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KOLs call for updated Build Back Better to level playing field

Biopharma CEOs, investors call for same timeline for biologics, small molecules and lower out-of-pocket costs

BY STEVE USDIN, WASHINGTON EDITOR

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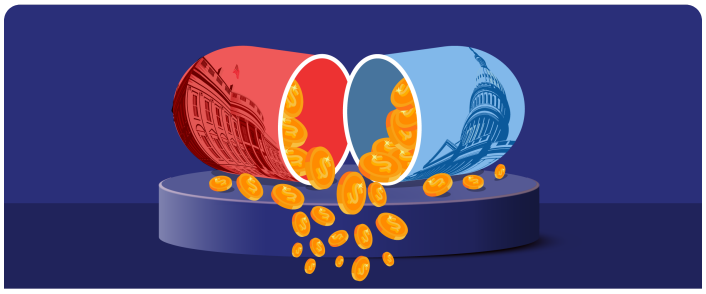

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Biopharmaceutical companies and investors are lobbying Congress to modify the Build Back Better Act so that it doesn't favor biologics over small molecules. They are also seeking a more generous reduction in out-of-pocket costs for Medicare Part D beneficiaries. And in a surprising twist, industry is supporting a dramatic expansion in the number of drugs subject to price-setting in exchange for adding a year of freedom from price regulation.

The industry has moved from trying to prevent any and all price regulation to ensuring that price regulations do not create unintended consequences that would skew drug development in ways that do not benefit the public or drug companies.

The proposal is spelled out in a public letter to President Joe Biden, HHS Secretary Xavier Becerra and congressional leadership, and drafted by Peter Kolchinsky, managing partner of RA Capital Management; Alex Karnal, chief investment officer & co-founder of Braidwell Management; Roderick Wong, managing partner and chief investment officer of RTW Investments; Gunnar Esiason, a cystic fibrosis patient and advocate; and Daphne Zohar, founder and CEO of PureTech Health plc (LSE:PRTC; NASDAQ:PRTC).

The letter has been signed by over 200 CEOs of small- and mid-sized biotechs, which collectively invest more than $11 billion in R&D, and by investors who manage about $46 billion in life-science focused capital.

It calls for Congress to decrease the maximum out-of-pocket drug costs for Medicare beneficiaries to $1,200 per year, or $100 per month, from the $2,000 annual cap in the Build Back Better Act that the House of Representatives has passed. The act would allow patients to spread the $2,000 throughout the calendar year.

Paul Hastings, president and CEO of Nkarta Inc. (NASDAQ:NKTX) and chairman of BIO, told BioCentury he signed the letter on behalf of BIO, as it reflects positions BIO is advocating with members of Congress.

BIO is working closely with PhRMA to persuade members of Congress to create a level playing field for biologics and small molecules, Hastings said. "It is great to incentivize biologics, but if you do that by hurting small molecules you are hurting patients."

The BBB Act passed by the House, as well as a version proposed by the Senate Finance Committee, subjects small molecules to Medicare price-setting nine years after they are launched, while the price-setting provisions kick in 13 years after launch for biologics.

"Whereas the 13 years chosen for biologics is only slightly shorter than the ~14 years that drugs have historically had market exclusivity before going generic, the BBB's nine years for small molecules is much shorter and problematic," according to the biopharma industry letter. "The differential discourages investment in small-molecule R&D for diseases primarily covered by Medicare."

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While a "very modest increase in average prices" would compensate for the reduction of a year of unrestrained pricing for biologics, cutting the period to nine years for small molecules "throws a wrench into what would otherwise be a reasonable reform," the letter argues.

Rather than view the policy as a way to impose price controls, the letter implicitly suggests that it could be used to enforce the social contract created by the Hatch-Waxman Act by eliminating the ability of drug companies to avoid competition beyond a fixed period.

The open letter proposes extending the period before CMS can regulate the price of both small molecule drugs and biologics to 14 years and compensating for any reduction in savings by expanding the number of drugs subject to price controls.

"We are not arguing for 14 years because it would be more profitable than 13 or nine years," the letter states. "We are arguing for it because it keeps as closely as possible to what we know works." It adds: "Those drugs with less than 14 years of patent protection would still go generic in less than 14 years."

The letter doesn't spare companies that many critics, including biopharma executives, believe have violated the social contract by engaging in anticompetitive behaviors. It states that setting a 14-year threshold for price regulation will prevent "patent gaming" or manufacturing complexity from delaying competition. "It's a good solution to the excess rent-seeking that had been a growing problem with outlier drugs like insulin analogs, Humira, and Revlimid."

Under the BBB Act, the prices of 10 drugs would be regulated in 2025, with the number increasing to 20 drugs after 2028. The process is cumulative, meaning that when the number increases to 15 drugs in 2026, it will bring the total to 25 drugs. In 2028, HHS could be regulating prices of up to 60 drugs.

Biopharma companies and industry would be willing to have the number of drugs subject to price regulation increased to 50 per year starting in 2025, the open letter states.

It also opens the door to setting a 14-year limit for free pricing of all drugs. "Companies that are selling the targeted drugs would certainly object to this, but it would not impact the incentives for all those focused on development of novel medicines."