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Strategies for Technology Companies Entering the Health Care Internet of Things

By Bradley Merrill Thompson

Background

Technology companies such as Intel, IBM, Google, Qualcomm, and even Amazon are diving into the healthcare space.

More than that, new companies focused on the software components of the Healthcare Internet of Things (''HCIoT'') are sprouting up and developers of wearable technologies, like Fitbit and HealthPatch MD, are piling in. They all are drawn by the opportunity to carve out their roles in the emerging technology ecosystem destined to disrupt healthcare.

In this new ecosystem, body sensors and traditional medical devices may be connected through the cloud to analytics software, which in turn guides clinical decision-making. According to a report from Market-Research.com, the HCIoT market segment is poised to hit $117 billion by 2020.

FDA regulation presents these new entrants with some strategic choices that can have profound implications on competitive dynamics and profitability. Partly because they want to connect their technologies with existing medical devices, but also partly out of a recognition that they lack expertise in medical device development, manufacturing, marketing and regulatory compliance, many technology companies have opted to partner with established healthcare players.

There are actually several different ways technology companies can enter, or at least profit from, the FDA-regulated portion of the Internet of Things. This article will examine a case study involving patients with asthma, and how the Internet of Things can help manage that chronic disease. In that context, the article will provide as much clarity as possible—within the current regulatory uncertainties—on exactly which portions of

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the Internet of Things FDA regulates. And finally, the article will examine a range of strategies that technology companies can pursue to participate in those regulated aspects, and assess the relative merits of each.

Recent Tech Partnerships with MedTech Firms

Tech Company	MedTech Firm Partner	Strategy
IBM	Medtronic	Combining analytics and cognitive computing with diabetes medical devices and health data to develop new personalized diabetes management solutions
IBM	Johnson & Johnson	Using advanced data analysis and insights to help develop personalized patient engagement and coaching solutions that span consumer wellness and chronic condition management
Cisco Systems	UC San Francisco	Developing an interoperability platform for sharing healthcare information among multiple entities to enable health systems, providers and application vendors to share and integrate health data from multiple sources
Verily (Google)	Sanofi	Improving care and outcomes for people with type 1 and type 2 diabetes by pursuing analytics, miniaturized electronics and low power chip design
Verily (Google)	Novartis	Developing a "smart" contact lens to help restore the eye's natural autofocus
Intel	GE Healthcare	Through the joint venture Care Innovations®, developing QuietCare® smart sensor technology that uses motion sensors to collect and interpret patient data points to provide up-to-date pictures of patient care
Samsung Electronics	UC San Francisco	Building a laboratory to conduct validation and commercialization of promising new sensors, algorithms, and digital health technologies for preventive health solutions
Samsung Electronics	Partners Healthcare	Developing mhealth solutions to improve chronic disease management
Qualcomm	Roche Diagnostics	Improving remote monitoring and management of chronic disease patients
Qualcomm	Dozens of medical device companies	Promoting a system that includes the 2net™ Platform, a wireless health platform that captures and delivers medical device data to integrated portals or databases from technology partners' wireless medical devices for storage
Amazon Web Services (AWS)	Royal Philips	Enabling a digital health IoT for new types of connected and personalized devices that includes AWS' IoT, a new platform that allows devices to connect to AWS services and Philips' HealthSuite digital platform, an open IT infrastructure that supports the secure management of data

Recent Tech Partnerships With MedTech Firms

I. The Healthcare Internet of Things: Asthma Case Study

Most people are already familiar with the HCIoT—typically some form of connected sensors that produce data that are analyzed, leading to actionable information. Here, I'd like to make the analysis very concrete, and focus on a particular example of how the Internet of Things can facilitate the management of asthma.

If your child has asthma, you know just how difficult it can be to manage an adolescent with that disease. Inhalers, it turns out, are not cool. Further, getting your kid to consistently use his inhaler to properly manage his condition is a guessing game once he starts school. Compounding the problem, kids are often blissfully unaware of themselves, and the early warning signs of an attack. Sometimes, even if they are aware, they might stubbornly avoid changing their behavior if, for example, they are in a social situation such as an after-school soccer game.

The Healthcare Internet of Things radically changes that dynamic. Imagine your son is at school, and when the time comes to take his inhaled corticosteroids (used to manage asthma over the long term), his smart inhaler sends data to his cell phone over Bluetooth recording exactly when and how much of the drug he took. After gym class, when your son is struggling to breathe, and he similarly takes a short acting beta antagonist delivered through a different inhaler, the same thing happens. After being collected by your son's phone, this information goes to both mom and your son's pediatrician.

At certain times of the day, your son can also use a portable handheld spirometer to measure peak flow as well as a variety of other breath functions. This data also goes to both mom and doctor, in addition to being available to your son on his smart phone.

Not only does this create a way to avoid having to simply take your son's word for it, at a deeper level, the system allows for sophisticated analysis by the doctor of when and where your son struggles most to manage his asthma. But the HCIoT certainly does not stop there. In many ways, that is just the low hanging fruit. While that system produces data that helps manage the patient better, the potential is even greater.

So let's make this interesting. Your son has an athletic shirt with embedded environmental sensors. The sensors monitor such things as airborne gases including ozone, carbon monoxide, pollen and other irritants. The sensors are part of nanosystems that use optical measures to assess the size and composition of any particles. Basically your son's shirt tells his smart phone when he is around irritants that maybe he can't sense himself. More fundamentally, the system helps identify environments encountered throughout the day that have high levels of asthma irritants.

Your son also wears a cool looking wristband that includes sensors such as an accelerometer. The sensors are great for measuring your son's movements, and taking vital signs such as heart rate, hydration and blood oxygen saturation.

Let's say your son's asthma has been not been well controlled for a couple of years, and so more invasive measures are prudent. To help your son, you ask him to wear a small sensor that simply sticks to his chest with an adhesive that can be easily peeled off. The sensor measures respiration rate, but also listens for coughing and wheezing signs. The sensor is so sensitive that it can hear the very early stages of asthma, to which your son himself is not yet attuned.

All of this sensor data is collected by your son's smart phone, and transmitted to the cloud where software analyzes it on a nearly real-time basis. The software is looking for trends that show an asthma attack may be on its way. If the software detects such an early warning signal, the software sends a warning to your son on his cell phone, as well as an alert to mom. A record of this data is also stored with your son's physician.

This case study may look like a bit of technology overkill, but it illustrates the range of possible solutions to the problem of better managing adolescents with asthma. All of these products exist or are in development. Helicopter parents will love it, but beyond those of us who like to micromanage our children, the system provides very practical warnings and information alerts to the child, the parent and the physician that allow concrete action to be taken.

Indeed, some early studies have already shown that these sorts of systems can have a rather dramatic impact on patient compliance with drug regimens. One study, for example, has shown that average adherence among children using inhaled corticosteroids for asthma improved from 30% to 84% with the introduction of smart inhalers that produce audiovisual reminders.

Such innovations are needed. The World Health Organization reports that, according to one study, chil-

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dren in the United States with asthma only take all of their recommended daily doses of inhaled steroids 5 percent of the time, and indeed only 42 percent of the time even took a single dose during the day. Considering that asthma in the United States currently causes about 1.8 million emergency department visits, 439,000 hospitalizations, and 3,630 deaths each year, and much of those consequences could be avoided by better medication adherence, such technology may not, in fact, be overkill.

This case study focuses on technology that your son would use directly. It would not be hard to imagine other technology being connected to the system that does not necessarily even touch your son. Environmental sensors that are constantly monitoring pollen and other irritants in different geographic locations could connect to the system to offer input on whether it might be prudent to increase medicine today. Beyond just medication dosage decisions, these data sources might alert you to places that your son really ought not go today.

Of course, this is just an example of a healthcare use case for the Internet of Things. Nearly any chronic disease could be a candidate for using the Internet of Things to help manage the condition long-term. Diabetes and obesity, for example, could be better managed by a wide array of smart technologies working together as a system.

II. FDA Regulation of the Internet of Things

A. Deciding When A Part Of The Internet Of Things Is An FDA-Regulated Medical Device

Technology developers looking at the opportunities presented by the HCIoT for managing chronic disease often ask themselves whether a given piece of hardware or software to be used in that ecosystem would be subject to FDA regulation. The question is a natural one, as FDA regulation carries with it certain costs and timelines associated with compliance that have a direct impact on the attractiveness of the market. Certainly not all regulated medical devices must receive FDA clearance before being marketed, but some do, and obtaining that clearance or approval in some cases requires expensive data as well as the patience to go through the process.

While the answer to the question of whether a given product is regulated isn't always clear (because the facts get complicated very quickly and FDA has not issued guidance for many of the more complex areas), at a high level, FDA's jurisdiction is actually fairly simple to explain. Medical devices include just about anything that is ''intended for use'' in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man.

The first three words of that definition—intended for use—turn out to be extremely important. The scope of FDA medical device regulation is based on the ''intended use'' of the product being sold. The phrase ''intended use'' has a specific meaning, and it is often different from the actual use to which a product is put. The intended use is the use the seller intends the buyer make of the product. In other words, to determine whether a product is FDA regulated, the task is to look inside the seller's mind at exactly for what the seller intends its product to be used.

This makes sense. It would be completely unworkable, and frankly unfair, if we held sellers responsible for unforeseen uses that a particular customer makes of a given article. Instead, to make the system objective and predictable, we base the decision of FDA jurisdiction on the seller's intent.

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How do we know what the seller intends? The question of intent is a very familiar concept in the law. Many laws depend heavily on intent. Anyone who watches TV knows that there are different levels of homicide depending on the killer's intent. We punish premeditated murder very differently than we do accidental homicide. And it is up to a jury, looking at all of the evidence, to decide what the accused intended to do.

In the case of FDA regulation, since we do not have a mind probe, we establish intent by looking at the words used to describe the product, and the actions that the seller takes with respect to the product. More specifically, with regard to words, obviously promotional claims and labeling that accompany the product are of greatest relevance. But it certainly doesn't stop there. Sometimes sellers can be disingenuous, labeling a product one way, but then extolling the virtues of other uses of the product through social media and other forums.

With regard to actions, the law looks at any actions that reflect how the seller intends the product to be used. Design decisions obviously play a major role in the sense that the design of a product tells a lot about how the designer intends the product to be used. But our focus on actions is not limited to the physical product itself. The law looks at the channels of commerce the seller uses, the customers the seller visits and the professional meetings the seller attends.

If all of this sounds a bit squishy, it is. The intended use is determined by looking at all of these things together to see what kind of picture they paint. And as with anything that involves the English language, there are incredibly fine shades of gray involved. Intended uses are not standardized units of measure. The intended use is whatever the seller makes it to be.

For example, on the one hand, the intended use can be conveyed very generally, or at the other extreme, very specifically. I can sell a scalpel and promote it for use in cutting tissue, or I can sell the exact same scalpel and promote it for use in hernia repairs, together with step-by-step instructions regarding how to perform the specific, intended hernia repair. I can sell a scalpel for use generally with children, or I can sell a scalpel for abdominal surgeries for patients between the ages of 6 and 10. In other words, I can make it whatever I want, and I can make it as specific or general or contoured as I wish.

FDA regulation has to cope with that. It does so by perhaps paying a little less attention to the mechanical divisions between specific wording, and a little more at-

tention to the associated risk. In the example concerning scalpels, even though the physical product is identical in each one of those situations, the risk is not identical. If I take it upon myself in connection with selling scalpels to also provide step-by-step instructions for a particular kind of hernia repair, then really in a sense I am selling that hernia repair procedure (together with my scalpel). In doing so, from an FDA regulatory standpoint, I have taken on the risk of ensuring that the hernia repair procedure is in fact safe and effective when done with my scalpel. If instead I just say that my scalpel cuts tissue, my customers will not conclude that I have validated the use of the scalpel with any particular surgery.

This concept, it turns out, has a radical impact not only on whether certain parts of the HCIoT are regulated, but to what degree. If it is determined that a particular article is a regulated medical device, the next question is: in what classification will FDA regulate it? Medical devices range from low risk tongue depressors to high risk pacemakers, so the law divides all medical devices into three classifications, cleverly called class I, II and III. Class III includes the highest risk devices and has the most demanding regulatory requirements, while, you guessed it, class I is the lowest risk. The intended use determines not only whether a particular article constitutes a regulated medical device, but the classification in which FDA puts the device.

One more aspect of the definition of a medical device is important. The statute says that FDA regulates finished medical devices, as well as accessories to devices and components of devices. Accessories and components are very similar, and in fact a widget can be either one depending on the intended use. The distinction between an accessory and a component is the intended user. An accessory is intended to be sold to and used by the ultimate customer, while a component is intended to be sold to and used by a manufacturer making a finished medical device. If I make test strips for blood glucose meters and I sell them at retail to patients who have blood glucose meters, those test strips are accessories. If I take the same test strips

The distinction between an accessory and a component is the intended user.

and sell them in bulk to blood glucose meter manufacturers for resale with the meters, the test strips are components.

The difference is important, because the regulatory responsibilities differ depending on whether a product is an accessory or merely a component. The obligations are less for components, because FDA puts the regulatory obligations on the finished device manufacturer. If a product is sold directly to end-users as an accessory, there is no one other than the accessory seller to take responsibility for meeting the FDA requirements.

B. Applying that Framework to the Asthma Case Study

With those general rules in mind, it becomes possible to then look at each part of the HCIoT and make a judgment about whether it is regulated. To do so, as just explained, we need to consider whether a particular item is ''intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man.''

That's a very general standard. And to be sure, two people can look at the exact same set of facts and disagree about whether something is regulated. That's why FDA periodically issues guidance to help the public understand how the agency applies that broad standard to specific product categories and specific situations. Unfortunately, however, FDA has not issued much guidance specific to the HCIoT.

Not all is lost, however. In many cases, the rules are quite clear. Inhalers used to deliver the drug are FDA-regulated medical devices. They have been recognized as such for years. But the articles involved in the asthma case study described above take us into some areas where FDA has not, to date, expressed its view as to where the lines are drawn. This is especially true for a category of software called clinical decision support software. As of this writing, FDA has been promising to issue a guidance document on that topic, but has not yet done so. It is the agency's highest priority to do so in 2016.

Another ambiguity that we have been grappling with is the distinction between healthy living on the one hand, and articles intended for the ''prevention of disease,'' which is explicitly part of the medical device definition, on the other hand. In 2016, FDA issued a guidance document that parses the line between wellness and disease. Generally, that document allows product manufacturers to mention certain diseases without tripping the line into regulated territory, so long as the intended use is framed clearly enough to be promoting a healthy lifestyle.

Conclusion

FDA regulates much of the hardware and software used in the HCIoT. At the same time, there could be some HCIoT technologies outside of FDA's reach, depending on how the products are marketed. In the next two articles, we will explore marketing and then business strategies technology companies can use to enter those markets without the cost and delays associated with FDA regulation.

The following tables include a list of the primary components described in the asthma case study, and indicates their regulatory status generally. At a high level, the tables use a red/yellow/green indicator to characterize whether a particular component is regulated (red), may be regulated but there are some open questions (yellow), or not regulated (green). All of the regulatory classifications assume that the manufacturer's intended use for the product is the use described above in the case study.

All of these innovations exist in some form, but they may be in an early stage of development.

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Products Not Likely to Be Regulated

Component	Function	FDA Regulatory Status
1. A smart phone with Bluetooth sold with a software operating system	This would be any generic smart phone on which an app could operate.	Unregulated, so long as the manufacturer does not make any special claims about its suitability for this or any other medical purpose.
2. Various cell phone signal transmission devices such as cell towers owned by telephone carriers	These components are responsible merely for transmitting data from the cell phone to the cloud.	Unregulated.
3. Cloud-based storage software	This software is merely responsible for preserving the data in a HIPAA compliant fashion.	Unregulated.
4. A tablet computer for the healthcare professional to use	This tablet would be loaded with the healthcare professional viewing software, and it would also include standard functionality to allow the professional to communicate with the patient via text.	Unregulated.

Products That Could Be Regulated

Component	Function	FDA Regulatory Status
1. A shirt with embedded environmental sensors	These sensors monitor such things as airborne gases, including ozone, carbon monoxide and nitrogen dioxide, particulates, biological entities such as pollen and other irritants like polycyclic aromatic hydrocarbons, formaldehyde and acrolein. Several technologies are available to do this, including nanosystems and optical sensors that measure scattered light from airborne dust particles to assess their size and composition.	On the one hand, if this were simply marketed without any claims beyond saying that it was for environmental monitoring, the shirt would not be regulated. On the other hand, if the shirt is marketed for people with asthma for use in avoiding future asthma attacks, it would be an FDA-regulated medical device.
2. A wristband set of sensors that measures vitals, and includes an accelerometer	The accelerometer measures the patient's movements, and the vital signs measured include heart rate, hydration, and blood oxygen saturation.	On the one hand, these can be marketed generally for people engaged in athletic training to monitor their vital signs. But if the wristband is marketed as a way to detect early warning signs of an asthma attack, it would be an FDA-regulated medical device.
3. An app that resides on the smart phone	The app is designed to collect data from all of the smart components listed above. The app is designed to then transmit those data to the cloud. The app also includes display functionality to present the collected data and to communicate recommendations received from the cloud.	If the software can be shown to only function as transmission and display of information in its original form, this app might escape FDA regulation. But if the software does anything more than those very ministerial functions, it will be FDA regulated.
4. Software that resides on a tablet for use by the healthcare professional	This software allows the healthcare professional to review the results of the data analytics.	Software that only transmits and displays data in its original form can avoid FDA regulation. But FDA often concludes that this sort of software does more than just transmit or display, in which case it would be regulated.

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Products That Would Be Regulated

Component	Function	FDA Regulatory Status
1. Portable handheld spirometer with Bluetooth capability	Superseding the peak flow meter, this new generation of spirometers can measure the full range of breath functions traditionally done by an office machine.	While it is not certain, it seems likely that these products are class II medical devices.
2. Inhaled corticosteroids delivered via a smart inhaler with Bluetooth capability	These anti-inflammatory drugs help manage asthma over the long-term.	An FDA-regulated drug, together with an FDA-regulated medical device – the inhaler.
3. Short acting beta antagonists delivered via a smart inhaler with Bluetooth capability	These inhaled, quick relief bronchodilators act within minutes to rapidly ease symptoms during an asthma attack.	An FDA-regulated drug, together with an FDA-regulated medical device – the inhaler.
4. A wearable sensor that is stuck to the patient's chest	This sensor measures respiration rate, but also listens for coughing and wheezing sounds.	FDA regulated, because presumably it would be marketed for use by people with asthma to detect early warning signs of an attack. It would be hard to market this as a general purpose wellness product because coughing and wheezing are not part of everyday, healthy living.
5. Cloud based analytics software	The software, which resides in the cloud, would apply algorithms to the data collected for the purpose of assessing both the long-term state of control for asthma, as well as predicting acute episodes of asthma attacks. The software algorithms would be designed to send advisories to the patient, such as recommendations to take either the long-term or short-term medications, as well as recommendations to get away from environmental irritants. The software would also send summaries of both the analysis and the recommendations to the designated healthcare professional.	Likely regulated. FDA will be coming out with new guidelines on clinical decision support software, but this functionality will probably be marketed with claims that the software helps people with asthma to avoid attacks and better manage their condition over time. There is a good possibility that FDA will choose to regulate this sort of software.