Life Sciences and Health Care

Skadden

Skadden attorneys partner with life sciences and health care clients to address the most complex issues in transactional, litigation and enforcement, regulatory, finance, international arbitration, and intellectual property matters and to anticipate future issues that may arise throughout the industry. Companies and investors around the globe in every sector of the industry — including pharmaceutical, biotechnology and medical device companies; food and dietary supplement companies; hospital and health care systems and service providers; and long-term care facilities — rely on our sector-specific insights, timely and relevant legal advice, and all-encompassing collaboration to help them carve pathways through a quickly evolving landscape and to help realize scientific innovations.

- We offer a full spectrum of transactional services to life sciences and health care companies, including advising on M&A, financings, corporate restructurings, and complex licensing and collaboration transactions. We handle critical matters of all sizes, from the largest mergers in the industry to transformative deals for smaller companies.
- We provide compliance counseling on a range of intricate regulatory issues and help resolve disputes with the government or other parties before they blossom into more serious matters. Our attorneys have extensive experience with the Federal Food, Drug, and Cosmetic Act; the Public Health Service Act; the Civil Monetary Penalties Act; the Stark Law; the Anti-Kickback Statute; the Foreign Corrupt Practices Act; the Controlled Substances Act; and the False Claims Act.
- We provide a comprehensive array of litigation and dispute resolution services, including representing clients in product liability defense; commercial, intellectual property and licensing disputes in litigation and arbitration (both domestic and international); internal investigations and government investigations and enforcement (civil and criminal); antitrust matters; and securities litigation.

The Skadden team was awarded the 2021 Healthcare, Pharma & Biotech Deal of the Year (Large Cap) by *The Deal*. In 2020, Skadden was named M&A Firm of the Year and received the award for Impact Deal of the Year by *LMG Life Sciences*, and in *LMG Life Sciences*' 2019 rankings, Skadden was cited as a leading firm for both M&A and Products Liability within the life sciences industry. We were also recognized among the top firms for Health Care Law by *U.S. News — Best Lawyers* Best Law Firms 2020 and have been ranked as a leading firm for Healthcare in *Chambers USA* and for Life Sciences by *The Legal 500 U.S.*

Life Sciences

Our clients have included one-half of the top 40 global pharmaceutical companies and one-quarter of the top 40 global medical device companies (by market capitalization), as well as numerous emerging biotechnology firms, across all aspects of their businesses, counseling on transactions, litigation and enforcement, international arbitration, regulation, intellectual property, tax, antitrust, finance and other matters. advises life sciences and health care clients worldwide on the full spectrum of corporate matters.

FDA

Skadden advises on the full spectrum of FDA regulatory and compliance issues, including those arising in the context of clinical development, manufacturing, advertising and promotion, medical affairs and drug safety. We counsel FDA-regulated companies in managing product recalls and other enterprise-critical situations. Our experience addresses all FDA-regulated articles — including pharmaceuticals, biologicals/vaccines, medical devices, foods, dietary supplements and tobacco. Skadden assists clients with FDA's premarket pathways and submissions, including Orphan designation, and has helped numerous technology companies navigate the FDA's Wellness and SaMD polices as applied to medical devices. We help clients pressure test and comply with their Good Manufacturing Practices (GMP), Quality System Regulation (QSR), and Hazard Analysis and Risk-Based Preventive Controls (HARPC) obligations, and are experienced with post-market safety reporting requirements, combination products and FDA labeling requirements. We also represent clients in offensive and defensive litigation against the FDA, handle responses to FDA 483s

and warning letters, and work closely with clients' quality assurance teams and technical consultants to remediate FDA compliance issues.

Intellectual Property

Our IP attorneys, many of whom have relevant scientific training and in-house experience in life sciences companies, perform "deep-dive" intellectual property diligence relating to acquisitions, joint ventures, divestitures, financings and investments, and effect transactions in the pharma, biotech and related life sciences areas. We help structure clinical studies, product and technology licenses, and royalty interest sales and securitizations. Lawyers on our team are registered to practice before the U.S. Patent and Trademark Office, are experienced in handling matters before the Patent Trial and Appeal Board, and regularly handle IP enforcement and disputes in litigation and arbitration involving pharmaceuticals, biologics, medical devices and other technologies employed in the life sciences arena.

Litigation

We handle investigations by a range of law enforcement agencies, including U.S. attorney's offices, the Criminal and Civil Divisions of the DOJ, and state attorneys general. Specifically, we have defended numerous global pharmaceutical and medical device companies in government investigations into alleged violations under the Federal Food, Drug and Cosmetic Act; the Anti-Kickback Statute; and state and federal False Claims Acts. We have experience handling complex multiagency government investigations, including managing parallel investigations by federal and state government entities. Our attorneys also have defended clients against False Claims Act cases pursued by *qui tam* relators following government declination.

We also manage a full range of controversies for life sciences industry clients. Our attorneys have successfully defended numerous federal and state securities class actions against pharmaceutical, biotechnology and medical device clients. Our team has extensive experience managing mass tort litigation for a variety of FDA-regulated companies. We also handle a variety of commercial disputes involving life sciences companies in litigation and arbitration in the United States and internationally, including disputes arising out of collaborations among large and small life sciences companies and contract manufacturing organizations, disputes involving complex licensing arrangements, and disputes relating to substantial corporate and commercial transactions in the industry.

M&A

We integrate our depth of experience with life sciences companies and our global leadership in mergers and acquisitions and other corporate transactions to advise public and private clients on critical deals and in connection with takeover preparedness and shareholder activism.

We represent established pharmaceutical and medical device companies in merger transactions and significant acquisitions, investments and collaborations; development and early commercial stage companies in sale or partnering transactions with larger industry participants; and private equity, venture capital and other financial clients with portfolios focused in this sector across the range of their investment structures. Our industry experience also includes capital markets, spin-off and restructuring transactions. We understand the unique legal, regulatory, tax and commercial issues that transactions in this industry present, and we offer extensive experience in transactions involving the design of contingent value rights or earnout structures to bridge valuation gaps. Our regulatory and intellectual property experience enable us to target issues affecting critical assets. Our executive compensation attorneys are fluent in the structures for retaining and incentivizing key talent in this sector throughout pivotal transactions. Our global tax practice assists with optimizing efficiency of a transaction itself and any subsequent integration.

Health Care

Our attorneys have represented some of the largest publicly traded, private and not-for-profit health care systems and businesses. We advise hospitals, academic medical centers, health care systems and service providers, managed care organizations, pharmacies, pharmacy benefit managers, health plan and insurance providers, and skilled nursing and senior living facilities and related REITs. We have counseled these clients in responding to government investigations, FDA enforcement challenges, mergers and acquisitions, restructurings, antitrust matters, tax issues, and litigation and international arbitration, among other matters.

Litigation

Our attorneys — many of whom have held senior positions in government — represent health care companies in the full range of civil and criminal litigation. We have counseled in state and federal individual and class action cases, as well as related multidistrict litigation proceedings. Our team has represented clients in connection with civil and criminal allegations involving Medicaid and Medicare fraud, including alleged violations of the Anti-Kickback Statute, the Stark Law and federal and state False Claims Acts, including those brought by *qui tam* relators, as well as commercial insurance fraud. The team regularly helps clients navigate Foreign Corrupt Practices Act investigations conducted by the DOJ and the SEC; Federal Food, Drug and Cosmetic Act investigations; securities litigation; and mass tort litigation]. We also represent health care companies

in a full range of commercial disputes in litigation and arbitration in the U.S. and internationally, including disputes relating to substantial corporate and commercial transactions in the industry.

M&A

We represent clients throughout the health care industry in merger transactions and significant acquisitions, leveraging our understanding of regulatory and business trends. We also routinely advise in connection with takeover preparedness and shareholder activism. In addition, we represent financial sponsors with a focus on M&A and financings in this sector. We provide innovative solutions to industry participants in distressed situations, including in both in-court and out-of-court restructurings.

We have advised on some of the largest health insurance mergers, bringing to bear our insurance M&A and reinsurance expertise.

Our attorneys also represent health care-related REITs in numerous mergers, acquisitions, joint ventures and spin-offs of REITs and their subsidiaries, as well as in IPOs and offerings of debt, equity, hybrid and synthetic securities in both private and public transactions.

Health Care Regulatory Compliance

We counsel clients on FDA, Medicare, Medicaid and other federal health care program laws and regulations as well as state health law matters (*e.g.*, corporate practice of medicine and pharmacy laws). Our attorneys frequently advise on the regulatory aspects of sales and marketing practices, premarket review and licensure of medical products, financial relationships with physicians and health care providers, post-market regulatory and reporting requirements, medical affairs and clinical research, research funding, and grants for investigative studies. Our team has considerable experience conducting internal compliance reviews and, where appropriate, counseling on voluntary disclosures to government regulators. We also provide regulatory due diligence on corporate transactions, including mergers and acquisitions, financings, restructurings and insurance-related matters. Skadden attorneys have worked with numerous companies on matters before the U.S. Food and Drug Administration (FDA); the Centers for Medicare and Medicaid Services; and the U.S. Department of Health and Human Services, Office of Inspector General (HHS OIG) on reporting obligations and voluntary disclosures.

Compliance Programs

We have extensive experience developing, implementing and assessing corporate compliance programs in line with the U.S. Sentencing Commission and HHS OIG guidelines and in negotiating corporate integrity agreements and settlements with federal and state authorities. We also advise management and boards of directors of health care companies on corporate governance practices and developments specific to the industry.

Congressional Investigations

Our team has intimate knowledge of congressional processes, as well as experience working with congressional staff to understand a committee's focus and needs, and, where possible, to narrow the scope of an inquiry. We are experienced in parallel government enforcement inquiries and grand jury and civil proceedings. In response to a congressional investigation, we provide counseling and judgment beyond the scope of typical government relations advice. Skadden has represented numerous *Fortune* 500 companies, executives and public officials in high-profile congressional investigations, including inquiries conducted by the major investigatory committees of Congress.

HIPAA and Privacy

Our attorneys counsel and defend a wide range of clients on privacy-related matters, including compliance with the Privacy Rule and Security Rule of the Health Insurance Portability and Accountability Act (HIPAA). We also advise on HIPAA data breaches and violations and the attendant litigation risks.