Should mHealth Companies *Want* FDA Regulation?

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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.

This article is the fourth in a series of seven planned articles about FDA regulation of mHealth. The series started off by explaining the scope of FDA regulation, and then the second and third articles explained how companies could comply with FDA regulation in the cell phone accessory and software app fields. With that basic framework behind us, this article 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--

1. Along the bottom the sequence of steps necessary to produce a product, and
2. In the rows at the top the overhead necessary for the firm to function.

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.

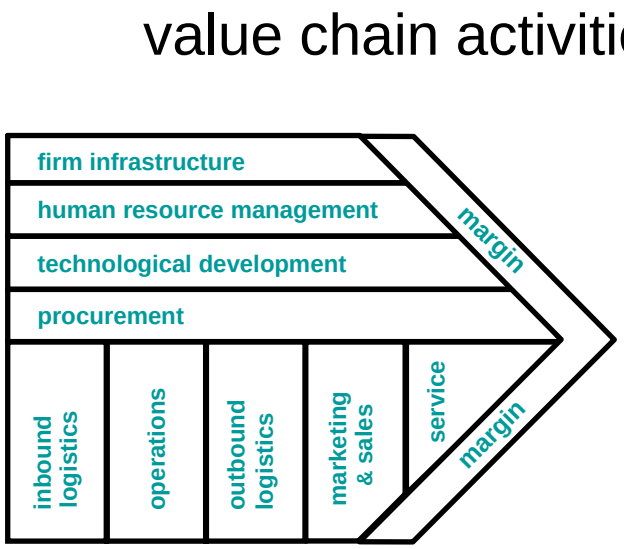

Diagram 1

source: Michael Porter, competitive advantage

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. 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.

FDA impact on value chain activities

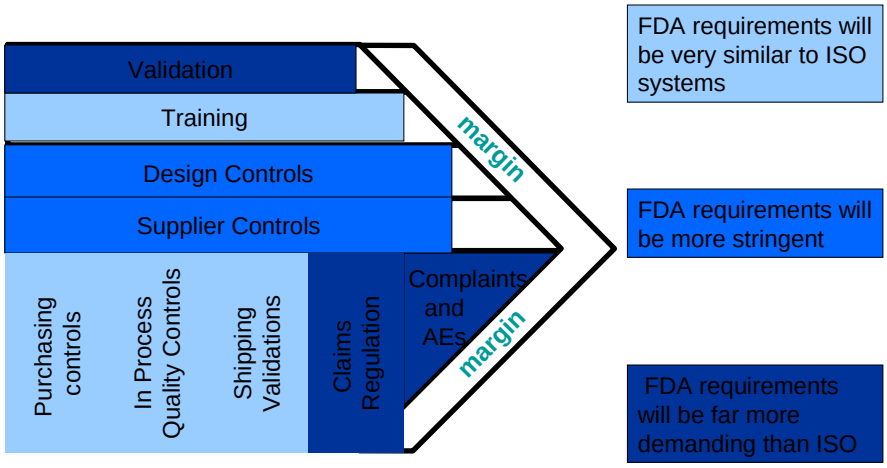

Diagram 2

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

1. 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.

2. 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” 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.

3. 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.

4. 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.

5. 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.

6. 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:

1. Impose added cost.
2. Lengthen lead times in product development.
3. Add complexity.
4. Can be difficult to implement from a cultural standpoint for a company unaccustomed to that environment because they require discipline and rigor.
5. 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.

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.

five forces: impact of FDA regulation

Diagram 3

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.

In Diagram 3, I also indicate that suppliers have considerable power for the simple reason that qualifying suppliers can take quite a bit of time and effort. So once a supplier is qualified, the manufacturer will have an incentive to stay with a particular supplier. Further, some companies are not willing to supply inputs to the medical device industry for perceived risk reasons related to product liability, reducing the pool of potential qualified suppliers.

Finally, and this is perhaps the most important point, companies that dive into the FDA-regulated waters often find they have greater leverage in the sale of their products. Companies that do not

seek and obtain FDA clearance for products that serve a regulated need often must be merely suppliers to a regulated manufacturer, or avoid regulated claims altogether. Thus, perhaps instead of selling to hundreds if not thousands of customers in the medical marketplace, the company is completely dependent on negotiating with a single or perhaps a handful of regulated manufacturers. The company further has little ability to promote any unique virtues of its product. Unless it has some intellectual property protection, the company's products may be relegated to commodity status.

Thus FDA regulated status can have a significant, positive impact on the company's competitive status and profitability.

An additional Plus and Minus of FDA Regulation of mHealth

On the plus side, FDA regulation can serve as a validation of the safety and effectiveness of the product category, effectively expanding the market. The risk that the public will reject a mhealth product as "unsafe" is a clear and present danger. Why? The mhealth network comprises a myriad of interoperating technology presenting many points of failure. Software is among the trickiest of products to validated, and conflicts between programs are commonplace. So FDA regulation could be a welcome vote of confidence for the consumer and greatly assist in market development.

On the minus side, what if FDA does not do its job well? Successful regulation is clear and sensible regulation. Unfortunately, presently many of the rules for device interoperability are unclear, and may in fact disfavor attempts at seeking interoperability. Further, in the first three articles of this series, I outlined several ambiguities in discerning the limits of the scope of FDA regulation. Compounding matters, the whole framework for regulating devices is undergoing significant change due to complaints that FDA has been too lax in approving new devices, and it is too early to predict where that reform will come out. This uncertainty in the FDA's position is itself a barrier to enter the mhealth market in that it increases the cost of doing business, and makes it harder for companies to secure needed investment. The seventh and last article in this series will address this uncertainty, and offer some thoughts on where FDA regulation is headed.

Conclusion

As explained at the outset, I've taken a tremendously complex topic and dealt with it at a high level. As to whether a particular company should take the plunge into FDA regulated territory, in classic legal speak: "It depends." For an individual firm to figure out whether entering FDA-regulated space makes sense requires detailed analysis of the company's individual strengths, weaknesses and competitive advantages (that is its value chain), the markets of interest and the competitive dynamics of its industry.

But the point of this article is that companies ought to consider the whole picture, and not merely stop their analysis out of fear of a somewhat opaque and difficult regulatory system. Literally thousands of companies have entered this regulatory arena successfully. Further, it's not all in or all out. The regulatory scheme includes important nuances. Companies have many choices in selecting the optimal position for their products within varying levels of FDA regulation. Of

course, there also are ways to avoid FDA regulation altogether, but naturally those come with diminished opportunities. All that will be explained in the next article. So stay tuned.