medical devices that are safe for home use, FDA will develop a guidance document within 8-10 months recommending actions manufacturers should take to receive FDA approval. During a May 24 workshop, FDA signaled a strong intention also to address "wireless issues" pertaining to home use medical devices.

Second, various trade associations such as the Continua Health Alliance are engaged in dialogues with FDA regarding the requirements for interoperable devices. An important example of that is an ad hoc roundtable discussion among several participants in the FDA's January public meeting on medical device interoperability. That group meets periodically to develop what would basically be a mock FDA submission for an interoperable medical



device platform. The goal is to develop a submission the agency would find acceptable, such that other folks in industry can use that submission as a model for their own.

Third, there is a very good opportunity to discuss these issues in an upcoming public workshop on "Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development." This June 24 workshop will focus on identifying health needs that 1) affect many individuals (2) could be significantly improved by new devices and (3) the devices are not being developed due to barriers caused by FDA. To me, they might as well have said we would like to hear about mHealth. As I discuss below, the ambiguities around FDA regulation are significantly impeding investment in technologies that could make an enormous difference for those suffering from chronic disease. I would urge people to consider attending or commenting in writing, but don't mention I suggested it.

Fourth, there are governmental policy forums beginning to study and debate FDA regulation of mHealth. An example is an NIH initiative to gather leaders from throughout government and the private sector to look broadly at the policy and regulatory issues associated with mHealth research. A small group of those people met June 7-8 to debate some of the basic issues, and then the NIH Foundation will hold a broader meeting on November 8-10 to "convene leaders in research, technology and policy to share their expertise and draft a blueprint for the future of mobile health."

Fifth, per the National Broadband Plan, the FCC will engage FDA directly in a meeting at the end of July. While that announcement has not yet come out (expect it very soon), the meeting is likely to address specifically the areas of overlap between the two agencies. At the same time, it's clear that FCC sees the benefit of mHealth and wants to identify ways to encourage it through public policy.

Sixth, at least some industry participants are beginning a dialogue with members of Congress regarding the nature and scope of the regulatory issues. At this juncture, those meetings seem to be mostly educational for members of Congress, but they may at some juncture result in further letters from members to the Administration expressing opinions on where the Administration should take mHealth policy.

Those proactive discussions may not be the last word: we may see some reactive discussions. As an observer of FDA over the years, I'm guessing that in addition to the direct dialogue, we will see the agency reacting through an enforcement action or two against what the agency considers to be egregious conduct. Often the agency will pick activity that is both egregious and high profile to be the subject of a warning letter. Sending such a letter begins a dialogue with the recipient, but also communicates to a broader audience. There may be some high profile products out there stepping over the line in a way that makes them likely targets.

II. The open substantive questions

Okay, so these forces collide in either proactive or reactive communication: where does that mean FDA is going? To address that, I will identify six basic open questions, and suggest how they might be resolved through these discussions.

1. Scope of FDA Regulation

Hardware and software companies need to know which mHealth products FDA regulates, but unfortunately the answers aren't always clear. For example, FDA generally regulates medical intended uses for products, but not products directed at general wellness or fitness. The problem is there's a whole lot a

gray area between those categories. As examples, there are mobile phone apps focused on helping people with weight loss and everyday management of diabetes. When might certain claims in those areas trigger FDA regulation?

Further, it might be obvious that a blood glucose meter is a medical device. But as that device connects to a cell phone which connects to a server somewhere which connects to a doctor's computer, where does FDA regulation begin and end?

Rather than just focusing on what the statute authorizes, I would hope that industry and FDA through discussion could arrive at a risk-based model that limits FDA's active regulation to those devices where a malfunction could realistically hurt someone.

2. The Level of FDA Regulation

FDA's medical device regulatory scheme is deliberately risk-based and stratified. Currently, high-risk medical devices such as certain cardiovascular therapeutic devices are regulated quite extensively. When those devices get connected to a doctor's office either through a dedicated pathway or through a mobile phone, it is unclear whether the communication devices that carry the signal should also be considered medical devices regulated to that same highest level.

Here again the resolution is likely to be risk-based. Industry and FDA will need to bring many of their various risk assessment tools to bear on assessing at which junctures in the connected lines of communication risk is the greatest, and the regulatory requirements will likely focus on those junctures. By using risk assessment tools, industry may be able to convince FDA the cell phone is not a significant source of risk, and therefore should not be subject to much regulatory scrutiny.

3. Network Intended Use

The existing medical device regulatory scheme does not embrace a network mentality. Individual medical devices are cleared or approved for specific, individual uses. Very rarely would FDA clear a medical device for unspecified interoperability with a whole class of other medical devices. But that interoperability is precisely Continua's business model. Further, FDA has a long-standing rule that when two articles are sold together expressly as a kit, the combination of devices changes their intended use and requires special clearance for the kit unless exempt or the individual clearances already contemplate the kit.

FDA will need to come up with a regulatory model to address devices cleared to a standard that allows them to interoperate with other such devices, where the range of other possible devices is open-ended. As with its other regulatory challenges, FDA likely will develop this model on the basis of risk management tools. The agency will have to identify the features and characteristics that produce risk, and develop appropriate regulatory requirements to assure the safe and effective performance of devices with those features and characteristics. Compliance currently is especially difficult in the area of design controls, which do not contemplate open-ended, interoperable claims.

The development of this new regulatory model will require substantial interaction with industry to arrive at something practical. Indeed, this is part of the work of the ongoing dialogue between Continua and FDA, stemming from the January meeting on interoperability.

4. Standards for Clearance

For those mHealth products that do require FDA clearance, manufacturers need to know whether FDA has any minimum requirements addressing such areas as:

- Latency
- Human factors design issues
- Limits on appropriate user
- Ability to use open source platform
- Acceptable use environments
- Usability issues
- Protection against interference by other software
- Security

Again working with industry, I suspect FDA will develop basic standards in those areas based on risk, but don't expect those standards to be written any time soon. Normally FDA hangs back on committing such information to writing until they have substantial experience with a new technology.

5. Hospital-Directed Modifications

As I discussed in the seventh chapter, hospitals and other healthcare providers often modify systems or even act as integrators of a variety of components to produce mHealth remote monitoring systems. Under the law, when they do so, FDA might decide the hospitals are functioning as manufacturers and regulate them. In chapter, I ran through a variety of factors that impact the likelihood of FDA regulation. Eventually, FDA hopefully will come out with some guidance to define the circumstances in which hospitals and others can serve as systems integrators without having to meet the specific requirements of FDA's medical device laws. This can be done under the FDA's enforcement discretion. The factors that FDA might consider would be probably similar to the ones contained earlier in this report, including the risk associated with the specific activities of the hospital, the scale of the activities, and the availability of suitable systems designed and made by FDA-registered manufacturers.

6. Multiple Vendors—Post Market Compliance Issues

Often multiple hardware and software components are connected to form an mHealth system, for example a blood glucose meter, a cell phone, a server, and a PC in the doctor's office. In those cases, when something goes wrong and an erroneous result is displayed on the doctors monitor, which component manufacturer has the postmarket obligations to report the so-called adverse event to the FDA? If it's not clear where the hiccup occurred, who would have responsibility to investigate and fix the breakdown?

The medical device laws contemplate relatively clear responsibility, and do not take into account the concept of a network of interconnected devices. As a result, these postmarket obligations are ambiguous in this context. FDA will have to work out some practical rules for assigning responsibility to one particular manufacturer when a network produces erroneous results for unknown reasons. Through discussion with industry, the FDA will probably come up with rules of thumb for identifying the device that either embodies the most risk or is otherwise most likely to be responsible for the failure.

III. Suggestions for Advocacy

1. Arguments to Use

I don't want to pick on Nick, but the sentiments he expresses in his Crying Wolf post are similar to what many in the IT industry are saying. At its essence, they're suggesting mHealth technologies are too important for FDA to regulate. To be blunt, I would urge all those connected with the mHealth industry to stop making that argument. Rather than helping, it's hurting your cause.

The issue of importance actually cuts the other way, in favor of regulation. Saying that mHealth is too important for FDA to regulate is a little bit like saying a patient is too sick to need a doctor. FDA only regulates products that are important, and the more important they are, the more FDA feels the need to regulate. FDA expends its greatest amount of time and resources on class III medical devices, which are arguably the most "important" in a clinical sense.

Second, please don't simplistically argue FDA shouldn't regulate mHealth because we need innovation. The argument suggests that we don't need innovation for those areas FDA does regulate, like traditional medical devices, but that's kind of silly. I suspect most patients would say that they want innovation in medical devices that can save their lives.

At the end of the day it's not the importance of the technology or the need for innovation that determines whether FDA should regulate, but rather balancing the benefits of regulation against the harm of regulation. And the benefit of regulation is the protection of the patient. So in my mind, the policy debate should be around whether the risks of any particular mHealth technology merit the cost of regulation, where that cost includes not just the cost of compliance by the company but also the inhibition on innovation of helpful products.

2. A New, Temporary Coalition

Nick and I probably share quite a bit of common ground in that I suspect we both believe there are a number of technologies used in mHealth where balancing those factors would lead a reasonable person to conclude that regulation is unnecessary. Because of that, recently several of us got together and announced the formation of a coalition—the mHealth Regulatory Coalition or MRC– to develop a consensus among industry participants regarding the scope of what FDA should and should not regulate in the area of mHealth technologies, and propose that approach to FDA for adoption. Dr. Jeffrey Shuren, the Director of the Center for Devices and Radiological Health of FDA, as the recent annual meeting of FDLI invited industry to propose guidance documents on policy issues of importance to industry. FDA will take those documents, make any changes they feel are necessary, and then propose them for formal adoption. We think this topic is ideal for a proposed guidance.

The MRC is very narrowly focused on the one task, and indeed is only temporary. It will only continue so long as it takes to complete that task, hopefully within months. We are inviting members of the mHealth industry to participate alongside existing trade groups to be inclusive. We plan to have our first meeting on July 8 in Washington, to get organized.

Our concern is that there are a variety of companies and investors sitting on the sidelines out of fear they may be regulated. The uncertainty is helping no one. We plan to tackle the scope of FDA regulation head on by developing a proposed list of mHealth technologies and intended uses that FDA should regulate, and a list of those they should not. Our preference is to achieve as much specificity as possible, so we can move closer to the efficient frontier.

IV. Speculations

FDA obviously will regulate at least certain hardware and software used in mHealth, such as the blood glucose meters they already regulate. As to exactly where the line will be drawn around the scope of FDA regulation is yet to be determined, and I suspect will be very much risk-based, and determined by an evaluation of the evidence. FDA doesn't have to actively regulate everything the statute says is a medical device, and the agency routinely draws lines short of everything it could theoretically regulate. Helping them figure out where to draw that line is industry's job, subject to all of the other forces being exerted on the process.

The mHealth industry will thrive: it has to. We need it to. But along the way industry will adapt to whatever regulatory scheme ultimately emerges, and likely much of that adaptation will be accomplished through partnerships typical of a network technology industry. So, to ensure mHealth reaches its potential, we need to figure out creative and effective ways to work together. I'm confident we will succeed.