

Bringing a new medical device to market was a lot easier in the good old days. It was essentially a two-step process. Step one: Develop a product that improved patient care. Step two: Show it to a doctor. If the doctor liked it, you had a winner.

Over the past 15 years, payment issues and increased regulatory requirements have made things a lot more complicated. Today a new device must fit a considerably more complex model in order to be successful in the marketplace. The woods are still full of good (and bad) ideas for new devices; the challenge is picking a likely winner from among the possibilities. Here, in approximate order of importance, are the factors that we consider most critical in evaluating ideas for a new device.

Clinical need

A new product should be something that is really needed. This may seem obvious, but in my experience the failure of many new medical devices is the result of not paying enough attention to this critical requirement.

Bringing a new medical device to market

The challenges of picking a winner

By Curt Miller

I define a clinical need as something that improves the results of patient care and/or the delivery of patient care. The improvement should be significant; marginal product improvements can't justify the expense of product development, regulatory approval, and marketing. In addition, for product buyers, marginal improvements won't justify the expense of changing buying habits and retraining users.

Once a clinical need has been defined, there are other pitfalls. For example, product developers frequently fall in love with a new technology. As a result, they may fail to establish that the problem the new technology addresses is one that is actually worth solving. (This is known as inventing the solution to a problem that does not exist.) This technology-driven approach can also lead developers to develop the most advanced technical product possible, not neces-

sarily the best solution to the problem. The perfect technical product is often too difficult or time-consuming to use.

Some years ago I was approached by product development engineers from a large, well-known company to partner in developing a new system for surgery. The product was useful, but the design required the surgeon to perform experiments "off-line" with the equipment during surgery to optimize its performance. I suggested that surgeons don't have time to experiment during surgery, don't have room in the OR to experiment, and don't usually adjust surgical equipment (other OR personnel do that). I suggested that they design a simple single-use instrument, with fixed output, that would work for most patients—even if that output was not optimized for each individual patient. The engineers went ahead with the original design. The resulting prod-

uct was not accepted by surgeons. It never went beyond its initial trials, and the project was eventually scrapped—along with the company's development investment.

Sometimes developers don't ask the right people. Health care delivery is a team effort. It isn't enough to ask a surgeon about a new surgical instrument without asking the OR supervisor, the physician assistant, the surgical tech, the operating room nurse, the sterile processing technician, the buyer, the hospital administrator, etc. I have seen useful new products fail because they were too difficult to get out of the package, couldn't be easily cleaned, required capital budget approval, or required the hospital to carry too much inventory. Failure to ask questions of the entire team can cause developers to overlook potentially critical shortcomings of the new product.

At Micromedics, we developed a range of sterile single-use instruments for the application of biomaterials in surgery. Surgeons loved the instruments and wanted to use them. But sales didn't really take off until, in consultation with

operating room nurses, we developed a kit of ancillary materials to assist the rest of the surgical team in delivering the instruments into the hands of the surgeon using good sterile technique.

Benefits and payment

Right after clinical need, the most important things to understand are who benefits from the new device and who pays for the new device.

Patient benefits tend to take the form of faster healing, less pain, or better cosmetic results. Providers and third-party payers, on the other hand, like products that save money. The best new devices do both: They benefit the patient and save money. If a new product increases the provider's cost, it will be a hard sell regardless of patient benefit.

Payment issues get more confusing when group-purchasing contracts enter the picture. Under group-purchasing contracts, hospitals are rewarded with discounts for purchasing only items that are on the contract. Under this system, hospitals may pay more for individual products, on the assumption that they are saving money on the total bundle of products they purchase on contract. Thus, there is a disincentive for a hospital to buy a new device "off contract"—even if the new device is a less expensive and better product than a similar one the hospital is already buying.

Another confounding layer of payment issues is third-party payment. The decision to pay for a new device is made by the Centers for Medicare & Medicaid Services (CMS). CMS also makes reimburse-

ment decisions for the private insurers. It is almost impossible for a manufacturer to persuade CMS to pay for a new device. CMS has to get the request from another payer, such as a large health insurance company. Manufacturers face a chicken-or-egg situation: they can't get a decision to reimburse without the support of a third-party payer, but they can't get a third-party payer to support the product without a decision to reimburse. Although there are no guarantees, hiring a consultant with expertise in this area of specialized knowledge can dramatically improve the odds of getting a favorable decision.

Marketing

For most medical device companies, marketing is the second-biggest expense in the corporate budget, right after the cost of manufacturing the product. Clearly, the potential sales of the product must justify the costs of product development and market entry.

Marketing involves awareness and education of potential product users. Our experience is that medical professionals are best persuaded by other medical professionals. Therefore, the best marketing tool is a well-constructed clinical study using the new device, published in a peer-reviewed medical journal. It is also useful to have the support of a product champion in the profession and a well-known institution.

The direct cost to the provider of purchasing a new product is often more than the direct cost of the product it replaces, with the cost benefit coming from some other area such as

reduced use of facilities, labor, services, or supplies. New device marketers should not expect providers to make this cost/benefit calculation. Clear and convincing cost/benefit data are crucial for successfully marketing a new device.

Regulatory approval

Marketing a new medical device within the United States requires the approval of the U.S. Food and Drug Administration (FDA). All new devices are classified by the FDA as Class I (General Controls), Class II (Special Controls), or Class III (Premarket Approval), according to the perceived risk they pose to patients and users. Applications for approval are reviewed by one of 16 FDA panels of experts within the appropriate medical specialty. (Countries outside the U.S. have different regulatory requirements for marketing.)

It is important for a company developing a new device to have a regulatory strategy at the very outset of product development. Failure to properly anticipate the requirements for regulatory requirements for a new device can result in unnecessary cost and delay, or even outright failure to obtain approval.

Litigation/intellectual property issues

Medical devices are among the products most frequently involved in patent litigation. It is estimated that the average cost of patent litigation—win or lose—now exceeds \$2 million. Damages, if awarded, can be much higher. In recent years, for example, Cordis Corp. was awarded \$425 million in damages from

Guidant Corp. and nearly \$600 million in damages from Medtronic and Boston Scientific in litigation over Cordis's vascular stent patents. In 2005, Medtronic agreed to pay \$1.35 billion (that's billion with a "b") in settlement of patent litigation related to spinal fusion technology.

In general, the more successful a new product is, the more likely it is to be copied. It is important to include an intellectual property attorney as part of the product development team to avoid potential litigation and protect the company's product development investment against infringement.

Therapeutic, safety, cost opportunities

Innovative medical devices can benefit physicians and patients by improving both medical treatments and the way they are administered. When a new device is successful, potential benefits to the overall health care delivery system include improved safety and effectiveness and reduced costs. Physicians play a critical part in developing new devices. While the task of bringing a new medical device to market is daunting, time spent overcoming the challenges can be exciting and extremely rewarding. In short, it's well worth the effort. ▣

Curt Miller is co-founder and CEO of Micromedics, Inc., a St. Paul-based developer, manufacturer, and marketer of medical devices. Micromedics was recently named by Inc. Magazine as one of the fastest growing private companies in the country.
