SpencerFane®

Life Sciences

Supporting innovation from lab bench to bedside.

Our national Life Sciences team advises companies, investors, manufacturers, and scientific leaders across the ecosystem and a range of industries. We guide products and technologies through development, commercialization, and protection, drawing on multidisciplinary strengths – including regulatory, IP, transactional, and AI / ML – across every stage of the product life cycle.

Overview

Propelling safe and effective product development for real-world advancements

With dedicated attorneys across all major sector hubs in the U.S., our national Life Sciences legal practice works with life science companies and their scientific and medical teams from startup to commercial maturity – as well as investors, banks, and others in the life sciences ecosystem. Our dynamic, multidisciplinary approach allows us to address the unique challenges life science innovators and follow-on companies face in securing funding, licensing, safeguarding intellectual property, establishing partnerships, bringing new products to market, opening new revenue streams, protecting existing product lines, and defending products and investments in investigations, disputes, or litigation.

We understand the complexities of delivering patient-centric products throughout their life cycle, drawing on deep knowledge and experience across technology, including Artificial Intelligence (AI) / Machine Learning (ML) and cybersecurity; antitrust, including CREATES Act, product-hopping, evergreening, and settlement scrutiny; health care; real estate; private equity; financial services; venture capital; labor and employment; and other related services.

We provide strategic guidance on market entry and exit strategies, international IP, and the navigation of multifaceted cross-border transactions and disputes. We also create the legal and commercial infrastructure needed to monetize and commercialize life sciences discoveries and technologies. This includes support for FDA-regulated products involving New Chemical Entity (NCE) and New Clinical Data exclusivities, Pediatric Exclusivity, Patent Term Extensions (PTE), Orange Book (human drugs) and Purple Book (human biologics) listings, and use code or skinny-label strategies.

We protect IP at every phase and defend products and investments when challenges arise from regulatory agencies, investigations, disputes, or litigation, including FDA exclusivity and listing matters; Citizen Petitions or Administrative Procedure Act (APA) challenges / defense tied to approvals, labeling, or exclusivity; and antitrust interfaces such as product hopping or settlement.

Our team comprises experienced former government regulators and in-house general counsels, seasoned corporate attorneys, and accomplished negotiators with decades of experience supporting clients in industries impacted by today's complex and rapidly evolving global environment.

Our clients operate in a wide variety of shared federal and state-regulated life sciences sectors, including:

- Animal medical and food products (feed and animals as food)

- Biologics (human), including cell, tissue, and gene therapies
- Botanicals
- Complementary and alternative medicine products including cannabis, psychedelics, and kratom
- Cosmetics
- Dietary supplements
- Drugs (human)
- Foods, including medical foods
- Medical devices, including wellness products and devices with AI / ML components
- Tobacco products, including electronic nicotine delivery systems (ENDS)

No matter the size of your company or the nature of your international legal needs, Spencer Fane is equipped with the knowledge, resources, and global network to support you at every stage.

As a member of the TAGLaw network of law firms, we have attorneys who maintain personal relationships with excellent firms and local attorneys in virtually every industrialized country in the world, providing trusted access to global resources and localized insights.

Areas of Focus

Comprehensive Regulatory Counseling and Dispute Resolution Experience

End-to-end regulatory strategy for complex products and high-impact decisions. Our regulatory advice and strategic counseling spans the product life cycle, including preclinical and clinical product development, adaptive and AI / ML-supported evidence generation, product approval or labeling reviews (including advertising and promotion considerations), and post-marketing regulatory, distribution (including pharmacy and specialized distribution), and risk management and competition issues.

We are routinely requested to develop comprehensive strategies or responses to Complete Response Letters (CRLs) – including considerations related to public disclosures – or Information Requests, as well as guide informal and formal dispute resolution efforts, including ombudsman interventions.

We are trusted partners with our clients, advising on their business and legal objectives and delivering tailored solutions and innovative, value-driven strategies across related practices and regions. Our team of life sciences attorneys handles complex transactional, regulatory, and litigation matters, providing industry insight, while remaining targeted and nimble for each project and business objective.

Enforcement and Litigation

Practical strategies to manage regulatory risk, scrutiny, and enforcement. Our team draws on significant government and industry experience to counsel clients on effective strategies to identify and mitigate regulatory and legal risks. We aim to identify practical and achievable ways to assess and sustain compliance both in and out of the courtroom.

Our attorneys regularly assist clients facing regulatory scrutiny related to GxP, including GMP (manufacturing), GCP (clinical trials), and GLP (laboratory testing). We work with clients to develop comprehensive responses to inspectional observations, FDA Form 483s, Untitled Letters, Warning Letters, and Import Alerts, and to conduct pre-inspection audits,

remediations, and inspection preparedness efforts.

As needed, we advise on product quality issues and conduct internal investigations and remediations based on customer complaints, including field and product audits, and assist with communications with regulators.

Our team includes leaders in product liability to help proactively reduce legal exposure and develop coordinated approaches for addressing potential concerns from multiple health authorities.

Our Cybersecurity and Artificial Intelligence team helps align regulatory strategies with IT safeguards and measures that ensure data integrity.

To prepare for following product approvals and launches, we review advertising and promotion materials based on FDA regulatory and industry benchmarking, enforcement trends, and risk analyses. Then, following launch, we continue risk monitoring and pharmacovigilance efforts, including recommending labeling changes or corrective measures and coordinating with health authorities on recalls, market withdrawals, and safety alerts.

Throughout the product life cycle, we support clients in internal reviews of sensitive matters related to regulatory compliance — including issues raised through hotline and internal reporting systems. This positions us to defend clients in government investigations and qui tam litigation alleging violations of the Federal Food, Drug and Cosmetic Act (FD&C) and other federal and state statutes.

We also defend clients in civil and criminal investigations by the U.S. Department of Justice for alleged violations of the FD&C Act, Title 18, and related statutes, including actions involving injunctions, product seizures, and consent decrees.

FDA Regulatory Compliance and Litigation

Where FDA regulation meets real-world business risk. We advise companies at the points where FDA regulation acutely intersects with business risk, enforcement exposure, and product strategy, including matters that involve litigation or strategy.

Our team has worked with all FDA-regulated product types and technologies, spanning biologics, drugs, and devices, as well as advised on a wide variety of FDA regulatory issues. We have provided compliance and enforcement support for all aspects of the product life cycle. Because our team has worked for both innovator and generic / biosimilar companies (or sponsors), medical devices, and combination products, we have a keen understanding of product life cycle considerations as they relate to our clients' needs and the FDA's priorities, enabling us to guide companies successfully through the constantly changing regulatory and enforcement landscape.

Our work also includes advising in contexts where Hatch-Waxman, the Biologics Price Competition and Innovation Act (BPCIA), Preliminary Injunction (PI) / Temporary Restraining Order (TRO) issues, or at-risk launch considerations may arise, and we offer dedicated Hatch-Waxman / Abbreviated New Drug Application (ANDA) and BPCIA support to help clients navigate the statutory and regulatory pathways for both small molecule and biologic products.