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# Congressional Investigations and the Life Sciences Industry

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*This alert is issued in conjunction with a webinar on congressional investigations issues for life sciences companies that Covington & Burling conducted on June 17, 2015. A recording of the webinar may be accessed here.*

Life sciences companies have attracted bipartisan scrutiny from Congress on a range of issues in recent years. Both Republican and Democratic members on key committees have a history of conducting investigations or hearings to examine perceived abuses or misconduct by individual companies, often triggered by reports about drug and device safety or pricing concerns. Such event-driven inquiries continue to be a risk for the industry. Similarly, congressional investigations directed at executive branch agencies, such as the FDA, are common when the branches are controlled by different parties. Although not targeted at companies, companies often find that they are swept into these investigations because the agency's oversight of their operations is often a focus of the inquiry.

On the Senate side, the Finance Committee and the Health, Education, Labor and Pensions ("HELP") Committee have conducted multiple investigations of life sciences companies, often on a bipartisan basis, and Senator Charles Grassley (R-Iowa) earned a reputation for tough investigations of drug company advertising practices; relationships with physicians, researchers and medical groups; drug pricing; and drug and device safety, among other issues. Grassley is no longer in the leadership of the Finance Committee, but he chairs the Judiciary Committee and remains an influential senior member of the Finance Committee. On the House side, both the Energy and Commerce Committee and the Committee on Oversight and Government Reform have held hearings on drug safety and supply chain concerns.

The following is a summary of issues involving the life sciences industry that have captured, and may continue to capture, Congress's attention.

**Drug Pricing**

Some pharmaceutical and biotechnology companies have found themselves in Congress's crosshairs as a result of how they price their drugs. Drugs that are likely to have a significant impact on Medicare and Medicaid spending are most likely to draw attention from relevant committees, especially if they are available in other countries for substantially lower prices. In late 2014, a Senate HELP Subcommittee and House Oversight and Government Reform Committee Ranking Member Elijah Cummings (D-Md.) launched a joint investigation of generic drug pricing targeting 14 companies. The Senate Finance Committee and House Energy and Commerce Committee also launched drug pricing inquiries last year. In 2012, a Senate HELP subcommittee held a hearing to examine the high cost of HIV/AIDS drugs. And in 2011, Rep.

Cummings investigated five "gray market" drug companies alleged to have engaged in price-gouging hospitals in the wake of nationwide shortages of key drugs.

**Drug and Medical Device Safety**

Medical studies or press reports raising drug or device safety concerns also frequently draw Congress's attention. For example, the House Oversight and Government Reform Committee launched a wide-ranging investigation in 2005 after safety issues emerged involving an anti-inflammatory drug. Similarly, a 2007 study raising concerns about the safety of a diabetes drug led to a multi-year investigation by the Senate Finance Committee. In May 2010, the House Committee on Oversight and Government Reform held a hearing on the recall of certain pediatric medicines. And in May 2013, the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations sought documents and communications from two manufacturers of dietary supplements containing the stimulant dimethylamylamine. In a further sign of Congress's ongoing interest in drug safety, the House Energy and Commerce Committee and Senate HELP Committee have both held hearings in recent years on securing the nation's pharmaceutical supply chain.

**Marketing Practices**

Congress has a history of scrutinizing drug company marketing practices. In some cases, such investigations have been prompted by safety concerns involving specific drugs. A prime example is the House Oversight and Government Reform Committee's 2005 investigation of Merck for its marketing of Vioxx. Similarly, in 2007, following press reports about safety risks and off-label usage of certain anti-psychotic and pain medications, the House Committee on Oversight and Reform sought information from three pharmaceutical companies about allegedly inappropriate marketing practices.

Pharmaceutical company relationships with physicians and medical groups have also sparked congressional concern. For example, in May 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and Ranking Member Grassley launched an investigation into the relationship between several drug manufacturers and medical groups that advocated the use of narcotic painkillers. In February 2010, after learning that WebMD was running a television advertisement promoting a depression-screening test sponsored by a pharmaceutical company, Senator Grassley launched an investigation into the financial ties between the two companies. And in 2008, Senator Grassley conducted an investigation into potential conflicts of interest stemming from pharmaceutical company payments to physicians and researchers.

Rep. Cummings, the Ranking Member on the House Committee on Oversight and Government Reform, has stated that companies that pay doctors to promote their products or tie sales representatives' compensation to the number of prescriptions doctors write would face scrutiny from Congress through the Affordable Care Act's transparency and disclosure requirements. In addition, the 21st Century Cures Act, recently approved by the House Energy and Commerce Committee, has the potential, if enacted, to create ambiguity with regard to the types of physician payments and interactions that are exempt from these requirements. The potential for confusion or lack of clarity in this area poses the risk of further attention from congressional investigators in the future.

### FDA Regulatory Dealings

Interactions between pharmaceutical companies and the FDA have also been the subject of congressional investigations. Congress has conducted investigations into allegations that companies inappropriately influenced FDA regulatory actions by, for example, cooperating with groups lobbying against the approval of generic alternatives, failing to disclose relevant data, or attempting to discredit individual FDA employees. In almost every investigation of a drug or device safety issue, Congress can be expected to ask whether FDA's oversight is sufficient or inadequate.

### Tax Avoidance Issues

From 2009 to 2011, the Senate Permanent Subcommittee on Investigations conducted an extensive investigation into offshore tax avoidance that targeted a number of major pharmaceutical companies.

### Emerging Life Sciences Issues of Interest to Congress

Because congressional investigations are usually driven by events, it is hard to predict Congress's future focus. Congress's recently demonstrated interest in several topics, however, could indicate likely areas of scrutiny.

- *"Pay for delay"*: Senators Grassley and Amy Klobuchar (D-Minn.) have introduced legislation to prevent so-called "pay for delay" agreements between pharmaceutical companies and prospective generic competitors.
- *Fraud and abuse in government programs*: Medicare and Medicaid programs are always potential targets for investigations. The changing and expanding nature of these programs as a result of the Affordable Care Act may lead to new areas of inquiry. Senator Grassley last month sent letters to the Centers for Medicare and Medicaid Services and the Department of Justice urging a crack-down in overpayments in the Medicare Advantage program.
- *340B federal drug discount program*: Members of Congress in both the House and the Senate have expressed concern about abuse within the 340B federal drug discount program, eligibility for which was expanded by the Affordable Care Act.
- *Bio-threat preparedness*: Congress regularly holds hearings on public health preparedness issues including, for example, Ebola and seasonal and pandemic influenza.

Covington's Congressional Investigations and Food and Drug Practices

Covington has unparalleled experience representing corporations and individuals in congressional investigations. Our experiences span the full scope of investigations – from discrete requests resolved with little public attention, to some of the most high-profile and contentious investigations and oversight hearings posing significant legal and reputational risks for global companies. We frequently engage with the key congressional investigations staff, with whom we have many years of experience. Major corporations regularly turn to us to prepare their CEOs and other senior executives for congressional investigations testimony.

We draw on the firm's significant experience in white collar litigation, government relations, political law, and specific regulated industries. Our lawyers are particularly adept at balancing the risks associated with parallel congressional investigation, civil and criminal litigation, and

regulatory enforcement actions. Our practitioners include veterans of the House and Senate, the White House, and numerous federal agencies, on a bipartisan basis, including former senior staff and Members of Congress who have run congressional investigations.

Covington's internationally leading Food and Drug Practice, tracing to the firm's founding in 1919, features numerous alumni of the U.S. Food and Drug Administration and covers every facet of food and drug regulatory law, including all matters within the FDA's regulatory purview, federal and state fraud and abuse issues, Medicare, Medicaid, and related reimbursement areas. Our global client base encompasses pharmaceutical, biotechnology, medical device, food, organic, veterinary, cosmetic, and agricultural companies, ranging from major multinationals to mid-size and emerging companies to start-up ventures. Over the years, we have represented the vast majority of the world's pharmaceutical, biotechnology, medical device, veterinary, and agricultural companies, as well as the leading industry trade associations. We are the only firm recognized as a "Band 1" firm for Life Sciences by *Chambers & Partners* across their US, UK, Europe, China and Global surveys.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Public Policy & Government Affairs practice group:


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