

## Congressional control big biopharma risk in 2016 election



[Jonathan Gardner](#)

If the polls are correct, biopharma's biggest worry regarding the US election is not whether Hillary Clinton or Donald Trump is chosen to be president, but rather whether the Republican party holds its congressional majority.

Both Ms Clinton and Mr Trump have argued in favour of allowing the US government's Medicare programme for the elderly to negotiate drug prices, an event that would send shock waves through the sector. Therefore, Republican majorities in one or both houses of Congress will be essential to slowing or stopping such a proposal – and [the big pharma lobbying group is reportedly topping up its war chest](#) in anticipation of 2017's big legislative battle.

In spite of some erosion as the campaign closes, polls favour Ms Clinton, the Democratic nominee, to win a majority of the Electoral College next week, and her performance may have a big impact on down-ticket members of the Senate and House of Representatives also up for election. The esteemed Fivethirtyeight.com poll aggregation site today gives Clinton's Democratic allies running for Senate seats [a 63% chance of winning the four seats](#) necessary to secure a majority.

### The \$50bn recording

The House looks less likely. Nevertheless, Leerink analyst Geoffrey Porges wrote that revelations last month that Mr Trump had used "locker room language" in discussing women shook the race enough that investors began considering a Democratic sweep a more realistic possibility and started selling biotech shares.

Mr Porges estimated the cost was \$50bn in biotech valuations and resulted in a 13-14% valuation discount. Therefore, Republicans retaining control of the House, and perhaps the Senate too, could result in as much as a 20% recovery for biotech stocks next Wednesday.

Ironically, drug pricing is one area where the two nominees have found common ground, and where members of Congress put aside their differences and got involved in the practices of Mylan, Valeant and Turing. Both Ms Clinton and Mr Trump have spoken in favour of allowing Medicare to directly negotiate prices with drug companies, although that is not included in Mr Trump's formal [health care reform plan](#) published by his campaign.

However, reimportation of drugs – meaning that the US government would allow less expensive versions of FDA-approved drugs marketed overseas to be brought into the US for sale – is one provision both nominees still endorse.

Ms Clinton has thrown an [additional pricing proposal](#) in the mix – demanding that Medicare pay the same amount for drugs for low-income beneficiaries as Medicaid does. This mirrors a closely-watched referendum in California that if successful would require drug companies to charge state agencies no more than they charge the US Department of Veterans Affairs health system.

Without a Democratic majority in both houses, those national pricing initiatives will be hard goals to achieve, which is why the sector will closely watch if the balance of power shifts with this election.

But even with a Congress partly controlled by Republicans, a president can initiate programmes through regulation and other executive action that can affect pharma reimbursement. For example, Rick Weissenstein, a Washington-based health care analyst with Cowen, points to a proposal by President Barack Obama's administration that would limit the markup physicians can claim for high-cost, complex drugs that must be administered in health care facilities ([Medicare opens limited front in US pricing war, March 10, 2016](#)). That proposal, opposed by many in the sector, is one that Ms Clinton is more likely to retain than is Mr Trump.

Furthermore, Ms Clinton has endorsed work in cost-effectiveness evaluations like that of the Institute for Clinical and Economic Research (ICER) as a means of controlling high prices.

### Repeal and replace

As with Republican congressional allies, Mr Trump has endorsed repealing and replacing the Affordable Care Act (ACA), which perhaps should be viewed with some concern by the pharma sector as it could lead to an erosion in coverage, either in terms of the number of people who have health insurance or how generously their plans reimburse for drugs.

However, Mr Weissenstein notes that Congress is not likely to pass any changes to health insurance laws that would jeopardise coverage for the 20 million people who have obtained it under the ACA. Mr Trump has suggested policies endorsed by Republicans in the past, such as health savings accounts backed by high-deductible catastrophic coverage and reducing the cost of health insurance policies to individuals not covered by employers by ending state-by-state licensing of such plans.

A change in administration also brings about transitions at regulatory agencies, and the FDA is not immune from this. Should Mr Trump win, Mr Weissenstein believes that senior officials would be more likely to depart than if voters elect Ms Clinton, who would probably be more eager to maintain some continuity.

The current commissioner, Robert Califf, has been in office only since February. Should staff turnover occur, that has the potential to slow drug review while a new commissioner gets a new team in place.

Given the central place drug pricing has taken in this campaign and, indeed, policy debate in the last two years, the results of the election next week have the potential to drive big biopharma share price moves on Wednesday. These should not be taken as an endorsement or condemnation of the victor, but rather as investors' judgements of the sector's risks following the inauguration of the next US president.

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