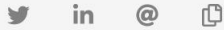


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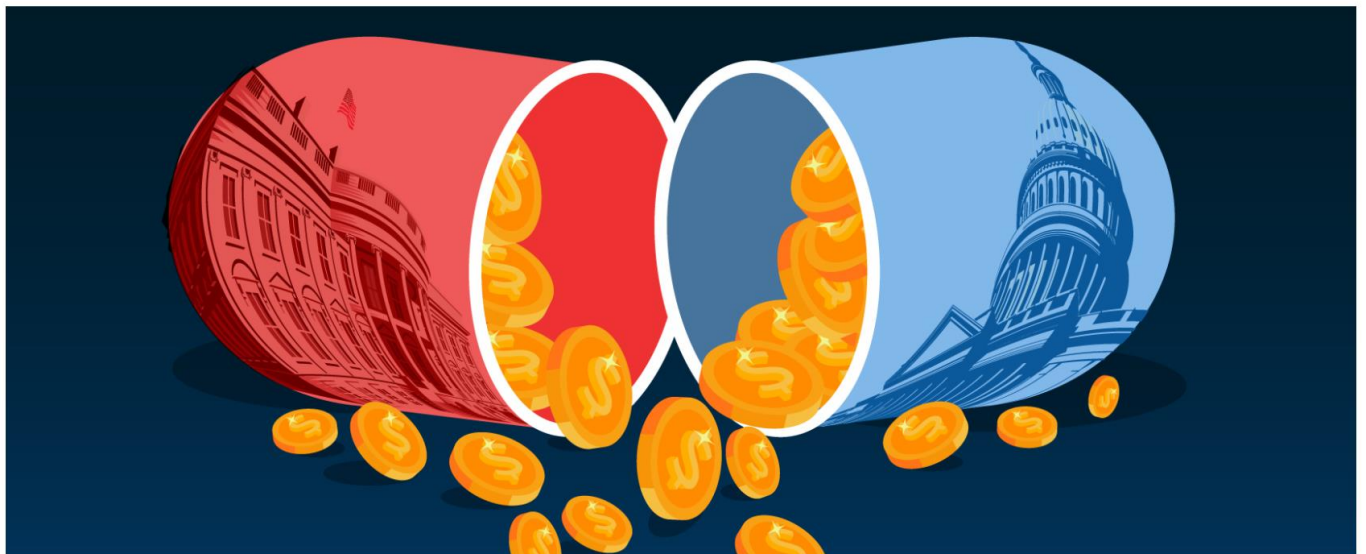
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Investors, biopharma companies sound alarms on drug pricing legislation

BY STEVE USDIN, WASHINGTON EDITOR

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As Democrats in the U.S. House and Senate race to finalize a spending bill, investors are combining forces with drug developers and some patient advocates in a battle to block or blunt attempts to include drug pricing provisions they contend would hobble the U.S. biopharma industry.

Many of the most prominent VCs in the biomedical ecosystem signed onto a [letter](#) released Wednesday warning that price control policies that are being considered on Capitol Hill “would defund R&D, like flipping off a light switch.” Investors who manage over \$183 billion of life science focused capital signed on, according to the letter.

The voices of investors are critical to supporting arguments from drug developers that the [Congressional Budget Office](#) and members of Congress have overlooked the effects of drug price controls on the ability of biotech companies to attract investment.

Pharma companies have launched their own war against drug price controls. On a PhRMA-organized press call Wednesday, David Ricks, chairman and CEO, Eli Lilly and Company, Ramona Sequeira, president, US business unit, Takeda Pharmaceutical Company Limited, and Kenneth Frazier, executive chairman of Merck, said the proposals circulating on the Hill would decimate the industry, forcing them to slash R&D budgets.

Proponents of drug price controls and advocates for an industry that has thrived in their absence are fighting to influence legislation that Democrats believe is their best, and possibly last opportunity for the foreseeable future to enact fundamental changes to the prices drug companies receive for their products and the costs patients and society pay for medicines.

President Joe Biden has requested that Congress give HHS power to negotiate drug prices, create a cap on Medicare Part D beneficiaries’ out-of-pocket costs, and penalize drug companies for raising prices higher than the inflation rate.

There is a sense of urgency for Democrats because they believe fulfilling promises to curtail drug prices will help them retain control of Congress, and because they would have few chances to advance drug pricing agendas if they lose their razor thin majorities in the House or Senate in the 2022 midterm elections.

“The proposals we are seeing come out of Congress would devastate the industry.”

Kenneth Frazier, Merck

To make it through the reconciliation process, the bill must be endorsed by every Democrat in the Senate and all but three of their colleagues in the House. While biopharma companies are publicly targeting the entire Democratic caucus, industry

lobbyists told BioCentury they are focused on a handful of senators. They hope to persuade Ron Wyden (D-Oreg.), chairman of the Senate Finance Committee, to focus on improving access to medicines and avoid taking steps that could hurt the industry.

Pharma companies are also courting Bob Menendez (D-NJ), a strong supporter of the industry.

Lobbyists for biopharma companies and trade associations said they are most concerned by the prospect that drug price controls will be slipped into legislation out of the public eye as part of legislative horse trading.

The House Democratic leadership has set a non-binding deadline of September 15 for committees to submit provisions of the reconciliation bill to the Budget Committee and have committed to schedule a vote on the bill by September 27.

FRYING PAN, MEET FIRE

Biden, House Speaker Nancy Pelosi (D-Calif.) and Senate Majority Leader Chuck Schumer (D-N.Y.) have made drug pricing one of the fulcrums for passing a budget reconciliation bill that includes many of the Democratic Party's top priorities.

In addition to broad popular support for reducing costs to patients, savings from drug price controls are a key part of equations for offsetting the cost of social programs such as expanding Medicare benefits to include dental and vision services.

Responding to bipartisan criticism, Democrats have dropped proposals to link Medicare drug prices to an international reference pricing index. Instead, they are turning to proposals for HHS to negotiate Medicare Part D drug prices, and to enforce negotiations by giving government the power to impose a retroactive 95% tax on the previous year's gross sales of a drug.

The policy would apply to drugs that account for the largest portion of Part D spending.

Investors and biopharma executives think international reference pricing is terrible – and that the form of negotiation under consideration now is worse.

The threat of price negotiations backed up by the ability to impose crippling taxes would quickly desiccate the biopharma landscape, according to biopharma CEOs.

“The proposals we are seeing come out of Congress would devastate the industry,” Merck's Frazier said on the PhRMA briefing call. “Large companies like Merck will survive, but we will do significantly less research.” He estimated that the Medicare drug pricing proposals under consideration in Washington would force Merck to reduce its

R&D by almost half, and that research on treatments for the “most difficult disease states, the most risky and most expensive projects would be at risk.”

Frazier added that while pharmas would find ways to stay afloat, “the hundreds and thousands of small biotechs that rely on venture capital and investments from large pharmaceutical companies will disappear.”

While consumer groups such as Public Citizen are among the strongest proponents of Medicare drug price negotiations, or price setting, some patient advocates are aligning themselves with biopharma innovators.

Gunnar Esiason, a cystic fibrosis patient and advocate, told BioCentury he plans to join biotech CEOs and VCs to press Congress to abandon plans for Medicare to set drug prices.

Esiason said he and other CF patients “are uniquely positioned to talk about how the industry is working, where it falls short,” and the negative consequences of policies that disincentivize investment.

On the one hand, Trikafta elexacaftor from Vertex Pharmaceuticals Inc. (NASDAQ:VRTX) saved and is allowing him to lead a normal life, and on the other hand the collapse in antibiotic drug development poses a constant threat to CF patients, Esiason said. He will urge members of Congress to avoid policies that could add create an investment drought for drugs that for conditions that are common among Medicare beneficiaries.

ACTIVATING INVESTORS

Investors have kept a lower profile in Washington on life sciences policy issues than the companies they fund and have generally maintained a distance from drug companies and patient advocates when lobbying Congress.

Indications that the bulwarks that have kept price control legislation from reaching the president’s desk might be breached have pushed investors and biotech CEOs to join forces.

Peter Kolchinsky, managing partner of RA Capital, is leading the initiative to focus the attention of investors and the companies they make possible on drug price control legislation.

The letter released Wednesday is the first public display of their collaboration.

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Peter Kolchinsky, RA Capital

“The process started about two weeks ago,” Kolchinsky said, “when I got wind that Congress was considering dropping international reference pricing and, thinking it was somehow being more reasonable, planning to just go straight to redefining the word negotiation to mean imposing a 95% tax if a company won’t accept the government’s price.”

The investor letter calls the Medicare drug negotiation proposal “draconian” and predicts that it “would immediately halt private funding of drug discovery and development.” The letter adds: “As an industry, we would no longer be able to infer what insurance plans might value and pay tomorrow from what they value and pay today, which is the premise of a market economy. Unpredictable government-dictated prices would supplant the current market-based framework that inspires biomedical R&D investment.”

The price control policy is being presented as a compromise, but “this isn’t a compromise, it is the end, the result that we feared reference pricing would have led to,” Kolchinsky told BioCentury. “It would destroy the market-based R&D framework by swapping the word 'market' with the words 'government-dictated' and that should be off the table. It would be a total decimation of anything that requires investors to risk capital with an expectation of a market-based return, as opposed, for example, to a BARDA contractual return.”

Kolchinsky was quickly joined by five investors and CEOs to recruit their peers and craft messages to politicians and the public: Aoife Brennan, CEO, Synlogic Inc. (NASDAQ:SYBX); Alex Karnal, chief investment officer & co-founder of Braidwell Management; Jeremy Levin, CEO, Ovid Therapeutics Inc. (NASDAQ:OVID); Laura Shawver, CEO, Silverback Therapeutics Inc.; and Daphne Zohar, founder and CEO, PureTech Health plc (LSE:PRTC; NASDAQ:PRTC).

Puretech and its companies have 25 therapies under development, 15 in the clinic, and have received marketing authorizations for two products. “We would not have been able to do that without the investor ecosystem” that is threatened by the price controls that are under consideration on Congress, Zohar told BioCentury.

“This is a unique instance of investors stepping forward,” Levin told BioCentury. “That’s not happened before.”

Bringing the issues to the attention of members of Congress and the public is critical to avoiding “an historic mistake,” Levin, the immediate past chairman of BIO, told BioCentury.

“The failure to negotiate the drug pricing provisions publicly and to understand the complexity is of great concern,” he said. “By doing this behind closed doors without any scrutiny an historic error could be made.”

The drug price control proposals Democrats are considering, Levin contends, “rely on factual inaccuracies in the CBO analysis and would create key changes in the way that we operate and bring medicines into the healthcare system without addressing the critical elements of out-of-pocket expenditures or taking advantage of the demand to genericize drugs very quickly at the time when their patents have expired.”

Paul Hastings, president and CEO of [Nkarta Inc.](#) (NASDAQ:NKTX), and chairman of BIO, said that the letter isn’t a BIO initiative, but the trade association supports and circulated it to emerging companies.

“We have been very clear on our concerns with price fixing policies,” Michelle McMurry-Heath, BIO’s president & CEO, said in a statement. “It’s important for the administration and lawmakers to hear first-hand the concerns of innovators and investors.”

The emerging companies BIO represents “all started because of VCs,” Hastings told BioCentury. “BIO wanted to make sure we support investors having a voice. They are saying they believe in healthcare. Price controls hurt the ecosystem, hurt the companies we fund, and if you impose them VCs will invest in other kinds of companies.”