Michael J. Halaiko, CIPP/E

Shareholder
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Mr. Halaiko is a shareholder in Baker Donelson's Baltimore and Washington, D.C. offices and a member of the Health Law Group and Data Protection, Privacy and Cybersecurity Team.

Mr. Halaiko focuses on providing strategic guidance to life science companies, clinical research organizations, and businesses across diverse industries, particularly focusing on clinical research, life sciences, and health law. With extensive experience in AI governance and compliance, he adeptly navigates clients through the intricate landscape of artificial intelligence, privacy, and data protection issues.

As a Certified Information Privacy Professional (CIPP/E), Mike offers invaluable insights into GDPR and the EU's Clinical Trial Information System (CTIS), ensuring clients receive comprehensive counsel on international regulations. His thought leadership extends to regular publications and presentations on AI governance, with a specific emphasis on safeguarding personal data within AI models.

Acting as outside general counsel for numerous companies, Mike provides tailored advice on risk management, insurance, employment, and litigation matters. By deeply understanding each client's business dynamics and risk tolerance, he delivers pragmatic solutions aligned with their unique needs and priorities.

With a litigation background spanning decades, Mike brings invaluable experience in contract disputes, commercial litigation, and catastrophic personal injury cases. His courtroom experience, including trials and arbitrations across multiple jurisdictions, equips him with a nuanced understanding of legal language and dispute resolution strategies.

Previously, Mike chaired a prominent national law firm's Pre-Clinical and Clinical Study Practice Group, further enhancing his capabilities in the intricacies of clinical research and health law.

Whether it's guiding clients through regulatory complexities or protecting their interests in litigation, Mike's diverse skill set and industry insight make him a trusted advisor in the intersection of law, life sciences, and technology.

Representative Matters

- Developed master clinical trial agreements templates for numerous pharmaceutical companies entering the clinical study phase of research and development for trials in the U.S., E.U., APAC and Latin America.
- Served as external arm of inhouse counsel team for major pharmaceutical company handling all contracting and privacy aspects of multiple global phase III studies.
- Developed "playbooks" for pharmaceutical companies for use in negotiating and enrolling clinical trial sites. The "playbooks" provide a negotiating matrix of acceptable alternative language to most provisions of the master clinical trial agreement. The "playbooks" allow clinical research organizations (CROs), and the clients' in-house contract management staff, to negotiate with the clinical trial sites without escalation to legal on many routine contract negotiation issues.

- Negotiated numerous clinical site agreements, investigator-initiated trial agreement, letters of indemnification, nondisclosure agreements, informed consent forms, and other documents involved in all phases of clinical research and product development for U.S.-based and global clinical trials.
- Drafted master form agreements of sale, construction contracts, terms and conditions, warranty disclaimers and subcontract agreements for product manufacturers, contractors, and construction companies.
- Counseled a European-based global pharmaceutical company on the applicability of GDPR to clinical trials conducted in the U.S. with exclusively non-EU study subjects. Despite the trial occurring entirely outside the EEA, advised on the company's ongoing GDPR obligations because it is "established" in the EU. Work included guidance on GDPR's minimization requirements, the distinctions between de-identified data under U.S. law and anonymized data under GDPR, and appropriate privacy documentation to ensure regulatory compliance.
- Advised a U.S.-based pharmaceutical company conducting clinical trials in the EU regarding the appropriate data protection role allocation between the sponsor, European clinical trial sites, and CROs. Conducted a detailed analysis of GDPR's definitions regarding independent controllership versus joint controllership versus controller-processor relationships, ensuring the company appropriately structured its data protection agreements, responsibilities, and liability allocations.
- Assisted a pharmaceutical sponsor in drafting GDPR-compliant data processing agreements with clinical trial sites and CROs across Europe to enable cross-border data transfers from the EU to non-adequate jurisdictions. Work included ensuring the incorporation of standard contractual clauses and advising on supplementary measures to mitigate risks associated with data transfers to the U.S.

Professional Honors & Activities

- Listed in *The Best Lawyers in America*® in the areas of Commercial Litigation (2023 – 2025); Mass Tort Litigation/Class Actions – Defendants (2023 – 2025); Medical Malpractice Law - Defendants (2024 – 2025); Personal Injury Litigation - Defendants (2025); Product Liability Litigation – Defendants (2020 – 2025)
- Named among *The Daily Record*'s Leaders in Law: Leadership in Law (2025)
- Listed in *Maryland Super Lawyers* for Personal Injury Defense: Products (2021)
- AV® Preeminent™ Peer Review Rated by Martindale-Hubbell
- SmartCEO's Centers of Influence Award (2016)
- Listed in *Maryland Super Lawyers* as a Rising Star in Construction Litigation and Personal Injury Defense: General (2011 – 2012); Personal Injury Defense: Products (2013 – 2014)
- Member – American Bar Association
- Member – Baltimore City Bar Association
- Member – Maryland Bar Association
- Member – Sports and Fitness Industry Association, Legal Task Force
- Member – International Association of Privacy Professionals
- Gorilla Doctors
  - Board President (2018 – 2022)
  - Board Vice President (2023 – present)
  - Board Member (2023 – present)
- KIND (Kids in Need of Defense) Pro Bono Attorney (2019 – present)
- Maryland Volunteer Legal Services Pro Bono Lawyer (2003 – present)

Publications

- "OCR Issues "Dear Colleagues" Letter Regarding AI in Medicine," republished January 27, 2025, in *The American Lawyer* (January 2025)
- "Texas Court Issues Injunction on 2024 HIPAA Reproductive Privacy Rule" (December 2024)

- Co-author – "AI Use Cases in Clinical Research," *Bloomberg Law* (November 2024)
- Co-author – "Maryland: The Online Data Privacy Act of 2024 Gains Traction – What Businesses Need To Know Regarding The Proposed Legislation," *OneTrust Data Guidance* (April 2024)
- Co-author – "AI: Considering the Regulatory and Legal Implications," *Medical Device & Diagnostic Industry* (November 2023)
- Co-author – "Considerations For Compliance With CTIS Submissions Under The EU-CTR," *Life Science Leader* (May 2023)
- Co-author – "The Anatomy of a Clinical Trial Agreement," *Compliance Today* (February 2023)

Speaking Engagements

- Host – "Data Governance and Privacy Compliance," Roundtable, Sixth Annual Maryland Tech Council Technology Transformation Conference (February 2025)
- "Artificial Intelligence: A Brave New World," Mid Atlantic Society of Healthcare Risk Management AI Seminar (December 2024)
- "AI Governance and Risk Management: Legal Considerations in the Development and Deployment of Generative AI," Perrin Conferences (April 2024)

Education

- Ohio State University Moritz College of Law, J.D., 1999
- Capital University, B.A., 1996, magna cum laude

Admissions

- District of Columbia, 2000
- Maryland, 2000
- Pennsylvania, 2011
- West Virginia, 1999
- Supreme Court of the United States
- U.S. Court of Appeals for the Fourth Circuit
- U.S. District Court for the District of Columbia, the District of Maryland, the Eastern District of Pennsylvania, and the Northern and Southern Districts of West Virginia