



Michael R. Hoernlein

Partner

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Related Services

White Collar, Government & Internal Investigations ■ Health Care ■ Litigation ■ Business Litigation ■ False Claims Act ■ FDA Compliance & Enforcement ■ Health Care Fraud ■ FDA/Food, Drug & Device

Mike Hoernlein is a litigation attorney and Certified Fraud Examiner in the firm's Litigation & Trial Practice Group. Mike is a seasoned investigator with a long track record of helping clients uncover the truth in complex—and sensitive—internal investigations. Mike represents corporations and individuals in a wide range of industries, with a focus on health care—including providers, insurers, pharmaceutical companies, and medical device manufacturers. Mike also counsels and defends clients before state and federal authorities (including the Department of Justice and the Securities and Exchange Commission) in criminal and civil investigations into potential False Claims Act violations, Food, Drug, and Cosmetic Act violations, accounting fraud, insider trading, money laundering, price fixing, and public corruption.

Mike is ranked Band 2 in *Chambers USA* in Litigation: White Collar Crime & Government Investigations for North Carolina. He is also recognized by *The Best Lawyers in America*® for his white collar work. Mike is admitted to practice in North Carolina and New York, including all federal courts in North Carolina and the District Courts for the Southern and Eastern Districts of New York, as well as the Fourth Circuit Court of Appeals and the U.S. Supreme Court.

Representative Experience

White Collar Enforcement Defense

- Representing a medical device manufacturer in criminal investigation into potential violations of the Food, Drug, and Cosmetic Act.
- Representing C-suite insurance executives in a federal financial fraud investigation.
- Second chair in a federal criminal trial defending an accountant against securities fraud charges.
- Represented two state agencies in separate federal grand jury investigations into alleged public corruption, resulting in no adverse action.
- Represented two for-profit educational institutions in separate grand jury investigations into alleged fraud, resulting in no adverse action.
- Represented a high net-worth individual in a federal grand jury investigation into fraud allegations, resulting in no adverse action.
- Defended an individual client in a federal insider trading investigation and convinced the government to close the investigation with no adverse action.

Internal Investigations

- Performed an internal investigation for a pharmaceutical company into a variety of CGMP and data integrity issues.
- Performed an internal investigation for a pharmaceutical company into allegations of fraudulent testing data.
- Performed an independent fraud investigation for a national non-profit organization.
- Performed an internal money laundering investigation for a foreign bank.
- Performed an internal investigation for a major insurance company relating to bribery allegations in a Medicaid program.
- Performed an internal investigation for an insurance company into allegations of forgery of patient signatures.

False Claims Act Defense

- Defending an insurance company in a False Claims Act qui tam lawsuit relating to the Medicaid program.
- Represented a health care provider in a False Claims Act investigation and qui tam lawsuit relating to home health services.
- Represented a hospital system in a False Claims Act investigation and qui tam lawsuit relating to billing for lab services.
- Defended a large health care provider in a False Claims Act investigation into billing for long-term acute care hospitals.

Commercial Litigation

- Representing a global insurance company in civil litigation arising out of a massive counterfeit insurance policy fraud.
- Won full dismissal of all claims against a former corporate officer in a case alleging, among other things, fraud and breach of contract.
- Defended a manufacturing company in a price fixing class action/multidistrict litigation (MDL).
- Counsel for a manufacturer of composite race-car parts in a commercial dispute with a part-owner, securing a favorable settlement.
- Negotiated a favorable settlement for a major insurance company in a contract dispute with a former employee.
- Negotiated a favorable settlement for an insurer in a breach of contract case arising out of a life insurance claim.
- Counsel for a North Carolina manufacturing company in an ownership dispute arising out of a buy-sell agreement, securing a favorable settlement.

Publications & Presentations

Publications

- *Topics in Food and Drug Law: How to Comply with Drug CGMPs*, 3rd ed., Food and Drug Law Institute, June 2023.
- "Comment: WYSIATI and False Confessions," *Washington and Lee Law Review*, Vol. 78, No. 1, Winter 2021.
- "Clues Mandatory Vaccines Would Pass Muster at High Court," *Law360*, December 15, 2020.
- "Measles Vaccine Mandates Have Strong Legal Footing," *Law360*, April 23, 2019

Professional & Community Engagement

- CFE, Association of Certified Fraud Examiners
- North Carolina Bar Association

- Mecklenburg County Bar Grievance Committee (2012–2015; 2021–present), Diversity & Inclusion Committee (2015–2017)
- Hemophilia of North Carolina, board of directors, treasurer (2012–2018)

Education

- New York University (J.D., 2001)
- Rutgers University (B.A., 1998)

Admitted to Practice

- North Carolina
- New York