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BLOOMBERG LAW INSIGHTS

Marketing Strategies for Technology Companies Wanting to Play in the Health Care Internet of Things *(Part 2 in a Series)*

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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 article, I will share some tips for the avoidance of FDA regulation, not the evasion of FDA regulation.

In a (previous article), I laid out an overview of FDA's regulation of the Health Care Internet of Things (HCIoT). As a part of that, I presented an asthma use case to illustrate the various elements, showing which of them are most likely to be regulated and why. This article will continue to use that use case to illustrate the analysis.

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Subjecting a company to FDA regulation is not for everyone, so this begins by presenting the marketing options for those who have decided to stay out of FDA-regulated space.

In the next article, we will look at business strategies outside of marketing. Further, for those who want to at least test the waters, the third article describes will describe a few entrance strategies into the regulated space that at least minimize the regulatory obstacles.

A. The Binary Misunderstanding

Some technology 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, they think a company is either a manufacturer of medical devices and subject to the full panoply of FDA requirements, or they're not, and therefore, are not subject to any FDA restrictions. But that's not an accurate depiction.

Instead, companies should think of FDA regulation as a continuum. The diagram below illustrates the two extremes and a few of the cases in between.

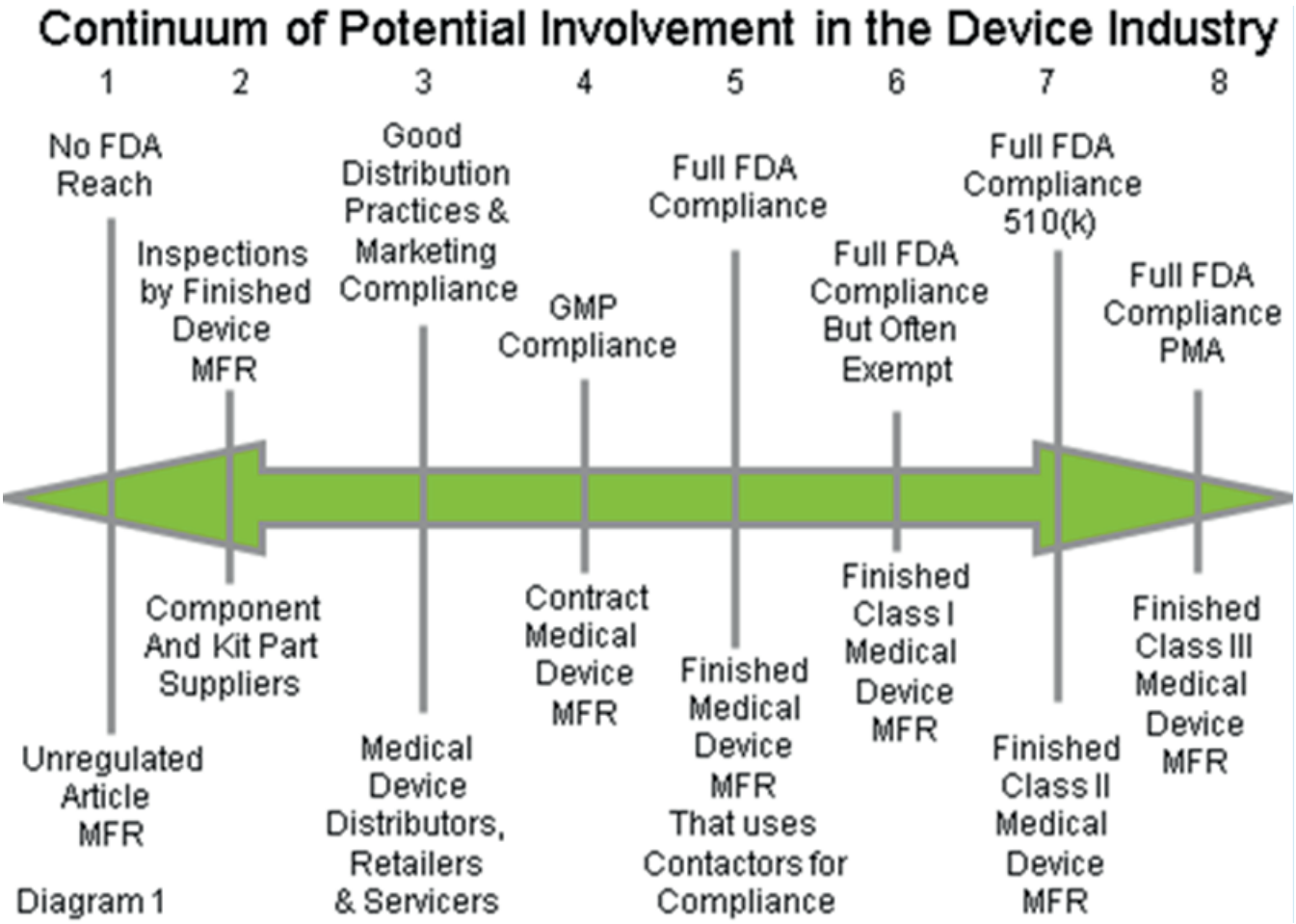

Diagram 1

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 above, devices are classified into three different classifications, and the types and burdens of FDA regulations vary considerably. Class III medical devices, which 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 parts of the asthma case study described above might fall into class I or class II.

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 Health Care Internet of Things ("HCIoT") 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 products 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 pos-

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sible relationships before talking about ways to reduce or avoid FDA requirements, and exactly what that means.

B. Options For Staying Out Of FDA-Regulated Territory But Nonetheless Profiting

1. Limit Marketing Claims And Features To Unregulated Purposes With respect to marketing, unregulated purposes include any purpose which does not meet the definition of a medical device, or in other words it is not intended for use in the diagnosis, cure, mitigation or treatment of disease or other condition in man. Obviously, that category is wide open. Neither hardware and software used for purely communication purposes nor products used for business purposes are regulated. While it covers the waterfront, I'd like to call out two categories in particular, though, which seem relevant to the asthma use case. Those two categories are products used for general wellness, as well as products which have general uses not limited to medical functionality.

a) Wellness Claims

FDA recently has been looking for ways to lighten the regulatory burden on digital health, and this is especially true for those developing solutions for chronic condition management and treatment for such diseases as asthma. The FDA published a new guidance document on ''General Wellness: Policy for Low Risk Devices'' in July of 2016. Under this guidance, FDA does not plan to regulate digital health solutions and other products that make ''an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.''

More specifically, FDA intends not to regulate products intended ''to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, may help:''

1. ''reduce the risk of certain chronic diseases or conditions;'' or

2. ''living well with certain chronic diseases or conditions.''

Elsewhere in the guidance document, FDA explains that only low risk products fall within this unregulated category. As you can see, that guidance has the potential to impact the regulatory treatment of items sold to help people with asthma, for example, live healthier lives. FDA packs a lot of nuances into that framework, but a deep analysis of it is beyond the scope of this article (see Bradley Merrill Thompson, *FDA Releases from Regulation Certain Digital Health Solutions Aimed at Chronic Disease.*).

The point is that FDA has decided not to regulate products used to live a healthy life in the face of chronic diseases such as asthma, and that opens up a whole slew of possibilities for technology companies wanting to enter the Internet of Things as exemplified by the asthma use case. Remember that the design of the product in many cases does not definitively determine its regulatory status, but rather the promotional claims play a major role. So if your company can reach its commercial objectives without claims that fall within FDA jurisdiction, and if the product has legitimate and material wellness related uses, you might be able to avoid FDA regulation by avoiding medical claims.

What does it mean to limit promotional claims to wellness claims? Let's consider this item from the asthma case study.

Component	Function	FDA Regulatory Status
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.

The question is—can this wristband be sold as a wellness device, unregulated by FDA? To answer that, we need to look at the functionality and determine whether there are legitimate and material wellness uses for which the product can be sold.

The only way to figure that out is to go function by function.

■ *Accelerometer*. It seems commonly accepted that accelerometers are useful to people who want to track their exercise levels. They are routinely sold and used for that purpose, without any apparent FDA objection.

■ *Heart rate*. Heart rate is commonly used by people who exercise to determine the vigor with which they exercise, and indeed exercise enthusiasts closely monitor heart rate in order to bring it up and down repeatedly during exercise. It appears that the science confirms the value of that regimen.

■ *Hydration.* Hydration is a bodily function that needs to be managed during exercise. It's not that hydration improves the effectiveness of exercise so much as the fact that hydration is something that needs to be managed to stay healthy. But that function is too general in nature to trigger FDA jurisdiction.

■ *Blood oxygen saturation.* Here, we come very close to crossing the line into FDA jurisdiction. There would have to be a reasonably widely held view that blood oxygen monitoring serves a general wellness and/or exercise utility before FDA would permit nonmedical blood oxygen saturation monitors onto the market. It turns out that FDA has recently determined that pulse oximeters, while on paper are class II medical devices, belong in enforcement discretion *when promoted for wellness purposes*. Frankly, the lawyer in me wants to argue that treating the product as a class II medical device is nonsense, in that if the product is truly intended for used for wellness, FDA has no jurisdiction claim over the device at all. But FDA seems to be offering up some sort of compromise to address this emerging wellness market. FDA seems to be trying to deregulate this product while not losing control altogether. Some companies, and in particular developers of mobile apps, seem to be trying to fit within this category of pulse oximeter, even though mobile apps may not fit the technological definition of a pulse oximeter. It is also not clear whether enforcement discretion in this context just means that a 510(k) is not required, or the product is also exempt from all FDA regulation including the quality system regulations and adverse event reporting, I suspect FDA means the former and not the latter. A pulse oximeter not intended for wellness, but instead used for traditional medicine, is treated as a traditional class II medical device.

The bottom line is that it appears a vendor of this wristband could produce and market the product without complying with FDA regulation, so long as the vendor limits its claims to wellness use, including athletic training. More specifically, the vendor of the wristband would not be able to make any claims that even suggest that its wristband is suitable for use in the asthma case study described above. That may be too big a limitation for a vendor to live with, and may cause them to miss out on an important marketing opportunity.

b) General Use Claims

Apart from limiting the claims made to wellness purposes, technology companies have the option of limiting their claims to general purpose claims, not specific to medical device functionality. Let's look at another part of this HCIoT.

Component	Function	FDA Regulatory Status
A smart phone with Bluetooth sold with a software operating system	This would be any generic smart phone on which the app in item 8 could operate.	Unregulated, so long as the manufacturer does not make any special claims about its suitability for this or any other medical purpose.

Here, the way to avoid FDA regulation is through the generality of the claims made by the smart phone manufacturer. Hypothetically, let's call the phone a mePhone. If the cell phone manufacturer makes no medical claims about the mePhone, the cell phone manufacturer will have no FDA responsibilities. It is the generality of the claims the mePhone manufacturer makes that keeps it out of FDA jurisdiction. The product is a smart phone, which serves as a general computing platform on which apps may operate and through which telephone conversations can be had. It includes functionality such as a camera, a speaker and a microphone. Those hardware elements can be used for probably a gazillion different purposes.

To be sure, to make its point that this hardware and software platform has a gazillion different purposes, the manufacturer can provide a broad range of examples of those purposes that may even include a medical purpose. But in the context of listing a gazillion different purposes, such incidental mention of a medical purpose would not be enough to cross the line into FDA-regulated territory.

So those are two ways that individual products can be sold into the HCIoT without the burden of FDA compliance. Articles that are sold for a wellness purpose, and are only promoted for that purpose, as well as articles sold for general purposes, do not need to comply with FDA requirements.

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 bringing enforcement actions against everything coming out of the IT industry that technically falls into FDA-regulated waters, but someday I suspect FDA will get more active in this space.

What makes this interesting is that although the vendors cannot promote their products for FDA-regulated intended uses, the vendors of other articles in the asthma use case scenario could promote their products for use with these general purpose articles. For example, the following app developer could promote its app explicitly to be used on the mePhone, even though the mePhone is not a regulated medical device.

Component	Function	FDA Regulatory Status
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.

So even if that app ends up FDA regulated because it is intended to perform FDA regulated functions, the mePhone's unregulated status would not be impacted. In the hands of the mePhone's manufacturer (remember it is the manufacturer's intended use that governs), the mePhone is an unregulated article. And that remains true even if some other seller intends their medical device to be used with the mePhone.

To be clear, in this scenario, the app developer bears a burden of proving that the mePhone is and will continue to be a suitable computing platform on which its app can run. This gets pretty complicated when the app developer has absolutely no control over changes that the mePhone manufacturer might make in its phone. So either the app developer has to enter into a contract that allows it some measure of control over the mePhone—which is typically unlikely if the mePhone has a wide variety of other uses—or the app developer needs to develop a risk management strategy for continuously evaluating the mePhone to detect any compatibility issues.

As I said, there are limits to this strategy of marketing general use articles. 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 and actions.

Finally, to employ this strategy, the maker of the equipment must be duly *diligent* in avoiding making medical claims. My emphasis in that sentence is on the word diligence. That means the company 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 personnel. Specifically, the vendor of the wristband needs to be very careful to instruct its employees to stay on message, ensuring that the wristband is only promoted for the wellness use. Likewise, the vendor of the mePhone needs to instruct its employees to only promote the broad, general use of the phone.

2. Develop Components For Incorporation By A Medical Device Manufacturer As explained above, the difference between a component and an accessory is the intended user. The exact same article can be either a component or an accessory depending on to whom the manufacturer intends to sell the article. The reason is pretty simple: when selling a component to a finished product manufacturer, that finished product manufacturer can

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and should take responsibility for all regulatory compliance. If the same article is sold directly to a consumer, the accessory manufacturer is really the only one who can take responsibility for FDA compliance.

Let's look at an example from the asthma case study.

Component	Function	FDA Regulatory Status
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.

While that product as a whole cannot be marketed without triggering FDA regulation, a company could develop the electronic sensor, and sell that sensor to a medical device company that combines it with an adhesive patch before selling the finished product.

FDA frankly doesn't care how big or how complex or how critically important the component is to the finished device, the agency is still, by law, supposed to impose the regulatory responsibilities on the finished device manufacturer. Component manufacturers were exempted from the regulatory requirements because FDA well understood that finished device manufacturers need the latitude to purchase components from a variety of manufacturers without burdening those component manufacturers with FDA responsibilities. Among other things, policymakers feared that to impose regulatory obligations on component manufacturers would lead to shortages of important components. Thus, it was determined that extending the regulatory obligations to reach component manufacturers was unnecessary, so long as there was a finished manufacturer to take responsibility for the full range of compliance.

And that is indeed the key. There must be a finished device manufacturer who is not only taking responsibility for the regulatory requirements, but in a position to ensure that the product itself is safe and effective. This means there must be a plan in place for that finished device manufacturer to work with its various components suppliers to ensure that the components are meeting the specifications required for inclusion in the finished device and otherwise are meeting quality objectives.

Thus, while component manufacturers are exempt from direct regulatory obligations, they are burdened with whatever obligations the finished device manufacturer imposes by way of contract. Indeed, in negotiating the contract, it is the obligation of the finished device manufacturer to impose whatever is in fact necessary to ensure that the components meet the specifications and quality objectives. If, for example, that assurance cannot be obtained by the inspection of incoming products at the finished device manufacturer, other steps are necessary. This can include periodic inspections of the component manufacturer by the finished device manufacturer. This falls under the general rubric of supplier controls of the finished device manufacturer.

The bottom line is: a company can develop a very complex and valuable widget, and so long as that widget is combined with another component by a finished device manufacturer, the widget manufacturer is not directly subject to FDA requirements. From an economic standpoint, therefore, the valuable widget can be priced quite high, and indeed may account for the vast majority of the cost of the finished device, and still not be directly subject to FDA requirements in the hands of the widget manufacturer. FDA is not troubled by that so long as there is a finished device manufacturer that is taking full responsibility for FDA compliance, and is in a position to assure the safety and effectiveness of the finished device.

3. Sell A Service, Not A Product This strategy is sometimes risky, but sometimes it can work. FDA's jurisdiction is very clear: the agency regulates products. There needs to be 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 medical professionals 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 (laboratory developed tests or LDTs). 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 (already regulated by states) rather than makers of devices or drugs. I should mention, though, that both LDTs and compounding have proven to be controversial and FDA is threatening to extend regulation into certain high risk products even though the companies that make them claim to be selling a service.

Conceptually, it may be possible to position certain health care offerings as services, rather than the sale of products. But be mindful that this is not simply converting outright sales to rentals, or selling software as a service. That makes no difference to FDA. Instead, the difference between a service and a product is the predominance of the human element. Services are performed by humans, whereas FDA regulates products and machinery no matter how they are provided. Accounting services sold by an accounting firm are indeed services because the essence of the value is created by human accountants even if those accountants use computers to perform calculations and send email. Call center software, on the other hand, if sold on the basis of software as a service, is still a product-based model because it is the software that is doing the work, even if aided by human beings who fix glitches in the software as they arise.

Let's take a look at how this might play out in the asthma case study. Specifically, let's consider the software that the health care professional would use to make judgments about the best way to manage patients suffering from asthma.

Component	Function	FDA Regulatory Status
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.

Let's say that this software is developed by doctors. If these doctors wish, it is possible for them to develop the software for their own use in managing their own pa-

tients. And indeed, while it's not completely free of doubt, it's likely that the doctors could greatly expand the service they offer by creating, for example, a call center through which they remotely manage patients with asthma, for example, on a large scale. Set aside for a minute all of the health care regulatory issues like state licensing and telemedicine issues. If we only look at the FDA issues, the doctors could set up a process through which the information from the various gadgets all comes to them for analysis by their software, and the doctors themselves make treatment decisions and recommendations that they communicate to their patients. If all of that happens within the confines of the practice of medicine, it is likely that FDA would not assert jurisdiction over the software that the doctors create for their own purpose. The principal service is the doctor's decision-making in the management of the asthma patients. The software plays a subservient role to the human decision-making. While not free from doubt, this is likely to be a service, and indeed the practice of medicine, and not the commercialization of a medical device.

As you might guess, if a particular operation starts to look too much like manufacturing a product, FDA will regulate it. My only point is that health care professionals have a certain latitude to provide services to their patients without FDA intrusion. People have the ability to sell services, and so long as any products are merely incidental to the human service, FDA would not have jurisdiction.

Conclusion

The intended use is a pivotal concept that determines FDA regulation, and frankly is far more a determinant than the physical characteristics of the product itself. By carefully managing its intended use, technology companies can make products useful for the Health Care Internet of Things without subjecting themselves to FDA regulation.

But beyond marketing, technology companies can adopt business strategies that also help to manage regulatory risk. In the next article, we will examine business strategies such as partnering with medical device companies so as to minimize the regulatory obligations on the technology company.

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