

## State of the Union

### Innovation Agenda, COVID PHE & Supply Chain, Drug Reforms & Insulin

On Tuesday March 1, President Biden is slated to deliver his first State of the Union. Masks will not be required in the chamber, and security measures are already in place in the Capitol area. The State of the Union is an opportunity for the President to tout successes in the first year, and discuss the path forward. Below we lay out the main messages we expect to hear on healthcare, as the President's approval rating hovers ~37% (per Washington Post – ABC News poll) .

- **COVID-19.** Not a declaration of victory, but progress. We expect Biden to list successes -- on the innovation side with vaccine development and distribution, along with therapeutic advances. Mask mandates are being lifted by CDC and the states, Cases and deaths as well as hospitalizations are dropping in the US. Biden is likely to discuss the endemic nature going forward as something to live with versus abolishing altogether.
- **Supply Chain & Lessons Learned.** Biden will acknowledge COVID related supply chain issues as weighing on industry, so that Americans can be better prepared 'next time.' The US has been too reliant on off shore supplies, devices, as well as biopharmaceutical ingredients, and the Congress is simultaneously looking into this issue so Americans aren't caught flat footed yet again.
- **Public Health Emergency (PHE).** We expect the PHE to end mid-year, but it won't be a light switch event. Biden may point to a mid-summer timeline. Telehealth may be touted, as it was a life-saver during COVID, and we believe that the telehealth waivers (~40) will be extended for 2 years in an upcoming appropriations bill that must be addressed by March 11.
- **Behavioral Health & Equity.** After two years of captivity, Americans are struggling. The Administration is committed to addressing substance abuse, mental health and Biden may mention the public health dilemma, at the very least. The Senate Finance Committee is compiling a mental health package which we could see passing by year end.
- **Drug Price Reform.** Biden will try to breathe life into BBB. Democrats want manufacturers to be penalized for pricing above inflation, a key part of BBB. Manufacturers that raise prices above inflation would have to "rebate" back to the government, which would start in 2023. Part D would be restructured, with a popular OOP cap of \$2k, which starts in 2024. The most controversial policy, drug negotiation for a limited subset of Part B&D products, would start in 2025+.
- **Diabetes -- Insulin \$35 Cap.** An insulin OOP cap of \$35 will be urged (per BBB), and the President spoke in VA last month, highlighting a young diabetic who 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 at that speech that insulin costs less than \$10 to make.
- **German System?** Biden may state (again) that the US system ought to emulate the German one. Biden provided that messaging in drug reform speech in February (at Germanna Community College in rural Virginia) on the Presidential campaign trail. We do not believe that an ICER like system for drug & device coverage will happen in the US.
- **Innovation.** We have a new, well-regarded FDA commissioner, one who will reform the Accelerated Approval & EUA process, address advanced manufacturing, and also likely create new Centers of

Excellence in Cardiology and Neurology. Medical technology and biopharmaceutical innovation is key to jobs and competitiveness in the US and abroad, and Biden will likely highlight our dominance.

- **Cancer Moonshot.** Recall the President has revived the Moonshot. A RFI (Request for Information) was issued around cancer diagnostics, and we await funding to further the oncology agenda. Biden may discuss the 2.0 Moonshot goals, funding sources, and next steps in his State of the Union speech.
- **ARPA-H.** ARPA-H is a DARPA inspired investment to fund high risk, game-changing investments in public health but is dangling on life support. Recall DARPA is noted for bringing the internet to scale and accelerating investment in artificial intelligence. ARPA-H is designed to be vehicle for accelerating innovation that doesn't fall into a specific "public" or "private" investment category. ARPA-H would re-define previously siloed investment strategies by creating a hybrid model leveraging public private partnerships that bring scientific discovery to market. Congress is finalizing the ARPA-H budget (\$3 B is the current allocation), enabling OSTP to begin work this year.
- **Affordable Care Act (ACA).** Marketplace subsidies sunset at the close of 2022. Record enrollment has taken place throughout the PHE. We expect that bipartisan lawmakers will rally to pass an extension of said subsidies this year. We would expect ACA subsidies to ride alongside Rx reforms as the latter pays for the former.
- **OUR TAKE / NEXT UP:** With inflation (gas, groceries, autos, furniture) being Americans' #1 concern, along with the geopolitical issues in Ukraine/Russia, healthcare is not likely a top priority for Biden at his first State of the Union. However, Biden is likely to discuss drug reforms, ACA coverage continuation, and the need for robust medical technology and innovation, public-private partnerships, per Cancer Moonshot, ARPA-H, and pandemic preparedness. Mental health reforms and health equity top the Biden agenda, as well, and could get a mention.

## 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.