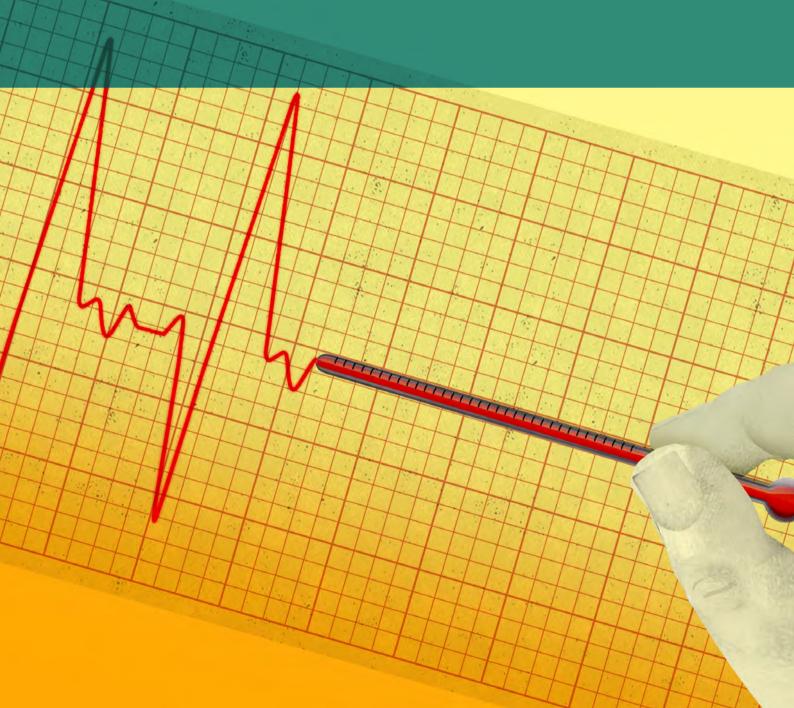




Boiling Point

The Need to Transform the Medtech Model in Europe



The Boston Consulting Group (BCG) is a global management consulting firm and the world's leading advisor on business strategy. We partner with clients from the private, public, and not-forprofit sectors in all regions to identify their highest-value opportunities, address their most critical challenges, and transform their enterprises. Our customized approach combines deep insight into the dynamics of companies and markets with close collaboration at all levels of the client organization. This ensures that our clients achieve sustainable competitive advantage, build more capable organizations, and secure lasting results. Founded in 1963, BCG is a private company with 78 offices in 43 countries. For more information, please visit bcg.com.

MedTech Europe is an alliance of European medical-technology-industry associations. The alliance was founded by EDMA, representing the European in vitro diagnostic industry; and Eucomed, representing the European medicaldevices industry. Other European medtech associations are welcome to join the alliance, which was established to represent the common policy interests of its members more effectively and efficiently. Our mission is to make value-based, innovative medical technology available to more people while supporting the transformation of health care systems onto a sustainable path. We promote a balanced policy environment that enables the medtech industry to meet the growing health-care needs and expectations of its stakeholders. In addition, we demonstrate the value of medical technology by encouraging our members to execute the industry's fiveyear strategy. For more information, visit www.medtecheurope.org.





Boiling Point

The Need to Transform the Medtech Model in Europe

AT A GLANCE

Pressure is rising in Europe and will force the medical-technology (medtech) industry to fundamentally change how it operates.

CHALLENGES ON A NUMBER OF FRONTS

The outlook for medtech in Europe is deteriorating as pricing pressure mounts, competition intensifies, and payers demand clear evidence of the cost-benefit tradeoff for products.

COMPANIES MUST OPTIMIZE THE EXISTING BUSINESS

Medtech companies need to make the most of their current operations by taking steps to transform their commercial model, prove the clinical and economic value of products, and improve their cost structure.

CHANGING THE PLAYING FIELD

Medtech companies must also reinvent how and where they compete—an effort that includes innovating differently, expanding to adjacent markets, and exploring the "value" segment.

It is not the strongest of the species that survives, nor the most intelligent. It is the one that is most adaptable to change.

THIS QUOTE—WHICH REFERS TO the work of Charles Darwin but is often erroneously attributed to him—underscores the need for all organisms to transform in
the face of change. Medical-technology (medtech) companies in Europe will
understand the power of that insight in the years ahead. While the industry
enjoyed robust top-line growth and healthy margins in the first decade of the
twenty-first century, that performance is now threatened. Driving this shift are
pricing pressures, the emergence of more sophisticated buyers, intensifying competition, new market-access schemes, and regulatory changes. The critical question is
whether medtech companies will respond quickly and effectively enough to the
altered landscape.

The Boston Consulting Group—with market insights, data, and input from MedTech Europe, an alliance of medtech industry associations—has taken an in-depth look at how companies must respond to the new European market realities and has assessed where the industry stands in terms of making the necessary changes. This work is a follow-up to the MedTech Europe industry-strategy report *Contract for a Healthy Future* (available at http://www.reforminghealthcare.eu/medtech-europe-reports) and BCG's *Fixing the Medtech Commercial Model: Are You Still Deploying Milkmen in a Megastore World?* (BCG Focus, July 2013). It is based on extensive research involving interviews with more than 50 senior leaders, including both industry and health care stakeholders, as well as a separate survey of 100 industry leaders and stakeholders.¹

Our research indicates that companies need to move now to maximize the value of their existing business while embracing new markets and approaches, including reinventing how they innovate and positioning themselves as catalysts of efficiency in the health care system. But our interviews and survey highlight that most companies are only just beginning this journey.

Consequently, the greatest threat facing medtech companies might ultimately be their own complacency. Those businesses that fail to respond effectively to the pressures around them risk the fate of the "boiling frog," a popular metaphor for the danger of inattentiveness and inaction. Although a frog dropped in hot water will jump out quickly to save itself, a frog dropped in cold water that is slowly and gradually heated won't notice the change and won't respond to it—ultimately succumbing to the heat.

Our research indicates that companies need to move now to maximize the value of their existing business while embracing new markets and approaches.

The Heat Is Rising

Medtech companies in Europe are facing challenges on a number of fronts. Among the most powerful trends reshaping the market are the increased demand from payers that companies prove the value of their products and lower their prices, intensifying competition, regulatory changes, and a slowdown in the pace of innovation. The result: a deteriorating financial outlook and significant operational challenges.

The medtech industry's troubles stem, in part, from the double-edged sword of growing health-care demand.

Increasing Demand for Value. The medtech industry's troubles stem, in part, from the double-edged sword of rising health-care demand. Demographic changes—most notably an aging population—are driving major shifts in health care, including an increase in the incidence of chronic diseases, rising demand for medical technology and services, and a move toward e-health solutions as well as toward community and home care.

But that rising demand is also driving up the health care bills of European governments. The result: governments are attempting to dampen health care inflation by exerting downward pressure on the price of medical technology, which currently accounts for 5 to 10 percent of total health-care expenditures. Such pressure comes on top of already low prices in Europe compared with the U.S. For example, the cost of a hip replacement in the U.S. runs \$40,634, but the average cost in France, the U.K., and Spain is \$10,182.² And the average cost of a magnetic resonance imaging scan in those three nations is \$309 as opposed to \$1,121 in the U.S.

At the same time, government and private payers are increasingly demanding evidence that medtech products are worth the cost, requesting not only clinical information but also evidence of their health-economic impact over the full cycle of care. This development comes as purchasing decisions are increasingly driven by more professional and cost-conscious buyers, such as purchasing groups. Although pricing pressure and the focus on value have been at work in the market for years, industry leaders confirm that the recent economic crisis has accelerated the pace and intensified the impact.

As the demands of payers shift, the patient landscape is also evolving. The role of patient associations has grown in recent years in Europe. For instance, in France the number of patient associations has grown from just 100 in the 1980s to 14,000 to-day. Meanwhile, the Internet and social media are also changing the game. Through sites such as Patientslikeme.com in the U.S. and Carenity.com in France, patients can share information about their experiences with medical devices, procedures, and outcomes—increasing transparency and empowering patients to make better-informed decisions.

Intensifying Competition. The increased demand for value comes as competition is intensifying in Europe. Many midsize European companies are fighting to reach critical size in a slower-growth market—a trend some interviewees point out is manifested, for example, in the recent increase in the number of bidders for hospital contracts. And a potential growing threat may come from emerging-market companies, some of which are opening branches and subsidiaries in European countries. While the degree to which they will gain ground in Europe is unclear,

according to the senior leaders we interviewed, this is a development that bears watching.

Regulatory Changes. Shifts are also occurring on the regulatory front. Ongoing regulatory revisions—notably those of the European Medical Devices Directives (the rules governing the industry in the EU)—are likely to trigger an increase in the cost of bringing new products to market. And the EU is creating a new framework, including the Cross-Border Healthcare directive, to foster cooperation across EU countries, particularly in areas such as health technology assessments and understanding the value delivered by medtech. This, together with the rise of European procurement networks, will push medtech companies to rethink their pricing strategy in order to ensure consistency across Europe. Such an effort will include adopting more top-down pricing strategies and controls to ensure local compliance with the pricing guidelines. In addition, companies must identify where they can provide new value-added services to differentiate their products in the eyes of physicians, patients, and payers.

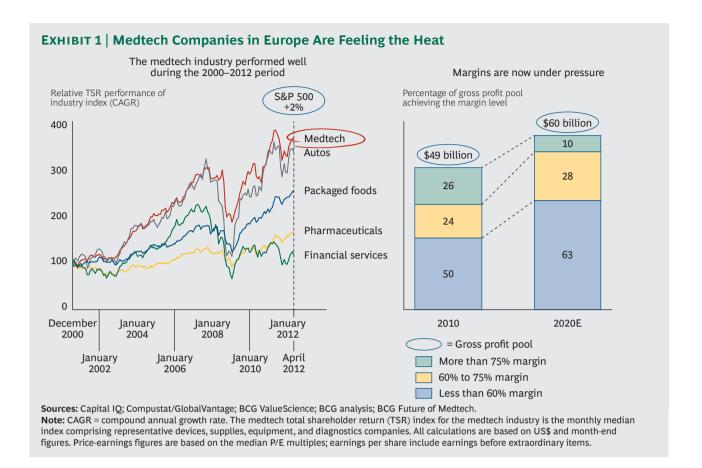
Slowdown in the Pace of Innovation. Much of the medtech industry's growth and performance over the past decade has been driven by innovation. And while medtech still outperforms other industries—medtech's patent applications in Europe in 2012 match those filed in the pharmaceutical and biotechnology fields combined—new-product development in the industry appears less robust than in the past. Medtech patent applications in the European Patent Office increased at an 8 percent annual rate between 2003 and 2009, but they then increased less than 2 percent annually in the following three-year period.³

Even greater challenges stem from the perception that new products do not offer a compelling cost-benefit tradeoff. In fact, as true advances become more difficult to achieve, medtech companies run the risk of overshooting with new products—delivering new devices or enhancements on existing ones that add only marginal value for payers, users, and patients and that address needs that are already sufficiently met in some segments.

The Result: A Deteriorating Financial Outlook. Medtech has been an attractive spot for investors in recent years. Between 2000 and 2012, the average total shareholder return (TSR) for medtech companies amounted to 12 percent per year, compared with 2 percent for the S&P 500. But as the heat rises for medtech companies, our analysis shows that their outstanding performance is at risk. (See Exhibit 1.) European sales for the industry are projected to grow 3 percent annually between 2010 and 2020, down from an annual growth rate of 10 percent for the period between 2000 and 2010. And while price increases and so-called mix benefits (the launch of new products that replace less expensive, older products) were a key growth driver from 2000 to 2010, companies will find that they will no longer be able to rely as heavily on those levers.

Meanwhile, volume growth will be moderate at best. Although trends such as an aging population will drive demand in Europe, actions by payers—for example, the restrictions that have been placed on reimbursement for certain products—will constrain that expansion.

As the heat rises for medtech companies, our analysis shows that their outstanding performance is at risk.

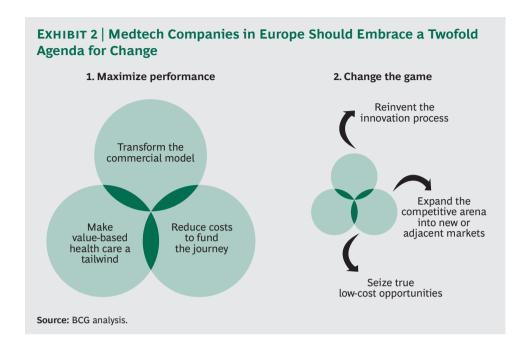


All of this explains why average gross profit per product segment is forecast to slide from 56 percent in 2010 to 52 percent in 2020.

To succeed in this challenging environment, our research makes clear that the status quo is not an option. Companies must shift from a technology and product focus to concentrating on delivering solutions that truly address customer and patient needs and have proven clinical and health-economic value—a concept stressed in *Contract for a Healthy Future*. The shift requires action on two fronts. (See Exhibit 2.) First, it is critical to maximize the performance of the existing business—leaders should do the most with what they have. The second effort involves changing the game—that is, moving beyond the existing core business. Here, companies have opportunities to revamp how they innovate and to expand the definition of their business by moving into adjacent markets.

Maximizing Performance

Medtech companies have a tremendous opportunity to improve their existing businesses. This should include transforming the commercial model and building a solid case for the value of their products, as well as making value-based health care a tailwind. At the same time, the industry has significant room to improve its cost structure and to use the cost savings to "fund the journey" to maximized performance. Consider that the pharmaceutical industry in Europe employs just



20 percent more people than the 575,000 employees who work in the European medtech sector—but its market is more than twice as large as the \$100 billion medtech market. Moving simultaneously on these three efforts will go a long way toward improving the industry's competitiveness.

Transform the commercial model. In order to maximize the opportunity within the existing business, medtech companies must transform their commercial model and build best-in-class commercial capabilities. (See *Fixing the Medtech Commercial Model: Still Deploying Milkmen in a Megastore World?*, BCG Focus, July 2013.) Six key moves can help companies progress along this path:

- It is critical to customize the go-to-market strategy. This includes a systematic
 review that prioritizes the most valuable market segments, determines what is
 required to win in each segment, and tailors the commercial model for each
 segment accordingly.
- Companies should reinvent clinical selling to reflect the changes in how purchasing decisions are made in the market. This includes a move to do less—but more focused—clinical selling.
- The medtech industry lags behind other sectors when it comes to key account management. Companies must put a greater emphasis on this effort—based on a solid analysis of the business potential and profitability of specific customers.
- While the sales rep has historically been the driver of the commercial operation
 in medtech, marketing must now take on the primary role. This is imperative if
 companies are to successfully build and communicate the case for the value of
 their products.

- Securing reimbursement and adequate pricing is more difficult than ever. As a
 result, developing reimbursement and pricing capabilities is essential, though it
 is an effort that is just beginning within many medtech companies.
- A tremendous opportunity exists to offer services that not only bolster revenues but also differentiate a company's product offering.

Make value-based health care a tailwind. Value-based health care shifts the focus on efficacy and safety during a single episode of care to a focus on achieving better outcomes at a reasonable price over the full cycle of care. This shift is now well reflected in medtech company strategies. In its 2012 annual report, Medtronic notes, "Moving forward, the clinical value of products will continue to be important, but an additional focus will be on translating clinical value into corresponding economic value, ... a transformational opportunity." BioMérieux echoes that view in its annual report, asserting that "Our diagnostic solutions must have ... a demonstrated benefit for the patient, the hospital, the health care system, and the community in general."

Value-based health care shifts the focus on efficacy and safety during a single episode of care to a focus on achieving better outcomes at a reasonable price over the full cycle of care.

Medtech companies are certainly in a position to seize this opportunity, particularly by supporting providers in their decision making. This can include, for example, developing applications that help users select the right diagnostic test and interpret the results. And there is also demand for offerings that help reduce the variability of clinical outcomes, an effort that medtech players can support with products such as computer-assisted surgery, real-time imaging, and virtual-training systems for health care professionals.

A key element in this effort is reprioritizing budgets toward cost-efficient products that are supported by solid evidence of value based on outcomes data. As one interviewee pointed out, "Our challenge in value-based health care is a resource allocation dilemma—knowing where to disinvest to develop the required capabilities in a budget-constrained environment."

There are a variety of ways to address this challenge. One option is to form partner-ships with providers in order to evaluate the cost effectiveness of treatments in a real-world setting and compare them to other therapeutic options. Pricing and contracting efforts should also be centered on delivering value. This may involve new funding and pricing models based upon both the demonstrated value offered by a product and a clearer definition of the populations that will benefit the most from that product.

A prerequisite for the activities listed above is to generate the data that prove value, integrating evidence of clinical outcomes with information on the overall social impact and lifetime cost of various medical interventions.

Reduce costs to fund the journey. A significant opportunity exists for medtech companies to improve their cost structure. The ratio of operating expenditures to sales for the industry increased 510 basis points between 2003 and 2012—while pharma companies managed to cut that ratio by 350 basis points over the same period.

Cost reduction opportunities exist in two key areas: selling, general, and administrative (SG&A) costs and costs of goods sold. In both categories, examining the company's operations through the three lenses of structure, processes, and resourcing practices can lead to savings.

For SG&A, this can include addressing structural issues by taking steps such as bundling some administrative tasks in shared service centers or removing management layers throughout the organization. In addition, SG&A costs can be reduced by improving processes and activities. This may involve clarifying the responsibilities of local and central operations to avoid duplicate work or eliminating reporting procedures that require time and resources but add little to overall effectiveness. Additionally, SG&A costs can be pared by evaluating opportunities such as outsourcing and moving certain activities to less expensive offshore locations.

When it comes to reducing the cost of goods sold, organizations can rethink their manufacturing footprint and sourcing strategy, improve inventory management, and integrate resource cost issues into product design.

Changing the Game

Improving the existing business is not enough. What is also required is a fundamental rethinking of how and where to compete, including reinventing the innovation process, expanding the competitive arena into new or adjacent markets, and seizing true low-cost opportunities without compromising on margin and product quality.

Reinvent the innovation process. High-performing companies in medtech have a track record of making bigger, less-incremental bets on new-product development. They are also more open to external innovation through licensing, partnerships, and acquisitions—all of which can be a way (but not the only way) to bring critical new skills on board. The innovation process should be driven by a deep and broad understanding of the needs of key stakeholders. It should be focused not only on clinical outcomes but also, for example, on an optimization of the customer's workflow. (See the sidebar "Cepheid: Zeroing in on Customer Needs.")

One way to ensure this happens is to involve customers—patients, payers, and physicians—more directly in new-product development. GE Healthcare embraced this approach in the development of its Discovery IGS 730 imaging system, flying in surgeons and cardiologists from St. Luke's University Health Network to test and provide input throughout the process. At the same time, GE partnered with experts in robotics and holonomic laser-guidance systems to gain access to new, critical expertise. The result: an innovation that offers surgeons a chance to reinvent the way they work. The new imaging system glides into position when needed and otherwise can be parked in a corner, thereby breaking the paradigm of fixed imaging systems for surgery.

Expand the competitive arena into new or adjacent markets. To move beyond their core business, companies should identify opportunities to expand into adjacent markets. This can include products or services that are upstream or downstream

One way to reinvent the innovation process is to involve customers—patients, payers, and physicians—more directly in new-product development.

CEPHEID

Zeroing In on Customer Needs

For instrument and medical-test provider Cepheid, winning in the growing and crowded molecular-diagnostics market requires customer-driven innovation. This means a focus on innovation that addresses true customer needs for diagnostic tests that are accurate and fast and offer clinically actionable results, not just new features or improvements that do not have real impact.

The key for Cepheid has been delivering a product, the GeneXpert System, that offers clinical performance coupled with an improved workflow, enabling efficiency gains for customers. This innovation applies a single-cartridge design to the company's expanding menu of diagnostic tests (The company had 14 tests available outside the U.S. in 2013 and has more than 25 planned by 2016, including tests for high-volume hospital-acquired infections, women's health, and virology.) This unique design allows all tests to be run on the same machine, a major change compared with traditional systems in which different machines are needed for each type of test. Furthermore, while competing technologies are designed to process tests in sizable batches, Cepheid's system can work with individual samples. The result: greater flexibility and scalability for customers.

The system also yields labor cost savings. For one thing, it takes less of a technician's time to run the tests. For another, the results are easy to read—through what is called "sample in, result out" functionality—which

reduces the need for skilled technicians to interpret those results. Taken together, these elements speed up the turnaround times for test results. Diagnostic results can be delivered while the patient is still in consultation, allowing for early treatment and mitigating infection risks—a key advantage for hospitals and patients.

The benefits to customers have been significant. A 700-bed hospital in Italy, for example, saved \$2 million annually after adopting the system. Those savings came, in part, from a reduction in the average length of stay for patients with infection with the bacterium Clostridrium difficile, widely known as C-diff. Thanks to Cepheid's system, patients with the infection were diagnosed and treated more quickly.

For Cepheid, the improved value delivered by its innovative system enables the company to compete effectively while charging prices higher than those associated with traditional molecular-testing technologies.

This model has produced significant returns: Cepheid revenues grew 25 percent annually between 2010 and 2012. As a recent analyst report noted, the "key lesson of Cepheid's success is ... that customers have shown willingness to pay for workflow simplification and platform consolidation."

NOTE

1. J.P. Morgan analyst report, September 2012.

from their current offerings, as well as those that are in different but related markets. These moves can be defensive (protecting the core), offensive (building new profit streams), or both. Most important, companies have to expand the definition of their core business. One interviewee noted that while it is still early days in this effort, "It is very interesting to see companies changing their description from medical device companies to health care solutions companies."

Some medtech companies have begun this process—vertically integrating into medical services that are commonly required by the patients who use their devices. These companies may offer disease management programs or patient support services, or they may even take on the operation of hospitals or clinics. There are also likely to be opportunities to develop services for purchasers of medtech products such as software and data management. And companies can become a critical component in the improvement of the overall health-care system by finding ways to reduce costs or improve the efficiency of operations beyond the scope of their particular device. (See the sidebar "Fresenius: Beyond the Machine.")

Seize true low-cost opportunities. Companies should dispense with some common myths: low cost is not low quality, low cost is not low margin, and low cost is not necessarily unbranded. In fact, not only are low-cost companies often highly profitable but there are also examples in which the profitability of these low-cost operators exceeds that of most competitors. (See the sidebar "Mindray: A Profitable Low-Cost Model.")

FRESENIUS Beyond the Machine

Dialysis leader Fresenius Medical Care has succeeded by harnessing its deep understanding of dialysis treatment to expand its offerings in that fast-growing market.

The company started more than 40 years ago with hospital-based dialysis machines, and it has continuously developed new products, including home dialysis products, that increase patient comfort. Looking to take this a step further, Fresenius is now working on the development of a portable artificial kidney.

But Fresenius has also expanded into other areas based on the company's expertise in dialysis. Leveraging its understanding of the disease, Frese-

nius vertically integrated, opening in 1994 the first of what would become a chain of 800 dialysis centers. This has given the company a solid leadership position, both as a manufacturer (50 percent of all hospital dialysis machines are Fresenius) and as a clinic operator (in 2012, the company treated 258,000 patientsthe most of any dialysis provider worldwide). In addition, the company moved into pharmaceuticals for renal patients in 2011. And looking to harness its expertise to expand into other fields, Fresenius is exploring how it can apply the blood cleansing process of dialysis to other diseases, including liver disease.

MINDRAY A Profitable Low-Cost Model

Medical-device manufacturer Mindray has proven that grabbing the low-cost mantle can lead to great rewards. But for the Chinese company, the strategy is not about discounting products over time but building a fundamentally more efficient and competitive operation.

To achieve this goal, Mindray has focused on cost efficiency throughout the value chain while maintaining high levels of investment in R&D (in excess of 10 percent of sales) and high levels of customer service. The company's approach includes focused innovation (offering fewer products per category than competitors do) and

lean manufacturing that uses shortterm contracts to allow renegotiation.

That structure, along with a key acquisition in 2008, has allowed Mindray to price aggressively and rapidly expand its reach outside China. While 25 percent of Mindray's 2003 revenues came from developed and emerging markets outside of China, that share rose to 55 percent by 2012. And the company has accomplished all this with gross margins comparable with those of multinational corporations (MNCs) and a ratio of earnings before interest and taxes (EBIT) to sales of 21 percent, well above the 16 percent average for MNCs.

To remain competitive, companies should consider when they can develop high-quality, efficiently priced offerings for newly cost-conscious customers and how they can do so without compromising on margin levels. This can require shifts in manufacturing and supply chain operations, as well as designing products to ensure that those with low prices have commensurately low manufacturing costs. Low cost is not just about achieving a lower cost of goods sold. High-performing, low-cost companies have managed to reduce their total system cost, sometimes transferring part of their costs to customers. Companies will often find that it makes sense to create distinct brands in different pricing categories in order to minimize cannibalization.

The Journey Has Just Begun

To understand where the industry stands today and what areas require the most aggressive action, BCG and MedTech Europe conducted extensive industry research. Among the key elements of that work was a survey of 100 senior leaders, including company executives and other health-care stakeholders, such as payers and patient association representatives. (See the sidebar "Assessing the Industry.") The survey focused on the six moves identified in this report, asking respondents to rate how important each move is for future success and then assess the current capability of their company to make each move (or in the case of noncompany respondents, the capability level of the industry in general). (See Exhibit 3.)

On the question of which moves were most crucial for success in the years ahead, all six moves were rated as highly important by the majority of the respondents. Making value-based health care a tailwind stood out as the most important for all

ASSESSING THE INDUSTRY

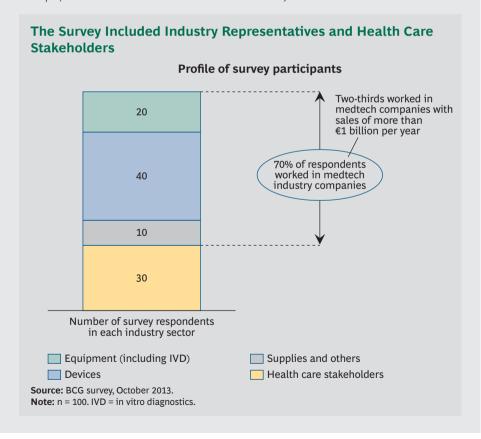
Our research into the current state of the medtech industry involved three key steps.

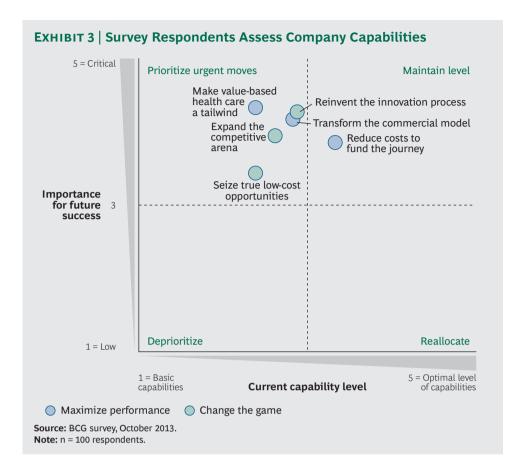
The first was an in-depth analysis of the industry that leveraged proprietary information from MedTech Europe, BCG research and project experience, and publicly available data from industry, broker, and annual reports.

We then undertook a series of interviews with 50 senior leaders in all industry subsegments, from equipment to supplies to in vitro diagnostics and devices. In these interviews, we covered topics including key changes affecting medtech in Europe, the extent to which those

shifts were specific to Europe, and how they differed by country. We also discussed how to prepare for these changes and where the industry stands in making such shifts, as well as potential best practices for confronting the new landscape.

In October, preliminary results were shared with attendees during the European MedTech Forum 2013, and we surveyed 100 selected industry participants. The panel of participants offered a balance of industry executives from the various industry subsegments and health care stakeholders, including representatives from purchasing groups and trade and patient associations. (See the exhibit below.)



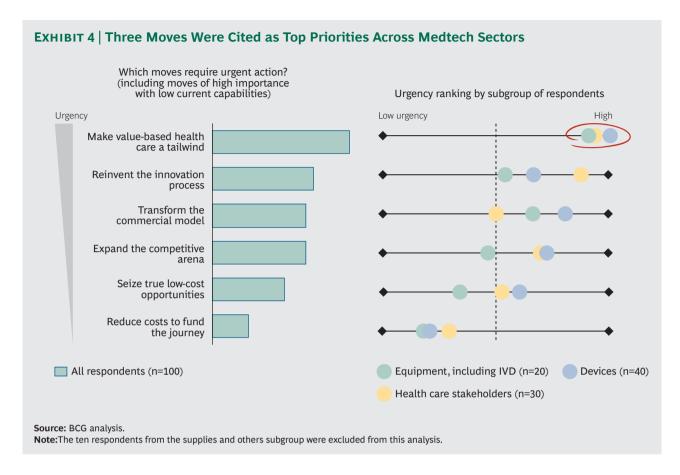


segments of respondents, followed by reinventing the innovation process. Transforming the commercial model ranked third. For nonindustry respondents, however, one of our changing-the-game moves—expanding the competitive arena (through steps such as integrating along the value chain or acting as a catalyst of health care efficiency)—ranked third.

In the assessment of current capability levels, respondents found the industry to be well below target level in five of six moves—most notably in making value-based health care a tailwind, expanding the competitive arena, and reinventing the innovation process. Industry respondents said that reducing costs to fund the journey is the only area in which they are closer to the targeted level of capabilities. Even so, external research indicates that, despite tangible efforts to reduce costs, there remains significant room for improving costs in medtech relative to other industries.

So what moves most urgently call for action? The survey highlighted three high-priority moves that are critical for future success and currently have low capability levels: making value-based health care a tailwind, reinventing the innovation process, and transforming the commercial model. (See Exhibit 4.)

While making value-based health care a tailwind was the highest priority for all respondents, the survey also found some interesting differences among various groups within the industry. For instance, leaders of companies with revenues of less than



€1 billion rates expanding the competitive arena as the second-highest priority while those at larger companies (with revenues in excess of €1 billion) considered transforming the commercial model to be of higher priority. This may reflect the challenge larger companies face in trying to optimize and protect their sizable, existing business while at the same time responding to the changing industry landscape.

Our analysis also found differences within industry subsegments. Equipment, diagnostic, and device companies all ranked value-based health care and transforming the commercial model as the two highest priorities. But device company respondents reported the greatest urgency to act, largely because they also saw their companies as lagging the furthest behind. This results from differences in the self-assessed capability levels. Indeed, for all six moves, respondents from equipment and diagnostic companies reported a better self-assessment of their company's current capability level than respondents of device companies did. This was notably true on reinventing the innovation process—for which the stated current capability level was 25 percent higher among equipment and diagnostic companies than among device companies.

A Call to Action

In undertaking this research, we set out to answer three key questions. Does the industry appreciate the challenges it is facing? Do company leaders know what

changes to make? And if they do, how far along are they in implementing those changes? A concern was that, in the words of one survey respondent, "current organizations come from a track record of success and will find it hard to understand the need for change. If they do, [it is] not easy in any case to really identify what needs to be changed and then implement it."

On the first question, our research is reassuring. The findings of the survey highlight that the importance of change is now widely acknowledged. On the second question, information gleaned from senior interviews and experience indicate which actions need to be taken.

Judging by our survey—and the industry's self-assessed capability level—implementing those changes will not come easily. For companies looking to adapt, interviewees cited four major challenges that must be overcome. Leaders must abandon the old mindset and embrace change. They must cascade this resolution throughout the rest of the organization. Medtech companies must also find a way to hire people with the necessary skills and capabilities without alienating or causing disengagement within the existing workforce. And they must do all this in a still-evolving environment that is tremendously complex, particularly given Europe's heterogeneity.

The industry has much to gain by acting in unison. National and regional trade associations such as MedTech Europe can play a critical role. This role includes not only promoting the industry's image but also ensuring that the need for change is well understood. In addition, these groups can promote policies that foster an ecosystem in which change can thrive. And they can build bridges with other industries and stakeholders to promote progress toward improved efficiency in the health care system.

In the end, however, success will depend on whether companies respond to the fundamental shifts in the medtech industry with the requisite force. Those that do must move ahead with a clear vision, a strong commitment to change, and a well-designed roadmap in order to move the company toward its goal. Those that do not will find that the heat only continues to rise.

NOTES

- 1. Stakeholder interviewees included selected senior representatives from purchasing groups, patient organizations, government agencies, medtech regulatory authorities, and academic research groups.
- 2. Price comparisons come from the International Federation of Health Plans' 2012 Comparative Price Report. The cost of a hip prosthesis is \$12,222 in the U.S. and \$2,682 in Spain.
- 3. These are updated figures from the European Patent Office for 2012.

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