

08 Feb 2024 | Analysis

Senate CEO Hearing On Drug Prices Could (Almost) Have Taken Place Five Years Ago

by Cathy Kelly

Discussion around the landmark developments in pricing reform established by the Inflation Reduction Act of 2022 were largely absent from the hearing involving Johnson & Johnson's Joaquin Duato, Merck's Robert Davis and Bristol Myers Squibb's Chris Boerner.

Senate Health, Education Labor and Pensions Committee chairman Bernie Sanders, I-VT, got three big pharma CEOs to Capitol Hill to defend their companies' pricing practices at a much-hyped hearing on 8 February. But the discussion followed a well-worn path of lawmaker challenges and industry explanations regarding drug prices.

For the most part, the hearing did not address the significant reforms now being implemented in Medicare under the Inflation Reduction Act or proposals to build on those reforms. So it seems unlikely to lead to new policies.

In that sense it seemed to cover much of the same ground that the high-profile CEO hearing on drug prices held by the Senate Finance Committee in 2019 did. (Also see "Big Pharma Defuses Drug Pricing Landmines On Capitol Hill" - Pink Sheet, 26 Feb, 2019.)

The lack of discussion about the IRA reforms was particularly notable because star witnesses *Johnson & Johnson* CEO

Key Takeaways

- Medicare price negotiation got very little attention at the hearing.
- The three executives defended their pricing practices, and the fact that prices are substantially higher in the US than abroad, with many familiar arguments.
- The CEOs urged PBM reforms, a lifting of the prohibition on manufacturer copay assistance in Medicare Part D, and policies that could further remove obstacles to



Joaquin Duato, <u>Merck & Co., Inc.</u> CEO Robert Davis and <u>Bristol Myers Squibb</u> <u>Company</u> CEO Chris Boerner each have drugs that are currently undergoing the Medicare price negotiation process.

value-based contracting.

 Members on both sides of the aisle supported PBM reform.

J&J's Stelara and Xarelto, Merck's Januvia and Bristol's Eliquis have all been selected

for negotiation and all three companies have filed lawsuits challenging the program.

Duato and Davis originally balked at the committee's invitation to testify because they were concerned they would be asked to defend the litigation during the hearing. (Also see "Bernie vs. CEOs: Are J&I, Merck, And Bristol On Hot Seat, Or Is Medicare Price Negotiation?" - Pink Sheet, 18 Jan, 2024.) In the end, perhaps the lack of focus on the IRA was an agreed-upon condition for their appearance.

The Elephant In The Room?

The IRA only came up a handful of times. Sen. Ben Ray Lujan, D-NM, called into question Bristol Myers Squibb's arguments that the Medicare negotiation program will significantly impede innovation by suggesting that recent public statements by the company regarding that issue are at odds with each other.

He noted the company said in its lawsuit challenging the negotiation program that "the IRA's real victim is innovation and in turn, the millions of patients who are counting on the pharmaceutical industry to develop new therapies that will improve lives and health and wellbeing."

But in its recent fourth earnings report, Bristol said, "'we have a legacy portfolio of well-established products facing headwinds such as IRA. Although this portfolio is declining it is expected to generate strong cash flow to invest in our future cash drivers,'" Lujan continued, asking whether Boerner stood by both statements.

"We have serious concerns about elements of the IRA, including that this is not an actual negotiation," Boerner responded. He also noted that negotiated prices have not yet gone into effect, so it is early to discuss the extent of the impact.

Other Democrats mentioned that reforms established by the IRA are making progress on lowering drug costs but that the job is not finished.

Sen. Robert Casey, D-PA, said his constituents are "happy" about Medicare price negotiation, lower-cost insulin and the \$2,000 out-of-pocket cap in Medicare Part D established by the IRA.



But "they think Congress is not doing enough" to address their struggles with drug costs, he added. Sen. Tammy Baldwin, D-WI, similarly observed that while her constituents' struggles will be aided by Medicare negotiation, "we have more work to do." Sen. Tim Kaine, D-VA, made similar comments.

Fixing The 'Pill Penalty'

Sen. Tommy Tuberville, R-AL, was the only member to raise possible revisions to the negotiation program. He asked the CEOs about the burden presented by the so-called "pill penalty" in the IRA, which established that small molecule drugs can be subject to negotiated prices nine years after they are approved. The policy has been targeted as a high priority fix by the pharma industry, which wants to extend the runway to 13 years.

Merck's Davis answered that small molecule development is "disfavored" by the policy and noted that oral drugs for cancer and central nervous system disorders, such as Alzheimer's disease, are among the important treatment categories that could be undermined.

Democrats on the committee, led by Sanders, challenged many of the same aspects of US drug pricing that they've emphasized for years: how US prices are so much higher than those abroad for the same drug, how the patent system is being abused by manufacturers, how companies spend more on stock buybacks and dividends than on research and development, and how they constantly

Sen. Cassidy Gives Strong Defense – And Asks Tough Questions – Of Pharma CEOs At Hearing

By Sue Sutter

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Despite objecting to Democrats' reasons for hauling three pharma CEOs in front of the Senate Health Committee, Ranking Member Bill Cassidy pressed the execs on anticompetitive tactics on biosimilars and how to keep gene therapies from bankrupting state Medicaid programs.

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hear from constituents about how high prices are adversely impacting their lives.

A number of Republicans (and Democrats) agreed with the need for pharmacy benefit manager reforms, and the committee's ranking Republican, Bill Cassidy of Louisiana, was among those raising concerns about patent gaming. Cassidy also questioned how the health care system will manage the high price of cell and gene therapies. (*See sidebar for coverage of his comments*.)

The CEOs responded with many familiar arguments and proposals. They stressed the importance of funding innovation, how supply chain intermediaries contribute to high list prices and how companies underwrite many forms of patient assistance to defray out-of-pocket costs for patients.



CEO Solutions Echo Past Suggestions

To help reduce drug costs, the executives urged reforms targeting pharmacy benefit managers, legislation that would allow manufacturers to offer copay support in Medicare Part D and policies that would remove regulatory barriers to value-based contracting.

Sanders opened the hearing with an analysis showing the wide disparity between drug prices in the US versus other developed nations. He asked the CEOs whether Keytruda, Eliquis and Stelara are profitable in Japan, Canada and Spain, even though they sell for much lower prices in those countries and the CEOs acknowledged their drugs are profitable in those regions.

In that case, Sanders asked them to commit to lowering their prices to the levels abroad, which they declined to do, pointing out that higher prices in the US allow for broader access to advanced therapies in this country.

"I acknowledge that the price in the United States are higher than they are in many countries," Merck's Davis said. "But I think it's also important to point out that you get access in the United State, faster and more than anywhere in the world. We have 39 indications for Keytruda.... If you look across Europe, [the indications are] in the 20s. If you look at Japan that number is a little bit less. So there is a reason why the prices are different and we need to be careful."

Boerner and Duato made similar points and also cautioned that the committee's analysis focused on US list prices and net prices for Eliquis and Stelara are actually much lower in the US because of rebates. Duato maintained that Stelara's list price is discounted by 70% in the US.