LeClairRyan’s attorneys are well qualified to assist biopharma companies in managing the risks of conducting business in a highly regulated environment and providing defense against any adverse occurrences.

Our attorneys regularly represent pharmaceutical companies, medical device and equipment companies, and clinical laboratories, as well as individual officers and employees of such companies in a variety of matters involving allegations of fraud and abuse. These matters pertain to:

- Federal and state government investigations and inquiries
- Internal investigations and corporate compliance
- Civil and administrative enforcement proceedings, such as actions under the False Claims Act and state counterparts (including qui tam actions)
- State consumer fraud and deceptive practices statutes
- Deceptive practices and class action cases brought by state Attorneys General’s Offices or private plaintiffs
- Alleged violations of the Stark Law and Anti-Kickback Statute and the Food, Drug and Cosmetic Act
- Federal Trade Commission actions
- Manufacturing practices laws and regulations (e.g., the manufacturing of products regulated by the Food and Drug Administration)
- Regulations governing federal and state price reporting (e.g., the Medicaid Drug Rebate Program)
- Marketing, sales and promotional practices, including off-label promotion
- Research and educational grants
- Clinical research fraud
- Continuing medical education
- White collar criminal defense

Federal Regulation and Investigations

Increasingly, biopharma companies under government investigation must simultaneously manage a criminal grand jury investigation, related civil investigation or ongoing civil litigation by the government, congressional inquiry, and private civil litigation. Such situations require careful management of these parallel proceedings to ensure the best possible outcome for our clients.

Our attorneys have extensive knowledge of the sometimes competing and conflicting interests that arise during government investigations, and our team includes several former federal prosecutors and government lawyers who have valuable experience and insights into the investigation and prosecution of these matters. As a result, we have successfully resolved criminal investigations with no criminal charges against our clients and litigated numerous cases brought under the qui tam provisions of the False Claims Act.

In recent years, the U.S. Department of Justice and U.S. Securities and Exchange Commission have placed an increased emphasis on compliance with the Foreign Corrupt Practices Act (FCPA), particularly within the biopharma industry. Expanded government oversight as well as new whistleblower protections compound the level of complexity under which biopharma enterprises operate.

LeClairRyan regularly helps biopharma companies navigate the complex legal environment that regulates their operations. We represent public and private companies in matters related to all
aspects of FCPA compliance, including transactional due diligence, internal investigations and the
defense of governmental enforcement actions.

**Risk Management and Corporate Compliance**

One of the most effective ways to protect the enterprise is to prevent problems and liabilities before they occur. To that end, our attorneys regularly advise our biopharma clients on fraud and abuse and other regulatory issues, including risk assessments, to avoid situations that might lead to government investigations or other litigation.

We also develop compliance programs for our biopharma clients and work with them to implement and enhance such programs. As part of our work in this area, we have negotiated Corporate Integrity Agreements with the U.S. Department of Health and Human Services’ Office of Inspector General and assisted clients with fulfilling their obligations under such agreements.