Life Sciences

Skadden

Skadden provides comprehensive legal services to life sciences clients, guiding them through their most complex corporate, regulatory and litigation opportunities and challenges. Our multidisciplinary team advises on:

- High-stakes M&A, licensing and collaboration agreements
- Intellectual property acquisition and enforcement
- FDA regulatory compliance and enforcement defense
- Tax planning and transaction structuring
- Government and internal investigations
- Compliance program development
- Dispute resolution
- AI considerations

Drawing on deep industry knowledge and a collaborative approach, we help pharmaceutical, biotechnology, medical device and other FDA-regulated companies — and their investors — navigate the evolving legal landscape, realize scientific innovations and achieve their business objectives.

Integrated Cross-Disciplinary Experience

We offer life sciences clients the advantage of an integrated, cross-practice team. Legal challenges in this sector often span multiple areas, including corporate transactions, IP, regulatory compliance, tax and litigation. Bringing together attorneys with deep experience in each of these fields enables us to deliver holistic advice that addresses both legal and business needs, anticipate and resolve issues at the intersection of different legal disciplines and provide seamless support throughout a matter's lifecycle.

Tailored, Industry-Specific Solutions

Life sciences companies operate in a highly regulated, rapidly evolving environment. Our team — including attorneys with scientific backgrounds, and governmental and in-house industry experience — understands these unique challenges and delivers practical, tailored solutions to address them. Whether structuring a complex merger, navigating FDA regulations, managing IP portfolios, responding to government investigations or addressing AI implications, our advice is both legally sound and commercially relevant.

Efficient and Strategic Problem-Solving

Our integrated team approach allows us to quickly assemble the right mix of skills for each client's situation, streamlining communication, reducing duplication of effort and efficiently resolving urgent and multifaceted issues. This coordinated strategy considers legal, regulatory and business implications, helping clients mitigate risks, capitalize on opportunities and achieve their objectives in a competitive marketplace.

Proven Track Record and Recognition

Skadden's multidisciplinary, cross-office approach underpins our strong record of success and industry recognition. Our clients, including many leading life sciences companies, can be confident they are supported by a team with the experience, resources and reputation to handle their most high-profile transactions, regulatory matters, investigations and disputes. We have represented more than two-thirds of *Pharmaceutical Executive*'s Pharma 50 in corporate matters and more than half in regulatory matters.

Accolades

- Consistently ranked as a leading firm for Life Sciences by *The Legal 500 U.S.*
- Recognized among the top firms for FDA Law by *Best Lawyers* Best Law Firms.
- Named M&A Firm of the Year and the recipient of two Impact Deal of the Year awards by *LMG Life Sciences*.
- Received the U.S. Firm of the Year — IP Transactions award from *Managing IP*.

Comprehensive Services Across Key Areas

Transactions

Our extensive experience advising on life sciences transactions includes:

- Representing companies and special committees in mergers, acquisitions and divestitures, including spin-offs, bolt-on acquisitions, carveouts and licensing and collaboration agreements.
- Structuring product and technology licenses and royalty interest sales and securitizations, including synthetic royalty transactions.
- Advising boards of directors on takeover preparedness and shareholder activism.
- Handling financing and capital markets transactions.
- Representing investors and lenders focused on M&A and financings in the sector.
- Providing innovative solutions in distressed situations, such as asset liability management (including for private equity portfolio companies) and both in-court and out-of-court restructurings.

> Our sector-savvy team possesses in-depth knowledge of the nuances specific to life sciences transactions and works to ensure each deal is executed successfully.

Intellectual Property

Our intellectual property attorneys, including those who hold degrees in relevant life sciences disciplines and have served as in-house counsel for life sciences companies, handle:

- "Deep dive" IP diligence for acquisitions, joint ventures, divestitures, financings and investments.
- Representations before the U.S. Patent and Trademark Office and Patent Trial and Appeal Board.
- IP enforcement and disputes in litigation and arbitration involving pharmaceuticals, biologics, medical devices and other life sciences technologies.

Regulatory

We advise life sciences clients on their most complex regulatory issues across multiple disciplines, including FDA regulatory counseling and enforcement defense, and compliance program design and implementation.

Our comprehensive FDA regulatory experience spans all product areas regulated by the agency, from prescription and OTC drugs to medical devices — including laboratory-developed tests, combination products, digital health products, cosmetics, dietary supplements and food.

We have extensive experience navigating complex life sciences regulatory issues in connection with mergers, acquisitions, financings and investments. Our team adeptly:

- Analyzes and advises on requirements triggered by transactions.
- Assesses and procures required permits and licenses.
- Performs "deep dive" regulatory diligence and addresses identified issues.

Beyond transactions, our regulatory team regularly counsels FDA-regulated companies in managing enterprise-critical situations, such as:

- Regulatory inspections.
- Warning letters and consent decrees.
- Product recalls.
- All manner of regulatory and commercial disputes.

> Skadden approaches regulatory issues from a commercial point of view, delivering practical advice that aligns with our clients' business goals.

Tax

Skadden's renowned tax practice addresses the full spectrum of life sciences companies' tax needs, helping maximize tax efficiency and mitigate risks at every stage of growth. We provide:

- Strategic tax advice and sophisticated corporate tax planning.
- Supply chain advisory services to manage cross-border complexities.
- Guidance on transactional tax matters, including collaboration and licensing deals, equity investments, buyouts, IPOs and a wide range of financing transactions.
- A robust tax controversy practice, representing clients in IRS audits, administrative proceedings and complex tax litigation.

Investigations, Enforcement and FCA Actions

Skadden frequently advises life sciences clients on high-stakes internal and government investigations, enforcement actions, litigation and other high-profile disputes. Our lawyers' knowledge across these areas allows us to help clients anticipate complexities and develop well-rounded strategies to address their most pressing issues.

> We offer varied perspectives, deep experience and outside-the-box thinking — helping clients proactively address both deals and compliance gaps to avoid investigations and enforcement actions.

Government and Internal Investigations

We handle investigations by various federal and state law enforcement agencies, including U.S. attorneys' offices, the Criminal and Civil Divisions of the Department of Justice (DOJ) and state attorneys general. Skadden has successfully advised numerous life sciences companies, their boards and laboratories in:

- Criminal, civil and internal investigations arising under the Federal Food, Drug and Cosmetic Act (FDCA) and health care fraud and abuse laws, such as the Anti-Kickback Statute.
- Complex multidistrict and multiagency government investigations, such as parallel investigations by federal and state entities.
- Numerous matters involving voluntary disclosures to the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG), DOJ and other federal agencies.
- Foreign Corrupt Practices Act (FCPA) investigations by the DOJ and Securities and Exchange Commission (SEC).
- Judicial challenges to agency decision-making.

False Claims Act

We represent companies, boards, management and individuals in all aspects of False Claims Act (FCA) matters, including:

- FCA cases pursued by federal and state governments and *qui tam* relators.
- Internal investigations.
- Defense of government investigations, enforcement actions and criminal and civil proceedings.
- Implementation of remedial measures and compliance programs.

We have handled numerous FCA matters in the life sciences industry arising from investigations by U.S. attorneys, inspectors general and state attorneys general, often in response to whistleblower reports or lawsuits, as well as from audits by the General Services Administration (GSA), Defense Contract Audit Agency and Defense Contract Management Agency.

Additional Litigation

Our attorneys, including many with senior government experience, provide comprehensive litigation and dispute resolution services. In addition to FCA litigation, we represent life sciences clients in:

- Deal litigation and corporate control disputes, including representation in contested mergers and acquisitions, shareholder activism matters, proxy contests and related litigation involving change-of-control transactions and governance challenges.
- Product liability and mass tort defense, with extensive experience on behalf of FDA-regulated companies.
- Commercial, IP and licensing disputes in litigation and arbitration (U.S. and international), including commercial disputes involving collaborations among large and small life sciences companies and contract manufacturing organizations, and substantial corporate and commercial transactions.

- Antitrust matters.
- Securities litigation, including the successful defense of numerous federal and state class actions against pharmaceutical, biotechnology and medical device clients.

Our experience spans many state and federal individual and class action cases, as well as multidistrict litigation proceedings.

> Skadden's litigators stand out for their exceptional ability to navigate intricate disputes and consistently achieve outstanding results.

Artificial Intelligence

AI is quickly altering the life sciences industry, introducing both innovation and new legal challenges. Key areas implicating regulatory compliance, IP, data protection and ethical considerations include:

- Drug discovery and development.
- Clinical trial recruitment and management.
- Use and disclosure of clinical and genomic data.

Our global AI attorneys offer years of experience with complex AI legal matters, helping clients understand the key technology issues, business drivers and evolving global regulatory landscape surrounding this cutting-edge technology.