

# Danielle Pelot

Partner

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Danielle Pelot helps clients in life sciences, healthcare, financial services, higher education, and similar regulated sectors to effectively 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, FBI, and/or 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.

Danielle previously served as a Special Assistant District Attorney for the Middlesex District Attorney's Office where she prosecuted various criminal matters and tried cases to verdict. Clients value her industry-specific knowledge and sensitivity to organizational dynamics in working closely with stakeholders at all levels.

## 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

- International pharmaceutical company in prominent federal and state investigation alleging off-label promotion, kickbacks, and pricing violations.
- Biopharmaceutical company in government-declined *qui tam* litigation alleging submission of false claims for unapproved treatments.
- Multi-national medical device manufacturer in federal investigation and *qui tam* action involving alleged False Claims Act (FCA) violations.

**EDUCATION**

Boston College Law School  
JD, 2004

Harvard College  
AB, 1999, *cum laude*

**ADMISSIONS**

Massachusetts

- 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.
- 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.
- Assessment of multi-national company's compliance policies and procedures as part of Independent Review Organization (IRO) team.
- Senior executive at major pharmaceutical company in federal investigation into compliance with current Good Manufacturing Practices (cGMPs) and the Food Drug & Cosmetics Act (FDCA).
- Target pharmaceutical sales executive in federal investigation involving allegations of off-label promotion and anti-kickback violations.
- Medical, engineering, and sales and marketing professionals in federal grand jury investigations of pharmaceutical company promotional practices.
- Providers in federal investigation involving allegations of kickbacks and medical necessity violations related to laboratory testing and pain management.
- 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.
- 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.
- Academic institutions in government-related matters, including responding to antitrust inquiries and review of federal grant management practices.

- Telecommunications company in connection with Securities and Exchange Commission (SEC) investigation of potential insider trading.

## PUBLICATIONS AND PRESENTATIONS

- “Current Enforcement Trends, Best Practice Benchmarks and Future Fate,” *moderator*, Informa Connect Pharmaceutical Compliance Congress, August 2020.
- “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*.

## PROFESSIONAL AND COMMUNITY INVOLVEMENT

- 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