Pharma Futures

# Pharma's New Productivity Challenge:

## Cost and Choice in the US Market

## What is PharmaFutures?

*PharmaFutures* was created in 2003 as a dialogue between pharmaceutical executives, institutional investors and societal stakeholders to explore long-term value drivers for the pharmaceutical industry and its evolving social contract. The dialogues are based on the premise that the industry and its investors thrive when it is seen as socially useful and that if that perception falters, so does the business model. The fifth *PharmaFutures* dialogue began in November 2011 and focuses on one of the greatest challenges facing the pharmaceutical industry today: that of persuading purchasers of pharmaceutical products that these products offer value, not just to patients, but also to cash-strapped health systems seeking productivity gains and health improvements. This is a two year global dialogue focusing on three major markets: Europe, emerging markets and the US. It will conclude with the publication of a global report on its findings in June 2013.

*PharmaFutures* provides insights for pharmaceutical executives and investors from a wide range of stakeholders and experts whose views about the social utility of the industry help shape the industry's licence to operate. *PharmaFutures* is based on the assumption that while pharmaceutical development lies in the hands of publicly quoted companies, it is imperative that investors, companies and global health experts better understand one another's viewpoints, the constraints each faces, and their room for manoeuvre when seeking to reconcile unmet need for medicines with the commercial imperatives of a business.

## Methodology

The *PharmaFutures* dialogues are run by not-for-profit company, Meteos Ltd. The analysis produced by *PharmaFutures* is drawn from an extensive process of research, interviews, synthesis and dialogue among participants. It relies on the willingness of a wide-ranging group of experts to share their time and insights in semi-structured interviews, and of the members of the *PharmaFutures* Working Group to engage in open and frank discussions. We would like to thank all those who contributed to this process. A list of those interviewed appears in the Appendix. This report is written by Sophia Tickell, with invaluable contributions from Charis Gresser, Becky Buell, John Schaetzl, Constance Mackworth-Young and Cassie Painter.

### Disclaimer:

# Introduction

**This *PharmaFutures* report focuses on the US – the world's largest and most profitable market for the pharmaceutical industry. The country has historically been the most significant source of pharmaceutical growth, driven largely by price increases (nine-fold average real price rises since 1980) and expanding volumes.[1] Europe's growth is currently sluggish, Japan's moderate, and while the emerging markets offer great potential, there are also significant price and margin challenges. Consequently, in the near-to-medium term, at least, the fortunes of the industry will continue to be shaped by what happens in the US.**

The US market is changing. Gone is the "golden age" in which insurers accepted physicians' seemingly limitless appetite to prescribe new products, irrespective of cost. In its place is a new era in which the 18% of GDP spent on health in the US is under scrutiny as never before.[2] The country may remain content to pay a much higher percentage of its GDP on health than others in the OECD. Nevertheless, it is clear that growing anxiety over the sustainability of growing levels of spending is leading both public and private payers to seek to contain costs and to focus on proven clinical benefit in a way that is transforming the market. And they are being helped to do so by advances in technology that permit them to aggregate and interpret data in ways that have never before been possible.

Economics are one powerful driver of this change, particularly in light of the huge federal budget deficit. Another driver is the combination of demographic and epidemiological changes. As the population ages, increasing numbers of older Americans need and expect more healthcare, including ever more expensive health technologies. At the same time, America's growing burden of chronic disease and disappointing health outcomes relative to other OECD countries add to the pressure to change the status-quo.

How the changes will unfold is open to question. The US model of healthcare is highly fragmented as a result of its commitment to individual choice and market forces, and the legacy of World War Two wage controls which led to employer-sponsored health coverage. These characteristics led to the evolution of a decentralised and diversified system in which healthcare was first and foremost the responsibility of individuals and their employers. Only later did it become the responsibility of government to provide for elderly, disabled and poor people under Medicare and Medicaid.

Unlike the European model, which starts with a commitment to healthcare for all, and an acceptance that this brings with it in-built resource constraints, the US healthcare market reflects a belief that the best healthcare is achieved by allowing the interplay of multiple strong and competing interests. Hundreds of health plans and a mix of private and public sector payers – which vary from state to state – compete to offer multiple, tiered offerings, ranging from the very best of care to its total absence, except in direst emergencies. The resulting system has proved remarkably durable and, until now, resistant to change.

The government's health reform, the Patient Protection and Affordable Care Act (ACA) will test the resilience of the system as never before. On the one hand, it gives unprecedented influence to the government in healthcare, at federal and state levels, through insurance subsidies, new insurance

exchanges and expanded Medicaid eligibility. It also looks likely to change how other players in US healthcare operate as new incentives and costs alter the behaviours of large employers, healthcare providers, insurers and patients. On the other hand, however, the multi-actor US health system has historically proved remarkably resilient. And it is precisely because it is highly fragmented, crowded and complex that this is the case. Recent reforms do not change its basic characteristic as a free-market, consumer-led model in which fragmentation is a defining feature. What the reforms do change is the balance of power between the system's major protagonists.

The implications of these changes for the pharma industry specifically are not yet entirely clear. Industry optimists argue that changes to the system, including the use of new effectiveness metrics, will allow pharma companies to demonstrate how, when used appropriately, innovative medicines can offer payers significant tertiary care savings. A more pessimistic view argues that the introduction of cost containment measures will focus attention on the readily identifiable upfront costs of medicines (especially higher-priced new ones), and that pharma will struggle to persuade the system that it is offering sufficient value in the new environment.

It is likely that two critical factors will overshadow others in determining the impact of health reform on pharma. The first is how the increasingly sophisticated use of data in defining value will play out, and whether the industry will be able to be an active participant in this process. New data management capabilities are allowing providers and payers to link inputs to health outcomes and to use this analysis to guide reimbursement. If pharma is not at the table, new definitions of value will be made in its absence. The second is how – and indeed whether – the industry chooses to address the thorny issue of pricing. Difficult choices need to be made in the face of increasingly cost-conscious patients, payers and providers, facing mounting economic constraints. The choices the industry makes will, in turn, influence the future for innovation, since investment in the next generation of R&D is dependent on the industry's confidence in a long-term sustainable market for its products. And the challenge is made harder by the fact that the changes will take place over years of trial and error, requiring difficult judgement calls on strategy and tactics along the way.

Investors will play an influential role in determining pharma's next steps, as they anticipate – and in the process to some extent pre-determine – the winners and losers. The financial markets are today more upbeat about pharma than they have been for some time. The industry's recent track record on R&D is likely to have contributed to this. Last year, some big pharma stocks outperformed the S&P 500 index – which itself rose over 10%.[3] There are a number of reasons for this return to favour. Pharma still produces a high dividend yield (between 3% - 4%) relative to the market; the industry appears to be addressing some investor concerns on costs and overcapacity and, finally, the short-term impact of the ACA is viewed by many as expanding the market for drugs because of wider insurance coverage. To this list of potential value drivers investors are adding an assessment of increasingly differentiated company strategies on pricing and reimbursement.

# US Healthcare Market Fundamentals

**The US health system is changing, with implications for all its protagonists: government at the federal and state level; providers; insurers; hospitals; doctors; pharma and device companies; and patients. The biggest impulse behind this change is the need to expand access to healthcare, with the ACA as the expression of this. But change in the system is also being driven by the need to urgently address America's spiralling healthcare costs as well as to improve on its relatively poor health outcomes.**

## Economic Pressures

At 18% of GDP and rising faster than economic growth, health costs are making a significant contribution to the US deficit, which for 2012 stood at an eye-watering $1.1 trillion.[4] Inevitably, much of the debate has focused on those areas of healthcare that are publicly financed. Federal health spending is forecast to grow from 5.6% of GDP in 2011 to over 9% by 2035[5] and, despite recent signals that growth in health costs is slowing, many worry about the long-term sustainability of parts of these programmes (see Fig. 1).[6]

Escalating health costs are not just a government problem. They also place a heavy burden on US employers who provide the lion's share of private health insurance. For some time, economists have speculated about the impact this may have on US competitiveness in terms of jobs and economic output.[7] Investor Warren Buffett has likened the US health system to a tapeworm inside the economy that drags down its global competitiveness.[8]

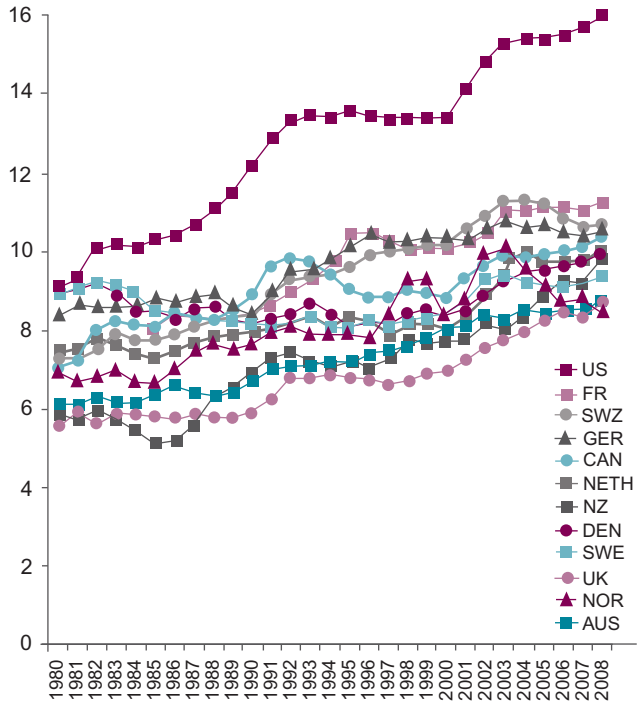
Health costs also exact a high personal toll on the millions of uninsured or under-insured Americans; over 60% of bankruptcies in 2007 stemmed from medical debt[9] and a full three-quarters of people who go bankrupt because of unpaid bills have insurance.[10]

## Drivers of Cost

Health costs in the US are driven by a number of complex factors and many theories have tried to

Figure 1:

**International comparison of total expenditures on Health as a percentage of GDP, 1980-2008**




Source: OECD Health Data. 2010. Cited in: Squires D. The US health system in perspective: a comparison of 12 industrialized nations. Issues in international health policy. The Commonwealth Fund. 2011.

explain why they keep rising and are so high relative to other countries. One key source of healthcare inflation is the fee-for-service[i] payment model, which generates demand for products and services that may not be needed.

In addition to the payment model the three key differentiators between health costs in the US and elsewhere appear to be: much higher expenditure on acute care and hospitalisation, particularly on high tech imaging; poor management of chronic diseases, which leads to episodes of expensive hospitalisation; and, finally, the high administrative costs of managing a fragmented system.[11]

### Cost Containment

The result has been a fierce drive to contain healthcare costs in both public and private sectors. The hard-won ACA was passed, in part, in recognition of the urgent need to curb the contribution health costs make to the fiscal deficit. To achieve this ACA introduces a number of measures designed to make the public system more efficient. These include the introduction of more Accountable Care Organisations (ACOs) whereby networks of healthcare providers are paid a lump sum for all the care that a patient receives rather than for each individual service. Through new agreements to share in any savings generated, they are incentivised to coordinate care, improve quality and reduce costs. Other cost containment measures include payment models such as capitation and bundled payments, designed to counter incentives to over-treat patients and to encourage scrutiny of the relative merits of treatment options.[ii] More specifically, a new and

## The Patient Protection and Affordable Care Act (ACA)

**In 2010, President Obama signed into law the US's landmark health reform act, the ACA, which will expand health insurance to over 30 million more people. The cost of expanding health coverage under the ACA is estimated to be around $938bn over ten years, which will be funded through a mix of savings to Medicare and Medicaid as well as new taxes and fees.**

The ACA, at the time of signing, included the following:

- **Individual health insurance requirement.** People on low incomes will receive subsidies to purchase private plans.
- **Inclusion.** Insurance plans must cover patients with pre-existing conditions; they cannot rescind coverage, nor set lifetime limits on health care benefits.
- **Medicaid expansion.** Broadened eligibility criteria for this publicly-funded programme for those on low incomes, potentially expanding Medicaid rolls by over 20m people.
- **Creation of Health Insurance Exchanges** at state level which offer a regulated minimum level of essential health benefits and a choice of plans.
- **Creation of the Independent Payment Advisory Board (IPAB)**, an advisory body to support cost containment in Medicare, the publicly-funded programme for the over 65s. IPAB recommendations cannot, however, involve changes to benefits or eligibility.
- **Accountable Care Organizations.** Incentives for providers of publicly-funded services to organise themselves into ACOs that will be eligible to share in cost savings, provided they meet certain quality targets.
- **Creation of the Patient-Centered Outcomes Research Institute (PCORI),** an independent body to evaluate and research comparative effectiveness. There are constraints on how PCORI findings are used in publicly-funded programmes, with specific limitations on the use of cost effectiveness analysis.
- **Changes to employer-sponsored health insurance**, introducing penalties for large businesses that don't offer coverage, new taxes (on high-cost plans), and tax credits for small businesses.

Adapted from Focus on Health Reform. Summary of New Health Reform Law. Henry J. Kaiser Family Foundation; 2010. Accessed at: http://www.kff.org/healthreform/8061.cfm

controversial Independent Payment Advisory Board (IPAB) is planned, designed to contain rising Medicare costs, without using direct price controls on medicines.

The ACA has resulted in some cost concerns shifting from federal to the state level. The Act's expansion of Medicaid, which could add over 20m people to its rolls by 2022[12], is a state-run programme; and it is at state level that the ACA's momentous consumer reforms – the setting up of insurance exchanges and the benefits packages they offer – will play out. The impact of the ACA on individual state budgets is unclear; incremental costs will be minimal compared to federal spending and there could even be small net budget gains.[13] However, states have already demonstrated their appetite for controlling healthcare costs in a number of ways – through limiting rises in insurance premium rates and, in some places, cutting reimbursement rates for Medicaid. Other moves include preferred drugs lists and managed Medicaid plans.

Despite these public sector moves, many believe that greatest innovation to contain costs will come from the private sector. The private sector has sought to contain rising healthcare costs, and the drugs bill in particular, for some time. Efforts have focused on the design of insurance plans to promote generics and preferred brands via the use of tiers in formularies, and to steer beneficiaries towards lower cost drugs through the use of step therapy[iii] and the requirement for prior authorisation. Negotiations over the place of drugs on formularies have involved complex pricing and rebate deals. With the introduction of the ACA, private insurers and providers have a new reference point for developments in quality measures and cost containment and new models in the payment and delivery of services that they may seek to emulate.

## Demographic and Epidemiological Pressures

A second driver of change in US healthcare is the fact that, with the exception of oncology, the US underperforms on many measures of health outcomes compared with international peers. Although at the top end of the scale US healthcare is second to none, life expectancy for the average American is lower than their counterparts in almost all other high-income countries.[14] Nearly half of all Americans have at least one chronic disease, which cause seven out of ten deaths in America.[15] The second driver of change in the US system is therefore the desire to improve health outcomes.

### Expansion of Health Coverage

Poor population health outcomes have partly been the result of millions of Americans lacking health insurance. The ACA seeks to address this through its federally mandated insurance coverage which will add over 30 million people to those who already have health insurance by 2019.[16] By 2014 each state is to have a Health Insurance Exchange – either set up by the state or run by the federal government. These will be marketplaces where individuals can purchase an essential health benefits package that provides a comprehensive set of services. Some of the recently insured will come from among the poorest of America's communities, meaning they may have complex and expensive health requirements. While the health reform has been designed to be paid for by a range of new taxes and savings, this rapid expansion in coverage is likely to add further impetus to the desire both to improve outcomes and contain costs within the public system.

### Improving Outcomes

A key part of the ACA reform is therefore the introduction of measures to assess and improve health outcomes. The ACOs are not only designed to encourage savings, but, by encouraging the move to integrated care, they are also intended to achieve better coordination of patient care and better health outcomes. They will be accompanied by the introduction and evaluation of specific new quality measures. Another ACA creation, the Patient-Centred Outcomes Research Institute (PCORI), seeks to produce independent research on comparative effectiveness.

i Fee for service, refers to payment for each service a patient receives.

ii Capitation payments are lump sum payments to cover any care a patient might need. A bundled payment – someway between fee for service and capitation payments – refers to payments linked to an episode of care (range of treatment for a particular health episode).

iii Step therapy is an approach set out in a patient's health plan: it works by putting patients on a first-step drug treatment for their condition (often a generic) and only moving to a second-step therapy (which may be more expensive) if medically required.

The private sector has also ramped up its ability to hold healthcare providers to account for improved performance and outcomes. Payers, ranging from health plans to employers, are using key assets, such as vast amounts of claims data, to innovate with new models of primary care.[17] They are also experimenting with value-based insurance design, which uses cost-sharing to steer patients towards more efficient and high-value health services. Providers, in turn, are carrying this agenda through their own organisations by influencing the prescribing behaviours of physicians in their networks.

Pharma has been a partner in some of the newer outcomes-focused initiatives. Risk-sharing deals on certain drugs, for instance, have linked part of the payment for a drug to specific outcomes, such as blood sugar control in the case of diabetes or non-spinal fractures in the case of osteoporosis.[18]

Amid the welter of pilots and experiments, the system is undergoing a quiet revolution in which major players are obtaining and acting on a new understanding of population-based health outcomes.

## The Enabler of Change: Big Data

The scaling up of efforts to rationalise and streamline costs and to evaluate outcomes has been made possible by dramatic advances in technology. It is now possible to aggregate and analyse vast amounts of claims data, which provide an indication of drug utilisation. The ambition is to integrate this data with the relevant clinical data, which would provide insights into patient outcomes. If successful, these changes offer the prospect of revolutionising definitions of value by accelerating new approaches to comparative effectiveness. The task of integrating such complex sets of data is difficult and time-consuming, and remains an imperfect science, but is likely to evolve rapidly as more is invested in this area. A high profile example of this trend is the recent agreement between UnitedHealth and the Mayo Clinic, which, between them, will bring together millions of health insurance claims and clinical patient records for researchers to analyse.[19]

# Hallmarks of Change

**The core value proposition of the global pharma industry continues to be the development of innovative medicines that offer improvements on existing therapies or breakthrough treatments. After a long drought in R&D productivity, there are signs of a turnaround for pharma. Last year the FDA approved over 30 new drugs, the highest level since 1996. Coming after a good year in 2011, the pick-up in approvals is prompting hopes of a sustained improvement over the last decade, when drug approvals were much lower.**

Although the majority of recent approvals were for specialty pharma, they ranged across many therapeutic categories, including the first new treatment for TB in 40 years, as well as an anticlotting drug. Other disease areas that have been in focus in the past couple of years include Hepatitis C, auto-immune and oncology. The therapeutic landscape is also changing with growing interest in using combinations of drugs, use of diagnostics and a shift from injectable to oral specialist drugs. How any successful medicine will fare in the changing US healthcare market will, however, be determined by the evolution of the following hallmarks of health reform and related reimbursement trends.

## Expansion of Drug Market

The ACA is almost certain to increase the volume of pharmaceutical sales, as a result of expanded coverage. The market is likely to expand further if ACOs succeed in offering more integrated treatment of chronic diseases in a primary care setting, and focus on greater adherence to avoid expensive hospital admissions and re-admissions. The focus on primary care also provides an opportunity for medicines (anti-hypertensives, anti-diabetics and osteoporosis, for example) to be used to avoid the expense of poorly managed chronic conditions.

## Comparative Effectiveness Research

Comparative Effectiveness Research (CER) is likely to be strengthened and to become more widely used by private providers and payers. It is not clear, however, whether this makes things easier or more difficult for pharma. There are many interpretations and sources of CER – with companies, payers and research bodies all potentially coming up with their own versions. ACA also raises the profile of CER, via the creation of a new research body, PCORI, which will generate and review existing evidence on effectiveness. The long-term impact of PCORI on the market is unclear, as, at present, its findings cannot be used to mandate or deny payment or coverage of healthcare treatments across Medicare.

*"My fear is that CER will be costly and time-consuming and dependent on regular data from thousands of individuals, and because of that CER will fall back into the hands of pharma."*

*"Realistically, comparative effectiveness is ten years away, or more."* *

## The Rise of the Patient

The patient voice is becoming increasingly important in US healthcare. Patients' views on where and how they want to be treated will be more influential, as has been shown in diabetes programmes in the context of Patient Centred Medical Homes.[20] As patients emerge as an independent force in the purchasing of healthcare, their views on quality of care and value for money will acquire more resonance. Their choices will be

* Direct, unattributed quotes drawn from conversations and interviews during the course of the PharmaFutures project.

*"Pushing more cost onto the consumer is a megatrend."*

felt more clearly in the market as they select which health plans they want through the variable offerings available on the insurance exchanges. They will also have a direct influence on the ACOs, whose quality performance will be measured, in part, on how patients rate their experience.

## Consolidation

The previous sales model in which industry reps knew who they needed to influence (key people within Pharmacy Benefits Managers (PBMs) and insurers as well as individual prescribers) has been replaced by multiple new players – providers, hospitals, patients – as well as the doctors and PBMs. The push to integrate care and the scope for cost savings has already led to significant consolidation, which is strengthening the bargaining power of payers and providers, and leading some in the industry to express fears of an 'oligopoly', distorting the US marketplace.

*"Payers are taking less risk, and increasingly function as an intermediary. This means the patient will have more at risk themselves."*

# Uncertainties

**Reforming the highly complex, fragmented US health system, across the public and private sectors, is likely to mean several additional waves of reform and adjustment over the coming decade. This makes predictions of what is to come highly problematic. However, for pharma, it is nevertheless possible to identify two key uncertainties that are likely to be critical determinants of its ability to generate value over time.**

## Linking Data and Outcomes in Regulation and Reimbursement

There is widespread agreement that the narrow regulatory focus on efficacy and safety data, generated by clinical trials, is insufficient to determine the value of a medicine. There is a growing disconnect between the approval process for innovative drugs and their reimbursement by payers. The Food and Drug Administration (FDA) has introduced greater flexibility on oncology, and recently on Alzheimer's Disease, but more is needed for other therapeutic areas. There is a need to explore the potential for alternative regulatory processes, such as adaptive licensing, to allow real-world data (data from normal clinical settings) to build on clinical trial data. This would require more institutional dialogue between the FDA and CMS (Centers for Medicare and Medicaid Services), and a wider dialogue with stakeholders about the nature of the evidence that would be required and would be considered relevant.

*"It is completely and utterly wrong that someone could do a trial and not publish it, on an ethical, moral, no, from every basis."*

*"Transparency of data is accelerating and that's generally a good thing, but I can see schisms in the industry about how you make the data transparent."*

The most significant change is that providers and payers now require data that helps them to measure clinical and quality outcomes. This includes a growing need for real world data on specific populations, often with complex disease profiles. New measures of accountability are being introduced for both payers and providers, and data therefore has to help them demonstrate how interventions are helping meet targets. Can a drug demonstrably improve the overall costs of delivering care, for example; or can it be shown to avoid downstream complications such as hospital readmissions or to improve adherence rates? Electronic medical records will be a key source of this data, although it will take time before they are widely embedded in the US healthcare system.

The role of pharma in contributing to new types of data is the subject of debate and has many dimensions. First, it is not clear how credible pharma will be in generating or disseminating real world data, given the legacy of mistrust that dogs the industry regarding more established forms of data such as clinical trial data. Second, pharma faces considerable challenges in communicating this data. For instance, there is regulatory uncertainty over how far pharma will be allowed to go, in using new types of evidence in discussions with payers. Thirdly, there is the question of how such data will translate into improved clinical practice. There may be a role here for independent third parties, such as medical societies, to analyse the data in a credible and relevant way to inform clinical guidelines. Pharma's role here may

*"For the last 3-5 years the US has been the only place where you can raise drug prices. Price increases in the US will continue for at least 5-10 years."*

*"The industry is under-prepared for the big pricing cuts that are coming their way."*

involve a conversation with a whole new set of stakeholders. Lastly, the industry is unlikely to be united in its approach to any of these issues, which will add to the complexity.

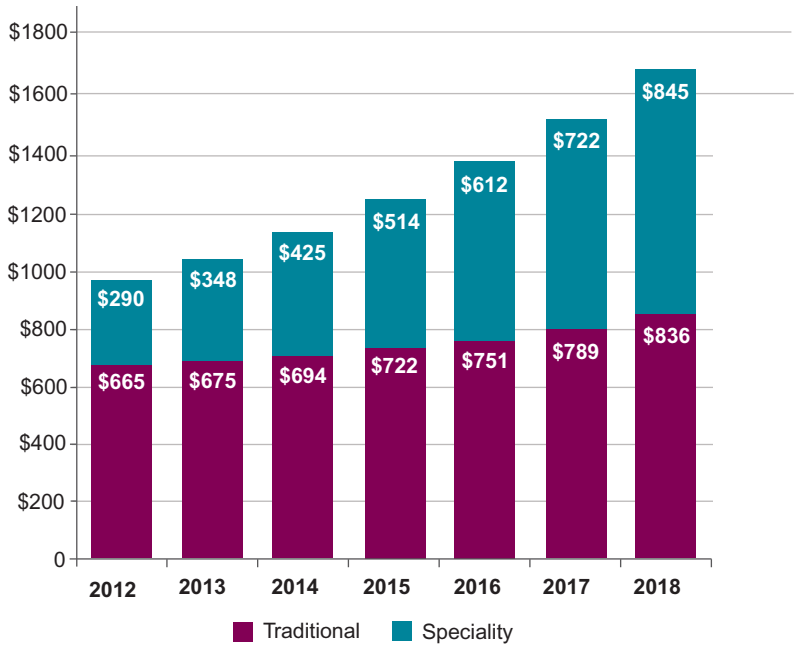
## Pricing

The crucial question for pharma and its investors is what impact these changes are likely to have on the pricing of its products – especially the launch price of new drugs. There are conflicting views – from both within and outside the industry – on whether pharma will be able to retain pricing power in the medium term. Some support for high and rising prices is likely to come from the system itself: a fragmented system where pricing is not transparent. In addition, some of the reform measures might take a long time before they have any effect on costs (such as bundled payment models). Lastly, pharma's pricing power may be bolstered if it were able to communicate the value of its products better, and convince payers that pharmaceuticals can save on hospitalisation expenses.

However, an alternative view argues that payers and providers will become increasingly aggressive, introducing measures to "bend the cost curve" in a context of growing demand. This line of argument asserts that the combined impact of the ACA and other changes in healthcare will lead to inexorable and permanent downward pricing pressure. There is a discernible pathway that would lead to this outcome: first, plans offered by health insurance exchanges are likely to be lower-value than employer-sponsored schemes because they are competing for more budget-constrained consumers. Second, it is likely that companies who carry high health insurance costs will seek to shift some of the employees in their health plans onto the exchanges. Third, the lower value of what is offered in Medicaid could affect pricing elsewhere in the system (Medicaid pays approximately 30% less, on a weighted basis, for healthcare services and products than the commercial sector, though in the case of some drugs it could be less).[21] Fourth, the adoption of new processes by payers and providers, such as disease pathways and protocols, could prioritise some drugs over others, generating savings without harming outcomes.[22] Finally, despite current prohibitions, over time, economic pressures could

Figure 2:

**Forecasted net drug spend* across the pharmacy and medical benefit for commercial plan sponsors**




Source: Artemetrx. Specialty drug trend across the pharmacy and medical benefit. 2013

*per member per year

make it acceptable for IPAB to recommend cost control measures in Medicare spending that focuses on originator products.

A number of factors could serve to accelerate these trends. First, the multiple patent expiries that have shielded payers from the implications of the increasing drug bill for the last ten years are coming to an end. The cost of innovative medicines will no longer be quite so cushioned by savings from generic substitution, leading payers to seek to reduce the highly visible drugs line item in the budget. Even though this may only be a small percentage of the whole, it may prove easier for providers to cut pharmaceuticals than endure the highly politicised fall-out of cutting costs at hospitals, for instance, which are sometimes seen as bastions of local economies.

Second, providers are increasingly aligning with payers to push back on prices, with the private sector moving quickly and aggressively on this. Third, there is a change in patient expectations and provider behaviours that could combine to reduce healthcare utilisation and temper expectations in the long term. Some experts argue that patients have been "conditioned" by several years of recession to accept constraints on their healthcare choices and are more sensitive to high prices through co-pays and co-insurance. This may affect the price point at which new drugs come to market. There is also evidence to suggest that the trend towards engaging patients in shared decision-making can lead to them opting for less intervention.[23]

However, the most important trigger for private healthcare providers and insurers to take radical action on pricing is likely to be the inexorable increase in the prices of specialty medicines and biologics (with attention focusing on certain disease areas such as autoimmune, cancer, HIV and MS). Prices for these medicines are rising much faster than other medicines: 17% in 2011 compared with overall trend of 2.7%.[24] Although these medicines account for only 1% of total prescription volume for private insurers, they account for 17% of total prescription spending, and the proportion is growing.[25] Some predict that insurers could be spending more on specialty drugs than on traditional drugs by 2018.[26] It is little wonder that the sustainability of the specialty and biologic prices has come under intense scrutiny (see Fig. 2).

# Conclusion

**The US health system is in flux and high levels of uncertainty will remain as healthcare markets adjust to the expansion of publicly funded programmes, the advent of the insurance exchanges, the growing voice of patients, the greater focus on the value of medicines, and the shift to outcomes-based reimbursement.**

For some, these changes do not change the industry's strong position. In a market characterised by choice, if pharma succeeds in bringing innovative drugs through development, it will continue to find a lucrative market for them. And it has multiple potential partners for demonstrating the value of prescription drugs, and the resources and skills to succeed within the changed system, however complex. For others, the cost containment challenges fundamentally change the industry from being a price maker to a price taker. In this context, innovation is a harder sell, contingent on how value is perceived by a much wider group of stakeholders. And the situation is made more difficult by the fact that the industry starts with a trust deficit.

Which opinion proves correct will depend on the interplay of many things. What is clear is that industry executives and investors alike face difficult questions about what a strategic response looks like – and whether that response should be company by company or an industry-wide – in the face of a dramatically changed US health system.

The *PharmaFutures* dialogue brought together industry, investors and societal stakeholders to share analysis and perspectives about the US market.

**Investor participants** in the dialogue reaffirmed their cautious optimism about pharma pipelines, but acknowledged that the prospects for pharma would increasingly be determined by reimbursement trends. It may be that investors come to differentiate between companies on the basis of their distinctive reimbursement strategies, as well as comparing them on R&D, pipeline and choice of therapeutic category. In addition, investors are increasingly interested in the sustainability of specialty pricing, approaches to data management and the growing demands for transparency as well as the nature of the industry's response to provisions of the ACA.

For **payer and provider participants** bending the all-important cost curve in the face of the "silver tsunami" of older patients is of paramount concern. For them too, specialty products are of particular of interest due to annual price hikes that they deem unsustainable.

**Patient participants** shared this concern, and highlighted the growing trend to accept constraints on choice as an acceptable trade-off for cost reductions, though this is not true for rare disease treatments.

**Industry participants** accepted that there will be winners and losers in this transition. They acknowledged that their industry faces a strategic decision about whether to adopt a defensive position, seeking to maximise returns in the short-term, irrespective of the long-term consequences, or to take a more collaborative approach, which though costly and complex, will ultimately position pharma as part of the solution to the problem of outcomes and costs.

*PharmaFutures* discussions concluded with a sense of opportunity for the industry. As the health system adopts greater understanding of the impacts of health interventions, the outlook for medicines that can help to save the system money, at the same time as preventing disease progression is bright. To achieve this end, however, will require the industry to collaborate with payers and providers, understand the constraints they face and commit to reframing the relationship to one of negotiation, rather than an all-or-nothing stand-off on a price. There is no guarantee that the pharma sector as a whole will do this. It is likely, however, that tomorrow's successful companies will be those who chose this path.

# Appendix

## PharmaFutures US Participants and External Interviewees

**Stewart Adkins,** Director, Stewart Adkins Advisors Ltd

**Jack Bailey,** Senior Vice President, Policy, Payers & Vaccines, GlaxoSmithKline

**Lauren Barnes,** Senior Vice President, Avalere Health

**Prof Ernst Berndt,** Louis E. Seley Professor in Applied Economics, MIT Sloan School of Management

**Dr Scott Braunstein,** Managing Director, JP Morgan Asset Management

**Kathy Buto,** Vice President Health Policy Government Affairs, Johnson & Johnson

**Joseph Canzolino,** Deputy Chief Consultant, Pharmacy Benefits Management, Veterans Affairs

**Dr Benjamin Chu,** Group President Southern California and Hawaii, Kaiser Permanente

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