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**Who Will Be Pharma's Man?**

Surprisingly few policy initiatives have been discussed in detail by the candidates in the build up to the November 2008 US Presidential election. Rising gas prices and the stuttering economy received relatively little attention as candidates shared their vision for healthcare during their respective primary runoffs. While John McCain and Barack Obama continue to try to differentiate themselves from one another in attempt to both rally their bases and capture independent voters, those in the pharmaceutical industry should ask, 'What is the real difference between the two?'

Historically, presidential candidates from the Republican and Democratic parties have offered divergent approaches to addressing the growing crisis in healthcare access. Republicans often have espoused a non-interventionist approach utilizing free-market mechanisms to provide more consistent access and budget management via competitive

**Guess the candidate #1:**

*"Drug companies and the lobbyists they pay in Washington want to keep your drug prices high. Obviously, I want them to be affordable."*

forces (e.g., the great focus on healthcare savings accounts (HSAs) since the late 90s), while Democrats often espouse a greater role for the hand of government in ensuring access and moderating costs (e.g., the failed attempt at national reform from the first Clinton term). The reality of major change has been limited primarily to reforms within the Medicare program, including government-led changes to reimbursement rates; the creation of the large Part D program, based on a mix of entitlement and market competition; and a variety of state efforts to broaden

coverage such as Massachusetts' attempts at mandatory health insurance.

Meanwhile, a rapidly increasing number of individuals outside of already existing government programs lack insurance entirely (47 million people, according to most estimates) or are underinsured (meaning that they face potentially devastating costs in the event of severe illness). Healthcare costs in general continue to rise – including spending on biopharmaceuticals – while exposure to drug costs is increasingly consolidated among a smaller number of payers, both government and commercial.

As a result, reform of the US healthcare system may play a key role in this November's presidential election, and industry must be prepared to participate in and help shape the dialog – with recognition of the impact it will have on pricing policies, patient access, and overall market attractiveness – that will likely occur in the new President's first term.

At first blush, it may be surprising to note the degree of consensus that would appear to exist between the healthcare reform platforms of John McCain and Barack Obama, the two leading presidential candidates. The traditional tug of war between proponents of a free-market system and advocates of government-funded universal healthcare, while still evident, has become more of a fight over the degree to which the government will intervene.

**Guess the candidate #2:**

*"Why shouldn't we be able to re-import drugs from Canada? It's because of the power of the pharmaceutical companies... Well, they are [the bad guys]."*

Intuitively and historically, the most significant risks to US pricing is associated with Obama and the Democratic Party. The cost containment mechanisms currently included in his platform are well known and have popular appeal: reimportation, direct pricing negotiations with the Government and limits on intellectual property rights. However, McCain's platform very closely reflects – if not mirrors – some of those same positions, a fact reflected in the low volume of contributions to the McCain campaign by big pharma (in fact, Obama has raised approximately four times what McCain has from the pharmaceutical industry, whereas George W. Bush's 2004 campaign brought in nearly twice what John Kerry's did).

The goal of “coverage for all” is one that few Americans will argue with. However, even that moniker is misleading, as neither platform espouses mandated coverage (apart from Obama’s requirement that children be insured) and, perhaps more importantly, both would realize different forms of government-subsidized access to competitive insurance

options. Despite all the similarities, however, McCain’s campaign would still claim that its great differentiator is the avoidance of federal government intervention into the free market and states’ affairs. A high-level side-by-side comparison helps illustrate (in bold) where the main differences exist between the two candidates’ positions.

|                           | McCain   | Obama  |
|---------------------------|--|--|
| Mandatory vs. optional    | Optional   | Optional (except mandatory for children)   |
| Source of Funding         | Tax credits to fund access when needed (if not covered by employer)                                      | Undefined subsidy to fund access (if not covered by employer)  |
| Implementation            | <b>Work with states to determine best path of implementing a competition-driven program</b>              | <b>National plan establishing National Health Insurance Exchange as clearinghouse for commercially run insurance options, ensuring consistent benefits and fair and stable premiums; still allow state experimentation</b> |
| Outcomes metrics          | Create national standards for transparency on and linking of outcomes, quality, cost, and prices         | Develop systems to collect and report data on quality of care, cost, etc.  |
| Payment evolution         | Bundled/capitated payments for disease treatment (i.e., across sites of care and physicians)             | Physician compensation linked to outcomes  |
| Drug budget savings       | Focus on drug costs as a fast-growing key area to realize savings  | Focus on drug costs as a fast-growing key area to realize savings  |
| Reimportation             | Allow drug reimportation   | Allow drug reimportation   |
| Role of generics          | Realize faster introduction and uptake of generic drugs  | Increase use of generics in federal programs, prevent brand-protection agreements between originator and generic companies   |
| Federal price negotiation |  | <b>Repeal the ban preventing the federal government from negotiating price with drug manufacturers</b>   |
| Long-term outcomes focus  | <b>Focus on prevention and early intervention in chronic disease (note: opportunity for innovation?)</b> |  |
| Employer cost exposure    |  | <b>Reimburse employers for some catastrophic costs (note: could affect budgets for drugs in acute disease states?)</b>   |

Specifically, the desire to “fix” healthcare in the US most commonly consists of variations on the theme of government

**Guess the candidate #3:**

*“I ask for a Senate vote to allow safe imports of US-approved drugs that are manufactured in US-approved plants.”*

intervention vs. reliance on market forces. To some extent these may be guided by experience in other major markets’ attempts at providing broad coverage and cost containment, and clearly Obama’s proposal to allow direct price negotiation by the federal government takes a giant step away from the principle of free, value-based pricing and toward the type of budget-oriented interventionism that characterizes many other major markets.

In any case, a significant change in the US system will have ramifications for global markets as their relative attractiveness or contribution to revenue potential changes regardless of which party is in the Oval Office. Manufacturers’ reliance on other established and emerging markets could increase: additional strains created by US reforms will make pricing and reimbursement performance in the EU more critical, and the focus on rapidly growing markets (e.g., Turkey, China, India) may increase. Innovation may be at risk as the US government takes a greater role in product pricing – or has a clearer pathway to do so.

With this in mind, manufacturers must recognize that change is afoot in a system seen by many as unsustainably expensive and selective. Effective scenario evaluation and planning appropriate product value strategies will be more important than ever to ensure success in an environment of shifting stakeholder strengths.

**Guess the candidate #4:**

*“The federal government... could not negotiate for the best possible price with the drug companies, so that they could actually get the kinds of discounts the Canadians enjoy for the drugs that are manufactured here in the US. That was done because the drug companies didn’t let it happen.”*

Answers to **Guess the Candidate:**

#1 McCain; #2 McCain; #3 Obama; #4 Obama

## Industry Dodges OFT Value Bullet

For months, many in the UK pharmaceutical arena as well as outside the UK have been eagerly waiting to see what would happen to the Pharmaceutical Price Regulation Scheme (PPRS) – a system that has secured relatively free pricing in the UK. The Association of the British Pharmaceutical Industry (ABPI) and the Department of Health (DOH) have been behind closed doors tackling the key question of the PPRS’ future since November 2007. Breaking their silence on 18 June 2008, the Department of Health and the ABPI released a joint press statement announcing a new PPRS, preserving free pricing in the UK at the expense of delivering a series of price cuts. The savings to the NHS amount to 5% derived from a 2% across the board cut and 3% from brands that lose exclusivity. While some in the industry may be giving a collective sigh of relief that only a 5% savings has been agreed upon, there are key questions left unanswered and negotiations have not yet concluded.

### Background

An agreement of a 5% saving to the NHS seems like a relatively good deal considering the build up to the negotiations. The Office of Fair Trading’s (OFT) now notorious and highly critical report of the PPRS recommended its replacement with a more “value-based” approach and was a major push for the re-negotiations. The OFT continued its scrutiny of the pharmaceutical industry and recommended using the PPRS re-negotiations to consider how pharmacy clawbacks (money the Government currently recoups from wholesaler discounts to pharmacies) could be protected or replaced as more manufacturers move to direct-to-pharmacy distribution.

Meanwhile, the Treasury’s 2007 Comprehensive Spending Review (CSR) outlined a spending growth cap on the NHS of 4% in real terms for three years from April 2008 – this is a substantial policy statement as the Treasury has been flooding the NHS with cash since Labour came to office (nearly doubling the budget). Together, these three reports serve as the underlying catalyst to the discussions between the pharmaceutical industry and the DOH.

### The New Deal

Despite concerns that the PPRS would be binned (as encouraged by the OFT) in favour of an undefined value-based approach to pricing, the DOH and the ABPI have agreed to another 5 year contract, which comes into effect in January 2009. If the drugs budget should exceed 6.7%

growth in either 2008 or 2009, there will be an additional price cut of 2%.

While most of the OFT report seems to be discarded, confirming the use of the OFT report as more of a negotiation tool than policy setter, some OFT recommendations regarding off-patent products may have made their way into the new PPRS. The 2007 OFT report suggested pricing branded, off-patent products at 25% premium to the price of their generic equivalents. This appears very similar to the reference price system used for off-patent products in many European countries and may open a Pandora's box to therapeutic reference pricing in the UK that has occurred in Germany and to some extent in Italy. Reference pricing is a method of price control that grates against the UK's history of being a relatively free-price market. In addition, the DOH and ABPI state that negotiations are still underway to address measures that better reflect the concept of value—a large bone of contention between industry and government.

Perhaps most dear to the industry, the new PPRS preserves the right of pharmaceutical companies to freely price new products and to modulate the prices of products covered by the PPRS rather than making defined cuts across the board. Innovation and uptake provisions were also agreed to, however most do not go as far as the industry would like. Such measures include a piloting extension of prescribing incentive schemes with primary care trusts (PCTs) and development of new metrics for uptake of clinically and cost-effective medicines, starting with NICE approved drugs. Agreement has also been reached to establish a single horizon scanning process for new drugs in development. Similar to the French requirement of submitting forecasts for new drugs prior to launch, this provision will help PCTs plan ahead for new and innovative products.

This is not the first time industry has been forced to cut its prices in the UK. Previous price cuts include 7% in 2005, 4.5% in 1999, 2.5% in 1993 and 3.0% in 1978. Given this historical context and Health Secretary Alan Johnson's statement to the Financial Times in January 2008 that the DOH was seeking a price cut of 'at least 10% or about £1 billion,' on first review, it appears that industry has brokered a very generous deal.

The outcome may also be welcomed across Europe because a higher price cut may have led to downward price adjustments in a number of other countries that reference the UK market—further reducing pharmaceutical profit margins on a global scale. Meanwhile, parallel traders are probably relieved. A larger price reduction may have jeopardised the viability of imports of some products into the UK, which is one of the largest import markets for traders.

However, with most things, the devil is in the details and, in this case, the details are very unclear. Clarification is needed on how off-patent products can deliver the additional 3% in savings and if it even possible to find that amount of savings in a market that has amongst highest generic prescribing rates. Back of the envelope calculations suggest that this may be questionable, even if off-patent products are reference priced to their generic counterparts.

### **Bullet proof**

Neither Government nor the pharmaceutical industry is bullet proof. It is likely that during negotiations, industry gave comparative examples, such as the disinvestment that occurred in Germany after reference pricing was introduced. This message of disinvestment was publicly followed up by companies such as AstraZeneca who announced that it would not rule out moving out of the UK in favour of more industry friendly country such as Ireland. Significant loss to the British economy is sensitive topic for Government, especially given the current credit crisis. The Brown Government is likely trying to avoid any additional bad economic news.

The recent fall of sterling may have also contributed to preliminary negotiation outcome. UK prices have been falling in comparison to European prices, weakening the Government's negotiation position. Sterling has fallen 14% against the euro since the negotiations began—deflating any European cross-country price comparisons. Meanwhile, industry surely concerned about what impact a price cut would have not only in the UK but also in other markets that reference the UK.

Threats to pull out of the market and currency fluctuations will not always insulate industry from the mounting financial burden of healthcare. To preserve free pricing in the UK, industry will no longer be able to rest on its laurels of innovation and economic contribution to the UK. Rather, the industry will need to sharpen its messages around the value its products. The UK has pioneered cost effectiveness, however it is now critical that the industry and Government alike better refine how they approach evaluation of products and, importantly, demonstrating differential value. This is now vital in other countries such as France and the Transparency Commission's ASMR rating—the UK should not trail too far behind.

## Lord Darzi's High Quality Care for All: Nice Sentiment but Little Impact

Perhaps one of the most commented on services of the UK Government is the National Health Services. Regularly flooded by white papers, Lord Ara Darzi released a laundry list of patient-oriented reforms for the NHS on 30 June 2008. Recommendations based on the promise to "guarantee patients access to the most clinically and cost effective drugs and treatments" pose interesting challenges to the NHS that are unlikely to impact the UK market access environment in the near future.

The report's primary criticism is the variance in access to treatments between regions, commonly referred to as the "post-code lottery," and is the primary rationale behind the existence of the National Institute for Health and Clinical Excellence (NICE). Darzi points out that there are marked differences in the way Primary Care Trusts (PCTs) manage products that have yet to be reviewed by NICE and, perhaps more egregiously, that some PCTs do not necessarily comply with guidance once it is issued. Further addressing market access shortcomings, Darzi's report takes note of NICE's lengthy appraisal process and states that NICE should be reformed to review "significant new drugs" within a few months of launch. However, there was no mention of any of the Office of Fair Trade (OFT) recommendations, including those to have NICE set drug prices. Meanwhile, the report avoids a recent hot button issue: NHS charging some patients for the full cost of cancer therapy (including NHS funded products) because they choose to privately purchase certain targeted oncology agents not approved by NICE.

This critical attention on market access is warranted but falls short of providing any immediate measures. The industry has continuously been victim of NICE blight, even with the streamlined single technology appraisal. Asking it to review all new products (or even those ambiguously referred to as "significant") will either take major investment or require NICE to further streamline its appraisal process, perhaps adopting an approach similar to the much-shortened analyses of the Scottish Medicines Consortium (SMC). With spending growth capped at 4%, it is unlikely that NICE will be the recipient of sizable new funds. Meanwhile, mirroring the SMC will erode much of the "progress" made in cost effective analysis. These recommendations, with little if any guidance on their implementation, will make the NHS a continued battle ground between the industry, patients and budget holders.

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