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Congress Puts Focus Back On Drug Pricing With AbbVie Subpoena

by Brenda Sandburg

House Oversight Committee Chair says AbbVie has failed to comply with requests for documents in committee's investigation of the drug pricing of 12 pharma companies.

Eighteen months after launching an investigation of the drug pricing practices of 12 companies, the House Committee on Oversight and Reform is singling out *AbbVie Inc.*, claiming it has failed to turn over documents about the pricing of Humira (adalimumab) and Imbruvica (ibrutinib). The legal action brings the issue of drug pricing back to the forefront and could spur further policy debate as the presidential election campaign enters its final months.

Committee Chairwoman Carolyn Maloney, D-NY, announced on 1 September that she had sent a memo to committee members notifying them of her intent to issue a subpoena to AbbVie for documents because it has demonstrated an unwillingness to comply with the investigation.

“The volume and quality of AbbVie’s responses are inconsistent with the expected recordkeeping and decision-making processes of a large multi-national corporation regarding two of its most profitable drugs,” the *memo* states. “AbbVie’s responses are particularly poor in comparison to the documents produced by other companies that are the subject of the Committee’s investigation.”

Maloney notes that Humira, the treatment for rheumatoid arthritis and other inflammatory diseases that has become the world’s best-selling drug, had nearly $19.2bn in worldwide net revenues in 2019; and Imbruvica, a treatment for mantle cell lymphoma, generated total net revenues of more than $4.6bn last year.

Maloney's memo says that Republican committee members do not support the investigation, which was launched by the late Elijah Cummings, D-MD, in January 2019. The memo notes that the Republicans sent letters to each drug company in April 2019 urging them not to cooperate with the investigation. For example, the memo says that in their letter to AbbVie CEO Richard Gonzalez, then-Ranking Member Jim Jordan and then-committee member (now White House chief of staff) Mark Meadows questioned Cummings' motives for conducting the investigation.

AbbVie said it has been working cooperatively with the House Oversight Committee since receiving the committee's initial letter. "In fact we've provided thousands of documents and have had numerous conversations with the Committee staff. While we are surprised and disappointed the Committee chose to take this action, we will continue to work in good faith with them on this important subject," the company said in a statement.

Data Sought On Market Exclusivity, Rebate Pricing, Exec Bonuses

The planned *subpoena* to Gonzalez shows the extent of the investigation and the pricing practices targeted by the committee. It demands production of all documents, including communications, referring or relating to pricing or lifecycle management strategies for Humira and Imbruvica from 1 January 2009 to 14 January 2019.

The subpoena specifically cites documents on increasing the price of Humira in response to or in anticipation of changes in prices of *Amgen, Inc.*'s Enbrel (etanercept) or any other products that compete with Humira, and the impact of any change in the price of Humira on the company's earnings, revenues and earnings per share.

It also seeks documents relating to strategies to increase the period of market exclusivity for both drugs beyond their patent expiration date or period of market exclusivity, and documents on the impact on sales, revenue or market share of introduction of a single dosage or single tablet regimen.

In addition, the subpoena requires production of:

- Documents relating to AbbVie's expenditures on drug donation or co-pay assistance programs for Humira;
- Documents sufficient to show AbbVie's exact method of calculation of bonuses for the ten highest-paid employees between 1 January 2014 and 14 January 2019;
- Documents to show the average net price for Humira and Imbruvica each year from 2009 to 2019, as well as the highest, lowest, and average net price and rebate per unit price for both drugs by channel, including Medicare, Medicaid, commercial, Veterans Affairs, and Department of Defense sales channels; and

- AbbVie or Abbott Laboratories' yearly research and development costs related to Humira and Imbruvica.

Drug Pricing Is Lower Priority

In January 2019, Cummings sent letters to 12 companies requesting information on the reasons behind their price increases. In addition to AbbVie, they included Amgen, Inc., *AstraZeneca PLC*, *Celgene Corporation*, *Eli Lilly and Company*, *Johnson & Johnson*, *Mallinckrodt plc*, *Novartis AG*, *Novo Nordisk A/S*, *Pfizer Inc.*, *Sanofi* and *Teva Pharmaceutical Industries Ltd.* (Also see "*House Oversight Drug Pricing Hearings Will Begin With Expert, Patient Witnesses*" - Pink Sheet, 14 Jan, 2019.)

In his 14 January *letter* to Gonzalez, Cummings noted that 2016 Medicare Part D spending was $490.1m for Humira, $1.6bn for Humira Pen, and $978.3m for Imbruvica. He noted that the five-year annual growth rate in average spending per unit from 2012 to 2016 for each drug respectively was 17.9%, 18%, and 6.71%.

Cummings sent a follow-up letter to AbbVie on 21 June 2019 and a *third letter* on 27 September 2019, in which he said AbbVie's responses had been "woefully inadequate." He said the company failed to provide key materials, including board materials and communications relating to pricing strategies and lifecycle management for Humira and Imbruvica and failed to produce communications regarding its acquisition of *Pharmacyclics, Inc.* and executive compensation. AbbVie acquired Pharmacyclics, co-developer of Imbruvica, in 2015.

The cost of prescription drugs was a hot button issue at the time the oversight committee launched its investigation. The following month, the Senate Finance Committee held a high-profile hearing on drug prices at which AbbVie's Gonzalez and the top leaders of six other pharma companies testified. (Also see "*Big Pharma Defuses Drug Pricing Landmines On Capitol Hill* " - Pink Sheet, 26 Feb, 2019.)

At the hearing, Gonzalez was grilled about the patent estate for Humira and its patent settlement agreements with potential biosimilar manufacturers. (Also see "*From Pricing To Patents: Hearing Signals A Potential New Focus*" - Pink Sheet, 27 Feb, 2019.)

Drug pricing has become a lower priority since then. However, it remains a target of both President Trump and Democratic presidential nominee Joseph Biden.

Trump issued four executive orders on drug pricing in July, which among other things would allow states to develop plans for importing prescription drugs from Canada and advance international reference pricing. (Also see "*Presidential Arm Twisting: Drug Pricing Order Would Advance International Benchmarks Unless Industry Offers Alternative*" - Pink Sheet, 24 Jul, 2020.)

Former Vice President Biden has also pledged to tackle drug pricing if he is elected. The "unity

platform" his campaign crafted with Senator Bernie Sanders, I-VT, pledges to ensure that Americans do not pay more for prescription drugs than people in other advanced countries. And the plan adopted by the Democratic National Convention says Democrats would "crack down on anticompetitive efforts to manipulate the patent system or collude on prices" and would eliminate tax breaks for drug advertisements. (Also see "*Does Biden Bode Well For Pharma? Convention Sets Promising Tone For Campaign*" - Pink Sheet, 21 Aug, 2020.)