

Sara K. Frank

Principal

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



Sara Frank provides legal and compliance advice to companies and individuals, most often based on Anti-Kickback Statute, False Claims Act, and HIPAA 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 compliance investigations and a trusted advisor in times of critical decision-making for her clients.

Sara also works with clients in Choate's Healthcare Group, advising providers 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.

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.

PRACTICE AREAS

Government Enforcement & Compliance

RECOGNITION

- "Associates to Watch" by *Chambers USA*

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.
-

EDUCATION

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

Smith College
BA, 2000

ADMISSIONS

Massachusetts

- 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

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