



HEALTHCARE AND LIFE SCIENCES – GOVERNMENT INVESTIGATIONS AND DEFENSE

Overview

We provide comprehensive legal and strategic services to our healthcare and life sciences clients in response to criminal and/or civil enforcement actions and related investigations. In a space as complex and heavily regulated as this, we appreciate that is incumbent on us, as counselors to our clients, to understand the policy and technology landscape as much as the legal landscape, and we bring that multi-disciplinary approach to each matter. We also bring to bear decades of institutional knowledge and focus in life sciences and healthcare, with lawyers who are skilled and thoughtful practitioners.

We regularly defend clients against and investigate claims under federal and state statutes, including the False Claims Act, the Anti-Kickback Statute, and the Physician Self-Referral Law. Our experience is broad: at the federal level, we have experience not just with the Department of Justice, but also in FDA regulatory investigations and Congressional oversight investigations.

We guide our clients through the various phases of investigation, defense, and resolution, appreciating each client's specific circumstances and recognizing that a variety of considerations will drive our approach. We assist clients with the sensible design and implementation of compliance programs and provide compliance advice that builds off our experience handling the investigation and defense of these matters.

Our work in these areas includes:

- Representing healthcare and life sciences companies and their boards and executives in complex criminal investigations and related civil proceedings brought by U.S. federal or state regulators and prosecutors, civil lawsuits initiated by “whistleblowers” or other qui tam plaintiffs, and foreign regulators.

- Conducting confidential internal investigations concerning allegations of fraud and abuse, False Claims Act violations, and kickbacks, and advising clients on effective responses.
- Assisting clients in assessing compliance risks and developing and implementing compliance policies and practices tailored to their unique business needs.
- Providing FCPA and anti-corruption compliance training to healthcare and life sciences clients.
- Advising U.S. and non-U.S. clients regarding anti-corruption due diligence in connection with mergers and acquisitions and other business transactions in the U.S. and abroad.

Representative Experience

Company Defense

- Represented a large public company in responding to federal healthcare False Claims Act investigation conducted jointly by US Attorney's Offices in several districts across the country concerning potential federal health care program reimbursement fraud arising out of alleged sales, marketing and pricing practices, including practices related to discounts, credits, and acquisition cost or average sales price reporting.
- Represented several health care payers in connection with antitrust merger investigations by DOJ, state AG and state Divisions of Insurance.
- Served as lead counsel to a human genomics company in an FTC investigation regarding consumer protection and privacy issues.
- Represented a private health insurer in response to its recent CID that involved an investigation into federal price reporting practices and the appropriate treatment of various price concessions paid by a manufacturer to health plans, PBMs, and certain exempt entities.
- Represented a major pharmaceutical manufacturer in state investigation of sales and pricing practices.
- Represented specialty health care provider in False Claims Act litigation.
- Represented a pharmaceutical company in an anti-kickback/False Claims Act investigation related to speaker programs.
- Represented genetic testing company in responding to HHS-OIG subpoena in connection with investigation regarding false claims for payment under the Medicare and Medicaid programs; sales and marketing practices at issue included coding & reimbursement, cost vs. reimbursement marketing, marketing co-pay, discount and maximum out-of-pocket price caps.
- Represented a dental services organization in enforcement action alleging violation of state consumer protection laws.

- Represented healthcare company in responding to HHS-OIG subpoena in connection with anti-kickback investigation; sales and marketing practices at issue included payments for provider expenses, marketing reimbursement value, and compliance policies, procedures and training.
- Represented healthcare diagnostics company responding to a federal grand jury subpoena concerning confidentiality issues and internal compliance practices.
- Represented healthcare company in responding to Medicaid fraud unit civil investigative subpoena concerning potential anti-kickback and Stark law violations.
- Represented healthcare provider in reimbursement appeal arising out of Medicare related-party principles; provider prevailed after administrative hearing
- Represented healthcare insurer in responding to civil investigative demand concerning pricing issues; matter concluded without charges.
- Represented a physicians' association in responding to grand jury subpoena in connection with False Claims Act and anti-kickback investigation; practices at issue included pricing, marketing discounts, rebates, pharmacy management and product substitution, grants and sponsorships.
- Successfully resolved State Attorney General investigation of home health agency related to allegations of overbilling.
- Defended compound pharmacy manufacturer against criminal and civil investigations conducted by the Department of Justice and the Food and Drug Administration (the FDA). Successfully negotiated a consent decree and declination of criminal charges.*
- Defended pharmaceutical distributor against allegations by the DEA of violating the federal Controlled Substances Act and related regulations. Successfully negotiated a memorandum of agreement (probation) with no fine or penalty.*
- Defended pharmaceutical distributor against allegations by the MA Board of Pharmacy related to the distribution of controlled substances. Successfully negotiated a term of probation without financial penalty.*
- Represented a global pharmaceutical company before the SEC in a global compliance review.*
- Represented a global pharmaceutical company before the SEC in an investigation into revenue recognition practices.*
- Successfully defended a pharmaceutical company in a TRO hearing in federal court involving Lanham Act violations related to comparative safety claims.*

Internal Investigations

- Represented a Fortune 100 Life Sciences company to coordinate the investigation of suspected FCPA violations in India, Ukraine, China and Brazil.
- Represented a multinational medical device company in connection with an internal investigation related to the distribution of certain lab tests and a submission to the FDA regarding same to stave off a potential referral to DOJ to investigate potential FDCA violations.

- Conducted internal investigation for a diagnostic testing company concerning alleged kickbacks provided in violation of the FCPA in Brazil.
- Conducted internal investigation for regional healthcare system related to high-profile incident of patient who was unable to access the emergency department.
- Conducted internal investigation for academic medical center related to allegations of impropriety in physician training.
- Conducted internal investigation at long term care pharmacy and provided compliance guidance to company management and the Board of Directors.*
- Advised academic medical center in defense of federal False Claims Act investigation into alleged research grant fraud.*
- Conducted an internal investigation on behalf of and represented a global pharmaceutical company in a joint DOJ and SEC investigation of alleged FCPA violations in several countries in Eastern Europe, the Middle East, and Asia.*

Representation of Individuals

- Represented the CEO of a health care diagnostics company in a False Claims Act investigation by the Department of Justice and the U.S. Attorney's Office in New Jersey; resolved with no charges brought against our client.
- Represent several current and former employees of a life sciences company in a federal investigation for alleged violations of the Food, Drug and Cosmetic Act and alleged violations of Good Manufacturing Practices.
- Represented corporate executives at subsidiaries of a multinational dialysis company in Spain, Portugal, Morocco and Germany in connection with a DOJ/SEC FCPA (anti-bribery) investigation.
- Defended CEO of Telemedicine company accused in a federal Indictment of health care fraud and related offenses.*
- Successfully negotiated a rare misdemeanor resolution for an executive under federal investigation for alleged felony offenses, including wire fraud, price gouging, and other federal criminal offenses related to the sale of personal protective equipment (PPE) during the COVID-19 lockdown.*
- Defended the CEO of multiple Durable Medical Equipment (DME) companies against federal criminal investigation resulting in no charges having been brought.*
- Defended physician in connection with False Claims Act investigation involving Durable Medical Equipment (DME) and alleged violations of the federal anti-kickback statute (AKS).*

Audits, Self-Assessments and Due Diligence

- Conducted due diligence and provided FCPA counsel for startup related to potential African government customer.

- Conducted a global FCPA (anti-bribery) compliance review for a multinational pharmacy chain following its acquisition of a global competitor, including directing forensic reviews of the acquiree's operations in the Middle East, Asia and Europe.
- Conducted FCPA due diligence on behalf of a healthcare technology company in connection with the proposed acquisition of a patient engagement platform provider.
- Represented state-wide integrated home health organization in responding to annual Medicaid audits.

Compliance Program Development and Training

- Advised regional hospital system regarding improvements to its compliance program in connection with and in advance of potential settlement.
- Advised medical device and pharmaceutical manufacturers on federal and state "sunshine" laws regarding payments to physicians.
- Provided compliance and regulatory advice to multiple outpatient rehab facilities and sober homes (recovery houses).*
- Provided compliance and regulatory advice to European DME company looking to enter the United States market.*

** Denotes matter handled by Foley Hoag LLP attorney prior to joining the firm*