

Drug, Device Manufacturers to Face Hill Scrutiny in 2019

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By Jaime L.M. Jones and Amy L. DeLine

Combating high drug and device prices is a bipartisan goal in Congress, and House Democrats in control of key oversight committees have made clear their plans to pursue investigations putting pharma CEOs under scrutiny. Sidley Austin LLP attorneys Jaime L.M. Jones and Amy L. DeLine say manufacturers need to prep now to explain policies and prepare for public relations issues.

Democratic leaders in both the House and the Senate ended 2018 with promises to combat rising drug and device prices. On the House side, expect more scrutiny from the new Democratic chairman of the House Oversight Committee who has signaled intentions to use unilateral authority to issue subpoenas to launch and pursue investigations into the pricing practices of pharmaceutical companies.

Lawmakers in the House and Senate are focused on reducing prices, lowering out-of-pockets costs to consumers, increasing transparency around pricing and price increases, and decreasing government spending on health care.

House Side: Pharma CEOs on Alert

Rep. Elijah Cummings (D-Md.), incoming chair of the House Oversight & Government Reform Committee and a longtime outspoken critic of the high cost of drugs and drugmakers' price increases, has said he intends to bring pharmaceutical company CEOs in to testify before Congress to explain why drug prices are so high.

As the ranking Democrat on the Oversight Committee, he was consistently frustrated by the Republican leadership in investigating these issues --having 64 subpoena requests, many related to these and other healthcare issues, squashed since 2016. As chair, House rules will grant him unilateral authority to issue those or similar subpoenas on behalf of the committee. (Senate rules, by contrast, require that a committee's chair and ranking member both approve subpoenas.)

Likewise, both Reps. Frank Pallone (D-N.J.) and Richard Neal (D-Mass.), incoming chairs of the House Energy & Commerce and House Ways & Means Committees, respectively, declared that health care will be a top priority for their committees, with drug pricing as a central issue. Both Pallone and Neal, like many policymakers and lawmakers, have focused particularly on controlling out-of-pocket costs for consumers and other consumer protection initiatives.

Senate Democrats Gearing Up

Democratic leaders in the Senate are likewise making their intentions known. Sen. Elizabeth Warren (D-Mass.), for example, introduced legislation in mid-December, the Affordable Drug Manufacturing Act, to establish an Office of Drug Manufacturing to manufacture generic drugs and increase their availability.

On the same day, Sen. Ron Wyden (D-Ore.), the ranking Democrat on the Senate Finance Committee, sent Pfizer a letter asking the company to explain its price increases for Lyrica, a nerve pain medication. That demand followed demands in October by congressional Democrats to the CEOs of Pfizer and four other drug manufacturers requesting information about their drug pricing practices, investments in research and development, executive compensation, and other topics.

A divided government would typically mean that Warren's legislation and other legislative proposals from Democrats on drug pricing issues have little hope of passing. However, drug pricing may be common ground for Republicans and Democrats.

These issues have been a pillar of the Trump administration's agenda since 2016 and leaders of both parties, including the likely Speaker of the House Nancy Pelosi (D-Calif.) and Senate Majority Leader Mitch McConnell (R-Ky.), have indicated that they hope to work in a bipartisan way to bring down drug prices and spending.

Importantly, Sen. Chuck Grassley (R-Iowa), a longtime critic of drug and device manufacturers, will take over as Chair of the Senate Finance Committee with Sen. Wyden (D-Ore.) as the ranking Democrat. The two have previously worked together on the Finance Committee to investigate pricing issues and are in a position to resume their efforts in 2019. Select Committee on Aging Chair Susan Collins (R-Maine) is also expected to work closely with Democrats on these issues.

Manufacturers Need to Prepare Now

Congressional inquiries and investigations may be an even bigger concern for drug companies if bipartisan legislation cannot get through the new Congress. House Democrats likely will use investigations to draw public attention to and influence pharmaceutical companies' business practices.

The ability unilaterally to issue subpoenas means that House Democratic committee chairs have the power to launch and pursue investigations, including the authority to hold informal, private briefings with companies; demand company documents; conduct hearings on priority matters; and compel testimony, as Rep. Cummings (D-MD) has indicated he will do from industry CEOs. These investigations present a particular challenge to manufacturers because there are few rules, no neutral decision makers, no appeals, and no evidentiary standards.

Drug and device manufacturers are taking steps now to prepare for these all-but-certain inquiries and investigations, while also defending their pricing and pricing-related practices on numerous other fronts.

Many companies are or will be facing similar state-level legislative inquiries as well as federal and state enforcement activity, in addition to engaging on policy proposals and regulatory action by both federal and state executive agencies, including the Drug Price Transparency proposal recently announced by the Trump Administration.

Little is certain about how the politics around drug and device pricing will evolve into action in 2019, but what is certain is that the intense focus on the issues will continue. Manufacturers are advised to get ahead of the legal, policy, and public relations challenges that are coming.

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