Biopharma executives are worrying about a nightmare scenario in which new drug pricing legislation, combined with an international reference pricing scheme, importation and additional price controls, would deal the industry what they perceive as a major blow.

The Prescription Drug Pricing Reduction Act (PDPRA) of 2019, introduced Tuesday by Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and ranking member Ron Wyden (D-Ore.), would cut biopharma revenues by more than $100 billion over 10 years, according to Congressional Budget Office (CBO) estimates.

Biopharma CEOs told BioCentury that they are willing to accept a hit of up to $150 billion in exchange for a cap on out-of-pocket costs for patients and assurances that there will be no further price controls. An out-of-pocket cap ensures that patients can access drugs and could reduce long-term pressure to regulate drug prices.

Industry is concerned about the way the bill’s cap is structured, including the size of a new subsidy paid by industry, and especially about the prospect that other measures that reduce revenues and control prices will be added on top of that.

Broad outlines of the legislation have been discussed for weeks, but it included provisions that surprised policy wonks and lobbyists. Surprises include requirements to justify launch prices for new drugs by disclosing a variety of development and marketing costs, incentives to use biosimilars, and the absence of measures that target PBMs or rebates.

“It avoids the core issue of the pricing system and does nothing to hold the PBMs or insurers accountable.”

Jeremy Levin, BIO

The legislation was created in consultation with and has been endorsed by the Trump administration. The White House has not said whether it will pile on additional price controls such as the International Pricing Index reference pricing scheme for Part B drugs.

“The @WhiteHouse is encouraged by the bipartisan work of Chairman Grassley and Senator Wyden to craft a comprehensive package to lower outrageously high drug prices, and today we are engaging with coalitions to help build support,” White House spokesperson Judd Deere tweeted.

PhRMA said in a statement that the bill would “siphon more than $150 billion from researching and developing new medicines while giving those savings to the government, insurers and PBMs -- not seniors.”

BIO endorsed aspects of the legislation, especially its inclusion of a cap on Part D beneficiary out-of-pocket spending, but expressed alarm at its adoption of a “framework that punishes some of the most innovative biotech cures and transformative therapies.”

In addition to the specific provisions, BIO said it is trying to assess how the bill fits into the bigger picture of Trump administration initiatives and potential legislation.

“Our first priority is to understand the universe of things that are on and off the table, especially the International Pricing Index,” Tom DiLenge, president for advocacy, law & public policy at BIO, told BioCentury.

BIO’s second priority is “ensuring that the out-of-pocket cap is structured properly. That’s a huge issue for us and for patients,” he said.

Perhaps more than what is in the bill, BIO is upset by what was left out. The bill would leave in place many of the perverse incentives that reduce access to medicines, including incentivizing PBMs to demand rebates in exchange for formulary placement and allowing payers to charge co-pays for life-saving medicines.
“It avoids the core issue of the pricing system and does nothing to hold the PBMs or insurers accountable,” BIO Chairman Jeremy Levin told BioCentury. Levin is CEO of Ovid Therapeutics Inc.

PDPRA would achieve most of its savings by imposing inflation caps on drug price increases for Medicare Parts B and D, and by restructuring the Part D benefit.

It seeks to modify the Part D benefit to eliminate the coverage gap, or donut hole, and require drug manufacturers to pay a 20% subsidy on prices above $10,000 per year.

Grassley has scheduled a July 25 Finance Committee markup hearing to consider amendments to PDPRA and to vote on advancing it for a vote by the full Senate. Pharma lobbyists are scrambling to persuade Republicans on the committee to ask Grassley to postpone the markup but don’t expect to succeed, an industry lobbyist told BioCentury.

If the markup is held, the bill is likely to be passed with few changes. While some Republicans may oppose it, given the White House’s backing and strong support from Democrats for addressing drug prices, the legislation is almost certain to be enacted by the full Senate.

Biopharma lobbyists hope to be able to modify the bill prior to enactment, and to gain commitments from the administration to kill the International Pricing Index for Part B drugs and drop plans for commercial-scale drug importation.

House Democrats are pushing for more direct price controls, including giving HHS power to set Part D prices, but they are likely to vote for PDPRA as an interim measure.

PART D BENEFIT REDESIGN

The restructure to Part D triggers the 20% liability to companies on drug costs after a beneficiary’s out-of-pocket drug spending reaches a threshold level.

The initial coverage phase would remain unchanged, with beneficiaries paying 25% of drug costs and plans paying 75%.

Instead of a donut hole in which drug companies pay 70% of costs to reduce costs to beneficiaries and plans pay 5% of costs, the catastrophic phase would start as soon as out-of-pocket costs exceed the maximum level for the initial phase.

The initial phase ceiling -- and the out-of-pocket cap -- would be $3,100 in 2022 and would be indexed to Part D spending growth in future years.

In the catastrophic phase, drug manufacturers would be responsible for 20% of drug costs, plans 60%, and Medicare 20%.

Drug company executives told BioCentury they are shocked by the 20% liability in the catastrophic phase. Based on discussions with Trump administration officials and Senate staff, they were expecting a liability of 9-14%.

CBO estimates that the Part D redesign would reduce out-of-pocket costs by $20 billion over a decade, while the inflation cap would save beneficiaries $7 billion, according to the Finance Committee.

WINNERS AND LOSERS

Exchanging the 70% donut hole subsidy for what amounts to a 20% tax on costs that exceed $10,000 would create winners and losers.

The most obvious losers are companies with products used primarily by beneficiaries who receive a low-income subsidy (LIS). Under the current structure there is no donut hole, and hence no subsidy, for LIS beneficiaries. Individuals with incomes up to 150% of the poverty level are eligible for the LIS program, and more than 12 million of the 43 million Part D enrollees in 2018 were eligible for LIS subsidies.

The 20% liability for LIS patients “would have serious negative consequences, both for patients with serious mental illness and addiction and for companies that have been pricing medicines fairly to facilitate patient access to them,” Richard Pops, CEO of Alkermes plc, told BioCentury.

“Without question, this policy would threaten access to existing medicines and future investment in treating” serious mental illness and addiction, Pops said.

Even more than lower-cost drugs for LIS populations, the 20% subsidy would be targeted at drugs for rare conditions and at curative drugs that, regardless of price control measures, will be priced far above the $10,000 level catastrophic phase threshold.

According to an analysis by Evercore ISI analyst Umer Raffat, manufacturers of drugs with annual wholesale acquisition costs (WACs) lower than $17,000 may benefit from exchanging the donut hole subsidy for the new rebate. Reductions in the donut hole subsidy for a drug with a WAC of $5,500 would lead to an increase in net revenues to the manufacturer of $1,176, he calculated.

Net revenues would be cut for higher-priced drugs such as oral cancer drugs. For a drug with a WAC of $150,000, net revenues would be slashed by $24,745, according to Raffat.
INFLATION CAPS

PDPRA would limit Medicare Part B and Part D drug price increases to the Consumer Price Index for All Urban Consumers (CPI-U).

CBO scores the inflation caps as saving Medicare $50 billion over a decade, according to the Senate Finance Committee.

The bill would require drug companies to pay a rebate to Medicare for any price increase above the CPI-U.

Biosimilars, generic drugs and vaccines purchased by Part B are excluded from the inflation rebates.

Manufacturer rebates would be deposited in the Medicare Supplementary Medical Insurance Trust Fund.

JUSTIFYING PRICES

The bill would require manufacturers to justify price increases, as well as launch prices of new drugs if the list price for a year’s supply or course of treatment is higher than the annual Part D out-of-pocket threshold.

The inclusion of requirements to justify the costs of new drugs was not included in previously introduced legislation and it came as a surprise to industry.

In 2022 the threshold for justifying launch prices of new drugs would be $10,000.

The new drug justification would apply only to drugs for which there are no therapeutic equivalents.

Information required in price justifications, which would be posted on the CMS website, “may include: individual factors contributing to the price increase; the role of each factor in the price increase; and manufacturer spending for materials and manufacturing, patents and licenses, or purchasing or acquiring the drug from another company, if applicable,” according to a summary of the bill.

In addition, manufacturers “may describe the percentage of total research and development spending for the drug that came from federal funds; total manufacturer research and development spending on the drug; total revenue and net profit from the drug each year since approval; total costs for marketing and advertising the drug; and additional information about the manufacturer such as total revenue and net profit for the period of the price increase, metrics for setting executive compensation, and other information such as total spending on drug research and development or clinical trials on drugs that failed to receive FDA approval.”

The bill would require HHS to create a process for manufacturers to designate information as proprietary and for the HHS secretary to redact data from the website if “public disclosure would directly lead to increased prescription drug prices.”

To increase biosimilar competition, PDPRA would increase the add-on payment in Part B for a biosimilar from 6% of the reference product's average sales price (ASP) to 8% of the reference product ASP for a period of five years.

COMPANIES AND INSTITUTIONS MENTIONED

Alkermes plc (NASDAQ:ALKS), Dublin, Ireland
Biotechnology Innovation Organization (BIO), Washington D.C.
Ovid Therapeutics Inc. (NASDAQ:OVID), New York, N.Y.
Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.