

US Elections: The Impact of “Change” on Tomorrow

The 2008 US election results have now sunk in – President Barack Obama will bring a new approach to national policy across a range of issues, and he will enjoy Democratic Party majorities in both houses of Congress. Democrats will control the Presidency and Congress for the first time since the 1992 elections brought Bill Clinton to power. Then, as now, equity in access to healthcare was a burning issue. In the four presidential terms since then much has changed and great advances have been made in the potential of biopharmaceutical management of a myriad of diseases and conditions. Yet – with the notable exception of Medicare Part D, the outpatient prescription drug program for seniors – fundamental questions about lack of insurance, underinsurance, and the Federal Government’s role in ensuring healthcare still loom large. Will the US intervene more heavily in price determination or negotiation? Can a national plan to improve the status of uninsured Americans (whose numbers could swell to 67 million if no action is takenⁱ) be wrought and implemented? How will the pitfalls of the Clintonian healthcare reform plan – which went down in flames a decade and a half ago – be navigated?

Given Obama’s goal of increasing and improving access while controlling costs, government under his direction is likely to play a major role in establishing policies that encourage coverage. (Obama’s proposals technically mandate coverage only for those 25 years old and younger. While requiring employers to provide insurance or else pay the government, they do maintain current tax treatment of insurance premiums and provide subsidies to ensure affordability, with the result that, according to independent analysis, they will cover 47% of the currently projected uninsured over 10 yearsⁱⁱ). Due to his belief of a failure by markets to operate on the scale necessary to provide broad coverage, tens of millions of individuals would be able to seek coverage through a new national insurance scheme.

“The market alone cannot solve the problem – in part because the market has proven incapable of creating large enough insurance pools to keep costs to individuals affordable.”ⁱⁱⁱ
 – Obama 2006

The totality of this proposed new program is expected to cost \$1.6 trillion over 10 years, with costs

continuing to rise every year. To put that cost in proportion, federal spending on the Medicare and Medicaid programs in fiscal 2008 was over \$660 billion.^{iv} The vast majority of that goes to non-drug costs; for example, Medicare Part D (one of several federally supported programs that have a drug budget) came in under budget in 2008 at less than \$40 billion. However, drug prices remain a relatively easy and politically attractive target for management, in comparison to areas such as hospital costs (although the federal and state governments already pay for more than half of hospital spending), notoriously difficult to control issues like fraudulent claims^v, and so on.

While the Obama proposals contain numerous important means by which to achieve cost savings, such as general improvements in efficiency and greater use of technology, there are two that should create significant pause within the biopharmaceutical industry. The first is the potential for the Federal Government to negotiate prices directly with manufacturers for drugs paid for within the Medicare program. The second is the potential creation of a national cost effectiveness evaluation body, a controversial and likely costly step.

Uncertainty in the Markets

Unpredictable forces will continue to be at play in the US economy as the new government takes office in January. On the one hand, it is entirely possible that turmoil in financial markets, economic recession, and growing unemployment will distract policymakers from seeking a solution to the nation’s un/underinsurance and ballooning healthcare budgets. On the other, the same forces may result in an even worse coverage situation and a heightened sense of urgency, as individuals lose jobs and as companies scale back on benefits for employees.

In addition, healthcare equality figures prominently in the Democratic Party’s platform^{vi}, and has been a pillar of Obama’s campaign. Like other key areas targeted for change^{vii}, the President-elect will seek to maintain momentum on this critical issue. At the same time, there is likely to be a desire to reconcile political differences with the disparate Democratic Party and even to reach across the aisle for some degree of Republican support. In an environment in which federal bailouts are expanding and the

government is taking ownership stakes in financial institutions, the possibility of even greater government intervention in free markets through direct price negotiations – which, with the purchasing power of the government behind them will easily become price controls – may hit a sour note among the more non-interventionist members of Congress.

However, the questions of government-led price negotiations and cost-effectiveness evaluations are also linked to the long-term sustainability of advances in healthcare. While history points to the flight of R&D from Europe following the advent of state price controls, current proposals need to be considered and in the light of current pressures.

Risk Abounds

Continuing on the current path of healthcare coverage in the United States is not realistic. The worsening economic crisis creates tremendous new risks for individual insurance, and may have ramifications in insurance companies' ability to offer best-in-class benefits. However, the future of drugs' role in healthcare does not solely consist of products that are currently on the market. In fact, their continued use, many of which represent major advancements in therapy, will provide on-going clinical benefits (see accompanying article in this Bulletin) and eventually lead to cost savings due to the generic competition already provided for under US law. The other major value offered by drugs is housed in the industry's pipeline that exists today and will emerge from tomorrow's research. Of course, the sustainability of the industry's ability to deliver new benefits and breakthroughs depends upon the health of that pipeline. It is well recognized that many of these future advances will originate not in the labs of big pharma, but in smaller specialty companies that have no product revenue stream.

Given these dynamics, government intervention in drug pricing may have unintended but serious long-term ramifications. Big pharma will indeed view price controls negatively due to the direct impact on profitability, at a time when the industry has already been battered. However, the engine of future development – the small biotechs and specialty pharma companies – face an even more dire situation. Many companies have only 6-12 months' cash on hand. Nearly 200 publicly traded US biotechs trade at nearly no multiple to cash, and with market capitalizations under \$100 million face delisting^{viii}. Considering the current risk avoidance in capital markets, the near-term shakeout in biotech may be startling as new financing rounds and the opportunities to float new shares have, at least temporarily for many companies, nearly dried up.

While this creates an attractive buying opportunity for larger biotech and pharma companies, who may be able to pick up valuable assets at a low cost, the resulting lack of development activity could create a hole in the future pipeline. Government pricing intervention in the world's largest and most valuable biopharmaceutical market could have even more dire implications for asset valuation and funding of R&D through both private and public markets. According to Scott Gottlieb, former Deputy and Acting Chair of the FDA and current Forbes columnist, this is not a spurious argument.

The last time policy makers waged a concerted effort to control the price of and the access to the most innovative, but expensive new drugs as part of broader health-care reform in the mid 1990s, the percent of venture capital going into biotech fell by almost half in a single year. A lot of that money shifted into Internet companies.^{ix}

The question of how to offer healthcare to the entire US population has been characterized as much by agreement on the necessity of finding a solution, as by disagreement on the means by which to accomplish the goal (many in big pharma had concerns about Medicare Part D, which were in part resolved by a prohibition on government price intervention; since its inception, the program has proven to be a significant contributor to many companies' growth). Much of the contention hinges on philosophical differences around government's role. It is clear that national policy shifts (as well as initiatives at the state and local levels) will be instrumental in causing change. What is unclear is the position the new administration and Congress will take on the question of value. Steps toward price control and imposed metrics of cost effectiveness create enormous risks for the biopharmaceutical industry, the research and development of which serves as a leading indicator of the nation's long-term health.

i Burman, Leonard E., Surachai Khitatrakun, Greg Leiserson, Jeff Rohaly, Eric Toder, Robertson Williams. "An Updated Analysis of the 2008 Presidential Candidates' Tax Plans" Urban Institute/Brookings Institution Tax Policy Center, July 23, 2008

secondary source: <http://www.epi.org/content.cfm/pm126> May 23, 2008 | EPI Policy Memorandum #126, Obama health plan outperforms McCain plan in coverage and efficiency, by L. Josh Bivens and Elise Gould

ii Burman, Leonard E., Surachai Khitatrakun, Greg Leiserson, Jeff Rohaly, Eric Toder, Robertson Williams. "An Updated Analysis of the 2008 Presidential Candidates' Tax Plans" Urban Institute/Brookings Institution Tax Policy Center, July 23, 2008

secondary source: <http://www.epi.org/content.cfm/pm126> May 23, 2008 | EPI Policy Memorandum #126, Obama health plan outperforms McCain plan in coverage and efficiency, by L. Josh Bivens and Elise Gould

iii The Audacity of Hope, by Barack Obama, p.183 Oct 1, 2006

- iv Joint Statement of Henry M. Paulson, Jr., Secretary of the Treasury, and Jim Nussle, Director of the Office of Management and Budget, on Budget Results for Fiscal Year 2008; October 14, 2008. <http://www.ustreas.gov/press/releases/hp1213.htm>
- v For example: "Report Rejects Medicare Boast of Paring Fraud" Charles Duhigg, The New York Times, 20 August 2008
- vi It is the first point on the party's agenda at the official website <http://www.democrats.org/agenda.html>
- vii For example, climate change. Obama to Act Quickly on Global Warming in 2009 (Update1) By Jim Efstathiou Jr. <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aL32Caq6UNuw>
- viii Biotech reels from one of the worst months on record for the capital markets Burrill & Company press release November 03, 2008 http://www.burrillandco.com/news-319-Biotech_reels_from_one_of_the_worst_months_on_record_for_the_capital_markets.html
- ix How Obama Would Stifle Drug Innovation: If you want cutting-edge health care, don't make it a cost-controlled commodity. By Scott Gottlieb. Wall Street Journal, October 18, 2008

PriceSpective is a management consulting firm specializing in innovative strategies to identify, capture, and communicate value for products, portfolios, and companies in the biopharmaceutical arena.

Editors:

Keiron Sparrowhawk, PriceSpective Ltd, U.K.
+44 (0) 207 832 1086
ksparrowhawk@pricespective.com

Ted Sweeney, PriceSpective, LLC., U.S.A.
+1 415 567 9066
tsweeney@pricespective.com

www.pricespective.com <<http://www.pricespective.com>>