GIBSON DUNN

Webcast: The False Claims Act – 2021 Update for Drug & Device Manufacturers

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Third of Four Industry-Specific Programs

The False Claims Act (FCA) is one of the most powerful tools in the government's arsenal to combat fraud, waste, and abuse involving government funds. After several years of statements and guidance indicating that the Department of Justice (DOJ) might alter its approach to FCA enforcement, the Biden Administration appears to be taking a different, more aggressive approach. Meanwhile, newly filed FCA cases remain at historical peak levels, and the government has recovered nearly $3 billion or more annually under the FCA for a decade. The government also continues to pursue new, large spending projects in COVID-related stimulus and infrastructure—which may bring yet more vigorous efforts by DOJ to pursue fraud, waste, and abuse in government spending. As much as ever, any company that receives government funds—especially in the drug and medical device sector—needs to understand how the government and private whistleblowers alike are wielding the FCA, and how they can defend themselves.

Please join us to discuss developments in the FCA, including:

- The latest trends in FCA enforcement actions and associated litigation affecting drug and medical device manufacturers;
- Updates on the Biden Administration's approach to FCA enforcement, including developments impacting DOJ's use of its statutory dismissal authority;
- New proposed amendments to the FCA introduced by Senator Grassley; and
- The latest trends in FCA jurisprudence, including developments in particular FCA legal theories affecting your industry and the continued evolution of how lower courts are interpreting the Supreme Court's *Escobar* decision.

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PANELISTS:

Winston Y. Chan is a former federal prosecutor and litigation partner in the San Francisco office, and Co-Chair of the Firm's False Claims Act Practice Group. He has particular experience leading matters for health care and life sciences companies involving government enforcement defense, internal investigations and compliance counseling. From 2003 to 2011, Mr. Chan served as an Assistant United States Attorney in the Eastern District of New York, where he held a number of supervisory positions and investigated a wide range of matters, including False Claims Act violations and health care fraud.

Marian J. Lee is a partner in the Washington, D.C. office and Co-Chair of the Firm's FDA& Health Care Practice Group. She has significant experience advising clients on FDA regulatory strategy, risk management, and enforcement actions. Her practice spans the product life cycle, including the conduct of preclinical and clinical studies, good

Related People

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manufacturing practices and quality systems, premarket approvals and clearances, scientific communications, product labeling and advertising, and postmarket compliance.

John D. W. Partridge is a partner in the Denver office where he focuses on white collar defense, internal investigations, regulatory inquiries, corporate compliance programs, and complex commercial litigation. He has particular experience with the FCA and the Foreign Corrupt Practices Act ("FCPA"), including advising major corporations regarding their compliance programs.

Brendan Stewart is of counsel in the New York office and a former federal prosecutor. He previously served as an Assistant Chief in the Fraud Section of the U.S. Department of Justice's Criminal Division where he oversaw a unit of health care fraud prosecutors in the Eastern District of New York from 2017 to 2021. As a prosecutor since 2012, he has led numerous complex investigations—in coordination with the U.S. Attorney's Office, the FBI, the Department of Health and Human Services' Office of Inspector General, State Attorneys General —focusing on potential violations of federal statutes barring health care fraud and false medical statements and other crimes.

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- The False Claims Act – 2021 Update for Financial Services (October 6, 2021)
- The False Claims Act – 2021 Update for Government Contractors (October 14, 2021)
- The False Claims Act – 2021 Update for Health Care Providers (October 26, 2021)

Related Capabilities

False Claims Act / Qui Tam Defense