CHOATE

Sara K. Frank
Principal

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Practice Areas

Government Enforcement & Compliance

Education

Suffolk University Law School
JD (2015) *magna cum laude*
Editor-in-Chief, *Journal of Health & Biomedical Law*

Smith College
BA (2000)

Admissions

Massachusetts

Sara Frank provides legal and compliance advice to companies and individuals, most often based on Anti-Kickback Statute, False Claims Act, HIPAA, and Food, Drug, and Cosmetic Act concerns, primarily in the life sciences sector. Sara's knowledge and insight earned while working as the U.S. Compliance Officer for one of the oldest independent biotech companies in the world make her a valuable contributor in complex investigations and a trusted advisor in times of critical decision-making for her clients.

Working with Choate's healthcare clients, Sara advises providers and life sciences companies in handling compliance and regulatory issues. This work includes helping emerging companies develop and implement key compliance initiatives and helping more established companies assess the legal risks associated with new business plans, conduct internal investigations, and manage government inquiries.

In addition, Sara has served on task forces for both PhRMA and BIO trade groups and has been active in national pharmaceutical and biotechnology compliance forums. She is certified in healthcare compliance by the Healthcare Compliance Association.

Representative Engagements

- Draft and assess compliance policies for pharmaceutical, biotech, medical device, vaccine, laboratory services, and diagnostic testing companies.
- Counsel life sciences clients on patient support services; financial assistance programs; sales and marketing practices; medical affairs; clinical trials; privacy; REMS; and labeling, advertising, and promotion of FDA-regulated products.
- Advise life sciences clients on business activities in order to comply with FDA regulatory schemes.
- Serve as external legal reviewer for a promotional review committee.
- Serve as interim Commercial Counsel and Compliance Officer for life science clients.
- Address emerging issues in the commercialization of gene therapies and rare disease products.
- Counsel clients on federal Sunshine Act and related state law questions.
- Draft self-disclosure letter to OIG for a major academic medical institution regarding the hiring of an excluded employee.

- Represent major pharmaceutical company in federal investigation into sales and marketing practices.
- Assist in internal investigations regarding commercial business practices.
- Defend a pharmaceutical executive of a public healthcare company in multi-year investigations by the Securities and Exchange Commission and the Department of Justice.
- Defend an individual employee in the Department of Justice's investigation of a pharmaceutical company's commercial business practices.
- Represented a university in investigations of faculty time and effort reporting issues, including voluntary self-disclosures to the grant-awarding government agencies.
- Assisted a hospital in evaluating and refunding overpayments associated with physician billing and coding errors.
- Advise college on compliance with FEMA grant conditions and drafted attestations based on the requirements of the award.

Publications and Presentations

- "Qui Tam Declinations—Analysis and Trends When DOJ Declines to Intervene," moderator, 25th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress, October 2024
- "The Rise of Cell and Gene Therapy and How to Remain Compliant Amid Industry Shifts," moderator, Informa Connect Compliance Congress For Specialty Products, September 2023
- "Navigating the Legal Considerations of Patient Assistance," panelist, Pharmaceutical Compliance Congress, April 2023
- "Compliance and Ethics in Emerging Companies," moderator, 23rd Annual Pharmaceutical and Medical Device Ethics and Compliance Congress, October 2022
- "HIPAAtheticals: HIPAA in the Promotional Context," panelist, Boston Bar Association, November 2019
- "Ramp Up Resources for Clinical and R&D Oversight to Achieve Compliance Excellence Throughout the Product Lifecycle," moderator, CBI Annual Life Sciences Compliance Congress for Specialty Products, September 2019
- "Expanded Access – A Regulatory Balancing Act For Drug Cos." co-author, *IP Law360*
- "1st Circ. Crime-Fraud Ruling Challenges Atty-Client Privilege," co-author, *White Collar Law360*
- "Eligibility Discrimination of the Intellectually Disabled in Pediatric Organ Transplantation," author, *Journal of Health & Biomedical Law 101*
- "Credentialing: Why Proper Certification is Crucial and How It May Affect the Success of Your Sales Force and Sampling Initiatives," speaker, 7th Multi-Channel Sampling Strategies Conference, Philadelphia, PA
- "Bracing for Mandatory Federal Sunshine Reporting Requirements: Immediate Action Plans for 2012 Spend," panelist, Physician Payments Disclosure & Aggregate Spend Conference, New York, NY
- "Insight on Executing State Marketing Laws," panelist, Pharmaceutical & Medical Device Sales & Marketing Compliance Conference, Chicago, IL

Professional and Community Involvement

- Member, Boston Bar Association
- Member, American Health Lawyers Association
- Volunteer, Silver Lining Mentoring as a long-term mentor to a young woman in foster care
- Co-Chair, Choate's legal clinic for the homeless program through the Lawyers Clearinghouse

Recognition

- *Chambers USA:* "Associates to Watch" (2023-2024)
- High Honors Recipient, Massachusetts Supreme Judicial Court Pro Bono Honor Roll (2023)