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Elections mark start of next chapter in drug pricing controversy



Presidential and Senate races plus California

Proposition 61 are key perception drivers. Hillary Clinton is perceived to be more negative for the drug industry than Donald Trump. If the Democrats take the Senate as many investors fear, Democratic Senators such as Sanders and Warren could chair committees and call hearings to investigate pharma-bio pricing. A surprising Democratic sweep would be the most negative for perception. If the Republicans

maintain control of the Senate and the House, it would be a perception positive for pharma-bio. Prop 61 intends to prohibit California from paying any more for a drug than the U.S. Department of Veterans Affairs pays, but the VA may not disclose net prices to CA. See Key Nov. 8 swing factors.

Part B demo could be finalized soon after the election—will it be watered down and by how much? Centers for Medicare Medicaid Services (CMS) still needs to finalize the proposed demo. Investors expect the demo to be watered down, and the more it is diluted the better for perception. It is unclear how much CMS will back down as it was likely expecting to receive significant criticism when it designed the demo. See Medicare Part B demo.

In 2017 IPAB is expected to be triggered and PDUFA will be up for reauthorization. The Independent Payment Advisory Board (IPAB) is designed to limit Medicare pricing/access for drugs and devices, and most industry insiders expect the Medicare Trustees to trigger it next year, after which the next President and HHS could pursue authority to implement it. Separately, the Prescription Drug User Fee Act (PDUFA) VI has to be reauthorized in 2017, and we understand that some Democrats want to tie drug pricing reforms to PDUFA. See IPAB in 2017.

Last but not least, market forces are driving greater pressure in crowded categories with me-toos and the situation is likely to worsen in 2017 and beyond.

For example, during 3Q earnings call, Lilly and Amgen highlighted net pricing pressure for Humalog and Enbrel, respectively, while Novo lowered long-term expectations citing diabetes price pressure. This winter, we will be watching how much branded pharma raises list prices relative to prior years, company guidance for 2017 (which will reflect expected US prices net of rebates/discounts), and the initial impact of biosimilars in major categories, including Lilly's Basaglar (version of Sanofi's Lantus) in diabetes and Pfizer's Inflectra (version of JNJ's Remicade) in rheumatology.

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