

UPDATES

Manufacturers Face Congressional Scrutiny of Drug Pricing

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Pressure from the Trump Administration and Congress on drug pricing issues continues to mount. Through requests for information, guidance statements, rulemaking activities, and legislative bills and enactments, among other activities, policy officials and lawmakers have expressed a clear focus on efforts to reduce prices for drugs and biologicals, to lower out-of-pocket costs for consumers, and to decrease spending on drugs by government programs. On both the regulatory and legislative fronts, a number of initiatives and proposals have highlighted transparency in various forms as a key mechanism to facilitate reform. (Please see our recent Sidley Update: [HHS Secretary Azar Announces DTC Drug Price Transparency Proposal, Foreshadows Additional Regulatory Action to Address Drug Prices](#))

Taking another step on these issues, on October 15, 2018, Congresswoman Jan Schakowsky (D-IL) and 15 additional congressional Democrats sent letters to the CEOs of five drug manufacturers requesting information about the companies' drug pricing practices following enactment of the Tax Cuts and Jobs Act in December 2017. The letters, available [here](#), ask the manufacturers to respond in writing with information on any pharmaceutical products for which the manufacturer changed the list price since November 28, 2017. The letters also request that the manufacturers quantify their investments in research and clinical development; acquisition startup firms, patent licenses, or other drug development assets; and direct-to-consumer and direct-to-prescriber marketing and advertising. In addition, the letters ask the manufacturers to include any drug development portfolio discontinuations, executive compensation information, and country-by-country financial reports. These letters underscore the reality that Members of Congress, whether in the majority or the minority, can—and do—inquire and see responses from companies about topics of interest to lawmakers and the public.

The risk of congressional inquiries and investigations is an important consideration for biopharmaceutical manufacturers, particularly given the focus of both Republicans and Democrats on issues of drug pricing. Moreover, in light of recent polling suggesting that Democrats may be in position to retake the majority in the House of Representatives following the November mid-term elections, manufacturers should anticipate the potential for additional, rigorous scrutiny from Congressional investigators if that were to occur. Notably, Congresswoman Schakowsky is in line to become the top Democrat on the Health Subcommittee of the House Energy and Commerce Committee (a key congressional committee with healthcare jurisdiction) if control of the House shifts to Democrats.

Other House Democrats in leadership positions likewise have indicated a focus on issues of drug pricing and healthcare reform more broadly. For example, Congressman Elijah Cummings (D-MD), currently the ranking member of the House Oversight and Government Reform Committee, has made 64 subpoena requests during the last two years, a number of which have focused on drug pricing issues, although all such requests were denied. (Under House rules, only the majority Chair can authorize subpoenas.) If he were to become Committee Chair following the mid-term elections, Congressman Cummings has said that his agenda would likely include probing the Trump Administration's prescription drug policies. As another example, Congressman Frank Pallone (D-NJ), currently the ranking member of the House Energy and Commerce Committee, has expressed a desire to focus on healthcare reform, with drug pricing identified as a component of those issues.

Congressional inquiries and investigations often thrive in periods of divided government. Even under the current circumstances of a Republican-controlled White House, Senate, and House of Representatives, inquiries and other efforts focused on drug pricing are active and ongoing. Under a potential scenario of divided government following the mid-term elections, enacting legislation would become increasingly difficult. In such an environment (e.g., the potential for a Democratic-controlled House and a Republican-controlled Senate and White House), the House likely would turn to investigations as a way to influence private sector business practices. And House Democratic committee chairs would have virtually unbridled power in launching and pursuing these investigations, including the authority to hold informal, private briefings with companies; demand company documents; conduct hearings on priority matters; and compel senior company executives to testify in public. In the House, one of the most significant powers that comes with a majority is the ability of a committee chair to issue subpoenas unilaterally. (In the Senate, in contrast, the rules require a committee's chair and ranking member to authorize subpoenas together.) Compounding the complexity of dealing with these inquiries is the fact that Congressional investigations take place on a unique landscape where there are few rules, no neutral decision makers, no appeals and no evidentiary standards.

If Democrats were to take control of the House, the shift would not take effect until January 1, 2019. In the meantime, particularly in light of ongoing activities and inquiries focused on drug pricing, drug and biologics manufacturers should consider preparing for inquiries and investigations now by evaluating the risk of an inquiry or investigation, weighing strategic options, understanding company policies and procedures, assessing potential vulnerabilities, and documenting the rationale for company decisions. Managing legal, policy, political, and public relations risks before a formal investigation advances will increase the chances for positive outcomes.

For more on other breaking drug pricing related news, visit [Sidley's Global Drug Pricing](#) page.

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