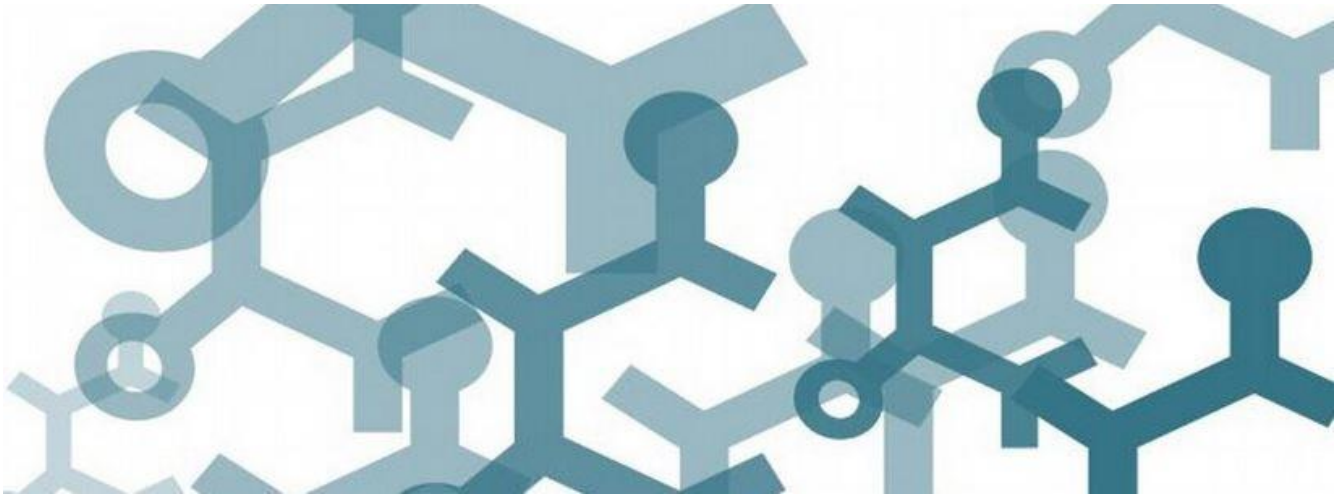

Reimbursement and Selling into the Medical Marketplace

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A couple of weeks ago I facilitated a discussion with a variety of entrepreneurs about reimbursement strategies in medical devices and diagnostics. Reimbursement is how a doctor, or hospital, gets paid for the use of a device, therapy or diagnostic service that companies sell. The opportunity to speak about this subject had special meaning for me as I was once part of a startup whose investors and management did not anticipate how important reimbursement would be. Of course this was a long time ago in the late 1900's when the awareness of reimbursement was not at the level it is today. But I think my particular story is worth telling. We sometimes learn more from our mistakes than we do from what went right. By definition, this makes me pretty smart by now.

Back in the late 1980's I was busy working as an inventor and designer of medical equipment for various research laboratories in hospitals in the NYC metropolitan area. I had teamed up with a group in Brooklyn that did theatrical special effects. They sometimes needed somebody to design an electronic gadget, a service I would provide. In return I got an office in an old soap factory and access to a bunch of machine tools I could use to build my equipment. As it turns out, this business was located on Bridge Street in what is now known as the DUMBO neighborhood. Before the business incubators were there and before the coffee shops, it was a “different” neighborhood back then. One morning we found police lines cordoning off the empty lot adjacent to our building. Officers were examining the morbid contents of garbage bags used by gangs to dispose of parts of erstwhile gang members who were “made redundant” or were otherwise not appreciated by their buddies. Those were exciting times.

While working in DUMBO I was contacted by a group of scientists and neonatologists, who knew of my work doing digital signal processing of cardiopulmonary signals. They told me that if I could come up with a way to calibrate a whole-body flow-through plethysmograph in real time, they had investors to back a new company. I put together a team of two other programmers, an electrical engineer, a

mechanical engineer, QA and manufacturing and the support technicians to deliver. We worked very hard for four years on our product. As engineers, we were extremely proud of our creation, focusing on performance, elegance of design and leading the way in clinical information technology. None of us knew thing one about selling products in the medical market place.

What resulted was the very first bedside real time clinical information system that recorded the complete cardiopulmonary profile, and also allowed the user to enter laboratory results, blood gases and even annotate the clinical record with events so that views of trends could show before and after treatment data. It was a thing of beauty. To quote King Crimson, “no matter how we broke it down, it remained consistent.” Now, some 20 years later, neonatologists tell me that this product remains ahead of the current state of the art in 2013. The patent on the technology is probably the most often cited prior art in the field of respiratory care.

What happened?

We went out to sell it and neonatologists loved it. But the product was expensive: it needed two computers and an entire warming bed for premature babies. Since it retailed for over $50,000 the neonatologists needed to charge for the use of the device but there was no diagnostic related group code they could use to make a charge! What do I mean? There was no Medicare sanctioned billing code for the diagnosis or therapy so the insurance companies would not reimburse the neonatologist for the use of the technology. What happened then? We panicked, the investors pulled me from directing R&D, since I knew all the key opinion leaders in the industry, and put me out there selling and running the company. But it did no good. The neonataologists couldn't buy something they couldn't use to generate revenue even if it did benefit their patients.

The rest of the story is predictable. The stock market started to go up, the investors were told to dump all non-performing inventory and the company was put into Chapter 7. As an engineer who had spent four years devoted to this product's development, it was devastating for me personally.

What did I learn from this experience? It is not enough to be a good inventor or engineer and think you can go to market with a better mousetrap and expect to be able to attain commercial success. You need to know that your product has either an equivalent predecessor that is already being used and is approved for payment by the payers (insurance companies and medicare) or that you are specifically planning to establish your reimbursement goals before you get to market.

How can you ensure that you have thought through your reimbursement strategy carefully enough to convince potential investors that you will be able to generate revenue when you hit the market? The field is complicated enough that a casual approach to what you write in your business plan and present to others is risky. Your messaging has to be consistent for all of your audiences: investors, physicians and other providers, and payers, including Medicare. Reimbursement is not based on outcomes... it is based on resource utilization and work so if you tell investors that your technology is quick and easy, you may very well be undermining the true complexity of what is being done. Many minimally invasive procedures are, in fact, technically complex to perform, and this sort of message may be difficult to overcome when defining the procedure and device for payment. You never want your device to appear "cheap" or Medicare may agree and only allow a certain level of reimbursement you don't want. So before you go out to shop your business plan, you should be aware of the implications of what you write in regard to reimbursement.

Why is reimbursement such a difficult issue for companies that want to sell goods and services into the medical market place? Too many cooks in the kitchen, and none of them working off the same recipe. Insurance companies want to assure that new technologies are safe and effective and worth the cost, the FDA approves technology irrespective of whether a company can or cannot sell that technology and clinicians push for new technologies they feel will be helpful and through their clinical associations will even lobby for new technology. But all of these activities are happening with independent stakeholders whose interests are not aligned.

As Jo Ellen Slurzberg of JR Associates (jrareimbursement.com) said at a recent Entrepreneurship Lab presentation facilitated (www.elabnyc.com):

> "The medical startup company's management team needs to plan their reimbursement strategy by understanding the relationship between Coverage (the scope of services for which a payer will pay), Coding (the language that describes a medical encounter), Payment (remuneration for services and/or a medical encounter) and an understanding of the economy that describes the health system."

Speaking of the economy that describes the health care system, what if you have a technology that will surely lower the overall cost of care? Won't that be enough to convince hospitals to purchase your device? This is a common question I get asked by potential medical entrepreneurs.

In a recent conversation I had with the Corporate Director of Strategic Sourcing at a large teaching Hospital here in NYC, he said to me (and I quote from memory), "We look for clinical validation in peer reviewed journals, but in the end we also need to convince ourselves." He sited an instance of a consumable that cost $12 versus the established technology which cost $10. The $12 device was promised to reduce hospital-acquired infections. They instituted a three year risk sharing program, whereby the vendor agreed to pay for half the device, the hospital paid the other half and they would track outcomes internally. A Director of Infection Control at another reknowned local hospital (who also requested anonymity) indicated they also require the same type of risk sharing when exploring the possibility of having to pay more for a device that promises to reduce hospital-acquired infections.

That type of risk sharing expense and the time frame to complete an internal study, are a high bar for a startup company. In fact any company trying to establish this kind of efficacy would need to have deep pockets so that they could carry a loss for this amount of time. This means that certain products, unless they promise to generate the large revenues that justify the investment, may not be ideally suited for a startup company to sell, but rather may be suited for a partnership with a large established player already in the market (a strategic partner).

So whether you plan on getting a new reimbursement code, or you are planning on selling to the hospital on the merits of saving them money, you need to have thought through your reimbursement strategy carefully. A specific line item ought to be budgeted in your fore-casted expenditures for developing a reimbursement strategy. Reimbursement should be one of the very first things you are thinking about when you are thinking about starting a company that sells in to the medical market.

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