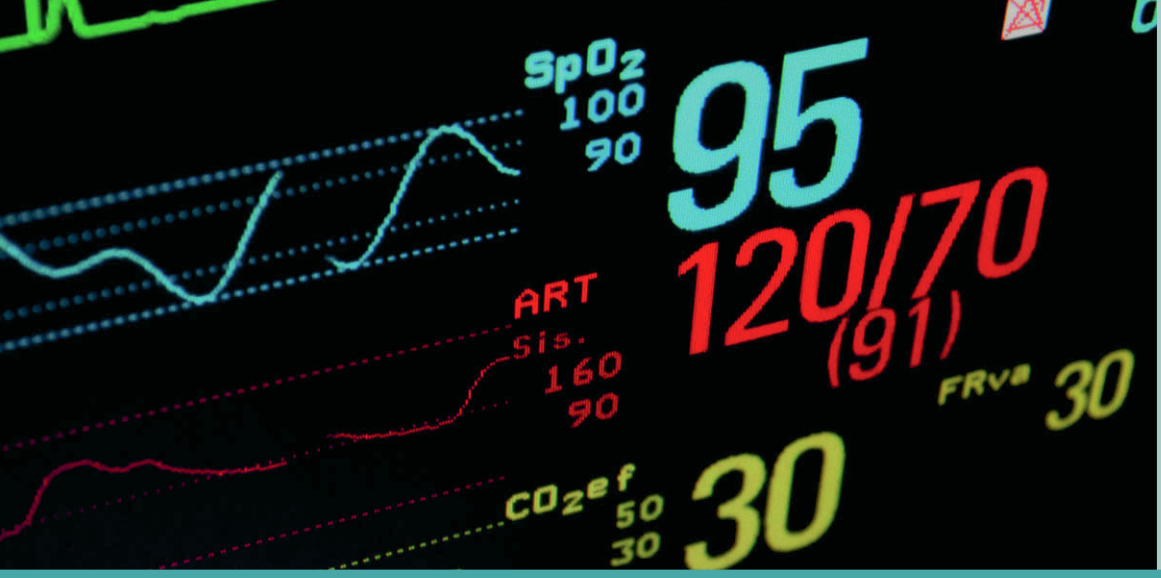

5.7 Marketing and Stakeholder Strategy

INTRODUCTION

Two new medical devices with similar clinical data establishing their safety and efficacy. One is hailed as an important advancement, receives broad professional society support, and is quickly adopted upon its commercial launch. Another is dubbed "experimental," blocked by key opinion leaders, and struggles in the market. Although there are many factors that can affect the adoption of a new technology, the difference in its success or failure often comes down to how well the company develops and executes a proactive, forward-looking, multifaceted marketing and stakeholder strategy. In particular, this strategy must effectively communicate the value of the offering in such a way that the improvement–cost equation compels key decision makers to change their behavior and adopt it.

OBJECTIVES

- Appreciate the importance of more deeply understanding the perceptions of key stakeholders toward a specific need and/or new solution.
- Learn how to develop evidence-based value propositions that clearly articulate an improvement/cost equation that compels key stakeholders to change their behavior.
- Understand how to develop a marketing mix that enables a company to effectively support and implement its value propositions.

The greatest medtech innovations are disruptive. They deliver breakthrough improvements in patient outcomes and fundamentally change the practice of medicine. Yet, the "do no harm" principle of medical ethics supports a conservative culture that can be at odds with the adoption of new technologies. Similarly, unsustainable growth in healthcare spending in many developed countries and the need to extend health services to millions more citizens in emerging economies both contribute to a cautious attitude toward embracing new medtech products. This tension presents a challenge for innovators and requires them to establish and communicate the value of new device technologies in such a way that the information serves as a catalyst for the desired change. A well-designed marketing and stakeholder strategy seeks to accomplish this by compelling key decision makers and influencers into action. Because there are multiple stakeholders in the medical device field who can sway adoption decisions, an effective strategy must be multidimensional and tailored to the unique perspectives of each primary stakeholder group. The essential components of the strategy are the value proposition, along with the marketing mix, which is used to communicate the value of the innovation to members of the target audience and drive them to adopt.

The decisions made in developing a marketing and stakeholder strategy must be supported by important choices related to 5.3 Clinical Strategy, 5.4 Regulatory Strategy,

and 5.6 Reimbursement Strategy (these topics are referenced, but not addressed in detail within this chapter). The marketing and stakeholder strategy also informs the activities described in 5.8 Sales and Distribution Strategy.

See ebiodesign.org for featured videos on marketing and stakeholder strategy.

MARKETING AND STAKEHOLDER STRATEGY FUNDAMENTALS

Early in the biodesign innovation process, through the initial examination of the market, innovators gain a foundational understanding of the **value** associated with a **need** area and the cost/improvement threshold that any new solution would have to meet (or exceed) to cause key **stakeholders** to change their behavior and adopt it. But now that a specific solution has been designed and is under development, the **value proposition** for the new offering can be studied and constructed in much greater detail. Once defined, the value proposition is supported by and implemented via the company's **marketing mix** – the "4 Ps," which traditionally include product/service mix, price, positioning, and place.[1] However, in this text, "place" (or the channels and approach to selling and distributing an offering) is covered in chapter 5.8 Sales and Distribution Strategy. The fourth "P" addressed in this chapter is "promotion" (as shown in Figure 5.7.1).

Revisiting stakeholder analysis

The way in which the value proposition is formulated and then supported by all four elements of the marketing mix directly affects how the new solution is received by the customer. Accordingly, one of the team's first priorities should be to revisit its initial stakeholder analysis. With the new solution squarely in mind (not just the need area that was studied in 2.3 Stakeholder Analysis), the innovators should confirm a solid understanding of the following three factors:

1. Who are the most important stakeholders and who among them will be the critical decision maker(s)?
2. What are their opinions toward the need *and* the new solution; and are these opinions strong enough to cause a change in behavior?
3. Who is most likely to resist the new solution and/or create conflicts between stakeholder groups?

As outlined in chapter 2.3, **cycle of care** and **flow of money** analyses provide a good baseline for identifying relevant stakeholders and beginning to prioritize their importance as decision makers and influencers. Repeating these assessments can be helpful because much more is now understood about the specific solution, how it will be implemented, and by whom. More is also known about regulatory, intellectual property (IP),

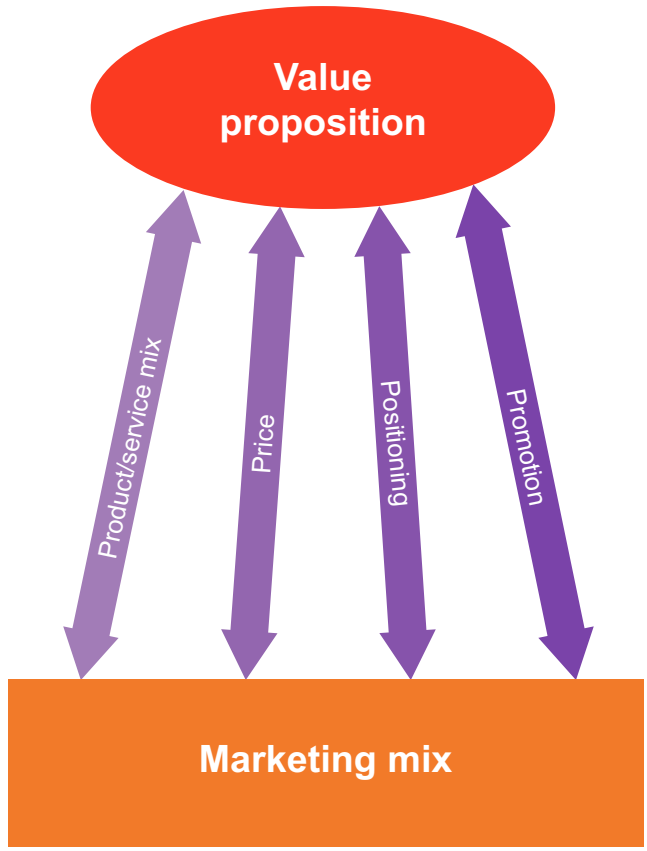

FIGURE 5.7.1
The value proposition is supported by the marketing mix in the creation of an effective marketing and stakeholder strategy.

reimbursement, and clinical issues that will affect adoption decisions. For example, with a proposed solution in hand, the team is now better equipped to assess the impact on workflow with consideration for the detailed practical challenges that may arise. As a result, the cycle of care and flow of money analyses may show different results from the original assessments (which were performed even before the need was clearly specified).

At this point in the biodesign innovation process, innovators are often well served to dive even deeper into stakeholder analysis. Their emphasis should now shift from identifying influencers and decision makers and understanding what drives their behaviors at a high level to gaining an in-depth familiarity with their how, when, and why they are most likely to act and in what ways the company can affect their perspectives and decisions. Innovators can choose from any number of different techniques for gathering this more detailed information that range from relatively simple to fairly elaborate. At one end of the spectrum, they can conduct in-person demonstrations of the offering, "walk throughs," and/or interviews with potential **users**. For example, innovators sometimes set a goal to meet with anywhere from 10 to 100 stakeholders before they begin constructing a marketing strategy. They can also conduct surveys of various types. Market research surveys have been effectively used in other industries, such as consumer packaged goods, for decades, but they are largely underutilized in the medical technology field. Carefully designed and executed studies can yield invaluable insights about stakeholder preferences and beliefs, as well as their likelihood of adopting a new technology or taking another desired action in different scenarios. At the other of the spectrum, innovators may choose to conduct pilot studies that involve a limited commercial launch in a specific geography or with a first-generation product (see the Miramar Labs story below).

The key with all of these methods is to ensure that the right questions are being asked, using an approach that minimizes **bias** and other subjective input that can distort the validity of the data in terms of their applicability to a larger population. Closely related is the issue of identifying respondents who will be honest and objective in providing their responses. Working with an expert in marketing research to design a survey instrument or interview guide and define the target audience can add cost to the project, but it is often well worth the investment.

When conducting primary data collection from stakeholders, innovators are looking for indicators that the new solution will matter enough for the target audience to take notice and change its behavior (incremental enhancements and innovations that respondents describe as "interesting" are often not compelling enough to drive a behavior change). They are also looking for direct input to help them craft value propositions and define a marketing mix that optimizes how these stakeholders will respond to the new offering. The story of Miramar Labs illustrates the value of conducting primary stakeholder research. It also previews how this information can be used to shape an effective marketing strategy.

FROM THE FIELD MIRAMAR LABS

Leveraging market research in developing a marketing strategy

Darrell Zoromski joined Miramar Labs with a background in consumer packaged goods (Proctor & Gamble, General Mills, and S.C. Johnson) and consumer medical devices (Carl Zeiss Vision and Align Technology, maker of Invisalign). At the time, Miramar Labs was in the midst of conducting a **pivotal** clinical study for its novel technology for treating excessive underarm sweat. Axillary hyperhidrosis, a medical condition that causes excessive underarm perspiration, affects 1.4 percent of the US population (or approximately 4 million people). A full 1.3 million individuals report that the condition is barely tolerable and frequently interferes, or is intolerable and always interferes, with their daily activities.[2] Axillary hyperhidrosis is currently treated most frequently with antiperspirants or underarm BOTOX® (botulinum toxin)

FIGURE 5.7.2
The miraDry system (courtesy of Darrell Zoromski).

injections that temporarily block the chemical signals from the nerves from stimulating the sweat glands. However, both of these interventions have low satisfaction rates among patients. Antiperspirants are not very effective, and BOTOX requires multiple injections and lasts an average of seven months before the procedure needs to be repeated. Miramar Lab's technology, miraDry, uses microwave energy to provide a non-invasive, permanent solution to axillary hyperhidrosis. The miraDry system consists of a capital equipment console and a disposable bioTip used to deliver each procedure (see Figure 5.7.2).

As the company's new CEO, one of Zoromski's first priorities was to focus on a commercialization strategy for the technology, including the creation of a detailed approach for marketing to key stakeholders. At the time, the US was Miramar's primary (although not sole) market focus due to its large domestic demand for aesthetic procedures. "Our goal was to be sure that we would be successful in the US when we launched because we expected this market to make up a large portion of our sales and be a critical value driver for the company," he explained.[3]

Through a thorough review of the reimbursement landscape, Miramar had determined that the most practical approach in the US would be to make miraDry a patient-pay procedure. Although there was some chance of securing reimbursement based on several favorable characteristics of the treatment relative to available alternatives (e.g., it was permanent while BOTOX injections had to be re-administered every 7 months), Miramar had reasons to believe that the **payment** rate might be set relatively low, making its technology less appealing to physicians.

With a patient-pay model in mind, the company identified the patients who would receive (and fund) the treatment, as well as the physicians who would purchase the technology and deliver the intervention, as its top-priority stakeholders. To jumpstart the creation of a stakeholder and marketing strategy, Zoromski hired a market research firm to survey a representative sample of individuals in both of these stakeholder groups. "These types of studies are common in the marketing toolkit in the consumer packaged goods industry, where consumers are critical stakeholders in the product or service purchase decision," he said. "But medical device companies can benefit from that same approach, particularly given the increasing importance of consumers in making medical care decisions." According to Zoromski, formal market research studies could take roughly three to six months and $75,000–250,000 to complete, depending on the specific scope and approach, but the information could be invaluable to helping shape a company's marketing strategy.

The patient survey sampled 3,000 prospective users of the treatment from the general US population, aged 18–65. Four percent of the respondents indicated that they had previously been diagnosed with excessive underarm sweating, and another 17 percent were

severely bothered by the problem. This quantitative research was rounded out with qualitative focus groups and one-on-one interviews. The result was a consumer target profile, indicating that individuals in both groups tended to be younger (18–44 years of age), female, career and relationship oriented, and concerned about how they appeared to other people. Zoromski and his team decided to make the 21 percent of individuals who were diagnosed and/or seriously concerned about underarm sweat the company's first patient targets.

The physician survey similarly helped Miramar Labs identify a target audience within the physician population. This survey went to 300 US-based specialists in dermatology and plastic surgery. The results indicated that physicians in both specialties potentially would have an interest in performing the procedure, but the company should start with dermatologists because they had a higher preliminary purchasing intent. That is, both groups saw the value of the proposed solution, but dermatologists were more inclined to take action on the opportunity in the near term. In particular, the study revealed that the ideal target would be dermatologists who had already been treating axillary hyperhidrosis, had other forms of capital equipment in their offices, and were used to paying/charging for disposable product as part of a procedure.

In addition to helping Miramar Labs determine which stakeholders to focus on, the company used the survey to gather input that would form the basis of its value propositions and marketing mix. One technique used in the survey was to present both audiences with a series of benefit statements and ask respondents to rank the ones that were most meaningful to them. The survey also included questions to help with positioning, understanding pricing, and optimal ways to promote the procedure to the target audiences. Once the company had the results, it was ready to go to work on devising its marketing strategy. As Zoromski explained, "The quantitative and qualitative results gave us a more objective basis for constructing our plans. They provided about 50 percent of the information we needed; the other 50 percent came from intuition and experience of the team."

To appeal to patients, Miramar defined a value proposition that focused on a series of simple ideas: the procedure was safe, highly effective, and permanent, all of which make it a good value relative to the cost of other solutions. "Even for patients who weren't receiving BOTOX, we tried to communicate that miraDry would provide strong value compared to even antiperspirants, given the high lifetime cost of coping and dealing with excessive sweat. If you look at how much people spend on antiperspirants, keeping one at home, one in the car, one in an office drawer; dry cleaning expenses to try eliminating yellow underarm stains; and the nice clothing that's ruined after four wears," Zoromski said, "it can really add up. And then there's the emotional cost of embarrassing underarm sweat outbreaks, which are just as important.

For physicians, the value proposition centered primarily on the safety and efficacy of the treatment, and secondarily on the fact that it was a leading-edge intervention that would be a lucrative addition to their practice. As Zoromski pointed out, "In the survey, the physicians expressed that profitability wasn't that important to them [normative response], but we knew that it actually would be based on prior experience and candid one-on-one discussions with physicians. So we had to be a little bit thoughtful about how we addressed this key factor."

With both audiences concerned about safety and efficacy, Miramar Labs recognized that its **clinical trial** data would play an important role in supporting its value propositions. When the company completed its pivotal clinical trial to support its **510(k)** application to the **FDA**, the results demonstrated that the procedure had an 89 percent efficacy rate after one month, but then declined and stabilized at 70 percent over time. Together with the R&D team, Zoromski decided that they would work on doing better than 70 percent, even though many dermatologic procedures deliver efficacy in that range. This would ultimately deliver more satisfied patients and

physicians, and differentiate Miramar Labs from other "share of physician chair" competition. Diving into the clinical results, they ultimately discovered that physicians in the trial were missing some sweat glands during treatment, which was having a negative impact on the effectiveness of the procedure. By making some adjustments to how the technology worked, Miramar Labs was able to address this issue and provide long-term, stable efficacy of over 90 percent.

In terms of setting a price, Zoromski acknowledged that this decision required some "complex analyses." Specifically, the team had to reconcile (1) patient willingness to pay with (2) physician's willingness to pay and (3) the financial return required for Miramar Labs to become a viable, sustainable business. Using data from the survey as one input into the equation, the company ultimately determined that, for a high level of efficacy, consumers would bear a total price of approximately $3,000 for the two visits necessary to receive the treatment. By comparison, BOTOX injections, which were only covered under certain insurance plans, cost $1,000–$1,500 for up to 30 injections in a single visit to achieve temporary results. For prospective patients not receiving any medical treatment for their condition, Miramar Labs created a calculator that would enable them to estimate the cost of their "coping mechanisms," such as deodorant and dry cleaning bills. "miraDry was a great value if you were using BOTOX and not getting reimbursed, but still a good value for those who were simply coping with the problem," Zoromski said. In the survey, the company had tested different pricing scenarios with physicians that involved either a higher cost for the capital equipment and a lower cost for the disposables or vice versa. In the end, Zoromski and colleagues determined that the "sweet spot" was to charge approximately $50,000 for the capital equipment and $350 for each consumable (for a total of $700 per patient across the two visits). The company also confirmed that this pricing scheme compared favorably to other in-office procedures being performed by specialists in the target audience. With these prices, Miramar Labs would achieve a reasonable gross margin over time that would allow the company to fund the amount of marketing and sales required to reach its customers while creating a profitable business that is attractive to investors and sustainable in the long run.

Going back to the quantitative and qualitative survey data, the take-aways around how to position miraDry were also helpful to the company. For example, the Miramar Labs team learned that while physicians were excited about the fact that the technology was new and innovative, and that it operated on microwave technology, this same information scared many patients. This caused the company to use the term "microwave energy" only with physicians and refer to "electromagnetic energy" when interacting with patients. Another issue related to the concept that the treatment permanently prevented underarm sweating. To the team's surprise, patients reacted negatively to this terminology, reporting that it made the procedure seem irreversible. However, when the company talked about the treatment being "lasting," this was perceived as a major benefit in patient's eyes, even with patients acknowledging that "lasting" means roughly the same thing as "permanent." "Very subtle differences in wording actually can make a pretty significant difference in how appealing you are to your target group," Zoromski commented.

From a promotion perspective, the survey and qualitative research also revealed important information about the best ways to communicate with patients and physicians in the company's target markets. With patients, establishing a strong online presence would be key. "We knew that the web was going to be our most significant area of focus because it's a cost-efficient way to get a lot of information out. Consumers, especially the younger, female, image-conscious consumers who are our target, start with the web," Zoromski described. The company began by developing its own robust patient-centered website and then established a presence on other sites that its target consumers would perceive as credible, such as WebMD.

To promote miraDry to physicians, Miramar Labs similarly invested in building a strong physician-oriented

website. The company also built a strong network of key opinion leaders (**KOL**s) who would act as advocates for the procedure. Zoromski noted that the company's physician advisory board ended up being helpful in this regard, as well. "In addition to advising us on our clinical approach and how physicians will perceive the offering, they also spoke to some of their peers about miraDry," he said. "So they provided another credible way for us to raise awareness." Other aspects of its promotion efforts to physicians included presentations and a strong presence at trade shows and conferences directed at plastic surgeons and dermatologists, publishing clinical data in **peer-reviewed** journals, authoring white papers, and conducting some limited advertising in specialty trade journals. The company also employed a small direct sales force and a team of clinical specialists in the US to help target and train physician customers.

With both consumers and physicians, Miramar Labs realized that early adopters may make a purchase decision quickly, but the majority would require multiple "touches" to move them through the conversion funnel. A web-based lead management program was established for both stakeholder groups to provide topical updates and relevant information to those expressing any interest in the miraDry procedure.

Outside the US, Miramar Labs intended to expand into other countries with large aesthetic products markets, such as Japan, South Korea, and Brazil. Accordingly, it was working on commercialization plans in these other geographies in parallel with its US marketing strategy. However, given the importance of the US market to the company in terms of its overall size and prominence, Zoromski and team decided they would benefit from gaining some fast commercial experience prior to the US launch. They conducted a comprehensive analysis of the other regions of interest and determined that Japan would be the best location to validate their approach to marketing and their commercial assumptions. One of the main reasons they chose this market was that they could move quickly and begin importing the device for direct sale by physicians without first having to seek regulatory approval by Japan's Pharmaceutical and Medical Device

FIGURE 5.7.3
Zoromski (left) with one of the company's early customers in Japan, Dr. Hiroyuki Kanamaru (courtesy of Darrell Zoromski).

Agency (**PMDA**).[4] Over the course of approximately 12 months, Miramar representatives interacted with Japanese physicians and patients and observed how the company's value propositions and marketing mix were received (see Figure 5.7.3). Although the company made a handful of adjustments to address unique factors and preferences in the Japanese market (e.g., placing more emphasis on odor reduction versus excessive sweat; targeting the plastic surgeons who were more likely to treat axillary hyperhidrosis than Japanese dermatologists), the commercial test resulted in rich learning and also helped stimulate early revenues. Most importantly, Miramar Labs confirmed its approach: physicians performed twice as many procedures as the company had originally modeled and the technology was able to command a higher price than initially planned.

Reflecting on the experience in Japan, Zoromski encouraged other innovators to consider running commercial experiments. "Before you move into your primary market, get some fast learning," he advised. "If you're wrong, that's fine. You've only failed on a small

scale and can rethink the business model and the marketing approach. And if you're right, that's even better. Just keep accelerating your commercialization."

In terms of creating an overall marketing strategy, he also underscored the value that can come from conducting a well-designed market research study. "Figuring out how to commercialize a B2B2C [business to business to consumer] offering like ours is complex," Zoromski said. "You really need to understand what's in it for each stakeholder, who the influencers are, who the decision makers are, and what are the most important benefits they're seeking. How should you talk about those benefits? And what language should you use to do it?" The advantages of getting this information directly from the source are significant, he added, "Because small differences in your approach can make a big difference in your commercial success. There's no one perfect way to do this, but a combination of quantitative research, qualitative research, and experience-based intuition is a pretty good recipe."

Importantly, not all market research has to be as extensive (or expensive) as the Miramar Labs example, especially during the early stages of a start-up business. Many innovators have successfully used online survey tools (e.g., SurveyMonkey) to collect preliminary user feedback at a fraction of the cost of a professional market study. One Stanford Biodesign team even placed an inexpensive classified ad in a parenting magazine on the topic of children's night terrors and received more than 500 responses. Again, the key is to carefully prepare so that the right questions are asked in a manner that minimizes bias and maximizes the validity of the data in terms of its applicability to a larger population.

Developing value propositions

Value propositions are central to convincing stakeholders to change their behavior and adopt a new technology or offering (recall that value propositions directed at **payers** were introduced in chapter 5.6). In marketing, a value proposition refers to the sum total of the improvement that a company promises to a customer in exchange for payment (or other value transfer).[5] Another way to think about a value proposition is as a marketing statement that summarizes why a customer should adopt a particular product or service. This statement should convince a potential customer that the new product or service will add more value or better solve a problem than other competitive offerings at a reasonable price. Again, in today's value-oriented environment, it is not enough to offer an incremental improvement at a price that it marginally more (or even less) than available options.

Importantly, the improvement offered by a new solution must be perceived as compelling enough to overcome the entire collective cost of making a change. For customers in many situations, this goes well beyond the price of the offering and includes the cost of aligning other stakeholders around the new technology, making a purchase decision, and then implementing the required modifications to standards of care and established workflows to put the new solution into practice.

Companies almost always create value propositions for the key decision makers involved in making a purchasing decision. However, it is important to keep in mind that many health-related solutions involve multiple decision makers and require multiple value propositions as a result. For example, in the Miramar Labs case, the company needed a unique value proposition to influence the physicians who would purchase the technology and perform the procedures, as well as another to target the patients who would elect to receive and pay for treatment. If the company eventually decides to seek reimbursement for the intervention, it will then need to develop value propositions that resonate with the public and private payers.

In addition to decision makers, innovators should pay special attention to the individuals or groups that can help or hinder the adoption of the solution. These

secondary value proposition can be devised to help activate other stakeholders as advocates for the offering or to attempt to minimize their resistance to the solution if it may negatively affect them in some way. Again referencing the Miramar Labs example, the company may need to develop value propositions (and a marketing strategy) to anticipate and address potential concerns among the members of physician professional societies in dermatology and plastic and reconstructive surgery.

A value proposition is closely related to the **value estimate** that the team developed as part of 2.4 Market Analysis. However, it is much more specific (addressing the solution, not just the need), comprehensive (taking into account more detailed information about the solution and factors related to its market entry, such as regulatory, IP, reimbursement, and clinical issues), and actionable (based on a more thorough understanding of the target stakeholders and what drives them). As a result, it is a more useful tool for preparing for commercialization and anticipating stakeholder responses.

Recall that the treatment landscape charts developed in chapter 2.4 plotted the available solutions in a need area in terms of their general efficacy and cost (see Figures 2.4.1 and 2.4.2). The development of a value proposition directly builds on this work. First, innovators must choose the existing treatment that their solution is most likely to displace. The cost and efficacy of this treatment becomes the baseline against which they can construct the value proposition for the new solution. Keep in mind that, in this context, the term "efficacy" is used as a proxy for almost any attribute of value not specifically related to cost (e.g., quality, patient satisfaction, waiting time to diagnosis). Similarly, the notion of "cost" can reflect cost to the system, product unit cost, or even time of procedure, which is a proxy for labor cost per patient.

As shown in Figure 5.7.4, there are three viable quadrants in which a value proposition can exist: a solution can offer (1) higher efficacy at a higher cost; (2) lower efficacy at a lower cost; or (3) higher efficacy at a lower

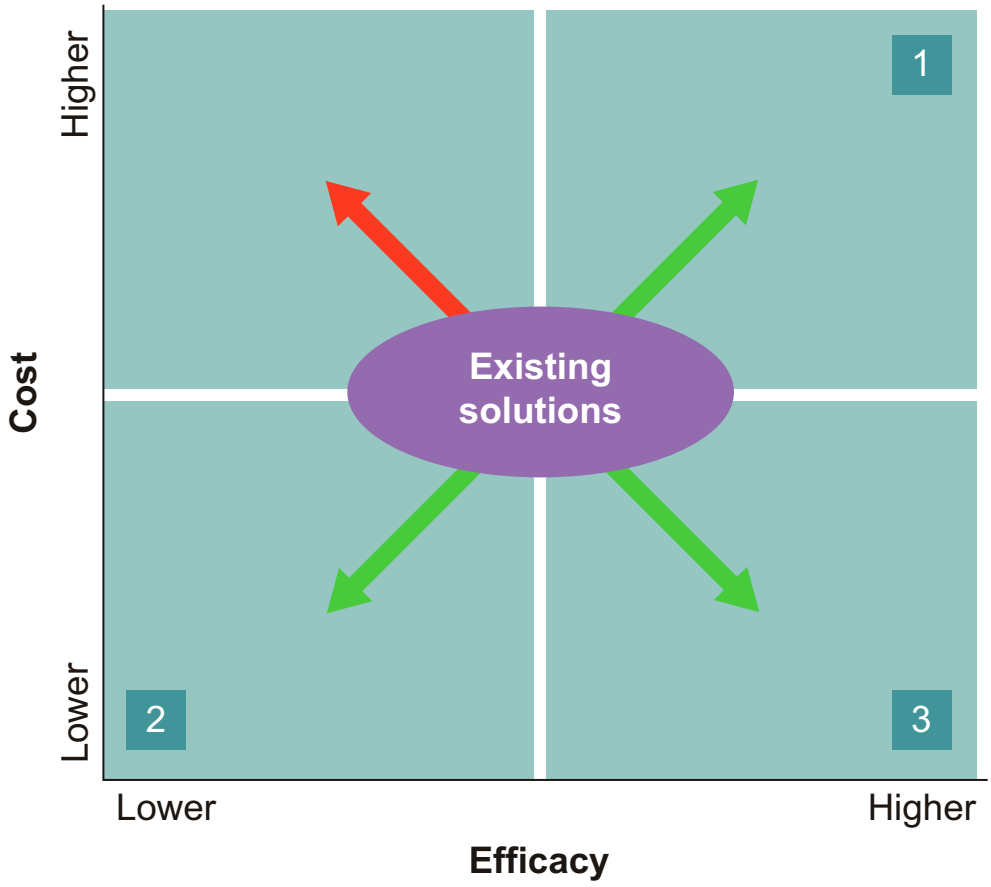

FIGURE 5.7.4
Value propositions help communicate how a new solution is positioned relative to available treatments.

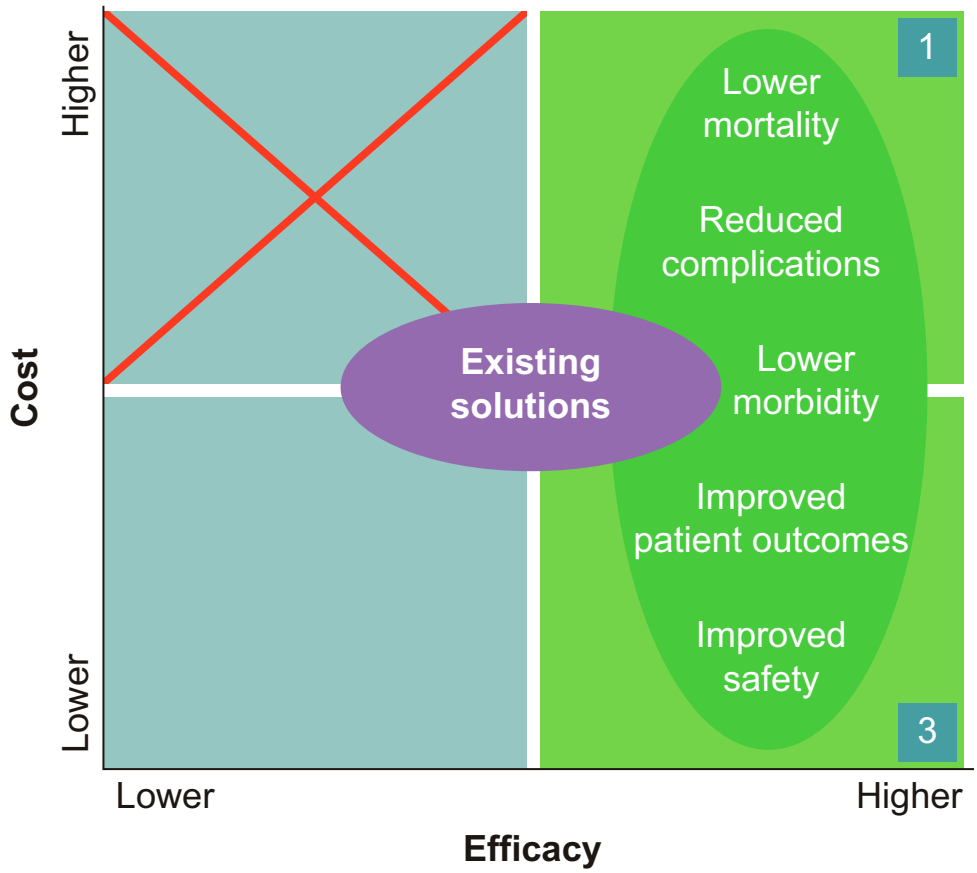

FIGURE 5.7.5
Innovators can differentiate solutions in quadrants 1 and 3 from existing solutions based on the improvements in efficacy that they offer.

cost. Solutions in the upper and lower right quadrants (#1 and 3) compete on the fact they offer better efficacy than existing solutions. Figure 5.7.5 outlines the types of improvements that innovators might highlight in their value propositions for these offerings.

Offerings in the lower quadrants (#2 and 3) compete on their ability to offer a solution at a lower cost than available alternatives. Lower cost offerings tend of reflect one or more of the improvements outlined in Figure 5.7.6.

Importantly, solutions that can be mapped to quadrant #3 offer a particularly powerful dual advantage in that they promise to deliver improved efficacy at a lower cost than the benchmark. Given the current focus of all healthcare stakeholders on optimizing value, solutions in this zone are now often perceived as offering a stronger value proposition (although the extent of the improvement in efficacy must still be sufficient relative to the reduction in cost to warrant a behavior change).

A few examples help demonstrate how this approach translates to actual products (see Figure 5.7.7). Consider the case of stents for treating coronary artery disease, which would appear in upper-right quadrant #1. As described in 2.1 Disease State Fundamentals, angioplasty was introduced as a less invasive, lower-risk alternative to coronary artery bypass (CABG) surgery for treating coronary artery disease. However, restenosis occurred in 30–40 percent of patients within 6 months of the procedure as the body sought to heal the artery. For these reasons, many patients required repeat angioplasty procedures or CABG, which resulted in increased risk for the patient and added cost for the healthcare system. Device manufacturers first began marketing bare metal stents (BMS) in the US in 1992 to hold open the artery, prevent it from recoiling, and reduce the rate of longer-term restenosis. This new technology improved the efficacy of the treatment by reducing complications and the need for repeat procedures, but added approximately $1,600 per stent to the cost of an angioplasty procedure.[6] When drug-eluting stents (DES) were launched in the US 10 years later, they were intended to displace BMS by further improving efficacy rates. For example, head-to-

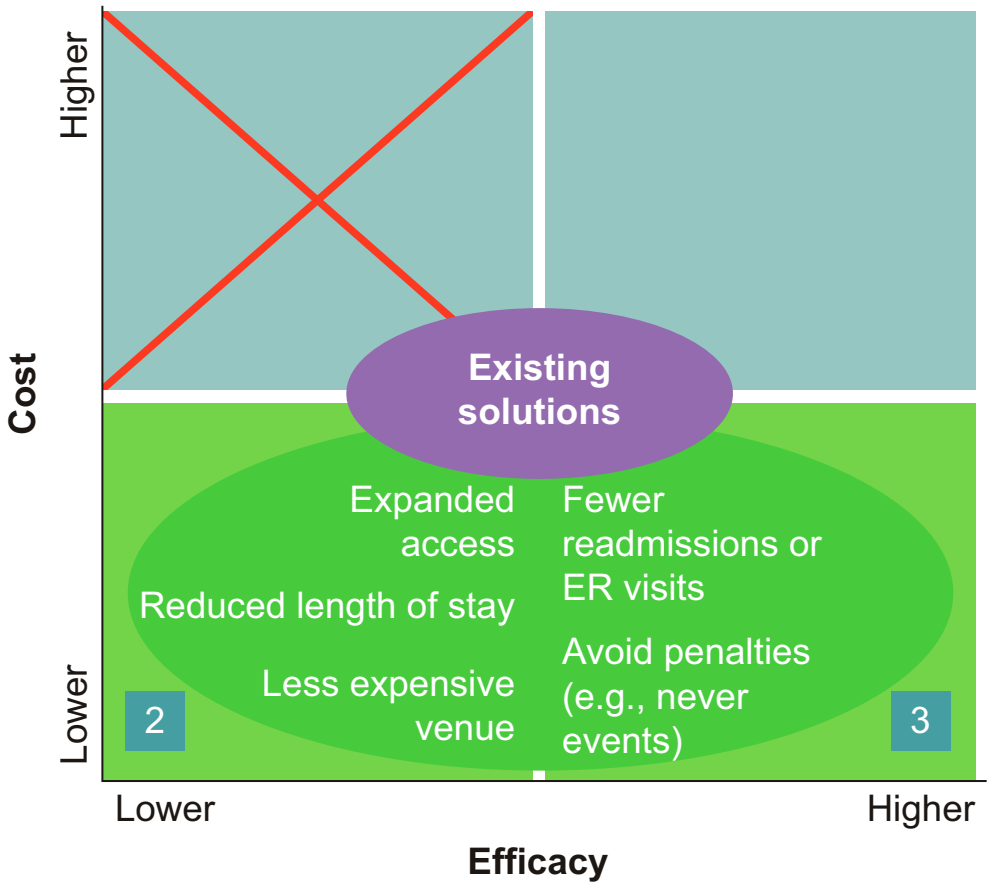

FIGURE 5.7.6
Innovators can differentiate solutions in quadrants 2 and 3 from available alternatives based on the cost reduction (and related benefits) they provide.

head clinical studies demonstrated up to 9 percent in-segment restenosis rates for DES compared to rates up to 33 percent for BMS.[7] By that time, the price of a BMS had dropped to approximately $1,000 per stent, but each DES commanded more than $3,000 per unit.[8] Although payers and facilities were realizing some reduction in cost through the avoidance of repeat procedures linked to restenosis, the additional expense associated with the technology was far greater than the aggregate savings. Value propositions of this type (based on higher efficacy at a higher cost) were common, especially in the US, before unsustainable healthcare spending forced many stakeholders to reconsider the economics related to unrestricted escalations in the **standard of care**.

A second example focused on the HiCARE LIMO team, which developed a new lower-limb splint that is effective, inexpensive, and easy to use, would appear in lower-left quadrant #2. The idea for the new technology stemmed from the observation that many ambulance drivers and other healthcare providers in India had access to modern splint alternatives, but were hesitant to use them on patients or leave them behind after transport due to their high cost (see chapter 1.2 for more on this story). In this case, the team was willing to trade-off some of the more advanced features of top-quality splints (and the efficacy they delivered) in favor of making a device that could be produced at a fraction of the cost. With a device that was cheap enough to leave behind, healthcare providers would be more willing to deploy it, which would in turn increase patients' access to splints when they needed them. Value propositions of this type (developing a de-featured solution at a significantly lower cost) have become increasingly common among companies working in emerging economies where large portions of the patient population may have limited resources and there is a generally higher portion of private-pay health spending. These value propositions also can be used to target smaller segments of larger traditional markets where a subset of customers is seeking a lower-cost alternative to current solutions. For

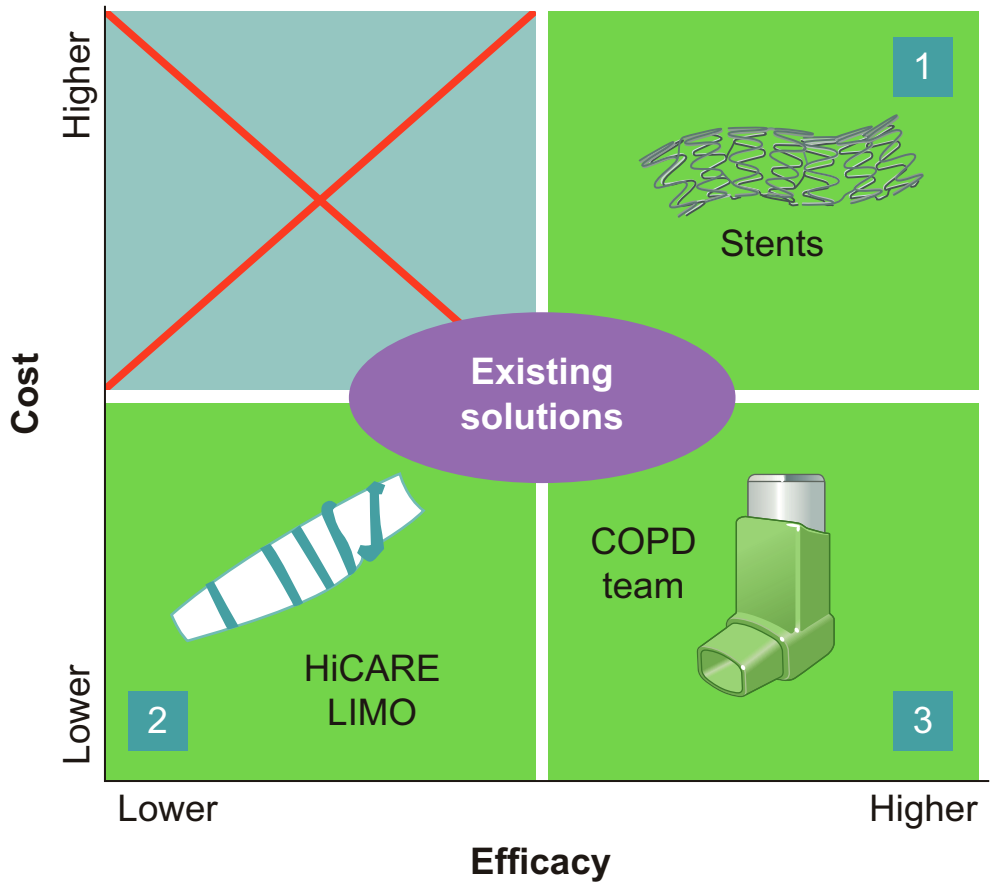

FIGURE 5.7.7
Innovators can devise effective value propositions in quadrants #1, 2, or 3, but those that reduce costs while improving efficacy (as in quadrant 3) can be particularly compelling to stakeholders in today's value-oriented healthcare environment.

example, a company called the Orthopaedic Implant Company (OIC) is seeking to dramatically reduce the cost screws and similar hardware that orthopedic surgeons use in procedures to repair fractures or replace joints. The company's strategy is to identify devices coming off **patent** and then use a lean, outsourced manufacturing model to make comparable products available at 50 to 60 percent less than average prevailing market prices for premium implants.[9,10] Admittedly, these off-patent products do not include all of the latest advancements offered by the current generation of products from major orthopedic implant manufacturers, but certain segments of the total customer base are likely to conclude that these lower-cost alternatives adequately address their basic needs.

A final example focused on the COPD team profiled in chapter 2.4 illustrates a technology that would appear in lower-right quadrant #3. This team went on to design a smart inhaler that could be used to remotely monitor risk factors for exacerbations, allowing the nurses staffed within care management call centers to preemptively intervene when these signals were detected. This device was intended to increase the efficacy (or effectiveness) of the care management call centers by providing them data to help direct their outreach rather than requiring them to perform semi-random outbound calls with the hope of catching patients experiencing exacerbations. In combination, it would reduce the overall cost of care by preventing a greater number of emergency room visits and hospital readmissions, as well as allowing facilities using the system to avoid COPD readmission penalties. This type of value proposition (where efficacy can be still be improved while simultaneously lowering cost to the system) is generally thought to be the most powerful approach to gaining stakeholder support in an era of more limited resources and an increasing focus on the cost of treatment.

Different types of improvements appeal to different stakeholders, which is why value propositions must be highly customized to each stakeholder group. For instance, reimbursement penalties imposed by the

Affordable Care Act (**ACA**) in the US based on quality metrics desired by payers may not capture the attention of individual physicians and patients, but they are likely to be of great importance to healthcare facilities looking to prevent avoidable expenses and negative publicity.

There is no prescribed format that value propositions should take, but they often are constructed as a concise statement or series of statements that articulate the improvement–cost equation of the new offering in terms that the target stakeholder group will find most appealing. At a minimum, this statement should include the audience to which the value proposition is directed, the improvement(s) offered by the solution, and an indication of the cost at which those benefits can be realized. Another approach to creating value propositions suggests that they encapsulate the need, the solution, and the improvement it offers relative to the competition.[11]

Taking the Miramar case as an example, one can speculate how the company might have approached the development of its primary value propositions. Starting with the **need statement**, the company may have framed its focus accordingly: *a way to treat patients with severe hyperhidrosis, which results in a more permanent and effective treatment at or around the cost of current alternatives*. Once the team developed its solution, conducted its early studies, and performed its preliminary market research, its value statements might have read:

- **For patients**: Miramar Labs offers a treatment in the physician's office that is safe, highly effective, and long lasting – with stable efficacy of over 90 percent – that is fast and affordable compared to less effective alternatives such as BOTOX treatments that must be repeated every seven months and the lifetime cost of coping mechanisms that fail to adequately address the problem.
- **For physicians**: Miramar Labs provides a safe and effective private-pay treatment that allows physicians to offer their patients with severe hyperhidrosis a leading-edge solution that is longer lasting than BOTOX – with stable efficacy over 90 percent – while profitably expanding their practice.

As described previously, qualitative data can be used to support a value proposition (e.g., testimonials and anecdotes from key opinion leaders), but they should ideally be augmented with quantitative information that supports those claims to achieve maximum impact. In fact, stakeholders routinely ascribe greater validity to quantified propositions that are supported by high-quality clinical and economic evidence.[12] These data can be collected via surveys, other forms of market research, clinical trials, and/or value modeling (see 5.6 Reimbursement Strategy) and then used as the basis for structuring the value propositions.

Referencing the hypothetical value propositions for Miramar Labs, the company could weave in additional quantitative information by expanding these single value statements into a series of statements for each audience. For example, for patients, the company could highlight the specific cost of recurring BOTOX treatments or cite the average lifetime expense that patients with severe hyperhidrosis devote to dry cleaning and antiperspirants compared to the one-time $3,000 cost of miraDry. For physicians, they could demonstrate how with just $700 in disposable equipment to cover for each patient, the $3,000 per-treatment cost would quickly allow them to recoup the $50,000 up-front investment and make the procedure a profitable addition to their practice.

Chris Wasden, the Executive Director of the Sorenson Center for Discovery and Innovation at the University of Utah, recommends five key dimensions across which innovators can create and measure value:[13]

- **Cost** – How much will the innovation decrease cost relative to the customer's available alternatives?
- **Convenience** – How much easier is the solution compared to available alternatives?
- **Confidence** – How much more accurate or better is the solution than available alternatives?
- **Compensation** – How much more money can key stakeholders make over the alternative?
- **Connection** – How much more fashionable, cool, social, emotional, and avant-garde is the solution than available alternatives?

An example involving an automated hearing device called the Otogram demonstrates what a quantified value proposition might look across these dimensions. When

the team developing the commercialization plan for this device began experimenting with value propositions, it found little enthusiasm for an approach that stated, "We can decrease your testing costs and improve your testing accuracy." Instead, more quantified and specific statements, such as the following, had more powerful effect on physician stakeholders.[14]

For an average physician practice, the Otogram can:

- Decrease your hearing testing costs by 75 percent (or about $100,000) per year. (Cost)
- Increase the convenience for patients by testing in 11 languages and at any time of the day without an audiologist. (Convenience)
- Deliver the 99 percent accuracy of an expert audiologist, based upon side-by-side clinical trials. (Confidence)
- Increase practice revenue by $30,000 per year in hearing testing and double hearing aid sales to $100,000 per year. (Compensation)
- Demonstrate that the practice is at the cutting edge of the hearing health technology field with an intuitive and elegant design that connect the patient to the clinician. (Connection)

Initially, innovators may not have all of the data required to support quantified value propositions, but this is what they should be working toward as they develop their marketing mix, set pricing, and conduct clinical and economic studies. (For technologies with value propositions focused on delivering improved efficiencies, variations of traditional time-in-motion studies can also be informative.) The important point is that some data must be embedded into the value proposition before the innovators begin promoting their offering. They must work cross-functionally to design studies that will produce the evidence needed to satisfy the data requirements of the many different stakeholder groups they will seek to influence. Of course, studies will need to be prioritized and/or sequenced based on their relative importance and potential impact on the company's ability to achieve its goals, especially in light of early-stage resource constraints. But, over time, as more data are gathered, a company's value propositions will evolve and become increasingly robust. For instance, at market launch innovators may find themselves working with little more than the clinical data used for regulatory approval and stakeholder testimonials from their market research. Accordingly, their value propositions may leverage this information, but place greater emphasis on appealing to customers that want to be first adopters and pioneers in the field. Later, after additional clinical and/or economic studies have been completed and published, the value propositions can shift to attract customers who want the confidence of knowing the innovation is backed by data from multiple trials. For more information about the types of studies that may be helpful, see 5.3 Clinical Strategy and 5.6 Reimbursement Strategy.

As a team or company determines what studies to conduct, it is helpful to consider who will be involved in those studies from a stakeholder perspective. Study design and management provides an effective way to get key opinion leaders involved with the company and familiar with its offering. Physicians who are considered KOLs have deep experience that can be leveraged to help design and implement studies with a high probability of success. Their expertise and involvement also lends credibility and helps generate interest in the study results among the KOL's peer group. When deciding which KOLs to target, companies must think about factors such as whether they prefer academic or community physicians, and the geographic location where the studies will be performed (see 5.3 Clinical Strategy).

In advance of study design and execution, KOLs can also be engaged to help a company develop and/or refine its critical value propositions. While KOLs are traditionally targeted within the physician population, innovators should remember that influential individuals can be found among facility administrators, biostatisticians, health economists, academics, allied professionals (e.g., nurses and technicians), and patient groups. All such experts can provide invaluable advice regarding which value proposition is most compelling to their associated target audience, and what data are required to effectively support that value proposition.

Sometimes, before a company can convince certain stakeholders of the value of its specific technology, it

must persuade them that the need for a solution exists at all. Often referred to as "market development," creating awareness of a need and, in turn, demand for a solution can be a time-consuming, complex, and expensive endeavor – and one that should not be undertaken lightly by a start-up. For example, a company may have to perform or sponsor studies simply to establish the sense of a necessity in the minds of the target audience before it can effectively market its specific technology.

Consider the case of implantable cardioverter defibrillators (ICDs). Before the results of the MADIT-II and SCD-HeFT trial results were released, ICDs were primarily used to treat a relatively small number of secondary prevention patients – those with a prior episode of sudden cardiac arrest. However, MADIT-II and SCD-HeFT demonstrated that ICDs dramatically reduced the mortality rates of primary prevention patients – those at high risk of sudden cardiac arrest who had not yet experienced it. As a result, the FDA expanded the indications for ICD implantation to include primary prevention patients. Similarly, Medicare and private payers modified their policies to provide **coverage** for ICDs used for primary prevention. This increased the market for ICDs by an additional 1 million patients, since this group was much larger than the secondary prevention group. Physicians, payers, and patients just had to be shown in definitive terms that a legitimate need existed within this broader population.

A similar example exists within the treatment of patients with chronic kidney disease (CKD) before their condition progresses to end-stage renal disease (ESRD). While the need to manage heart disease in patients with ESRD was relatively well understood, heart disease was not proactively nor consistently managed in most pre-ESRD patients. However, when a study was published in the *New England Journal of Medicine*[15] that showed pre-ESRD patients have a high risk of heart failure, it was enough to establish the need for a new treatment paradigm for this patient population. It also opened up a new field of treatment to innovators and companies pursuing opportunities related to CKD.

Note that the company's competitive advantage and business strategy can also support the value propositions it has defined. For each value proposition, the team should carefully evaluate what strategies and potential company strengths will enable it to successfully deliver as promised (see 5.9 Competitive Advantage and Business Strategy for more information). The company's position in the healthcare value chain and its unique capabilities are an important source of leverage in bringing value propositions to fruition.

Marketing mix

With clear value propositions defined for key stakeholder groups, innovators must next make a series of decisions about the marketing mix it will use to support and communicate these value statements. Without an effective marketing mix, value propositions will never reach their intended audience and adoption is likely to falter.

Product/service mix

The first element of the marketing mix presented in this chapter is deciding on the product/service mix. The idea is to define an offering with the greatest likelihood of delivering on the value propositions the company has constructed. In general, the product/service mix is driven by the business model the company has adopted (see 4.4 Business Models). For example, many **medtech** companies with disposable or implantable devices feature a pure product offering, which they may support through ancillary services (e.g., education and training). Capital equipment companies, on the other hand, generally have a more complex product/service mix that involves the bundling of multiple products (e.g., equipment, plus a disposable or reusable component), as well as a service (e.g., maintenance contracts and upgrade agreements). For instance, Accuray (profiled later in this chapter) includes future product upgrades as part of its basic product offering.

The bundling of products and services into cohesive offerings is becoming increasingly common as the providers and payers/purchasers of medical interventions become more value oriented. One emerging business strategy that reflects this shift is called disease management or "**owning the disease**" (see chapter 5.9). With this approach, technology companies are attempting to provide integrated products and services that allow them to solve problems for their customers across the continuum of care. If this trend continues, fewer and fewer medtech companies will remain "pure" product companies and more will bring hybrid product/service offerings to market.

Pricing

Pricing begins with a deceptively simple question: what is the appropriate baseline price for an offering? The price of a product and/or service can play a critical role in encouraging or discouraging adoption, particularly as all stakeholders become more cost conscious. Therefore, pricing not only involves establishing a baseline price for the decision maker who will directly bear the cost of the offering, but recognizing the different ways through which prices (and the related issue of reimbursement) will influence adoption. Reimbursement-related issues are covered at length in 5.6 Reimbursement Strategy. However, they warrant some discussion in this chapter to the extent that they relate to marketing.

Before innovators think about setting a baseline price, they must first understand all of the costs associated with developing, manufacturing, and commercializing the offering. They should also determine what sort of mark-up (profit) the company would ideally earn to support its overhead and ongoing development efforts. Once these factors are clearly understood, the next step is to perform an evaluation of real and perceived value associated with the offering. Survey data, the value propositions defined for the offering, and more advanced analysis such as a cost/benefit model can provide important inputs to this assessment.

Value-based pricing is typically the most effective pricing strategy for a company to support. If the price of a new technology can be directly linked to the value of the improvements it will deliver (with the value exceeding the cost), buyers and payers are far more likely to support the adoption of the offering. The most persuasive value-based pricing argument is related to direct savings in healthcare costs. However, innovators must appreciate that customers will often require a high level of documentation in order to be convinced of a potential savings and justify value-based purchases internally. If a physician or hospital will save money with each device used (relative to the current standard of care), this gives the company a strong argument for justifying its price. Another common pricing argument is related to improved outcomes. If a device leads to improved results such that a payer or provider saves money on follow-up care and/or treatment related to complications, this is frequently a compelling argument. Companies can sometimes encounter resistance, however, when the pricing argument is based on **quality of life**. In some geographies, such as the UK, buyers and payers are generally willing to support the adoption of devices that lead to significant, measurable, **evidence-based** improvements in quality of life. Yet, their standards for demonstrating such a change are growing increasingly stringent, especially for high-end, high-cost devices that represent a sizable potential cost burden to the healthcare system.

Another way that companies can establish a baseline price is to perform a **comparables analysis**. By evaluating the pricing strategies (and associated reimbursement status) of similar offerings in the field, companies can gain valuable information to help them set a price. In general, medical device pricing for established products should give the innovators a strong sense of what the market will bear. Comparables analysis can be accomplished through primary and secondary research. As discussed, performing market research can also be helpful in terms of understanding the price sensitivity of key stakeholders (i.e., exploring different pricing scenarios and identifying the price point at which they will resist the technology).

The story of Genomic Health demonstrates how one company approached the challenge of establishing a price for its product.

FROM THE FIELD GENOMIC HEALTH

Value-based pricing for a novel diagnostic tool

As described in 2.4 Market Analysis, Genomic Health, a company addressing the need for high-value, information-rich diagnostics based on patient-level genomic testing to predict the recurrence of early stage, N–, ER+ breast cancer and enable personalized treatment decisions, faced an interesting pricing challenge with its product. Because diagnostic

companies traditionally charged between $25 and $50 for their tests, commanding margins of just 5–10 percent, the company had to pioneer an entirely different pricing paradigm to support the high cost of R&D and clinical studies necessary to bring its genomic-based test to market.

Three types of analysis suggested that a price in the range of $1,000 to $7,000 per test could be viable. The first was comparables analysis. Kim Popovits, COO of Genomic Health, recalled, "There was another diagnostic in the marketplace at that time, a genetic test that looked at the mutation of the BRAC-1 and -2 genes to assess a woman's hereditary risk of breast cancer." This test was priced around $3,000 and was on its way to being reimbursed on a relatively broad scale.

The second approach was based on the value estimate for the need. Over time, Genomic Health's test had the potential to save money for the overall healthcare system and could, thus, shift the pricing power from therapeutics to diagnostics. Specifically, the total cost of chemotherapy for early-stage breast cancer patients was conservatively $15,000. If the test cut the number of patients undergoing chemotherapy by 50 percent (by predicting low recurrence risk), then the total savings to the healthcare system would be roughly $7,000 per patient. This meant that Genomic Health could potertially command a price of up to $7,000 per test.

Finally, the company performed additional market research, including a market survey with 30 or 40 US medical directors. Through this effort, Genomic Health tested the price sensitivity of payers and discovered that they considered any test over $1,000 to be expensive. However, their reaction was not significantly different between price points of $1,500 and $4,500, assuming the test had clinical value and adequate validation to support high value pricing. Evaluating all of these inputs, the company eventually decided on a price of roughly $3,500 for its product.

Despite the relatively high costs of its test (by traditional diagnostics standards), Genomic Health anticipated that it might take the company approximately 18 to 24 months to gain consistent reimbursement for the product. However, when the company met substantial resistance from payers (driven, in part, by the concern that patients would take the test but then still pursue chemotherapy regardless of the test results), it took an innovative approach to driving adoption.

Genomic Health agreed to enter into a pay-for-performance deal with major payer UnitedHealthcare. The insurer said it would reimburse for the test for 18 months while it monitored the results with Genomic Health. If too many women still elected to receive chemotherapy, even if the test suggested they did not need it, then UnitedHealthcare would seek to negotiate a lower price on the grounds that the test was not having the intended impact on actual medical practice.[16] Genomic Health's management team was confident that women would follow the course of treatment recommended by the test, and believed that the pay-for-performance agreement could be used as a way to advertise the company's confidence in the test. As it turned out, the trial was a success and United Healthcare issued a national payer contract for the technology, which established coverage across all of UnitedHealthcare's plans following the trial period.[17]

As the Genomic Health example suggests, choosing a baseline price has many subtleties. Additionally, the company must decide under what circumstances it might be convinced to deviate from its baseline price. Pricing strategies that require a company to adopt a more complex approach to pricing include **differential** and **bundled pricing**, **gainsharing**, and **pay-for-performance**. Details on each of these alternatives can be found below.

Differential pricing Differential pricing refers to the basic concept of pricing the same product or service

differently for different customer segments. For example, in some cases, medical device companies might negotiate discounted pricing with large purchasers (e.g., group purchasing organization, integrated delivery facilities). While this strategy can be effective in driving volume, it has the potential to create conflict in the market among customers, as well as payers. It may also create legal challenges, if it is perceived as creating a financial inducement to physicians.

Differential pricing strategies are becoming increasingly common when companies are working across geographies. In particular, they are growing in popularity with organizations that have a mission to address the needs of underserved populations in resource-constrained settings. For example, Cycle Technologies offers its natural family planning device CycleBeads (developed with researchers at the University of Georgetown's Institute for Reproductive Health) in countries around the world using a differential pricing approach. The company's primary goal is to reach users in developing countries where medical and surgical contraception options are limited or unacceptable; its secondary focus is on meeting the needs of women in developed countries who are seeking effective, non-invasive birth control and proactive family planning tools. To enable the company to achieve both of these objectives on a sustainable basis, Cycle Technologies sells the device at a profit in the US and then uses the proceeds to help it make the product available at close to cost in low-resource settings such as India and parts of Africa.[18]

Bundled pricing Bundled pricing refers to setting a single price for a combination of products and/or services. A medical device manufacturer might bundle service contracts or ancillary products and services with its primary offering to try to drive increased revenue. Bundled pricing can be a way of offering discounts to buyers while incentivizing them to buy a wider range of products and services than they would otherwise. While this works in some cases, it is not successful for all offerings. As classic examples of this is when Guidant offered bundled pricing on its catheter and guidewire products in an effort to drive more widespread adoption. However, because physician preference was so strong in this particular area, practitioners wanted to choose products à la carte despite the discounts that could be realized by purchasing bundled products.

From a health system perspective, research has shown that bundled payments can align incentives for providers, including hospitals, post-acute care providers, physicians, and other practitioners, and encourage them to work together more closely across an **episode of care**. The Centers for Medicare & Medicaid Services (**CMS**), through the CMS Innovation Center, launched a program known as the Bundled Payments for Care Improvement Initiative to experiment with four new types of payment models. The goal of the program is to determine which models can lead to higher quality and more coordinated care at a lower cost to Medicare.[19]

Gainsharing Gainsharing agreements between a hospital and its physicians represent another subtlety in pricing. Under these agreements, hospitals can negotiate reduced prices with certain manufacturers in exchange for increased volume. Gainsharing differs from differential pricing in that physicians are given direct incentives to adopt certain devices. For instance, these plans often provide physicians with a percentage of the cost savings derived from reduction of waste and use of specific supplies during procedures.[20] While some observers view gainsharing as an effective cost-cutting tool, others perceive it to be laden with inherent conflicts of interest, an obstacle to innovation and proper patient care, and possibly even a violation of anti-kickback statutes.[21] Recently, some hospitals have used gainsharing to help them standardize purchases of high-value orthopedic implants, including hips and knees. Prior to the initiation of gainsharing arrangements, orthopedic surgeons were successful in protecting their individual product preferences, which resulted in a proliferation of products being purchased by each hospital. By selecting a preferred vendor and implementing gainsharing, the hospitals have been able to significantly streamline purchasing and realize cost economies by doing more business with a smaller number of suppliers.

Although gainsharing is still somewhat controversial, the four payment models being tested as part of the CMS Bundled Payments for Care Improvement Initiative allow

participating facilities to propose gainsharing arrangements among provider partners.[22]

Pay-for-performance As the Genomic Health example illustrates, companies may agree to set their prices contingent on the realization of specific results. If the company delivers on its value proposition (as measured by mutually agreed-upon performance metrics), a payer or customer will pay its baseline price. If not, certain discounts will be expected to justify the lower "payback" on the device. As with gainsharing, pay-for-performance arrangements are relatively new and are still somewhat controversial within the industry. However, interest in these types of arrangements seems to be growing as purchasers of all types become more cost and value focused.

Any company should seek legal counsel when creating pricing strategies. The healthcare space is highly regulated and arrangements that may be perceived as creating an inducement for a physician to use a particular device or procedure can run afoul of the Stark Law. This law governs physician self-referrals, or the practice of a physician referring a patient to a medical facility (or form of treatment) in which s/he has a financial interest, be it ownership, investment, or a structured compensation arrangement.[23] While the law remains controversial, innovators should exercise appropriate caution to avoid a potential conflict of interest.

Positioning

Positioning refers to the way a company represents its offering in the market in order to differentiate it from the competition and a make distinct and lasting impression on the customer. Because the medical marketplace is "noisy," with many messages vying for the attention of prospective customers and/or seeking to enlist the support of influential stakeholders, innovators should treat positioning as a selection exercise. They must ask themselves, "What are the most important aspects of our solution that will engage the customer when we begin promoting it?" And, "How can we optimally differentiate the solution from available alternatives (or from the absence of another solution)?" The most compelling answers to these questions then form the basis of the company's positioning messages.

Importantly, not every product feature or aspect of the value proposition rises to the level of a key positioning message. The goal is not to present customers with a "laundry list" of messages – it is to focus on just a few of the most convincing arguments that are most likely to drive a behavior change. These messages can appeal to customers on a rational or emotional level (or ideally some combination of the two).

When defining and customizing their preliminary value propositions, innovators will have considered what is most important to each core stakeholder group. However, now, during positioning, they have more specific information regarding the product/service mix and price for the offering. This enables the team to more clearly and precisely focus attention on what attributes distinguish the solution from the customer's other alternatives and should drive them to try it.

Language is another important factor to consider when crafting positioning messages. As the Miramar Labs story illustrates, small differences in the words and terms chosen to describe a product or service can have a significant impact on whether customers respond favorably (or not) to the messages when they are delivered. Without the benefit of market research with prospective patients, the Miramar team would not have been likely to appreciate the negative connotations associated with the word "permanent" versus "lasting" among target patients.

Keep in mind that positioning is not about telling the story of the innovators and how the innovation came to fruition. It is also not about sharing what the team or company finds most important or exciting about the offering. Positioning should be focused entirely on isolating what is most important to each stakeholder group and devising the optimal way to communicate these factors in a manner that will be meaningful to those audiences.

Intuitive Surgical (introduced in chapter 5.1) provides an example. When this company was pioneering the field of robotic-assisted surgery with its da Vinci® Surgical System, the development team was enthusiastic about the technical capabilities enabled by its device. By translating the surgeon's natural hand and wrist movements on instrument controls on a console into the corresponding micro-movements of specialized surgical instruments

positioned inside the patient through small incisions, da Vinci enabled a minimally invasive approach to procedures such as prostatectomy, hysterectomy, myomectomy, gastric bypass, and mitral valve repair. The company might have led with messages about improved precision and reduced complications in positioning the product if it had not discovered that the hospital executives, who would make the purchasing decisions to acquire the system, were more interested in the prestige their facilities could garner from being the first in a geographic area to adopt the technology. Eager to differentiate themselves from competing hospitals, facility executives were actively seeking ways to enhance the reputation of their institutions, and purchasing a da Vinci system was one way to accomplish this. Over time, as more facilities adopted the system and it became less of competitive differentiator, Intuitive Surgical had the opportunity to highlight the technical benefits offered by the device. However, many of its initial sales were based on the perceived ability of the device to enhance a hospital's reputation. It was their hope that this increase in stature would result in higher patient flow, stronger referrals, and an improved ability to retain key surgeons.

Another interesting example can be found in the TRUE Dilatation™ Balloon Valvuloplasty Catheter. Loma Vista Medical, which was later acquired by C.R. Bard, developed an effective approach to positioning in preparation for marketing its product for use in transcatheter aortic valve replacement (TAVR) and balloon valvuloplasty (BAV). The product offered multiple benefits over traditional balloons, including the following:[24]

- Highly resistant to ruptures, punctures, and tears.
- Rip-stop fibers to prevent the catastrophic failures seen with other balloons.
- Fiber reinforcement precisely limits the maximum balloon diameter to the labeled size, while allowing conformance to anatomical variation.
- Diameter control within 1.5 percent over its rated pressure range (compared to 15 to 40 percent for competing products).
- Inflates and deflates two to three times faster than competitors' balloons, minimizing pacing time.
- Clean re-wrap and low withdrawal profile after dilatation.
- Able to confirm de-airing before insertion.

The company carefully considered these benefits and how to prioritize them for its primary customer – the physician. Of course, all of this information would be important when answering their questions and helping them understand the total value of the product. But the team had to decide which messages to lead with and how to make an immediate and lasting impression. Ultimately, they narrowed in on four simple, direct ideas, as shown in Figure 5.7.8.

The positioning – "Truly Precise. Truly Tough. Truly Fast. Truly Better" – encapsulated the core ideas from the list of benefits, but articulated them in a way that was compelling to physicians and memorable in its power and simplicity (see 6.3 Funding Approaches for more about Loma Vista Medical).

Promotion and advocacy

The final aspect of the marketing mix covered in this chapter is promotion. Promotion involves how a company communicates with the target audiences. A company generally manages these interactions through a marketing communication and/or public awareness strategy.

Raising awareness through a marketing communication strategy The purpose of a marketing communication strategy is to raise awareness among stakeholders regarding the need and/or solution to prepare them to make a buying decision or change their behavior in some other desired way.

Information that is disseminated by the company is considered a form of *direct awareness*. Information that comes from other sources – such as publications, conferences, KOLs, etc. – is considered *indirect awareness*. An effective marketing communication strategy typically leverages both direct and indirect awareness mechanisms in reaching its target audience.

Usually, a marketing communication strategy outlines which communication vehicles will be used for each key stakeholder group, what the key messages will be for

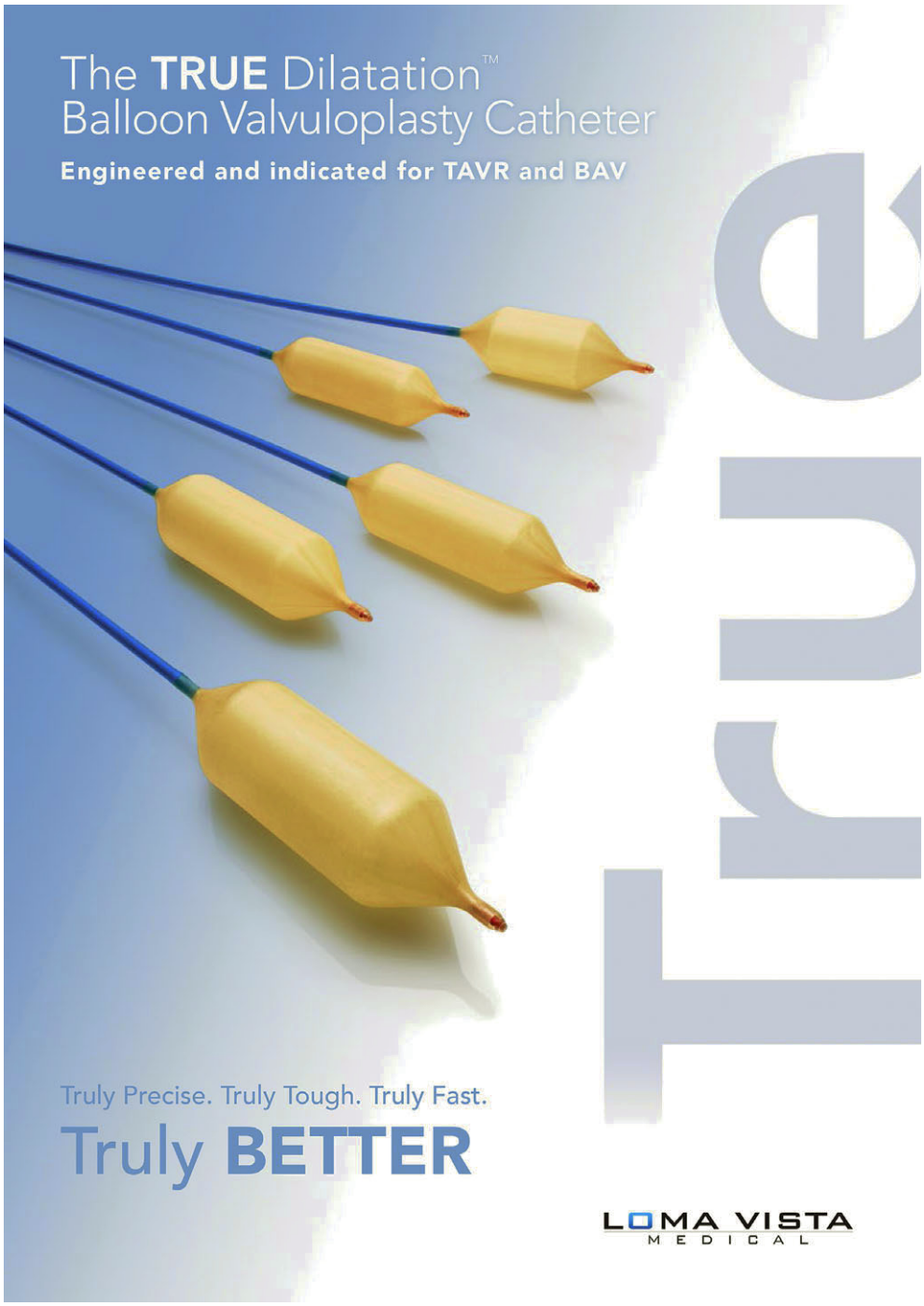

FIGURE 5.7.8
Product positioning for the TRUE Dilatation™ Balloon Valvuloplasty Catheter (courtesy of C.R. Bard).

each communication, and when each communication will be released. The idea is to create a sequence of communications for each stakeholder group that builds their awareness, introduces and then reinforces key messages (e.g., the value proposition and associated positioning messages), and prepares the target audience to make a decision or change its behavior at the time the device is launched. Table 5.7.1 presents some of the different communication vehicles that can be incorporated into a marketing communication strategy. Note that detailing – when sales representatives and clinical specialists visit physicians or hospitals – is omitted since this

Table 5.7.1 A combination of communication vehicles is the most effective way to reach target stakeholders.

Vehicle	Description	Issues to consider
Peer-reviewed publications	Peer review is the process of subjecting an author's scholarly work or research to the scrutiny of others (peers) who are experts in the same field. Peer-reviewed publications are considered more credible than other sources because they aggregate, filter, and validate author submissions independent of any outside influence or interested third party.	• Submitted data must be based on clear evidence. • Publication can take anywhere from 3 months to 2 years from the time of submission, depending on the publication, topic, and strength of the data; as a result, planning is difficult. • Revisions/rewrites may be required prior to publication. • Publication is not guaranteed. • Any potential conflicts of interest between the company and the authors must be disclosed. • May cost as little as $15,000 but can require hundreds of thousands of dollars to support the research that leads to the publication (conflicts of interest caused by the relationship between the research sponsor and the investigator that may undermine the scientific validity of any studies will need to be managed and disclosed properly).
Peer-reviewed (abstract) conference presentations	An abstract provides a concise statement of the major elements of a research project. Abstracts are reviewed against other submissions, with some subset being chosen for a brief presentation (or a poster) presentation based on their fit with conference criteria.	• Submitted data must be based on clear evidence. • Abstract requirements vary from conference to conference and should be well understood before a submission is made. • The abstract, stating the purpose, methods, and findings of the research project, is submitted to conference organizers to inform them of work-in-progress or completed work that is available to be presented. • Abstracts must be submitted an average of 6 to 8 months prior to the conference.
Technology/clinical talks	Technology talks are given by KOLs, either in the context of a meeting, as an evening session, or pre-conference session.	• Can be used to satisfy CME requirement (see below). • More extensive than the peer reviewed presentation; provides opportunities for more in-depth coverage of a new. technology.
Continuing Medical Education (CME)	**CME** is required by physicians in most US states to maintain their licenses. It provides a way for physicians to stay informed and learn about new developments in their field. Content for	• CME programs must be certified by the Accreditation Council for Continuing Medical Education. • Any potential conflicts of interest between the company and the authors must be disclosed. • CME programs can be sponsored directly by companies or through professional societies. • The costs are significant: a professional conference attended by 200 people for 2 days could be $100,000 or more; a 1–2

Table 5.7.1 (*cont.*)

Vehicle	Description	Issues to consider
	CME programs is typically developed, reviewed, and delivered by faculty who are experts in their individual clinical areas.	day academic conference for 50 people could be more than $50,000 (start with speaker honoraria of $5,999 to $15,000 for 10 speakers, then add room, board, travel expenses, etc.).
Reimbursement dossier	**Reimbursement dossiers** typically serve as the official source for all key information about the product, including the place of product in the diagnostic and therapeutic chain, results from key clinical and economic studies, disease management strategies, modeling report, product value and overall cost, and references (see 5.6 Reimbursement Strategy).	• Must be based on well-established and tested facts about the product. • Can be time-consuming and resource-intensive to prepare, requiring specialized expertise and significant lead-time. • Must be customized to meet the needs and interest of each target audience. • Cost can range from $50,000 (for a simple dossier) to as much as $250,000 (for a more complete deliverable).
Direct-to-consumer (DTC) advertising	**DTC** advertising refers to the promotion of medical devices to patients through newspapers, magazines, television, and the Internet. Companies also use brochures, videos, and other materials that are made available to patients in doctors' offices.[33] One recent trend is to focus on direct-to-patient (**DTP**) advertising (i.e., advertising in channels accessed more exclusively by patients, such as the *Diabetes Digest* for diabetic patients).	• DTC advertising is only legal in two developed countries: the US and New Zealand. • Not all medical technologies are well-suited to DTC advertising and this approach traditionally has been used sparingly in the medtech field (exceptions: elective Lasik surgery, BOTOX, drug-eluting stents, Lap Band for bariatric surgery). • However, with the recent proliferation of consumer-oriented medical devices, DTC and DTP advertising is becoming more common. • Online consumer/patient outreach and the use of social media have become the dominant channels for DTC and DTP advertising, especially for consumer-oriented medical devices and health/lifestyle technologies. • DTC advertising is still considered somewhat controversial among regulators, some physicians, and some patient groups, although this varies by product category. • DTC advertising can be complicated and expensive.

is considered part of the sales process, as discussed in 5.8 Sales and Distribution Strategy.

As Table 5.7.1 suggests, the role of marketing in the promotion and adoption of new medical devices is not without controversies. When used properly, relationships between medical device companies and KOLs can be advantageous to a company and can lead to better, more innovative products. However, in some cases, they may be perceived as undermining scientific integrity and unduly influencing medical care. The Advanced Medical Technology Association (**AdvaMed**) has developed a code of ethics on its interactions with healthcare professionals that aims to address concerns about potential conflicts of interest. This code provides guidelines on product training and education, support of education conferences (such as those used for CME), restrictions on gifts and meals provided as part of sales and marketing, and limitations on arrangements with consultants.[25]

More than anything, innovators are advised to protect their clinical activities from the possibility of conflicts and bias by ensuring that those who perform and evaluate clinical studies do not have incentives linked to the success of the company. If research is conducted in this way, the data used to support value propositions and the marketing mix have a much higher likelihood of being perceived as credible and compelling.

Companies should be careful not to create awareness of their technology among patients *before* physicians are fully informed. If a physician is blindsided by patient inquiries regarding a new product, it can cause resentment toward the company and negatively affect adoption or even drive adoption of competing products. This problem, while most common in the pharmaceutical business, is still something to watch out for in the medical device field. And it will only become a larger problem as online and social media-related communication channels continue to proliferate. Traditionally, the best approach was to raise awareness first among KOLs, then expand communications to facilities and payers. Once these stakeholders had a basic understanding of the technology and its value propositions, the company could begin targeting other physicians (who are not necessarily KOLs) and then patients (as appropriate) with its marketing messages. In today's online world, news of health-related innovations travels rapidly and messaging is more difficult to stage in this manner. Patients are more active than ever before in researching their alternatives and proactively seeking emerging therapies. In some instances, they can be advocates and first-line customers for new medical solutions, such as new methods for parents to monitor chronic conditions in their children.

As noted, professional societies and thought leaders can be especially valuable advocates for a new technology. Societies can create awareness by incorporating new medical technologies in their practice guidelines, sponsoring symposia, and advocating payers for reimbursement (see 5.6 Reimbursement Strategy). KOLs not only influence other physicians, but can guide future generations of product development to create and sustain additional value. Ron Dollens, president and CEO of Guidant from 1994 to late 2005, credits relationships with thought leaders as one of the key factors behind the success of one of medtech's early pioneers, Advanced Cardiovascular Systems (ACS). ACS was acquired by Eli Lilly in 1984 and led by Dollens from 1988 until its spin-off in 1994 to form Guidant. According to Dollens:[26]

> *ACS had a sales organization that developed great relationships with the thought leaders. So it was associated with the kinds of people that were taking the therapy to another level.*

Promoting through a public awareness strategy

A public awareness strategy can be an imperative element of a marketing/stakeholder strategy if the company anticipates strong resistance from one or more stakeholder groups. The concept of public awareness refers to the methods and activities employed by a company to establish and promote a favorable relationship with the public. While public relations (PR) companies are mostly accessible to large companies, focused and shrewd public awareness efforts can also work for smaller companies. For example, athenahealth, a company that initially provided web-based medical billing software and services for physician practices, published a ranking of insurers based on the timeliness of claim processing, which attracted considerable media attention and generated interest among physicians for its products.[27]

Not all device companies require an explicit public awareness strategy. However, if the company is concerned about certain potential barriers to the adoption of its technology, this may be necessary. For instance, payers are more likely to resist a new technology if it requires new reimbursement codes. Yet, if a company launches an effective public awareness campaign that engenders meaningful support from physicians (and their professional societies), payers will have a more difficult time delaying or declining coverage for the device. Similarly, if a physician turf war ensues upon the introduction of a new device, a public awareness campaign targeted at creating patient demand for the new technology can be an effective way to drive physician adoption, despite the conflict surrounding who will administer it.

Guidant employed a public awareness campaign to apply pressure to the Centers for Medicare and Medicaid Services (CMS) while seeking more widespread coverage for its ICDs. Although ICDs had been shown in several studies to prevent sudden death by detecting dangerous abnormal rhythms and shocking a patient back into normal rhythm, CMS was willing to reimburse for the technology in only a fraction of the patients who could benefit from the device. Guidant sought to address this issue by funding a $7 million dollar prospective trial looking at the effect of ICDs on cardiac deaths among those who had suffered at least one heart attack. When the results became available, many private payers recognized the value of the device and agreed to reimburse for all patient types that had shown benefit in the study. However, Medicare took a more conservative approach, limiting its coverage to a high-risk subset of the patients studied in the trial (due largely to the potential billion-dollar price tag associated with expanding coverage to such a large group of patients). To help overcome this resistance, Guidant had advocates for the device place editorials in prominent mainstream newspapers and medical journals and took other steps over a two-year period to rally support among patient groups, specialty societies, and other ICD manufacturers (Medtronic and St. Jude). Eventually, at least partially in response to criticism that it was, to some extent, rationing medical care, CMS finally agreed to expand coverage.[28]

When a company is developing a public awareness strategy, some of the best resources to target include news organizations and journalists, patient advocacy groups, physician professional societies, hospital associations, and even members of Congress (if the value proposition associated with the device is compelling enough to capture the attention of this audience). U-Systems is one organization that has realized positive awareness, as well as legislative benefits through public awareness and patient advocacy. The company developed the first ultrasound imaging device for use in combination with standard mammography in women with dense breast tissue. Nearly 40 percent of women have dense breast tissue, a condition that makes detection of early-stage breast cancer more difficult.[29] In 2003, patient Nancy Capello was diagnosed with stage-three breast cancer after 11 years of "clean" mammograms using standard mammography equipment. Upon learning that a missed diagnosis is not uncommon in women with dense breast tissue, she became an advocate for greater disclosure and better screening practices. Starting in her home state of Connecticut, she championed for a law requiring payers to cover breast ultrasound (not just standard mammography) for women with dense breast tissue, which was passed in 2004. She then fought for legislation mandating that physicians inform patients if they have dense breast tissue, which was passed in 2009. Both were landmark bills that provided a template for other states to follow.[30] In 2011, as the U-Systems technology was nearing the market, the company teamed up with Capello and her organization, Are You Dense, Inc., to continue increasing awareness of dense breast tissue and its significance in the early detection of breast cancer and to push forward similar legislation in other states. These new laws are favorable for U-Systems because they increase the demand for alternatives to mammography for screening patients for breast cancer. As of 2014, 14 states in the US had enacted breast density laws.[31]

The Accuray story below highlights how marketing communication and public awareness techniques and activities have been applied in the past as part of a comprehensive marketing and stakeholder strategy.

FROM THE FIELD ACCURAY INCORPORATED

Using stakeholder analysis to develop an effective marketing strategy

Accuray Incorporated was founded in 1999 by John Adler, a Stanford neurosurgeon, to develop an image-guided radiosurgical device that could be used to ablate tumors without the need for traditional surgical resection. Adler first conceived of the idea while observing procedures performed with a predecessor device, called the GammaKnife, in Sweden in the 1980s. As Adler described, "Accuray really was developed in response to the shortcoming of the GammaKnife," which was able to treat brain tumors through non-invasive radiosurgery, but had to be anchored to the patient's body via bone screws. Accuray's product, a frameless stereotactic radiosurgical system, simplified radiosurgery by eliminating the need for these invasive, painful anchors while achieving comparable results. The Accuray system, called the CyberKnife,® also would enable radiosurgery in other less anchorable areas of the body, including the spine, chest, and abdomen. By expanding non-invasive surgical technology, Accuray would give surgeons the option to be more aggressive in treating cancer in multiple anatomic locations or near vital organs, while simultaneously lowering risk and patient recovery times (see Figure 5.7.9).

Starting with his connections at Stanford, Adler put together a team to develop the CyberKnife idea and bring it to the marketplace. Despite difficulties raising enough money to sustain the high, ongoing R&D-related expenses associated with a capital equipment device, Accuray managed to get the CyberKnife ready for human testing under an investigational device exemption by 1994. Although the frameless design of the CyberKnife allowed Accuray to treat tumors in different parts of the body, the company

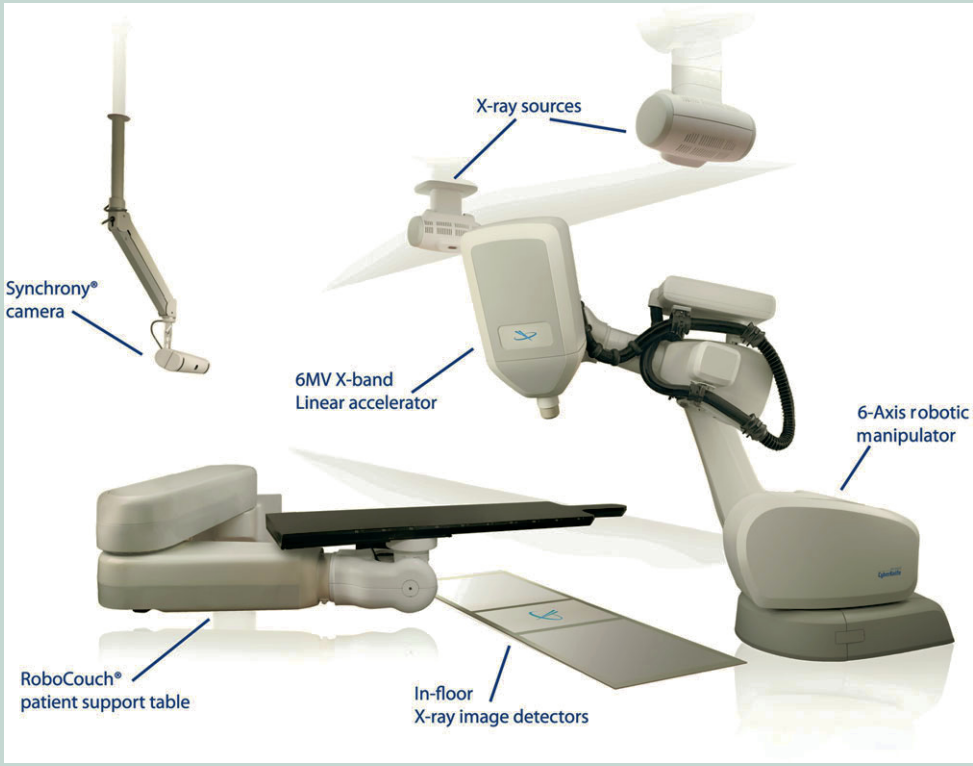

FIGURE 5.7.9
Accuray's CyberKnife system (courtesy of Accuray).

originally focused on brain tumors (much like the GammaKnife), modifying existing procedures but not yet expanding outside the field of neurosurgery. "The first generation was dedicated to replacing many of the GammaKnife's procedures," said Adler, "because we could do it without the frame and modify what had been done to make it biologically a somewhat better procedure."

The decision to begin by targeting neurosurgery was driven, in part, by a series of stakeholder issues. In this market, Accuray believed that it clearly understood the interests of key stakeholders and had the best chance of addressing their concerns. According to the company, the two most prominent stakeholder groups were neurosurgeons and radiation oncologists. Neurosurgeons had the primary relationships with brain tumor patients and had traditionally performed the open operations (to remove solid tumors) that the CyberKnife would replace. This population was receptive to new surgical procedures and innovations. Adler's personal connections with many neurosurgeons also helped generate excitement about CyberKnife within this community, paving the way for the acceptance of the device. With limited resources and funds to attract early adopters to the technology, Accuray became convinced that neurosurgeons would be a receptive audience.

Radiation oncologists, on the other hand, represented a stakeholder group that could be somewhat less receptive to the new device. Yet, Accuray had to earn their support because government regulations required radiation oncologists to participate in any form of radiation delivery, including radiosurgery. Because of various turf wars and financial issues, Accuray anticipated some resistance from radiation oncologists as physicians in different surgical specialties began using the CyberKnife. However, the company believed that it could mitigate these concerns in the neurosurgery field. Adler explained why: "Radiosurgery was developed by neurosurgeons and has been driven by this field for 35 or 40 years now. So, over time, radiation oncologists have come to accept neurosurgeons' role in this type of radiation delivery. Given such a history, the opposition from radiation oncologists could not be based simply on the fact that they control other forms of radiation." Having arrived at this conclusion, Accuray moved forward with efforts to attract both radiation oncologists and neurosurgeons to the use of CyberKnife in the field of neurosurgery.

When the company launched an improved version of the CyberKnife in 2000, the technology was ready to begin expanding indications for the device beyond neurosurgery. However, with this move, the company recognized that it would face an even greater challenge convincing surgeons outside neurosurgery and radiation oncologists to begin using the CyberKnife to treat patients with tumors in other regions of the body. For Accuray to have success in the long run, the company needed to fully understand the stakeholders involved in the broader radiosurgery arena and how to reach them.

Starting with physician stakeholders, Adler observed that surgeons in other specialties (non-neurosurgeons) tended to be less open to new innovations. Many of them were also threatened in other ways, having already seen their practices reduced by interventional pulmonologists, cardiologists, and gastroenterologists performing less invasive procedures for conditions that had traditionally been addressed through surgery. "What Accuray is doing is pretty heretical," said Adler. "It is anti-surgery in the eyes of true-blue surgeons because we're not cutting people open, there's no general anesthesia, and there's no blood loss – it's not nearly as dramatic as conventional surgery. So it strikes at the heart of what surgeons see themselves as being. It's not a trivial cultural shift to get surgeons to understand that they needn't be defined by blood loss and pain."

To help address concerns within this stakeholder group, Accuray had two primary arguments in its favor. The first, according to Adler, was that 90 percent of patients given the option would choose radiosurgery over traditional surgery. Additionally, surgeons reluctantly recognized that they needed to get involved in such procedures or risk losing this entire portion of their business to the radiation oncologists. Within the current healthcare delivery model, radiosurgery called for a surgeon and a

radiation oncologist to be present during the procedure, with both specialists reimbursed separately for their time. Because of the manner in which it is used, CyberKnife procedures could possibly be performed by a single physician, and since most state regulations necessitated the participation of radiation oncologists, surgeons could potentially be seen as expendable participants. Recognizing this fact helped motivate surgeons to involve themselves in the adoption of the CyberKnife and carve out their role in the procedure, beyond just referring patients for treatment. "We achieved a sort of critical mass when surgeons started to realize that this was inevitable," recalled Adler. "They recognized they either had to get in the game, or they were going to be left behind."

Because the use of the CyberKnife in areas beyond neurosurgery would dramatically increase the involvement of radiation oncologists in treating a new class of patient, Accuray hoped that this stakeholder group might be receptive to the company's efforts to expand the use of the device. However, in reality, this turf battle turned out to be what Adler described as one of the company's "biggest problems." Instead of seeing opportunity to expand the use of radiation treatments to more patients "they worried about a new group of physicians playing with what was traditionally their toy. From a regulatory standpoint, it's pretty clear that radiation oncologists have been given complete authority by the state and federal governments to oversee all of this type of work, but they were still threatened." He continued, "They never looked and said, 'This is good because now we're going to be treating 80 or 90 percent more patients.' They don't think that way. Especially the more senior practitioners seemed more committed to creating their little fiefdom and keeping out any interlopers."

With both surgeons and radiation oncologists showing some reluctance to adopt the CyberKnife in areas outside the neurosurgery field, Accuray developed a robust marketing communication strategy to help drive adoption. The activities that the company undertook directly targeted the specific concerns of these surgeons and radiation oncologists, as well as patients, payers, and hospitals where the procedures would be performed.

When asked about the most successful marketing activity that Accuray employed to convince radiation oncologists and surgeons in other specialties of the benefits of the CyberKnife, Adler was adamant that it was the use of publications. "The single most effective strategy is to perform clinical outcomes studies and publish them in peer-reviewed journals," he said. When asked how many studies Accuray had performed, Adler answered, "Maybe a hundred. It never ends." The company's strategy was to perform relevant studies in specific specialty markets and then publish the results in the most prominent peer-reviewed journals in those fields to maximize the credibility of the results. Although it is more expensive to set up multiple studies, showing improved clinical outcome for each condition makes it much easier to market to surgeons, radiation oncologists, and payers. Accuray also presented its data to the targeted specialists at numerous conferences, as well as networking extensively with potential users.

Another interesting move by the company was the development of its own professional society: The CyberKnife Society (now called the Radiosurgery Society). The purpose of this group was "bringing together diverse medical professionals affiliated with radiosurgery worldwide to foster scholarly exchange of clinical information, and to educate the general public with patient information on treating medical conditions, such as cancers, lesions, and tumors anywhere throughout the body using the CyberKnife, most of which are unreachable by other radiotherapy systems." With a strong online presence, Adler said, "The society is focused on providing ongoing professional training and a way to give [surgeons and radiation oncologists] updates and the medical tools they need to use this technology to its latest and greatest capacity." For patients, it is another source of information for learning about their conditions, creating demand for the technology, and networking with other CyberKnife patients.

According to Adler, once patients understand the CyberKnife procedure and how it compares to traditional, open surgery, most of them become intrigued and request more information about the procedure from their surgeons. Accuray seeks to encourage this behavior by sending "evangelists" (patients who have successfully undergone CyberKnife treatment) to patient advocacy and support groups. In their role as evangelists, patients also are vitally important to influencing the next groups of stakeholders: Medicare, private insurance companies, and other payers.

Accuray realized early on that its first adopters would be extremely important in helping the company convince the American Medical Association (**AMA**) and Medicare to create new codes and coverage rates that would allow physicians and facilities to be adequately reimbursed for CyberKnife procedures. The company leveraged its relationship with an early CyberKnife adopter, Georgetown University Hospital in Washington D.C., to help influence the Center for Medicare and Medicaid Services (CMS) regarding the value of its device during the decision-making process. "It's all a matter of persistence," he said, "and of applying enough pressure." To assist in swaying payers, Accuray assisted customers in the formation of the CyberKnife Coalition, a membership of the product's users, to work with lobbyists on issues related to reimbursement.

The last stakeholder group, which is among the most important for Accuray, includes the hospital administrators who make the decision to approve the multi-million dollar purchase of the CyberKnife. To justify such a sizable expenditure, Accuray needed physicians to actively lobby hospitals to buy the equipment. The decision to start with the neurosurgery field proved to be beneficial to the company, as neurosurgeons are often influential within hospitals based on the revenue and profits they generate. However, Accuray also discovered that it needed physicians who would be aggressive in their support for the product and willing to persevere through the lengthy, bureaucratic buying process typical in most hospitals. To help convince hospital administrators to invest in its systems, Accuray developed a customized, detailed business case that outlined how much income each hospital could generate, across specialties, through the CyberKnife product (see 5.8 Sales and Distribution Strategy for more information about Accuray's approach to sales). Although the company had experienced some success in driving adoption among hospitals, this stakeholder group remained difficult to satisfy and could be the primary impediment to more widespread adoption in the future.

Using what Adler referred to as "guerilla marketing techniques," Accuray managed to successfully grow its business. The company went public in 2007.[32]

Online Resources

Visit www.ebiodesign.org/5.7 for more content, including:

Activities and links for "Getting Started"

- Revisit preliminary stakeholder analysis
- Develop value propositions and collect required evidence
- Define product/service mix
- Develop a pricing strategy
- Decide on positioning
- Develop an approach to promotion

Videos on marketing and stakeholder strategy

CREDITS

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NOTES

1 Stephen N. Silverman, "An Historical Review and Modern Assessment of the Marketing Mix Concept," *7th Marketing History Conference Proceedings*, 1995, http://faculty.quinnipiac.edu/charm/CHARM%20proceedings/CHARM%20article%20archive%20pdf%20format/Volume%207%201995/25%20silverman.pdf (February 24, 2014).

2 D.R. Strutton, J.W. Kowalski, D.A. Glaser, and P.E. Stang, "U.S. Prevalence of Hyperhidrosis and Impact on Individuals with Axillary Hyperhidrosis: Results from a National Survey," *Journal of the American Academy of Dermatology*, August 2004, http://www.ncbi.nlm.nih.gov/pubmed/15280843 (February 11, 2014).

3 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

4 Japan's regulatory system allows for devices that are approved in other markets or undergoing clinical trials in Japan to be directly imported by a physician into the country without Japanese regulatory approval if the physician receiving the device is: (1) able to name the specific patient that will use the device, and (2) is willing to personally accept the risks associated with importing the product.

5 Kotler and Keller, *Marketing Management*, 14th edn. (Prentice Hall, 2011).

6 Lyn Denend and Stefanos Zenios, "Drug Eluting Stents: A Paradigm Shift in the Medical Device Industry," Stanford Graduate School of Business, February 13, 2006, https://gsbapps.stanford.edu/cases/detail1.asp?Document_ID=2787 (February 26, 2014).

7 Ibid.

8 Ibid.

9 Tiger Buford, "OIC, the Generic Implant Company in Reno, Is Revolutionizing the Price of Implants," May 9, 2012, Orthostreams, http://orthostreams.com/2012/05/oic-the-generic-implant-company-in-reno-is-revolutionizing-the-price-of-implants/ (February 26, 2014).

10 "OIC Releases High Value Proximal Humerus Plate," OIC press release, December 13, 2010, http://orthoimplantcompany.com/category/news-and-events/ (February 26, 2014).

11 "NABC Value Creation," SRI International, September 15, 2010, http://www.slideshare.net/HumInno/nabc-value-creation-5204311 (February 19, 2014).

12 Christopher L. Wasden and Mitchell L. Wasden, *Ride the Innovation Cycle* (expected release date 2015).

13 Ibid. Reprinted with permission.

14 Ibid.

15 A.S. Go, G.M. Chertow, D. Fan, C.E. McCulloch, and C.Y. Hsu, "Chronic Kidney Disease and the Risks of Death, Cardiovascular Events, and Hospitalization," *New England Journal of Medicine*, September 23, 2004, http://www.ncbi.nlm.nih.gov/pubmed/15385656?dopt=Abstract (March 11, 2008).

16 Brandon Keim, "Pay-For-Performance Pharmaceuticals: Satisfaction Guaranteed or Your Money Back," *Wired*, July 16, 2007, http://blog.wired.com/wiredscience/2007/07/pay-for-perform.html (February 5, 2014).

17 "Genomic Health Announces National Payor Agreement With UnitedHealthcare Insurance Company," Genomic Health press release. http://investor.genomichealth.com/releasedetail.cfm?ReleaseID=225085 (February 5, 2014).

18 Julie Manrriquez, Lyn Denend, and Stefanos Zenios, "CycleBeads II: Creating a Dual-Market," Global Health Innovation Insight Series, March 2012, http://csi.gsb.stanford.edu/sites/csi.gsb.stanford.edu/files/CycleBeadsII-CreatingaDualMarket.pdf (February 12, 2014).

19 "Fact Sheet: Bundled Payments for Care Improvement Initiative," Centers for Medicare and Medicaid Services, http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2014-Fact-sheets-items/2014-01-30-2.html (March 10, 2014).

20 Lauren Uzdienski, "OIG Approves New Gainsharing Plan," HealthPoint Capital, November 28, 2006, http://www.healthpointcapital.com/research/2006/11/28/oig_approves_new_gainsharing_plan_advamed_critical/ (February 5, 2014).

21 Mark Prodger, "A Primer on Gainsharing," Hospital Buyer, http://www.hospitalbuyer.com/materials-management/cost-savings/a-primer-on-gainsharing-145/ (February 5, 2014).

22 "Fact Sheet: Bundled Payments for Care Improvement Initiative," op. cit.

23 "Stark Law Guidelines," Stark Law, http://starklaw.org/stark_guidelines.htm (February 5, 2014).

24 "TRUE Dilatation™ Balloon Valvuloplasty Catheter," C.R. Bard, http://lomavistamedical.com/wp-content/uploads/2013/05/Datasheet.pdf (March 13, 2014).

25 "Code of Ethics," AdvaMed, http://advamed.org/issues/1/code-of-ethics (February 5, 2014).
26 From remarks made by Ron Dollens as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, March 21, 2005, http://biodesign.stanford.edu/bdn/networking/pastinnovators.jsp. Reprinted with permission.
27 "athenahealth causing Trouble Again," The Health Care Blog, May 7, 2007, http://www.thehealthcareblog.com/the_health_care_blog/2007/05/cigna_ranks_no_.html (February 5, 2014).
28 Thomas M. Burton, "More Are Eligible for Heart Device – Accused of Rationing Care, Medicare Expands Use of Implantable Defibrillators," *The Wall Street Journal*, September 29, 2004, p. D4.
29 "FDA Approves First Breast Ultrasound Imaging System for Dense Breast Tissue," U.S. Food and Drug Administration press release, September 18, 2012, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm319867.htm (February 12, 2014).
30 "Are You Dense, Inc. and U-Systems Announce Partnership to Increase Awareness of Breast Density and Access to Adjunctive Screening Tools," U-Systems press release, April 4, 2011, http://www.businesswire.com/news/home/20110404005186/en#.UvvsJvldV8E (February 12, 2014).
31 "New Jersey Passes Breast Density Law," American Society of Radiologic Technologists, February 5, 2014, http://www.asrt.org/main/standards-regulations/regulatory-legislative-news/2014/02/05/new-jersey-passes-breast-density-law (February 12, 2014).
32 "CyberKnife Frequently Asked Questions," Accuray, Inc., http://www.cyberknife.com/faq/index.aspx (February 5, 2014).
33 "Direct-to-Consumer Advertising," SourceWatch, http://www.sourcewatch.org/index.php?title = Direct-to-consumer_advertising (February 5, 2014).