US lawmakers seek cuts in prescription drug prices

A committee brought together Senators and drug company representatives to discuss why drug pricing in the USA is so high, but little progress was made. Susan Jaffe reports.

Executives of seven multinational drug companies appeared before the US Senate Committee on Finance on Feb 26, to explain why Americans pay some of the highest—and rising—drug prices in the world. But their testimony did little to placate the committee.

The senators' concern went beyond policy and politics. They recalled relatives and constituents back home who worry about affording their medication,

"I wouldn't be able to be here today if it wasn't for the pharmaceutical industry", Senator Johnny Isakson, a Georgia Republican, told the pharmaceutical representatives. "I have Parkinson's disease, but I can function every day and do my job because of that and I appreciate it every day." But he was surprised when one of his eight daily medications cost US$90 more in January than it did in December.

Before the hearing, committee chairman Charles Grassley, an Iowa Republican, warned the pharmaceutical executives in a Tweet not "to blame everyone but themselves" or try to avoid "responsibility for their role in fixing the problem".

The drug industry, along with the Trump administration, often blame pharmacy benefit managers (PBMs) for driving up drug prices. PBMs manage drug coverage on behalf of insurance companies by negotiating prices with drug manufacturers and insurers and processing claims. In most cases, lower-priced drugs receive preferential placement on the insurance plan's list of covered drugs, or formulary. These drugs might have a lower patient copayment and little or no restrictions, such as quantity limits or prior authorisation.

In return for their services, PBMs receive rebates, as much as 30% of the negotiated price, while the patient's share of the cost is based on that price before rebates are deducted. Critics argue that the system encourages PBMs to accept increasing prices in order to get higher rebates. PBMs counter that they do not decide what manufacturers charge for their drugs.

The committee's senior Democrat, Oregon Senator Ron Wyden, pointed out substantial price hikes by each of the manufacturers testifying, who he said treated patients and taxpayers as "unlocked ATMs full of cash to be extracted".

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Insulin made by Sanofi rose in price from $100 per vial in 2010 to $300 in 2018, and went up again this year, said Wyden, yet this drug has been on the market "since the roaring twenties".

AbbVie raised the price of a 12-month supply of the popular arthritis medicine Humira from $19 000 to $38 000 over the past 6 years, while obtaining patent protections that block development of cheaper generic alternatives, he said.

Pfizer pledged last year it would not raise prices, but then announced increases in January, Wyden continued. Merck cut prices of some drugs that were not selling well but not those of its most profitable drugs, he said.

Johnson & Johnson and AstraZeneca have also raised prices, Wyden said. And, rather than cut prices, he said Bristol-Myers Squibb spent almost $11 billion last year on dividends, stock buybacks, marketing, and administrative costs.

AbbVie's chairman and CEO Richard Gonzalez said price increases are necessary to offset inflation, employee bonuses, and the costs of drug research and development.

Ten months ago, President Donald Trump unveiled his *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, which included recommendations aimed at cutting prices by boosting competition and basing prices on what other countries pay.

On Jan 31, the Trump administration proposed a rule based on one of the blueprint ideas that would allow Medicare patients to receive the rebates that normally go to PBMs. The measure removes a ban on such payments, currently considered illegal kickbacks designed to promote drug sales.

"The President's proposal will eliminate the single biggest reason for these seemingly perpetual drug price increases: today's rebate system", Health and Human Services Secretary Alex Azar said in a recent speech. In 2017, rebates in the Medicare drug insurance programme generated more than $29 billion, he said.

Although Azar and other administration officials estimate that the proposal would cut drug costs for Medicare patients by as much as 30%, such predictions might be overly optimistic.

"Nothing in the rule requires, or even incentivises, Big Pharma to lower their drug prices", Kristine Grow, a spokeswoman for America's Health Insurance Plans, told *The Lancet*.

The proposed rule does not mandate drug manufacturers to reduce prices

Win McNamee/Getty Images

to account for the elimination of the rebate, according to an aide to Senator Wyden. "More safeguards are needed to ensure drug makers do not pocket some or most of the difference as profit", the aide said.

"We are glad to have a conversation with policy makers about the best way to use the savings we negotiate to benefit consumers both in the form of premium reductions and costs at the counter", said JC Scott, president and CEO of the Pharmaceutical Care Management Association, which represents PBMs. "The real question, which wasn't well answered at the [finance committee] hearing, is whether, in the absence of negotiated savings, manufacturers would willingly lower their prices."

If the administration adopts the rebate proposal, several pharmaceutical representatives told the committee they would lower their prices only if the federal government applies the rebate rule to commercial drug insurance plans, not just Medicare. Others said they could not respond until they saw the final rule, which is expected later this year and would take effect on Jan 1, 2020.

Despite the lukewarm support from the drug company representatives, the Pharmaceutical Research and Manufacturers of America, an industry trade group, has "long advocated for sharing negotiated rebates and discounts with patients at the pharmacy counter", Holly Campbell, a spokeswoman, told *The Lancet*.

If drug companies do agree to pass some portion of the rebate to patients, critics say it will not be easy to work out if it was correctly deducted from their drug bill. "Absolutely not," said Gerard Anderson, professor of medicine at the Johns Hopkins University School of Medicine in Baltimore, MD, and director of the Hopkins Center for Hospital Finance and Management. It could take federal government a year or more to review its contracts with drug plans and determine whether something was wrong, he said.

Patients will be unable to track down any payment errors themselves because Medicare officials are prohibited from publicly disclosing manufacturers' rebates or other price reductions, according to a government website listing Medicare's drug spending.

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In addition, even without rebates, Anderson said price increases could appear for different reasons. "So it's a bit of whack-a-mole."

The senators also asked about other ways to make drugs more affordable.

The drug makers told the committee they support the CREATES Act, legislation that would prohibit companies from withholding samples of their brand name drugs so that generic pharmaceutical competitors cannot develop less expensive alternatives. The abuse of patents to prolong one company's right to produce a drug also stifles competition, several senators said, noting that Humira has more than 100 patents.

"I support drug companies recovering a profit based on their [research and development]," said Texas Republican Senator John Cornyn. "But at some point, that patent has to end, that exclusivity has to end so that the patients get access to those drugs at a much cheaper cost."

With Chairman Grassley's support, Cornyn said he would take the issue to the judiciary committee, which oversees the nation's patent system and where both men are members.

In the US House of Representatives, the Committee on Oversight and Reform is investigating price hikes by a dozen pharmaceutical firms and also holding hearings on the issue . Several senators criticised the disparity between much lower costs of drugs in other countries compared with prices in the USA. Senator Bill Cassidy, a Louisiana Republican and physician, cited the example of Humira, which he said is sold at an 80% discount in Denmark.

"Something is fundamentally broken in our system that the Danes get an 80% discount and we are not", he said .

In October, the Trump administration proposed limiting Medicare payments for some physician-administered medications, such as intravenous drugs, to a target price of 126% of the drugs' average cost in other economically similar countries. Officials would phase in the programme, known as the International Pricing Index, over 5 years and estimate it would save taxpayers and patients $17·2 billion.

Several of the drug company executives oppose the plan, claiming that such restrictions would trigger a decrease in research and development investment. Others objected to adopting a system in this country that is based on foreign price negotiations. Neither argument was very persuasive. "If you can turn a profit in a country with dramatically lower prices, you can do the same thing in the United States", said Wyden .

"I think that you charge more here because you can", said Senator Debbie Stabenow, a Democrat from Michigan, which borders Canada. She cited a recent report that found American taxpayers provided $200 billion in research grants from National Institutes of Health to help to develop 210 new drugs that went on the market between 2010 and 2016.

"The people in Michigan and across the country deserve better; they need to be able to afford their medicine and not have to go to another country to get it."

As the hearing wrapped up, Wyden asked the drug makers to tell him whether they support legislation to do what the Trump proposal would not—require them to lower prices by passing along rebates to patients. He expects their response by the end of the month.

Susan Jaffe