FOLEY HOAG LLP

Driving Business Advantage

Life Sciences Government Strategies

Biotechnology, Pharmaceuticals, and Medical Devices

Legislative and regulatory matters are critically important for life sciences companies. The lawyers and policy specialists in Foley Hoag's Government Strategies Practice have extensive experience in the development and implementation of legislation and regulations affecting the biotechnology, pharmaceutical, medical device, and healthcare provider industries. The regulatory environment can pose significant burdens to life sciences companies, but intelligent strategic advocacy on Capitol Hill and appropriate engagement of federal regulatory agencies can also provide new markets and opportunities for innovative products. Our team works directly with Congressional staff and federal agencies, including the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS), on a variety of matters relating to the life sciences.

Legislative

The Government Strategies Practice provides a comprehensive approach to legislative advice and advocacy. Our team has led legislative campaigns. On behalf of our individual and corporate clients, we formulate strategic initiatives, draft legislation, analyze legislative proposals, advise Members of Congress and their staffs, prepare Congressional testimony, and counsel clients for hearings. While serving as Congressional staff members, our lawyers and specialists helped craft key legislation, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA); the Deficit Reduction Act of 2006; the FDA Modernization Act of 1997; revisions to the Orphan Drug Act; the Biodefense and Pandemic Vaccine and Drug Development Act of 2005; and the Health Insurance Portability and Accountability Act of 1996. Drawing on our experience, our growing team has been engaged in every major piece of legislation affecting the pharmaceutical, medical device, and biotech industries over the past several years.

Most recently, Government Strategies lawyers:

- Crafted and negotiated major legislative proposals for the FDA Amendments Act of 2007 that reauthorized user fees and extended new authorities to the FDA
- Provided biopharmaceutical clients regulatory relief for a cutting-edge cancer therapy with language in the Medicare Extension Act of 2007
- Counseled and assisted the development of follow-on biologics legislative proposals
- Represented leading pharmaceutical and biotech companies in the successful enactment of the MMA and have continued representation for all follow-up legislation seeking to amend this Act

Coverage and Reimbursement

Medicare and Medicaid finance nearly one-half of the nation's health expenditures, and Medicare policy decisions have great impact on private sector medical coverage and reimbursement. Medicare reimbursement issues span the full range of healthcare, including biotechnology and pharmaceutical products, medical devices, and hospital and physician procedures. Obtaining coverage and reimbursement in the Medicare system is crucial to patient access to new services. However, health care companies must navigate a myriad of complex and shifting coverage, reimbursement, coding, and billing policies.

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Our team has extensive experience obtaining appropriate coverage and payment for a wide range of health care products and services. Foley Hoag's Government Strategies lawyers and specialists regularly represent clients before CMS and have helped shape the outcomes of administrative processes for federal policies and programs.

Foley Hoag has developed deep expertise in securing appropriate payment from public and private payers for new innovative products and therapies that might otherwise receive inadequate payment. Frequently, our strategy involves both convincing legal arguments and a rich understanding of the clinical evidence key to the product's successful presentation. Government Strategies lawyers in our coverage and reimbursement group have:

- Developed persuasive legal arguments and assembled compelling scientific evidence that secured a critical policy decision affecting the coding and payment of one of the leading biotechnology products used for Medicare beneficiaries
- Helped CMS create one of the first data registries in its Coverage with Evidence Development program, by advising a coalition of leading academic medical centers and medical device manufacturers
- Represented a leading cancer center in obtaining a DRG reclassification for hospital inpatient reimbursement for anti-cancer therapy for renal cell carcinoma and melanoma

Food and Drug

The Government Strategies Practice provides regulatory and legislative advice to leading biotechnology, pharmaceutical, medical device, and health care companies regulated by the FDA. Foley Hoag lawyers have played key roles in the enactment of landmark laws and the implementation of critical regulations and policies affecting product development schedules, regulatory compliance, and timely product approvals. We work with senior agency managers, congressional staff, and Members of Congress to shape agency interpretations, clarify regulatory guidance, challenge adverse decisions, and enact legislation. Our clients rely on us for strategic, business-focused solutions as well as for providing technical guidance and counseling on virtually all facets of regulatory compliance.

Government Strategies lawyers in our Food and Drug Group have:

- Engaged the FDA and Congress on behalf of a national coalition of innovative medical technology companies regarding the appropriate regulation of breakthrough genetic and molecular diagnostic tests
- On behalf of a medical technology company, devised a strategy to persuade an FDA review division to accept the company's proposed development plan, after the company had reached an impasse with the review division over its data requirements
- Represented a company regarding a combination of product issues with respect to a medicinal product used in conjunction with a medical device subject to the Medical Devices Directive

Bioterrorism and Pandemic Preparedness

The Government Strategies practice has played a leading role since 2001 in the development and enactment of bioterrorism and biosecurity preparedness legislation. In 2006 our team helped steer through passage the Pandemic and All-Hazards Preparedness Act (PAHPA), which created the Biomedical Advanced Research and Development Authority (BARDA). BARDA revitalized the federal government's efforts to support and fund the development of medical countermeasures critical to protecting the nation and has generated enormous opportunities for early-stage life sciences companies. BARDA will inject more than $1 billion into the research, development, and procurement of vaccines, antivirals, and diagnostics and will enable vital new forms of coordination between the government and life sciences innovators. Foley Hoag lawyers and specialists assist life sciences innovators to navigate the complex process of obtaining and managing high-value BARDA contracts.

Lawyers in Foley Hoag's Biosecurity Group have:

- Negotiated passage of the Pandemic and All-Hazards Preparedness Act and the Biodefense and Pandemic Vaccine and Drug Development Act
- Provided strategic counsel to a coalition of leading venture capitalists in support of Congress' passage of the All-Hazards Preparedness Act, creating BARDA
- Advised an innovative early-stage company on obtaining a $102 million contract with the U.S. Department of Health and Human Services, to develop an influenza neuraminidase inhibitor for the treatment of pandemic influenza