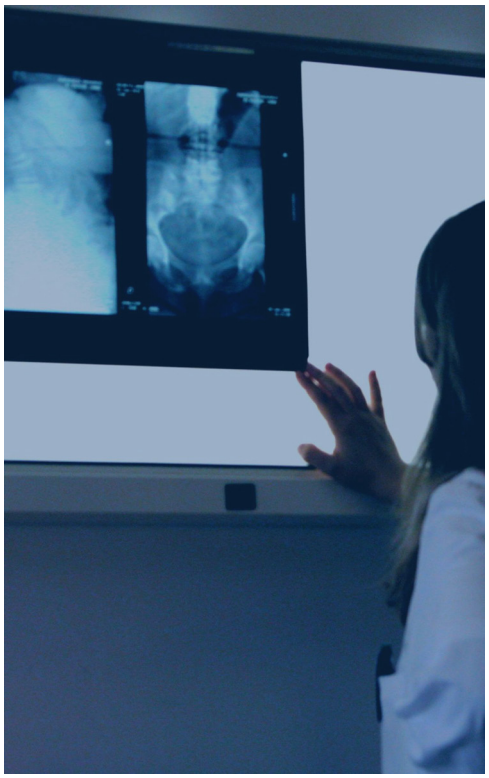
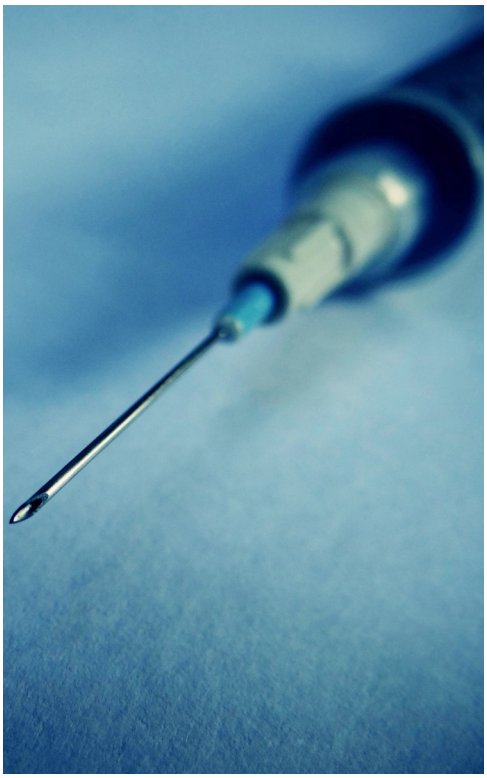
MEDICAL DEVICES

Lessons Learned from Product Marketing Executives





DON'T ASSUME, ASK!

How unquestioned assumptions can imperil medical device success

By Yvonne Nomizu and Jonathan Honiball

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Questioning Assumptions

"The one mistake that seems common to early stage companies is the belief that the idea on the table is so great that it will conquer all obstacles and sell itself." These are the words of a medical device development consultant Derek Richardson, quoted in Med City News.

Alan Czeszynski, Vice President of Marketing and Business Development at medical device manufacturer Oraya Therapeutics, couldn't agree more. "One thing I've learned in this industry is that we tend to be optimistic when it comes to clinical and financial outcomes, when in fact we should question our assumptions. I've learned the hard way to use data more than opinions when it comes to making decisions. Trusting your assumptions can be dangerous."

Czeszynski and Oraya offer a groundbreaking treatment for Age-Related Macular Degeneration (AMD), where a single session of low-level radiation can reduce or eliminate the need for costly, uncomfortable injections into patients' eyes. "We thought that the reduction of injections, and the corresponding reduction of the money and suffering that they represent, would be a game changer for ophthalmologists," he says. But, the industry had a different reaction.

The first dangerous assumption to question is everyone wants to "do the right thing" in healthcare.

"It is unbelievably difficult to change the practice of medicine," Czeszynski says. "If you don't understand the financial and therapeutic incentives for payers and providers, your device, even if it is dramatically superior to existing products, will go nowhere. It can be very frustrating."

Many of the obstacles to product adoption that Oraya came up against were entirely non-medical. One hospital said "no thank you" because it had just adopted an injection based therapy, and it was profitable enough to make up for less profitable procedures. Many physicians were medically and financially comfortable with the status quo and had no interest in considering a new device. In the U.S., doctors and hospitals can ask for large sums to try a new procedure. In Europe, university professors are the gateway to adoption, and many have their own businesses, essentially charging device makers for access to their labs.

"If I had the information five years ago that I have now—about how doctors and hospitals work, want they want, and what will drive them to adopt a new treatment—we would have saved mountains of time, money and stress." The information is out there, Czeszyski says, and it is market researchable. "You can survey doctors and ask, 'if this product comes to your doorstep, what would you do?' You can discover how much better a new product has to be than existing options to win adoption. We learned the hard way."

"We've got two significant challenges," Czeszynski says. "We have to convince providers that they'll make more money while delivering better treatment, and payers that they'll save more money. Each calls for reliable, credible data." When it comes to payers, the information needed is different. The parameters they care about are primarily financial.

Bringing them a bunch of data about the therapeutic outcomes a product delivers will fall on deaf ears. It is critical to understand the economics of the existing treatment and to be able to demonstrate how much financial improvement a new device will deliver.

The IRAY® Radiotherapy System

Dangerous assumption number two is that you know the right clinical trial endpoint and have the right trial population to reach it.

"We had to reduce the number of injections required for AMD treatment by 50 percent to induce physicians to see the net value/impact, but our first trial reduced injections by 30 percent," Czeszynski says. "So we had to dig into the data to identify the best responder group, which thankfully had a 55 percent reduction in injections to maintain equivalent vision. Still, the first study pushed us into a positioning nightmare with customers and regulators, and cost us about a year in the development process."

Often companies are concerned about defining the patient population too narrowly for trials and, in so doing, reduce the potential market for the product. The reality, Czeszynski says, is that device makers need compelling results for any population, just to get the product noticed and to get customers excited. "Once the product is in use, doctors will figure out how to expand the patient pool," he says. "Not having good data puts you in the position having to go to battle with the very people who you want using your product...which is not a good position to be in."

SIDEBAR

Alan Czeszinski's Medical Device Marketing Lessons Learned

- Medical results are just one of many criteria that drive adoption
- Never under estimate the effort needed to change the practice of medicine
- Define the right endpoints and population for clinical trials
- Collect the right data to commercialize
- Have a "Plan B" for every critical milestone
- Invest in the market as early as possible

A third dangerous assumption is you know the path to market.

Oraya spent months discovering—the hard way—that the routes to market can vary from state to state in the U.S., and from country to country as well—especially for products using radiation therapy, which is regulated differently than other technologies. In some places the physicians are the routes to market; sometimes the channels are hospitals, and others, the route goes through universities. At the same time regulations and financial incentives can differ widely for each of these pathways, and pose different barriers to adopting new medical practices.

"We spent considerable time in target markets identifying key stakeholders and charting the conduits and gatekeepers to adoption. Each market is unique, and working this out on our own took a great deal of time and effort," Czeszynski says. When he joined the company - while the European trial was in progress - they investigated the cost and effort of a U.S. market entry and quickly realized that it would be longer, more complex, and hence more costly and risky to approach the U.S. market immediately. For example, Oraya engaged a consulting firm to survey state radiation regulatory requirements and quickly learned that state-by-state differences in radiation regulation could require state-unique strategies, effectively dividing the country into many different markets. Based on this knowledge, Oraya hired a research firm to help them identify the European countries most likely to embrace the product, surveying 12 countries and landing on three viable options. This market-specific knowledge was critical to redirect the company's commercial strategy.

A fourth dangerous assumption is that your projected outcomes will all go as planned.

It's hard to think of an industry more prone to experiencing Murphy's Law—that everything that possibly can go wrong will go wrong. Developing a medical device requires projecting into the future all the issues that might affect the device's success, and build a go-to-market strategy while knowing that it will take years from the initial business plan until commercialization. Company leadership tends to be optimistic, minimizing potential pitfalls, making it all the more challenging to respond to inevitable bumps in the road. "It's a never ending series of surprises," says Czeszynski. "You have to plan for bad outcomes," he says. "The more you can anticipate possible negative events the more you can prevent them," he says.

"We thought medical benefits would sell the product, and that doctors and hospitals would jump on the bandwagon, Czeszynski says. "That didn't happen, over and over again, for a lot of different reasons. The trial population, the plan to launch in the U.S.-- we were set back in each case because we didn't always have a 'Plan B.'" Lesson learned in this case: "It pays to be skeptical," he says. Things will go wrong. People will be wrong. Manufacturers would be well served by investing in market intelligence ahead of time that can help identify obstacles and to develop alternative plans.

Pay now or pay later.

"We like to think we know the answers," says Czeszinski. "We all want to be right. But we won't always be right. Validating our assumptions with cold hard facts is one of the best investments we can make. Which costs more, commissioning a study to figure out drivers and influencers of adoption of a new device, or travelling from country to country, knocking on doors?"

"There is never enough good information," he says. "The problem is getting the budget to get this information early. It's sort of a pay now or pay later equation. When we invested in gathering objective information to inform decisions, we moved faster and smarter. When we didn't, we often suffered the consequences of unquestioned assumptions."

For companies seeking to bring new medical technology to market, objective, quantitative research can fill in the gaps in knowledge that exist all along the marketing pathway, from validating the market need, to understanding all the forces—medical, technical, financial and human—that will influence a product's success. Sound market research can transform dangerous assumptions into actionable information, saving companies precious time and money in the device development process. Studies like market sizing and segmentation, product optimization, user experience, pricing and value assessment, and behavioral influence strategies can deliver data that takes go-to-market strategies out of the realm of opinion and speculation.

However, it is not always easy for a marketer to obtain the market information he/she needs, especially early in the development process when it is needed most. One of the constraints is lack of budget, but time-to-market and belief systems are also factors.

HOW TO MAKE THE CASE FOR MARKET RESEARCH?

Be specific.
Identify exactly what you believe needs to be better understood or what assumption needs to be tested.

Be prepared with numbers.
Bring a rationalized budget and time frame for the project based on competitive bids from professional research firms.

Link research to key investment decisions.
Articulate the adoption levels, revenues or market share upside that the research will promote. Estimate the product R&D investments that will be optimized. Describe the financial and brand risks of not confirming market assumptions.

Focus on the upside for each stakeholder.
Communicate how market/customer/intermediary feedback will help company stakeholders achieve their goals faster or with more certainty.

Appeal to the zeal.
Belief in the product, commitment to the mission and fervor for the initial concept are all motivational and part of the company's success. Link the market research proposal to this zeal and demonstrate how it will support, not detract, from the zeal.

Oraya Therapeutics is a privately held company founded in 2007 that develops innovative and non- invasive therpaies for diseases of the eye, including orayah Therapy for wet age-related macular degneration. Oryah Therpay is commercially avialabe int eh United Kingdom, Germany and Switzerland. Investors include Essec Woodlands Health Ventures, Domain Associates, Scale Venture Partners, and Carl Zeiss Meditec AG. More information can be found at www.orayinc.com.

Pacific Consulting Group (PCG) is a customer insights firm which consults to medical device and other healthcare innovators on market anaylsis, customer adoption drivers and product optimization. With state-of-the art research techniques and technology tools, PCG has superior turnaround times and economic solutions. This agility, coupled with 15+ years life science market research experience, enables firms to make smart, swift decisions leading to faster revenue streams.

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