Life Sciences and Health Care

Skadden

Skadden advises life sciences and health care clients on their most complex legal and regulatory issues across multiple disciplines, including Food and Drug Administration (FDA) regulatory counseling and enforcement defense; government and internal investigations; compliance program design and implementation; litigation and dispute resolution; complex corporate transactions; and the acquisition, enforcement and commercialization of intellectual property and technology assets. Companies and investors across the industry rely on the sector-specific insights of our life sciences and health care attorneys, who work as an integrated team and collaborate to help clients realize scientific innovations as they navigate an ever-evolving landscape.

Skadden is consistently ranked as a leading firm for Healthcare in *Chambers USA* and for Life Sciences by *The Legal 500 U.S.* We have been recognized among the top firms for Health Care and FDA Law by *Best Lawyers* Best Law Firms. In 2022, Skadden was named M&A Firm of the Year and received the award for Impact Deal of the Year from *LMG Life Sciences*, and was cited as a leading firm for M&A within the life sciences industry in the publication's rankings. We also received the Healthcare, Pharma & Biotech Deal of the Year (Large Cap) award from *The Deal* in 2021.

Life Sciences Compliance Counseling and Enforcement Defense

Skadden frequently advises on complex FDA matters, internal and government investigations, compliance program design and implementation, litigation and other high-profile disputes. Our lawyers' knowledge across these areas allows them to help clients anticipate complexities and develop well-rounded strategies to address their most pressing issues.

FDA

Skadden advises established life sciences companies and startups seeking to leverage new technologies relating to medical products and food on critical FDA regulatory and compliance issues, including product promotion and advertising; labeling requirements; recalls and risk management strategies; warning letter and 483 responses; GxP and Quality System Regulation (QSR) compliance; Hazard Analysis and Risk-Based Preventive Controls (HARPC) obligations; medical affairs and drug safety; clinical trials; premarket approval pathways and submissions, including Orphan designations, accelerated approval and other review pathways; digital health and Software as a Medical Device (SaMD) policies; combination products; and affirmative advocacy, including citizen petitions. Our experience serving at and working with the FDA helps us develop creative solutions to address our clients' mission-critical challenges.

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 DOJ, and state attorneys general. We have successfully defended numerous life sciences and health care companies and their boards, laboratories, nursing homes and health plans in criminal and civil government investigations into alleged violations under the Federal Food, Drug and Cosmetic Act (FDCA); the Anti-Kickback Statute and state law analogs; the Stark Law; and state and federal False Claims Acts. We have experience handling complex multidistrict and multiagency government investigations, including managing parallel investigations by federal and state government entities. We routinely undertake internal investigations implicating the FDCA and fraud and abuse laws on behalf of companies and their boards and audit committees. We have counseled clients in 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.

False Claims Act

Our attorneys defend clients against False Claims Act (FCA) cases pursued by federal and state governments and *qui tam* relators following government declination. Our team represents companies, their boards and management, and individuals in all aspects of FCA matters, including internal investigations; transactional due diligence; the implementation of remedial measures and compliance programs; and the defense of government investigations, enforcement actions, and criminal and civil proceedings. We have handled numerous FCA matters in the life sciences and health care industries arising from investigations by United States Attorneys' Offices, the Offices of Inspector General and state attorneys general, often in response to a whistleblower report or lawsuit, as well as from audits by the General Services Administration (GSA), the Defense Contract Audit Agency and the Defense Contract Management Agency.

Compliance Programs

We have extensive experience developing, implementing and assessing corporate compliance programs in line with the U.S. Sentencing Commission and DOJ and HHS OIG guidelines. Skadden has negotiated numerous corporate integrity agreements with HHS OIG and advised clients regarding their implementation. We regularly advise management and boards of life sciences and health care companies on compliance and corporate governance practices and developments specific to the industries. Our attorneys also provide strategic guidance on the fraud and abuse implications of product support programs and other client initiatives, and have represented life sciences and health care industry clients seeking HHS OIG advisory opinions.

HIPAA and Privacy

Our attorneys counsel and defend clients on privacy-related matters, including compliance with the Health Insurance Portability and Accountability Act (HIPAA). Our work in this area includes advising on HIPAA-related aspects of complex digital health deals and counseling life sciences companies on HIPAA privacy standards and Business Associate Agreement compliance. We also are experienced in guiding clients through HIPAA data breaches, other privacy challenges and attendant enforcement and litigation risks.

Litigation

Our attorneys — many of whom have held senior positions in government — provide comprehensive litigation and dispute resolution services, including representing life science and health care clients in product liability defense; commercial, intellectual property and licensing disputes in litigation and arbitration (domestic and international); internal investigations and government investigations and enforcement (civil and criminal); antitrust matters; and securities litigation. We have handled numerous state and federal individual and class action cases, as well as related multidistrict litigation proceedings.

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

Our team also 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 FCAs, as well as commercial insurance fraud.

The team regularly helps clients navigate Foreign Corrupt Practices Act investigations conducted by the DOJ and the SEC and FDCA investigations, as well as judicial challenges to agency decision-making.

Corporate Transactions

We represent life sciences and health care clients in merger transactions and significant acquisitions, leveraging our understanding of regulatory and business trends. Our team also advises on takeover preparedness and shareholder activism. We represent established pharmaceutical, biotechnology and medical device companies; food and dietary supplement companies; genomic and clinical laboratories; digital health companies; consumer product companies; tobacco companies; hospital and health care systems and service providers; long-term care facilities; nursing homes; and managed care 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.

In addition, we represent financial sponsors with a focus on M&A and financings in these sectors. We provide innovative solutions to industry participants in distressed situations, including in-court and out-of-court restructurings. We have advised on some of the largest health insurance and government program managed care mergers, bringing to bear our insurance M&A and reinsurance know-how. 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.

Intellectual Property

Our intellectual property attorneys, many of whom have scientific training and in-house experience at life sciences companies, perform "deep-dive" intellectual property diligence relating to acquisitions, joint ventures, divestitures, financings and investments, and effect transactions in the pharmaceutical, biotechnology 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.

Artificial Intelligence

Artificial intelligence (AI) is quickly altering the life sciences industry, and with innovation, legal challenges arise. Key areas we are seeing impacted include drug discovery and development; clinical trial recruitment and management; use and disclosure of clinical and genomic data; and related regulatory compliance, intellectual property, data protection and ethical considerations. Skadden's life sciences team regularly works with our global AI attorneys, who offer years of experience with complex AI legal matters. Together, we offer clients an understanding of key AI technology issues, business drivers and the evolving global regulatory landscape as companies navigate the impact of this complex and cutting-edge technology.