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Business Strategies for Technology Companies Wanting to Play in the Health Care Internet of Things *(Part 3 in a Series)*

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Generally speaking, FDA regulates many aspects of the HCIoT, but not all. Discerning which portions FDA regulates and which they do not generally revolves around the intended use of the product when sold by the manufacturer.

In a previous article (*see previous article*), we examined the present state of FDA regulation of the Health Care Internet of Things (HCIoT). Building on that, in a second article (*see previous article*) we analyze various marketing strategies that could reduce the scope of FDA regulation. There are, however, limits on just how much careful marketing can limit the scope of FDA's reach, so this third article examines business strategies that will reduce the burden of FDA regulation on those portions that the agency oversees.

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We begin by considering various scenarios through which a technology company can partner with a medical device company to avoid taking on the regulatory obligations. We end this series by analyzing scenarios where the technology company can enter the regulated space, but do so in a way that minimizes the regulatory burdens. Throughout this series, we've been using a concrete example of an asthma case study that makes use of various typical elements of the HCIoT.

A. Partner With A Traditional Drug Or Device Company

While FDA regulations make it appear pretty complicated, the definition of a manufacturer for purposes of determining FDA regulatory responsibilities is actually pretty simple. The manufacturer for purposes of FDA requirements is the entity which both (1) controls the specifications and (2) controls the claims. 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.

At a very simplistic level, collaborations on product development fall into one of two buckets: (1) working jointly or (2) working separately. Let's look at each approach.

1. Joint Collaboration

Joint collaboration refers to a situation where two parties—in this case a tech company and a MedTech company—decide to work together perhaps as equals, and indeed to collaborate very closely at the product development stage. Let's look at the software example.

Component	Function	FDA Regulatory Status
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 then 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.

Let's say the tech company brings with it a very high acumen in the development of software, including such things as machine learning. Its people are on the cutting edge of software development.

Let's say the MedTech company does not have that same level of software expertise, but does have enormous clinical expertise in the area of asthma. Let's say it has a physician advisory of some of the leading thinkers in the area of asthma management, as well as significant databases and other intellectual property on what works and what does not in the management of asthma.

So the two decide to work together at a very operational level in the research and development of this software, that will be comprised of algorithms and machine learning capabilities that will help the software make the best recommendations possible with regard to the management of people with asthma.

Who bears the FDA regulatory responsibilities? The fact is the two companies have a wide degree of latitude to structure their relationship so that the MedTech company—if it is the wish of both of the companies—takes on the regulatory responsibilities. To accomplish that, as a starting point, it will have to be clear through their collaboration that the MedTech company has control and ownership of the final specifications of the product, and the claims to be made about the product.

If the parties can agree on that, the rest of the commercial relationship will not significantly affect the FDA responsibilities. For example, FDA does not care how much a co-venturer earns. Further, FDA doesn't care about the allocation of the intellectual property that might come out of the collaboration. The tech company might end up owning the patent on new innovations, while the MedTech company still controls the specifications and claims to be made concerning the resulting product. Indeed, it really doesn't even matter who sells the product in the marketplace. Obviously, companies use distributors and others to sell products without those distributors becoming responsible for the regulatory compliance of the manufacturer. It doesn't matter who manufactures the product, although obviously there is little traditional manufacturing when we are talking about software. With laser like focus, what matters is the two factors: control of the specifications and the claims made.

2. Subservient Collaboration

This is probably an overly fancy reference to the case where the tech company agrees to work for the MedTech company, not as peers, but as a servant. These sorts of collaborations are honestly much easier to analyze, because the dominant party typically bears the regulatory responsibilities.

As a broad statement, a MedTech company can hire a tech company to do anything the MedTech company needs. This can include research and development, manufacturing, marketing: really anything. And in each case, the regulatory responsibilities typically remain with the MedTech company. As already explained, that's true so long as the MedTech company retains control over the product specifications and the claims made about the product.

i. Contract Manufacturing

For example, in most cases, a contract manufacturer makes the product specified by its customer. That's true even if the contract manufacturer produces a finished product and drop ships it to the ultimate purchaser on behalf of the specification owner. And it's true even if the tech company designs the product. So long as the MedTech company calls the shots on the final specifications and claims, it is the MedTech company as the specification owner that has the FDA regulatory responsibilities. FDA looks to the specification owner for compliance, even if the specification owner never even touches the device.

This control rule is also the basis for organizations such as distributors and retailers to pass regulatory re-

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sponsibility 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.

ii. Contract Development Work

In the asthma use case example, one scenario is for the tech company to bring certain intellectual property and design capability to the smart inhaler project.

Component	Function	FDA Regulatory Status
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.

It would not be unusual for a manufacturer of a ''dumb'' inhaler that includes the necessary plastic components to seek out the help of a tech company to add the electronics in support of its smart strategy. If the tech company takes on the task of developing sophisticated electronics for the inhaler, the tech company does not directly take on the FDA obligations, except whatever the inhaler company imposes by contract. Thus, the tech company can provide all sorts of design services without direct FDA responsibilities. The inhaler company might need the tech company to observe certain process and documentation requirements to meet the inhaler company's obligations under FDA's design controls, but that would be a contractual obligation on the tech company, not a direct legal obligation from FDA.

3. Ambiguous Collaborations

Over the last several years, I have read a dizzying array of corporate agreements that provide for various kinds of collaborations 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.

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. They must also cooperate in the event of a recall. 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. Although a component is exempt from the quality system requirements, it still falls within the regulatory definition of a medical device.

B. Options For More Directly Entering Regulated Territory

1. Start With A Class I Product With Limited Regulatory Obligations

In the FDA regulatory world, there is a well-established strategy for new entrants generally referred to as ''crawl, walk, then run.'' That strategy refers to the practice of entering the medical device industry by taking on the lowest risk category products first, and then moving up into moderate and perhaps high risk products after the company gets comfortable at each stage. In regulatory terms, this means starting off with a class I medical device, then going to class II and then if appropriate, class III.

This does not necessarily mean different physical products. As explained above, FDA regulation turns almost entirely on intended use. So a company can start with a product and intend that customers use it for only a low risk use, and thus the product will be regulated in class I. Then, either with the existing design or through product modifications, expand the claims and therefore the intended use into moderate risk areas, and ending up in class II.

Consider product number four from the asthma case study.

Component	Function	FDA Regulatory Status
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 order to avoid future attacks, it would be an FDA-regulated medical device.

For the first generation of the device, where the company basically wants to start to get some revenue from the product and work out all of the technical glitches, the company may want to avoid health-related claims altogether. To do that, the company would have to intend that shirt be used for some nonmedical purpose, for example, monitoring air-quality for purposes of environmental research. Maybe there's a small market where the company could sell this for use by environmental inspectors as they walk around power plants. It would need to be a legitimate market, and all of the company's marketing strategies would need to be focused on that use. From a sales and marketing standpoint, the company would need to go to environmental detection tradeshows and visit environmental air inspection companies.

Then, let's say the company decides it is ready to enter the FDA space, and the company is prepared to en-

sure that the shirts are made in compliance with the FDA quality system. The company would also need to be prepared to register its facility and report any adverse events that the company becomes aware of. So the company wants to market this as a class I medical device.

I don't want to get too technical about the FDA classification process, but for this strategy to work, there has to be an existing product on the market like it. The existing product does not need to be exactly like the new product, but the existing product needs to serve the same general purpose and use the same general technology. So the company might look around to see whether there are products, for example, that are already on the market that serve a general purpose of detecting contaminants in the air.

Here, the case study breaks down a little bit, because FDA doesn't currently have an available classification for general use air pollution detectors. Parenthetically, FDA does regulate air cleaners with claims for either particulate or bacterial cleansing for health-related purposes (21 CFR 880.5045 and 21 CFR 880.6500) but does not yet have an existing category for air pollution detectors for a medical purpose. So the first company to market a product in this particular category would have to ask FDA to create a category, which frankly is a bunch of extra work. But at least in theory, FDA would probably be willing to create a category for general purpose air detectors perhaps in class I.

Then, in theory, with no change in the design of the product, the company could decide to make more aggressive claims that would put it in class II. An example of a more aggressive claim would be statements that the shirt is useful in managing asthma, and indeed can help the patient avoid asthma attacks by providing an early warning sentinel system directing the patient to stay away from asthmatic triggers.

To make such a claim, the company would have to develop evidence using patients with asthma to demonstrate that the shirt actually detects those pollutants which are triggers of asthma in a defined population, and alerts the patient early enough that the patient could actually avoid the onset of asthma symptoms. As with my class I example above, presently, a specific classification for products in this category does not exist. But at least in theory, a company could request FDA to establish one, arguably in class II. After the category is established, new entrants into this category would probably need to file a 510(k) to demonstrate that their products are substantially equivalent to other products in this category. [*Editor's note: Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers to notify FDA of their intent to market a medical device at least 90 days in advance.*]

This case analysis is simply to illustrate the concept that within a given product design, a company can gradually escalate the claims, and gradually take on additional regulatory burdens. The company doesn't have to, if it doesn't want to, immediately go to market with a class II medical device.

2. Contract Away The Regulatory Work, But Not The Responsibility

Even if a company markets what is admittedly a medical device and controls the specifications and the promotional claims so that the company is clearly regulated by FDA, that doesn't mean the 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 the development, manufacturing and marketing of medical devices on a contract basis 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 on the work associated with complying with FDA regulations. There are regulatory consultants who can quite ably prepare premarket submissions. There are contract manufacturers who specialize in producing products under FDA quality system requirements, and there are other consultants who can help bring the specification owners' own 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 do it for you or help you do it.

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

3. Create A Limited Purpose Health Care Subsidiary To Limit The Scope Of The Quality System And Other Requirements

Without trying to be pejorative, think of FDA regulation as a virus that needs to be contained. Then, think through how best a company can use corporate structures to limit the scope of FDA regulation on its operations. In tandem with creating separate corporate forms, the company will need a relatively clear delineation between those operations that are subject to the quality system, and those that are not. In addition to limiting regulatory risk, this separation might also be an opportunity to limit reputational risk to the company's brand. In the table below, I have outlined some of the pros and cons of creating a separate corporate structure to own and operate the medical device operations.

As an example, let's look at the handheld spirometer.

Component	Function	FDA Regulatory Status
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.

Let's say a tech company makes all sorts of handheld consumer electronics. The company decides that it has several technological innovations that would allow it to make an even better, more sophisticated and perhaps smaller and cheaper handheld spirometer. But the company, a large and established one, does not want to put its entire franchise at risk as it enters the medical device market.

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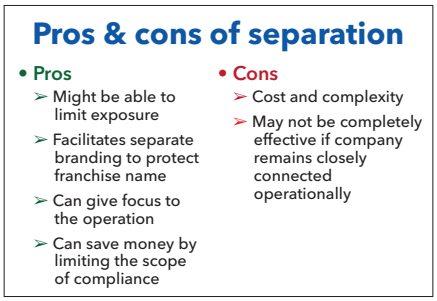
This tech company may decide to create a separate, dedicated subsidiary to finish the design work for the spirometer, and then to produce it.



If a company decides to pursue this, though, the company should be aware that separation might prove to be complicated. One of the most heavily regulated aspects under the quality system is the design control process, but figuring out how to separate R&D in a meaningful way might be difficult. Generally, the research side would not need to be separated, but the development side would. Further, just like any divorce, the two companies must separate the assets including the plant, equipment, intellectual property and records. All of the records associated with the quality system must belong to the regulated medical device corporation. In addition to assets, the actual manufacturing processes will need to be separated. It is possible though, to use one company as a contract manufacturer for the other, but that means the contract manufacturer is subject to the quality system. People and governance need to be separated, keeping control at the strategic level at the tech company without destroying the separation. If the separation is not sufficient, the regulatory requirements could carry over to the mother ship.

Conclusion: The Trade-Offs

Throughout this three-part series of articles, we've examined various options that technology companies have to either avoid or at least minimize FDA oversight. As in all things in life, none of these options is cost free. They all require some form of compromise. In some cases, they may limit the upside marketing potential for the products the company is selling. In other cases, they may require sharing profits with corporate partners. Some options allow getting to market quickly, while other options require more patience.

Technology companies need to sort through these options to figure out what is the best fit for their particular company culture, as well as their market strategy and ambitions. One size will not fit all. But the good news is that there are a range of approaches, and hopefully technology companies that see opportunities in the HCIoT can find a good fit.