



The Future of Pharma: A U.S. Sector Review

Executive Summary

Two powerful megatrends – dramatic deceleration in U.S. market growth and significant restructuring of the healthcare system – are at play in the U.S. pharmaceuticals industry. On the one hand, market growth in “developed” markets (mostly the U.S., Western Europe and Japan) are significantly lagging the “pharmerging” markets (mostly China, India, Brazil and Russia), exerting enormous margin pressure on global pharma companies. On the other hand, the U.S. healthcare market is fundamentally restructuring how healthcare is cost-effectively developed, delivered and reimbursed to improve the overall health of the population.

For an industry whose business has sustained decades of respectable growth and margins, the new environment is testing the resilience and ingenuity of pharma companies across the sector. Some business models lack the adaptability to survive the imminent end of the “blockbuster drug” era, even while resource constraints and sluggish innovation hinder the development of new capabilities needed to thrive in a rapidly evolving market. These are indeed disruptive times for the U.S. pharma industry.

Succeeding in a shifting global market and evolving healthcare landscape will require pharmaceutical companies to adopt innovative business models focused on novel strategies, including:

- **Emphasis on “economic” outcomes:** More attention to the “economic value” of a therapy as a determinant for research funding and commercialization.
- **Personalized medicine:** Shifting from “blockbuster drugs” to “personalized health and wellness.”
- **Externalization and collaboration:** More reliance on external partners, academia, industry consortia and entrepreneurs for innovation, productivity and global expansion.
- **Globalization:** Rapid expansion to pharmerging countries for scientific talent and new markets.
- **Health IT adoption:** Investing in new technologies to enable innovation and drive efficiencies.

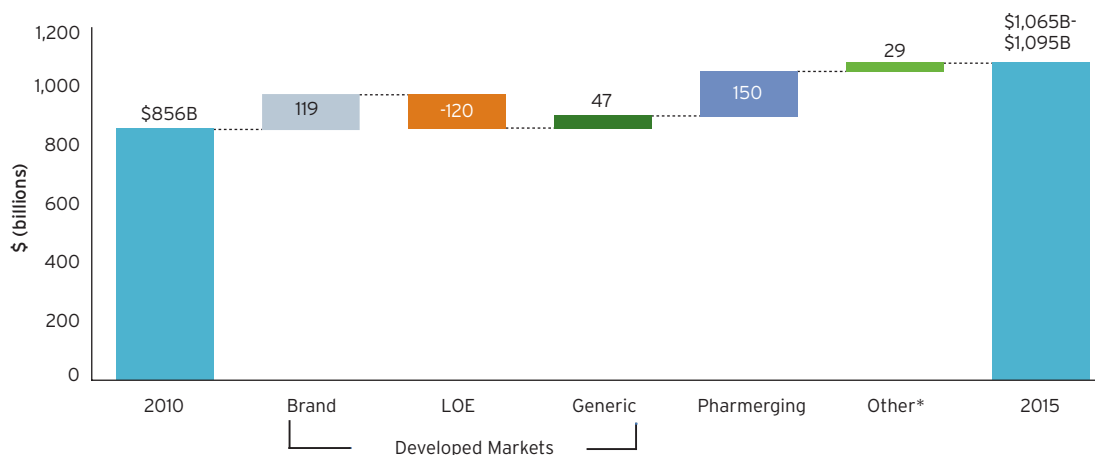
The future of U.S. pharma will depend on whether companies can overcome structural shifts and adopt operating models aligned to new business priorities. For example, some companies are implementing strategies that respond to structural shifts by diversifying products and services to address global demand, and others are rethinking their operating models by leveraging externalization as a means to boost R&D productivity. Regardless of whether one follows a single or multi-pronged approach, it is imperative for U.S. pharma companies to develop strategies in response to these megatrends and take steps to sustain their next phase of growth and competitiveness in the global market.

U.S. Market Landscape

According to a report by IMS Institute for Healthcare Informatics, the global pharmaceutical market is expected to reach \$1.1 trillion by 2015.¹ In absolute terms, this number presents a rosy outlook for the U.S. pharma industry; however, the anticipated growth is mostly driven by spend in pharmerging countries and on generics (see Figure 1).

Today, the U.S. pharmaceutical industry is facing a challenging business environment and slowing growth. This is in stark contrast to the double digit growth rates it experienced in the first half of the decade (see Figure 2). Further, over the next five years the U.S. market is expected to grow only 0% to 3%. Despite the stagnant growth, the U.S. segment will continue to be the single largest market, reaching between \$320 billion and \$350 billion in 2015.²

Components of Change in Total Spending

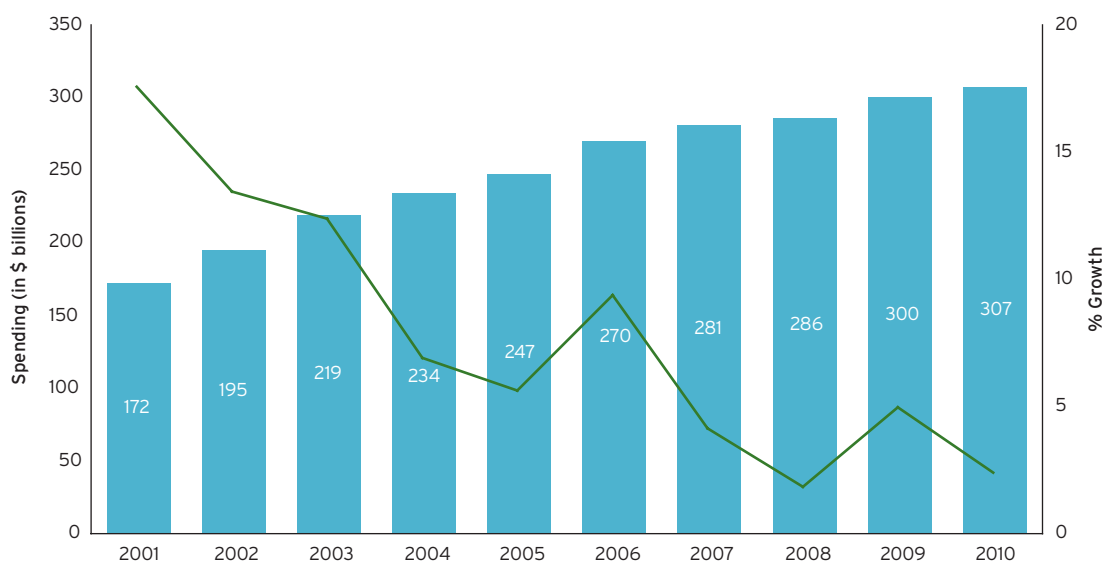


Source: IMS Market Prognosis, April 2011

*Includes "rest of world" +\$27B, other developed market growth +\$17B, exchange rate change -\$15B.

Figure 1

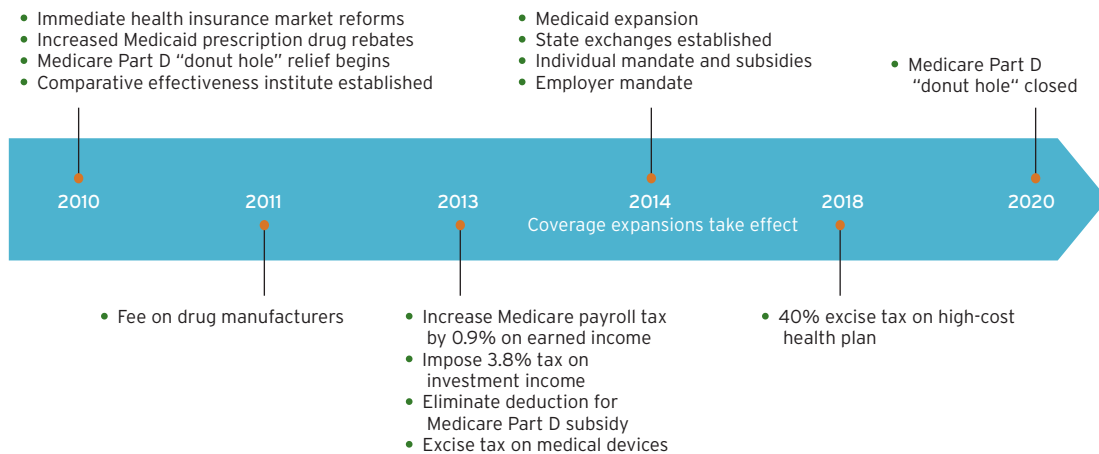
Spending Growth 2001 - 2010



Source: IMS Health, National Sales Perspectives, December 2010

Figure 2

PPACA Highlights



Source: Ernst & Young LLP

Figure 3

With its position of prominence, winning in the U.S. healthcare market is a priority for global pharma companies. Consequently, the changes to the U.S. healthcare system, triggered by the passing of the Patient Protection and Affordable Care Act (PPACA), are a top priority for the pharma industry. While major portions of the legislation do not take effect until 2014 (see Figure 3),³ the bill has put in motion several important changes that the industry has already begun to address, such as coping with imminent price reductions, greater transparency, comparative effectiveness and health IT.

Collectively, a bleak outlook for U.S. market growth and an inevitable restructuring of the healthcare system are two megatrends that will influence the U.S. pharma industry.

Forces Shaping the Pharma Industry

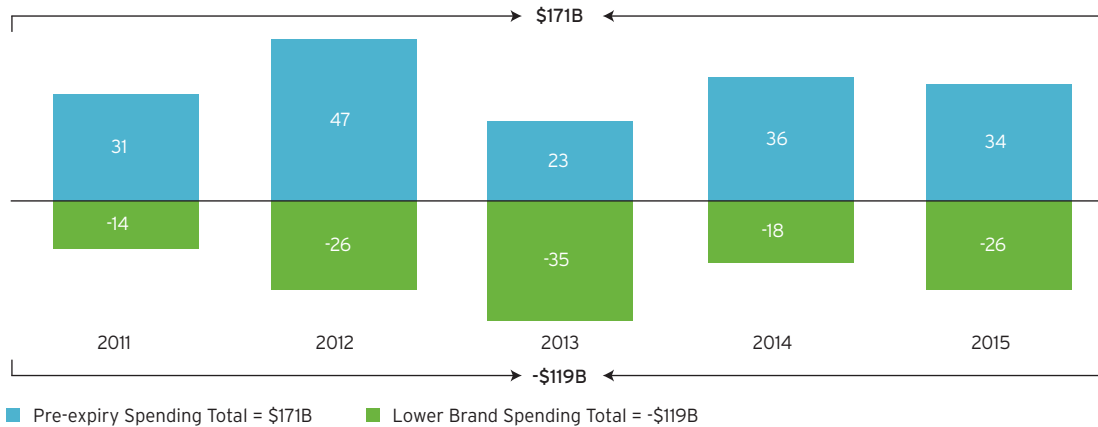
Underlying the megatrends are fundamental forces shaping the future of the pharmaceutical industry. A slowdown in U.S. pharma spend was expected, but the combined forces of a looming patent cliff, a rapid switch to generics and

a prolonged economic malaise have precipitated a much steeper decline. Also, the 2010 PPACA bill gave impetus to a much-needed restructuring of the healthcare system, setting priorities for a favorable regulatory environment, a focus on patient-centric healthcare and the use of IT to enable cost-effective and quality healthcare.

The Looming Patent Cliff

The impact of loss of exclusivity (LOE) on developed markets is assessed at \$120 billion over the next five years, with a single-year plunge of \$35 billion in 2013 (i.e., the "patent cliff"). This "loss" is barely offset by protected brands and new launches during the same period (see Figure 4, next page). The era of blockbuster drugs has ended; current drug pipelines lack the potential to generate the sizeable revenue and margins that the industry once enjoyed. Despite being among the top industries in R&D investments, the number of new drugs brought to market continues to fall (see sidebar, next page). Further, institutions and patients alike have rapidly switched to the use of generics to contain the cost of healthcare.

Developed Markets Patent Expiries



Source: IMS Institute for Healthcare Informatics; MIDAS, December 2010

Notes: Pre-expiry spending is the projected sales in the year prior to expiry. Lower brand spending reflects the expected impact in that year on drug spending of patent expiries (including continuing impact from expiries in prior years).

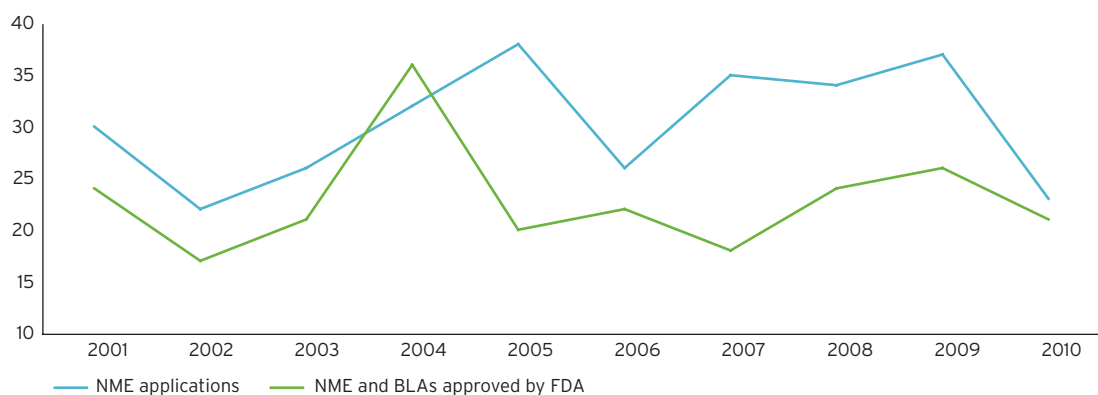
Figure 4

Declining R&D Productivity

R&D productivity, key to the growth and success of the industry, has declined dramatically in the last few years. The cost of developing and bringing a molecule to market is now estimated at \$1.3 billion. However, company revenues are not growing fast enough to sustain such spending levels. The FDA numbers on new drug applications and approvals illustrate the decline in R&D productivity.

The 23 new molecular entity applications filed in 2010 with the Center for Drug Evaluation and Research is the lowest number recorded in the last 10 years, if the year 2002 is excluded, when only 22 were submitted (see Figure 5). R&D spend has also risen considerably, from \$47.6 billion in 2005 to \$67.4 billion in 2010, while drug approvals stagnated, with only 22 approved on average in the last five years (see Figure 6, next page). This doesn't bode well for an industry that spent close to one-fifth of its revenues⁴ on R&D in 2010. Many companies relied on mergers and acquisitions to work themselves out of the R&D crisis. Although this approach built scale and broadened the product portfolios of many companies, it hasn't really improved their ability to innovate.

Drug Applications Filed with FDA

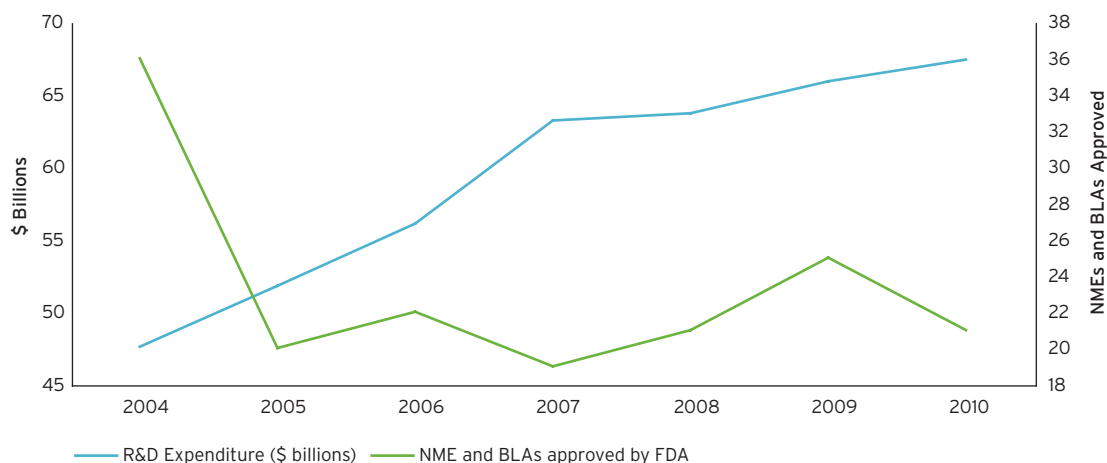


Source: "New Molecular Entity Approvals for 2010," FDA.

* 2004 - 2010 represents applications for new molecular entities (NMEs) filed under new drug applications (NDAs) and therapeutic biologics filed under original biologics license applications (BLAs).
2001 - 2003 represents NMEs but not therapeutic biologics.

Figure 5

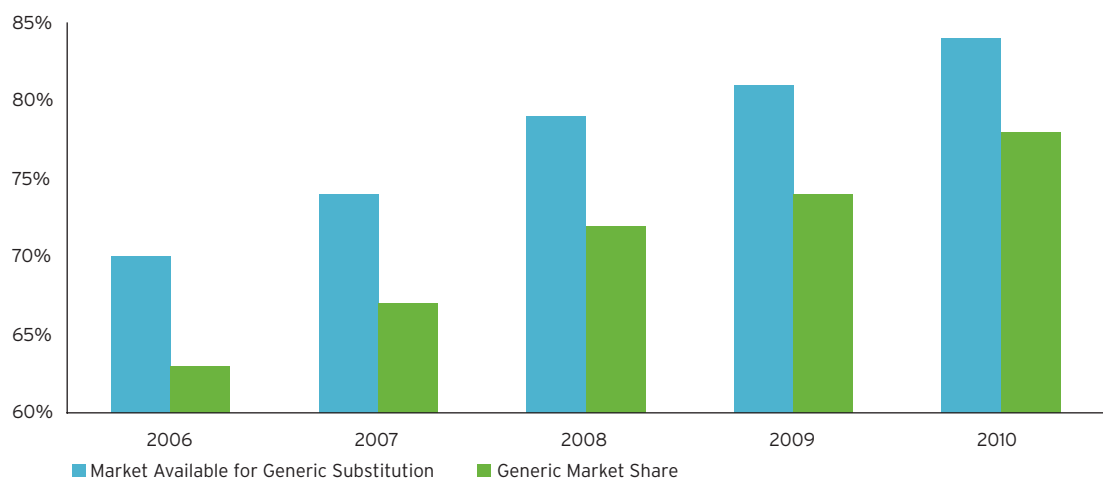
U.S. Pharma R&D Productivity



Source: PhRMA and Nature Reviews Drug Discovery

Figure 6

Growth in Generics Market Share



Source: IMS Health, National Prescription Audit, December 2010

Figure 7

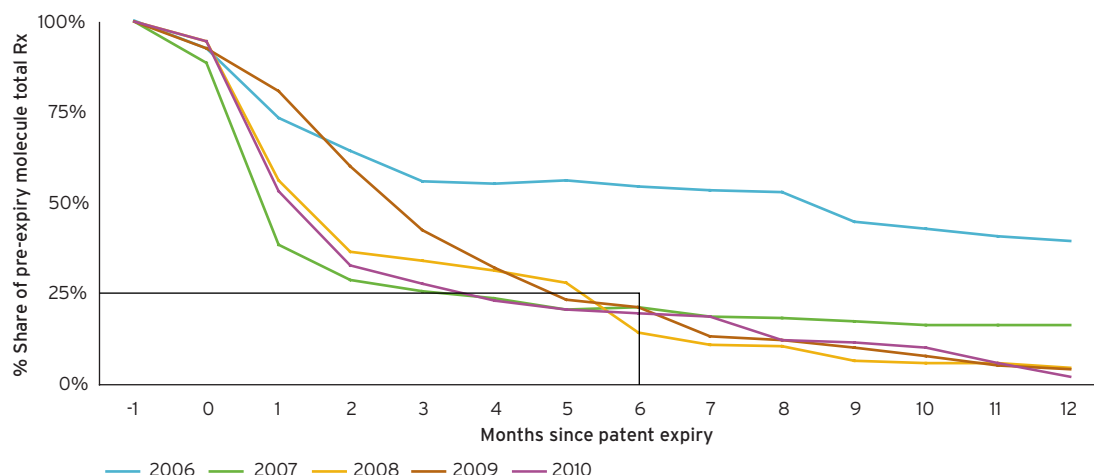
Preference for Generics

A growing trend that is hurting established players is the introduction of newer generics to substitute for blockbuster drugs that are losing patent protection. Moreover, an increased drive by payers to switch to lower-cost generics, when available, has created a surge in demand for these products. The generics market in the U.S., according to a market report by RNCOS,⁵ is set to grow at 10% CAGR from 2010 to 2013 and reach \$108.5 billion over that timeframe. Already, generics constituted 78% of all dispensed prescriptions in the U.S. in 2010 (see Figure 7).

And it now takes only six months to replace over 80% of the prescription volume of a drug that loses its patent (see Figure 8, next page).

While the market's shift to generics puts pressure on margins and revenue in developed markets, it is also an opportunity for future growth in pharmaceuticals in emerging nations. To capitalize on this growth, many top U.S. pharmaceuticals companies have entered into alliances or acquired big generic players in developed and emerging markets (see Figure 9, next page).

Brand Prescription Share of Molecule Post-Expiry



Source: IMS Health, National Prescription Audit, February 2011

Figure 8

Historical Generic Drugmaker Acquisitions Over \$1 Billion

Year	Acquisition Target	Acquirer	Purchase Price (\$ billions)
2010	Ratiopharm	Teva	5.0
2009	Arrow Group	Watson	1.0
2009	EBEWE Pharma	Sandoz	1.3
2008	Barr	Teva	7.5
2007	Merck KGaA	Mylan	6.7
2007	Mayne	Hospira	2.1
2006	Ivax	Teva	7.4
2006	Andrix	Watson	1.9
2005	Hexal	Sandoz	5.3
2005	Eon Labs	Sandoz	2.6
2004	Sicor	Teva	3.4

Source: Morningstar

Figure 9

Economic Slowdown

Starting in 2008, the current period has been termed the worst economic climate in the U.S. since the Great Depression. Economic performance in 2009 was especially dismal, with peak unemployment reaching 10.1%, the Consumer Confidence Index dipping to 25.3 in February and GDP contracting 5% in October.⁶

With the deteriorating economic situation in the U.S., more patients have entered the rolls of the uninsured, requiring many to make trade-offs on their healthcare costs, including noncompliance with medication regimens, deferment of care and greater reliance on government subsidized care. The IMS Institute for Health Informatics reports

that patient office visits declined by 4.2% in 2010, and the number of patients initiated into new therapy for chronic health conditions decreased by 3.4 million.⁷ The report also observed a shift toward Medicaid and Medicare Part D, with increases of 13.7% and 6.4%, respectively.

Rethinking the Regulatory Framework

The Pharmaceutical Research and Manufacturers of America (PhRMA) reports that it takes between 10 and 15 years – and costs \$1.3 billion – to bring a drug to market. Also, the FDA has noted that the number of new drug submissions has not kept pace with increasing R&D budgets (see Figure 6, previous page). The FDA has attributed this decline in R&D productivity to the fact that

“the medical product development process is no longer able to keep pace with basic scientific innovation.” The FDA’s recent “Strategic Plan for Regulatory Science”⁸ attempts to apply 21st century techniques and technology for modernizing the regulatory framework to speed innovation and improve public health.

Among the eight priority areas identified by the FDA, two relate to the pre-clinical and clinical development of medicines (“Modernize Toxicology to Enhance Product Safety” and “Stimulate

Innovation in Clinical Evaluations & Personalized Medicine to Improve Product Development and Patient Outcomes”), and one relates to the novel use of information technology (“Harness Diverse Data Through Information Sciences to Improve Health Outcomes”). In an industry that is heavily regulated, any change might be viewed with skepticism, but with a vision of modernization and an implementation path involving public-private partnership, the FDA’s plan is a much needed step in the right direction.

Legislative Reform

U.S. healthcare reform is centered on the core issues of access, affordability and quality healthcare. Providing health insurance for the currently uninsured, improving the quality of care delivered and lowering costs of existing activities will impact pharmaceutical companies, directly and indirectly.

An increasing focus on drug safety, constraints on marketing and continuing healthcare regulations govern every aspect of the drug value chain, from bringing a product to market, to its eventual use in patient care. In addition, U.S. healthcare reform may fundamentally impact how a product reaches a patient, at what price and who pays for it. Provisions in the reform require pharmaceutical companies to offer discounts on branded prescription drugs for Medicare Part D participants, shrinking the margins on such drugs. It will also significantly add to the number of patients covered under insurance.

Governments in developed and emerging markets – sensitive to price largely due to the absence of widespread healthcare insurance and out-of-pocket payments made by uninsured consumers – are enacting healthcare regulations and reforms to reduce spiraling healthcare costs. Pharmaceutical companies need to understand the tradeoffs they must make to factor in necessary price cuts with ways to improve profitability.

Patient-Centric Healthcare

Traditionally, healthcare has mainly been developed for and delivered to large populations of people with therapies that apply to a shared human physiology. However, over the past decade, scientific and technology advances have opened up the possibility of developing diagnostics and therapies targeted at specific individual traits (a genetic or risk profile, for example) – in other words, personalized for the patient. A patient-centric approach to healthcare goes beyond developing personalized therapies but includes the complete involvement of the patient and caregivers in the detection, prevention, treatment and management of the medical condition.

This approach necessitates the open and collaborative sharing of medical information, which can be enabled through effective use of information technology, for example, through electronic medical

records or social media (e.g., PatientsLikeMe). The information gleaned from this data has the potential to vastly improve development of new drugs and identification of adverse events.⁹

Health IT

Health information technology (HIT) makes it possible for healthcare providers to better manage patient care through secure use and sharing of health information.¹⁰ Collectively, these technologies – including the use of electronic health/medical records (EHR/EMR), telehealth devices, remote monitoring technologies and mobile health applications – have the potential to improve quality of care, reduce costs and empower consumers.

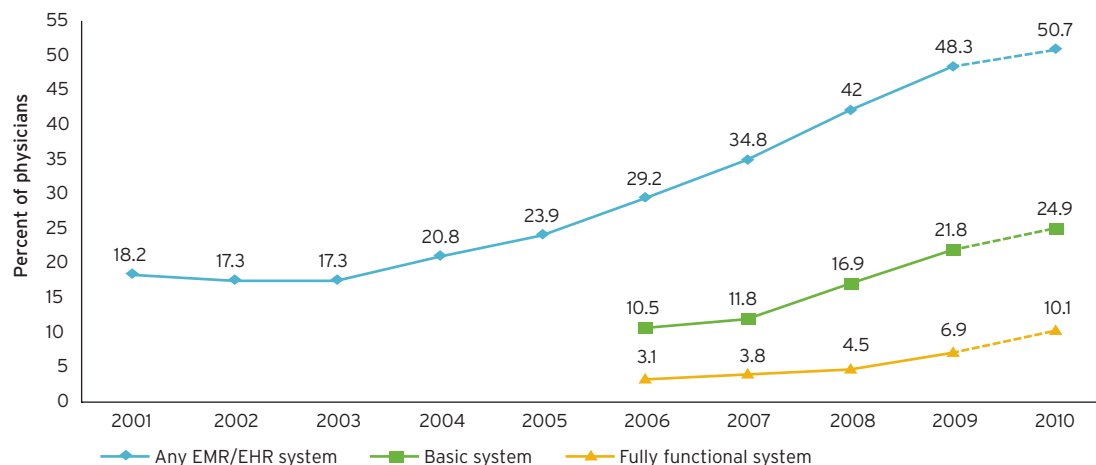
As part of the federal strategic plan for HIT, the first goal is to achieve adoption and information exchange through meaningful use of health IT.

The widespread adoption and meaningful use of EMR is the cornerstone of a successful HIT strategy, and one that will make all the subsequent benefits achievable. Despite a slow start, EMR

adoption rates (see Figure 10) have improved over the past year, paving the way for more widespread use of health IT.

Percentage of Office-Based Physicians with EMR/EHR

U.S., 2001 - 2009 and preliminary 2010



Source: CDC/NCHS, National Ambulatory Medical Care Survey, 2001 - 2010

Note: 2010 data is based on preliminary estimates.

Figure 10

Future of U.S. Pharma

The inevitable transformation across all segments of the U.S. healthcare industry will recast the pharma industry landscape. To survive and grow, companies need to overcome structural shifts and adopt alternate operating models that emphasize new business priorities.

The issues confronting the industry are significant; however, the winning companies are already taking steps to overcome the challenges and capture new opportunities. Some of the new priorities for the leaders in the industry are:

- **Emphasis on "economic" outcomes:** Increasingly, payers prefer and demand therapies that improve overall patient outcomes (represented by clinical, economic and health outcomes). The economic outcome signifies the cost/benefit trade-off of a novel therapy, taking into consideration the total cost of treatment and subsequent disease management. Comparative effectiveness supported by credible evidence is now a key factor in most pricing and reimbursement levels set by government and private payers. Pharma companies should develop the capabilities to conduct health economics studies and outcome research and incorporate comparative effectiveness as an important gating factor in their com-

mercialization process. Health economics and outcomes research teams have been blessed with additional resources year-on-year. In fact, 67% of pharmaceutical and device companies report continually increasing budgets; only 7% anticipate fewer resources in coming years.¹¹ But growing resources means growing responsibilities and challenges.

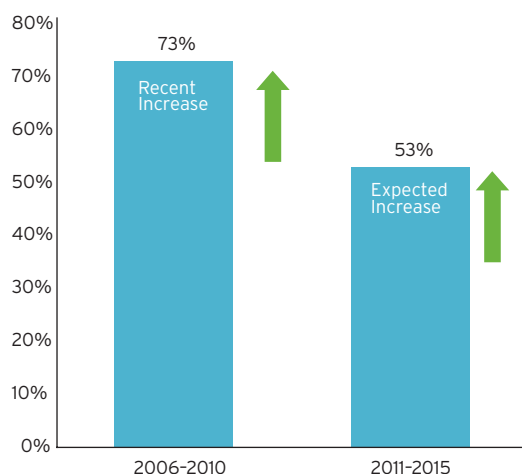
- **Personalized medicine:** This has the potential to revolutionize the way therapies are discovered, developed and delivered. The approach is no longer confined to research laboratories in academia but is now a mainstay in many companies in the industry. Roughly 94% of companies increased their investments in personalized medicine by 75% in the last five years and plan to increase it by another 53% in the coming five years, according to a survey by Tufts Center for Drug Development (see Figure 11, next page). Also, personalized medicines make up 12% to 50% of current clinical pipelines, according to the report. Already, a few notable examples, such as Gleevec®/Novartis and Herceptin®/Roche-Genentech, have shown great success.
- **Externalization and collaboration:** Large pharma's significant assets in research and sales force have been the industry's answer to growth in the past decade; however, the end of

the blockbuster era requires companies to refocus their attention on core capabilities required for future growth. Refocusing on the core helps companies operate from a position of strength and seek external partners and collaborators for complementary strengths, making a whole that's greater than the sum of the parts. Whether the partnership is with academia, startups, consortia for new scientific discoveries or with functional service providers for cost-efficient, scalable and global operations, pharma companies view externalization as an integral part of their growth strategy.

- **Globalization:** Growth in developed markets is on the decline, while pharmerging markets are promising solid growth. These markets are expected to grow at 15% to 17% in 2011. Over the next five years, spending on medicines in these markets is projected to reach \$285 billion to \$315 billion, double the \$151 billion spent in 2010. According to IMS, they are also expected to contribute 46% of the global market growth from 2009 through 2014, up from 30% in 2005 to 2009 (see Figure 12).

A significant portion of the pharmerging markets are from generics sales, which poses a particular challenge for U.S. pharma companies that have typically focused on branded drugs for their revenue. As companies look to expand their reach to global markets, we expect to see more M&A activity as a means to acquire local capabilities and diversification.

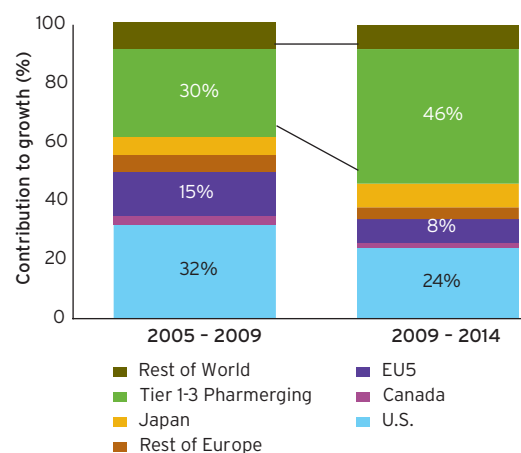
Increase in Personalized Medicine Research Investment



Source: Tufts Center for the Study of Drug Development, November/December 2010

Figure 11

Contribution to Global Growth



Source: IMS Health Market Prognosis, March 2010

Tier 1 = China

Tier 2 = Brazil, Russia, India

Tier 3 = Venezuela, Poland, Argentina, Turkey, Mexico, Vietnam, South Africa, Thailand, Indonesia, Romania, Egypt, Pakistan, Ukraine

Figure 12

- **Health IT adoption:** With the goals of improving quality, affordability and innovation in healthcare, the federal government has allotted up to \$20 billion to fund the infrastructure and programs for health IT. The implementation of EMR/EHR among patients and providers aims to improve coordination of care and clinical decision-making, reduce medical errors and increase the sharing of patient outcomes.

Also, the secondary use of EMR/EHR data has the potential to augment and improve clinical development, reduce adverse events and develop credible evidence for comparative effectiveness. For instance, the Partnership to Advance Clinical Electronic Research consortium (PACeR) is investigating ways to utilize EMR data to improve patient selection, protocol design and modeling. Other technologies such as mobile and cloud platforms are transforming business processes to achieve cost savings and better outcomes.¹²

The Road Ahead

With sales nearing \$300 billion in a sector known for innovation and exports, the pharma industry is a major contributor to the U.S. economy. Even as the industry faces tremendous challenges, the leading companies will overcome today's issues and emerge with their sights set on new opportunities. The progress achieved so far, points to a shared optimism for the industry.

Footnotes

- ¹ "The Global Use of Medicines: Outlook Through 2015," IMS Institute for Healthcare Informatics, May 2011.
- ² Ibid.
- ³ "Healthcare Reform: Five Challenges Life Sciences Companies Must Face and Address," Ernst & Young, May 2010.
- ⁴ "2011 Profile: U.S. Pharmaceutical Industry," PhRMA, 2011.
- ⁵ "Booming U.S. Generic Drug Market," RNCOS Industry Research Solutions, 2011.
- ⁶ U.S. National Statistical Data, TradingEconomics.com.
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- ⁸ Advancing Regulatory Science Initiative, U.S. Food & Drug Administration, February 2010.
- ⁹ Christian Torres, "Pharma Sets its Sights on Secondary Data Use," Nature Medicine, Vol 16, Page 251, 2010.
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- ¹² "A New Wellness-Centric Ecosystem," PharmaVoice, January 2011.

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