



CRA Insights: Life Sciences

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The pharmaceutical industry under the new US administration: policy, the political agenda, (and pricing)

Background

Until November 9, 2016, there was a consensus regarding the future of US health policy—at least among policy analysts. Recent controversies over prices and the challenges in terms of healthcare spend would lead to changes in the US policy landscape with increased intervention seemingly inevitable.

There was almost incessant controversy. Manufacturers were questioned about pricing for innovative products such as Sovaldi (HCV) and Iclusig (leukemia), to name a few. On the campaign trail, Hillary Clinton promised new enforcement tools and action on price hikes: “I’m ready to hold drug companies accountable when they try to put profits ahead of patients, instead of back into research and innovation.”¹

Potential policy reforms were coalescing, including:

- A debate over legislation to allow negotiation of Medicare prices;
- An increasing role for value assessment; and
- Greater transparency requirements, such as those set out in the Fair Drug Pricing Act.²

¹ Barney Jopson and David Crow, “Clinton promises panel to vet drug price rises,” *Financial Times*, September 2, 2016, <https://www.ft.com/content/56424e1c-712b-11e6-9ac1-1055824ca907>.

² See Medicare Prescription Drug Price Negotiation Act 2015, <https://www.congress.gov/bill/114th-congress/senate-bill/31/text>; Center for American Progress, “Negotiation Plus: A Framework for Value-Based Drug Pricing Negotiation,” September 26, 2016, <https://www.americanprogress.org/issues/healthcare/reports/2016/09/26/144760/negotiation-plus-a-framework-for-value-based-drug-pricing-negotiation/>; the Fair Drug Pricing Act, introduced by Senators McCain (R-AZ) & Baldwin (D-WI), requires drug manufacturers to notify the US Department of Health and Human Services (HHS) and submit a transparency and justification report 30 days before they increase the price of certain drug products by more than 10%. See “Senators McCain & Baldwin introduce Bill to require transparency in prescription drug price increases,” Press release, September 15, 2016, <http://www.mccain.senate.gov/>.

In sum, the US appeared to be echoing European approaches to health policy with respect to pricing of medicines. The election, however, would appear to have changed everything. Or did it?

In this issue of *Insights*, we summarize the discussion at a recent CRA dinner with attendees from a number of pharmaceutical companies. The discussion was led by Tim Wilsdon, an expert in international policy issues affecting the development and commercialization of medicines. Here he shares some of the key points from the discussion on US health policy, potential priorities for the Trump administration, and yes, pricing.³

Policy picture

Following the election, the policy priorities of President-elect Trump appeared to focus on repealing the Affordable Care Act, or perhaps, tweaking it. While the Trump policy web site states: “Completely repeal Obamacare,” Trump subsequently moderated his stance indicating he favors provisions that allow for coverage of pre-existing conditions and for coverage of children on their parents’ health plan until the age of 26.

Other Trump policies are generally supportive of the healthcare industry, for example: repatriation of corporation tax and making the FDA quicker and less burdensome. Indeed the Nasdaq biotech stock index was up 9% following the election.⁴ Even with recent comments to “control” drug prices and introduce a form of national “bidding”, the received wisdom is that reform of the ACA will take considerable political attention and the imminent threat of price regulation appears to have diminished.⁵ However, there are several reasons to question this assumption.

Market fundamentals still apply

The US policy environment remains challenging and the pressure to address pricing will continue with pharmaceutical spending increasing by 8.5% a year, driven largely by speciality products focused on relatively small patient populations.⁶ There are significant concerns regarding the sustainability of the cost of Social Security, Medicare, and Medicaid.

³ To understand policy priorities of President-elect Trump, we referred to statements made during debates, recent comments, and a web site that outlines his positions: <https://www.donaldjtrump.com/positions/healthcare-reform>.

⁴ Rebecca Robbins, “Biotech stocks rally after Donald Trump’s win,” *STAT*, November 9, 2016, <https://www.statnews.com/2016/11/09/trump-biotech-stock-rally/>.

⁵ Jared S. Hopkins, “Trump’s Vow to Control Drug Costs Alerts Another Industry,” *Bloomberg*, December 7, 2016, <https://www.bloomberg.com/news/articles/2016-12-07/trump-says-he-ll-bring-down-drug-prices-biotech-stocks-fall>; Carolyn Y. Johnson, “Trump on drug prices: Pharma companies are ‘getting away with murder’,” *Washington Post*, January 11 2017, <https://www.washingtonpost.com/news/wonk/wp/2017/01/11/trump-on-drug-prices-pharma-companies-are-getting-away-with-murder/>.

⁶ QuintilesIMS, “IMS Health Study: U.S. Drug Spending Growth Reaches 8.5 Percent in 2015,” Press release, April 14, 2016, <https://www.imshealth.com/en/about-us/news/ims-health-study-us-drug-spending-growth-reaches-8.5-percent-in-2015>.

Pricing in the headlines

The media focus on drug pricing is likely to continue—be it the cost of innovative therapies or company positions such as Allergan and Novo Nordisk that could potentially highlight rather than mitigate the impact of pricing. Both firms have announced that future price increases will be limited to single digits.⁷ Additionally, significant price increases for off-patent medicines will quickly lead to the media returning to concerns about “price gouging” and the effectiveness of competition.

Doubts regarding the effectiveness of competition to restrain prices

The argument that competition is restraining drug prices is being challenged in many states. A report by the Massachusetts Office of the Attorney General found that “While the growth rate for prescription drug spending reported to the Center for Health Information and Analysis (“CHIA”) abated from 13.5% in 2014 to 10.1% in 2015, it has continued to significantly outpace overall health care spending growth.”⁸

That the US appears to pay significantly higher prices for drugs than other international countries will continue to attract attention. Pressure on prices in international markets will continue in 2017, and the situation in the US could be exacerbated by other wealthy countries – apparently paying lower prices than the US – calling for international discussions on drug pricing.⁹

Stakeholders

Where there is concern from voters, continued interest by the media, and implications for financial sustainability, there will be policy proposals.

States

California’s Proposition 61, a proposal to regulate price increases for Medicaid and link prices to those charged by the US Department for Veteran Affairs (VA), did not pass; however the state of Ohio has a similar ballot initiative planned for November 2017.¹⁰ If Trump’s proposals on Medicaid block grants are implemented, this will increase the pressure on states to manage the cost of these benefits and could stimulate more state-level initiatives.

⁷ Allergan, “Our Social Contract with Patients,” September 6, 2016, <http://www.allergan.com/NEWS/CEO-Blog/September-2016/Our-Social-Contract-with-Patients>; Denise Roland, “Novo Nordisk Pledges to Limit Price Increases in U.S. for Its Drugs,” *Wall Street Journal*, December 6, 2016, <http://www.wsj.com/articles/novo-nordisk-pledges-to-limit-price-increases-in-u-s-for-its-drugs-1481054637>.

⁸ “Examination of Health Care Cost Trends and Cost Drivers Pursuant to G.L. c. 12, § 11N,” Massachusetts Office of Attorney General Maura Healey, September 18, 2015, <http://www.mass.gov/ago/docs/healthcare/cctcd5.pdf>.

⁹ As illustrated by France’s request to discuss prices at the G7. Matthias Blamont and Jean-Baptiste Vey, “France gets G7 to discuss global regulation of medicine prices,” *Reuters*, May 3, 2016, <http://www.reuters.com/article/us-g7-japan-pharmaceuticals-idUSKCN0XT0TU>.

¹⁰ Ed Silverman, “Pharma may have defeated Prop 61, but state battles over pricing will continue,” *STAT*, November 9, 2016, <https://www.statnews.com/pharmalot/2016/11/09/prop-61-california-drug-prices/>.

There is a danger that the arguments used to counter the use of price benchmarks (such as referencing VA prices which could raise prices for the VA and reduce access) become less effective over time, as experienced in parallel debates in other parts of the world. European experience has shown that once one payer uses pricing benchmarking, this encourages even more requests for price transparency. Indeed, many of the state-level proposals for price transparency are strikingly similar to each other. It is unsurprising that the pharmaceutical industry fought hard to defeat Proposition 61 because of the principle that if passed, VA prices could become a signal or benchmark for other prices.

Clinicians

Some of the proposals to more formally integrate value frameworks into a price negotiation system (along the lines of those suggested by the Center for American Progress), which seemed possible under a Clinton administration, are now being mothballed. Nonetheless, value frameworks will become more influential and feed into decisions by patients, physicians and even, ultimately, payers. Proponents of these initiatives, not to mention organizations such as the Institute of Clinical and Economic Review (ICER) and Abacus,¹¹ have ready access to the experience of health technology assessment agencies in Europe.

Patients

In the coming months, the debate will continue to focus on the replacement or reform of the ACA, the pressure on Medicaid budgets, and the corresponding impact on patients. Facing increased cost of coverage, or reduced coverage, patients may question costs and thus turn attention back to drug prices or requirements by companies to offer ever more generous Patient Assistance Programs (PAP).

Conclusion

Although the election of Donald Trump appears to change the direction of US health policy, some initiatives have sufficient momentum that they are likely to continue. For example, efforts to move away from fee-for-service to value-based care: “This is a movement that’s happening independent of the ACA, or parallel to it.”¹² Not all health policy is partisan. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was a bi-partisan agreement allowing for physicians to be rewarded on outcomes and for alternative payment models to healthcare providers.

¹¹ ICER led an initiative to develop a framework which insurers can apply to guide their assessment of the value of medical services, including drugs, medical devices, and procedures (<https://icer-review.org/methodology/icers-methods/icer-value-assessment-framework/>). Abacus provides a tool allowing the value of products to be compared across a number of dimensions. (<http://www.drugabacus.org>).

¹² David Jones, Assistant Professor of Health Law, Policy and Management at Boston University’s School of Public Health, as quoted by Elizabeth Whitman, “Will value-based payment initiatives continue under Trump?,” *Modern Healthcare*, November 11, 2016, <http://www.modernhealthcare.com/article/20161111/MAGAZINE/161109907>.

In terms of pricing and price regulation, the focus, is likely to be on the ACA and even modest changes to the ACA will be a mammoth exercise. But, as demonstrated by recent announcements, this may represent only a brief respite in the pricing debate, with discussion regarding what to be done about prices (at the national or state-level) returning to the headlines and the dinner table.

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