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Health Care Regulatory and Legislative Update

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Weekly Health Care Criminal and Civil Fraud Enforcement Round-Up

The following highlights notable health care fraud and abuse news, settlements, and enforcement actions in the final two weeks of 2016.

Department of Justice Recovers over $4.7 Billion from False Claims Act Cases in Fiscal Year 2016; $2.5 Billion Arising from Health Care Industry. On December 14, 2016, the Department of Justice (*"DOJ"*) released its fiscal year-end False Claims Act recovery statistics. For the fiscal year ended September 30, 2016, the government obtained over $4.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government. Of the $4.7 billion recovered, $2.5 billion came from the health care industry, including including drug companies, medical device companies, hospitals, nursing homes, laboratories, and physicians. Other highlights from the press release:

- This is the seventh consecutive year the DOJ's civil health care fraud recoveries have exceeded $2 billion.
- The drug and medical device industry accounted for the largest amount of recoveries — $1.2 billion.
- Hospitals and outpatient clinics accounted for $360 million in recoveries.
- Of the $4.7 billion recovered for FY 2016, $2.9 billion related to lawsuits filed under the *qui tam* (whistleblower) provisions of the False Claims Act.

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- Whistleblowers received $519 million in rewards for FY 2016.
- False Claims Act *qui tam* whistleblower suits have grown significantly, with 702 *qui tam* suits filed in 2016 — an average of 13.5 new cases every week.
- The DOJ credits increased False Claims Act recoveries since 2009 to the growth of *qui tam* From January 2009 to the end of FY 2016, the government recovered nearly $24 billion in settlements and judgments related to *qui tam* suits and paid more than $4 billion in whistleblower awards during the same period.

Teva Pharmaceutical Industries Ltd. Agrees to Pay More Than $283 Million to Resolve Foreign Corrupt Practices Act Charges. On December 22, 2016, the DOJ announced that Teva Pharmaceutical Industries Ltd. (*"Teva"*), the world's largest manufacturer of generic pharmaceutical products, agreed to resolve criminal charges and to pay a criminal penalty of more than $283 million in connection with schemes involving the bribery of government officials in Russia, Ukraine, and Mexico in violation of the Foreign Corrupt Practices Act (*"FCPA"*). According to the press release, Teva executives or employees (1) paid bribes to a high-ranking Russian government officials to increase Teva drug sales in Russian Ministry of Health annual drug purchase auctions, (2) paid bribes to a senior government official within the Ukrainian Ministry of Health to influence the Ukrainian government's approval of Teva drug registrations, and (3) failed to implement an adequate system of internal accounting controls and failed to enforce the controls it had in place at its Mexican subsidiary, which allowed bribes to be paid to doctors employed by the Mexican government. This settlement serves as an important year-end reminder of the FCPA's long reach, particularly within the pharmaceutical industry, and the need to implement robust FCPA compliance programs. Please contact us if you would like additional information regarding the FCPA and its application to the health care industry.

Bay Sleep Clinic Agrees to Pay $2.6 Million to Settle False Claims Act Violations. On December 28, 2016, the DOJ announced that Bay Sleep Clinic and related entities have agreed to pay $2.6 million to settle allegations that they fraudulently billed the Medicare program for sleep tests (1) performed by technicians lacking the licenses or certifications required by Medicare payment rules or (2) conducted at unenrolled and unapproved locations. Specifically, the government alleged that company regularly falsified documents to represent that sleep tests performed at unapproved facilities had been performed at one of the company's two Medicare-approved facilities. Additionally, the government alleged the defendants fraudulently billed Medicare for medical devices in violation of Medicare rules and regulations that prohibit providers of diagnostic sleep tests from supplying medical devices and from sharing a sleep laboratory location with a durable medical equipment supplier. This case was initially filed by a whistleblower, who will receive $545,000 of the government's recovery. In addition to cash penalties, the company agreed to withdraw from the Medicare program participation for three years.

Forest Laboratories and Forest Pharmaceuticals to Pay $38 Million to Resolve Kickback Allegations under the False Claims Act. On December 15, 2016, the DOJ announced that Forest Laboratories LLC (*"Forest"*) has agreed to pay $38 million to resolve allegations that it violated the False Claims Act by paying kickbacks to induce physicians to prescribe three Forest drugs. The government specifically alleged that Forest violated the Anti-Kickback Statute, which prohibits the payment of remuneration to induce referrals of items or services covered by federal health care programs, by providing payments and meals to physicians in connection with speaker programs about the Forest drugs. The United States contend that the payments

and meals were intended as improper inducements because Forest provided these benefits even (1) when the speaker programs were cancelled (and Forest provided no evidence of a bona fide reason for the cancellation), (2) when no licensed health care professionals attended the programs, (3) when the same attendees had attended multiple programs over a short period of time, or (4) when the meals associated with the programs exceeded internal cost limitations. The suit was initially filed by a whistleblower, who will receive approximately $7.8 million of the government's recovery.

Food and Drug Administration Delays Off-Label Promotion Guidance

This month, the Food and Drug Administration (*"FDA"*) announced that it was extending the public comment period for feedback on how it should regulate the marketing of the unapproved uses of drugs and medical devices — known as "off-label promotion" — to April 10, 2017. The comment period extension was issued after over 60 speakers representing different stakeholders voiced their opinions on the issue over two full days of public hearings in November. The FDA's long-standing stance that the promotion or marketing of drugs for unapproved uses constitutes "misbranding" in violation of the Food, Drug and Cosmetic Act, was called into question earlier this year when Amarin Pharma, a small drug manufacturer, challenged the FDA under First Amendment grounds when it sought to promote the off-label use of its cardiovascular health drug for patients with a different condition. The United States District Court granted summary judgment in favor of Amarin, declaring that "Amarin may engage in truthful and non-misleading speech promoting the off-label use of [its drug], and … such speech may not form the basis of a prosecution for misbranding." We will continue to monitor developments in this area next year.

21st Century Cures Act Signed into Law

Earlier this month, President Obama signed the 21st Century Cures Act (*"Cures"*) into law — one of the most expansive pieces of health care legislation since the Affordable Care Act. The nearly 1,000-page law, which was passed with bipartisan support, aims to accelerate the discovery, development, and delivery of new disease treatments and cures. Cures is expansive in scope and will affect all pieces of the sector in some way — providers, patients, drug and device manufacturers, clinical researchers, and regulatory agencies. Cures authorized spending on a number of priorities, including funding for biomedical research initiatives such as President Obama's Precision Medicine Initiative ($1.4 billion), the Brain Research through Advancing Innovative Nuerotechnologies Initiative (known as the BRAIN Initiative) ($1.5 billion), Vice President Biden's Cancer Moonshot ($1.8 billion) and regenerative/stem cell medicine ($30 million), and funding to help states prevent opioid misuse and provide additional treatment options ($1 billion). While passed with bipartisan support, Cures has its critics, which argue that certain innovation and deregulation provisions of the law intended to accelerate the process for bringing drugs and devices to market benefits lucrative drug industry at the expensive of patient safety. The full text of the law can be viewed here. We will continue to monitor Cure's effect on the industry as we move into 2017.