Democratic Takeover of House Sparks Drug-Price Legislation Talks

But Strong Legislation Unlikely Given Patient and Industry Opposition

Stephen Barlas

Representative Elijah Cummings (D–MD), chairman of the House Oversight and Reform Committee, was apoplectic. He was delivering his opening statement at the committee's first hearing for 2019, titled Examining the Actions of Drug Companies in Raising Prescription Drug Prices. He was describing the devastation felt by his leading witness, Antoinette Worsham, whose diabetic daughter had died for lack of the insulin medicine she could not afford. "It would have cost $1,000 for three months of insulin!" Cummings thundered into the microphone in his opening statement. "She died."

On the other side of Capitol Hill, that same day, Senator Ron Wyden (D–OR), was pounding his right hand on the dais during the Finance Committee's first hearing of the year, probably not coincidentally titled (given the House committee's hearing the same day) Drug Pricing in America: A Prescription for Change, Part 1. Wyden had just addressed Kathy Sego, another mother whose college-age son with stage 1 diabetes had resorted to rationing insulin because the cost per month, even with insurance, was $1,700. "Manufacturers are taking advantage of families like yours," Wyden, the top Democrat on that important committee, said, his voice rising. Then pounding the tabletop in front of him, he added, "No one has been willing to take them on. That ends today."

President Trump has been condemning high drug prices since the start of his term, and his Department of Health and Human Services (HHS) has issued a number of proposed regulations that would attack high prices on a number of fronts. In the last Congress, there was plenty of fire and brimstone aimed at drug companies, and from both parties, but no significant pricing-reform legislation advanced. That was in large part a result of legislative roadblocks in the Republican-controlled House.

With Democrats taking control of the House this year, the 116th Congress looks to be in sync with Trump on drug prices and theoretically— theoretically being the key word—able to move forward with legislation clamping down on unreasonable drug prices. But although there is a lot of rhetorical thundering from Democrats in this new Congress, there are indications that actions may not speak louder than words. Already, key Democratic House committee chairmen have indicated opposition to some of the reforms pushed by the Trump administration, such as ending the current safe harbor for rebates paid to pharmacy benefit managers (PBMs) by drug manufacturers. The HHS proposed a rule in early February ending that safe harbor and proposing a new one that would cover rebates passed along to consumers at the pharmacy counter (see Prescription: Washington column on page xx). Numerous patient advocacy groups support the proposed rule.

However, key Democrats in the House are opposed to ending the current safe harbor for rebates in Medicare, putting them on the PBMs’ side and against consumers. Ways & Means Committee Chairman Richard Neal (D–MA) and Energy and Commerce Committee Chairman Frank Pallone, Jr. (D–NJ) issued a statement saying, “The Trump administration’s rebate proposal will increase government spending by nearly $200 billion and the majority of Medicare beneficiaries will see their premiums and total out-of-pocket costs increase if this proposal is finalized. While we agree that the cost of prescription drugs must be addressed, we are concerned that this is not the right approach.”

That pro-rebate position from Democrats surprised some patient advocacy groups, who are opposed to rebates and support HHS’ proposed rule. Carl Schmid, Deputy Executive Director of the AIDS Institute, says, “I was surprised they took that position. Maybe they didn’t have all the information; maybe it was a knee-jerk reaction because it came from the Trump administration.”

It is too early to tell whether Democrats will propose legislation to nix Trump’s proposed rule on rebates, and, if they do, whether they will gain any Republican support, which is crucial for passing any drug-pricing legislation on broader health care or otherwise. However, some bills that faltered in the last Congress because of Republican control of the House will undoubtedly advance in and probably be approved by this new Congress.

A key example is the Creating and Restoring Equal Access to Equivalent Samples (CREATEs) Act, which would give generic companies more leverage to force brand-name companies to supply drug samples. That bill passed the Senate Judiciary Committee last year with bipartisan support but never came up in the House because of GOP leadership opposition. This year, Pallone replaces Representative Greg Walden (R–OR) as chairman of the House Energy & Commerce Committee. Walden opposed the CREATEs Act; Pallone is an enthusiastic supporter. But Erik Komendant, Vice President of Federal Government Affairs at the Association for Accessible Medicines, the generic industry trade group, says, “Nothing is a done deal.” He points out that there are 90 new members in the House and 10 in the Senate. “Many of them campaigned on and heard from constituents about high drug prices,” he says. “And now is the time for Congress to pass CREATEs and take meaningful action to lower the cost of prescription

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however, creates does nothing to solve the more important brand-name versus-generic conflict: brand-name extension of patents to block the entry of generics, as has been the case of the best-selling drug in the world, abbvie’s humira, whose main patent expired in 2016. but abbvie has extended that drug’s patent to 2034 by gaining other, follow-on subsidiary patents. abbvie has licensed humira to seven companies that will be allowed to sell humira in 2022 in europe, but not in the u.s. humira, an arthritis drug, has a list price that has increased from $19,000 to $38,000 a year over six years, according to wyden.

but where democrats and republicans agree—either in substantial numbers as with the creates act, or when a bipartisan team of leading members of an influential committee sponsor a bill—legislation will move. wyden’s right rebate act (s.205), which closes a loophole that allowed the epiPen manufacturers to “rip off” consumers, according to finance committee chairman and act co-sponsor senator chuck grassley (r-ia), is an example of a bipartisan bill with a tailwind. at the hearings on february 26, grassley also referred to senator amy klobuchar’s (d-mn) pay for delay bill, of which he is an original co-sponsor. it would limit brand-name companies from paying generics companies to delay the introduction of generics, including biosimilars. another example is legislation forcing drug companies to include list prices in television advertisements. such a bill passed the senate last year by a bipartisan vote but never came up in the house because of gop committee chairmen opposition.

the trump administration has proposed a rule mandating the publication of list prices but the drug industry has threatened a lawsuit, so congressional passage of a bill would make any lawsuit null and void. there is also bipartisan support for a grassley bill allowing the importation of lower-priced foreign drugs, a proposal that some patient groups, not to mention the drug manufacturers, oppose.

in fact, the democrats who are now in control of the house will find republican members freer—no longer having to buck leadership—to support drug-pricing legislation. representative bob gibbs (r-oh) questioned gerard anderson, professor of health policy and management at johns Hopkins university, at the cummings hearings about a number of issues, including orphan drug pricing, the use of risk evaluation and mitigation strategies (rems) by patented companies to thwart generic introduction, and pbfms. “there are lots of problems about how the pbfms are operating. if we address the orphan issue, the rem, and the pbfms, we’ll make a lot of progress without over-regulating and disincentivizing, and let the market function,” gibbs said.

these bipartisan drug-pricing bills will probably not pass congress as separate legislation. rather, they will be added to a larger health care bill. senator lamar alexander (r-tn) began a hearing on february 5 in the senate health, education, labor and pensions committee, of which he is chairman, by referring to his request to health care groups to provide suggestions on what the federal government can do to lower the cost of health care for american families. “this year i am committed to passing legislation based on that input,” he stated. alexander said that he and senator patty murray (d-wa), the ranking democrat on the committee, have met with grassley and wyden “to see if we can find one or two big things and several medium-sized things that will help reduce health care costs.” alexander is retiring in 2020 so it is likely that the committee, on a bipartisan basis, will pass some health care legislation during this session of congress to memorialize his tenure.

house republicans closely aligned with drug industry

to get some idea as to why house gop leaders may have been protective of the pharmaceutical industry and opposed legislation such as the creates act, which drug manufacturers have also opposed, one only has to go to www.opensecrets.org and view the top recipients of drug industry political action committee (pac) contributions in the 2017–2018 congressional session (the category includes both pharmaceuticals and health care products). openscrets is a database run by the center for responsive politics. of the top four senators and representatives receiving pac contributions from the drug industry, three were house republicans, and all were in leadership positions, especially regarding drug industry legislation. representatives greg walden (r-or), kevin mccarthy (r-ca), and kevin brady (r-tx), who received contributions of between $315,000 and $460,000, were, respectively, chairman of the energy & commerce committee, majority leader of the house, and chairman of the ways & means committee.

the pharmaceutical research and manufacturers association (phrma) contributed $28 million in the 2017–2018 election cycle to candidates and party pacs. its biggest contribution was to the grand old party political action committee (gopac), whose motto is educating and electing a new generation of republican leaders. phrma’s $215,000 contribution was more than four times the amount of the next biggest contribution gopac received, and was a significant percentage of the pac’s $747,900 total revenue. phrma’s millions went to numerous washington lobbying firms, 10 of whom received more than $250,000 in 2018. their contributions put phrma in the number four position among trade associations, behind the u.s. chamber of commerce, the national association of realtors, and the open society policy center.

among drug industry companies, pfizer and amgen were number one and number two in regard to lobbying expenditures ($11.3 million and $10.9 million, respectively), with eight other companies spending over $6 million, including the biotechnology innovation organization (bio), the trade association for the biologics industry.

where debate is headed

the big question with regard to any legislation on drug prices is whether facts intercede with rhetoric and emotion. drug prices in general declined over the past year, according to the bureau of labor statistics, which says that the consumer price index (cpi) for the prescription drug category (all urban consumers) dropped 0.6% between the end of 2017 and the end of 2018. the increase in the cpi for all items was 1.9% over this period; medical care services as a whole were up 2.5%. however, regardless of whether prices are up or down, it is clear that prices for drugs in the u.s. are unquestionably higher than they are elsewhere in the world, often by substantial amounts.

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Forum, says, “Fundamentally, there is no broad prescription-drug pricing crisis. Indeed, in most instances, things are working just fine. Rather, what we face are more nuanced challenges.” Those nuanced challenges concern new, expensive, and often sole-source specialty drugs. Some sole-source generics have also posted ridiculous price increases. There are some problems, too, with the extension of brand patents in ways that have drawn criticisms—AbbVie’s Humira being a prime example—as well as efforts to block the entry of generics, which, in Humira’s case, the CREATES Act attempts to alleviate.

Any anger over drug prices and medical costs more broadly will only translate into legislative action where there is bipartisan agreement, Democratic takeover of the House aside. Thus, legislation giving Medicare the authority to negotiate drug prices, which is the topic of one bill sponsored by Senator Klobuchar, a presidential aspirant supported by many Democrats, is going nowhere.

Congress is likely to focus on current costly federal programs that need reform. At the top of that list are the Medicare Part D outpatient drug program, the Part B physician office/outpatient facility-reimbursement program, and the Medicaid drug-rebate program. Outside groups such as the Medicare Payment Advisory Commission (MedPAC) and its Medicaid counterpart annually recommend the reform of all three programs.

Part D spending was over $100 billion in 2016; Part B spending was close to $30 billion. Mark Miller, executive vice president of health care at the Laura and John Arnold Foundation, and former executive director of MedPAC, told the Finance Committee at its January 29 hearings that the average Medicare household will use approximately 15% of their total expenditure on health care. In Medicaid, spending on drugs grew by almost 50% between 2011 and 2017. “The federal government and states spent about $30 billion on drugs in Medicaid in 2017, after rebates,” Miller explained.

Miller said new treatments are launching at increasingly unsustainable prices that are not justified by their research and development costs. He cited life-extending cystic fibrosis treatments that cost close to $300,000 per year. Chimeric antigen receptor T-cell (CAR-T) therapy can easily top $500,000, and several companies have discussed pricing gene therapies in the region of $2 million.

Aaron Kesselheim, MD, director of the Program On Regulation, Therapeutics, And Law at Harvard Medical School, says list prices for brand-name drugs have increased from about 8% to 16% per year over the last decade, well beyond the CPI general inflation rate of 1–3% per year. U.S. drug prices and spending far exceed those of other, similar industrialized countries around the world. For example, in countries like Canada, Germany, France, and Australia, all of which have excellent health care systems, per-capita expenditure for prescription drugs is $400 a year compared to $850 a year in the U.S. The main driver behind the U.S. figure is brand-name drugs, which account for 10% of prescriptions and 75% of outlays.

But legislation to trim federal and patient spending on Part D, Part B, and Medicaid is hardly a done deal, given the broad opposition from drug manufacturers, PBMs, and patient advocacy groups to many of the Trump administration’s regulatory initiatives meant to cut federal and patient costs by reining in prices of specialty drugs, which account for the lion’s share of federal (and commercial) drug spending.

The Medicare Part B program allows physicians and hospital outpatient clinics to bill Medicare and patients, where there is a deductible or co-payment or both based on the “average sales price” alone—that is, what the market can bear—with no consideration as to the value or cost-effectiveness of the drug. Again, these are typically the expensive oncology, hepatitis C, and arthritis drugs, often biologicals. Among the 75 drugs with the highest annual Part B expenditures in 2016 (accounting for about $20 billion, or 77% of Part B drug spending), prices for 65 of the 67 drugs with evaluable data (97%) were considerably higher than the median prices in other high-income countries (Japan, Germany, Switzerland, and the UK), and generally made and sold by the same manufacturers as in the U.S. In May 2018, drug prices were, on average, 46–60% lower in those countries than in the U.S.’s Medicare drug-benefit program.

Pressure on Congress from Interest Groups

Trump’s Centers for Medicare and Medicaid Services has already proposed a major reimbursement change for Part B drugs (see the March 2019 issue of P&T), basing drug prices on international prices and a competitive acquisition program where hospitals and physicians would have less incentive to buy the highest-priced drugs, which spikes their reimbursement. But importing international drug prices into Medicare has been panned by Express Scripts and other PBMs, who argue that it would destroy the PBMs’ incentive to participate because they would buy drugs from U.S. manufacturers at high prices and have to sell them at low foreign prices. There has been considerable opposition to that from interest groups and drug manufacturers, among others.

Democrats in Congress have endorsed an international pricing index, not just for Part B drugs but for all drugs, paid for by the federal government and private employers. Their Prescription Drug Price Relief Act would peg the price of prescription drugs in the U.S. to the median rate in Canada, the UK, France, Germany, and Japan. If pharmaceutical manufacturers refuse to lower drug prices below that level, the federal government would approve cheaper generic versions of those drugs, regardless of any patents or market exclusivities in place. It is unclear, however, whether that bill will gain any Republican support. Schmid of the AIDS Institute says his group opposes the bill.

The flip side of questionable Republican support for those pricing caps is the questionable Democratic support for Trump-proposed changes to Part D, including new power for pharmacy and therapeutics committees to limit access to drugs. Chief among those changes is a constriction of the current six “protected classes” by allowing the use of step therapy and prior authorization, neither of which can be used in those six categories at present. That initiative, like the Part B initiative, is aimed at the specialty drug category by, for example, forcing cancer patients to try less expensive alternatives before being prescribed the most expensive oncology drugs. The American Society of Clinical Oncologists calls the proposal “misguided.” The six classes are: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for the treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics, except in limited circumstances. The Trump administration

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argued that the protected classes do not allow normal price negotiations and that there is “a strong incentive for the promotion of overutilization, particularly off-label overutilization, of some of these drugs.”

The Obama administration also published a proposed rule in 2014 that would have relieved Part D plans from providing “all or substantially all” of the drugs in the six protected categories. But patient groups complained to Congress and bipartisan pressure forced the Obama administration to cease and desist. Now the Trump administration has picked up the cudgel against the six protected classes.

Patient and physician groups and drug companies are besieg-ing Congress once again. In response, Senators Marco Rubio (R–FL) and Kyrsten Sinema (D–AZ) have circulated a letter to HHS Secretary Alex Azar decrying the changes. They wrote that although they applauded the administration’s commitment to lowering drug prices, “undermining the protected class status of medications could have much larger consequences in the long term.” Representatives Barbara Lee (D–CA) and Will Hurd (R–TX) are readying a similar letter from House members.

Anyone who thinks Democratic control of the House will lead to congressional passage of important drug-pricing legislation oughtn’t bet their 401(k) on that. Although drug companies, PBMs, physician groups, and patient advocacy organizations swear they want to do “something” about high drug prices, they are simultaneously opposing many of the proposals that would reduce those prices the most. One almost can’t blame Congress for being frozen in its tracks.