

## Biden Pushes *Build Back Better* Drug Reforms in VA

### Drug Inflation, Insulin \$35 Cap Emphasized While FDA's Califf Vote Lines Up

This afternoon, President Biden traveled to rural Virginia (Germanna Community College) with Rep Abigail Spanberger (D-VA) to make a case for passing drug price reforms by the US Congress. The President pointed to higher prices in the US versus abroad, and that CEOs point to pricing new therapies at a “price the market will bear.” He singled out a \$14,000 per month lymphoma medication that is available at \$6,000 in France.

- **President Biden used inflation messaging around Rx drugs as he pushes for Drug Price reform passage (as a part of BBB).** Biden wants manufacturers to be penalized for pricing above inflation, a key part of BBB, and he mentioned that in his speech today. Manufacturers that raise prices above inflation would have to “rebate” back to the government This would start in 2023. Biden simultaneously acknowledged COVID related supply chain issues as weighing on industry.
- **An insulin OOP cap of \$35 was urged (per BBB), and a young diabetic took the stage to share his experiences along with his mom.** Shannon and Joshua Davis, a mom and her 12 year-old son, spoke to \$6-7K in annual costs for insulin alone. They share insulin and use expired insulin to stretch dollars. Biden noted that insulin costs less than \$10 to make.
- **Biden stated (again) that the US system should emulate the German one.** Biden provided similar messaging on the Presidential campaign trail. We do not believe that an ICER like system for drug & device coverage will happen in the US.
- **Simultaneously, Senate Leader Chuck Schumer (D-NY) appears to have lined up Senate votes for FDA Commissioner nominee, Dr. Robert Califf.** While Califf's nomination looked to be in trouble over the last 1-2 weeks, Califf has made the rounds on the Hill to assuage lawmakers' fears. He appears to have the needed 51 votes, and will likely garner GOP support as well (6-10 votes based on our latest count). There could be a vote as soon as next week.
  - Rob Califf pledged not to work with industry in any capacity (i.e., FTE, consulting) for 4 years post government service (Sen. Warren, D-MA).
  - Dr. Califf garnered Sen Wyden (D-OR) support around FDA's use of accelerated approvals. Wyden believes that the FDA should enforce sponsor post-market commitments more strongly.
- **OUT TAKE / NEXT UP:** See BBB drug reform(s) as a reminder below. Biden also touted Cancer Moonshot 2.0 today, with a goal of reducing deaths by 50% over the next 25 years as well as improving the lives of cancer survivors. Biden today urged the Senate to pass BBB, as the House has done, while in at a rural Virginia community college. We believe that once a budget deal is made and passed, Senators will pivot to a very skinny version of BBB: ACA subsidies, drug reforms, along with possibly universal Pre-K as well as green energy provisions. The bill appears dead in its most recent format, but we have seen legislation rise from the ashes before. We believe that Congress has until summer to pass BBB, despite mid-term election season campaigning. Lowering high drug prices is a bipartisan initiative.

## BBB DRUG REFORM HIGHLIGHTS

- **Inflationary Rebates in Part B & D starts 2023.** The floor would be 2021 prices. Rebating the delta between CPI and price increases back to the government is not a true negative for industry as it doesn't address launch prices. However it does generate significant savings (%80 B over ten).
  - Base year 2021
  - Rebate based on total units sold
  - All brand and generic drugs are subject to the Rebate
- **Part D reform starts in 2024:** We have called Part D restructuring low hanging fruit since the get-go as manufacturers, insurers, patient groups and Congress (both sides of the aisle) support updating the 2005 drug benefit. Creating an OOP cap as well as industry liabilities in the initial and catastrophic phases of Part D are re-jiggered. Minimal savings of \$2 B over ten.
  - \$2,000 OOP spending cap
  - "Smoothed" over the calendar year
  - Insulin co-pays capped at \$35 per year
  - Drugs that are negotiated are *exempt* from manufacturer liability
  - Initial phase: 25%/65%/10% for bene/plan/brand manufacturer (versus 25%/75%/0% in current law) *The 65% is 75% for generic drugs*
  - Catastrophic phase: 0%/60%/20%/20% for bene/plan/manufacturer/govt (versus 5%/15%/0%/80% in current law) *The 20% for brand is 0% for generics and 40% for Medicare*
  - Part D "Donut hole" is eliminated
- **Negotiation in Part B & D starts in 2025.** There would be an exclusion for small biotech firms and generates \$83 B over ten.
  - The Secretary would pick the highest gross spending (Parts B & D)
  - These would be single source drugs outside of their exclusivity period:
  - 9 years for small molecule products & 13 years for biologics & insulin included
  - Negotiate 10 drugs in 2025, rising to 20 drugs in 2028+
  - Manufacturers could submit R&D costs, prior financial support, extent to which product addresses unmet need, whether the drug represents an advance beyond existing treatments
  - Then, a back and forth ensues to agree to a "fair" price
  - The exceeded price cannot be > 76% of its non-federal AMP for a small molecule drug fewer than 12 years but more than 5 years passed initial exclusivity
  - > 65% of its 2021 non-federal AMP price for a drug 12-16 years passed initial exclusivity
  - > 40% of its 2021 non-federal AMP price for a drug more than 16 years passed initial exclusivity
  - Price reductions are akin to the relative price reduction of when a generic enters the market

## Background

### DEC 2021 -- FRAMEWORK OVERALL

- **A framework of the Deal on Reconciliation released October 28 contains the following insurer, home health and PBM-friendly healthcare measures.**
  - **4-years ACA tax credits (2022-25)**
  - **4-years Medicaid Gap access ACA plans (no federal option)**
  - **Medicaid FMAP phase out bump (to 3.0% then 1.5%, in 6 and 12 months respectively)**
  - **Rebate Rule repeal (saves \$145 B)**
  - **Homecare (\$150 B)**
  - **No MA pay rate reductions**
  - **New hearing aid benefit, with dental/vision coverage omitted.**
- **Affordable Care Act subsidies would continue for four years, but we think will be extended beyond that (if passed) given the popularity of Marketplace products.** The subsidies allow Americans to feel less price sensitive when purchasing Exchange products for low or \$0 premiums (SEP lasted about 6 months in 2021, with record enrollment). We had predicted a 5 year extension, and 4 years is the result of the haggling to trim spending.
- **Medicaid Gap (3 M Americans) Federal program involving third parties starting 2025 falls out. Four years (2022-25) of ACA premium tax credits aiding those Americans who fell through the cracks.** Subsidies would be provided for Americans to buy Marketplace plans in the 12 non-expansion states starting in 2025. The states are: AL, FL, GA, KS, MS, NC, SC, SD, TN, TX, WI, WY.
- **Hearing aids are in; the rest is out Medicare Dental, Vision.** The House asks for Dental (2028), Vision (2022) and Hearing (2023) benefits be added to basic Medicare, but we had said it would v. likely be pared down in the final package to, perhaps, Dental alone. Dental has the most support (CMS has added a new Chief Dental Officer FYI), and Biden mentioned the possibility of Dental vouchers (\$800) at a CNN town hall in late October.
- **\$150 B in homecare \$s.** We had said \$100-150 B is likely, to expand access to home-based services (AMED, LHCG, others) and care for millions of older adults and people with disabilities. It will also strengthen the direct care workforce by improving provider payment rates and giving states the resources to improve their care infrastructure. The legislation also makes permanent the Money Follows the Person and the spousal impoverishment program, both successful Medicaid programs that help low-income older adults and individuals with disabilities receive home-based services.