



Jonathan Stevens

Of Counsel, Litigation Department
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Jonathan Stevens is Of Counsel in the Investigations and White-Collar Defense practice. Prior to joining the Orange County, CA office, Mr. Stevens worked in the firm's Washington, D.C. office.

Mr. Stevens was former in-house counsel for a multi-national medical device company, and has broad experience in the life sciences sector. He focuses his practice on government and internal investigations, regulatory and anti-corruption compliance counseling, and white-collar litigation on behalf of pharmaceutical and medical device companies.

Mr. Stevens has extensive experience providing day-to-day compliance advice, developing and enhancing compliance programs, conducting proactive reviews and risk assessments, overseeing internal investigations, and representing companies before state and federal authorities in criminal and civil enforcement actions involving the Anti-Kickback Statute, False Claims Act, and other state and federal healthcare statutes. He has experience, as both outside and in-house counsel, advising companies under deferred prosecution agreements with the U.S. Department of Justice and corporate integrity agreements with the U.S. Department of Health and Human Services, Office of the Inspector General. Much of his practice is currently focused on rare disease and gene therapy market access challenges, including around patient support/assistance programs, specialty pharmacy arrangements, field reimbursement support, and the full range of interactions between manufacturers, prescribers, third-party vendors, patients, and payers.

Mr. Stevens has also conducted and managed significant foreign investigations, and has represented large multi-national companies in criminal enforcement actions before the Department of Justice and Securities and Exchange Commission involving the Foreign Corrupt Practices Act. Clients routinely rely on his unique insight and perspective into the Latin American region, and benefit from him having lived in Brazil and performing legal services in Portuguese and Spanish.

Orange County

T: 1(714) 668-6201
F: 1(714) 668-6301

Practice Areas

Anti-corruption and FCPA
Life Sciences and Healthcare
Litigation
Investigations and White
Collar Defense

Admissions

District of Columbia Bar
Florida Bar

Languages

Portuguese
Spanish

Education

Brigham Young University,
B.A. 2007
University of Florida, Levin
College of Law, J.D. 2010

Jonathan Stevens (Continued)

Admitted in the District of Columbia and Florida only. Not admitted in California.

Recent Representations

Investigations and White Collar Defense

- Representation of multi-national medical device manufacturer in connection with a voluntary disclosure to the U.S. Department of Justice related to potential violations of the Foreign Corrupt Practices Act in China and various other jurisdictions
- Representation of multi-national pharmaceutical company in connection with a U.S. Department of Justice subpoena and investigation into its patient support program, drug pricing, and specialty pharmacy relationships
- Representation of multi-national pharmaceutical company in connection with a U.S. Department of Justice subpoena and investigation into rebate payments to pharmacy benefit managers, its patient support program, and government price reporting
- Representation of multi-national pharmaceutical company in connection with state attorney general investigation into patient support program benefits provided to employees of state employee healthcare plans
- Representation of multi-national medical device company in voluntary disclosure to the U.S. Department of Justice related to potential violations of the Foreign Corrupt Practices Act in Brazil
- Representation of a domestic biopharmaceutical company in connection with U.S. Food and Drug Administration and U.S. Department of Justice investigations across multiple offices into its post-marketing approval study and sales and marketing practices with respect to a controlled substance
- Conducted internal investigation on behalf of domestic pharmaceutical company into whistleblower allegations of potential Anti-Kickback Statute violations related to clinical trials and advisory boards
- Conducted internal investigation on behalf of domestic pharmaceutical company into allegations of pre-approval promotion, off label promotion, and other sales and marketing practices
- Conducted internal review on behalf of specialty pharmaceutical company's patient access programs and conducted internal investigation into alleged pharmacy fraud and abuse
- Conducted review on behalf of multi-national medical device company into whistleblower allegations related to distributor conduct and potential Foreign Corrupt Practices Act violations in Brazil
- Conducted internal investigation on behalf of multi-national medical device company into allegations of corrupt payments related to building permits in

Jonathan Stevens (Continued)

Mexico

- Conducted internal investigation and audit of third party contractors in Vietnam on behalf of a multi-national engineering and construction company in connection with a Foreign Corrupt Practices Act investigation before the U.S. Department of Justice and multi-lateral development banks
- Conducted internal investigation and audit on behalf of multi-national medical device company in response to potential whistleblower allegations related to distributor conduct in Colombia
- Conducted internal investigations on behalf of multi-national defense contractor into alleged improper sub-contractor gratuities in violation of the Anti-Kickback Act, alleged conflict of interests in violation of the Procurement Integrity Act, and whistleblower safety concerns related to the False Claims Act
- Conducted internal investigation on behalf of multi-national defense contractor into alleged misappropriation of supplier trade secrets in anticipation of review by the U.S. Department of Defense's largest Joint Program Office
- Conducted internal investigations under Federal Acquisition Regulation mandatory disclosure rule on behalf of multi-national defense contractor, including overpayments on government contracts due to mischarging, violations of federal criminal law, fraud, conflicts of interest, and false claims

Risk Assessments and Diligence

- Conducted global anti-bribery and anti-corruption risk assessment on behalf of multi-national medical device company
- Conducted global anti-bribery and anti-corruption risk assessment on behalf of multi-national pharmaceutical company
- Conducted proactive compliance market reviews on behalf of multi-national rare disease company in Spain, Portugal, Middle East, and Brazilian markets
- Conducted anti-bribery and anti-corruption due diligence associated with the multi-billion-dollar acquisition of a multi-national injectable drug and biosimilar company in the Brazilian market
- Conducted anti-bribery and anti-corruption due diligence associated with the multi-billion-dollar acquisition of multi-national orphan drug company in the Brazilian market
- Acted as regulatory advisor on behalf of private credit, direct lenders, finance companies, and alternative and specialty lenders in both cross-border and U.S. focused healthcare transactions

Corporate Monitorships and Compliance Counseling

- Member of team appointed by the DOJ as an independent compliance monitor pursuant to a Deferred Prosecution Agreement related to alleged violations of the Foreign Corrupt Practices Act

Jonathan Stevens (Continued)

- Conducted internal review on behalf of multi-national medical device company into alleged misrepresentations made to the DOJ's independent compliance monitor during the company's Deferred Prosecution Agreement
- Advised multi-national medical device company on obligations associated with the company's Deferred Prosecution Agreement with the DOJ and the company's Corporate Integrity Agreement with the OIG-HHS related to alleged violations of the Anti-Kickback Statute and False Claims Act and made presentations to federal monitors on the development of the company's compliance and ethics program
- Drafted and submitted U.S. Health and Human Services, Office of Inspector General advisory opinion request on behalf of multi-national oncology company
- Developed and conducted anti-bribery and anti-corruption training in EMEA, LATAM, and APAC regions as well as targeted training to board of directors, corporate officers, finance, internal audit, and other risk managers
- Developed and drafted numerous corporate policies and procedures addressing interactions with healthcare professionals, including company and third-party education and training events, sales and marketing practices, charitable donations and grants, consulting arrangements, as well as an internal fair market valuation process for hourly, clinical, and royalty-based consultant arrangements
- Drafted and negotiated consulting agreements with domestic and international healthcare professionals, hospitals, and teaching institutions on behalf of multi-national medical device company

Speaking Engagements and Publications

- Presenter, Compliance for Innovative Therapies: A Spotlight on Rare Disease Companies CBI West Coast Compliance Congress, October 22, 2019
- Lecturer, University of Florida Levin College of Law Global Corporate Compliance LAW 6090 course
- Program Faculty, Seton Hall Law School, Latin American Compliance Certification Program

Publications

- Co-Author, Key Healthcare Compliance Governance Essentials for Small and Mid-Size Life Science Companies, Orange County Business Journal, October 14, 2019
- Co-Author, The Rise of Anti-Corruption Whistleblowers in Latin America Global Investigations Review, December 7, 2018
- Co-Author, Time to Clean Up: As Operation Car Wash Progresses, Are Medical Device and Pharmaceutical Companies Out of Time with Brazilian Authorities? Paul Hastings Client Alert, May 18, 2017

Jonathan Stevens (Continued)

- Co-Author, A Special Type of Government Scrutiny: Pharmaceutical Manufacturer Relationships with Specialty Pharmacies: Part I Bloomberg Law, March 29, 2017
- Co-Author, A Special Type of Government Scrutiny: Pharmaceutical Manufacturer Relationships with Specialty Pharmacies: Part II Bloomberg Law, April 7, 2017

Education

- University of Florida, Levin College of Law, J.D. (cum laude, Editor Florida Law Review, Member Philip C. Jessup International Law Moot Court Team)
- Brigham Young University, B.A.

Insights

July 01, 2020

Key Takeaways From the Novartis 345 Million Dollar FCPA Settlement

April 22, 2020

Compliance in the Era of COVID-19 – Where and How Life Sciences and Health Care Companies Should Focus in the Era of Social Distancing