



Medmarc Risk Management Webinar Series

Webinar Summary

Plan Ahead to Protect Your Innovation: Product Liability Risks for Medtech Startups

Presenter: Sean Burke | Partner, Vice Chair of Products Liability and Toxic Tort Trial Division | Duane Morris

In this on-demand webinar, recorded on March 18, 2026, Sean Burke from Duane Morris, focused on product liability risks for medical device startups. Sean discussed trends in medical device litigation, including the increase in the number of cases and larger verdicts. He explained the drivers of litigation and the three main theories of product liability: design defects, manufacturing defects, and failure to warn. He emphasized the importance of FDA compliance and the challenges of using FDA clearance as a defense in court. Sean provided recommendations for startups to mitigate litigation risks, including thorough documentation of design processes, careful consideration of warnings, and proper training of sales representatives. He also advised startups to be mindful of their relationships with key opinion leaders and to have products liability insurance in place. The webinar concluded with a discussion on the implications of AI innovation in the medical device industry and the need for startups to document their processes carefully when facing regulatory uncertainty.

[Full On-demand Recording](#)

On-demand Chapters:

- 00:00 – Introduction - About the Speaker Sean Burke**
- 05:46 – Trends in Medical Device Litigation**
- 16:12 – What Drives Litigation?**
- 18:49 – Products Liability Law 101**
- 24:19 – Use of FDA Evidence**
- 30:20 – Best Practices for Preventing Litigation and Minimizing Risk**
- 49:10 – Questions**



Presenter: Sean Burke | Partner, Vice Chair of Products Liability and Toxic Tort Trial Division | Duane Morris

Sean K. Burke is vice chair of the Products Liability and Toxic Torts division of Duane Morris' Trial Practice Group. Mr. Burke is a trial attorney representing clients nationally in complex products liability and commercial litigation matters. He has tried cases before juries in both state and federal courts.

He regularly represents manufacturers of medical implant devices and pharmaceuticals in product liability cases, including serving as lead counsel in consolidated multi-plaintiff matters in both federal court (MDL) and state courts in California, Illinois, and Tennessee—many of which involved hundreds of claimants. Mr. Burke guides clients through all aspects of MDL and state court coordinated proceedings, including management of complex pleadings, discovery issues, bellwether trials and settlement programs. Mr. Burke also has experience representing companies in defense of toxic tort and environmental litigation.

He also litigated dozens of matters across the country involving trade secret litigation, the breach of non-competition and other restrictive covenants, and commercial contract disputes. He has experience counseling clients on hiring issues. Mr. Burke served a one-year secondment, working on site for a Fortune 500 company, serving as national counsel for their business and employment related litigation.

Mr. Burke also represents and counsels clients in the gaming industry, with a focus on the horse racing industry, in a broad range of matters involving state regulatory compliance, contract negotiations, and litigation.

He is admitted to practice in the District of Columbia, Pennsylvania and New Jersey as well as six different United States District Courts. Prior to rejoining Duane Morris, Mr. Burke served as law clerk for the Honorable Joel H. Slomsky of the U.S. District Court for the Eastern District of Pennsylvania.