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Drug Pricing Concerns Drive Continued DOJ Focus on Life Sciences Companies

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In 2019, U.S. Department of Justice (DOJ) enforcement activity targeting drug and device manufacturers jumped sharply over the prior year, reflecting an increased focus on fraud and abuse in the life sciences sector. More than two-thirds of settlements involved Anti-Kickback Statute (AKS) violations, highlighting the DOJ's scrutiny of the financial relationships between drug and device manufacturers and those who purchase, prescribe or pay for their products. We expect attention on kickbacks and financial fraud to continue in 2020 as the DOJ targets the activities it believes contribute to high drug and medical device prices.

Although Congress and the Food and Drug Administration (FDA) took steps to reduce health care costs in 2019, the year ended without significant legislation. While it is unlikely in an election year that Congress will send a drug pricing bill to the president, we expect the Trump administration to continue its push to lower drug prices through price transparency requirements, faster FDA approval of generic and biosimilar products, and enforcement actions against manufacturers involving practices that the DOJ believes are unlawful and contribute to higher drug costs, particularly for specialty products. We also anticipate that various states will continue to enact bills aimed at lowering drug prices, although the impact on prices of such state initiatives has been modest to date.

DOJ Enforcement Trends: The Perils Persist

Pharmaceutical and device makers faced tough scrutiny in 2019 from DOJ prosecutors concerned about high drug costs and allegations of improper relationships with prescribers and users of their products, as well as promotional activities that encourage use of products for medically unnecessary indications. Speaker programs continued to face withering scrutiny, as did company interactions with physicians and insurance companies regarding coverage and reimbursement issues. Patient privacy concerns also appeared to motivate DOJ enforcement activities, with the DOJ increasingly utilizing the Health Insurance Portability and Accountability Act as an enforcement weapon. To address the greatest areas of risk, many companies are modernizing their compliance programs to include controls around patient and provider support activities that are becoming more central to the commercial success of many newer products, such as restricting access to protected health information through data privacy programs, auditing patient support services, outsourcing services related to financial or patient-reimbursement matters and building a firewall between patient-facing activities and marketing, to name a few.

The DOJ's interest in kickbacks and financial fraud rather than advertising and promotion reflects two important trends: (i) the evolving life sciences industry business model (which generally includes a more significant percentage of higher-cost therapies with smaller patient populations; greater interactions with payers, specialty pharmacies, reimbursement hubs and patient advocacy organizations; and more complex financial and reimbursement flows), and (ii) successful court challenges to DOJ actions premised on companies' provisions of truthful, non-misleading information about their products. As companies have increasingly developed and commercialized higher-cost specialty

products, the DOJ has scrutinized activity it believes facilitates those higher costs, including improper donations to independent charitable copay foundations and fraud involving reimbursement information provided by manufacturers to insurers. Although the DOJ does not technically have authority to regulate drug prices, it nevertheless has used a variety of statutes to target programs that it believes inappropriately support expensive prices.

The most common theory of liability in 2019 continued to be allegations of kickbacks paid to physicians. Nine of the 14 kickback-related settlements involved alleged (or admitted) kickbacks to physicians, most commonly in the form of payments to physicians to educate and train health care providers about the benefits, risks and appropriate uses of prescription drugs for patients. The DOJ continues to take a granular approach to its review, critiquing the number of program attendees, the need for the information provided, the number of programs attended by the same person (so-called "frequent flyers") and even low-dollar activities, such as the provision of in-office meals or snacks, where it believes inadequate evidence exists that the items were incidental to the provision of legitimate product.

The settlements also reflect the DOJ's pursuit of what some prosecutors have called a "refined" approach to off-label enforcement. In particular, several recent settlements resolved allegations that the company's promotion of off-label uses caused the submission of claims for medically unnecessary uses in violation of the False Claims Act. Thus, while resolutions premised solely on off-label promotion appear to be a thing of the past, the DOJ seems poised to use its enforcement tools against promotional conduct that causes claims to be submitted for medically unnecessary procedures or nonmedically accepted therapies. We expect that the DOJ's enforcement priorities on kickbacks and other forms of financial fraud will continue in 2020 and the years ahead.

Drug Pricing: The Debate Rages On

Though much debate in 2019 surrounded rising health care costs, including drug prices, the year came to a close without the enactment of any major drug pricing legislation. In December 2019, the House of Representatives passed Speaker Nancy Pelosi's drug pricing bill, known as the Lower Drug Costs Now Act, which would allow the U.S. government to negotiate lower drug prices on the costliest drugs each year. However, those who oppose the legislation argue that it would stifle medical innovation, result in fewer lifesaving medicines and curtail investment in small biotech companies. Senate Finance Committee Chair Chuck Grassley and Ranking Member Ron Wyden introduced a competing bipartisan health care bill, known as the Prescription Drug Pricing Reduction Act of 2019, which is viewed as a more moderate alternative. The bill would reduce Medicare Part D beneficiaries' out-of-pocket costs and cap annual out-of-pocket spending in Medicare Part D. Although there is clear bipartisan interest in lowering prescription drug costs, the challenge for lawmakers is doing something meaningful about drug prices that will not hurt innovation or the development of new products.

While drug pricing legislation was not passed in 2019, the FDA took notable regulatory actions toward delivering lower prices and more access to prescription drugs. The agency announced an all-time record of 1,171 generic drug approvals in fiscal year 2019, following record-setting approvals in FY 2018 (971) and FY 2017 (937). In the U.S., nine out of 10 prescriptions filled are for generic drugs, and increased generic approvals should continue to facilitate access to even more affordable alternatives. In December 2019, the FDA also updated its List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic to improve transparency and encourage the development and submission of applications for drugs with limited competition. The FDA does not consider the cost of drugs when making drug approval decisions (unlike authorities in other countries) but encourages competition and has publicly recognized that it can help reduce drug prices and improve access to medicines.

Most recently, in December 2019, the Trump administration, along with the United States Department of Health and Human Services and the FDA, took a historic step in proposing a new rule that could allow certain prescription drugs to be imported from Canada to help reduce drug prices and improve access. Under the proposed rule, states, wholesalers or pharmacists could submit proposals to the FDA for the importation of certain prescription drugs that are approved in Canada and meet the conditions in an FDA-approved drug application. Eligible prescription drugs would have to be relabeled prior to importation and undergo testing for authenticity, quality, purity and potency. Notably, the proposals would have to demonstrate significant cost reductions to the American consumer in order to gain approval. Also, in December 2019, the FDA issued a draft guidance for the industry that describes procedures drug manufacturers can follow to import less expensive versions of their FDA-approved products that are manufactured abroad and authorized for sale outside the United States. Both the proposed rule and draft guidance are open for public comment, and interested parties should submit comments prior to the deadlines.

Even though federal prescription drug pricing legislation is uncertain for 2020, states are continuing to move forward to rein in drug prices and expand access. As of September 2019, 33 states had enacted a record 51 laws, according to the National Academy for State Health Policy. State drug pricing legislation primarily relates to (i) limiting "gag" rules by pharmacy benefit managers to prevent pharmacists from discussing pricing with customers; (ii) allowing importation of less expensive foreign prescription drugs; (iii) creating drug affordability boards; and (iv) increasing price transparency. We expect federal lawmakers will be watching state initiatives to discern where legislative compromise may lie.

The affordability of prescription drugs is a high priority among voters, lawmakers and the industry, and vigorous public debate is likely to remain unabated throughout 2020. We expect the executive branch to continue to advance programs that address rising health care costs and for Congress to look for areas for bipartisan compromise. Finally, the complexity of prescription drug pricing calls for clarity, creativity and education, especially with regard to the connections between drug pricing and innovation, the connection between high-priced specialty pharmaceuticals (such as gene and cellular therapies designed for small populations) and the potential for overall health care savings for patients and payers.