Life Sciences Policy and Regulatory

Life sciences and healthcare businesses today face a wide variety of policy and regulatory challenges in a sector under intense scrutiny from federal and state elected officials, regulators, insurance companies, the public, and an aggressive plaintiffs' bar.

DLA Piper can help. Our Life Sciences Policy and Regulatory lawyers and policy advisors are industry leaders with in-depth experience in public policy and advocacy; market access, pricing, and reimbursement issues; interactions with regulators regarding product safety, marketing, Good Manufacturing Practices, and Good Clinical Practices; government investigations and enforcement actions; internal investigations and other compliance advice; and digital health and artificial intelligence. We combine subject matter experience with deep knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our healthcare, pharmaceutical, biologics, medical device, research, and diagnostics clients.

SERVICIOS RELACIONADOS

- Regulatory and Government Affairs
- Biotecnología
- Healthcare
- Digital Health

Many of our lawyers and policy advisors are former sector professionals who have PhDs, medical degrees, or other advanced degrees in the healthcare and life sciences fields, and some are economists and former government officials or prosecutors.

Life Sciences Policy and Advocacy

The members of DLA Piper's Life Sciences Policy and Regulatory team possess deep experience in a wide range of policy matters and legislative issues of critical importance to life science, pharma, medical device, and biotech companies, associations and other organizations.

We provide strategic counseling and advocacy for pharmaceutical, medical device, and biologics companies in a wide range of matters. Our lawyers, policy advisors, and consultants know how government works because most have held senior elected, appointed, and staff positions in one or more branches of government. The group has extensive experience representing businesses before federal agencies, Congress, and the White House. The team leverages their experience and broad relationships with key policymakers in Congress and the Administration to help businesses obtain successful outcomes on key policy initiatives.

The team is co-led by Jim Greenwood, former president of the Biotechnology Innovation Organization (BIO) trade association and a former member of Congress, having served for 12 years on the House Energy and Commerce Committee's Health subcommittee.

Regulatory

DLA Piper's regulatory practice provides strategic counseling and advocacy for our pharmaceutical, medical device, dietary supplement, biologics, and diagnostics and clinical laboratory clients in a wide range of matters ranging from clinical development and marketing authorization strategies to post-marketing compliance. We counsel on administrative and judicial enforcement actions and other proceedings involving the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), Federal Trade

Commission (FTC), Drug Enforcement Administration (DEA), US Department of Justice (DOJ), and other US federal and state agencies, as well as counterpart regulators in major markets around the world.

Our attorneys and policy advisors combine an understanding of agency practice, science, policy, and bioethics with practical strategies to meet business objectives and mitigate risk in an increasingly complex regulatory and enforcement environment.

The team is co-led by Geoff Levitt, who previously served as head of international affairs and policy for Viatris Inc., as senior vice president and chief counsel for Pfizer Inc.'s Upjohn division in China, and as chief regulatory counsel for Pfizer Inc. and Wyeth Pharmaceuticals.

Internal investigations and enforcement

Life sciences businesses in the United States and throughout the world operate in an aggressive enforcement environment. Government prosecutors and regulators are particularly active in the life sciences sector. Even in the absence of a government investigation, prompt and appropriate internal investigation of alleged or suspected misconduct is an essential component of an effective compliance program. Deep experience in white-collar matters and investigations, local knowledge of the enforcement environment in jurisdictions around the world. and the ability to deliver practical solutions to white-collar problems are critical to a company's response to such challenges – and hallmarks of DLA Piper's White Collar and Investigations practice.

Our White Collar and Investigations team is experienced and well respected. Many of our lawyers have served as federal or state prosecutors or in other government positions; our team includes two former US attorneys, numerous former assistant US attorneys and other top-level Department of Justice prosecutors and US Securities and Exchange Enforcement Division lawyers, as well as government counsel from many other state and federal agencies. The team's knowledge of the legal landscape and of the public officials responsible for shaping it enables us to provide reliable insight and advice on all aspects of a company's criminal and regulatory risk, from compliance issues to internal investigations to dealing with the regulators and prosecutors on bet-the-company litigation matters.

Market access, pricing and reimbursement

Along with the rising cost of getting products to market, pressure from healthcare payers is also intensifying, with increased market access challenges, mandatory price cuts, and broader use of reference and value-based pricing models. We advise on regulatory requirements and contracting opportunities relating to value-based healthcare models and reimbursement. We also advise on compliance regarding matters involving regulatory, reimbursement, fraud, and abuse.

Digital health

For businesses aiming to tackle cutting-edge issues in artificial intelligence, telehealth and telemedicine, digital therapeutics, apps and wearable technology, health IT, big data, cybersecurity, and privacy, our healthcare lawyers bring comprehensive experience and thought leadership. We collaborate as a multi-disciplinary team, considering obstacles and opportunities in concert with our healthcare regulatory, cybersecurity, litigation, corporate, and intellectual property attorneys and policy advisors.

Our experience spans providers, payors, tech companies, and ancillary services vendors and includes multinational companies expanding throughout the globe.

NOVEDADES

Publicaciones

The crossroad of science and law

16 December 2021

AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Lucas Przymusinski and Raymond Williams are joined by Michael King, Vice President and Associate General Counsel at Jazz Pharmaceuticals, to discuss the benefits of medical and science backgrounds when litigating matters for pharmaceutical and medical device companies.

NOTICIAS

DLA Piper announces new practice leadership

18 February 2022

DLA Piper is pleased to announce several changes to sub-practice leadership in its Finance, Corporate, Private Equity, Regulatory and Government Affairs, and Litigation practices.

DLA Piper joins with Duke, Mayo Clinic, UC Berkeley to launch innovative AI collaboration

21 December 2021

DLA Piper has joined with the Duke Institute for Health Innovation, the Mayo Clinic and UC Berkeley, among others, to launch an innovative collaboration designed to build an understanding of the AI software market and allow for its safe and responsible deployment, including of machine learning algorithms.

Geoffrey Levitt joins DLA Piper's Litigation and Regulatory practice as co-chair of Life Sciences Policy and Regulatory group

22 March 2021

DLA Piper announced today that Geoffrey Levitt has joined the firm's Litigation and Regulatory practice as co-chair of the Life Sciences Policy and Regulatory group.
