

GOVERNMENT PROGRAM FRAUD,
FALSE CLAIMS ACT,
AND QUI TAM LITIGATION

Government
Program
Fraud/FCA
Response Team

WINSTON
& STRAWN
LLP

Government Program Fraud/FCA Response Team

Investigations and litigation involving alleged fraud against the government pose a significant and growing threat to organizations and individuals across all industries that engage directly or indirectly in business with federal, state, and/or local governments.

The government makes aggressive use of its **extensive criminal and civil investigatory powers to root out alleged fraud and abuse implicating government funds, including one of its most powerful civil enforcement tools — the federal False Claims Act and similar state false claims statutes (FCA)**. The direct and collateral consequences of these investigations and related litigations can be devastating.

Winston & Strawn's **Government Program Fraud/FCA Response Team (Fraud Response Team)** provides clients with a powerful tool for defending these matters. Our Fraud Response Team includes attorneys from across the firm's U.S. offices with decades of experience representing clients in civil and criminal matters involving alleged government program fraud and FCA violations.

Our Fraud Response Team's coordinated cross-practice and cross-industry approach, enables our clients to **mount strong defenses** to government investigations and related litigation, including qui tam/whistleblower litigation, while also successfully **navigating the many collateral issues that impact multiple aspects of their businesses. We provide comprehensive solutions.**

COMPLIANCE IN THE AGE OF COVID-19

With the passage of many **COVID-19 response and relief programs**, and the related increase in the number of companies doing business with the government, the risk that individuals and organizations may find themselves in the government's crosshairs has grown tremendously. The government has taken **significant steps to police all COVID-related government programs**, including appointing special inspectors general and forming committees and task forces, to engage in rigorous oversight of the distribution and use of government funds. And nearly every U.S. Attorney's Office, along with the U.S. Department of Justice (DOJ), the Department of the Treasury, and the heads of various agencies, including the Small Business Administration (SBA) and the U.S. Department of Health and Human Services (HHS), have publicly announced their commitment and dedication of resources to root out fraud related to COVID-19 programs, including the creation and promotion of whistleblower hotlines.

What does that mean in practical terms? It means that all individuals and organizations that participate in these various programs, or otherwise do business with the government, are **at risk of heightened government scrutiny**. This includes people and companies across a **wide array of industries**, many of whom have recently pivoted to producing essential products or providing essential services funded by the government, or are

participating in funding relief programs, and are not accustomed to doing business, directly or indirectly, with the government. As a result, it is critical to have **robust procedures in place to mitigate the related risks and to be in a strong position to effectively and efficiently address and defend against allegations of wrongdoing.**

Winston & Strawn's Fraud Response Team is particularly helpful for clients participating in COVID-19 response and relief programs because of our experience helping clients in myriad industries **identify, assess, and mitigate the risks of potential liability** based on alleged government program fraud and FCA violations. Should a client find itself in the government's crosshairs, our **Fraud Response Team is prepared to jump into action,** and provide the strategic guidance needed to navigate these complex investigations, and present rigorous legal and factual defenses, while also providing comprehensive and efficient solutions for all aspects of a client's business that may be affected by these significant matters.

A SEASONED CROSS-PRACTICE FRAUD RESPONSE TEAM AT YOUR SIDE

DEPTH AND BREADTH OF EXPERIENCE

All the attorneys on our Fraud Response Team have a thorough understanding of the intricacies of government program fraud matters, the FCA, and related government investigations and litigation, including *qui tam* litigation filed by whistleblowers asserting FCA claims on behalf of the government. Our extensive experience navigating **complex government investigations, often on multiple fronts at once,** allows us to **develop strategic and coordinated approaches** to achieve favorable outcomes for our clients with **greater efficiency.**

Leveraging our deep experience with these types of matters, **on the defense side and as government lawyers,** our Fraud Response Team provides clients with comprehensive guidance that allows them to assert strong defenses to these matters, while also addressing the many related issues impacting their businesses.

Leaders of our Fraud Response Team include **several former government lawyers** who have significant experience investigating and prosecuting fraud matters, and who offer an **invaluable perspective** on how the government and whistleblowers approach civil and criminal fraud, FCA claims, and *qui tam* matters:

- **Matt Orwig**, a former presidentially appointed U.S. Attorney for the Eastern District of Texas and Assistant U.S. Attorney for both the Northern District of Texas and the Eastern District of Texas
- **Suzanne Jaffe Bloom**, a former prosecutor in both the U.S. Attorney's Office for the Southern District of New York and the U.S. Attorney's Office for the Eastern District of New York, and former Deputy Chief of the Long Island Criminal Division
- **Abbe Lowell**, a former Special Assistant U.S. Attorney, Special Assistant to the Deputy Attorney General, and Special Assistant to the Attorney General at the DOJ; former counsel to the U.S. House of Representatives, including as Chief Minority Counsel (during the impeachment of President Clinton), and a special ethics counsel to the House Committee of Standards of Official Conduct (Ethics Committee)
- **Reed Stephens**, a former DOJ Civil Division Trial Attorney, Civil Frauds Section, responsible for national FCA litigation
- **Jack Knight**, a former Assistant U.S. Attorney for the Western District of North Carolina
- **Alessandra Swanson**, a former Federal regulator at the U.S. Department of Health and Human Services – Office for Civil Rights

- **Sheryl Falk**, a former Assistant U.S. Attorney for the Eastern District of Texas, and Certified Computer Examiner

CROSS-PRACTICE TEAM ENSURES COMPREHENSIVE, COORDINATED, AND EFFICIENT SOLUTIONS

Our Fraud Response Team includes members from several different **practice areas with particularized subject matter experience** regarding the many diverse issues that often arise in connection with matters involving allegations of government program fraud and FCA violations. Our **cross-practice approach** allows us to work seamlessly together to spring into action quickly and efficiently to address the unique and varied challenges clients face **throughout the entire lifecycle** of these types of matters in a **coordinated** manner. We achieve optimal results for clients and provide them with comprehensive solutions by utilizing a team consisting of members from the following highly acclaimed Winston practice groups:

- Antitrust & Competition
- Appellate & Critical Motions
- Government Contracting
- Government Investigations, Enforcement, and Compliance

- Health Care & Life Sciences Regulatory, Litigation & Investigations
- Labor & Employment
- Privacy & Data Security
- Securities Litigation
- Tax

GOVERNMENT INVESTIGATIONS, ENFORCEMENT, AND COMPLIANCE

A significant number of our white collar attorneys are former government lawyers who were responsible for conducting civil and criminal investigations and litigation involving allegations of government program fraud and FCA violations, while working in various U.S. Attorney’s Offices and the DOJ. Their unique insider’s perspective and understanding is of tremendous benefit to clients, and allows them to develop highly effective strategic approaches to protecting clients’ interests in these types of matters. They are often able to persuade the government to decline prosecution or to issue declinations of intervention in connection with FCA *qui tam* complaints. Where charges and claims are unavoidable, our white collar attorneys employ targeted and cost-effective strategies aimed at defeating the charges or claims at the early stages of litigation.

INDUSTRY EXPERIENCE

OUR FRAUD RESPONSE TEAM IS ADEPT AT IDENTIFYING AND ADDRESSING THE MANY ISSUES INDUSTRY-SPECIFIC ISSUES IMPACTING OUR CLIENTS

CONSUMER PRODUCTS	DEFENSE	EDUCATION
FINANCIAL SERVICES	HEALTH CARE AND LIFE SCIENCES	INSURANCE
MANUFACTURING AND LOGISTICS	MEDIA	TECHNOLOGY

Where pre-trial dismissals are not possible, they conduct highly effective discovery and pre-trial motion practice and are prepared to vigorously defend clients at trial. If a pre-trial resolution is the client's preferred path, our attorneys are adept at negotiating and securing favorable dispositions that afford clients the broadest possible protection from future government actions, avoid exclusion from participation in government programs, and minimize any attendant reputational harm.

ANTITRUST & COMPETITION

Clients facing FCA and government program fraud investigations and litigations involving alleged anticompetitive conduct will benefit from our attorneys' deep experience in handling antitrust matters. The DOJ has prioritized investigations involving antitrust crimes and fraudulent schemes that undermine competition in government procurement through the newly created Procurement Collusion Strike Force, an interagency partnership led by the Antitrust Division of DOJ. In recent matters, the DOJ has used the FCA and Section 4A of the Clayton Act, both of which allow for the government to obtain treble damages for certain anticompetitive conduct, to bring parallel civil cases related to criminal antitrust offenses. Winston leverages its attorneys' prior government experience, trial experience, and relationships with prosecutors in the Antitrust Division, the Civil Division, and local U.S. Attorneys' Offices to help companies navigate interagency, parallel civil and criminal investigations involving bid-rigging, price-fixing, price-gauging, and fraud related to public procurement.

APPELLATE & CRITICAL MOTIONS

Motion practice is particularly important in FCA and government program fraud litigation, as it may provide a way to end the litigation before discovery or trial. This makes high-quality briefs and motions particularly important, both at the trial level and on

appeal. Our appellate and critical motions attorneys bring a wealth of substantive experience, and are known for work in FCA cases in particular. They partner with the trial team to formulate a compelling strategy that will see the case through to a successful resolution. Members of the appellate group have argued cases before the U.S. Supreme Court, including some of the most high-profile cases on the Court's docket, and submitted briefs in hundreds of other representations. The practice has "achieved prominence in Supreme Court practice and in bet-the-company cases," according to The National Law Journal, which named the firm's appellate practice to its "Appellate Hot List" three times in the past decade.

GOVERNMENT CONTRACTING

Our attorneys are experienced with the complicated web of federal, state, and local requirements governing contracts and other agreements funded by the government, including cooperative agreements, public/private partnerships, grants, and concessional loans, among others. We help contractors navigate the Federal Acquisition Regulation and related guidance to ensure compliance and minimize contract breach and fraud allegations on the front end, before expensive investigations, litigation, and attendant reputational damage arise. We provide cost-efficient, proactive counselling, bid review, compliance plans, and contract reviews at the initial phases and throughout the duration of the contract, mitigating the risk our clients will face whistleblower or government allegations of fraud or violations of the FCA, Truth in Negotiations Act, Procurement Integrity Act, National Industrial Security Program Operating Manual, Cost Accounting Standards, or other applicable statutes, rules, and regulations.

HEALTH CARE & LIFE SCIENCES REGULATORY, LITIGATION & INVESTIGATIONS

The health care and life sciences industries will continue to be areas of focus for investigations and litigation based on alleged government program fraud and FCA violations. This is particularly so given the rapid deployment of billions of dollars in federal COVID-19 response funds for manufacturing and production contracts under the CARES Act, the Defense Production Act, and numerous U.S. Food and Drug Administration (FDA) Emergency Use Authorizations, as well as widespread generalized waivers of regulatory restrictions and safeguards by the HHS in order to facilitate the delivery of health care to pandemic victims. Our team includes attorneys with government and in-house experience who routinely advise health care and life sciences clients on mission-critical issues central to the delivery of health care services and the research, approval, manufacture, sale, and marketing of life sciences products. We also provide guidance on government payer reimbursement, certificate of need, case management, and health care fraud and abuse considerations, including the Anti-Kickback Statute and the Stark Law, pharmaceutical clinical research and development, product approvals, sales and marketing, patient access, supply chain and distribution, good manufacturing practices, and all aspects of government drug price reporting. Tapping into this deep pool of experience allows our clients to mitigate regulatory and FCA risk and maintain sustainable business models. Where disputes are unavoidable, our team advises and supports clients in a full range of complex disputes, including investigations of alleged government program fraud and FCA violations, before all branches of government, including independent regulatory agencies.

LABOR & EMPLOYMENT

Government program fraud, FCA and qui tam matters often involve significant employment-related issues, including retaliation claims seeking steep financial recoveries, including double damages and penalties. Our team members are seasoned employment trial lawyers and counselors who have an unwavering commitment to helping employers navigate such challenges. We approach government program fraud and FCA matters, including whistleblower complaints, with a strategic, business-oriented mindset designed to minimize litigation risk, business disruption, and cost. This includes, for example, advising clients on their fraud-prevention and -reporting policies, their responses to internal (often anonymous) complaints, and their handling of internal investigations. And, in the event an adversarial proceeding cannot be avoided, we call upon our substantial litigation experience to achieve resolutions that minimize legal and financial consequences as well as public exposure.

PRIVACY & DATA SECURITY

Government program fraud and FCA matters inevitably require the disclosure of sensitive information to government agencies and other third parties, which can implicate a complicated web of state and federal privacy and data security requirements. Winston's privacy team includes a former federal prosecutor and a former federal regulator from the U.S. Department of Health and Human Services – Office for Civil Rights, uniquely positioning Winston to provide practical advice about how to navigate HIPAA, HITECH, 42 CFR Part 2, and other compliance obligations and address related risks. In addition, our team can help navigate the increasing number of cybersecurity obligations and certifications required in connection with government contracting.

Experienced with an array of privacy and data security-related statutes and regulations, our attorneys can help clients avoid missteps that could lead to government program fraud and FCA investigations and litigation based on alleged cybersecurity compliance failures. We routinely assist clients with the creation of privacy assessments and compliance programs and employee training, the review of business associate and other vendor agreements, and reasonable security measures, putting our clients in the best position to avoid privacy and data security breaches. We also lead data security breach response, notification, and regulatory and class action defense, to effectively address any incidents and related claims that occur.

SECURITIES LITIGATION

In the current environment, government investigations and qui tam lawsuits involving alleged government program fraud and violations of the FCA frequently lead to parallel or “piggyback” civil proceedings, most commonly, for public companies, in the form of federal securities class actions and shareholder derivative suits. Our securities litigators have made a name for themselves successfully defending such actions, including a high-profile victory in *Omnicare v. Laborers District Council Constr. Indus. Pension Fund*, one of the most important U.S. Supreme Court decisions on securities litigation under Section 11 of the '33 Act in decades.

With our deep securities litigation experience, our Fraud Response Team helps clients mitigate the risks of exposure to securities and shareholder derivative actions stemming from allegations of government program fraud and/or FCA violations. Should such an action be filed, our seasoned securities litigators can leverage their experience in this area to mount a strong defense in the most efficient and cost-effective manner.

TAX

Our Fraud Response Team includes tax attorneys who can ably guide clients through the tax implications of government program fraud and FCA matters in order to minimize financial consequences and any related tax liability exposure. Our team also includes one of the few tax attorneys who has defended companies regarding New York State’s False Claims Act. That Act expands investigations to include tax fraud and is conducted by New York State’s Attorney General’s Office, Taxpayer Protection Bureau. We have also represented companies facing allegations of state and local fraud across the United States, including the Illinois’ False Claims Act.

REPRESENTATIVE ENGAGEMENTS

We are happy to provide a list of our representative engagements upon request.

Meet Our Government Program Fraud/FCA Response Team Leaders

GOVERNMENT INVESTIGATIONS, ENFORCEMENT, AND COMPLIANCE



SUZANNE JAFFE BLOOM

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Suzanne Jaffe Bloom is consistently recognized as one of New York's top lawyers in white collar criminal defense and government investigations. She represents companies and individuals in all aspects of white collar criminal and regulatory matters, government and internal investigations, and related complex civil litigation, often on multiple fronts at once. Selected for inclusion in Benchmark Litigation's "Top 250 Women in Litigation" and ranked in *Chambers USA*, Suzanne is a dedicated advocate for her clients. She defends clients in connection with a wide range of issues, including the FCA, the Anti-Kickback Statute, the Foreign Corrupt Practices Act (FCPA), government program fraud, health care fraud, and government contracting fraud. Suzanne's clients benefit from her wealth of government experience, which allows her to achieve optimal results for her clients, at times preventing charges or claims from being filed in the first instance. She also provides clients with valuable guidance for achieving compliance objectives and minimizing the risk of government investigations and related actions.

As a former federal prosecutor in the U.S. Attorney's Offices for both the Southern District of New York and for the Eastern District of New York, where she was Deputy Chief of the Long Island

Criminal Division, Suzanne uses her keen insights regarding the government's varied investigative and trial strategies to help her clients achieve their goals. She led several joint criminal and civil investigations of alleged FCA violations and related fraud. Suzanne also conducted many grand jury investigations and criminal jury trials involving health care fraud, government contracting fraud, government program fraud, public corruption, money laundering, tax offenses, bank fraud, and securities fraud.



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Abbe Lowell is one of the nation's leading white collar defense and trial lawyers. His practice focuses on litigation, complex investigations, and regulatory enforcement. In his wide-ranging career, Abbe has represented numerous high-profile corporate and individual clients and provided counsel in matters of national and international importance. He has successfully tried numerous complex civil and criminal cases throughout the United States, and has briefed and argued dozens of appeals before federal and state appeals courts and before the United States Supreme Court.

In addition to trying cases and arguing appeals, Abbe advises clients in their dealings with the U.S. Congress and its committees, other legislative bodies, and numerous federal and state regulatory agencies.

He also works with clients on internal investigations, voluntary disclosure decisions, and developing compliance programs to prevent issues from arising with law enforcement agencies. He has conducted internal investigations responding to government, whistleblower, or other allegations of FCPA, money laundering, securities, and other law violations. His matters and cases often require him to navigate all of these legal issues under the glare of media scrutiny.



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Angela Machala has extensive experience representing corporate officers, directors and executives in high stakes white-collar criminal matters and regulatory enforcement cases. She advises clients in a broad range of industries, including financial services, health care, bio-tech, and technology, in FCA cases and matters involving securities fraud, health care fraud, FCPA violations, and other alleged offenses. She has successfully represented individuals in FCA and qui tam investigations and has 20 years of experience on the defense side.

Angela also advises clients on negotiating with the government and responding to civil investigative demands and broad investigative subpoenas. In addition, she assists companies in conducting sensitive internal investigations related to allegations of kickbacks, criminal export control violations, and other corporate impropriety.



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Cristina Calvar is an experienced litigator who represents clients in white collar matters, government and internal investigations, regulatory enforcement, and related civil litigation, often on multiple fronts at once. Her matters involve a wide range of issues primarily in the areas of finance and health care, including alleged violations of the False Claims Act (FCA), the Foreign Corrupt Practices Act (FCPA), the Racketeer Influenced and Corrupt Organizations Act (RICO), as well as alleged health care fraud, accounting fraud, bribery, and a variety of business torts and breach of contract actions. Prior to joining the firm, Cristina clerked for the Honorable David C. Guaderrama of the U.S. District Court for the Western District of Texas.



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Jack Knight is nationally recognized as a leading white collar defense attorney and he represents corporations and individuals in high-stakes investigations. He focuses his practice on white collar criminal defense, internal investigations, regulatory enforcement, grand jury investigations, and *qui tam* matters. He routinely handles complex white collar matters involving the DOJ, the SEC, State Attorneys General, and other federal and state enforcement agencies. As part of his practice, he regularly represents Fortune 500 companies and individuals involved in high-stakes federal investigations and parallel proceedings. Jack currently co-chairs Winston’s Financial Services Litigation Practice. Jack has particular experience representing clients in the banking and financial services industries in connection with FCA matters involving allegations of misrepresentations or omissions in government-required certifications, including those relating to eligibility to participate in government underwriting guarantees, various types of insurance, and government stimulus programs.

From 2000 to 2005, Jack served as an Assistant U.S. Attorney in the Western District of North Carolina, where he handled all types of white collar prosecutions, including bank fraud, accounting fraud, money laundering, environmental violations, and complex financial crimes. Jack has tried more than 50 cases to verdict in state and federal court.



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Matt Orwig focuses his practice on civil and criminal fraud investigations, FCA and *qui tam* actions, internal corporate investigations, health care fraud investigations and litigation, privacy and data security, complex civil litigation, and litigation involving government agencies. He has more than 30 years of experience investigating and litigating complex civil and criminal cases, including high-stakes FCA and *qui tam* cases in a wide range of industries and business sectors, program fraud cases, national pharma and health care cases and parallel civil and criminal matters.

Matt previously served at the DOJ, initially as an Assistant U.S. Attorney and culminating in his presidential appointment as the U.S. Attorney for the Eastern District of Texas. As an Assistant U.S. Attorney, he was both a criminal prosecutor and the lead civil enforcement attorney responsible for bringing all FCA cases on behalf of the U.S. Attorney’s Office. During his 20-year tenure, he acquired extensive experience in civil, criminal, and appellate law.

He has secret security clearance from the U.S. government that allows him to work on classified government programs.



BENJAMIN SOKOLY

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Ben Sokoly has extensive experience representing clients in all phases of government investigations, white collar criminal matters, and corporate internal investigations. He has represented clients in a wide array of industries, including the health care, technology and cybersecurity, insurance, and financial services industries. Ben routinely devotes the time and attention needed to gain a deep understanding of his clients' business and commercial realities in order to provide nuanced, practical advice on issues ranging from litigation strategy, business disputes, and regulatory, compliance and other risks.

Ben's practice also focuses on the preparation and trial of complex commercial cases presenting a broad range of legal issues, including complex qui tam litigation involving alleged violations of the FCA and the Anti-Kickback Statute, health care fraud, contracts and business torts, class actions, and securities matters. He has represented clients in all stages of litigation, including mediations, trials, and appeals, in federal and state courts and before arbitral panels across the country.

ANTITRUST & COMPETITION



JEFFREY AMATO

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Jeffrey Amato represents clients in a broad range of disputes and investigations and is skilled in the use of expert evidence and data analytics to devise innovative legal strategies for his clients. Jeffrey has experience in white collar criminal defense, including representing corporate and individual defendants in federal and state courts at the trial, appellate, and post-conviction levels. He also counsels clients with respect to navigating compliance with statutory, regulatory, and ethical obligations relating to data privacy and government-sponsored programs and contracts, including Medicare and Medicaid. During his career in private and public practice, Jeffrey has been involved in significant legal disputes concerning a wide range of issues, such as antitrust, class action defense, RICO, and the False Claims Act. His clients transcend a diverse array of business sectors, such as healthcare, technology, insurance, financial services, banking, life sciences, pharmaceuticals, energy, and consumer products.

Prior to joining Winston, Jeffrey worked at a law firm where, among other matters, he served as counsel to a court-appointed receiver for a multinational financial firm in securities litigation and investigations in New York federal court. Previous to that, he served as law clerk to the Honorable Arthur D. Spatt, U.S. District Judge for the Eastern District of New York. Before his clerkship, Jeffrey was an attorney with the U.S. Department of Homeland Security, where he prosecuted numerous civil enforcement actions against individuals, air carriers, shippers, and other regulated entities.

APPELLATE & CRITICAL MOTIONS



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Linda Coberly is the managing partner of Winston's oldest and largest office. She focuses her practice on appeals and on critical motions that resolve complex commercial lawsuits before trial. She is known for her strong business sense, excellent briefs, and clear and compelling oral advocacy. She counsels clients on appellate and strategic issues at all stages of litigation, from before trial through and including proceedings before the United States Supreme Court. She has briefed and argued appeals in eight different federal courts of appeals and a variety of state appellate and supreme courts. A significant portion of Linda's practice centers on advising and representing clients with regard to proceedings in the United States Supreme Court.

Linda has extensive experience in corporate fraud litigation, securities class actions, and administrative and government-facing matters. For example, she recently represented nearly an entire banking industry in the Fifth Circuit in an FCA case arising out of the banks' receipt and processing of government benefit payments, securing an affirmance of an order dismissing the suit on the pleadings.

GOVERNMENT CONTRACTING



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Bryant Gardner's practice is a diverse mix of government contract matters, including bid counselling and negotiation, contract disputes, Federal Acquisition Regulation, FCA, Truth in Negotiations Act, Procurement Integrity Act, Cost Accounting Standards, subcontracting best practices and management, lender financing, contractor mergers and acquisitions, data rights, and contract terminations. He has represented contractors in a wide variety of industries, including defense, energy, transportation, software, retail, medical, and information technology. Bryant regularly appears before the Court of Federal Claims, Government Accountability Office, SBA, contract appeals boards, and the Congress. Bryant's practice also involves experience in regulated transportation and logistics matters, including hazardous materials compliance and the transportation of sensitive military cargoes.

HEALTH CARE & LIFE SCIENCES REGULATORY, LITIGATION & INVESTIGATIONS



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Amandeep Sidhu is recognized as a highly skilled litigator, both in Washington, D.C. and nationally, and focuses his practice on a full range of clients across the health care and life sciences industries. In addition to extensive experience litigating FCA matters, his practice includes compliance and regulatory counseling and the full range of investigative matters – including internal investigations, federal and state government investigations, and congressional investigations.

Aman regularly represents clients in high-stakes disputes in the health care and life sciences industries, in defense of qui tam litigation involving the FCA, Stark Law, and Anti-Kickback Statute in federal district courts. His health care regulatory practice includes support for innovative providers utilizing telemedicine and other technology, and extensive experience helping organizations navigate the certificate of need (CON) laws in Virginia and Washington, D.C., to facilitate approval for the introduction or expansion of health care services in these jurisdictions. Aman also advises clients on domestic and international risk-management issues, including compliance with the FCPA.



T. REED STEPHENS

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Reed Stephens has a wide array of experience in the health care and life sciences industries, and represents pharmaceutical and biotech manufacturers, wholesalers and individuals, health care systems, managed care companies and non-healthcare-related companies in other global industries, including the defense industry. He is a nationally recognized authority in the pharmaceutical fraud and abuse and corporate compliance spaces, and has extensive experience actively litigating Anti-Kickback Statute and Stark Physician Self-Referral Law FCA matters nationwide.

Reed draws on both his lengthy past experience as a DOJ Trial Attorney in the FCA Section of the DOJ Civil Division, and his familiarity with the current DOJ FCA team to develop creative and proactive strategies for mitigating the costs and risks to clients of FCA litigation. Reed has experience in matters involving state and federal government law enforcement and investigations, including House and Senate Congressional investigations. He counsels clients on voluntary disclosures to the Department of Defense and in the government drug pricing areas of Medicaid Drug Rebate, Federal Supply Schedule/Department of Veterans Affairs, and the 340B program.

LABOR & EMPLOYMENT



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Bill Miozzi represents clients before federal and state courts, as well as the National Labor Relations Board (NLRB), Equal Employment Opportunity Commission, U.S. Department of Labor (DOL), Occupational and Safety Health Administration, arbitrators, and other state employment boards and regulatory agencies. He has over 30 years of experience defending clients in FCA retaliation and other whistleblower and retaliatory discharge claims in federal and state courts, as well as before the DOL. Bill represents employers in a wide range of industries, including energy, manufacturing, logistics, financial services and banking, food and beverage, health care, aerospace, maritime, and construction. In addition to Bill's extensive experience defending FCA and whistleblower claims, he also represents employers in class action, multi-plaintiff, and individual cases covering issues concerning: (1) employment discrimination, ERISA, FLSA/wage-and-hour, disability, and FMLA claims; (2) enforcement of noncompetition agreements and trade secret misappropriation; (3) multi-employer pension plan withdrawal liability claims; and (4) unfair labor practice and representation investigations and cases before the NLRB. Bill also provides labor and employment counsel in connection with business restructurings, acquisitions, sales, mergers, and reductions-in-force.



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Cardelle Spangler has represented clients in complex class action, collective action, multi-plaintiff, and single-plaintiff employment litigation. In her over 20-year career as an employment litigator and advisor, Cardelle has concentrated her practice on employment relations litigation and counseling matters. She has significant experience representing clients in the medical device, pharmaceutical, food service, financial service, and transportation industries. Cardelle has substantial trial experience before state and federal courts, as well as arbitrators. She has successfully defended collective action lawsuits brought under the Fair Labor Standards Act, class action lawsuits brought under ERISA alleging breaches of fiduciary duties against corporate and individual defendants, claims brought under ERISA for denial of benefits and discrimination, claims brought under various state and federal statutes for age, race, sex, color, religion, and disability discrimination and/or harassment, and common law and/or statutory claims for unfair competition, misappropriation of trade secrets, and various torts. Cardelle has also conducted harassment and other investigations, drafted employment and independent contractor agreements, and conducted labor and employment training.

PRIVACY & DATA SECURITY



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Sheryl Falk draws on her deep experience in privacy, data security, and forensic technology as well as her strong litigation background to handle complicated privacy and data-protection issues. Sheryl's knowledge, responsiveness, and unique strategic guidance have earned the trust of her clients. She has the special ability to understand how her clients' business may be impacted by the data and privacy laws in place today, as well as the laws likely to be in place tomorrow. Sheryl uses this proactive thinking to help her clients anticipate how privacy issues relate to their important business functions, and guides her clients on mitigating potential risks. One of the first attorneys in the United States to be certified in computer forensics, Sheryl is a former federal prosecutor and Certified Information Privacy Professional, and has been recognized in the *The Legal 500 U.S.*



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Alessandra Swanson primarily focuses her practice in several areas to help clients understand their obligations with respect to the collection, use, disclosure, and protection of personal information. Alessandra is a former federal privacy regulator, and spent almost six years working with the U.S. Department of Health and Human Services – Office for Civil Rights, where she focused on HIPAA and HITECH compliance and enforcement. She has deep experience advising substance abuse treatment centers with respect to their obligations under 42 C.F.R. Part 2. Alessandra works closely with Winston's FCA team to navigate the laws that regulate the disclosure of sensitive patient information during investigations and litigation proceedings, and also helps guide clients through security breach investigations, notification obligations, and the defense of related regulatory inquiries.

SECURITIES LITIGATION



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Jim Smith is ranked in the area of “New York Litigation: Securities” by *Chambers USA* 2017–2019 and 2021-2023, which notes that he is “increasingly recognized for his securities litigation practice, which includes a strong focus on M&A cases,” that “[c]lients praise his ‘extraordinary knowledge’ of Delaware law, as well as highlighting his ability to ‘provide practical and nuanced advice while being sensitive to the specifics of our situation,’” and that “[h]e is ‘an exceptionally good trial lawyer and excellent strategic thinker,’ according to impressed interviewees.” He is also recommended by *The Legal 500 U.S.* in “M&A Litigation” and “Securities Litigation—Defense” as a “great lawyer with excellent judgment” who is always in tune “with what will—and will not—impress a judge” and, according one interviewee, “remains one of the most eloquent lawyers I have ever encountered.”

His practice areas comprise a broad range of complex commercial litigation, with a focus on M&A-related litigation and contests for corporate control, federal securities fraud class action defense, corporate governance litigation and advice, the defense of shareholder derivative suits and shareholder derivative demand response, and state deceptive sales practices/consumer fraud class action defense. Jim is a first-chair trial lawyer and has tried numerous cases (including in the Delaware Court of Chancery) and argued notable appeals before various state and federal appellate courts. He has represented clients in a variety of industries, including technology/e-commerce, commercial and investment banking, private equity, hedge funds, derivatives and securitization, insurance, energy, oil and gas, health care, biotech, semiconductors, and telecommunications.



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John Schreiber has been recognized by numerous legal directories – including *The Legal 500 U.S.*, *Law360* and *Benchmark Litigation* – in the areas of securities and M&A litigation. Clients credit his “straight-shooter” approach and “credibility with judges” as the reasons they “just trust him” (Law360). He has, among other things, defended numerous securities class actions and shareholder derivative suits arising out of government investigations and qui tam lawsuits involving alleged violations of the federal FCA. Most notably, John led the defense of Omnicare, Inc. and certain of its former officers and directors in a federal securities class action and related shareholder derivative litigation arising out of alleged underlying violations of the FCA. The shareholder derivative litigation was dismissed with prejudice by the district court at the pleading stage, while in the securities class action, (i) plaintiffs’ claims under Section 10(b) and 20(a) of the Securities Exchange Act of 1934 were likewise dismissed with prejudice, with the dismissal affirmed by the U.S. Court of Appeals for the Sixth Circuit, and (ii) the U.S. Supreme Court, in one of the most significant decisions under the Securities Act of 1933 in decades, unanimously reversed and vacated a decision by the Sixth Circuit holding that the plaintiffs had adequately stated a claim under Section 11 based on certain expressions of opinion and belief concerning Omnicare’s compliance with the FCA and other applicable laws.

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James Mastracchio is widely recognized as one of the foremost advisers to the global tax community with regard to civil and criminal tax enforcement matters. Jim's practice focuses on solving clients' most difficult legal and tax regulatory challenges, whether in the context of civil, criminal or parallel proceedings. Jim is one of a few lawyers in the country who has served as lead counsel on international criminal tax cases. In that role, he has defended publicly traded companies, boards of directors and senior management facing criminal investigations and prosecutions for alleged tax violations. He routinely represents clients before the DOJ, U.S. Attorney offices, the IRS, the U.S. Competent Authority, and other regulatory agencies. Jim litigates in every U.S. federal court having jurisdiction over civil and criminal tax enforcement matters, and has appeared before competent tax authorities in numerous countries. He served as an Independent Examiner in Zürich, Switzerland, for the DOJ's Swiss Bank Program. Recently, Jim has represented companies facing False Claims Act investigations by various State Attorneys General.

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