Debra E. Schreck

Partner

New York

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Debra is a New York-based litigator with deep experience representing pharmaceutical, biotech, medical device, and other corporate clients in high-stakes litigation, as well as government and internal investigations. Her practice spans critical compliance and enforcement issues, including marketing and sales practices, product safety, pricing and competition, and workplace misconduct.

OVERVIEW

Debra defends clients in complex criminal and civil investigations brought by federal and state agencies, including the U.S. Department of Justice, U.S. Attorneys' Offices, and state attorneys general. She also defends clients in federal and state False Claims Act (FCA) actions brought by the government and *qui tam* whistleblowers, as well as products liability and general commercial litigation matters across the U.S. Her enforcement and litigation practice focuses heavily on health care fraud and abuse allegations, including under the FCA, Anti-Kickback Statute, and Food, Drug, and Cosmetic Act, as well as workplace integrity matters.

Leveraging her defense experience, Debra helps companies assess and mitigate risk even without a lawsuit or government inquiry. She conducts internal investigations, performs litigation risk assessments, and works alongside clients to design corporate compliance policies and training programs.

Having partnered with dozens of companies in the health care and life sciences sectors and beyond, clients rely on Debra for her industry insights, strategic counsel, and practical, solutions-oriented approach.

REPRESENTATIVE MATTERS

FCA Litigation

- Defended a pharmaceutical manufacturer against *qui tam* litigation in multiple jurisdictions alleging violations of the AKS and FCA through the use of nurse education and reimbursement support services. Obtained dismissals of the federal and New Jersey state cases.
- Defended multiple pharmaceutical manufacturers against *qui tam* suit in the District of New Jersey alleging misbranding and fraudulent inducement in connection with an antibiotic medication. Dismissal by the district court affirmed by the Third Circuit in 2025.
- Represented pharmaceutical manufacturers in successful defense of a *qui tam* suit brought in the District of Massachusetts by multiple relators, alleging off-label and kickback claims. On a motion to dismiss, obtained

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dismissal with prejudice of all claims. Dismissal with prejudice of all federal claims affirmed by the First Circuit. Relators then filed suits in multiple state courts under state FCA statutes; secured dismissals of all state court claims.

- Represented a pharmaceutical manufacturer in *qui tam* litigation brought in the Southern District of New York by the government and a relator, alleging kickbacks to specialty pharmacies in connection with various medications.

Commercial and Product Liability Litigation

- Represented a pharmaceutical manufacturer in litigation alleging antitrust and marketing claims relating to one of its products.
- Represented multiple companies in favorable resolution of data breach class action litigation in the Southern District of New York.
- Defended multiple pharmaceutical manufacturers in federal and state product liability litigation involving two antibiotic medications.

Government and Internal Investigations

- Represented a medical device manufacturer in a federal investigation involving allegations that pricing offers constituted kickbacks. Government declined intervention.
- Led successful response to state government investigation of a medical device manufacturer alleging violations of law in connection with price increases of several devices.
- Led successful response to government investigation of pharmaceutical manufacturer alleging retaliatory termination for reporting privacy/HIPAA violations.
- Represented pharmaceutical manufacturer in connection with congressional inquiry regarding drug pricing.
- Represented an international corporation in connection with pre-merger antitrust investigation by the DOJ, resulting in antitrust clearance.
- Represented pharmaceutical company in internal investigation of alleged violations of FDA regulations.
- Represented biotech company in internal investigation involving alleged violations of health care regulations.
- Represented medical device manufacturer in internal investigation in response to allegations of theft of trade secrets.
- Led internal investigation on behalf of biopharma company triggered by internal and external reports of off-label promotion, kickbacks, and commercial influence on medical activities.

Workplace Integrity Investigations

- Conducted internal investigation for media company in response to allegations of sexual misconduct by senior corporate executive.
- Conducted internal investigation for educational institution in response to allegations of sexual misconduct by faculty member.
- Represented the office of a state governor in response to inquiry by a state attorney general concerning allegations of sexual harassment.
- Conducted internal investigation for clinical research institution in response to allegations of bullying and workplace misconduct by clinical director.

AWARDS

- *LMG Life Sciences Guide*: “Rising Star” White-Collar/Government Investigations (2023-2025)

- *Lawdragon*: “Global Leaders in Crisis Management” (2025-2026)

TOP AREAS OF FOCUS

- False Claims Act + Other Whistleblower Actions
- Fraud + Abuse Litigation + Investigations
- Health Care + Life Sciences
- Health Care Litigation
- Pharmaceutical + Medical Device Litigation + Counseling
- White Collar Litigation + Investigations

ALL AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- False Claims Act + Other Whistleblower Actions
- Fraud + Abuse Litigation + Investigations
- Health Care + Life Sciences
- Health Care Litigation
- Litigation + Trial
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability
- White Collar Litigation + Investigations

EDUCATION AND CERTIFICATIONS

EDUCATION

- Fordham University School of Law, J.D., *magna cum laude*, 2006, Order of the Coif
- Yeshiva University, B.A., *summa cum laude*, 2003, Valedictorian

BAR ADMISSIONS

- New York
- New Jersey

COURT ADMISSIONS

- U.S. Court of Appeals, First Circuit
- U.S. Court of Appeals, Third Circuit
- U.S. District Court, Southern District of New York
- U.S. District Court, Eastern District of New York
- U.S. District Court, District of New Jersey