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Webcast: False Claims Act Enforcement in the Life Sciences and Health Care Sectors

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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—particularly federal health care program expenditures. DOJ and qui tam relators continued to pursue longstanding theories of fraud and abuse aggressively during the Biden Administration, while experimenting with new enforcement theories periodically. 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 over a decade. As much as ever, any company that receives government funds—especially in the life sciences and health care sectors—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 life sciences and health companies.
- Novel and aggressive theories advanced by DOJ and/or qui tam relators.
- Updates on DOJ's approach to FCA enforcement, including efforts to reward exemplary cooperation and to deter problematic qui tam filings.
- The latest trends in FCA jurisprudence, including the U.S. Supreme Court's Schutte decision on scienter, as well as appellate courts' approach to causation issues in Anti-Kickback Statute-based FCA cases and the statute's procedural bars.
- Recent FDA developments that may contribute to FCA enforcement risk.

PANELISTS:

John Partridge, a Co-Chair of Gibson Dunn's FDA and Health Care Practice Group and Chambers-ranked white collar defense and government investigations lawyer, focuses on government and internal investigations, white collar defense, and complex litigation for clients in the life science and health care industries, among others. John has particular experience with the Anti-Kickback Statute, the False Claims Act, the Foreign Corrupt Practices Act, and the Federal Food, Drug, and Cosmetic Act, including defending major corporations in investigations pursued by the U.S. Department of Justice (DOJ) and the U.S. Securities and Exchange Commission (SEC). John is admitted to practice law in the states of California and Colorado, as well as in the District of Columbia and the U.S. Courts of Appeal for the Eighth and Tenth Circuits, the U.S. District Courts for the District of Colorado and the Northern District of California.

Jonathan M. Phillips is a partner in Gibson Dunn's Washington, D.C. office where he

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focuses on compliance, enforcement, and litigation in the health care and government contracting fields, as well as other white collar enforcement matters and related litigation. A former Trial Attorney in DOJ's Civil Fraud section, he has particular experience representing clients in enforcement actions by the DOJ, Department of Health and Human Services, and Department of Defense brought under the False Claims Act and related statutes. Jonathan is a member of the bars of the State of Maryland and the District of Columbia.

Katlin McKelvie is a partner in Gibson Dunn's Washington, D.C. office and a member of the firm's Food and Drug Administration (FDA) and Health Care Practice Group. With over two decades of experience in food and drug law, including as Deputy General Counsel of the Department of Health and Human Services (HHS), Katlin offers clients expansive knowledge of the complex legal and policy issues associated with FDA regulation of food, drugs, medical devices, and cosmetics.

As Deputy General Counsel at HHS, Katlin was responsible for advising senior HHS officials on FDA-related regulatory, enforcement, and litigation matters. Prior to joining HHS, she served as Deputy Health Policy Director and Senior FDA Counsel to the Senate Committee on Health, Education, Labor, and Pensions for Chair Patty Murray. As Committee staff, Katlin played a pivotal role in shaping multiple pieces of legislation the FDA is currently working to implement, most notably the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Food and Drug Omnibus Reform Act of 2022 (FDORA). Before her time in the Senate, Katlin spent 11 years at FDA, first as Regulatory Counsel in the Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research and then as Associate Chief Counsel for Drugs in the Office of the Chief Counsel. She is admitted to practice law in the District of Columbia.

Jim Zelenay is a partner in Gibson Dunn's Los Angeles office where he practices in the firm's Litigation Department. Jim has extensive experience in defending clients involved in white collar investigations, assisting clients in responding to government subpoenas, and in government civil fraud litigation. Jim has represented clients in connection with alleged violations of environmental regulations, regulations governing trade with sanctioned countries, Department of Education rules and regulations, Food and Drug Administration regulations, Federal Emergency Management Agency regulations, government construction contracting matters, patent and telecommunication proceedings, and other administrative matters. Jim also has substantial experience with the federal and state False Claims Acts and whistleblower litigation, in which he has represented a breadth of industries and clients, including educational institutions, financial institutions, insurers, pharmaceutical companies, construction companies, telecommunication clients, emergency services personnel, and accounting firms, among others. Jim is a member of the California Bar.

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