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Opinion: Smart Device Firms (and Investors) Unwind Regulatory Risk

by Steve Silverman

Investments in medtech firms have been drying up, with some speculating the reason lies in the degree of regulatory uncertainty inherent to the field. In this opinion piece, consultant and former FDAer Steve Silverman describes how device companies can help investors clarify the risk.

Investment and acquisition is a key strategy for new medtech firms (and some that have been around a while). This means getting funding from outside parties and even selling whole operations to investors like venture capital funds.

Less Investor Funding Means Device Firms Must Do More

But there's been a decline in medtech investment. One explanation is the murkiness of regulatory risk – this risk is often opaque and hard to calculate. By "regulatory risk," I mean the regulatory requirements and costs to market a medical device (more on this later). Regulatory risk spans the device lifecycle, from premarket review to marketing and sales.

It's not news that defining and quantifying regulatory risk is tough. Several years ago, McKinsey & Company noted that "*healthcare tech is complex, making it difficult to understand the industry and identify good assets*." And there are many, many stories of device firms with good products and good execution still struggling to survive.

Given these challenges, the question is what should medtech firms seeking investment/acquisition do?

First, smart firms clarify regulatory risk *for* investors – they don't make investors do the work themselves. No doubt, investors understand and track all kinds of risk. But regulatory risk covers review paths (think 510(k) clearance and premarket approval (PMA)), product testing, timelines, costs, pitfalls, and more. Mastering these factors requires special knowledge and perspective, often gained from years of MedTech experience. There's no reason for investors to know this

stuff, let alone be able to quantify it.

But understanding regulatory risk is “bread and butter” for device firms. Strong firms have the people, perspectives, and experience to define and calculate regulatory risk. Firms that can’t do this raise doubts about whether they’re good investments.

Questions that Device Firms Must Answer

Device firms must paint a full regulatory risk picture. This includes:

What regulatory pathways is the firm following (i.e., 510(k), PMA or de novo)?

- Here’s a cautionary tale showing why this matters: A device firm with a strong product misunderstood the regulatory path to bring its product to market. This meant cash constraints and delayed timelines. The firm approached more than 50 investors, all of whom passed.

- Plus, the nature of a firm’s go-to-market strategy matters. Some acquired firms appeal to investors by using PMAs to bring their products to market. This means patented technology and other market-entry barriers for competitors. Other firms leverage the 510(k) process, making it easy for investors to tuck their products into portfolios.

- Where are the firm’s products in the review process? Products on different pathways face different evidentiary requirements, stage gates, and timelines.

- What is the expected review timeline?

- What are the expected costs?

- Are there possible derailers or disruptors? Derailers include regulator challenges to evidence and review pathways, while disruptors include novel approaches to new technology (like digital) and evidence types (like real world evidence).

For firms that are selling devices:

- Have regulators (U.S. and elsewhere) inspected the firm and what was the result?

- If remediation is required, what are the timing and cost effects?

- Did the inspection lead to regulatory action, such as an untitled letter or a warning letter? What are the steps and costs to respond and what’s the timeline?

- Are there other regulatory derailers or disruptors? Answering this question includes looking beyond US Food and Drug Administration; For example, a leading medtech company recently canceled a $200 million-plus acquisition after global regulators, including the US Federal Trade Commission, objected to the deal.

- What is the firm's regulatory strategy? For example, will the firm adopt best-quality practices or instead focus on basic compliance, adjusting if regulators raise concerns? Both strategies are defensible and each has advantages. Firms must be ready to explain why they chose a strategy and how its advantages (and drawbacks) make sense.

Why It Matters

Answering these questions is crucial. Bringing a device to market costs from tens of millions to more than $100 million, depending on factors like the regulatory path followed. Investors must understand these costs. Investors also must know where a device is on the regulatory pathway, how much it cost to get to that point, and what it will cost to get across the finish line. And the device review timeline must be clear.

This starts with marking the device on the timeline and accounting for remaining steps, evidentiary requirements (like product testing), and regulator demands. The sum is a regulatory review map, including the steps and time needed for a decision.

Likewise, investors must understand the postmarket status of firms actually selling devices, including whether regulators have inspected the firms and what were the results. The answers mean a lot. Regulatory violations are a big deal – fixing them often takes months and lots of money (six figures and up). And bad inspection findings are minor compared to FDA warning letters; the risk from these letters is existential. So, investors must know the difference between a warning letter and bad inspection findings, including the scope, timing, impact, and cost of these results.

That's a lot of information for investors to gather and process. But to be clear, this isn't their responsibility alone, or even their responsibility primarily. Device firms are better positioned to identify and explain regulatory risk, from premarket review to postmarket oversight. Smart firms describe and quantify this risk for investors. These calculations show expertise, reliability, and strategic and tactical insights. Investors prize these factors when making a deal.

Steve Silverman is the president of The Silverman Group, a consultancy that serves medical product companies on regulatory, strategy, and policy issues. Steve's professional experience includes extensive time in senior FDA roles. At the FDA, Steve directed the CDRH Office of Compliance, where he led device-quality initiatives, engaged Congress and the press, and guided the office's reorganization.