GOVERNMENT STRATEGY

Artificial Intelligence

EPSTEIN BECKER GREEN

Public policy for artificial intelligence ("AI") and other innovations in health care stands at a crossroads. Investors and developers look for guidance from regulators, but policy makers in Congress and the regulatory agencies struggle to keep up with innovation that regularly outpaces law. As a counterweight, populist momentum against "Big Tech" is on the rise among politicians, raising personal data privacy concerns to the forefront and creating a public affairs risk to health care innovators.

Our Professional Qualifications

The team at Epstein Becker Green ("EBG") has expansive knowledge of federal policy making, developed through decades of legal practice before regulatory agencies. In addition, our advocacy on AI-related issues is informed by the extensive prior professional experience of our team in various federal political, policy, and legal positions, including team members who served as:

- Staff of the U.S. Senate Committee on Health, Education, Labor & Pensions
- Compliance Advisor to political action committees ("PACs"), as well as a manager of federal and state reporting requirements for House, Senate, and state candidates
- Counselor to the Secretary of Health and Human Services ("HHS"), and Associate Director (Health) at the White House
- Professional staff of the Centers for Medicare & Medicaid Services ("CMS") Office of Legislation
- Staff of the HHS Office of Global Affairs, Division for Trade and Health
- Senior Advisor for Security and Privacy at CMS
- Privacy Advisor in the following agencies: U.S. Department of Energy, Federal Deposit Insurance Corporation, and National Nuclear Security Administration
- CMS officials

How We Can Help

At EBG, we assist clients in navigating the complex and ever-changing legislative and regulatory landscape for all issues impacting the various sectors of the health care system, including AI. Because our team is composed primarily of attorneys with industry subject-matter experience, many with prior government experience, we are able to provide clients with effective strategies for dealing with national policy makers. By integrating client objectives with our health regulatory experience and knowledge of "real world" policy making, EBG develops and implements government strategies built to go beyond merely "providing access" to creating client solutions. More specifically, we provide the following services:

Public Policy Analysis and Risk Assessment

EBG provides tracking, in-depth research, analysis, and risk assessment of emerging legislation, regulation, and guidance relevant to AI, technology, and other industries. The scope of our tracking and analysis includes institutions that "influence the influencers," namely the think tanks, advisory panels, industry collaboratives, and non-governmental organizations whose work is produced for Congressional and regulatory decision-makers. Our team offers critical analysis to determine areas of potential risk, as well as future opportunities. This leads to the development of customized strategies to address federal policy concerns through the appropriate legislative or administrative avenues.

Regulatory Advocacy

EBG understands that while Congress and legislative lobbying may grab the headlines, clients are, in fact, affected by actions made every day at federal regulatory agencies. Successful regulatory advocacy occurs when agencies are presented with proposals that address the needs of both the client and the regulatory agency. EBG prepares AI and technology clients to effectively inform agencies with advocacy plans that address all of the considerations driving regulatory decision-makers: policy, legal, scientific, operational, budgetary, and political. We are experienced in forming "pop-up coalitions" that assist diverse stakeholders to present a comprehensive unified, influential front to policy makers.

Legislative Advocacy

EBG, along with its network of affiliated lobbyists, can (i) connect AI and technology clients with key decision-makers in Congress, including the relevant committees of jurisdiction, on any particular issue, and (ii) provide insight into individual offices and committees. We help clients effectively explain complex legal, scientific, and business issues to Congressional staff who have limited background or time due to expansive portfolios of responsibility. Our affiliated lobbyists help us guide clients through (i) "relationship mapping" to identify what levers of influence with Congressional offices a client company may unknowingly possess, and (ii) strategic giving to PACs. As the actual passage of legislative vehicles becomes rarer, our affiliated lobbyists nevertheless continue to advance client objectives by informing and influencing Congress's oversight of federal regulatory agencies.

Representative Experience

- Advised clients in communications with numerous Congressional offices to effect the drafting of key provisions of the 21st Century Cures Act that direct the Food and Drug Administration ("FDA") to develop standards and guidelines for various emerging health care technologies, and then represented clients before the FDA during the development and release of those guidelines
- Guided payors and their technology vendors in educating Congress, CMS, and the HHS Office of the Secretary on needed modifications to federal regulatory interpretations that block access to cost-saving, health-improving innovations, such as health care copay incentivization algorithms, in-home health risk assessments, and advanced telemedicine
- Guided various developers of medical devices, drugs, and other innovative services and supplies on the process at CMS to obtain the coding, coverage, and reimbursement necessary for commercialization
- Drafted comment letters for official notice-and-comment rulemaking, drafted Congressional testimony for clients who have been called to testify to Congress, and drafted legislative proposals for clients seeking to impact legislation