

CAPITOL STREET

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Biotech & Pharma: Thoughts from the Road

IRA Prices, Orphan Fix, Part D, 340B, 40 Amino Acids, Biosecure Timing

Relevant Companies

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We spent time on the road discussing biopharma topics over the last two weeks. Highlights are below on key topics of interest in DC.

»» Key Points

BIOSECURE could pass on a stand-alone basis before December ([here](#)). The House is scheduled to vote on the bill on June 17. We could see full passage – by both chambers – ahead of December, the typical deadline for the Defense Authorization. There is momentum to get it done. Our recent analysis is [here](#) and [here](#).

There is more momentum to fix 9-13 ([EPIC Act](#)) and orphan drug exclusions ([ORPHAN Cures Act](#)) than 6 months ago. We will watch for lame duck action on the orphan drug fix, which we think is a commonsense fix to the IRA. 9-13 small molecule fix (parity at 13) is less likely because of the cost to the government.

Will Congress alter the amino acid count? Recall that 40 amino acids is the cut off between small molecule and biologic. We do not see Congress altering that threshold anytime soon.

We don't think CMS will peg Xarelto and Eliquis prices to Warfarin. CMS doesn't want to be blamed for killing innovation in our view, as it decides prices for year one (2026). We think the agency will be thoughtful about comparators and recall new prices will be out by Sept 1. We do think that with CMS looking at a bigger universe of comparable therapies (in 2027 proposed guidance [here](#)) that the agency will have more latitude to lower prices incrementally. Our take is [here](#).

Why is no one talking about Part D restructuring? They should be. A \$2,000 OOP cap means that prescription volume will only increase in 2025, positive for many manufacturers. Other therapies will be impacted (some positively, some negatively like HIV meds) with the new catastrophic liabilities (60% plans, 20% pharma, 20% Medicare).

340B reform has momentum – real momentum for 4Q24 – but no government budget impact. The Gang of Six in the Senate ([here](#)) has floated discussion drafts, with a version likely coming to fruition this fall. The bill

could pass in the lame duck session of Congress. As a reminder, 340B reforms do not cost or save the government dollars, so pharma and hospitals have been duking it out in court, with state 340B reforms passing in certain states as well (contract pharmacy protection: MD, MS, KS, WV, AR, LA; 340B reporting requirements: MN, ME, WA). Last week, NVS sued Maryland for contract pharmacy requirements; we could see more legal action in states with new 340B laws in place.

Most Favored Nation. The Part B policy – presented by President Trump in his first term but never implemented -- will likely be back if the former President is elected. We think it could be released, out of the gates, with the 2025 tax reauthorization / ACA subsidies deadline (Dec 31, 2025). Recall that prices of the 50 top high spend Part B therapies would be pegged to prices paid by OECD countries with a GDP that is at least 60% of the U.S. GDP per capita.

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