FTC Pharma Bills May Be In Mix With BBB

More Drug Pricing News, Anti-Pharma Meeting Next Week

BBB

- Renewed BBB talk has our dander up that a bill could pass in 2022, perhaps this fall as
 lawmakers understand spiking premium notices coming as subsidies expire. As we wrote last
 Tuesday, Sen. Manchin (D-WV) provided upbeat comments in Davos as well as at an AARP event.
 Members are optimistic a bill can get done: if not this work period, then perhaps next., ahead of
 9/30 Reconciliation deadline
- Drug pricing news is expected any day now...and remember this all could bleed to the fall. We note that negotiations are ongoing, but Manchin has voiced his support for drug reform in his public remarks both at Davos and at an AARP forum in his state, West Virginia. There is a feeling that something can be accomplished this year and we would assume CBO scores are being shared between Sens Manchin & Schumer.
- Sen. Joe Manchin (D-WV) stated recently that Drug reforms could go alone i.e., not as a payfor. That is, de-linked from ACA subsidies, per a CNN interview this week. We think it would be a
 missed opportunity not to extend ACA subsidies with Drug reform offsets, as Americans receive
 notices this fall that their premiums will spike.
- A reminder on the BBB Drug pricing reforms in the mix. We have said that a 'clean' way to pay for ACA subsidies is drug pricing reforms. One roughly offsets the other:
 - ACA subsidies made permanent cost over \$200 B (here) and \$25 B/ten (for one year, 2023)
 - Drug reforms in the prior version of Build Back Better Act save about \$170 B/ten
 - o CPI (Inflationary) rebates generates \$80 B/ten
 - o Part D restructuring generates \$2 B/ten
 - Limited Part B&D drug negotiation saves \$83/ten

FTC

- This week, CBO scored 3 patent related provisions that increase FTC's ability to regulate anticompetitive drug practices. These provisions, if implemented, could save the government \$1.9 B over 10 years.
 - The Affordable Prescriptions for Patients Act (<u>S.1435</u>) defines "product hopping" as an anticompetitive practice which allows FTC to penalize and sue companies that engage in the practice. It also limits the number of patents that can be included in infringement claims to 20. CBO reports savings of \$322 M over 5 years and \$1.1B over 10.
 - Preserve Access to Affordable Generics and Biosimilars Act (S.1428) bans pay for delay deals.
 CBO reports savings of \$358 M over five years and \$685 M over 10.
 - Stop STALLING Act (<u>S. 1425</u>) allows the FTC to sue individuals or entities that submit baseless FDA citizen petitions and allows the courts to impose civil penalties for each day the FDA reviews these petitions. CBO reports savings of \$42 M over five years and \$117 M over 10.
- Anti-competitive FTC/patent practice provisions, albeit small (<\$2B) could be a small pay-for in a slimmed down BBB. While BBB's potential drug provisions (\$170 B/ten) roughly offset costs from ACA subsidies (>\$200 B/ten if made permanent), new spending is still a major point of contention in BBB negotiations. Anticompetitive provisions may be bundled in a "slimmed" BBB. BBB provisions we may see include an extension of ACA subsidies, limited Medicare Part D drug

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negotiations, CPI (Inflationary) rebates, Part D benefit restructuring, green energy tax credits, and inflation/deficit reduction provisions.

- A Federal Trade Commission (FTC) meeting (June 14-15) next week looks at Biopharma mergers. Titled "The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers", the meeting will include the new FTC commissioner Rebecca Slaughter and a panel organized by members of the Multilateral Pharmaceutical Merger Task Force. Public comments on pharmaceutical mergers and their enforcement guidelines will help shape FTC/DOJ's reassessment of their competition analysis framework and M&A enforcement guidelines.
- NEXT STEPS: We think we could get more headlines this week into next. Senate Finance Chairman Wyden (D-OR) and House Leader Pelosi (D-CA) staff are reportedly working on drug reforms in tandem with the renewed talk of drug reforms at the leadership level. We note that negotiations are taking place behind the scenes. The common thinking is that ACA subsidies + Drug reform would need to be completed by July 4 recess. Congress has its hands full with gun reform, FDA User Fee bills, mental health legislation, inflation and ongoing negotiations for the US Innovation and Competition Act. FY22 Reconciliation instructions expire 9/30 so there is time after the August recess, but the upcoming Nov 8 mid-term elections complicates the process.