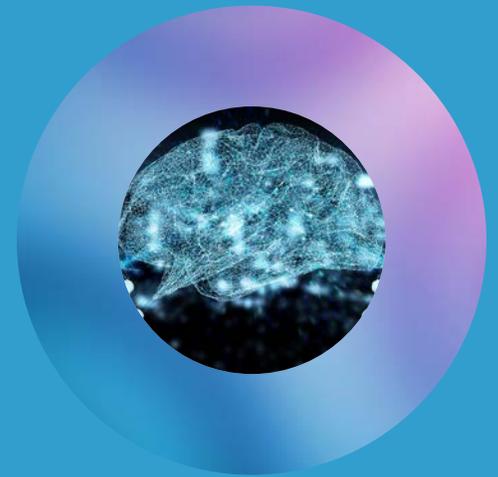


Artificial Intelligence (AI)

AI faces legal, regulatory, and business challenges.

Epstein Becker Green (EBG) and its affiliates marshal their knowledge and experience in areas such as diagnostic algorithms and machine learning-driven apps to offer informed legal and strategic advice.

We represent over 50 startups identified in the media as companies to watch in bringing AI to health care.



Who We Are

EBG (www.ebglaw.com)

is a national law firm with a primary focus on health care and life sciences; employment, labor, and workforce management; and litigation and business disputes.

EBG Advisors (www.ebgadvisors.com)

is a network of international attorneys, regulatory scientists well versed in the requirements of the U.S. Food and Drug Administration ("FDA"), experts in the quality system requirements for drugs and medical devices, engineers, computer scientists, clinicians, reimbursement experts, clinical trial experts, and other professionals who focus on providing coordinated guidance and solutions to the life science industry.

AI Developers and Users Encounter Many Challenges. We Can Address Them.

- **The regulation challenge.** Who regulates AI in health care? Is it FDA as a medical device, or state boards of medicine as part of the practice of medicine, or telemedicine regulators because AI cuts across state boundaries? We help guide you through the regulatory maze.
- **The data validation challenge.** Data validation is required to ensure that AI will do what its vendor says it will do. We guide you in identifying the appropriate tests and standards to be met to comply with the law.
- **The bias challenge.** Will racial bias be minimized when the algorithm is only as smart as the data that it ingests, and that data may be a reflection of historical bias? Currently, this is more of an ethical issue than a legal one, but it will likely become a legal issue in the future. We can help you think through governmental expectations.
- **The “black box” challenge.** AI is basically math. Machine learning produces an insight based on reviewing huge amounts of data, and the machine often can't explain the association it finds—it just identifies a connection. While we can't help you crack that technical nut, we can help you think through the regulatory and legal implications and ways to minimize legal risk.
- **The FDA approval challenge.** FDA is struggling to regulate a new technology that has mutable characteristics. In the old days, a company would walk into the agency with a medical device and say, “Based on our testing, these are the benefits and these are the risks.” But now, those risks and benefits change as the software “learns” in the hands of health care professionals and patients. FDA is trying to invent an entirely new regulatory paradigm for the approval process. But, in the meantime, companies are struggling to get products approved. We guide companies through the process and help them advocate for future improvements.
- **The coverage challenge.** Innovators are developing new diagnostics and treatments that incorporate AI. A critical issue is whether a health plan or program will cover that new technology. EBG has years of experience working with innovators and thought leaders to gather evidence and build strong cases for coverage by government and commercial plans and programs.
- **The reimbursement challenge.** We can help you think through and proactively address both phases of expected use:
 - Who will pay for AI when it is an additional cost that doesn't substitute for any current service? If the AI merely makes recommendations to a health care professional, it may improve care, but it's an additional cost. Who will pay for that higher quality? We can help you look for answers.
 - How will the reimbursement system pay for software when the software replaces the work of a health care professional? Will the reimbursement system compensate based on value, or based on average cost or marginal cost? Marginal cost is virtually zero, so we will help you advocate for value-based reimbursement.
- **The privacy and security challenge.** Will you be able to access the data you need, and what cybersecurity protections will you need to employ? EBG's industry-leading, credentialed privacy and cybersecurity attorneys will help you find the answers.
- **The liability challenge.** Here are just a few of the liability issues that we advise on:
 - When can a health care professional be liable for following, or failing to follow, a software-based recommendation?
 - When does liability shift from the doctor overseeing care to the software vendor?
 - For software vendors, what is the standard for judging negligence, design defects, manufacturing defects, or failure to warn?
- **The collaboration challenge.** AI revolves around data, and, more often than not, technology developers do not have all of the data they need and are compelled to partner with the health care providers that do. Such collaboration is difficult when the technology company is a vendor to the health care providers. We help come up with solutions compliant with anti-kickback laws and regulations.