As the 116th Congress gets up and running, the cost of prescription medications and therapies has quickly emerged as one of the top legislative and oversight priorities of lawmakers on both sides of the Capitol – with President Trump, who has already offered policy proposals, expressing an eagerness to address the issue in a bipartisan way. The rising cost of pharmaceutical drugs has already been the subject of two Congressional hearings, the first in what is expected to be a long series, as well as ongoing investigations of and requests for information from major drug manufacturers, and a growing list of legislative initiatives, several of which can be expected to actually be enacted with bipartisan support. And in a significant development, HHS on January 31 proposed a rule “to lower prescription drug prices and out-of-pocket costs by encouraging manufacturers to pass discounts directly on to patients.”

The Senate Finance Committee and the House Oversight and Reform Committee held virtually simultaneous hearings on the issue of pharmaceutical drug pricing on Tuesday, January 29. Both hearings featured testimony from academic experts and healthcare advocates. There were no representatives from the pharmaceutical industry at either hearing, nor from the Trump Administration, and there were no specific legislative proposals on Tuesday’s hearing agendas, though legislation approaching the issue from various angles has been introduced in both
chambers and more can be expected.

The leaders of both committees stressed that Tuesday's hearings were only the first of a series of sessions on the drug pricing issue – and that executives of major pharmaceutical companies can expect to be asked (or compelled) to testify.

The House and Senate hearings touched on many of the same themes, including:

- whether direct negotiations between Medicare and drug companies would lead to fairer prices than the current status quo
- criticisms of pharmaceutical benefit managers (PBMs) as unhelpful "middle men"
- comparisons between Medicare and the VA system's negotiations with producers that have led to lower prices
- comparisons between what US consumers and consumers in other countries pay for the same products, and proposals to allow for the importation of medicines from abroad
- the need for enhanced competition in the industry
- questions about whether higher prices truly reflect companies' R&D and innovation-related costs
- calls for more transparency at every step of the process.

Each hearing began with emotional testimony from a witness who is the mother of a child or children with insulin-dependent diabetes. Indeed, insulin specifically seems to be the major focus of some of the initial legislative and investigatory salvos from Congress. Several major pharma companies were frequently called out by name for criticism by committee members and witnesses at both sessions.

House Oversight Democrats criticized the industry for price "gouging" and "fixing," suggested pharma companies were spending more on marketing and buybacks than on R&D and called for such measures as direct government negotiation in the Medicare Part D drug program and allowing importation of lower-cost drugs. Republican committee members spoke out against what they called excessive government involvement in the healthcare sector generally, faulting Democrats for blaming the private sector for high prices when they said government interventions were behind many of the current price distortions.

In his opening statement, Oversight Committee Chairman Elijah Cummings (D-MD) accused drug makers of "aggressively increasing prices on existing drugs and setting higher launch prices for new drugs, all while recording windfall profits. Ranking member Rep. Jim Jordan (R-OH) expressed concerns about the handling of the Oversight Committee's recently launched investigation of major drug manufacturers and what he described as the exclusion of Republicans from the process.

On the Senate side, both Finance Committee Chairman Charles Grassley (R-IA) and ranking member Ron Wyden (D-OR) criticized pharmaceutical company executives for not participating in Tuesday's hearing, despite the committee's invitation to do so. Grassley said only two small companies offered to send someone to testify, while big companies declined and said they'd prefer to testify in a private setting. Grassley reiterated several times that going forward he and Wyden will be "more insistent" that pharma execs come before the committee to testify on the pricing issue. Wyden, who quipped that even tobacco company execs have been willing to testify before hostile questioning from Congress, said "even if it means using our power to compel the drug company CEOs to show up, they will come before this committee."

Beyond crafting legislation, Congress has sweeping oversight and investigatory powers that it is intent on using to probe the pricing practices of the pharmaceutical industry. Cummings on January 14 sent letters to 12 drug companies seeking detailed information, documents and communications on price increases, investments in research and development and corporate strategies to preserve market share and pricing power.

In addition to the Senate Finance and House Oversight committees, other Congressional committees will also be active on the drug pricing issue. On January 30, House Energy and Commerce Committee Chairman Frank Pallone, Jr., (D-NJ) and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) sent letters to major pharma companies "requesting information on the root causes of the rising cost of insulin and the obstacles to providing more affordable medication."

There has already been a flurry of initial legislative activity leading up to these hearings, with both bipartisan and party-line bills starting to fill the hopper, including (but by no means not limited to):
The Right Rebate Act (S. 205), sponsored by Wyden and Grassley and nine other senators from both sides of the aisle, which would "close a loophole in Medicaid that has allowed pharmaceutical manufacturers to misclassify their drugs and overcharge taxpayers by billions of dollars and provide HHS with additional authorities to ensure drugs are properly classified," the senators said in announcing the legislation. Said Grassley at Tuesday's hearing: "When enacted, this bill will close the loop hole that allowed the manufacturer of EpiPen to rip off taxpayers and consumers to as much as $1.27 billion."

The Medicare Drug Price Negotiation Act (H.R. 448), sponsored by Cummings, which would amend the Social Security Act to provide for the negotiation of lower covered Medicare Part D drug prices on behalf of Medicare beneficiaries and the establishment and application of a formulary by the Secretary of Health and Human Services under Part D. It has 21 co-sponsors, all Democrats.

The Affordable and Safe Prescription Drug Importation Act (H.R. 447), also sponsored by Cummings, which would amend the Food, Drug, and Cosmetic Act to allow for the importation of affordable and safe drugs by wholesale distributors, pharmacies, and individuals. It has 25 Democratic co-sponsors.

The Prescription Drug Price Relief Act, sponsored by Senator Bernie Sanders (I-VT) (S. 102), and Representative Ro Khanna (D-CA) (H.R. 465), would require the HHS Secretary to make sure that Americans don't pay more for prescription drugs than the median price of five countries – Canada, the UK, France, Germany, and Japan – and would require the federal government to approve cheaper generic versions if the pharmaceutical manufacturers don't comply. It has five Democratic co-sponsors in the Senate and 20 Democratic co-sponsors in the House.

Several pieces of legislation introduced but not passed in the previous session of Congress could also be reintroduced. For instance, the CREATES (Creating and Restoring Equal Access To Equivalent Samples) Act and the Preserve Access to Affordable Generics Act, both of which had bipartisan support, could resurface in the new Congress.

In addition to the aforementioned legislative action that is currently percolating, CMS has also recently moved forward with action to expand the Centers for Medicare and Medicaid Innovation (CMMI) demonstration model for Part D plans, which addresses those beneficiaries that reach the catastrophic phase of prescription drug coverage and shifts more of the cost burden onto Part D plans. It is still unknown whether this will impact the pharmaceutical industry uniformly and how insurance companies will try to shift that additional cost elsewhere, if at all.

On January 31, HHS unveiled a proposed rule to expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to PBMs, Part D plans and Medicaid managed care organizations. The HHS proposal would create a new safe harbor for prescription drug discounts offered directly to patients, as well as fixed fee service arrangements between drug manufacturers and PBMs.

And beyond the action seen across the legislative and regulatory spaces, there has also been a groundswell of advocacy group formations on this issue, representing both those who support clamping down on prescription drug costs and those in favor of protecting the pharmaceutical industry via preserving the status quo, perhaps with some small compromise adjustments. The dueling House and Senate hearings heard policy proposals from at least some of those advocates, from a variety of ideological perspectives, at Tuesday's hearings.

We expect there to be more hearings on this issue in the near future, in multiple committees. It can reasonably be assumed that Congress will push for executives from major pharma companies to testify and that they likely would be treated as hostile witness being called to the carpet. And, given the bipartisan interest on both sides of Capitol Hill – and on both ends of Pennsylvania Avenue – it is quite possible that legislation containing at least some of the provisions and proposals outlined above will be enacted before the 2020 elections.

Learn more about the implications of this trend by contacting either of the authors.

AUTHORS