New Congress Brings Heightened Risk of Investigations for Life Sciences Companies

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In the long run-up to this month's midterm elections, journalists spilled significant ink discussing the potential investigations that a Democrat-controlled House of Representatives could launch against figures in the Trump administration, while virtually ignoring potential targets in the private sector. But healthcare policy issues are hot-button topics for both Democratic and Republican voters, which could lead the new Congress to direct significant attention toward the life sciences industry.

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Pharmaceutical, biotech, and medical device companies therefore would be wise to prepare for a potential slate of requests, hearings, and investigations by the House's new leadership. The pharmaceutical and biotech industries are particularly vulnerable, because drug pricing is one of the few healthcare issues that could gain bipartisan support in the newly split Congress. This update provides an overview of the expected leaders of key committees and subcommittees in the newly elected House and likely congressional investigation priorities in the life sciences space. Companies that expect to be in the line of fire should preemptively seek expert advice about the unique legal and political challenges that accompany congressional investigations.

New House leadership. The most obvious risks to life sciences companies are potential investigations by the House Energy and Commerce Committee, which, along with the Senate Health, Education, Labor and Pensions Committee, has substantive oversight over many aspects of the life sciences industry. Rep. Frank Pallone (D-NJ), current ranking member of the Energy and Commerce Committee, handily won his reelection bid and is poised to become the committee's Chair. Pallone has shown interest in potential investigations relating to opioids. He is also a proponent of prescription drug price reductions, where he may have common ground with the White House.

The powerful House Ways and Means Committee is expected to be chaired by Rep. Richard Neal (D-MA), its current ranking member. Alongside the Energy and Commerce Committee, Ways and Means may have a role in inquiries that involve Medicare-related policy proposals—for example, efforts to empower Medicare to negotiate directly with drug companies, as Speaker-presumptive Nancy Pelosi (D-CA) promised in her election-night victory speech. Rep. Lloyd Doggett (D-TX), who is likely to chair the Ways and Means Health Subcommittee, worked with Rep. Elijah

Cummings (D-MD) and Rep. Peter Welch (D-VT) this past summer on draft legislation to enable Medicare price negotiation and to authorize the Department of Health and Human Services to grant licenses to additional drug makers to use patented information, clinical trial data, or other regulatory exclusivities when negotiations stall.

Cummings, who is the ranking member of the House Committee on Oversight and Government Reform for the 115th Congress, is positioned to chair his investigations-driven committee when the new Congress is sworn in. In his capacity as ranking member, Cummings spearheaded high-profile investigations into prescription drug prices in 2011 and 2014, and he can be expected to continue his focus on this issue. Although his committee's primary domain is oversight of federal agencies and policy, any industry player subject to regulation by the Food and Drug Administration ("FDA") or other federal agencies could be the subject of an inquiry by the committee.

Likely congressional priorities in 2019. Recent actions by these leaders and committees reveal likely priorities for the 116th Congress and possible targets for upcoming congressional investigations.

Drug pricing. Pharmaceutical companies will almost certainly face questions about their pricing of prescription drugs. Allegations of price hikes have garnered significant attention from Pelosi and other Democrats in the House. Companies subject to congressional inquiries may face similar scrutiny in the Senate, as Senate Majority Leader Mitch McConnell (R-KY) and President Donald Trump have expressed interest in bipartisan efforts to reduce drug prices.

In the weeks before the midterm elections, 16 Democrats, including Rep. Jan Schakowsky (D-IL), the ranking member of the Energy and Commerce Committee's Subcommittee for Digital Commerce and Consumer Protection, signed letters to the chief executives of multiple pharmaceutical companies requesting detailed information about their pharmaceutical prices. The requests included questions about company revenue and executive compensation—inquiries likely designed to raise the specter of negative public relations narratives. The companies were given a response deadline postdating the elections, signaling that the lawmakers intend to pursue their inquiry in the 116th Congress.

Within other House committees, inquiries from prior years may reappear in aggressive new forms or with new targets. In August 2017, Cummings sent document requests to seven pharmaceutical companies inquiring about their prescription drugs to treat multiple sclerosis. The requests sought communications at all levels of the distribution chain and referenced allegations about "shadow pricing," or lockstep price increases across competitor brands.

Competition. As evidenced by Cummings' "shadow pricing" requests, congressional attention on prescription drug pricing has included measures to increase industry competition.

In July, for example, Pallone wrote to the Republican Chair of the House Energy and Commerce Committee to request hearings into allegedly anticompetitive practices by pharmaceutical companies and purported abuses of FDA's regulatory processes to delay the entry of competitive generics into the market. Pallone's focus at the time was the Creating and Restoring Equal Access to Equivalent Samples ("CREATES") bill, which, if enacted, would permit generic companies to sue brand competitors in order to access drug samples needed for FDA-required testing and generic drug approval. With the Democrats retaking control of the House, the Energy and Commerce Committee may take up the bill once more, and its Chair Pallone may pursue the hearings he requested this summer.

Last month, President Trump signed the Patients' Right to Know Drug Prices Act, which both prohibits contractual "gag clauses" that limit pharmacy providers' ability to provide drug pricing information to health plan enrollees and requires pharmaceutical companies to submit details of settlements between biologic and biosimilar developers to the Federal Trade Commission ("FTC") for review. Over the summer, Senators Chuck Grassley (R-IA) and Amy Klobuchar (D-MN) asked the FTC to examine "pay-for-delay" deals that they allege may be hindering biosimilar competition and violating antitrust law. With additional information now available to the FTC, Congress could follow up with oversight hearings to supplement the FTC's response to specific settlements and to assess the need for further legislation.

Drug and medical device safety and marketing. Over the past year, both the Energy and Commerce Committee and its Subcommittee on Oversight and Investigations have shown ongoing interest in the regulation and marketing of opioids. It is likely that investigations will continue to develop out of negative headlines about opioids and other prescription drugs.

Medical device companies may also face continued congressional attention in this area. The Opioid Crisis Response Act of 2018, a bill passed nearly unanimously by the Senate in September, prompted some industry consternation due to a provision requiring public disclosure of payments by drug and medical device companies to nurse practitioners and physician assistants for consulting and promotional talks. Medical device companies have been under increased scrutiny following this year's release of a controversial Netflix documentary on medical device marketing and safety. Legislative demands for manufacturer disclosures may be a precursor to bipartisan oversight hearings or investigations.

Privacy. Privacy issues are also high on the Democrats' legislative agenda. In the past year, Senators Edward Markey (D-MA), Richard Blumenthal (D-CT), and Mark Warner (D-VA) have presented proposals to overhaul data privacy regulations. Their counterparts in the House may use their new committee posts to pursue investigations on the same topic. In light of recent reports of data breaches implicating patient histories and other sensitive information, companies that retain individual medical records may be vulnerable to highly charged cybersecurity and data privacy inquiries.

Preparing for congressional investigations. If contacted by congressional staff, companies should be aware of the high-stakes publicity and legal complications associated with congressional investigations. Given these unique risks and obstacles, potential target companies and/or individual executives are strongly advised to retain counsel with experience and expertise in each of these areas:

Privilege issues. If a committee or subcommittee requests or subpoenas documents and testimony, companies are not guaranteed a protection that is taken for granted in other scenarios: the attorney-client privilege. Because Congress officially does not recognize the privilege, sensitive documents and communications that were drafted under the assumption of confidentiality may be demanded by congressional staffers—a risky scenario given the high incidence of leaks from the legislative branch. An experienced congressional counsel can interface with committee staff and strike the correct balance between cooperation and the protection of key privacy and business interests.

Public relations. As officials who face periodic elections, members of Congress may be motivated as much by political opportunity as by an interest in fact-finding. As a result, members of Congress frequently publish their letters to targeted companies while investigations are ongoing and speak freely to the press about the investigation process—unlike regulators and criminal investigatory bodies, whose behaviors are governed by more stringent rules and customs. Hearings may present televised opportunities for members of Congress to score political points, often at the expense of the testifying witnesses. Companies that expect their executives to be called before Congress should retain counsel with the relevant experience and strategic skills to maximize opportunities for positive narratives while minimizing reputational damage.

Follow-on investigations and litigation. Public testimony, leaked documents, and even unsubstantiated accusations by congressional representatives may trigger investigations by regulators or lead to litigation from aggrieved shareholders and consumers. Witnesses are frequently placed in the challenging position of responding to questions that are accusatory and/or based on confused or inaccurate premises, while under the threat of potential criminal charges for making false statements to members of Congress or their staff. Potential target companies and their executives are advised to

consider not only public relations risks, but also potential collateral legal ramifications of their responses to congressional requests.

Regulatory expertise. For investigations involving complex FDA or Centers for Medicare and Medicaid Services ("CMS") regulations, it is imperative that counsel have a keen understanding of the applicable regulatory regime, including nuances not necessarily appreciated in Congress.

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Please do not hesitate to contact us with any questions regarding congressional inquiries or their collateral consequences. We would be happy to connect you with the experts from Debevoise's Crisis Management, Congressional Investigations, Health Care, White Collar & Regulatory Defense, FTC Regulatory Defense, and/or Civil Litigation teams who can best serve your company's needs.

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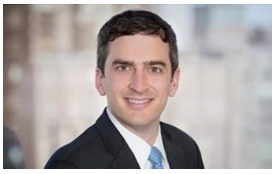

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