

Sara K. Frank

Associate

T +1 (617) 248-4765 | sfrank@choate.com



Sara Frank is an associate in Choate's Government Enforcement & Compliance and Healthcare Groups. Her practice focuses primarily on the life sciences sector. Ms. Frank previously served in roles of increasing responsibility at one of the oldest independent biotech companies in the world, including as the Director of Commercial Compliance, U.S. Compliance Officer. In that role, she helped develop the company's U.S. Commercial Compliance program and counseled sales, marketing, patient services, reimbursement and medical affairs leadership on issues related to interactions with healthcare professionals as well as relevant laws, regulations, industry standards and business practices. Ms. Frank led the team responsible for implementing the companywide transparency program to report spending on healthcare professionals in readiness for the federal Sunshine Act and other state and international disclosure requirements.

Ms. Frank has experience in policy writing and implementation, training, monitoring and creating monitoring programs, internal investigations, compliance committees, educational grant committees, promotional review committees, international compliance issues, structuring compliance programs, written information security programs, expanded access, pre-commercial activities, patient assistance programs, aggregate spend reporting and corporate compliance matters. She 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.

EDUCATION

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

Smith College
BA, 2000

PRACTICE FOCUS

Government Enforcement & Compliance

Representation of companies and individuals in government and internal investigations involving healthcare fraud, securities fraud, and other civil and criminal regulatory matters.

Healthcare

Representation of healthcare providers in handling compliance and regulatory issues and developing business solutions.

ADMISSIONS

Massachusetts

PRACTICE AREAS

Litigation

Government Enforcement &
Compliance

REPRESENTATIVE ENGAGEMENTS

- Draft compliance policies for genetic testing and laboratory services pharmaceutical, biotech, medical device and diagnostic testing companies.
- 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.

PUBLICATIONS AND PRESENTATIONS

- "Ramp Up Resources for Clinical and R&D Oversight to Achieve Compliance Excellence Throughout the Product Lifecycle," *moderator*, CBI 4th Annual Life Sciences Compliance Congress for Specialty Products, September 2019.
- "Expanded Access – A Regulatory Balancing Act For Drug Cos.," *co-author*, *IP Law360*, June 2016.
- "1st Circ. Crime-Fraud Ruling Challenges Atty-Client Privilege," *co-author*, *White Collar Law360*, February 2016.
- "Eligibility Discrimination of the Intellectually Disabled in Pediatric Organ Transplantation," *author*, *10 J. Health & Biomed. L.* 101, 2014.
- "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, October 2011.
- "Bracing for Mandatory Federal Sunshine Reporting Requirements: Immediate Action Plans for 2012 Spend," *panelist*, Physician Payments Disclosure & Aggregate Spend Conference, New York, NY, October 2011.
- "Insight on Executing State Marketing Laws," *panelist*, Pharmaceutical & Medical Device Sales & Marketing Compliance Conference, Chicago, IL, July 2011.

PROFESSIONAL AND COMMUNITY INVOLVEMENT

Ms. Frank is a member of the Boston Bar Association and the American Health Lawyers Association. She volunteers with Silver Lining Mentoring as a long-term mentor to a young woman in foster care. Ms. Frank co-chairs the firm's legal clinic for the homeless program through the Lawyers Clearinghouse.