Ronni E. Fuchs

Partner

Princeton

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Ronni helps pharmaceutical companies respond strategically when their products are challenged in litigation or regulatory actions. She also is experienced in advising clients on related securities disclosure policies and shareholder demands, as well as issues involving the promotion of pharmaceuticals and devices.

OVERVIEW

Ronni represents pharmaceutical and medical device companies as a litigator and as a counselor. She draws on more than 25 years of experience in product liability, consumer fraud and securities suits, government investigations, and congressional and regulatory inquiries to assess risks and defend companies.

Ronni represents clients in personal injury actions, formulating litigation and settlement strategy through assessing internal documents, interviewing fact witnesses, analyzing medical literature, and developing and presenting expert witnesses. She works extensively with in-house research and development personnel both to investigate factual allegations and to prepare witnesses for testimony. She has identified, worked with and deposed expert witnesses in myriad fields, including biostatisticians, clinical trialists, surgeons, cardiologists, neurologists, oncologists, hematologists, pharmacologists, and toxicologists. Ronni provides scientific and expert support to government investigations and securities teams, as well as to other firms in virtual law firm arrangements.

Ronni counsels clients on regulatory and compliance issues relating to clinical trials, transparency, and informed consent. She counsels companies prior to product approval as well as in response to challenges, such as adverse event reports, results from clinical trials and regulatory actions, and reviews regulatory filings.

REPRESENTATIVE MATTERS

- Defended as national and trial counsel pharmaceutical and medical device companies in products liability, consumer fraud, and class actions filed in multidistrict litigation, state court coordinated proceedings and individual cases throughout the U.S. Specific experience includes defending claims involving blood products, analgesics, cholesterol-lowering medications, opioids, antidepressants, diabetes treatments, spinal and surgical medical devices.
- Served as settlement counsel for medical device manufacturer facing significant claims relating to surgical device.
- Conducted internal investigations and risk assessments for pharmaceutical companies with regard to regulatory compliance and compliance with internal standard operating procedures.

- Counseled companies launching new products concerning regulatory, competitive and litigation risks.
- Counseled companies regarding compliance with Physician Payment Sunshine Act.
- Counseled companies regarding compliance with clinical trial regulations.
- Represented pharmaceutical companies in litigation involving adverse events in clinical trials.
- Defended medical device manufacturer in litigation involving MDR reporting and congressional and press investigations arising from same.
- Conducted early case assessment and product risk assessments for products.
- Counseled pharmaceutical and biologics companies regarding informed consent documents, including with regard to biospecimens and broad future consent.
- Counseled businesses performing corporate due diligence in mergers, acquisitions and other transactions involving pharmaceutical, medical device, or life sciences businesses.
- Counseled medical device and pharmaceutical companies concerning product labeling, instructions for use, REMS, and health care provider interactions.
- Served as science counsel to securities firm defending pharmaceutical companies in significant securities litigation, providing scientific and expert support in case hinging on alleged clinical trial misconduct.
- Represented pharmaceutical manufacturer in successful trial in New Jersey state court.
- Served as coordinating counsel for statewide coordinated discovery involving numerous firms and simultaneous discovery proceedings in 250 cases, as well as lead defense liaison to the court on discovery and case management issues.
- Served as special counsel for a leading marketer of ephedra-containing dietary supplements, defending claims of personal injury, and preparing bellwether stroke cases for trial.

AWARDS

- *Legal 500 United States* for Product Liability Litigation (2023-2025)

TOP AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Pharmaceutical + Medical Device Litigation + Counseling

ALL AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Litigation + Trial
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability

EDUCATION AND CERTIFICATIONS

EDUCATION

- University of Pennsylvania Carey Law School, J.D., *magna cum laude*, 1992, Order of the Coif
- University of Virginia, B.A., *with distinction*, 1988

BAR ADMISSIONS

- New Jersey
- Pennsylvania
- District of Columbia

COURT ADMISSIONS

- U.S. Court of Appeals, Third Circuit
- U.S. District Court, Eastern District of Pennsylvania
- U.S. District Court, District of New Jersey

SPEAKING ENGAGEMENTS

- Speaker, "Increasing Diversity in Clinical Trials: FDA Guidance and Industry Efforts," Medmarc Webinar, October 26, 2022.
- Speaker, "The Importance of Diversity in Clinical Trials: Implementing DE&I Principles Into the Development, Approval, and Commercialization of Drugs and Devices," Ninth Annual Summit on Women Leaders in Life Sciences Law, July 28, 2022.
- Speaker, "Counseling During the New Normal: Lessons Learned from Going Remote During COVID-19 ," Health, Biotech, and Pharma CLE Institute, May 18, 2021.

PUBLICATIONS

- Co-author, "Updated FDA Draft Guidance Instructs Sponsors on Content, Format, Timing, and Procedures for Submitting Diversity Action Plans for Clinical Studies," *Troutman Pepper*, July 9, 2024.
- Co-author, "FDA Draft Guidance Instructs Sponsors on Content and Timing of Diversity Plans for Clinical Trials ," *Troutman Pepper*, June 14, 2022.
- Co-author, "FDA Enforces ClinicalTrials.gov Results Posting Requirements, Including Threats of Financial Penalty," *Troutman Pepper*, January 27, 2022.