Focus on Value

What do we mean by "value" and why is it so important?

The escalation of healthcare costs is one of the major economic and political issues of our time. The problem is most apparent in the United States, where healthcare as a share of the economy has more than doubled over the past 35 years. Spending on health accounted for 7.2 percent of the nation's gross domestic product (GDP) in 1970, expanded to 16 percent in 2005, and is projected to be as high as 20 percent of GDP by 2015.[1]

Simply put, the US economy cannot sustain this spending trajectory, which has outpaced GDP growth for years (see Figure V1).[2] The problem is not just straining the federal budget: state and local governments have been forced to reduce support for education, infrastructure, and other critical expenditures as they struggle to fund Medicaid and other health programs. In the private sector, the cost of employment-based health insurance is one of the main reasons workers have seen their wages stagnate.[3]

Despite the fact that the US spends two-and-a-half times more per capita on health than most developed countries,[4] it does not necessarily provide the best care to its citizens. In 2000, when the World Health Organization ranked the health systems of its 191 member states for the first time ever, the US found itself in 37th position.[5] In a more recent study that compared the US to Australia, Canada, Germany, the Netherlands, New Zealand, and the United Kingdom on measures of quality, efficiency, access to care, equity, and the ability of citizens to lead long, healthy lives, America occupied last place. As the report pointed out, "While there is room for improvement in every country, the US stands out for not getting good value for its healthcare dollars."[6]

Against this backdrop, economists, researchers, and policy makers alike have pointed to medical technology as a dominant factor driving increased health expenditures in the US. Their estimates of the impact of technical innovation on accelerating costs vary considerably, but some argue that new technologies and the procedures that accompany them account for one-third to one-half of real long-term spending growth in healthcare.[7] To be sure, many of these technologies have provided major advancements in health and longevity, ranging from

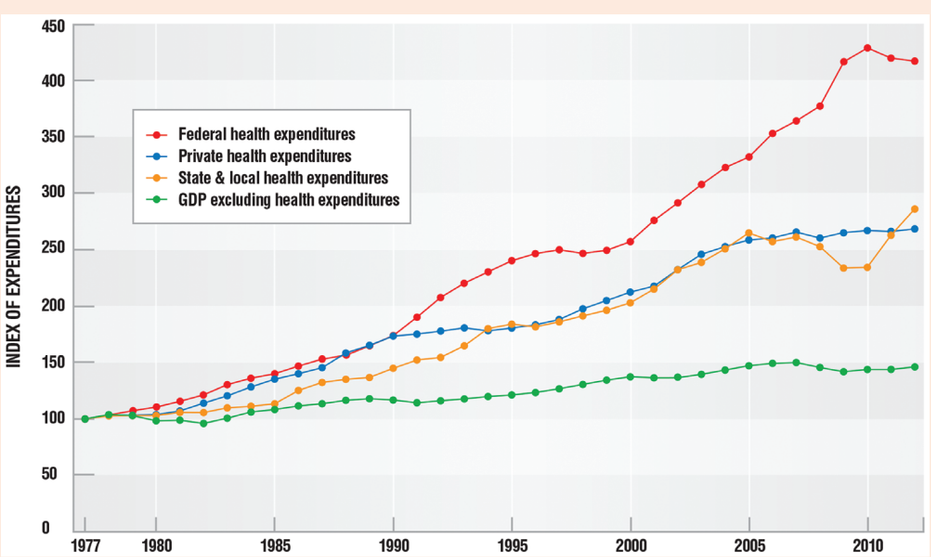

FIGURE V1
Indexes of US health expenditures and GDP (excluding health expenditures), per capita, adjusted for inflation, 1977–2007 (compiled based on National Health Expenditure data, CMS.gov).

diagnostic breakthroughs such as CT and MRI scanning to life-saving surgical and interventional therapies for the heart and brain. Increasingly, however, even revolutionary developments such as these are being weighed against the unsustainable rise in healthcare costs.

Since the birth of the modern medtech industry in the mid-twentieth century, the majority of medical technology companies pursued a philosophy that has been described as "progress at any price."[8] Innovators and companies were focused on developing new products that resulted in improved clinical outcomes, almost regardless of their associated cost. In some cases, this meant simply making marginal enhancements in order to sell a next-generation technology at a higher price. These strategies were successful for many years because the fee-for-service payment system in the US largely uncoupled the providers, who make the treatment decisions, from the payers, who bear the costs of their choices. In this way, the market forces that operate in other sectors of the economy have not been effective in maximizing the value of health technologies and services. By spending trillions of dollars on new innovations, the US fueled the growth of the medical technology industry and helped to foster a view that complex and expensive technology was the hallmark of superior healthcare.

While the US has been hardest hit by uncontrolled health spending, it certainly is not alone. The countries in the European Union and Japan, which together with the US account for 75 percent of all medtech sales today,[9] have also been wrestling with how to manage mounting healthcare costs. Moreover, as the middle class expands in developing countries such as India, China, and Brazil, these patients are demanding increased access to more advanced healthcare, potentially initiating the same spiral of escalating health expenditures. In fact, these issues are already emerging, with medical device sales growing two- to five-times faster in these markets than in developed countries.[10]

Together these forces have launched a fundamental shift in the healthcare sector. The affordability of care relative to its quality is now a primary focus in both developed and developing markets. "Progress at any price" is no longer a tenable strategy as health systems universally place increasing emphasis on ensuring a good value for the healthcare dollars they spend. In developed countries such as the US, providers, hospitals, clinics, and (in some cases) payers are consolidating to achieve economies of scale and organization. Value-based payment models are emerging. And purchasing managers and executives are playing a more central role in deciding which medical technologies to adopt, with physicians influencing, rather than dictating, those choices. In developing countries, health systems recognize they are facing increased demand for medical technologies but are actively pursuing more affordable, cost-effective products and services designed specifically to address the needs of patients and providers in settings with fewer resources. In other words, around the world, the need for medical technologies that deliver clear *value* to their intended users has never been more imperative.

The concept of value is widely understood in general terms, but is more difficult to articulate as a concept to be considered throughout the biodesign innovation process. Here are a few key points that resonate with us about value and value creation:

- Value is an expression of the improvement(s) a new technology and its associated services offer relative to the incremental cost. Just because a new technology provides an improvement doesn't mean it will create value.
- Importantly, value is not realized unless the cost/improvement equation is compelling enough – that is, has enough marginal benefit over other available solutions – to cause decision makers to change their behavior and adopt the new technology.
- We are in a period of transition with respect to who the key decision makers are in the healthcare field. In particular, purchasing power is shifting from individual physicians to integrated health systems and patients are becoming more knowledgeable and active healthcare consumers. In the process, both of these audiences are demanding greater cost transparency.
- In parallel, the assessment of value is evolving from being product specific to outcomes oriented. Stated another way, decision makers are increasingly evaluating total solution offerings across an episode of care rather than focusing on an individual technology or service. Within this context, new types

of value-based offerings and innovative business models are emerging.

Understanding what we mean by value is important because it has a major impact on how you approach the biodesign innovation process. In short, while medtech companies used to strive to produce products that delivered optimal improvement (without undue attention to cost), we are now seeing purchasers demand offerings that drive cost as low as possible. In certain situations there will be willingness to sacrifice some degree of performance for a better price (see Figure V2). Amidst the uncertainty of today's value-oriented environment, technologies that significantly – not incrementally – generate measurable savings while providing acceptable (or better) quality will be the ones with the clearest path forward.

So how can innovators practically address value in the design, development, and commercialization of their medtech offerings? There are multiple steps in the biodesign innovation process where opportunity exists to create and deliver value (as you navigate the book, you will see substantial attention to value in almost every chapter). But there are three critical points at which value should be a primary focus:

- **Value exploration** – Early in the biodesign innovation process (see chapters 1.1 and 1.2), innovators should begin scanning for problems and opportunities that are ripe for value realization. This means actively seeking *need areas* where improved economic outcomes can potentially be generated. As they perform research, observations, and interviews, innovators have traditionally watched for what we call *practice-based value signposts*; for example, opportunities to address problems such as keeping patients out of the hospital, shortening the length of hospital stays, and reducing procedure time. But in the new environment, they should take a more explicit plunge into investigating *budget-based value signposts*, such as big line items on facility budgets, negative outliers in the cost-effectiveness of existing treatments, and extreme variations in treatment costs across geographies. These and other economic signals will guide the next generation of medtech innovators to promising areas to begin needs finding.

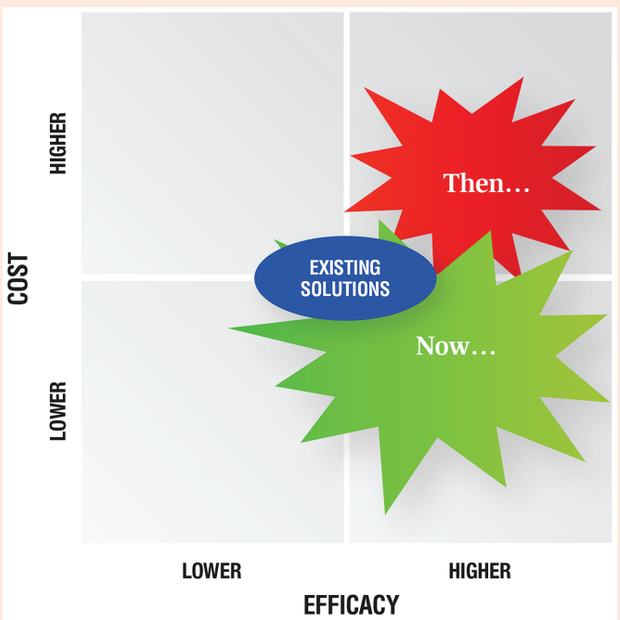

FIGURE V2
The medtech landscape – then and now.

- **Value estimate** – Once promising *needs* have been identified, innovators dive deeper into understanding the potential to create and deliver value through the needs screening stage of the process (especially chapters 2.4 and 2.5). Quantifying value in this stage of the process can be tricky since no specific solutions have yet to be defined. However, innovators can still develop directional estimates of the value associated with their needs in order to ensure it is worth moving forward into concept generation. These estimates are based broadly on understanding who the real decision makers are with respect to adoption/purchasing decisions in each need area, how significant they perceive the need to be, to what degree available solutions are effectively addressing the need, and therefore how much margin there is to offer a new technology with a different improvement/cost equation. The insights gleaned from explicitly considering value at this early stage can save innovators from investing time, resources, and energy in developing solutions that ultimately will not offer a significant enough value proposition (see below) to drive decision makers to adopt them.

- **Value proposition** – As the *solution* to a promising need begins to take shape, innovators can begin thinking about value in more concrete, concept-specific terms. A value proposition describes the net impact of the cost/improvement equation associated with a new offering in terms that are meaningful to decision makers and sufficiently convincing to elicit a change in their behavior. Value propositions form the core of a company's sales and marketing activities and become a source of its competitive advantage and differentiation (see chapters 5.7 and 5.9). Importantly, value propositions must be backed by strong evidence that resonates with decision makers and the influencers that surround them. In the new healthcare environment, value propositions increasingly require the company to share the risk of ensuring that the promised improvements and desired outcomes are realized at the stated cost.

These mechanisms for anchoring the biodesign innovation process on value are broad and directional. We are still in the early stages of what is clearly a profound shift in the way medical technology innovation will address the economics of healthcare. But we hope that these initial ideas, as well as the discussion of value that permeates the text, will serve as a useful starting point for innovators as they embrace this new paradigm in device innovation.

As with any major economic and social transformation, there are tremendous opportunities for those who can position themselves to understand and take advantage of the changes. And the wonderful part about this particular technology sector is that the innovators who are able to make the transition may have the opportunity to benefit millions of patients around the globe.

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NOTES

1 "Snapshots: How Changes in Medical Technology Affect Health Care Costs," Henry J. Kaiser Family Foundation, March 2, 2007, http://kff.org/health-costs/issue-brief/snapshots-how-changes-in-medical-technology-affect/ (March 25, 2014).

2 Victor R. Fuchs, "New Priorities for Biomedical Innovation," *New England Journal of Medicine*, August 19, 2010, http://www.nejm.org/doi/full/10.1056/NEJMp0906597 (March 25, 2014).

3 Ibid.

4 "Why is Health Spending in the United States so High?," *Health at a Glance 2011: OECD Indicators*, Organization for Economic Cooperation and Development, http://www.oecd.org/unitedstates/49084355.pdf (March 25, 2014).

5 "Health Systems: Improving Performance," *The World Health Report*, 2000, http://www.who.int/whr/2000/en/whr00_en.pdf (March 25, 2014).

6 "U.S. Ranks Last Among Seven Countries on Health System Performance Based on Measures of Quality, Efficiency, Access, Equity, and Healthy Lives," The Commonwealth Fund, June 23, 2010, http://www.commonwealthfund.org/News/News-Releases/2010/Jun/US-Ranks-Last-Among-Seven-Countries.aspx (March 25, 2014).

7 For an example, see Sheila Smith, Joseph P. Newhouse, and Mark Freeland, "Income, Insurance, and Technology: Why Does Health Spending Outpace Economic Growth," *Health Affairs*, September/October 2009, http://content.healthaffairs.org/content/28/5/1276.full (April 29, 2014).

8 Fuchs, op. cit.

9 "Medical Device Growth in Emerging Markets: Lessons from Other Industries," *In Vivo*, June 2012, file:///C:/Users/Lyn/Downloads/Medical_device_growth_in_emerging_markets_InVivo_1206%20(3).pdf (March 25, 2014).

10 Ibid.

Global Perspectives

A world of opportunity …

Although the United States and Europe remain global leaders in medical technology innovation, the story of the medtech sector has become much more diverse in recent years as healthcare has become a global priority. Inventors and companies in countries around the world are playing an increasingly important role in sourcing

FIGURE G1
A snapshot of health and health-related spending in select countries around the world (compiled from The World Bank data, 2011).

ideas, designing and developing them into viable products and services, and introducing them into patient care. In parallel, device sales in developing countries are expanding at a rapid pace. As the US and Europe both sustain growth rates in the low single digits, medtech revenues in countries such as India and China are forecast to increase at a compound annual growth rate of 14 percent and 26 percent, respectively.[1]

The global transformation of the medtech sector has been driven by multiple, interrelated factors. In developed markets, health systems are actively seeking to slow health spending associated with medical technologies as they become more cost conscious and attuned to the value these products deliver. Moreover, as the time, expense, and complexity of developing new solutions in environments like the US continues to increase, innovators are moving offshore and creating new innovation hubs in locations around the world.[2]

In developing markets, disease profiles are shifting from infectious to chronic conditions, which makes diagnostic and device solutions a more important part of efforts to meet the healthcare needs of patients. Governments and private healthcare providers alike are increasing health-related spending (see Figure G1). And innovators and companies in low-resource settings are becoming leaders in inventing more affordable solutions that enable care delivery in any setting and reduce (rather than increase) its cost.[3]

Medtech innovators can certainly find compelling opportunities in both environments. They can also benefit from thinking more globally about how – and where – they source, develop, and sell their new solutions. While many innovators historically used a single market as their base, got established, and then expanded into new markets in a serial manner, they can now take a more global approach from the very beginning of the biodesign innovation process. Various regions in the world are moving into prominence in different parts of the medtech innovation process. To take just a few examples: Israel is home to over 700 medical device companies and leads the world in the medtech patents filed per capita.[4] It has become a hotbed of invention and incubation of medical technologies, with a robust start-up scene. Argentina, Brazil, and Chile have become leaders in conducting high-quality, yet affordable clinical trials for pharmaceutical and medical device companies from around the world.[5] Ireland has developed into a prominent medtech manufacturing center, serving eight of the top 20 medtech multinationals[6] and attracting new enterprises of all sizes.

Of course, each region has its own unique challenges and opportunities. In the pages that follow, we have tried to give innovators a flavor for this range of issues and possibilities by profiling six important medtech markets. Europe and Japan represent geographies outside of the US with well-established device industries; India, China, Latin America, and Africa represent those in which the sector is still emerging. The purpose of these profiles is to provide a context for healthcare innovation in these locations, highlight some of the barriers that innovators may encounter in working there, and share tactics they can utilize to increase their chances of success. We're grateful to the experts who worked with us to develop this valuable content.

Additionally, innovators will find significantly more global content through the remainder of the *Biodesign* text. While the book is still grounded in what's required to identify, invent, and implement a new medical technology in the US, we expanded our treatment of other markets through the inclusion of more global guidance, as well as case studies that feature innovators and companies working across the globe.

Global expansion in the medtech sector can make it possible for patients traditionally underserved by medical devices to benefit from advanced technologies in new and different ways. With the global medtech market on its way to $440 billion by 2018,[7] a world of opportunity truly awaits medtech innovators and the patients they are committed to helping.

NOTES

1 "Global Market for Medical Devices, 4th Edition," *Kalorama Report*, 2013, http://www.kaloramainformation.com/Global-Medical-Devices-7546398/ (March 10, 2014).

2 "Medical Technology Innovation Scorecard: The Race for Global Leadership," PricewaterhouseCoopers, 2011, http://download.pwc.com/ie/pubs/2011_medical_technology_innovation_scorecard_the_race_for_global_leadership_jan.pdf (March 10, 2014).

3 Ibid.

4 "How Did Israel Become a Hotbed for Medical Devices?," Fierce Medical Devices, August 14, 2013, http://www.fiercemedicaldevices.com/story/how-did-israel-become-hotbed-medical-devices/2013-08-14 (January 24, 2014).

5 "Climate Change in Latin America Makes for Successful Clinical Trials," MEDPACE, http://www.medpace.com/pdf/conductingtrialsinlatinamerica.pdf (March 10, 2014).

6 "Business in Ireland," IDA Ireland, http://www.idaireland.com/business-in-ireland/life-sciences-medical-tec/ (January 27, 2014).

7 "Medtech Market to Achieve Global Sales of $440B by 2018," Evaluate press release, October 12, 2012, http://www.evaluategroup.com/public/PressReleases/Medtech-Market-to-Achieve-Global-Sales-of-$440-Billion-by-2018.aspx (January 27, 2014).

Africa

Background

Africa is on the rise. The twenty-first century has been called the "African Century" due to the continent's potential for increased economic development in the coming decades.[1] From 2000–2012, economic growth averaged more than 5 percent per year,[2] driven by the recovery of commodity prices, government economic and policy reforms, and restoration of international donor confidence and aid.[3] Africa's collective gross domestic product (GDP) topped US$1.7 trillion in 2012 (making it nearly comparable to Russia or Brazil),[4] and its middle class expanded to more than 34 percent of the continent's 1 billion people.[5]

Poverty is declining, yet Africa still has the highest poverty rate in the world with 47.5 percent of the population living on less than US$1.25 a day.[6] The continent also accounts for 25 percent of the global disease burden.[7] Maternal health, child health, HIV, tuberculosis, and malaria continue to be the continent's greatest health challenges. What may be surprising is that over the next 10 years, Africa will experience the largest increase in deaths from cardiovascular disease, cancer, respiratory disease, and diabetes of any continent in the world.[8] For instance, the World Health Organization estimated that in 2008 the prevalence of hypertension was highest in its Africa region, with nearly half of the population affected,[9] and this figure is on the rise.

Generalities are difficult to apply across this diverse continent. It is a massive, highly fragmented mosaic of more than 50 countries, with an estimated 2,000 languages spoken and thousands of distinct ethnic groups. The continent's diverse population is expected to double by 2050, from 1 billion to more than 2 billion.[10] Africa is endowed with more than 30 million square miles of varied geography and could fit China, India, the United States, and most of Europe within its physical boundaries.[11] Across this great expanse, the continent's healthcare infrastructure is evolving. African governments are working to expand healthcare delivery systems through public and private investment,[12] but in the meantime, millions of people must travel vast distances to receive basic medical care. As access to care improves, it is estimated that Africa will still require at least 800,000 additional doctors and nurses to adequately meet the healthcare needs of its population.[13]

However, advances are under way with the potential to improve healthcare delivery. Low-cost broadband mobile phones and Internet connections are reaching new populations and accelerating Africa's economic development. Mobile phone penetration surpassed 80 percent in late 2013.[14] Approximately 16 percent of people on the continent are now online, and that number is rapidly growing.[15] In the health sector, access to these technologies is expected to enable greater use of remote diagnosis, treatment, and education – extending the reach of scarce physician and nursing resources. Applying technology to improve healthcare in Africa is estimated to improve productivity, reduce costs, and deliver financial gains to the economy of US$84–$188 billion by 2025.[16]

While Africa has great potential for economic growth, the medical device industry is in its earliest stages of development. Combined sales of medical device and equipment across African countries are just over US$3.2 billion,[17] with most medtech products imported from Asia, Europe, and North America. Medical products imports expanded at a compound annual rate of 7.5 percent from 2006–2010, with the fastest growth seen in western and northern Africa.[18] Two key factors have prevented a stronger growth rate in medtech sales to date. First, Africa currently has insufficient buying power for high-end technologies. Second, in some countries there is not a medical technology ecosystem in place that can support adoption through the consistent and effective sale, distribution, and service of complex medtech products as well as the training of healthcare providers in their use. South Africa, Nigeria, and several North and East African countries represent the largest opportunities for medtech companies, both for adoption and local manufacture of medtech products. It is anticipated that