February 6, 2024

# Pill Penalty Fix Bill (9-to-13) Unlikely to Pass

## Orphan & Genetic Rx IRA Fix Bills Also Unlikely While GLP-1 Cost Savings Passes House Cmte

Relevant Companies

## Our Take & Next Up

**The *Ensuring Pathways to Innovative Cures (EPIC) Act* is unlikely to pass this year but Pharma CEOs are dragged to Capitol Hill and the Budget Committee acknowledges cost savings from GLP-1s via *Savings Act* passage.** The EPIC Act was introduced in the House to address the 9 to 13 disparity between small molecules and biologics in Medicare's Drug Negotiation Program (here). The bill has been referred to House E&C and Committee on Ways&Means for review. There are several other reforms in play for the IRA (also unlikely to pass near-term). (1) ORPHAN Cures Act expands the orphan drug exclusion to protect from being on the list and the (2) Maintaining Investments in New Innovation (MINI) Act which increases the timeline before gene therapies (including siRNAs & ASOs) would be negotiated from 9 be 13 years instead of being negotiated at the same time as small molecules. We preview the Senate HELP Pharma hearing featuring Pharma CEOs as well as GLP-1 cost savings per a bill passed today in the House.

## Key Points

**The pill penalty "fix" introduced in the House would address the "small molecule disincentive" providing parity at 13 years but scores as a cost and will unlikely pass this year** The EPIC Act introduced by Reps. Greg Murphy, MD (R-NC), Don Davis (D-NC), and Brett Guthrie (R-KY) would raise the small molecule drug eligibility period (9 years) for negotiations to be the same as biologics (13 years). As a reminder, CMS negotiated prices go into effect 9 years after approval for selected small molecule drugs and 13 years after approval for selected biologics. The bill does not have a Senate companion bill or a score yet, but it is expected to be costly.

**As a reminder, there are two other IRA fixes that have been introduced: (1) orphan exclusion expansion & (2) extending negotiation timeline for genetically targeted therapies**. Both bills cost the government dollars and are not expected to pass anytime soon.

- *The ORPHAN Cures Act* (here), introduced in both chambers last fall and has bipartisan support, would expand the IRA orphan drug exclusion (costs roughly $5 B over 10). The bill would (1) allow a negotiation exemption no matter how many orphan designations a co has (now limited to one orphan designation) and (2) if a second non-orphan designation triggers the IRA, then the clock starts ticking at the time of the second non-orphan indication.
- *The MINI Act* (here), also introduced in a bicameral manner with largely GOP co-sponsors, extends the Medicare drug negotiation threshold to 13 years for drugs that incorporate or utilize a genetically targeted

technology "that may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product." NVS noted last week that their siRNAs could be negotiated at the 9-year mark and CEO Vas Narasimhan commented that there is bipartisan support despite unlikely enactment this year.

**On Thursday Feb 8, the Senate HELP committee (Chair Sanders, I-VT) will hold a drug pricing hearing to name & shame Pharma CEOs (MRK, JNJ and BMY).** Joaquin Duato (CEO of JNJ), Robert Davis (CEO of MRK), and Chris Boerner (CEO of BMY) will testify on prescription drug prices. The committee is expected to discuss a range of pricing reforms including the IRA and PBMs. We expect no new policies to be introduced; the Chair will likely seek headlines versus an honest discussion of myriad drug pricing issues.

**GLP-1 downstream health benefits would be incorporated into the *Preventive Health Savings Act,* as passed by the House Budget Committee today.** Separately, today the House Budget Committee (Chair Arrington, R-TX) unanimously passed out of committee here. We do not think the bill is likely to pass the Senate but the issue of long-term benefits of GLP-1s continues to be front of mind for lawmakers. The bipartisan House bill requires the Congressional Budget Office (CBO) to determine whether proposed legislation would reduce spending outside of the 10-year budget window through the use of preventive health and preventive health services. Committee members called for CBO to have better data to make decisions accurately.

**As a reminder, please find our take on other prescription drug and PBM reform topics below.**

- FDA's state importation program – *Unlikely to matter*. FDA cleared FL's drug importation program a few weeks ago, and the state is now expected to submit a pre-important request. Multiple steps must take place before importation can start, we note that biologics are excluded and the Canadian government does not intend to ship millions of prescriptions outside of its borders. Next up, Colorado hopes to be the next to be approved for the FDA importation program after it submits an updated plan this year. Our 1/5 analysis is here.
- Medicare's drug negotiation program – *Lawsuits are ongoing, with industry aiming to take this to the Supreme Court if needed*. Initial price offers have been sent to selected manufacturers with the public unlikely to see any details on pricing until the release of the maximum fair price by September 1. Co's have 30 days to either accept the offer or propose a counteroffer with the negotiation period to continue through the summer. Our 1/31 analysis is here.
- March-In rights guidance – *Unlikely to materialize for any one drug/manufacturer near-term*. In December 2023, the Department of Commerce released guidance on how government agencies should review criteria to determine march-in rights authority for certain therapies. The price and availability of a product *will* be among the factors the department will recommend that agencies consider. Our 12/7 analysis is here.
- Inflationary rebates – *Not terribly impactful but penalties are steadily accruing for certain manufacturers (to be paid in 4Q2025).* In total, prices of 64 drugs increased faster than inflation over the last four quarters. CMS has until September 30, 2025, to send drug manufacturers invoices for Part B rebates and has until December 31, 2025, to send invoices for manufacturers that owe Part D rebates. Our most recent De12/14 analysis is here.
- Medicaid AMP cap removal – Starting in January 2024, Medicaid "best price" analysis must stack (aggregate) the cumulative discounts, rebates, or other arrangements provided to different entities. In response to the elimination of the rebate cap, some drug companies are lowering prices or discontinuing drugs in favor of lower priced alternatives to avoid paying additional Medicaid rebates. Companies with recent price cuts include LLY & NVO (for their insulin products), and GSK (asthma inhalers).
- CMMI's new cell & gene reimbursement pilot – *Slow going, helpful for Sickle Cell Disease (SCD) co's and Medicaid programs*. CMS announced it is prioritizing SCD as the first therapeutic area of focus for the Cell and Gene Therapy (CGT) model (start January 2025). CMS anticipates releasing a Request for

Application to manufacturers (VRTX, CRSP, BLUE) in early spring 2024 and an RFA and Notice of Funding Opportunity to states in summer 2024. Our Jan 30 analysis is here.

- Anti-PBM reform – *Reforms likely to pass 4Q24 with no draconian measures envisioned.* In December 2023, anti-PBM reform passed out of the House with price transparency, PBM reform healthcare package (here). The House reforms contained provisions on (a) Medicaid spread pricing bans (b) ERISA transparency provisions, and (c) disclosures on broker compensation. On the Senate side, Senate Finance (Chair Wyden, D-OR) passed a bipartisan mental health and anti-PBM package (here). The Senate bill includes a Medicaid spread pricing ban, Part D transparency requirements, de-linking. The Finance policies are the likely preferred reforms for the Senate as the chamber has not fully vetted the House's package. Transparency reforms seem most likely to pass on their commercial side but no individual company rates are expected to be disclosed to the public.

---

**Ipsita Smolinski**
**Managing Director I Capitol Street**
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

**900 19th St NW 6th Fl**
**Washington, D.C. 20006**

CAPITOL STREET

---