# CHOATE

# Danielle Pelot

Partner

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Danielle Pelot helps clients in life sciences, healthcare, financial services, higher education, and similar regulated sectors to efficiently and successfully address federal and state enforcement actions, fraud allegations, and related complex litigation. She has a particular emphasis in counseling pharmaceutical and medical device companies and life sciences industry professionals. She also assists clients to address sensitive government inquiries involving agencies such as NIH, NSF, HHS-OIG, GSA, DOT, FBI, and DOJ relating to research integrity and foreign influence risks at U.S. academic and research institutions. She works routinely with clients on proactive compliance measures and risk mitigation strategies.

Clients value her industry-specific knowledge and sensitivity to organizational dynamics in working closely with stakeholders at all levels.

Danielle previously served as a Special Assistant District Attorney for the Middlesex County District Attorney's Office where she prosecuted various criminal matters and tried cases to verdict.

# PRACTICE AREAS Government Enforcement & Compliance

#### RECOGNITION

- One of Boston's "40 Under 40" by Boston Business Journal
- "Rising Star" by Massachusetts Lawyers Weekly
- One of 30 "Up & Coming Lawyers" by Massachusetts Lawyers Weekly
- Massachusetts Super Lawyers

#### REPRESENTATIVE ENGAGEMENTS

- Multi-national medical device manufacturer in federal investigation and *qui tam* action involving alleged False Claims Act (FCA) violations related to manufacturing specifications, litigated in the District Court of Massachusetts and the First Circuit Court of Appeals.
- World-leading medical device company in federal industry investigation in New Jersey, including negotiating and implementing Corporate Integrity Agreement (CIA), Deferred Prosecution Agreement (DPA), and managing process of outside monitorship.
- Multinational government contractor in connection with federal public corruption investigation into criminal fraud activities of former employee and third party vendor.

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#### **EDUCATION**

Boston College Law School JD, 2004

Harvard College AB, 1999, cum laude

#### **ADMISSIONS**

Massachusetts

- Academic institution in coordination of response to law enforcement investigation and internal investigations related to foreign influence in research, espionage, conflict of interest and conflict of commitment.
- Research technology company in connection with government inquiry into GSA
  pricing, resulting in government declination to intervene in whistleblower action.
- Assessment of multi-national company's compliance policies and procedures as part of Independent Review Organization (IRO) team pursuant to CIA.
- Various board audit committees in connection with internal reviews prompted by whistleblower complaints regarding accounting and tax practices.
- Senior executive at major pharmaceutical company in federal investigation into compliance with current Good Manufacturing Practices (cGMPs) and the Food Drug & Cosmetics Act (FDCA).
- University in internal and external investigation and voluntary self disclosure to DOJ and NIH of time and effort reporting issues involving a faculty member and successfully resolving the matter with no damages multiplier.
- Academic institutions in government related matters, including responding to antitrust inquiries and review of federal grant management practices.
- Federal highway contractor in connection with *qui tam* action alleging fraud and misrepresentation regarding product safety.
- Multiple international pharmaceutical companies in various federal and state investigations of allegations such as off-label promotion, kickbacks, and pricing violations.
- Multiple medical, engineering, and sales and marketing professionals in various federal grand jury investigations of pharmaceutical and device company promotional practices, including a target sales executive in an investigation alleging kickbacks and illegal promotion.
- Providers in federal investigation involving allegations of kickbacks and medical necessity violations related to laboratory testing and pain management.
- Biopharmaceutical company in government-declined *qui tam* litigation alleging submission of false claims for unapproved treatments.
- Various life sciences companies in assessments of compliance program policies and procedures, including related to patient services, marketing and promotional activity, third party arrangements, and HCP interactions.
- Target pharmaceutical sales executive in federal investigation involving allegations of off-label promotion and anti-kickback violations.
- Nursing facility in connection with government investigation of third-party service providers.
- Pharmaceutical manufacturer in Average Wholesale Price ("AWP") civil litigation following investigations by state attorneys general.
- Special Counsel to state commission conducting confidential investigation of judicial disciplinary matter.

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- State legislative body in connection with federal public corruption inquiry.
- Executives and employees of company investigated for alleged fraud, negligence, and false claims on Boston's Big Dig tunnel collapse, in federal and state grand jury inquiries and private civil litigation.
- Construction-industry executive in federal investigation into government contracting "set aside" programs involving minority or disadvantaged business enterprises (DBEs).
- Individuals in connection with federal grand jury investigation into alleged campaign finance violations.
- National office supplies corporation in federal False Claims Act, Massachusetts False Claims Act, and New Hampshire False Claims Act charges brought by criminal and civil divisions at state and local level.
- Local manufacturer in Federal Trade Commission antitrust investigation.
- Telecommunications company in connection with Securities and Exchange Commission (SEC) investigation of potential insider trading.

#### PUBLICATIONS AND PRESENTATIONS

- "What Do Health Equity Initiatives Mean for Compliance?" *moderator*, 24<sup>th</sup> Annual Pharmaceutical and Medical Device Ethics and Compliance Congress, October 2023.
- "Diversity, Equity & Inclusion Breakfast Summit," *moderator*, Pharmaceutical Compliance Congress, April 2023.
- "Ethical Dos and Don'ts at Every Stage of a Qui Tam Case," panelist, Federal Bar Association's Qui Tam Conference, February 2023.
- "Tax Enforcement Under State False Claims Acts: As States Begin to Allow Tax-Based Qui Tam Suits, Is a New Kind of Tax Controversy Taking Hold?" panelist, American Bar Association 2023 Midyear Tax Meeting, February 2023.
- "Compliance Considerations Intersecting Corporate DE&I Initiatives," moderator, 23<sup>rd</sup> Annual Pharmaceutical and Medical Device Ethics and Compliance Congress, October 2022.
- "Spotlight on Rare Disease Compliance Risks," *moderator*, Pharmaceutical Compliance Congress, April 2022.
- "Assessing the Impact of Increased OIG Scrutiny on the Future of Speaker Programs," speaker, Informa Connect Speaker Programs Benchmarking Summit, July 2021.
- "DOJ Enforcement Trends Related to Speaker Programs," *presenter*, Informa Connect Pharmaceutical Compliance Congress, August 2020.
- "White Collar Crime Conference," *Advisory Committee member and speaker*, Boston Bar Association, 2018 and 2019.
- "The Vanishing FCPA 'Facilitating Payments' Exception," co-author, Law 360.

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## PROFESSIONAL AND COMMUNITY INVOLVEMENT

- Co-Chair of the 2023 Boston Bar Association Annual Meeting
- Member of the Steering Committee of the Choate Women's Network
- Member of The Links, Inc., a non-profit professional women's organization supporting community engagement
- Member of the Board of Directors of the Massachusetts Black Lawyers Association
- Lifetime member of the Massachusetts Black Lawyers Association
- Founding participant in Boston's Move The Needle, a working group focused on best practices for meaningful implementation of ABA Resolution 113 in corporations and law firms