

# POTENTIAL POLICY REFORM: UNITED STATES

## GOVERNMENT REGULATION OF PHARMACEUTICAL PRICING IN THE U.S.?

ASCENIAN HTA AND  
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### CONTEXT

- For years, US politicians have been discussing a role for the federal government in drug price negotiation
- Recently, with a Democrat in the White House and Democrat control of both chambers of the US Congress (i.e., Democrat majority in the US House; tie-breaking vote in the US Senate cast by a Democrat vice president), the discussion has picked up steam
- The most recent version of the Reconciliation bill, which may be signed into law during the week of November 15, 2021, calls for the federal government to negotiate the prices of certain drugs - a first for the US if it comes to pass

### DETAILS

- The latest version of the Reconciliation bill (also referred to as "Build Back Better") calls for establishment of a drug negotiation program (DNP)
- Under the DNP, starting in 2025, the Secretary of Health and Human Services (HHS) will select certain drugs for negotiation of maximum fair prices (MFPs)
- Identifying the drugs
  - Each year, HHS will start by identifying 100 branded, sole source, high-priced pharmaceuticals, for which 9 years have passed since FDA approval in the case of small molecules, 12 years in the case of biologics
  - From this list, HHS will negotiate MFP for up to 10 drugs in 2025, 15 in 2026 and 2027, and 20 in 2028 and later years
  - Insulin prices will be negotiated
  - Exempt: some orphan drugs and other drugs with < \$200 M expenditure
  - Part D plans will be required to cover selected drugs
- Negotiation and setting MFPs
  - HHS will negotiate with drug makers to set MFPs
  - The ceiling for MFPs will be:
    - 75% of non-federal average manufacturer price for drugs marketed for 9 to 12 years
    - 65% for drugs on the market for 12 to 16 years
    - 40% for drugs on the market for > 16 years

### CONCLUSIONS & POTENTIAL DIRECTION

This bill is not yet law. According to the best estimates, the bill may become law by the week of November 15th. It may change again before then. If this bill does become law in its current form, then starting in 2025, the US will move closer to other countries in having the government play a key role in drug price setting. Much remains uncertain. Stay tuned!

#### CONTACT:

MICHAEL.EPSTEIN@ASCENIAN-CONSULTING.COM