1.1 Strategic Focus

INTRODUCTION

An engineer with a needle-phobic mother decides to design an alternate method for administering the daily insulin she takes to control her diabetes. A spinal surgeon, frustrated with the limitations of the implants she uses to treat vertebral compression fractures, starts working on improvements to the device. A business student observing a birth at a hospital in Africa is surprised by the extent of blood spray during the process and becomes concerned about protecting healthcare workers when the mother is infected with HIV. A resident studying oncology becomes passionate about understanding the disease more fully and commits himself to cancer research and the pursuit of a cure. While all of these paths are worthwhile, they are not universally appealing. The course that excites one innovator may be uninteresting or overwhelming to another. But, the one thing that these paths have in common is that they are compelling to the people undertaking them. By aligning these passions with their unique competencies and using these factors to create criteria for selecting or rejecting specific projects, innovators increase their likelihood of choosing a successful path that will also keep them motivated and engaged as they navigate the many challenges that await them in the biodesign innovation process.

OBJECTIVES

- Understand that innovators must explicitly choose their strategic focus.
- Appreciate the importance of achieving alignment between the mission and strengths and weaknesses of the individual and/or team and the strategic focus area that is chosen.
- Recognize the steps involved in choosing a strategic focus.

One of the first, most important steps in the biodesign innovation process is for innovators to discover and commit themselves to the strategic focus area that stimulates their personal enthusiasm. By explicitly deciding in what areas to focus, innovators accept different risks, challenges, and potential rewards (e.g., working on heart problems is much different from working on wrinkle removal). To make an effective, meaningful decision about a strategic focus, innovators must ask themselves questions about why they want to pursue this path, what they hope to accomplish, and how their strengths and weaknesses may affect their efforts. Additionally, a high-level assessment of the characteristics of the focus area and the environmental factors affecting it should be taken into account relative to these goals. Ultimately, the most rewarding and successful biodesign projects are those that achieve a high degree of alignment

between the values and competencies of the innovators and the defining characteristics of the strategic focus area that is chosen.

See ebiodesign.org for featured videos on choosing a strategic focus.

STRATEGIC FOCUS FUNDAMENTALS

As Mir Imran, CEO of InCube Labs and founder of more than 20 medical device companies, said:[1]

> *I knew once I found a problem, I could solve it. The biggest challenge for me was which problem to solve.*

The most productive way to launch the biodesign innovation process is to choose a strategic focus – an area to pursue that matches the innovator's core competencies and personal or organizational mission. Determining a strategic focus involves:

- Deciding what the innovator or organization values or wants to achieve, independent of any specific vehicle or project for accomplishing it.
- Accurately assessing what competencies the innovator or the organization have (or do not have) that will affect the ability to realize those goals.
- And then translating these insights into criteria that can be used to objectively evaluate opportunities and decide which problems or focus areas to pursue.

If one thinks of the innovation process as a journey – from discovering medical needs to developing and commercializing new medical technologies to solve those needs – then the selection of a strategic focus is analogous to charting a course.

Developing a strategic focus

The notion that innovators typically create new inventions in a spontaneous stroke of genius is a myth. For most medtech innovators, ideas do not just happen – they are the result of an intentional decision to go out and seek opportunities and problems in a specific area.

Making this decision is not always easy. But using a structured approach can help (see Figure 1.1.1). Choosing a strategic focus begins with performing a personal inventory. Explicitly defining a mission and understanding their strengths and weaknesses helps innovators define "acceptance criteria" – conditions that they will used to determine whether a project is a good fit. Acceptance criteria are also shaped by factors in the external environment that may affect the ability of innovators to act on their interests and realize their goals. Once they are comfortable with their acceptance criteria, innovators can begin evaluating a variety of opportunity areas to arrive at a strategic focus.

Conducting a personal inventory

The personal inventory should be performed before the innovator begins thinking about any particular opportunity or problem area. The purpose of the inventory is to identify the mission of the individual or team, as well as their strengths and weaknesses.

Conducting a personal inventory is equally important for individual innovators, academics/researchers, small teams, young companies, and large corporations, in that it helps ensure that the person (or people) undertaking the innovation process are enthusiastic about the strategic focus that is chosen and that they have the necessary capabilities to pursue it. The issues and priorities that emerge as a result of the inventory will be different based on the constituency performing it; however, the value of the exercise will be the same.

Determining a mission Innovators must be unambiguous about their mission. A mission is a broad, directional aspiration that defines what an individual or group wants to accomplish. Articulating a mission sets a desired destination for an innovation project and provides clarity about the ultimate goal(s) the individual or group hopes to achieve.

To define a mission, individuals and groups should think about their priorities, beginning with questions

FIGURE 1.1.1
Using a structured approach that takes internal and external factors into account can help lead innovators to a strategic focus that provides a good fit.

about what is most important to them (or, conversely, not important to them). For example, a priority for someone pursuing a career in research or academia might be to engage in an exceptionally compelling research project that, if successful, would have a dramatic impact on healthcare worldwide. While such a long-term mission might take an entire career to achieve, the magnitude of the potential outcome would be large enough to make that commitment worthwhile to someone with this goal. Getting involved in a project with a less significant outcome might take less time and effort to achieve, but would be less interesting to the individual due to the misalignment with his/her mission.

In companies and other established organizations, the mission sometimes takes the form of what is commonly known as a mission statement. The Medtronic example that follows illustrates how a corporate mission statement might look.

Large corporations may also choose to define specific missions for their divisions or groups. At this level, other priorities may surface as they approach the innovation process. With established portfolios of products to leverage (and protect), a division might not always be interested in finding the biggest innovation. Instead, it may focus on driving incremental improvements in existing product lines that enable it to stay ahead of the competition. Or, with more extensive resources at its disposal, a company might be willing to make slightly larger, longer-term investments with the intent of leapfrogging competitors over time.

The missions of aspiring entrepreneurs or young start-up companies may be different still. These individuals and teams do not necessarily have to create mission statements that are as formal or expansive as those of a large company. As long as the mission is clearly articulated, it can be significantly more informal (although it is still advisable to put it in writing). Additionally, the mission might be somewhat more practical or applied. For example, without the resources to support a vast, long-term research program, two innovators working together on a shoestring budget might decide that an important aspect of their mission is to identify a solution that is readily achievable (within two to three years) and compelling enough from a business perspective to raise

FROM THE FIELD MEDTRONIC

Defining a meaningful mission statement

Medtronic was founded in 1949 by Earl Bakken and his brother-in-law Palmer Hermundslieco as a medical equipment repair shop. The fledgling company quickly expanded into services and then into device design, development, and manufacturing.[2]

During the early years, Bakken was moved by the emotional response patients had to the company's products. Many were overjoyed to regain mobility, to feel better, and sometimes even to be alive as a result of Medtronic's work (see Figure 1.1.2).[3]

Inspired by their stories and the desire to make this type of human benefit the purpose of the organization's efforts, he and the board of directors created the Medtronic Mission, which remains an integral part of the company's culture and the driving force behind every project that it undertakes. This Mission guides the company's day-to-day work and keeps employees focused on the goal of changing the face of chronic disease for millions of people around the world.

FIGURE 1.1.2
Earl Bakken with a young Medtronic patient (courtesy of Medtronic).

Medtronic's Mission is:[4]

- To **contribute to human welfare** by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.
- To **direct our growth in the areas of biomedical engineering where we display maximum strength and ability**; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
- To **strive without reserve for the greatest possible reliability and quality in our products**; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.
- To **make a fair profit** on current operations to meet our obligations, sustain our growth, and reach our goals.
- To **recognize the personal worth of employees** by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.
- To **maintain good citizenship** as a company.

As William Hawkins, former CEO of Medtronic explained while he was at the helm of the organization, "The mission is our moral compass. It is the glue that binds all of our businesses together. It underpins everything we do. In good times and tough times, the one constant in our business model is our core values. We use the mission to ensure that we work on the right things and that we strive to do things right."[5]

financial support. Unlike the researcher or aspiring academic, these innovators would be more focused on near-term opportunities that are meaningful, but not too expensive to pursue.

Identifying strengths and weaknesses In addition to thinking about a mission, individual innovators, academics/researchers, small teams, young companies, and large corporations will all benefit from assessing their strengths and weaknesses. Specifically, they should evaluate what they do well, and how they can capitalize on these strengths. They should also consider in what areas they are less experienced, competent, or confident, and how they can compensate for these relative weaknesses.

Some people can be successful in leading the innovation process (especially in its early stages) on their own. However, many individuals *and* groups recognize, after they assess their strengths and weaknesses, that they will benefit from collaborating with others who offer different, complementary skill sets. For example, if an innovator is a strong clinician, but not an engineer, it might be helpful to partner with an engineer if the mission is to develop a device technology. Or, if that same innovator is interested in developing a business plan to pursue a concept, s/he might want to consider collaborating with someone with business training or experience to help construct and execute that plan. Wildly creative types are best paired with grounded detail-oriented types, and so on. Fundamentally, the most important objective of this step is to identify where certain competency gaps and opportunities exist so that the innovator can address them when the time is right. It is rare for one person to embody all the talents necessary to identify, invent, develop, and commercialize a technology all alone. However, innovators are aware of areas where help may be necessary, they can begin building a team with the strengths that complement known weaknesses, and can make sure that team expands as requirements for more diverse skills increase.

Considering external factors

Finding the right fit from a personal (or internal) perspective is essential but, as the medtech field becomes increasingly complex, it is also important to evaluate what is happening in the external environment. Over the past several years, factors out of the innovator's direct control have shifted dramatically. In the US, for example, regulatory and reimbursement pathways have become significantly less predictable and more time and resource intensive. In parallel, access to capital is more uncertain and difficult to obtain. A similar shift is being felt in Europe where macroeconomic conditions are contributing to the adoption of more conservative policies with the potential to slow the pace of innovation. Against this backdrop, patients, physicians, facilities, and payers alike are looking more critically at the affordability of healthcare and the economic value associated with new innovations.

In combination with completing a personal inventory, innovators should think about how these external factors may affect their goals and/or play to their strengths and weaknesses. Factors in the external environment can add significantly more risk to a project by increasing the amount of time, money, and resources required to achieve results. Innovators will have different "appetites" for risk in the external environment. Some will be driven to pursue their goals at any cost, while others may prefer a more moderate level of challenge with the hope of increasing their chances of success. Understanding this at a conceptual level is an important input to subsequently defining project acceptance criteria.

Defining acceptance criteria

At their most basic, acceptance criteria are conditions that must be met to make an innovation project attractive to the innovator. These criteria are defined based on what the innovators have learned about themselves by conducting the personal inventory and considering the external environment. Innovators apply their acceptance criteria to choose an area of strategic focus, as well as to help assess the needs they discover in the early stages of the biodesign innovation process.

Of course, there is no single set of acceptance criteria that works for every individual or team. However, most acceptance criteria are built around common themes that, when customized by the innovator, become

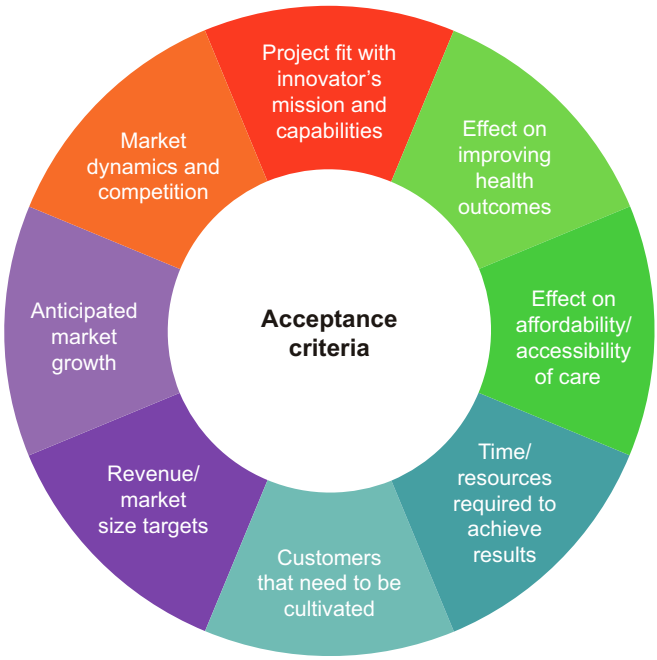


FIGURE 1.1.3
Acceptance criteria are frequently built around some combination of these common themes.

requirements that an innovation project must meet (see Figure 1.1.3).

For example, suppose that a large corporation has a mission to develop a product that expands its portfolio into a new clinical area that drives increased growth within the company. Before defining its acceptance criteria, the company would have to think about what strengths and weaknesses it has that would enable it to achieve this goal. The availability of resources (staff, funding, time) would certainly be an enabler. However, the way in which its existing sales force is deployed (i.e., which types of doctors it already calls on) could be a strength or a weakness, depending on the specific area of focus that is chosen. After performing an assessment, the corporation might decide to engage in a project only if it meets the following acceptance criteria:

- The clinical practice area is new to the company and is growing at a minimum of 10 percent per year and/or can generate a minimum of $100 million in revenue per year.
- Technologies in this space have a relatively well-understood regulatory pathway and clear clinical trial requirements so they can be brought to market within two to three years.
- The company's established sales force already calls on these same customers, so the commercial fit is good.
- A new solution can potentially be cost-neutral or cost-reducing to key healthcare stakeholders.

In the mid-1990s, American Medical Systems (AMS) had two primary products: an implantable urinary sphincter and a penile prosthetic line. Its mission was to become a well-rounded urology company by broadening its focus to include other urological products. As the company began to think about its acceptance criteria for new opportunities, the list included the following: (1) technologies that could be sold to the same customer or at the same "call point"; (2) technologies that were more mechanical in function than biological; and (3) opportunities/areas that could grow at greater than 20 percent per year to add to the company's revenue growth.[6] Under different circumstances (for instance, if the company had saturated its existing customer base), the corporation might have eliminated the criterion to stay within the same customer group. While this would have made a wider cross-section of potential projects attractive to the company, it might not have allowed it to achieve certain economies of scale by offering the same customers a wider line of products through the existing sales force. In this respect, the acceptance criteria defined by the AMS appropriately reflected its priorities at the time and capitalized on the perceived strength of its established sales arm.

Without any limitations imposed by a preexisting business, an innovator or young company might define acceptance criteria around the magnitude of the impact its solutions can have on peoples' lives. In this scenario, with a mission to improve important outcomes for patients on a major scale, the acceptance criteria might require a project that:

- Has a total potential market of $1 billion or more.
- Will be cost-neutral or cost-reducing (so it gets adopted).
- Will be attractive to investors (so it gets adequate financial support).
- Results in an innovation that has a significant impact on patients' **quality of life** (as opposed to an

innovation that makes a device cheaper, faster, or easier to use).
- Has platform potential so that the benefits from one medical specialty can be rapidly leveraged to affect patients in other practice areas.
- Is focused on a patient segment where head-to-head competition can be avoided, especially if the company is concerned about its ability to compete with entrenched firms.

The acceptance criteria above are similar to those used by medtech **incubators** such as ExploraMed, The Foundry, The Innovation Factory, or Coridea. Such criteria enable these organizations to continually deliver powerful innovations in a number of diverse fields. However, these particular criteria represent just one approach. Given the variety of players active in the medtech field, there are other incubators, as well as other organizations and innovators whose acceptance criteria would look completely different. For instance, a more philanthropically oriented organization might have acceptance criteria that guide them to projects that:

- Benefit individuals living on less than $2 per day.
- Significantly expand access to healthcare in areas where treatments exist but have previously been unaffordable.
- Have dual-market potential so that by charging customers "market rates" in wealthier settings the organization can subsidize costs in low-resource settings.
- Are aligned with the priorities of certain foundations and/or non-governmental organizations to help attract funding for product development.

Evaluating opportunities against acceptance criteria

Once specific acceptance criteria have been defined, innovators can start exploring different interest areas for a good fit. The idea is to screen each potential opportunity area against the acceptance criteria, setting aside the ones that do not provide a good match and looking more deeply at those that do. Innovators are encouraged to consider a broad range of possibilities, keeping in mind that deep expertise in a field is not necessarily required. All too often, people who are deeply immersed in a field fail to see the opportunities and problems that surround them because they have been indoctrinated into a certain way of doing things. Individuals and teams who bring diverse experiences and different backgrounds to a field can sometimes be more successful in uncovering opportunities and problems because they are more willing to question the status quo.

One approach is to start by evaluating problems and opportunities related to a personal interest or passion. For instance, someone might become committed to working in the breast cancer field after losing a loved one to the disease. While this is certainly a valid method for choosing a strategic focus, innovators must still conduct research in that area to determine the extent to which opportunities and problems in the space meet their defined acceptance criteria at more than just a superficial level. They must also be prepared to "walk away" if significant gaps are uncovered between the acceptance criteria and the area being explored. It can also be helpful to get more specific about the strategic focus area. For instance, would it be a better fit to embark on a long-term research-based path to cure the disease, or to pioneer near-term improvements in the effectiveness of breast cancer treatment? Innovators can use their other acceptance criteria to define a concentration within the desired field that is most likely to lead to a fulfilling experience and outcome.

If innovators do not have a specific passion for a particular opportunity or problem area, another way to begin the process of screening potential focus areas against their acceptance criteria is to examine high-level data related to a practice area or disease state (note that more in-depth research will be performed in subsequent steps of the biodesign innovation process). Statistics to consider include the number of people affected by a condition, the clinical impact of the disease, the outcomes and costs of existing treatments, the profitability of existing treatments, and the rate at which spending is growing (see Table 1.1.1). Innovators can also glean insights from the total revenue realized each year in a particular medical field (see Figures 1.1.4 and 1.1.5).

The more thoughtful this evaluation process, the better. However, even a cursory evaluation of different clinical areas (and their subspecialties) will potentially help to narrow one's focus. For example, an innovator or

Table 1.1.1 Data such as total expenses for selected conditions and percent distribution by type of service, as shown in the table, can be an interesting source of ideas regarding areas that might meet the innovator's acceptance criteria (Agency for Healthcare Research and Quality, "Total Expenses and Percent Distribution for Selected Conditions by Type of Service: United States, 2010," Medical Expenditure Panel Survey Household Component Data, generated interactively (September 19, 2013).

United States, 2010		Percent distribution by type of services				
Conditions	Total expenses (millions)	Hospital outpatient of office-based visits	Hospital inpatient stays	ER visits	Prescribed medicines	Home health
Heart conditions	107,186.40	18.0	62.9	5.2	9.2	4.7
Trauma-related disorders	82,303.57	43.2	38.0	13.3	1.8	3.7
Cancer	81,734.62	50.2	36.8	0.3	8.3	4.4*
Mental disorders	73,060.24	24.1	15.1	1.4	45.3	14.0
COPD, asthma	63,782.99	23.5	27.2	4.4	37.7	7.1
Osteoarthritis and other non-traumatic joint disorders	62,362.98	40.3	31.4	1.2	17.4	9.7
Diabetes mellitus	51,310.57	21.9	22.1	1.2	48.0	6.7
Hypertension	42,943.38	30.4	12.5	2.0	47.4	7.8
Back problems	39,259.66	56.6	28.4	2.4	9.4	3.2*
Hyperlipidemia	37,174.19	25.7	2.7*	0.1*	69.1	2.3*
Normal birth/live born	34,945.69	23.6	72.8	2.3*	1.0*	0.2*
Systemic lupus and connective tissues disorders	30,836.17	48.1	29.5	2.2*	12.3	7.9*
Other central nervous system disorders	25,898.88	44.0	42.6	2.8	7.5	3.1
Disorders of the upper GI	23,457.37	20.3	18.5	4.5	53.7	2.9*
Kidney disease	22,967.52	47.7	33.8	8.2	6.8	3.5*
Other circulatory conditions arteries, veins, and lymphatics	22,678.64	32.3	57.4	2.0	6.3	2.1*
Gallbladder, pancreatic, and liver disease	22,646.35	15.7	72.4	8.1*	2.7*	1.2*
Other endocrine, nutritional and immune disorder	22,097.34	52.4	25.3*	2.5*	15.4	4.3*
Infectious diseases	21,909.62	21.6	32.0	4.1*	39.1	3.2*
Cerebrovascular disease	20,576.60	12.4	59.1	8.3*	5.9	14.3*

* Relative standard error equal to or greater than 30 percent; total percentages do not always add to 100 due to rounding

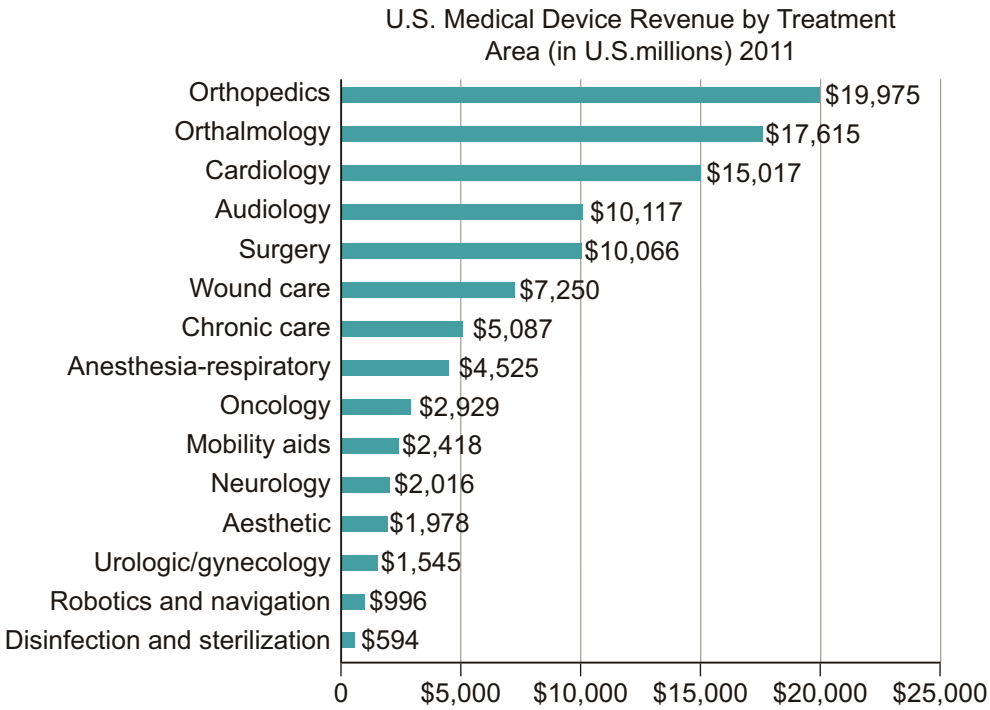


FIGURE 1.1.4
Information about medical device revenues by major medical segment can be helpful in choosing a strategic focus (from "U.S. Medical Devices Market Outlook," Frost & Sullivan, 2012; reprinted with permission).

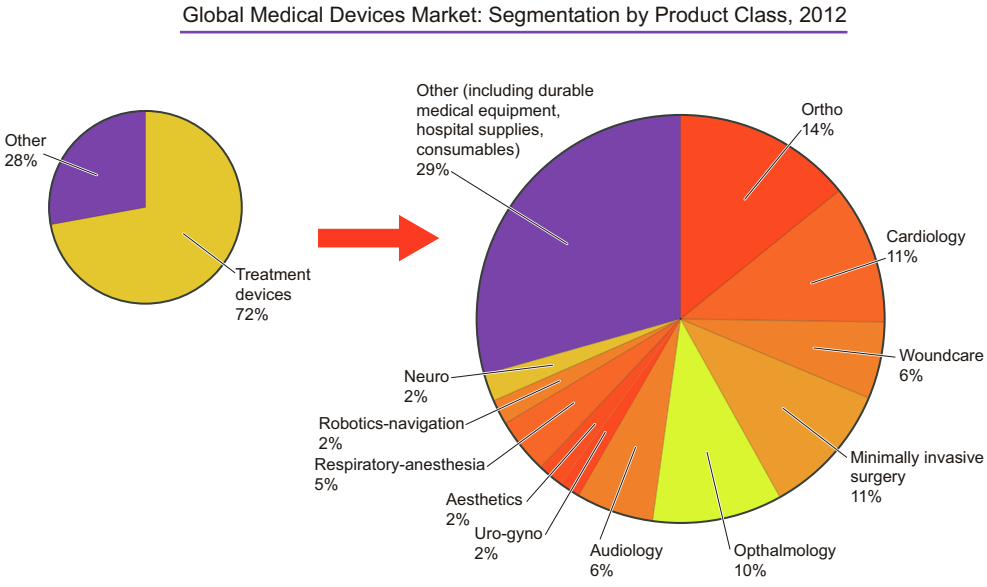


FIGURE 1.1.5
Market segmentation by product class can vary by geography, so innovators may wish to consider data for different locations. Note: all figures are rounded; the base year is 2012 (from "Global Medical Devices Market Outlook," Frost & Sullivan, 2013; reprinted with permission).

company seeking a large business opportunity might review certain statistics and other data (as shown in Table 1.1.1) and immediately become interested in the cardiovascular field. Yet, the fact that this is a relatively well-established, mature field may conflict with some of the other acceptance criteria that the innovator has defined. If the innovator is committed to new opportunities and problems that have not yet been defined or where innovation has not occurred for quite some time, another field outside of cardiology might be a better fit (e.g., respiratory medicine or urology). In an area with a well-defined market opportunity, there may be intense competition and a great deal of pressure to be first to market with technology that could set the new

standard of care. In less popular areas, the advantages of weaker competition are balanced by greater uncertainties – both regarding the ability to attract investment and motivate behavior change among physicians who are entrenched in the old ways of treating patients. This is where the innovator's acceptance criteria (and how they are prioritized) can help to resolve inherent conflicts and facilitate effective trade-offs, which become clearer when evaluating these different risks and rewards.

As innovators evaluate opportunity and problem areas against their acceptance criteria, a strategic focus or a few acceptable focus areas should begin to emerge. Regardless of the specific area that is chosen, a strong sense of "the right fit" is essential to anyone embarking on the biodesign innovation journey.

The following story from ExploraMed describes how one innovator worked through the process of choosing a strategic focus.

FROM THE FIELD EXPLORAMED

Applying acceptance criteria in evaluating a strategic focus

Making an explicit decision about the strategic focus to be pursued is an essential exercise for individual innovators, teams, companies, and incubators alike. According to Josh Makower, founder and CEO of medical device incubator ExploraMed, "Choosing what is not a fit is as important as determining what is."[7] ExploraMed has embedded this step in its process for identifying, creating, and developing new medical device businesses. When Makower initiates a new business, he and his team spend time assessing their relative strengths and weaknesses and articulating the acceptance criteria against which they will screen potential opportunities.

ExploraMed's defined mission is to "focus on clinical needs where there is an opportunity to dramatically improve outcomes and build freestanding businesses." As Makower explained, "I get excited about working on things that are going to have a major impact on medicine. We want to work on projects that make a substantial contribution, can potentially change the direction of healthcare, and affect outcomes for thousands or millions of patients. If a large number of people are affected by a problem and currently have poor outcomes from the existing set of treatments, it could be a hot area for us to investigate." Recognizing their own strengths and weaknesses, Makower and team further constrain their efforts to medical device opportunities, leaving drugs, diagnostics, and other healthcare technologies to a different set of innovators and entrepreneurs. Finally, they specifically like the idea of being "contrarians." "We like to go where others haven't gone and where people believe there aren't reasonable opportunities. You can create a competitive advantage for yourself by being the first to go in another direction. The other thing that we're trying to do is create big enterprises. To do this, we almost always have to be willing to go into a space where there aren't a lot of other players. A little fish can grow to be pretty big if he finds himself in a big pond all by himself. I like that a lot better than trying to establish a foothold in an already crowded market."

These defined acceptance criteria are routinely used by ExploraMed to evaluate which opportunities to pursue, as the following example demonstrates. Early in the company's history, when the team was actively investigating new projects, Makower's elderly aunt fell and broke her hip. "Before the accident, she was energetic, vibrant, and active. After she fell, her life changed dramatically. She had trouble with her daily activities, as well as doing the things she loved, like seeing her children and grandchildren. Suddenly, she was an old lady, when that wasn't how she lived before." With a new passion to address problems and opportunities in this area, Makower and Ted Lamson, an ExploraMed project creator at the time (see Figure 1.1.6),

FIGURE 1.1.6
Lamson working on a device test (courtesy of ExploraMed).

began to investigate the space. What they quickly learned was that hip fractures represent a sizable problem and account for 350,000 hospital admissions and 60,000 nursing home admissions each year. More than 4 percent of hip fracture patients die during their initial hospitalization, and a full 24 percent die within a year of the injury. 50 percent lose the ability to walk.[8] "It's a shocking mortality rate," noted Makower. "We speculated that there was a need for a less invasive alternative to hip replacement, and that the size of the incision or **morbidity** from the operation itself was the key to the problem. Eventually, we discovered that this guess was wrong and that the real problem was not in the surgery, but in post-surgery recovery. If we hadn't been following a defined process for researching the space, we easily could have become biased towards a solution early on that would have sent us in the wrong direction," he emphasized.

ExploraMed's first acceptance criterion – the size and severity of the problem – was the first screen the team applied to the problem, and hip fractures appeared to be a promising market. Makower and Lamson conducted further preliminary research to understand what companies and innovations were active in the space. It turned out that numerous advancements had been made in hip surgery and the devices used to support it, but that few new technologies existed to improve post-operative care and recovery. "If you get the patient up immediately post-procedure, and you effectively manage their pain locally so they can walk around and never waste any of their muscles, then their outcomes are fantastic. But if they stay in bed more than they should because their pain is not managed well, they do terribly. What happens is that they lose muscle mass, they get sick or become depressed, and then they die of pneumonia or some other complicating condition." With few individuals or companies working to address the non-surgical issues associated with hip fractures, the field appeared to be wide open to ExploraMed.

Unfortunately, as Makower and Lamson got further and further into their exploration, they identified a conflict with one of their important acceptance criteria. After weeks and weeks of interviewing patients and doctors and researching the space, they became concerned that the most compelling opportunities in the space might not be best addressed with device technology. "We discovered that the most pressing problems were related to improving local pain management to help patients ambulate more quickly," recalled Makower. "It was a big opportunity in an open market, but we realized it would probably be best addressed by a drug solution. However, we didn't have the right technology, skills, or resources to take on a drug project. We really wanted to figure it out, but we realized that we weren't the right guys to do it. Regardless of your passion for an area, you have to be honest with yourself about you and your team's strengths and weaknesses."

Wanting to be sure before abandoning hip fractures as an opportunity area, the team confirmed its hunch through additional research and consultations with experts in the field. "Upon further investigation we actually discovered systems to do exactly what we wanted to do already existed, but were not being utilized because of healthcare management constraints or cost. This was very discouraging . . . the answer was there and doctors were actually aware of it, but they were not using

it for one reason or another," Makower commented. Eventually, the team decided to reject the project and continue their search elsewhere. "You have to be willing to accept a lot of failure," he said, reflecting on the experience. "But you've got to keep on trying – and failing if necessary – in order to understand the parameters that will make you successful and ultimately enable you to choose the right path." Later, Makower and Lamson redirected their focus to an entirely different clinical area and, after several months of investigation, found a compelling opportunity that met all their criteria and became a company called NeoTract, Inc. (see 5.2 R&D Strategy for more information about NeoTract).

Global consideration in choosing a strategic focus

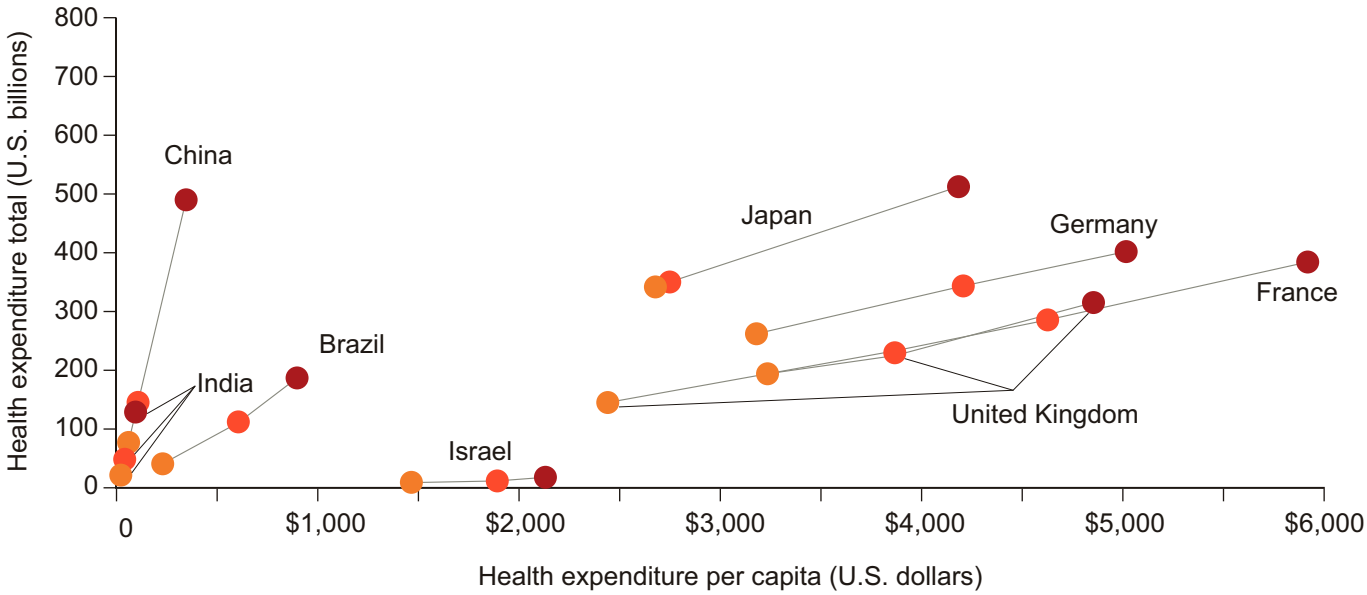
The fundamental process of choosing a strategic focus is the same whether the innovator wishes to work in the United States, Europe, China, India, or any other geographic market. Yet, as the epicenter of medical device innovation continues to gradually shift away from the US, innovators are encouraged to make their geographic focus an explicit part of their internal and external analysis before making a decision.

In 2012, the worldwide medical device market reached $331 billion.[9] Although the United States, Europe, and Japan still represent approximately 75 percent of that total, medical device sales in emerging markets are growing two to five times faster than in developed countries.[10] In the coming years, China, India, and Brazil are forecast to experience the sharpest increase in total and per capita healthcare spending. China is expected to be the world's third largest healthcare market by 2020, closing in on Japan in second place.[11] Health expenditures in these countries will be fueled by the demand for value-driven, lower-cost technologies to meet the needs of their vast populations. In contrast, Israel, Japan, and some European countries will continue to drive up per capita spending on a combination of value and premium products (see Figure 1.1.7).

Although the vast majority of medtech innovation is currently centered in the West, this will continue to shift over the next two decades. These changes are already underway as device manufacturers, seeking relief from the external factors noted above, establish new or move their operations elsewhere. Accordingly, greater numbers of innovators from inside and outside the US will find their focus drawn to opportunities that span the globe. Whether or not problems and opportunities in emerging countries provide a good fit depends on the innovators' acceptance criteria. For example, countries such as China, India, and Africa have large groups of patients with dire needs for effective, affordable solutions (see Figure 1.1.8). But mechanisms to pay for new medical technologies are still being developed, especially when it comes to treating low-income populations. Innovators with strong acceptance criteria around helping others and having a major impact on large numbers of prospective patients may choose to gravitate toward these opportunities, while those with a stronger interest in optimizing their financial return may choose other projects.

Innovators exploring strategic focus areas in emerging markets also face an increased level of risk. In places like China, for example, intellectual property (IP) protection and regulatory processes are still under development. This additional uncertainty prevents some companies and innovators from moving into these markets and creates additional challenges for those who do. Many of these types of risks will almost certainly be reduced or resolved over time. But it will take the efforts of many motivated and committed innovators to make this happen.

Another source of risk is related to the innovator's familiarity with a given market. A critical aspect of the biodesign innovation process is the ability to gain a deep understanding and a true sense of **empathy** for the patients being targeted, no matter where they are located. Anytime US-based innovators focus on opportunities overseas, or overseas innovators focus on problems in the US, they should be aware that extra time,



The World Bank, World Health Organization, and PwC analysis

FIGURE 1.1.7

This global trend analysis highlights how countries vary in their appetite for cost- versus outcome-driven innovation per capita. As a benchmark, US per capita spending on healthcare was $7,285 in 2007, compared to per capita spending shown in the chart, which ranges from $40 in India to $4,209 in France for the same time period. Total US spending on healthcare in 2007 was $2,159 (in U.S. billions). ("Medical Technology Innovation Scorecard: The Race for Global Leadership," PricewaterhouseCoopers, January 2011; reprinted with permission.)

effort, and resources will be required to access, research, and truly understand the problems and opportunities, the people experiencing them, and the context within which they exist. This work is certainly not impossible, but it must not be overlooked and rarely can be done from afar.

Ethics in the biodesign innovation process

Choosing a strategic focus is among the first of many steps in the biodesign innovation process where innovators may face ethical dilemmas. The potential for ethical conflicts exists at nearly every stage of an innovator's journey. Ethics are the intentional choices that people make and the basic moral principles that are used to guide these decisions. Ethics do not provide a specific value system for making choices, but rather a set of basic principles that can be followed to guide decision making.[12] Often, there is not one "right" choice. Stated another way, ethics provide the rules or standards that guide (but do not determine) the conduct of a person or the members of a profession. In developing and bringing new medical technologies to market, the need to maintain the highest ethical standards extends to everyone involved in the process.

At the heart of most ethical issues are conflicts of interest, which arise when one person's interests are at odds with another's. For example, confidentiality (or the practice of discerning what is privileged information and rigorously protecting it) is an important principle in the medical field. If one party has an incentive to disclose confidential information about another party, a conflict of interest may arise. Because there are so many individuals and groups in the development and commercialization of any medical innovation, conflicts of interest are inevitable. Realistically, the objective of any innovator should not be to avoid such conflicts, but to minimize their occurrence and ethically address and resolve them when they arise. In particular, in any scenario where conflicts of interests involve patients and the care they receive, innovators have a special obligation to act ethically because of the potential to both improve and harm human lives.

FIGURE 1.1.8
The Jaipur artificial knee (as shown above) is one example of an effective, affordable solution targeted at low-income patients with a limited ability to pay. The product costs $35–40 compared to $6,000–35,000 for similar technology in the US (courtesy of the Stanford–Jaipur Knee team from Professor Tom Andriacchi's mechanical engineering course: L. Ayo Roberts, Joel Sadler, Angelo Szychowski, and Eric Thorsell).

Ethics in the medical field have a difficult past, with trials, such as the Tuskegee syphilis experiment, creating issues of fear and distrust between medical providers and the patients they are meant to serve. In this particular case, the US Public Health Service ran an experiment on 399 black men from 1932 to 1972. These patients, who were mostly poor and illiterate, had late-stage syphilis but were not informed from what disease they were suffering. The doctors involved in the experiment had no intention of curing the men – instead, their objective was to collect scientific data from their autopsies. Over years, the patients experienced tumors, heart disease, paralysis, blindness, insanity and, eventually, death.[13] Since then, significant strides have been made, internal and external to the profession, in enforcing a strong code of ethics across the medical community. Moreover, every member of the medical community, medtech innovators included, has an important role to play in promoting and adhering to ethical behavior.

Early in the biodesign innovation process in particular, innovators often struggle with the tension between altruistically addressing important medical problems and the imperative to do so in such a way that the solution has a viable chance of reaching the market for which it is intended. An inspirational new therapy cannot, in most cases, reach patients without the necessary capital to develop it; yet capital will be provided by commercial investors primarily if they feel that a reasonable profit can be obtained. It can be frustrating to innovators to identify problems and opportunities only to discover that the market or profit potential for a solution is too small or risky to attract funding. Although capital can be obtained from government grants, non-governmental organizations (**NGOs**), or beneficent donors, there are inherent limitations associated with this type of funding that can prevent an innovation from achieving its full potential.

To develop a truly sustainable solution, most innovators have to strike a balance among satisfying the requirements of the target audience, optimizing patient benefit, and satisfying the interests of investors. Protecting investors is known as a fiduciary duty. A fiduciary is any individual or group that has the legal responsibility for managing somebody else's money.[14] As a fiduciary, the innovator has an obligation to carry out the responsibility of managing others' funds with the utmost degree of "good faith, honesty, integrity, loyalty, and undivided service of the beneficiary's interest."[15] At the most basic level, this means that

Table 1.1.2 An example of a medical ethics (from the American Medical Association's "Principles of Medical Ethics"; reprinted with permission).

American Medical Association's Principles of Medical Ethics
A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
A physician shall support access to medical care for all people.

innovators have a duty not to favor anyone else's interests (including their own) over those of the beneficiary.[16] If the fiduciary violates this responsibility, they may be subject to legal liability, which is another reason why ethical behavior is so important throughout the innovation process.

Striking an appropriate balance can be difficult when conflicting interests arise. The important thing to remember is that the "right" solution may vary for every innovator based on their individual ethical compass. By openly acknowledging the fact that "gray areas" exist and taking time for self-reflection, innovators can more readily determine the approach that is most closely aligned with their values.

Regarding other ethical conflicts in the innovation process, innovators are generally advised to maintain a primary focus on the best interests of patients in resolving issues. Seeking input and advice from objective third parties can be an invaluable resource for resolving conflicts. However, more often than not, innovators must rely on their own codes of personal and professional ethics. The following four principles are widely accepted as ethical standards in the medical field.[17,18]

Respect for autonomy

Respect for autonomy refers to others' rights to make their own choices. This means, for example, that all parties with an interest in a new innovation must be informed about its risks and benefits, any potential conflicts of interests among those involved in its development and delivery, and about any other factors that could conceivably affect their choice. Ultimately, the patient has the right to refuse the offer to participate in an investigative study.

Beneficence

Beneficence is the practice of doing good. Medical personnel are often taught, "First, Do No Harm," but there is usually the possibility of some harm if medical devices either provoke complications of their use or they malfunction. In the field of medical innovation, this mandate extends to maximizing benefits while seeking to minimize potential harm.

Non-maleficence

The mandate of non-maleficence also is captured by the phrase "First, Do No Harm." Often beneficence and non-maleficence cannot be separated. In the process of providing a medical benefit, healthcare providers may also expose patients to risk. For instance, in clinical trials, patients are exposed to risks for the sake of others, by making it possible for life-saving devices to reach the market. The Hippocratic oath taken by many physicians essentially combines the principles of beneficence with non-maleficence, by stating that the obligation of healthcare professionals is to provide the greatest net medical benefit at minimal risk.[19]

Justice or fairness

All those in the medical field have an obligation to fairly decide among competing concerns and interests. At a minimum, this requires recognizing potential conflicts of interest and objectively determining, sometimes with third-party assistance, how they should be resolved. This principle also extends to fairness in dealing with the subjects of clinical trials; and to the reporting of all data from such trials, including negative findings, so as to benefit others in general and specifically to prevent repetition of trials without benefit for patients.

Because so many interactions in the biodesign innovation process involve clinicians, innovators should become familiar with the specific ethical codes developed by relevant medical professional societies. For instance, it may be helpful to familiarize oneself with the World Medical Association's Physician's Oath as defined in the Declaration of Geneva in 1948.[20] Table 1.1.2 summarizes the American Medical Association's Principles of Medical Ethics, the foundation of the **AMA** Code of Medical Ethics, one of the most well-known and widely practiced codes of ethics in the medical field. The complete code, consisting of these Principles and the opinions of the Council on Ethical and Judicial Affairs, is available online.[21]

When conflicts must be resolved or difficult decisions must be made, a strong code of ethics can be used by innovators as an essential guide.

Online Resources

Visit www.ebiodesign.org/1.1 for more content, including:

- Activities and links for "Getting Started"
  - Take inventory
  - Articulate a strategic focus
- Videos on strategic focus
- An appendix that lists professional associations for select medical conditions

CREDITS

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NOTES

1 From remarks made by Mir Imran as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, April 28, 2004, http://biodesign.stanford.edu/bdn/networking/pastinnovators.jsp. Reprinted with permission.

2 "Our History," Medtronic.com, http://www.medtronic.com/about-medtronic/our-story/garage-years/index.htm (September 11, 2013).

3 "Our Mission," Medtronic.com, http://www.medtronic.com/about-medtronic/our-mission/index.htm (September 11, 2013). Reprinted with permission.

4 Ibid.

5 From an exchange with William Hawkins, CEO of Medtronic, Fall 2008. Reprinted with permission.

6 From an exchange with Thom Gunderson, Medical Device Analyst for Piper Jaffray, Fall 2008. Reprinted with permission.

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

8 "Hip Fractures in Seniors: A Call for Health System Reform," American Academy of Orthopaedic Surgeons and American Association of Orthopaedic Surgeons, 2008, http://www.aaos.org/about/papers/position/1144.asp (September 12, 2013).

9 Mary Mosquera, "Global Medical Device Market Increases Just 3 Percent in 2012," *Healthcare Finance News*, May 28, 2013,

http://www.healthcarefinancenews.com/news/medical-devices-grow-3-percent-2012 (September 11, 2013).

10 Nicholas Donoghoe, "Medical Device Growth in Emerging Markets: Lessons from Other Industries," *InVivo*, The Business and Medicine Report, June 2012, http://www.elsevierbi.com/publications/in-vivo/30/6/medical-device-growth-in-emerging-markets-lessons-from-other-industries (September 11, 2013).

11 "Medical Technology Innovation Scorecard: The Race for Global Leadership," PricewaterhouseCoopers, January 2011, http://download.pwc.com/ie/pubs/2011_medical_technology_innovation_scorecard_the_race_for_global_leadership_jan.pdf (September 19, 2013).

12 R. J. Devettere, *Practical Decision Making in Health Care Ethics* (Georgetown University Press, 2000).

13 "The Tuskegee Syphilis Experiment," Infoplease.com, http://www.infoplease.com/ipa/A0762136.html (September 18, 2008).

14 Jerry Sais Jr. and Melissa W. Sais, "Meeting Your Fiduciary Responsibility," Investopedia, http://www.investopedia.com/articles/08/fiduciary-responsiblity.asp (September 12, 2013).

15 Errold F. Moody, Jr., "Fiduciary Responsibility," EFMoody.com, http://www.efmoody.com/arbitration/fiduciary.html (September 12, 2013).

16 Ibid.

17 T.L. Beaucham and J.F. Childress, *Principles of Biomedical Ethics* (Oxford University Press, 1989).

18 "The Belmont Report: Ethical Principles and Guidelines for the Protection of HumanSubjects of Research," The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html (November 26, 2013).

19 R. Gillon, "Medical Ethics: Four Principles Plus Attention to Scope," *British Medical Journal*, July 16, 1994, p. 184.

20 See The World Medical Association's Physician's Oath, Declaration of Geneva, 1948, http://www.cirp.org/library/ethics/geneva/ (September 12, 2013).

21 See "Council on Ethical and Judicial Affairs," American Medical Association, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page? (September 12, 2013).