

Medmarc Risk Management Webinar Series Webinar Summary

Life Sciences Claims 2025 Navigating an Increasingly Difficult and Complex World for Life Sciences Companies

Presenters:

Ricky C. Benjamin | Partner, Head of Life Sciences Industry Practice | Burr & Forman, LLP Andy Hall | Executive Claims Specialist | Medmarc

In this on-demand webinar recorded live on December 10, 2025, Andy Hall along with guest Ricky Benjamin, explored legal and regulatory challenges in the medical device industry, with topics covering the admissibility of 510K evidence in court and its implications for preemption defenses. Discussions also covered the regulatory background of laboratory-developed tests and their classification under CMS or FDA jurisdiction, along with ongoing legal battles regarding GLP-1 drugs and acetaminophen. Andy and Ricky highlighted various legal and regulatory uncertainties in the industry, including FDA concerns and potential congressional intervention in drug classification and biosimilar development.

Full On-demand Recording

On-demand Chapters:

<u>00:00</u> - Introduction of the Presenters

03:11 - Admissibility of 510(k) evidence

12:04 - GLP-1s? Wonder drug? Litigation target? Both?

26:27 - Loper Bright—A year later

32:48 - Recent developments with LDTs

47:05 - Autism and Tylenol—still a litigation issue?

<u>54:50</u> - Closing





RICKY C. BENJAMIN, ESQ.

Partner, Head of Life Sciences Industry Practice | Burr & Forman, LLP

Ricky Benjamin leads our FDA & Life Sciences industry practice. Ricky advises companies on U.S. Food and Drug Administration (FDA) regulatory, compliance, and enforcement issues, as well as clinical trials and FDA-regulated product development programs. He also counsels clients on the safety, labeling, and reporting requirements for consumer products under the laws enforced by the U.S. Consumer Product Safety Commission (CPSC), unfair and deceptive trade practices involving the Federal Trade Commission (FTC), and related state enforcement agencies. Ricky's clients include pharmaceutical, medical device, biologic, dietary supplements, cosmetics and personal care products manufacturers, clinical laboratories, and compounding pharmacies.

Ricky has extensive litigation experience in the areas of medical malpractice defense, qui tam litigation, mass tort, product liability, and risk management counseling involving the Foreign Corrupt Practices Act (FCPA), the Federal Food, Drug, and Cosmetic Act (FDCA), and the Federal Tort Claims Act (FTCA), as well as involving the Federal Trade Commission (FTC), the Department of Justice (DOJ), the Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS).

As an FDA & Life Sciences Regulatory Industry Leader, Ricky provides comprehensive guidance on navigating the complex web of federal and state laws and regulations.

ANDY HALL, ESQ.

Executive Claims Specialist | Medmarc

Andy Hall is an Executive Claims Specialist with Medmarc. He joined Medmarc in 2017 and is responsible for claims investigation, coverage analysis, managing reserves, negotiating settlements, monitoring defense counsel activities, and maintaining good client relations. He is also a critical member of Medmarc's product development team where he assists with drafting language for our new products.

Andy began his career as an associate at Wilson Elser, where he was later named Of Counsel. He specialized in drafting coverage opinions and interpreting insurance policies.

Andy graduated from Wake Forest University with a BA in Political Science and History and attained his J.D. from the University of Pittsburgh School of Law.