

Medical Technology Innovation Scorecard

The race for global leadership

January 2011

*The PwC Medical
Technology Innovation
Scorecard explores the
changing nature of
healthcare innovation.
The results show that the
gap between innovation
leaders and emerging
economies is rapidly
narrowing.*

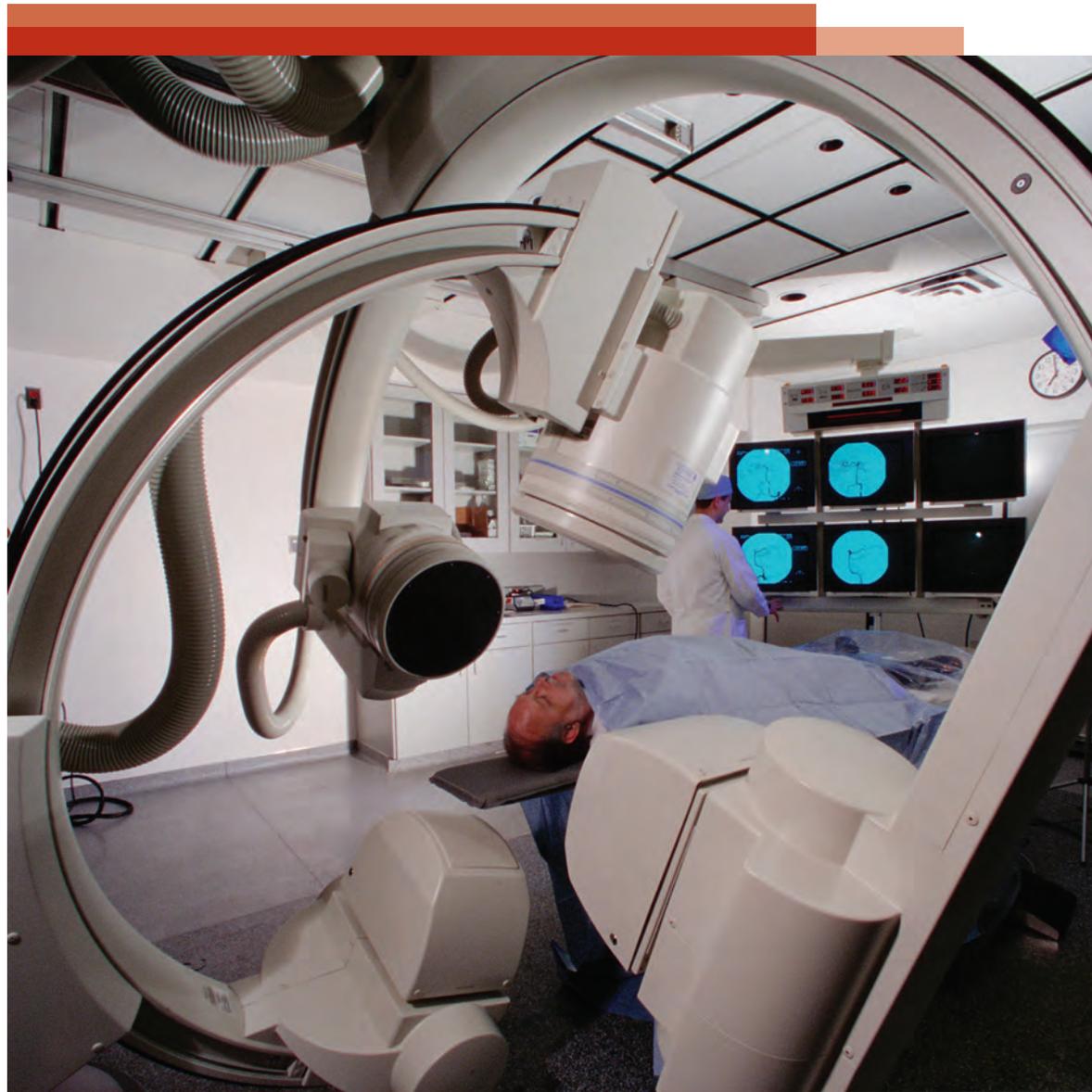


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The heart of the matter

New dynamic redefines
medical technology
innovation

The way we assess value in medical technology is changing radically. In Bangalore, the mantra “made in India for India” echoes throughout GE Healthcare’s John F. Welch Technology Centre and Philips’ Innovation Campus. These research and development facilities have spawned such revolutionary devices as low-cost, lightweight, battery-powered electrocardiogram machines to serve remote, rural areas with little access to healthcare. In Europe, Merck Serono is revolutionizing the delivery of human growth hormone with diagnostic screening, counseling, and monitoring services tied to its easypod™ wireless injection device. The company focuses on the individual needs of patients, providing support that encourages adherence to prescribed treatment, improving their chances for better health.

These companies recognize that the old dynamic of the physician as arbiter of value is giving way to a new one: Government and private insurers and “self-pay” consumers increasingly determine what sells and at what price. They refuse to pay for incremental innovations that add bells and whistles but do not significantly improve health or reduce cost. The faster, better, smaller, cheaper advances so common in consumer electronics portend the future of medical technology.

In addition, providers are assuming more of the financial risk in healthcare

as payers increasingly base compensation on quality and results. If a new technology doesn’t help patients get better at the same or lower treatment cost, providers might not be motivated to use it.

Emerging-market countries such as China, India, and Brazil, despite comparatively weak healthcare system infrastructure, are quickly taking the lead in developing lean, frugal, and reverse innovation. This type of innovation simplifies devices and processes, retaining essential functions while applying newer technologies that are more mobile, customized to consumers’ needs, and less costly. Such innovation will enable these nations to leapfrog developed countries in innovative healthcare delivery.

Healthcare could take a path in emerging markets similar to that of telephone communications. These nations bypassed development of broad landline infrastructures and jumped headlong into mobile technology, which the masses across the socioeconomic spectrum quickly adopted. Such technological coup d’états are not impossible in developed nations, but radical innovation cannot happen in the absence of some type of pain and constraints that create tension and an impetus for change.

The PwC Medical Technology Innovation Scorecard explores the changing nature of healthcare innovation. The results show that the

innovation leaders of today will find their position slipping during the next decade. Three trends are evident:

- The innovation ecosystem for medical device technology, long centered in the United States, is moving offshore. Increasingly, medical technology innovators are going outside the United States to seek clinical data, new-product registration, and first revenue.
- US consumers are not always the first to benefit from advances in medical technology and could eventually be last in line. Innovators already are going first to market in Europe and, by 2020, likely will move into emerging countries next before entering the United States.
- The nature of innovation is changing as developing nations become the leading markets for smaller, faster, more affordable devices that enable delivery of care anywhere and help bend the healthcare cost curve downward. These countries are free of the handicap of an entrenched healthcare system infrastructure that seeks to maintain the status quo. However, the difficulty of doing business in emerging countries and poor intellectual property protection could make these markets less attractive to multinational companies, despite their size, and could hinder these nations’ innovation leadership.

An in-depth discussion

US innovation
foundation weakening

Scorecard ranks nine countries' capacity for innovation

The Innovation Scorecard assesses the capacity of nine countries with strong medical technology market potential to adapt to the changing nature of innovation: Brazil, China, France, Germany, India, Israel, Japan, United Kingdom, and United States. It examines where these countries stand relative to five pillars that have supported US medical technology innovation for the past several decades: powerful financial incentives, leading resources for innovation, supportive regulatory system, demanding and price-insensitive patients, and supportive investment community.

As well as providing a current view of innovative capacity and capability, the Innovation Scorecard looks at the past five years to gain a

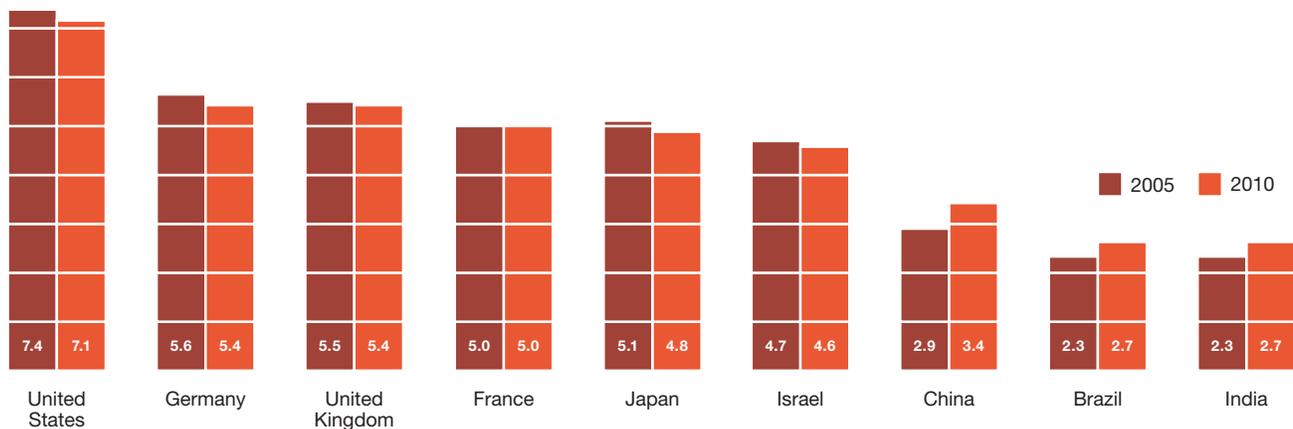
historical perspective and projects into the future to present the outlook for 2020. PwC sees the innovation pillars of today transforming into a new support system during the next decade (see page 8: “Five new pillars of innovation”).

The Innovation Scorecard combines primary and secondary data. It uses 86 metrics to calculate the current score and 56 for the historical score (see “Appendix” for methodology). These metrics range from objective to subjective and help to identify trends in medical technology innovation. A top-level view of current scores reveals:

- The United States at 7.1 (on a scale of 1 to 9, with 9 as best) holds a leadership position. Because of decades of innovation dominance, the United States demonstrates the strongest capacity for innovation in the medical technology market.

- The scores of the other developed economies (United Kingdom, Germany, Japan, and France) fall within a tight band of 4.8 to 5.4. Among the European countries included in this study, France demonstrates the weakest support for innovation.
- Israel, despite a population of only 7.5 million, ranks near the level of the European nations included in this study. The medical technology industry has long recognized Israel’s strong capacity to foster innovation.
- Developing economies lag behind developed ones. China, with its superior economic growth engine, scores 3.4, ranking it higher than India and Brazil, which each score 2.7.

Figure 1: Historical and current scores



Source: PwC analysis



Looking at past scores and the outlook for the future along with current scores changes the perspective and reveals that although the United States will hold its lead, the country will continue to lose ground during the next decade. The Innovation Scorecard also projects declines for Japan, Israel, France, the United Kingdom, and Germany.

China, India, and Brazil will experience the strongest gains during the next 10 years. Of the nine countries, China, which has shown the strongest improvement in innovative capacity during the past five years, is expected to continue to outpace other countries and reach near parity with the developed nations of Europe by 2020.

The remainder of this report presents some of the findings that have led to these projections.

Why create an Innovation Scorecard?

Hearsay and anecdotes have driven much of the discussion regarding threats to sustaining the US medical technology ecosystem. Lack of concrete evidence stifles the discussion regarding what is happening, what impact it will have, and whether something should be done about it. The Innovation Scorecard attempts to provide that evidence.

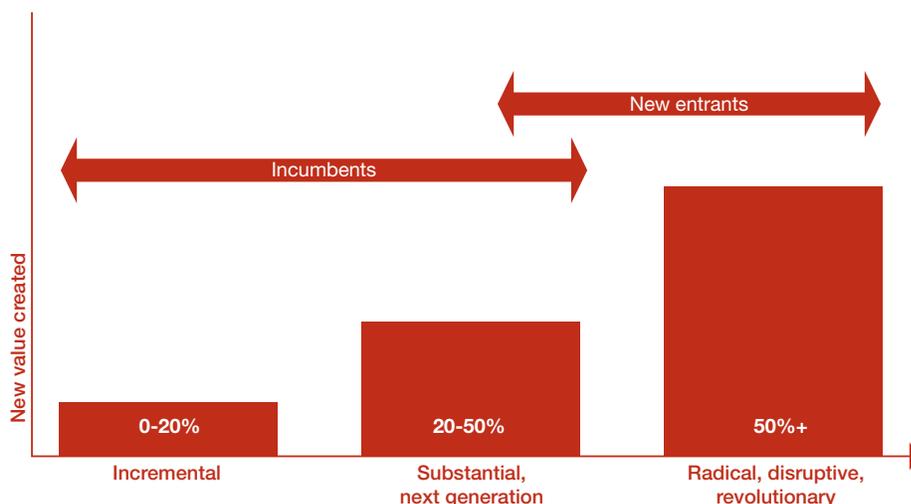
PwC believes that the Innovation Scorecard could help industry work with regulatory and political leaders in making decisions and setting policies that will determine medical technology leadership. More informed decisions could enable further advances within the new value-based paradigm in medicine.

Innovation = value-creating novelty

Innovation often is defined as something that is new, creative, and radically different from what has gone before. PwC defines *innovation* as *value-creating novelty*. A new idea or product becomes innovative only when it creates value. Are people willing to pay for it? Is it marketable? In business, innovation that is not commercialized is essentially worthless.

Not all innovation is equal. Based on the amount of value it generates, innovation can be classified as follows:

Classes of innovation



1. **Incremental** (adding a new feature to an existing product): new value creation of 0 percent to 20 percent—An example in medical technology is a next-iteration pacemaker that is safe for magnetic resonance imaging (MRI). An MRI scan can cause the wires of older pacemakers to over-heat. Among the millions of people worldwide who have a pacemaker today, a large percentage will develop a medical condition that calls for an MRI scan. Device manufacturers seeking to market pacemakers that would solve this problem have discovered that payers are unwilling to pay a premium for this added feature.

The pacemaker story points to a new reality facing medical technology companies: They cannot count on incremental innovation to increase profit. For many years, a similar market dynamic has driven the consumer electronics industry, where features and capabilities increase but prices decline. For example, with each iteration, the iPhone® has offered substantially greater features and functionality but for the same price, and consumers have stood in line to scoop up the new models as soon as they were introduced. For the medical technology industry, the days of feature creep with price increases are over as payers and consumers demand higher value at lower cost.

2. **Substantial** (next generation): new value creation of 20 percent to 50 percent—In healthcare,

examples of substantial innovation include remote patient monitoring and the application of mobile health technologies that employ new devices and sensors and the Internet to move physician consultations in densely populated and remote regions online. In mobile care, text messaging, e-mail, social media, and videoconferencing significantly decrease the need for physical networks of clinics, hospitals, and technicians. Pilot projects that have measured the benefits of this transformation of healthcare delivery from analog to digital have consistently shown cost savings and new value creation of 20 percent to 50 percent.

3. **Radical** (revolutionary): new value creation in excess of 50 percent—An example is GE Healthcare’s Vscan®, a pocket-sized, wireless ultrasound device, which costs about \$7,500 and weighs less than one pound. In comparison, a laptop-sized ultrasound machine can weigh more than 20 pounds and cost \$30,000 to \$40,000; a bulky, cart-based version can weigh hundreds of pounds and cost well above \$100,000. The Vscan potentially reduces the need for expensive tests and referrals and makes healthcare more accessible because of its portability and lower cost. The Vscan represents a radical innovation over its much more expensive predecessors because on many dimensions (quantity, price, location, time), it creates greater than 50 percent new value (see “Appendix” for PwC’s value-creation matrix).

The five pillars of medical technology innovation

During the past 50 years, the United States has provided an ideal innovation ecosystem that has fostered significant advances in medical technology. US-based companies dominate the roughly \$350 billion global device industry. Thirty-two of the 46 medical technology companies with more than \$1 billion in annual revenue are based in the United States. The country accounts for approximately 40 percent of the world market for medical devices and instruments.¹

US dominance of this industry stems from its strength in five innovation pillars (Figure 2), which form a structure for the Innovation Scorecard. The Scorecard divides each pillar into two dimensions containing several measures on which it scores the individual countries (see “Appendix” for the measures for each dimension).

On three of these five pillars, the US scores have declined between 2005 and 2010; on two pillars, the US score has improved. The biggest decline appears in the fifth pillar, where entrepreneurial activity and private foreign direct investment have dropped.

Between 2010 and 2020, PwC expects US performance to decline on every pillar (see Figure 3).

Figure 2: Five pillars of innovation

Powerful financial incentives	Leading resources for innovation	Supportive regulatory system	Demanding and price-insensitive patients	Supportive investment community
Market incentives Healthcare incentives	Innovative resources Innovative output	Regulatory approval process Legal environment	Healthcare demand Needs and infrastructure	Investment environment Medical technology commercialization
<p>The US spent more per capita on healthcare than the other eight Scorecard countries.</p> <p>High levels of reimbursement for medical procedures and generous coverage fueled physician adoption of new innovations.</p>	<p>The US established itself as a world leader in academic medical centers.</p> <p>Annual NIH grant funding exceeding \$25 billion per year supported the advancement of medicine.</p>	<p>The FDA has been a global leader in setting standards and guidelines for the safety and efficacy of medical technologies.</p> <p>Other countries would often wait to see FDA’s position before acting upon medical technology applications.</p>	<p>Americans seemed to have a higher demand for healthcare services as measured by their frequency of doctor visits.</p> <p>During the past 50 years, the proportion of healthcare costs paid by US patients has declined from 47% to 12%.</p>	<p>Medical technologies ranked as the second- or third-largest category among venture capital and angel investors.</p> <p>US venture capital funding averaged approximately \$2.5 billion annually during the last decade, enabling commercialization of innovations from academia and elsewhere.</p>

¹ Jeffrey W. Englander and Phillip M. Seligman: “Standard & Poor’s Industry Surveys: Healthcare: Products & Supplies,” February 4, 2010. *S&P is not responsible for errors or omissions in the data or for the context of the information.*

Figure 3: US scores by pillar

	Past	Present	Future
Powerful financial incentives	7.1	7.2	↓
Leading resources for innovation	7.2	7.3	↓
Supportive regulatory system	7.2	6.8	↓
Demanding and price-insensitive patients	7.3	7.1	↓
Supportive investment community	8.2	7.2	↓
Total	7.4	7.1	↓

Pillar 1: Powerful financial incentives

US performance: 7.1 (past), 7.2 (present), ↓ (future)

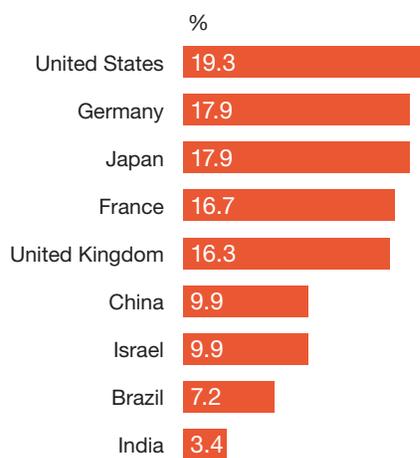
The US score for this pillar improved slightly between 2005 and 2010, but PwC expects it to drop during the next decade.

Key findings

- The United States spends a larger percentage of its GDP and more per capita on healthcare than any other country (Figure 4). It spends nearly twice as much on total healthcare per capita as Japan, 50 percent more than the European nations included in this study, and 15 times more than China. In 2009, the United States spent a record 17.3 percent of GDP (\$2.5 trillion) on healthcare—an average of \$8,050 per person. The US Centers for Medicare and Medicaid Services (CMS) predicts national health expenditures will increase an average of 6.3 percent annually from 2009 through 2019, reaching 19.6 percent of GDP by 2019.²

² CMS, “National Health Expenditure Projections 2009-2019 (September 2010),” <https://www.cms.gov/NationalHealthExpendData/Downloads/NHEProjections2009to2019.pdf>.

Figure 4: Government expenditure on health as percentage of total government expenditure



Source: World Health Organization, based on 2006 data, which was the latest available

Note: The US percentage in Figure 4 reflects government spending only. Unlike the European countries, where a single payer (the government) accounts for most of the spending, in the United States, employers and private individuals account for a large share of healthcare spending. If this chart included that share, the US bar would grow substantially.

- Market size provides critical mass for market access and adoption of innovation. The United States is the largest healthcare market today and should remain so during the next decade. Business Monitor International (BMI) estimates that US medical device sales will reach \$185.9 billion by 2019.³ But the US market will grow at a slower rate

³ Business Monitor International, 2010.

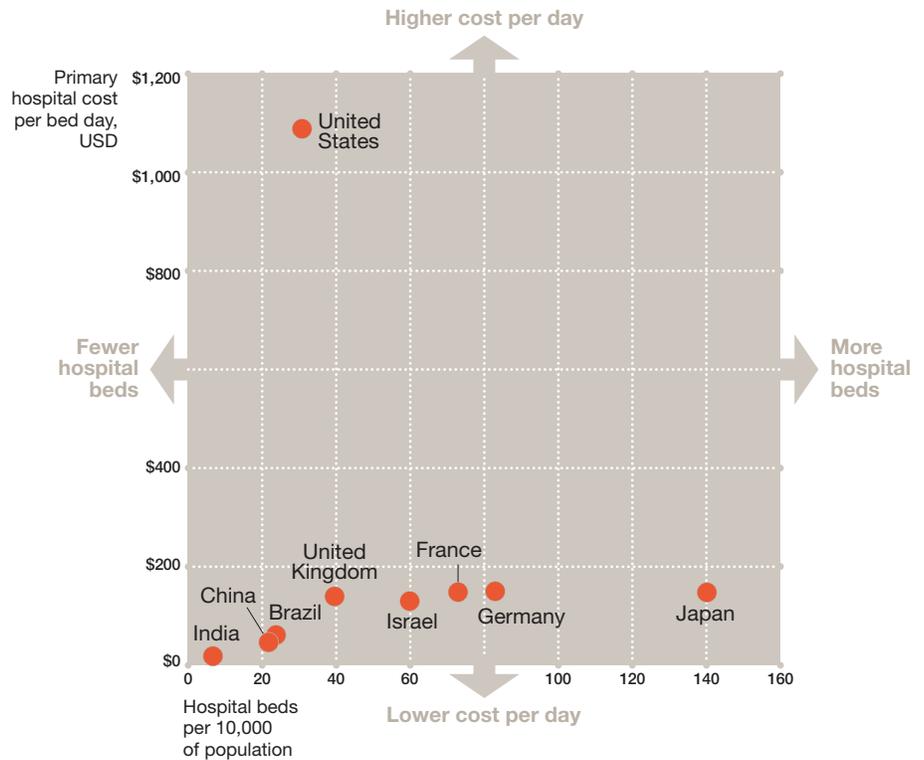
than that of the emerging nations. For this reason, the Innovation Scorecard predicts a downward direction for the US score over the next decade and an upward one for the scores of developing countries.

- The Chinese medical device market is predicted to expand about 15 percent annually during the next five years; and India’s, about 23 percent.⁴ BMI estimates that China’s medical device sales will reach \$42.8 billion by 2019; and India’s, \$10.7 billion.⁵ This shift in growth could draw the focus of multinational device manufacturers away from the United States and toward emerging markets. Domestic manufacturers in emerging markets may be content with the potential for growth within their own borders and might not seek regulatory approval in the United States and other developed countries. Citizens of those nations will benefit from domestically produced technology before the people who have been the first to benefit from medical advances in the past.

⁴ Phillip M. Seligman, Standard and Poor’s Industry Survey, “Healthcare: Products & Supplies,” August 12, 2010. S&P is not responsible for errors or omissions in the data or for the context of the information.

⁵ Business Monitor International, 2010.

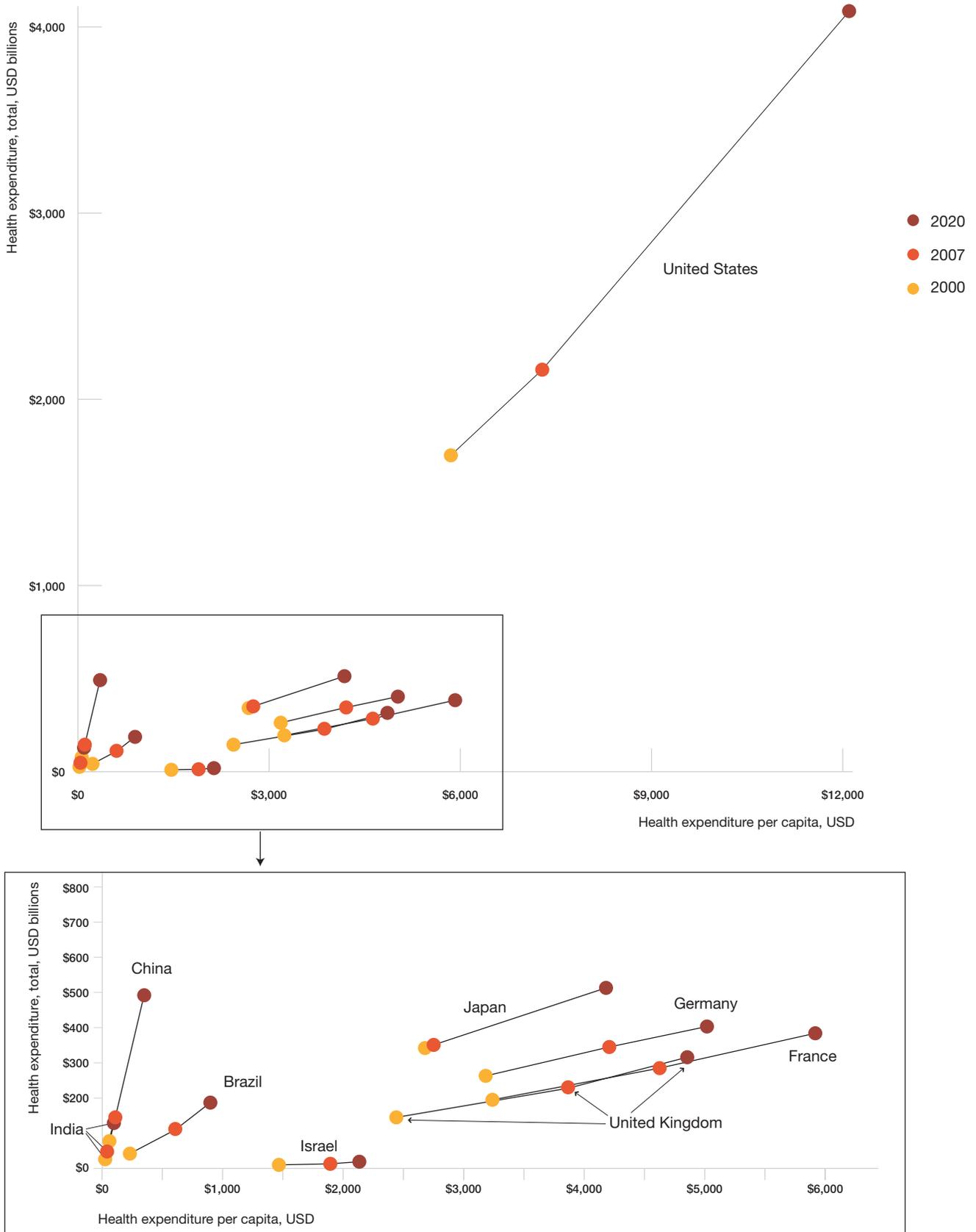
Figure 5: Hospital beds per capita versus hospital cost per bed day



Source: World Health Organization

- Today most developed countries' daily cost for a hospital stay falls within a tight range of \$100–\$200, but the US cost is seven times their average and approximately 25 times that of China, India, and Brazil. Despite extremely higher hospital costs, the US hospital bed density ratio ranks among the lowest of the nine countries, which should have a positive impact on future innovation and partially offset the effect of high hospital costs as the United States applies new digital technologies to increase access to healthcare rather than building new hospitals (Figure 5).
- All countries reviewed in the Scorecard expect to continue to see significant growth in per capita and total healthcare costs over the next decade. The US growth rate is expected to push its per capita spending to a level nearly double that of Europe and 2.5 times that of Japan. The three emerging economies will experience the steepest increase in total and per capita spending, with China emerging as the third-largest healthcare market by 2020, closing in on Japan at second place. The graying of Japan and Europe will continue to drive total and per capita healthcare spending upward.

Figure 6: Total health expenditure vs. health expenditure per capita



Sources: The World Bank, World Health Organization, and PwC analysis

Note: This chart depicts past, current, and future numbers for total and per capita healthcare spending. Because eight of the nine countries cluster close together, the bottom section is enlarged for easier viewing. This chart clearly shows that the United States is an outlier, far outspending the other countries in this study now and into the future.



Looking forward

Historically, building of system infrastructure, such as hospitals, encouraged innovation. In the future, excess capacity could have the reverse effect. Those countries with limited infrastructure will be more driven to innovate to stretch their resources.

PwC predicts that the US score on this pillar will drop because the US health-care system will suffer the “innovator’s dilemma.” That is, the United States has been so successful in medical technology innovation that it has created a legacy that the current system will continue to seek to defend, support, and protect. The powerful financial incentives that form the cornerstone of the US system will present a barrier to adopting faster, smaller, cheaper, and better technologies that would represent radical, disruptive innovations.

Such innovations are emerging more quickly in China, India, and Brazil. These developing nations are, in many

ways, starting without the “innovation handicap” of a comfortable level of performance and payment. A scarcity of financial resources is driving them to experiment with more efficient technologies, processes, distribution strategies, and business models (see sidebar: “Expanding access to health-care through frugal innovation”).

Developed nations do have some recourse. Government pressure to lower healthcare costs could eventually help offset the innovation handicap, forcing developed nations to turn to innovative technology to achieve better results at lower costs. In the United States, for example, the Patient Protection and Affordable Care Act of 2010 (PPACA) calls for reduced annual payment updates for most Medicare services, substantial cuts to managed care plan payments, and the creation of an Independent Payment Advisory Board. These are small steps in what will be a prolonged and complex effort by Western nations to reign in healthcare costs.

Expanding access to healthcare through frugal innovation

Dr. Devi Prasad Shetty of Bangalore, who hopes to export an Indian-borne model of care to other parts of the globe, exemplifies emerging-market innovation. Dr. Shetty, famous in India for performing heart surgery on Mother Teresa, is known worldwide for bringing low-cost, high-quality, mass-production healthcare to people who can afford it least. The doctor whom *The Wall Street Journal* has called “the Henry Ford of heart surgery” has become a prime example of “frugal innovation.”

In part driven by the absence of high payer reimbursement and a scarcity of resources, Dr. Shetty has become a master at refining process. He has perfected high-volume throughput and supply chain management to the point that he can break even on a \$1,500 heart surgery. Patients who can afford it pay full price, but many pay less.

At Dr. Shetty’s 1,000-bed flagship Narayana Hrudayalaya hospital, 42 cardiac surgeons perform about 600 operations a week. Physicians specialize in one type of operation and, as a result, become highly skilled, even in procedures considered rare. Dr. Shetty’s profit margin is reportedly higher than that of the average US hospital; and his quality, as good or better.⁶

6 Geeta Anand, “The Henry Ford of Heart Surgery,” *The Wall Street Journal*, November 25, 2009, http://online.wsj.com/article/NA_WSJ_PUB:SB125875892887958111.html.

Dr. Shetty has expanded his chain of hospitals to seven cities in India and hopes to have 30,000 beds there within the next few years.⁷ In comparison, Hospital Corporation of America, the largest hospital organization in the United States, has 41,000 beds.⁸

Dr. Shetty also has pioneered the use of telemedicine in India to provide digital healthcare delivery, setting up satellite-connected coronary care units in rural villages, where patients live days away from any type of specialist. The remote clinics transmit electrocardiogram results and connect patients and local physicians to specialists at hospitals in India, Malaysia, Nepal, and Mauritius via video conferencing.⁹

Dr. Shetty channels the tension generated by a resource-constrained healthcare system into process innovation. He uses medical technology efficiently to reduce his costs and increase patient access to care. Developed countries have less incentive for this type of innovation, which is much more common in emerging markets.

7 Anand.

8 SEC, Form S-1, HCA Inc., http://www.faqs.org/sec-filings/100507/HCA-INC-TN_S-1/.

9 The International Forum, “Devi Shetty, Narayana Hrudayalaya, Social Entrepreneurs provide examples of leadership and vision,” http://www.internationalforum.com/Text%20Pages/metaphores_for_leadership.htm.



Pillar 2: Leading resources for innovation

US performance: 7.2 (past), 7.3 (present), ↓ (future)

The United States slightly improved its score for this pillar between 2005 and 2010 primarily because of a relatively high level of R&D spending, strong labor productivity, high-quality academic medical centers (AMCs), and a high average of patent applications per capita. However, Scorecard data indicate that the US score will decline in the future as other countries improve their educational and research facilities and become more productive in patent applications.

Key findings

- The United States, home to 133 accredited medical schools and hundreds of teaching hospitals, is the current and historical leader in AMCs. During the past six years, US medical schools graduated more than 97,000 students.¹⁰ The AMCs associated with leading US educational institutions have spawned many breakthrough medical advances in the past half-century, including the first successful

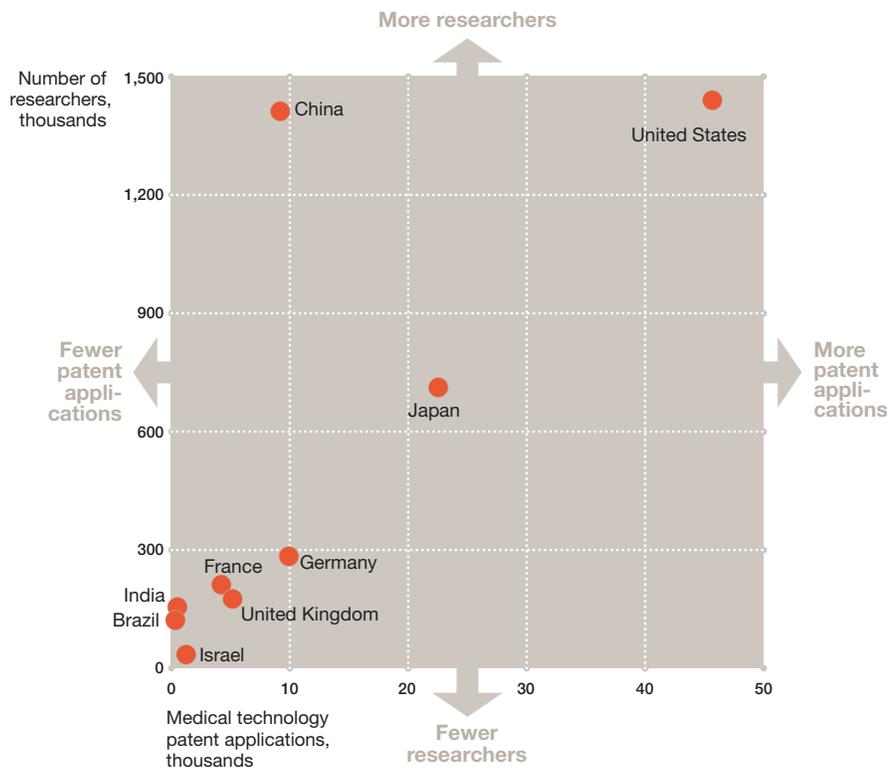
liver transplant and balloon angioplasty.¹¹

- The highly ranked US universities attract large numbers of foreign students. In the 2010 Academic Ranking of World Universities, the United States had 17 of the top 20, 58 of the top 100, and

¹⁰ American Association of Academic Medical Centers (AAMC), "FACTS: Applicants, Matriculants, Enrollment, Graduates, MD/PhD, and Residency Applicants Data," © 1995-2010.

¹¹ American Association of Academic Medical Centers, "America's Teaching Hospitals: Discovering Tomorrow's Cures," <https://www.aamc.org/download/148398/data/thfirsts.pdf.pdf>.

Figure 7: Researchers versus medical technology patent applications



Sources: United Nations Educational, Scientific and Cultural Organization and World Intellectual Property Organization

187 of the *top 500* institutions.¹²
 In 2006, foreign students earned approximately 36.2 percent of US doctorate degrees in the sciences

and approximately 63.6 percent of the doctorates in engineering.¹³

- China ranks second among the nine countries in number of research professionals. It has nearly as many as the United States and twice the number as Japan. Yet China has not been as productive in obtaining medical technology patents as the other countries. The United States obtains more patent applications on an absolute basis, averaging more than 44,000 per year; but Israel and Japan lead in filing medical technology patent applica-

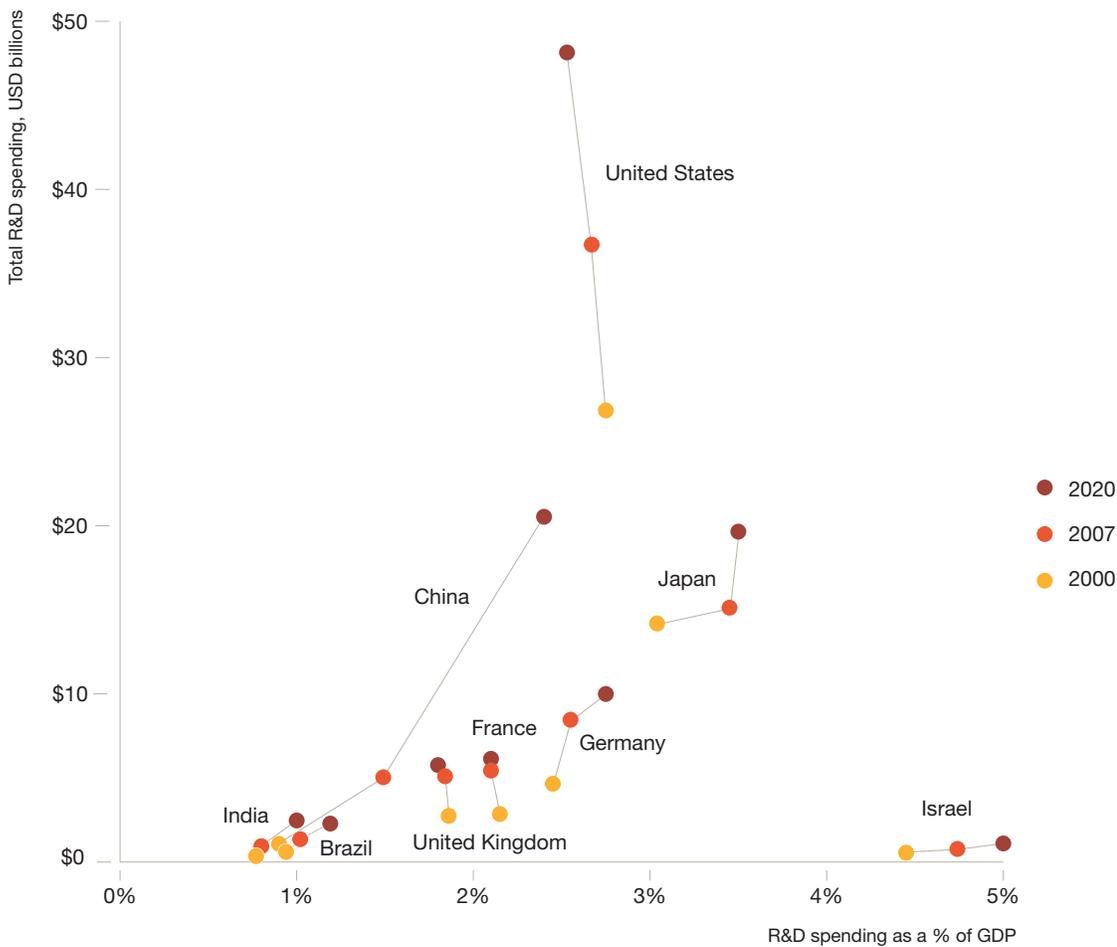
tions on a per capita basis. If China were as productive per researcher as the other countries, it could produce the second-largest number of medical technology patents in the world (Figure 7).

12 Academic Ranking of World Universities, “Statistics,” <http://www.arwu.org/ARWUStatistics2010.jsp>. [The Academic Ranking of World Universities, first published in June 2003 by the Center for World-Class Universities and the Institute of Higher Education of Shanghai Jiao Tong University, China, is updated on an annual basis. ARWU uses six objective indicators to rank world universities, including the number of alumni and staff winning Nobel Prizes and Fields Medals, number of highly cited researchers selected by Thomson Scientific, number of articles published in journals of *Nature* and *Science*, number of articles indexed in Science Citation Index: Expanded and Social Sciences Citation Index, and per capita performance with respect to the size of an institution. More than 1,000 universities are ranked every year, and the best 500 are published on the Web.]

13 Christine M. Matthews, “Foreign Science and Engineering Presence in U.S. Institutions and the Labor Force,” Congressional Research Service, March 23, 2010, <http://www.fas.org/sgp/crs/misc/97-746>.

- China and India show the most rapid rates of growth in triadic patent families, with China growing at 34 percent per year and India at 10 percent. This growth portends higher future scores for these two countries for this pillar. (Triadic patents are a series of corresponding patents filed in the United States, Europe, and Japan for the same invention.)
- With the exception of the United States and United Kingdom, R&D spending as a percentage of GDP is growing. The United States invests more in R&D than any other country in terms of dollar amount. However, in terms of percentage of GDP, the US investment in R&D is declining, which should lower its future score. Whereas China ranks sixth today, PwC expects it to have the second-largest R&D budget among the nine Innovation

Figure 8: R&D spending as percentage of GDP versus total R&D spending (USD), 2000, 2007, 2020



Sources: United Nations Educational, Scientific and Cultural Organization and PwC analysis

Scorecard countries by 2020. We expect China's R&D expenditure as a percentage of GDP to approach US levels within 10 years (Figure 8).

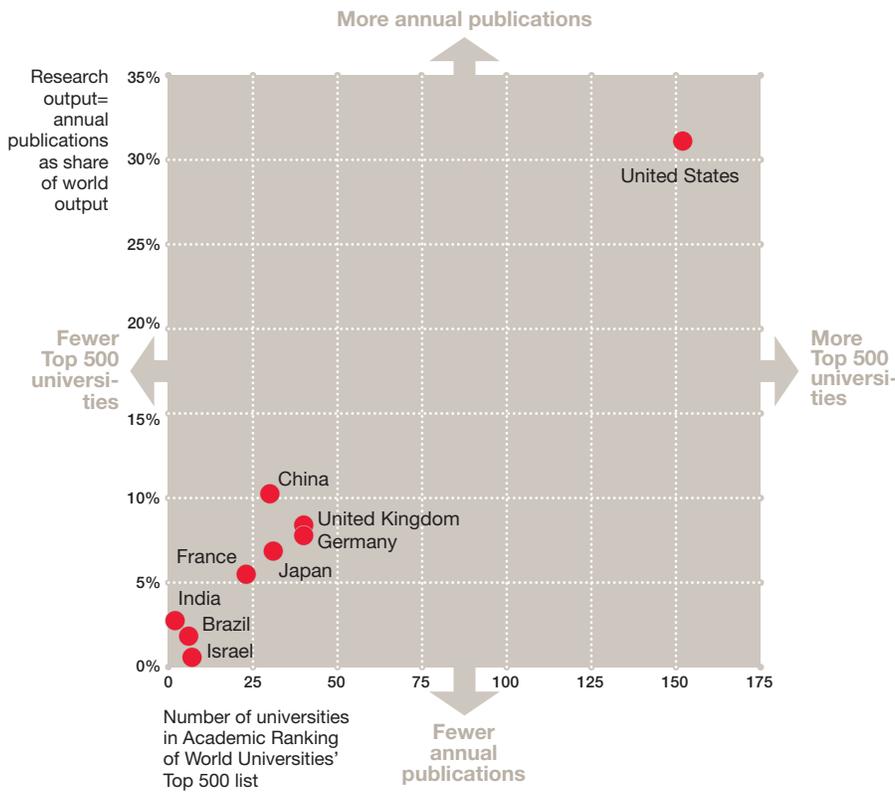
- China has already eclipsed all other countries except the United States in research publications, and the quality of its research institutions is improving (Figure 9).

Looking forward

PwC predicts that the US score for this pillar will drop and the emerging countries' scores will rise. As the quality of non-US educational and research institutions improves, R&D funding outside the United States increases, and other developing

nations' innovative output matches that of the developed countries, the United States will face increasing competition for innovative talent, resources, and output. China's innovative output will grow at a much faster rate than that of the United States and move its future score higher.

Figure 9: Research publications versus number of universities ranked in world's top 500



Sources: Thomson Reuters and Academic Ranking of World Universities

Pillar 3: Supportive regulatory system

US performance: 7.2 (past), 6.8 (present), ↓ (future)

The US score for this pillar dropped between 2005 and 2010, a trend that PwC expects will continue. PwC bases the current US score and future direction on data relating to the regulatory and legal environments in the nine countries and interviews with executives at 13 US-based medical technology companies, representing approximately 10 percent of global industry revenue.

US success in medical technology during recent decades stems partially from the global leadership of the US Food and Drug Administration (FDA). FDA's standards and guidelines to ensure safety and efficacy have instilled confidence in the industry's products worldwide. Other countries' regulators often wait to see FDA's position before acting on medical technology applications, and often model their own regulatory approach on FDA's.

During the past decade, however, FDA has faced growing responsibilities along with heightened public demand for drug and device safety. In a recent survey of 50 life sciences companies (including 19 companies developing medical device or diagnostic products), PwC found that respondents experienced frequent problems in gaining product approvals, even to the point of FDA changing its position during the application review process. Forty percent of survey participants agreed that FDA denied some product approvals primarily because of inadequate review resources.¹⁴

The industry also has expressed concern about FDA's effort to

14 "Improving America's Health V," PwC and BIOCOM survey of the life sciences industry, 2010.

Figure 10: Regulatory approval time versus ease of regulatory approval



Source: PwC survey

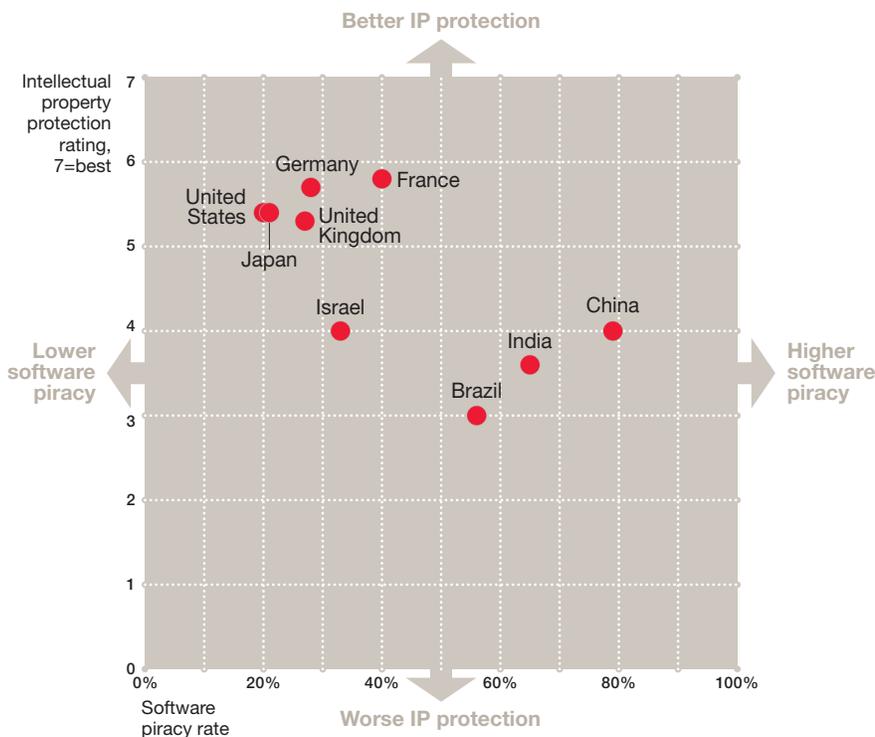
revamp its 510(k) process,¹⁵ through which 90 percent of devices gain US approval. The cost of a 510(k) application ranges from \$1 million

to \$50 million, compared with \$50 million to \$150 million for higher-risk device applications. The industry is concerned that additional 510(k) requirements calling for more extensive clinical or manufacturing data could drive up cost and lengthen time to market. The agency argues that requiring applicants to submit more thorough data upfront will make the process more efficient.¹⁶

15 The Center for Devices and Radiological Health (CDRH) within the Food and Drug Administration (FDA) reviews and processes Premarket Notification 510(k) submissions for medical devices. The Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) within CDRH are responsible for the processing and review of 510(k)s for marketing clearance in the United States. Branches within these offices are organized according to medical scientific disciplines. ODE and OIVD biomedical engineers, physicians, microbiologists, chemists, and other staff perform scientific reviews of 510(k)s and other research (Investigational Device Exemption) and marketing applications (Premarket Approval). Their recommendation determines whether a new device is substantially equivalent (SE) or not substantially equivalent (NSE).

16 David Olmos and Sophia Yan, "Medical Device Makers Face Revamped U.S. Rules for Approvals," Bloomberg, August 4, 2010, <http://www.bloomberg.com/news/2010-08-04/medical-device-makers-face-revamped-u-s-rules-for-approvals.html>.

Figure 11: Intellectual property protection versus software piracy rate



Sources: The World Bank and Business Software Alliance

Note: The Y-axis relates to how countries rate the strength of their intellectual property protection; whereas the X-axis reflects the extent to which intellectual property is protected.

Key findings

- New market entrants are going to Europe for approval in half the time it takes to obtain FDA approval, but the same devices eventually gain approval in both markets. Addressing the length and difficulty of obtaining government approvals for new medical devices, company executives said:
 - It takes twice as long for the United States to approve the same technology as it does the European countries included in this study and Israel. The United States takes six months, whereas the other countries take three.
 - Agencies in Brazil and India take longer than the United States for approvals.
- China ranks next, at about one year.
- Japan, at three years, takes the longest (Figure 10).
- Medical technology company executives ranked Israel first in overall ease of regulatory approval (Figure 10). Those executives said they found the US regulatory approval process the most uncertain of all countries in this study. They gave European regulators high marks for being more predictable.
- Medical technology company executives said they expect the ease of the US regulatory approval process to regress within five years compared with other countries. Survey respondents said they expect significant

improvement in China, India, and Brazil.

- Interviewees cited significant barriers to growth for medical technology companies in China, India, and Brazil: (1) difficulty of doing business in those countries, (2) poor protection of intellectual property, and (3) high level of piracy (Figure 11). These factors contributed to relatively low past and current scores for developing nations in the study. Their scores should rise in the future, but the degree depends upon whether they can improve on these measures.

Looking forward

PwC expects the US innovation score for this pillar to drop in the future, primarily because European countries will continue to provide more supportive regulatory processes that encourage innovation yet ensure safety and effectiveness on a timely basis. For this pillar, the future scores for France, Germany, and the United Kingdom should rank higher than the United States. The developing countries should see some improvement, but not to the level of the European nations.

The citizens of countries with more efficient and less uncertain, capricious, and complex regulatory approval processes will gain earlier access to innovative medical technology, and providers in those countries will benefit from more experience in using new devices. Those nations also will attract “medical tourists” who are willing to travel to obtain treatments unavailable in their home countries. Countries with long, complex, arbitrary, nontransparent, costly approval pathways will discourage entrepreneurs and investors, causing them to launch new products elsewhere. (See sidebar, “Four companies tell of a tortured road to product approval.”)

Four companies tell of a tortured road to product approval

As part of the research for the Innovation Scorecard, PwC interviewed industry executives about their experiences with the regulatory approval process. Information gained from some of those interviews follows. The opinions expressed are those of the people interviewed, not PwC. Those opinions consistently support PwC's finding that medical technology innovators are going outside the United States to seek clinical data, new-product registration, and first revenue because of a challenging US regulatory environment.

ExploraMed, a medical device incubator based on the West Coast, has developed a strategy of going outside the United States for first clinical studies in almost every one of the six companies it has created so far, said Chief Executive Officer Josh Makower, MD, who also serves as a consulting professor of medicine at Stanford University Medical School. "I prefer going to Tier 1 countries¹⁷ so that I don't risk experiencing the delays that might occur if I had to navigate the US IDE [investigational device exemption] or export approval process early on," he said. "Today, many device companies are experiencing substantial costs and delays attempting to obtain IDEs in the United States, so seeking other places in the

world where high-quality clinical work is prevalent, such as Tier 1 countries, is one of the few avenues left for US companies to advance their research into clinical testing quickly.

"We need an FDA that is more reasonable and supportive of innovation," said Makower, who is also a venture partner with New Enterprise Associates. Out of the four companies Makower has founded during the past six years, only one has obtained commercial status in the United States, and three have already received the European CE mark and initiated sales overseas. One of those companies has been in negotiations with the FDA for two years attempting to obtain an IDE. "When you have excessive delays, you have to come up with more money just to allow the enterprise to survive," he said. "This increases the cost of innovation and makes it more difficult for small companies to survive to the end of the approval process."

Fairway Medical Technologies spent two years and \$1 million to take a Class III application through the review process in the United States. Leo Womack, Fairway's chairman, said the FDA reviewer kept coming back to the company with more questions, lengthening the process by 90 days each time. The device eventually gained approval. Womack's company is commercializing a new device that it will take to Europe for approval and first revenue, but it will seek US approval later. Investors prefer that companies that launch in Europe also obtain US approval because, Womack said, "we are still the gorilla market."

¹⁷ FDA.gov. Tier 1 countries are: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, a member of the European Union (United Kingdom, Spain, Ireland, Denmark, Greece, Belgium, Portugal, Germany, France, Italy, Luxembourg, Netherlands, Sweden, Finland, Austria, Bulgaria, and Romania), or the European Economic Area (includes the European Union countries and Norway, Iceland, and Liechtenstein). As of May 2004, the European Union also includes Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia.

OrthoAccel Technologies, a Houston-based company, launched AcceleDent, a removable orthodontic device, in the United Kingdom in 2009 and Australia in 2010 as a lightly regulated Class IIa product (posing no serious harm or threat to patients). AcceleDent applies cyclic forces to accelerate the bone remodeling process performed by traditional braces to move teeth in bone faster than conventional orthodontic methods. Although the company began seeking approval in the United States at the same time as it did in other countries, the product remains under review by FDA as a Class II device.

Michael Lowe, OrthoAccel CEO, said this type of delay to market entry can increase the cash burn rate by several million dollars and force a start-up to raise additional funding before it can begin to earn US revenue. “We made the decision to pursue an international strategy as soon as we realized that the FDA pathway would be time consuming,” Lowe said. “We shifted our resources to hitting international revenue first.”

ThromboVision, a small biomedical start-up also based in Houston, failed to obtain 501(k) clearance from the FDA after five rounds of questions and two years. The company developed a device called the “T-Guide” to measure platelet aggregation (stickiness). To develop the T-Guide, ThromboVision licensed patented light-scattering technology developed by scientists affiliated with the Utah Artificial Heart Institute, Brigham Young University, and the University of Utah.¹⁸

¹⁸ Thrombovision, www.thrombovision.com.

Of the 28 million people who currently take Plavix (clopidogrel) to prevent heart attacks, strokes, blood clots, and stent occlusions, an estimated 20 percent respond poorly.¹⁹ FDA added a boxed warning this year to Plavix alerting patients and healthcare professionals that the drug can be less effective in people who cannot metabolize the drug to convert it to its active form. The T-Guide identifies which patients could benefit from this type of blood-thinning drug. Detecting which patients will not respond to Plavix could save money because they could be put on more effective alternatives. President and CEO Edward R. Teitel, MD, JD, said the FDA rejected T-Guide’s 510(k) based on its misunderstanding of the statistical analysis of the clinical data and the rigid application of guidance documents that were ill suited to this type of technology.

Teitel said his company has ceased operating and is in Chapter 7 bankruptcy. “In hindsight, we would seek regulatory approval in Europe, achieve early revenue, then secondarily focus on obtaining FDA clearance and US market entry. The United States has a very ugly regulatory environment right now,” he noted. “The US should rethink this whole paternalistic, zero-risk attitude because that regulatory environment makes it safe to do incremental change but very difficult to do dramatic, revolutionary change.”

¹⁹ Thrombovision.

Pillar 4: Demanding and price-insensitive patients

US performance: 7.3 (past), 7.1 (present), ↓ (future)

Low out-of-pocket spending and a relatively generous level of payer reimbursement account for high past and current US scores for this pillar. PwC expects a lower future US score as this trend reverses.

In the United States, patients' share of total health expenditures declined from 47 percent in 1960 to 12 percent today,²⁰ making them responsible for a small part of the total medical bill and often unaware of the entire cost of their treatment. US patients covered by health insurance have become accustomed to asking for the latest wonder drug, service, or device.

That scenario is changing. Most employers are increasing deductibles, copayments, and co-insurance. In 2011, most employers are expected to require a deductible of \$400 or more.²¹ In addition, according to a PwC survey, high-deductible plans are primary for 13 percent of employers surveyed in 2010, up from 6 percent in 2008. In these plans, consumers are forced to spend more out of pocket, often funding expenses with tax-favored

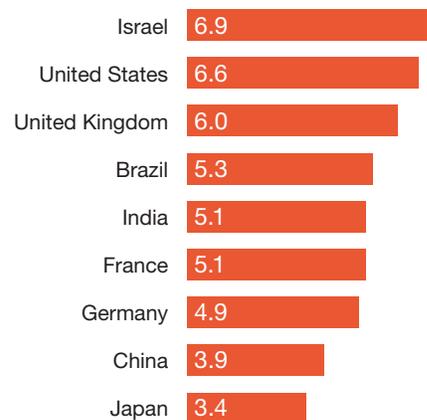
health savings accounts, which roll over from year to year and encourage shopping for lower-cost services.

A recent Kaiser Family Foundation and Health Research & Educational Trust survey confirms that patients' share of costs is going up. This survey finds that while total premiums for family coverage increased by 3 percent in 2010, workers' share shot up 14 percent, pushing more of the cost and risk to the healthcare consumer. The survey also reveals that 46 percent of small employers (3 to 199 workers) require workers to pay annual deductibles of at least \$1,000.²²

Key findings

- Medical technology companies interviewed by PwC regard Israel as the easiest market for obtaining reimbursement today, followed by the United States. Surprisingly, the United Kingdom, with its largely single-payer, government-controlled system, ranks third in ease of reimbursement and significantly above the other European countries included in this study. China and Japan rank lowest, indicating the most difficulty in obtaining reimbursement and payment approval (Figure 12).

Figure 12: Ease of reimbursement (1=most difficult, 9=easiest)



Source: PwC survey

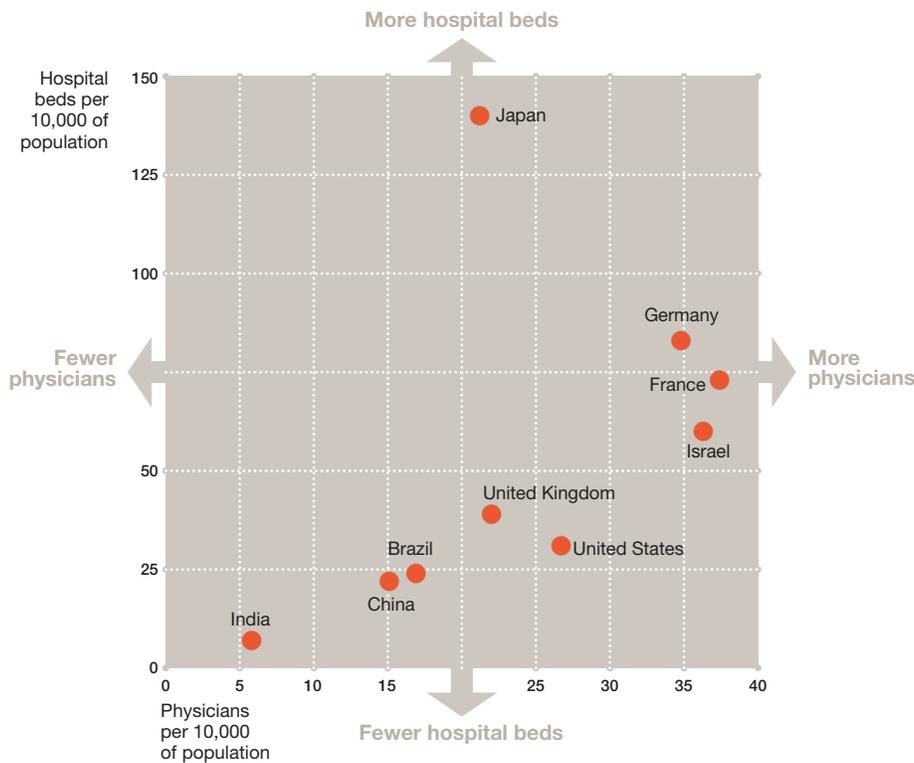
- Companies surveyed expect that obtaining reimbursement in the United States will become much more difficult in the future. These same companies expect it will become much easier to obtain reimbursement for their technologies in China, India, and Brazil. They foresee that it will remain difficult to receive payment for innovations in Japan during the next decade.

20 CMS, "National Health Expenditures Data, Historical," http://www.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp.

21 PwC Health Research Institute, "Behind the Numbers: Medical Cost Trends for 2011," June 2010.

22 Kaiser Family Foundation News Release, "Family Health Premiums Rise 3 percent to \$13,770 in 2010, but Workers' Share Jumps 14 percent as Firms Shift Cost Burden," September 2, 2010, <http://www.kff.org/insurance/090210nr.cfm>.

Figure 13: Hospital beds versus physicians per capita



Source: World Health Organization

- Significant investment in hospitals and high numbers of physicians tend to have a negative impact on the development of new medical technology, creating barriers to process and business model innovations as countries seek to increase utilization of existing healthcare infrastructure. Those systems that have an abundance of hospitals and physicians—Japan and the Continental European ones—have few tensions to drive the development and adoption of digital healthcare delivery. Lower hospital and physician density in the United States and United Kingdom—at levels more similar to those of Brazil and China than the rest of Europe or Japan—likely

will generate creative tensions to drive innovations that more effectively apply technology in mobile, care-anywhere networks. China, Brazil, and India, which lack a large physical delivery infrastructure, have already begun to channel tensions that result from shortages of physicians and hospitals into innovative ways to provide digital care (Figure 13).

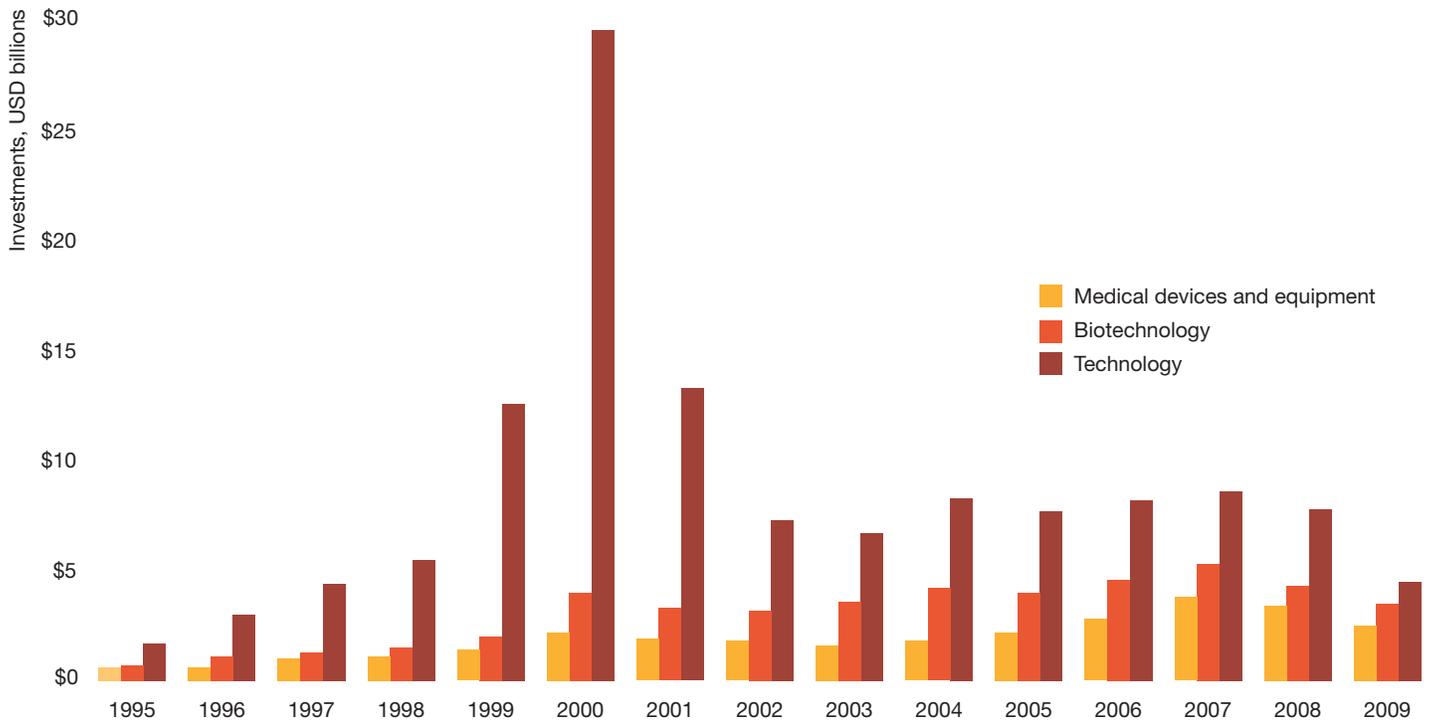
Looking forward

PwC expects that the US score for this pillar will drop, while scores for China, India, and Brazil will rise. In the United States, employers as well as government and private payers will push more of the financial risk to healthcare consumers and providers.

They will hold providers more accountable for health outcomes, penalizing them for poor quality and high cost. These actions will tend to drive reimbursement for medical technology lower.

Although payers in developed nations will tighten their purse strings and demand more efficient care delivery, countries that already experience the greatest tensions in access to care and availability of infrastructure and resources will move ahead in creating innovative delivery and payment models. By 2020, process innovation based on novel use of information technology to achieve better outcomes at lower cost will make China, India, and Brazil stand out as innovators.

Figure 14: US venture investment in life sciences and technology



Source: PwC and National Venture Capital Association, MoneyTree™ report based on data from Thomson Reuters, PwC analysis

Pillar 5: Supportive investment community

US performance: 8.2 (past), 7.2 (present), ↓ (future)

The US medical technology industry has benefited from the country’s unparalleled venture capital infrastructure, which no other nation has replicated. A historical abundance of capital has helped move innovations out of academia and laboratories and into the marketplace. The medical technology industry has consistently ranked among the top venture capital investment categories.

Yet the US score for this pillar dropped the most of the five pillars from past to present primarily because of a decline in domestic entrepreneurial activity, new business density, and private foreign direct investment. PwC expects the decline to last into the next decade.

Key findings

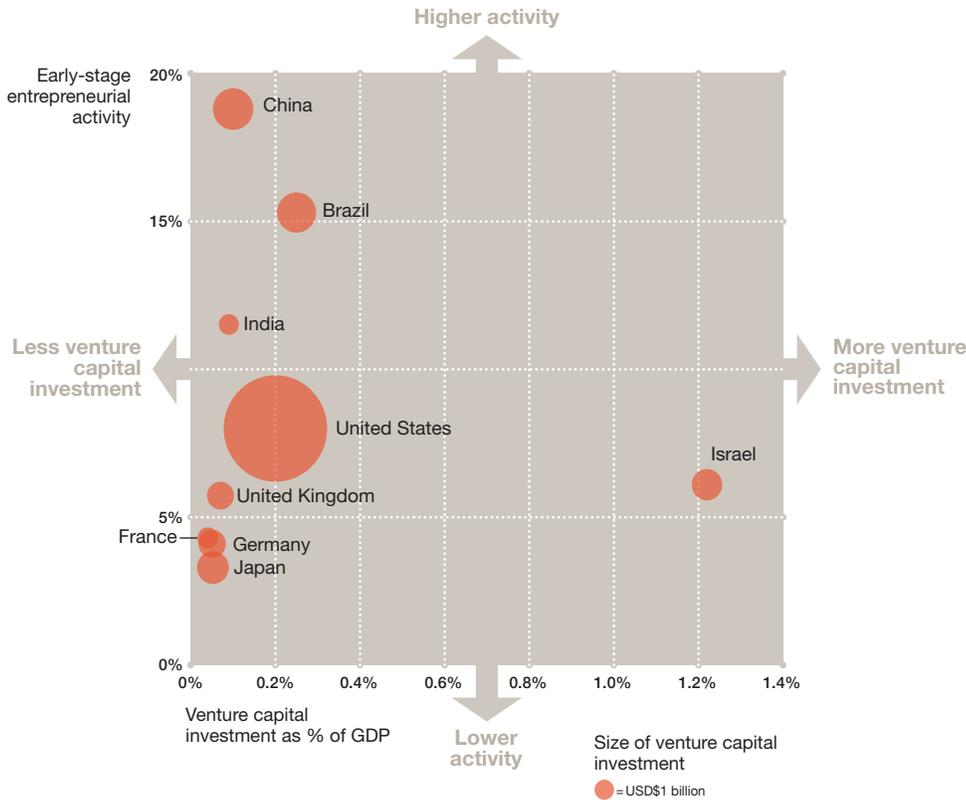
- Despite a relatively high level of support for the life sciences sector and a rise in the medical technology share, US venture capital investment has dropped since 2007 (Figure 14). From 2000 through 2009, although venture capital investment in medical technology grew about 40 percent in the

United States, it jumped almost 60 percent in Europe and Israel.²³

- Although the United States ranks first in venture capital investment, it ranks fourth among the countries in this study in entrepreneurial activity, behind the three emerging markets. China already represents the second-largest pool of venture capital, followed by Brazil. The developing nations are spending nearly as large a proportion of their GDP on venture investing as the United States (Figure 15).

²³ AdvaMed, “A Healthy Medical Technology Industry and a Healthy America: Testimony before the Senate Commerce Subcommittee on Competitiveness, Innovation, and Export Promotion,” June 22, 2010.

Figure 15: Early-stage entrepreneurial activity versus venture capital investment as percent of GDP

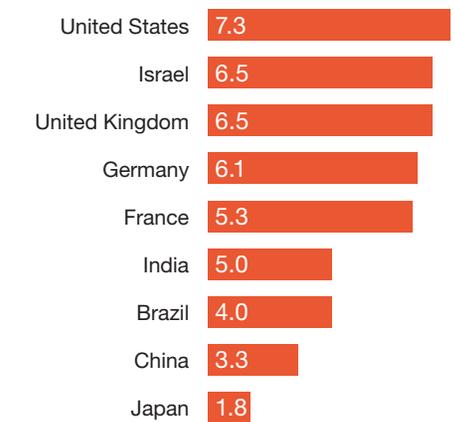


Sources: Global Entrepreneurship Monitor, Economist Intelligence Unit, and the World Bank

- The medical technology companies surveyed by PwC ranked the United Kingdom second to the United States in overall market attractiveness and access. Throughout the Innovation Scorecard, the United Kingdom consistently ranked near the United States in most measures of innovative capability and capacity. Innovation Scorecard interviewees saw the United Kingdom as much more attractive than the rest of Europe and second only to the United States in opportunities for commercializing innovation.

- Medical device executives interviewed by PwC expressed wide-ranging views of the attractiveness of market access in the United States, Israel, and Germany. They consistently ranked Japan, Brazil, and China lower than other countries. India performed better relative to the other emerging markets. Despite the absolute superior attractiveness of the US market, the country elicited widely varied responses regarding market access. With tight consensus, survey respondents saw Japan as least attractive for market access (Figure 16).

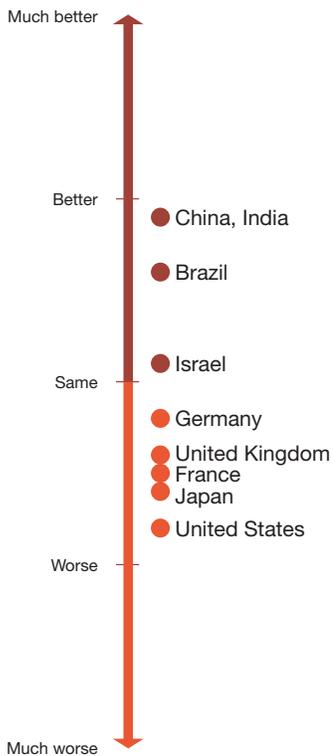
Figure 16: Market access by country 1=most difficult, 9=easiest



Source: PwC survey

Figure 17: Attractiveness of market commercialization opportunity

In 2015, do you believe that the attractiveness of the commercialization opportunity will become much worse, worse, same, better, or much better?



Source: PwC survey

- Survey respondents indicated that the emerging economies were the only ones they expect to become more attractive for medical technology commercialization opportunities. Device companies saw a new and growing consumer class in these markets (Figure 17).

Looking forward

PwC predicts that the US score for this pillar will decline during the next decade, but scores for emerging markets will rise. Rapid growth in venture capital investment in China, India, and Brazil, fueled by local and US investors, is building some of the world’s most entrepreneurial cultures. Although US private equity investors and venture capitalists are contributing to this expansion, their role is smaller than that of the governments of India and China, which are aggressively promoting venture funding and providing capital to early-stage firms within their borders.

Because most innovation in medical technology occurs in start-ups and is later acquired by larger companies, multinational medical technology companies will increasingly look to these emerging markets for acquisitions to fill their product pipelines. US medical technology firms, which already obtain 40 percent to 50 percent of their revenue in foreign markets²⁴ and see themselves as global companies, will not hesitate to invest where growth is most promising.

With the growth of emerging markets, global venture capital firms increasingly will see developing nations as more attractive. They will see the US market as less attractive because of the difficult regulatory environment, uncertain payment structure, and relatively weak rate of growth in R&D and resources for innovation. Venture capital will seek out countries where the growth opportunity is stronger and the approval process is less costly in time and money.

²⁴ Jeffrey W. Englander and Phillip M. Seligman: “Standard & Poor’s Industry Surveys: Healthcare: Products & Supplies,” February 4, 2010. *S&P is not responsible for errors or omissions in the data or for the context of the information.*

Incubators look outside United States for clinical studies and first revenue

For several years, pharmaceutical companies have been moving more clinical trials outside the United States. Urged by their investors, device companies have followed this lead.

The following case study reflects the growing attractiveness of medical technology markets outside the United States. It was the result of a PwC interview with an industry executive and reflects the opinions and experience of the interviewee, not PwC.

“For early-stage clinical experience, you want to go somewhere that the regulatory burden is not so high,” said Mike Dugery, a former Johnson & Johnson engineer who heads Vasculab Technologies, an early-stage device incubator/accelerator. “I look to Europe as one of the proving grounds because you can move quickly from your clinical phase into getting a CE mark. That enables you to use and assess the technology more broadly. You can still make improvements in the technology, but you benefit from what you learn early on in Europe.”

Dugery noted that countries also benefit when they host early-stage research. “Many European clinicians are sought after for clinical studies because they have so much experience with early-stage technology. That puts them on the map in terms of clinical studies and becoming thought leaders in technology adoption.” Dugery said that one example lies in the cardiovascular device field, where some European clinicians have been working with US device manufacturers for as many as 10 years.

He said Israel “is prolific in bringing out new innovative technologies” because of the following:

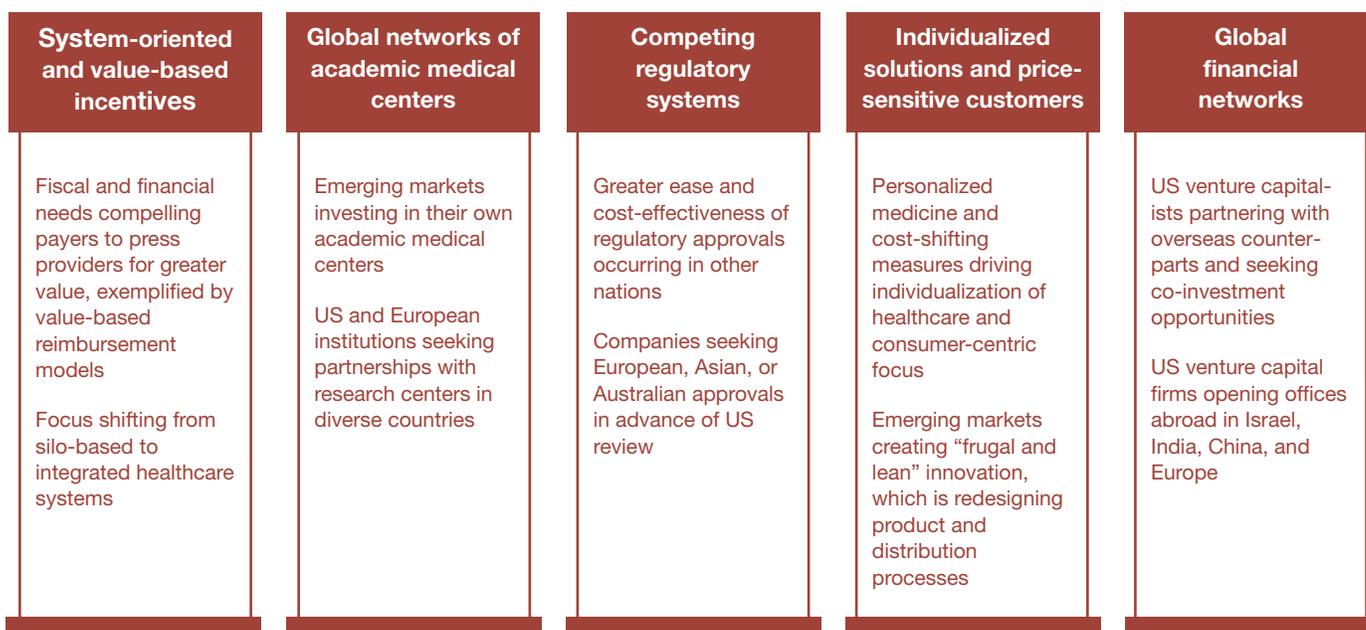
1. Regulatory environment: speed to get technology into the clinic
2. Excellent technical people: engineers, clinicians, technicians
3. Mature early-stage venture funding network and seasoned entrepreneurs

“You need all of those things to prove out a technology and bring it to market and even get it to the point that you can secure funding and move forward,” he added.

For sourcing innovation, Vasculab still looks primarily to the United States. “We source innovations primarily in the US by licensing technology or acquiring assets from other companies,” he said. “The clinical need for the disease states we target often presents in the US because of lifestyle, diet, and/or demographics. There are big markets throughout the world, but the US is still the one where you can generate large amounts of revenue.” That does not preclude Vasculab from looking outside the United States for talent and innovation. “We are ambivalent to borders; we will look anywhere,” Dugery said.

Vasculab does have qualms about intellectual property protection in countries such as China, where “it’s harder to do business” and “there is a concern that your technology would be copied.” He added, “When we source technology overseas, we make sure the IP is filed in the US.”

Figure 18: Five new pillars of innovation



Five new pillars of innovation

To develop the type of medical technology ecosystem required for 2020, countries and companies will have to adapt to five new pillars of innovation. The five pillars of today will give way to the following:

1. System-oriented and value-based incentives

Mobile health, value-based purchasing, and personalized medicine will combine to drive more cost-effective, outcome-based initiatives and greater collaboration among payers, providers, and the medical technology industry to develop and deliver whole-care, patient-centered solutions. Information technology will connect the elements of care throughout the entire healthcare system and validate results.

Emerging markets, where the cost of research and engineering can be a fraction of that in the West, will continue to function as living laboratories for the design of cost-effective

products that can translate to other markets. More importantly, the cost constraints on the demand side of innovation will create the tensions to drive radical innovations that deliver superior value at a fraction of the costs seen in the developed markets.

If companies can demonstrate the efficacy of new technologies in developing markets, they can present them to US and European regulators and payers as proven alternatives. Medical device marketing could take the same path as Tata’s \$2,000 Nano car, designed in India but exported to Europe. The Nano shows how lower-cost engineering, production, delivery, and service can translate across national boundaries and cultures to deliver value never thought possible.²⁵

²⁵ James Lamont, “The Age of ‘Indovation’ Dawns,” *The Financial Times*, June 14, 2010, <http://www.ft.com/cms/s/0/6762f77a-77de-11df-82c3-00144feabdc0.html#axzz16y7tfiAS>.

2. Global networks of academic medical centers

As emerging nations invest in academic medical centers, increase R&D funding, and attract returning nationals trained overseas, the academic leadership that helped enable innovative research in the West is migrating to Asia and South America. Already, Asian and Pacific universities are ascending the Academic Ranking of World Universities, accounting for 106 of the top 500 slots. China alone has 34 universities on the list, more than double the number seven years ago.²⁶

Some US and European universities and medical colleges have responded to this challenge by seeking partnerships abroad to reduce competitive overlap and create synergies. Notable programs already under way include the American Hospital MD Anderson in Istanbul, UPMC cancer centers in

²⁶ Academic Ranking of World Universities, “Statistics,” <http://www.arwu.org/ARWUStatistics2010.jsp>.

Ireland, Cleveland Clinic Abu Dhabi, and the Mayo Clinic-Karolinska Institute partnership in Sweden. Johns Hopkins recently announced a partnership with King Khaled Eye Specialist Hospital in Riyadh, Saudi Arabia.²⁷ In addition, Johns Hopkins recently signed an agreement with a Kuala Lumpur-based private development corporation to help Malaysia develop its first fully integrated, private four-year graduate medical school and teaching hospital.²⁸

Within the United States, examples of cooperation abound. The Michigan-headquartered Van Andel Research Institute (VARI) recently entered into a strategic alliance with the Arizona-based Translational Genomics Research Institute (TGen), which has its roots in the Human Genome Project. Both VARI and TGen seek to conquer cancer and other diseases through genetic research. By combining forces on certain projects, they have been able to share expertise and operate on a larger scale than

either could do independently. In addition, the partnership has generated jobs and economic activity in both states.²⁹

TGen also has formed a collaborative relationship with the government of Luxembourg to help the country establish a bioscience center of excellence. Two other US organizations—Seattle-based Partnership for Personalized Medicine and Institute for Systems Biology—are involved in the collaboration.³⁰

3. Competing regulatory systems

Medical technology companies will continue to move into markets where they can obtain regulatory approval more quickly, generate revenues faster, and engage patients and providers in the cycle of innovation to advance their products and services. The FDA and other more restrictive regulators will come under greater pressure to improve and streamline how they review new products.

“Regulatory policy must be driven by data, not anecdotes,” said ExploraMed’s Josh Makower. “People will have to decide whether they are willing to accept yesterday’s therapies” rather than taking a risk on new

technologies. “We will have to find a way to embrace the fact that innovation always comes with some risk.”

Regulators in some developing nations, such as China, are reluctant to grant regulatory approval unless a company already has it in its home country. This gives US companies an additional reason to operate in Europe because they can obtain approval there faster, opening the door to Asia.

4. Individualized solutions and price-sensitive customers

In the United States, employers, governments, and payers will force patients to assume a greater share of the financial burden, risk, and decision making in healthcare, which should make them use care more responsibly. In addition to shifting more of the healthcare cost to employees, many employers have instituted wellness programs that reward employees for healthy behaviors and penalize them for unhealthy lifestyle choices, such as smoking.

Providers, who will be more responsible for health outcomes, will look to companies worldwide for technology solutions that offer more integrated, holistic, cost-effective devices combined with wellness and disease management services.

Although patient-centered, personalized care requires individualized solutions, it accomplishes those within a complex, adaptive system that integrates devices, services, therapeutics,

27 Johns Hopkins Medical School, “Leading Ophthalmological Centers in the United States and Saudi Arabia Announce Affiliation,” January 11, 2010, http://www.hopkinsmedicine.org/news/media/releases/Leading_Ophthalmological_Centers_In_The_United_States_and_Saudi_Arabia_Announce_Affiliation.

28 Johns Hopkins Medical School, “Johns Hopkins to Develop Medical School and Teaching Hospital in Malaysia,” Johns Hopkins, November 2, 2010, http://www.hopkinsmedicine.org/news/media/releases/johns_hopkins_to_develop_medical_school_and_teaching_hospital_in_malaysia.

29 Proprietary PwC study, “The VARI-TGen Alliance.”

30 “Leading US Bioscience Pioneers Enter International Collaboration with Government of Luxembourg to Accelerate Biomedical Research,” TGen, June 6, 2008, <http://www.tgen.org/news/index.cfm?newsid=1167>.



and information technology. Like Merck Serono has done with disease management services surrounding its easypod device, companies must rethink their business models to align with personalized medicine and wireless technology. According to CEO Don Cowling, “You have to first blow up the current model.” Only then can companies deliver more targeted and effective solutions at lower cost.

5. Global financial networks

As investment opportunities shift offshore, more US-based venture capitalists will open local offices overseas, partner with counterparts outside the country, seek co-investment opportunities, and identify target investee companies abroad. Already, Bain Capital, Highland Capital Partners, and the Carlyle Group have offices in China;³¹ the Blackstone Group,

31 China Venture Capital Association, “Membership List,” <http://www.cvca.com.cn/membership/MembersList.asp>.

Providence Equity, and Trident Capital, in India;³² and Bessemer Venture Partners and Sequoia Capital, in Israel.³³

Beyond private funding, some policymakers have taken bold steps to encourage innovation within their borders. Denmark, Finland, Ireland, Japan, Singapore, South Korea, and Sweden have adopted national innovation strategies, while India established a National Innovation Foundation a decade ago.³⁴ The European Commission

32 Indian Venture Capital Association, “Members,” http://www.indiavca.org/mem_directory.aspx.

33 High Tech Industry Association (Israel), “Financial Investors,” http://www.iva.co.il/index.php?option=com_content&view=article&id=50&Itemid=58.

34 Stephen Ezell, “America and the World: We’re No. 40!” *Democracy: A Journal of Ideas*, Fall 2009, <http://www.democracyjournal.org/article.php?ID=6703>.

recently announced its intent to invest €6.4 billion (USD\$8.3 billion) in research and development during 2011.³⁵ Within the United States, individual states and regions have undertaken cooperative plans, such as the Massachusetts “super cluster” initiative, to foster innovation in the medical device and life sciences realms.

These efforts show increasing willingness on the part of policymakers, regulators, and companies in the historic and emerging technology powers to adapt to create the kinds of reform, efficiencies, and partnerships needed to maintain their position in innovation.

35 Matej Hruska, “Brussels to Invest \$8.3 Billion in Research,” *Bloomberg BusinessWeek*, July 20, 2010, http://www.businessweek.com/print/globalbiz/content/jul2010/gb20100720_317244.htm.

What this means for your business

Which countries
will lead medical
technology innovation
in 2020?

Global leadership of medical technology innovation is already in play. The Innovation Scorecard shows clearly that the developed nations are slipping in their capacity and capability for innovation, while the emerging markets are rapidly gaining ground.

Why should countries care who becomes tomorrow's leader? Innovative medical technology that follows the new value-creation dynamic will lead to better health outcomes at lower cost for a country's citizens. It also will drive jobs, tax revenue, and economic growth. A study conducted by the Lewin Group for AdvaMed shows that each medical technology job generates an additional 1.5 jobs; each medical technology payroll dollar generates an additional \$0.90 in earnings; and each dollar of medical technology industry earnings generates an additional \$0.90 in earnings elsewhere in the economy.³⁶ Those countries that can adapt quickly to the changing drivers of healthcare innovation and channel tensions into creative output will reap the greatest benefits from medical technology.

Although we expect the United States to maintain its lead in medical

technology innovation for years to come, long-term US dominance is no longer assured. The supportive ecosystem that fostered this dominance creates inherent limits to change, encourages an incremental and less radical path to innovation, and discourages innovations that could transform healthcare's cost structure and deliver greater value. Radical innovations that have a greater chance to bend the cost curve are more likely to emerge from developing countries such as China, India, and Brazil.

Looking toward 2020, the gap between the United States and other countries will narrow as emerging nations rapidly progress by a number of measures. These countries already have leapt forward in other industries. For example, a recent report by the PEW Charitable Trusts indicates that China may be winning the clean energy race. China took the top spot within the G-20 and globally for overall clean energy finance and investment in 2009, while the United States slipped to second place. In relative terms, China and Brazil, as well as the United Kingdom, invested three times more in clean energy than the United States.³⁷ Could medical

technology investment take the same direction?

Fledgling medical technology companies already seek regulatory approval of new products outside the United States first. By 2020, consumers and clinicians in Europe, Israel, and other countries where the approval process is faster and less complicated increasingly will benefit from new technology before those in the United States. Investors will lend their support where the ecosystem provides the greatest opportunity for innovative products to succeed.

By 2020, emerging markets with exceptional growth potential will gain more attention from medical technology companies and investors. Companies are already tailoring new products to the specific needs of developing countries, making use of digital technology to extend care to large populations with little income or access to hospitals and physicians. Brazil, China, and India most likely will move far ahead of the United States and Europe in digital healthcare delivery because this type of technology addresses their acute access shortages in cost-effective and valuable new ways.

36 The Lewin Group, "State Economic Impact of the Medical Technology Industry," June 7, 2010, http://www.socalbio.org/studies/MTI_Lewin_2010.pdf.

37 PEW Charitable Trusts, "Who's Winning the Clean Energy Race?" 2010, <http://www.pewglobalwarming.org/cleanenergyeconomy/pdf/PewG-20Report.pdf>.

Still, a decline in medical technology for the United States and Europe is hardly foreordained. Some of the other nations that are candidates for innovation leadership lack key essentials, whether it be a supportive regulatory regime, strong intellectual property protection, reliable suppliers, a robust venture capital market, or high-quality research institutions. These factors are not easily replicated, and most of the countries that trail in the Innovation Scorecard today lack one or more of them. For instance, easier regulatory approval in some countries is offset by poor reimbursement for many products. Poor intellectual property protection undoubtedly is holding back medical technology advancement in emerging markets.

Countries that overcome their current weaknesses and develop a supportive ecosystem to help medical technology companies seize the new value-driven innovation dynamic will lead in 2020. By taking the lead in medical technology, they will be able to deliver greater economic and health benefits to their citizens.



Appendix

What is medical technology?

The medical technology industry manufactures and sells medical instruments, devices, and equipment, including medical diagnostic machines (X-ray, CT scan, MRI); medical therapeutic devices (drug delivery, surgical instruments, pacemakers, artificial organs); and other health-related products, such as medical monitoring equipment, handicap aids, reading glasses, and contact lenses. Medical technology also includes molecular diagnostic devices and health information technology, such as smart phone and IT applications. This broad range of products goes from simple, noninvasive equipment, such as wheelchairs, to high-tech and highly regulated invasive devices, such as pacemakers and insulin pumps. The industry addresses patient needs in diverse clinical areas, including cardiovascular diseases, orthopedics, ophthalmic diseases and disorders, aesthetics, dental products, medical and surgical supplies, medical imaging, and in vitro diagnostics.

Methodology

The PwC Medical Technology Innovation Scorecard incorporates qualitative and quantitative data and analysis to identify and provide support for industry best practices. The overall scores and rankings in each dimension, as well as in aggregate, should be regarded as heuristics to help support the advancement of regulatory and advocacy work within the medical device industry.

PwC received guidance in development of the Innovation Scorecard from a steering committee, consisting of the following medical device professionals:

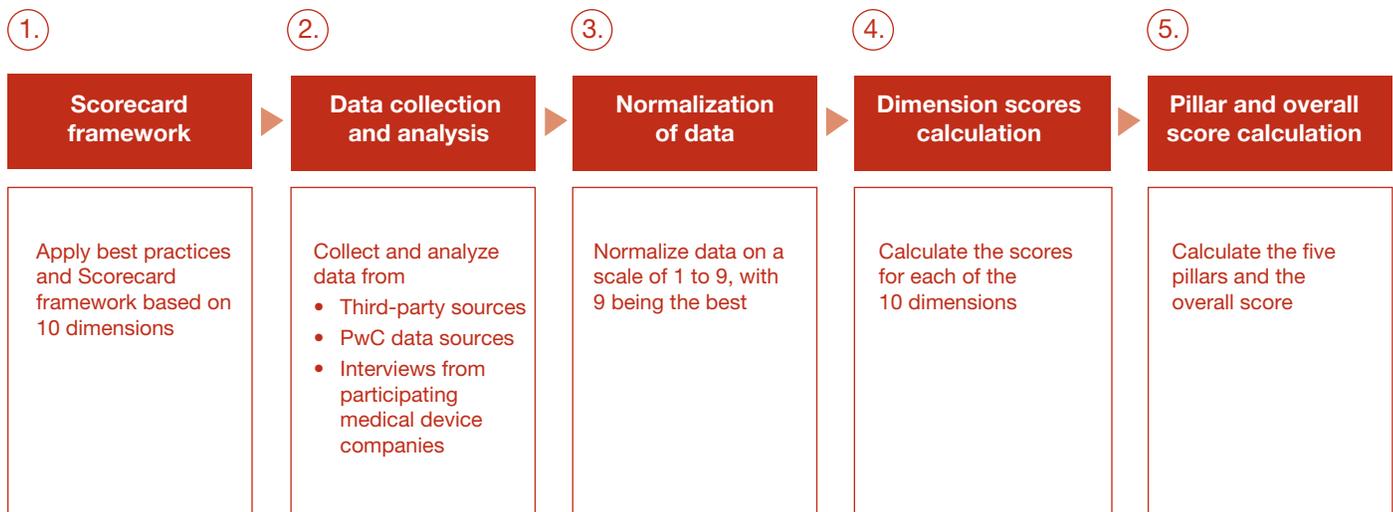
- Mark Gordon, vice president, global regulatory and clinical affairs, Synthes (At the time of his service, he was vice president, global regulatory advocacy and policy, at Boston Scientific.)
- Michael Gropp, vice president, global regulatory strategy, Medtronic

- Steve Phillips, director, health policy and reimbursement, government affairs and policy, Johnson & Johnson
- Stephen Dibert, president and CEO, Medec, Canada's national association for medical device technology companies

To understand and apply best practices, PwC conducted a benchmarking analysis of eight other innovation scorecards:

- Boston Consulting Group
- Deloitte
- INSEAD Business School
- World Economic Forum
- Economist Intelligence Unit
- ITIF (Information Technology & Innovation Foundation)
- IMD International
- *Scientific American*

To calculate historic and current scores, PwC applied the following five-step process.



Collect data

PwC collected data from third-party, publicly available sources, including but not limited to the World Bank and World Health Organization. PwC also gathered data from the firm's Health Industries practice. Additionally, with the help of AdvaMed, PwC analyzed data gathered during interviews with medical device company executives. PwC conducted 13 interviews

with medical device executives, who provided perspective on regulatory and reimbursement environment, market opportunity, and market success for the nine countries.

The medical device organizations represented by these 13 executives accounted for approximately \$34 billion in revenue for 2009.

They market a wide range of products, varying in risk level and

application, for diagnostics, therapeutics, and surgical use in the orthopedics, oncology, urology, and cardiovascular disciplines.

The following example shows the results of data collection for the third dimension (innovative resources) within the second pillar (leading resources for innovation) for the historical scores.

	Brazil	China	France	Germany	India	Israel	Japan	United Kingdom	United States
Researchers per million inhabitants	629	1,071	3,440	3,453	137	5,000	5,573	2,881	4,663
Expenditures on R&D as percentage of GDP	1.02	1.49	2.10	2.55	0.80	4.74	3.45	1.84	2.67
Number of universities in Academic Ranking of World Universities' Top 500 list per capita	6	30	23	40	2	7	31	40	152
Brain drain [1=no, the best and brightest normally leave to pursue opportunities in other countries; 7=yes, there are many opportunities for talented people within the country; Mean: 3.5] [WEF Survey]	4.3	4.2	4.1	4.4	4.2	4.2	4.8	4.8	6.0
International Internet bandwidth (bits/second/person)	1,041	280	29,356	25,654	32	2,003	3,734	39,650	11,289
Total fixed broadband subscribers per 100 population	5.3	6.3	28.4	27.5	0.5	23.0	23.6	28.1	24.0
Internet users per 100 population	35.2	22.3	51.2	75.7	6.9	28.9	68.9	79.9	71.2
Mobile telephone subscribers per 100 population	77.6	47.4	93.6	129.9	29.2	127.5	86.3	123.8	87.6
Availability of latest technologies [1=not available; 7=widely available; Mean: 4.9] [WEF Survey]	5.3	4.3	6.3	6.3	5.5	6.3	6.3	6.2	6.6
Policies to increase employment, R&D, production and overall growth in the medical device industry [6 companies] (1=least active policies, 9=most active policies) [PwC Survey]	3.3	6.9	3.9	5.9	5.2	7.1	3.0	4.9	5.9

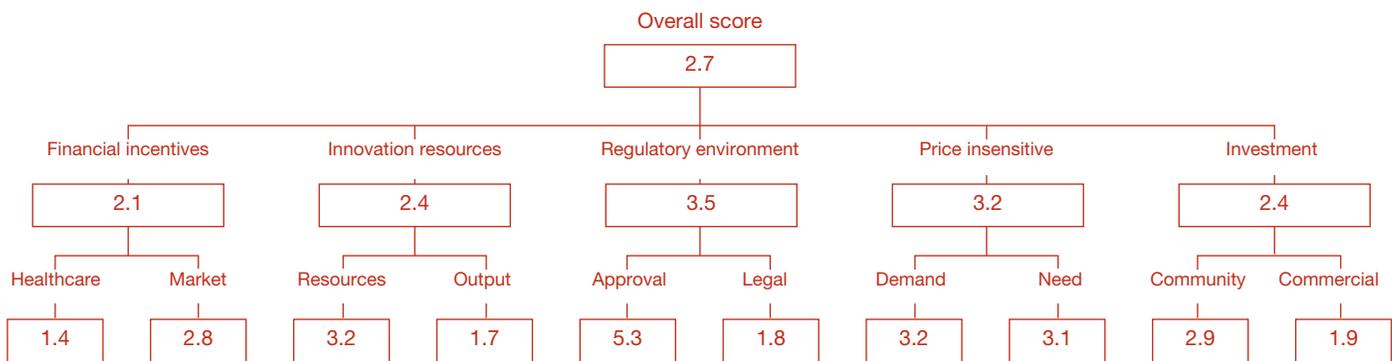
Normalize data

Next, PwC normalized and weighted the raw data on a scale of 1 to 9 by assigning the most favorable score in each metric a 9 and the least, a 1. The remaining scores were then plotted within that distribution. The chart below illustrates this step for the data shown below.

	Brazil	China	France	Germany	India	Israel	Japan	United Kingdom	United States
Researchers per million inhabitants	1.7	2.4	5.9	5.9	1.0	8.2	9.0	5.0	7.7
Expenditures on R&D as percentage of GDP	1.4	2.4	3.6	4.6	1.0	9.0	6.4	3.1	4.8
Number of universities in Academic Ranking of World Universities' Top 500 list	1.2	2.5	2.1	3.0	1.0	1.3	2.5	3.0	9.0
Brain drain [1=no, the best and brightest normally leave to pursue opportunities in other countries; 7=yes, there are many opportunities for talented people within the country; Mean: 3.5] [WEF Survey]	1.8	1.4	1.0	2.3	1.4	1.4	3.9	3.9	9.0
International Internet bandwidth (bits/second/person)	1.2	1.1	6.9	6.2	1.0	1.4	1.7	9.0	3.3
Total fixed broadband subscribers per 100 population	2.4	2.7	9.0	8.7	1.0	7.5	7.6	8.9	7.8
Internet users per 100 population	4.1	2.7	5.9	8.5	1.0	3.4	7.8	9.0	8.0
Mobile telephone subscribers per 100 population	4.8	2.4	6.1	9.0	1.0	8.8	5.5	8.5	5.6
Availability of latest technologies [1=not available; 7=widely available; Mean: 4.9] [WEF Survey]	4.5	1.0	8.0	8.0	5.2	8.0	8.0	7.6	9.0
Policies to increase employment, R&D, production and overall growth in the medical device industry [6 companies] (1=least active policies, 9=most active policies) [PwC Survey]	8.4	1.4	7.3	3.4	4.7	1.0	9.0	5.3	3.4

Calculate scores

To calculate the score for each pillar, PwC averaged the two dimensions included in that pillar. For example, the score for the “leading resources for innovation” pillar is the average of the scores for the “innovative resources” and “innovative output” dimensions. PwC used the same approach to calculate the overall score, which is the straight average of all five pillars. The example below uses Brazil’s data for 2010 :



Future scenario

To calculate the future outlook, PwC identified metrics within each dimension to serve as key indicators. In some instances, forecast metrics rely upon PwC interview survey data or forecast figures of GDP and population generated by Goldman Sachs and the World Health Organization, respectively. For other metrics, PwC assumed continued growth based on historical trends or estimated the change for an identified metric target.

Similar to the method for calculation of scores for 2005 and 2010, PwC

normalized the data for each of the chosen metrics on a scale from 1 to 9. Results were then compared with the 2010 dimension scores. Given the difference, an adjustment factor was applied to the 2010 score to determine the 2020 outlook.

Key metrics by dimension for creating the future scenario:

- Market incentive: GDP growth
- Health incentive: Consumer-class healthcare spend
- Innovative resources: Number of researchers

- Innovative output: Medical technology patent applications
- Regulatory approval process: PwC interview data
- Legal environment and impact on business: Intellectual property protection
- Demand and pricing factors: PwC interview data
- Needs and infrastructure: Physicians per capita
- Investment environment: Venture capital investment
- Medical technology commercialization: Medical device exports

Pillar 1: Powerful financial incentives dimensions and measures

Market incentives dimension

- Average GDP growth (2000-2007)
- Government procurement of advanced technologies (World Economic Forum [WEF] survey)
- Tariff rates
- Prevalence of trade barriers
- Business impact of foreign direct investment (WEF survey)
- Extent and effect on taxation (WEF survey)
- Total tax rate

Healthcare incentives dimension

- Health expenditures per capita
- Primary hospital cost per bed day
- Healthcare costs: Scans and imaging (four procedures)
- Total hospital and physician costs
- Reimbursement approval cost (PwC survey)
- Population covered by private health insurance
- Consumer class health expenditure (weighted 50 percent in this dimension)

Pillar 2: Leading resources for innovation dimensions and measures

Innovative resources dimension

- Researchers per million inhabitants
- Expenditures on R&D
- Universities in ranking of Top 500 World Universities
- Brain drain (WEF survey)
- International Internet bandwidth
- Total fixed broadband subscribers per capita
- Internet users per capita
- Mobile telephone subscribers per capita
- Availability of latest technologies (WEF survey)
- Policies to increase employment, R&D, production, and overall growth in the medical device industry (PwC survey)

Innovative output dimension

- Labor productivity: GDP growth per person employed
- Number of utility patents (patents for invention)
- Triadic patent families
- Medical technology patents per capita
- Quality of scientific research institutions
- Quality of math and science education
- Annual publications as share of world output
- Capacity for innovation (WEF survey)

Pillar 3: Supportive regulatory systems dimensions and measures

Regulatory approval process dimension

- Premarket approval fees for MRI (dollars)
- Premarket approval time for MRI (months)
- Regulatory approval costs (PwC survey)
- Regulatory approval time (PwC survey)
- Ease of regulatory approval process (PwC survey)
- Number of regulatory approvals granted (PwC survey)
- Duration of product registration (years)
- Number of clinical trials

Legal environment and impact on business dimension

- Intellectual property protection (WEF survey)
- Software piracy rate
- Ease of doing business
- Corruption perception index score
- Burden of government regulation
- Transparency of government policymaking
- Laws relating to information technology



Pillar 4: Demanding and price-insensitive patients dimensions and measures

Demand for healthcare dimension

- Health expenditures as percent of GDP (weighted 50 percent in this dimension)
- Medical device revenues per capita
- Government expenditure on health (percent of total government expenditure)
- Out-of-pocket expenditure on health (percent of private expenditure on health)
- Ease of reimbursement ranking (PwC survey)
- Number of home healthcare companies
- Medical technology intensity: availability
- Medical technology intensity: labor versus technology
- Medical technology intensity: investment

Needs and infrastructure dimension

- Life expectancy at birth
- Age-standardized mortality rates by cardiovascular diseases
- Age-standardized mortality rates by diabetes mellitus

- Age-standardized mortality rates by malignant neoplasms (cancers)
 - Age-standardized, disability-adjusted life years by musculoskeletal diseases
 - Age-standardized, disability-adjusted life years by unintentional injuries
 - Infant mortality rate
 - Physicians per capita (weighted 16.7 percent in this dimension)
 - Hospital beds per capita (weighted 16.7 percent in this dimension)
 - Nurses per capita (weighted 16.7 percent in this dimension)
- (Last three measures collectively weighted 50 percent in this dimension)

Pillar 5: Supportive investment community dimensions and measures

Investment environment dimension

- Venture capital investment (as percent of GDP)
- Venture capital private equity country attractiveness index
- Private foreign direct investment (as percent of GDP)
- Royalty and license fee receipts (as percent of GDP)

- University-industry collaboration in R&D (WEF survey)
- Firm-level technology absorption (WEF survey)
- Early-stage entrepreneurial activity
- New business density

Medical technology commercialization dimension

- Medical device exports (weighted 50 percent in this dimension)
- Number of medical device companies
- Number of medical device employees (PwC survey)
- Number of medical device facilities (PwC survey)
- Number of new product categories launched after reimbursement and regulatory approval (PwC survey)
- Ease of medical technology ability and willingness to pay (PwC survey)
- Overall risk-adjusted commercial opportunity (PwC survey)
- Market technology commercialization: market access (PwC survey)

Compare scores

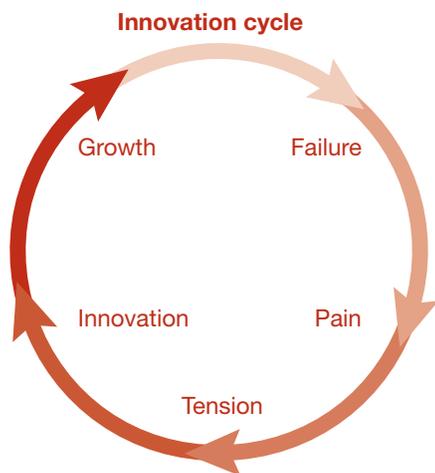
To compare country scores, visit pwc.com/InnovationScorecard. The interactive charts on this website will allow you to compare countries' scores for specific measures.

Historical scores	Brazil	China	France	Germany	India	Israel	Japan	United Kingdom	United States
Overall score	2.3	2.9	5.0	5.6	2.3	4.7	5.1	5.5	7.4
Powerful financial incentives	2.0	4.2	3.9	4.2	3.1	4.1	3.6	5.2	7.1
Leading resources for innovation	1.5	2.2	4.6	5.0	2.0	5.2	6.4	5.4	7.2
Supportive regulatory system	2.8	2.1	6.0	6.3	3.2	5.2	4.3	6.0	7.2
Demanding and price-insensitive patients	3.1	2.6	6.8	6.9	1.6	5.1	6.2	5.6	7.3
Supportive investment community	2.2	3.1	3.6	5.6	1.8	3.7	5.2	5.3	8.2
Market incentives	2.7	6.5	4.2	4.7	4.9	5.6	3.3	7.1	5.3
Healthcare incentives	1.2	1.8	3.6	3.7	1.2	2.6	3.9	3.3	8.9
Innovative resources	1.8	1.8	4.6	5.3	1.0	5.8	6.2	6.9	7.5
Innovative output	1.1	2.7	4.5	4.8	3.0	4.5	6.6	4.0	6.9
Regulatory approval process	3.5	1.0	4.6	4.6	3.1	5.1	2.5	3.5	6.4
Legal environment and impact on business	2.0	3.3	7.5	8.0	3.3	5.3	6.1	8.6	8.0
Demand for healthcare	3.3	2.0	6.7	6.7	1.1	3.7	4.9	4.6	8.9
Needs and infrastructure	2.9	3.2	6.8	7.1	2.1	6.5	7.5	6.6	5.8
Investment environment	3.3	3.3	3.7	5.9	2.5	5.8	5.1	6.7	7.5
Medical technology commercialization	1.1	2.9	3.5	5.4	1.1	1.7	5.3	3.9	9.0

Current scores	Brazil	China	France	Germany	India	Israel	Japan	United Kingdom	United States
Overall score	2.7	3.4	5.0	5.4	2.7	4.6	4.8	5.4	7.1
Powerful financial incentives	2.1	4.2	4.2	4.3	3.0	4.1	3.0	4.7	7.2
Leading resources for innovation	2.4	2.8	4.5	5.4	2.2	4.6	6.0	5.4	7.3
Supportive regulatory system	3.5	4.9	6.6	7.2	4.5	5.5	5.8	6.8	6.8
Demanding and price-insensitive patients	3.1	2.4	6.0	5.8	1.8	5.1	5.7	5.6	7.1
Supportive investment community	2.4	2.9	3.7	4.4	2.2	3.8	3.6	4.5	7.2
Market incentives	2.8	6.8	5.2	5.1	5.0	6.0	3.1	6.5	5.5
Healthcare incentives	1.4	1.6	3.2	3.4	1.0	2.3	2.9	2.9	9.0
Innovative resources	3.2	2.0	5.6	6.0	1.8	5.0	6.2	6.3	6.8
Innovative output	1.7	3.5	3.5	4.9	2.5	4.1	5.9	4.4	7.7
Regulatory approval process	5.3	5.7	6.5	6.5	5.8	6.2	3.7	6.0	5.3
Legal environment and impact on business	1.8	4.0	6.8	7.9	3.2	4.7	7.9	7.5	8.3
Demand for healthcare	3.2	1.6	5.1	4.7	1.4	3.6	3.7	4.7	8.3
Needs and infrastructure	3.1	3.2	7.0	6.9	2.2	6.5	7.7	6.5	5.9
Investment environment	2.9	3.2	3.9	3.5	2.9	5.6	4.0	5.4	5.8
Medical technology commercialization	1.9	2.7	3.4	5.3	1.4	2.0	3.2	3.7	8.5

Innovation cycle

Innovation emerges from the process the Austrian economist Joseph Schumpeter called “creative destruction,” which PwC represents as the “innovation cycle” that progresses as follows: failure ▶ pain ▶ tension ▶ innovation ▶ growth. In this cycle, tension represents the energy source that drives the innovation process. Without tension in a system, you can’t have innovation. The most successful innovators are those individuals and organizations that most effectively transform tensions to harness their energy and drive innovation and growth.



How to measure the value of an innovation

PwC has devised a value-creation matrix to measure the degree of innovation, as shown in the illustration below.

New value creation matrix

	Remove	Reduce	Retain	Reform	Replace
Quality					
Quantity					
Location					
Time					
Price					

New value proposition

Cost					
Convenience					
Confidence					
Compensation					

In what way does the idea affect:

- The quality of the product or service?
- The quantity of resources needed to create that product or perform that service, or the number of products or service providers needed to supply that offering?
- Where the product or service is offered?
- The time to reach the desired outcome? For example, does the idea remove the constraint of available clinic hours, or reduce time to diagnosis, or reduce the duration of patient hospitalizations?
- The price of the product or service?

Will the implementation of the idea:

- Reduce cost for the patient or healthcare provider?
- Increase convenience for the patient and the clinician or doctor?
- Increase the confidence of the doctor, clinician, and patient in the accuracy, efficacy, or durability of a product or service?
- Increase compensation for the provider, doctor, or clinician?

About PwC's Pharmaceuticals, Medical Device and Life Sciences Industry Group

PwC's Pharmaceuticals, Medical Device and Life Sciences Industry Group (www.pwc.com/us/pharma and www.pwc.com/us/medtech) is dedicated to delivering effective solutions to the complex strategic, operational and financial challenges facing pharmaceutical, biotechnology and medical device companies. We provide industry-focused assurance, tax and advisory services to build public trust and enhance value for our clients and their stakeholders. More than 163,000 people in 151 countries across our network share their thinking, experience and solutions to develop fresh perspectives and practical advice.

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