Life Sciences and Health Care

Skadden

Skadden counsels life sciences and health care clients in the areas of transactional, litigation and enforcement, regulatory, finance and intellectual property matters. We represent 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; long-term care facilities; and other service providers. We work with clients on matters of all sizes, from the largest mergers in the industry to smaller, early-stage transactions. We provide compliance counseling on a range of complex regulatory issues, and help resolve disputes with the government or other parties before they blossom into more serious matters. Our regulatory and litigation teams have extensive experience with the Federal Food, Drug, and Cosmetic Act; the Public Health Service Act; the Anti-Kickback Statute; the Foreign Corrupt Practices Act; the Controlled Substances Act; and the False Claims Act.

Our attorneys provide our clients with a unique combination of leading transactional capabilities as well as broad regulatory, compliance and litigation experience.

Skadden has navigated our life sciences and health care clients through virtually all issues that companies throughout the industry face:

- We offer a full range of transactional services, including advising on M&A, corporate restructurings, financings, private equity and complex licensing transactions.
- We offer a full range of litigation and defense services, including representing clients in product liability defenses, intellectual property matters, internal investigations, U.S. investigations and enforcement (civil and criminal), antitrust matters, and securities litigation matters.
- We offer a full range of regulatory and compliance counseling services, including on FDA premarket review; manufacturing and processing requirements (e.g., Good Manufacturing Practices (GMP), Quality System Regulation (QSR), Hazard Analysis and Risk-Based Preventive Controls (HARPC)); post-market safety reporting; medical product supply chain requirements; advertising and promotion of medical products; and addressing product recalls, FDA 483s and warning letters.
- Our global footprint with 22 offices in the Americas, Europe and Asia Pacific allows our attorneys to work seamlessly across our corporate, litigation and regulatory practices to provide service that balances the business prerogatives of our clients with the legal demands on the industry.
- Our extensive work in health care provides our attorneys with current, sector-specific insights that make our legal advice timely and relevant in the fast-moving life sciences and health care industries.

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 and health care businesses. Some of the largest publicly traded and not-for-profit health care systems are represented by our attorneys. 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*. In *LMG Life Science*'s 2019 rankings, Skadden is cited as a leading firm for both M&A and Products Liability within the life sciences industry. Additionally, we received two Finance and Transactional Deal of the Year awards from *LMG Life Sciences* in 2018 and recognized among the top firms for Health Care Law by *U.S. News — Best Lawyers* Best Law Firms 2020. We ranked as a leading firm for Life Sciences by *The Legal 500 U.S. 2018* and ranked among general counsel's top firms

for pharmaceutical work BTI Power Rankings 2017. Additionally, we were named *The American Lawyer*'s 2018 White Collar/Regulatory Litigation Department of the Year and a finalist in the general litigation category of the *New York Law Journal*'s 2019 and 2020 Litigation Department of the Year competitions.

Corporate and M&A

Skadden advises life sciences and health care clients worldwide on the full spectrum of corporate matters. Our areas of concentration include mergers, acquisitions and divestitures, joint ventures and other collaborations, corporate finance, banking, tax and insurance. We have been involved in some of the largest and most noteworthy deals in the industry, including a number of deals with cross-border aspects. Our clients include both public and private companies in the U.S. and abroad, and we have counseled on both negotiated and hostile transactions. We represent clients throughout the health care industry on shareholder activist and hostile takeover preparedness. In addition, we represent financial institutions (including private equity firms and venture capital funds) — acting either as principals, underwriters or financial advisors — in M&A, and debt and equity offerings throughout the life sciences and health care sectors. Skadden also works with life sciences and health care clients to provide innovative solutions in distressed company situations, including in both in-court and out-of-court restructurings, acquisitions and financings. Additionally, we represent health care-related REITs in a wide variety of corporate matters.

We have one of the largest, most experienced teams of transactional lawyers among the world's top law firms. Skadden has been recognized in numerous publications, including being named the top corporate law firm in the United States more times than any other firm in *Corporate Board Member* magazine's annual survey of "America's Best Corporate Law Firms." We also were one of only five firms ranked in *Chambers Global 2019*'s top tier for Global M&A.

Litigation and Enforcement

Our litigation attorneys — many of whom have held senior positions in government — represent life sciences and health care companies in the full range of offensive and defensive litigation matters facing clients in the industry. We have counseled in state and federal individual and class action cases, as well as related MDL proceedings. We represent clients in connection with civil and criminal allegations involving Medicaid and Medicare fraud; violations of the Anti-Kickback Statute and Stark Law; federal and state False Claims Act litigation, including those brought by *qui tam* relators; insurance fraud; Foreign Corrupt Practices Act investigations conducted by the DOJ and SEC; Federal Food, Drug and Cosmetic Act investigations; securities litigation; and mass tort litigation.

We also regularly represent corporations and individuals in criminal health care investigations and enforcement actions, often as part of a Skadden team assisting clients with related SEC investigations, private securities litigation, regulatory actions and other crisis management matters.

Intellectual Property

Our IP attorneys, many of whom have relevant scientific training and in-house experience in life sciences companies, are dedicated to transactional work on behalf of our clients. We perform "deep-dive" intellectual property diligence for clients in the pharmaceuticals, medical device and diagnostics, and biotechnology industries in connection with matters relating to acquisitions, divestitures, financings and investments. We also play a significant role in transactions in the pharma, biotech and related life sciences areas as members of Skadden teams responsible for structuring, negotiating and drafting agreements for asset sales, mergers, acquisitions, large investments, collaborations and joint ventures, supply, clinical studies, and product and technology licenses, as well as royalty interest sales and securitizations. Our IP attorneys also regularly handle IP enforcement and defense matters involving pharmaceuticals, biologics, medical devices and other technologies employed in the life sciences arena. Moreover, many of our IP attorneys are registered to practice before the U.S. Patent and Trademark Office and are experienced in handling matters before the Patent Trial and Appeal Board.

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 counsel 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. 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.

FDA
Skadden advises on the full range 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 covers all FDA-regulated articles — including pharmaceuticals, biologicals/vaccines, medical devices, foods, dietary supplements and tobacco. Skadden counsels clients on 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 cGMP, QSR, and 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.

Medicare and Medicaid Regulatory
We advise our clients and litigate regarding numerous Medicare and Medicaid issues, including billing, secondary payer and Part C risk adjustment payment system matters; data submissions to the Center for Medicare and Medicaid Services; and Medicare and Medicaid reimbursement, as well as fraud and abuse, Stark Law and Anti-Kickback investigations.

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.

International Trade Compliance
Skadden regularly advises companies throughout the industry on matters involving export controls, trade remedies, customs laws, country-of-origin issues, government procurement, Trade Agreements Act compliance, market access and related areas of international trade law. Skadden attorneys have counseled life sciences and health care companies on matters before the U.S. Department of Commerce's Bureau of Industry and Security, Census Bureau, Bureau of Economic Analysis, Office of Anti-boycott Compliance, International Trade Administration, the U.S. State Department's Directorate of Defense Trade Controls, U.S. Customs and Border Protection, and the Office of the U.S. Trade Representative.

Economic Sanctions
Skadden represents a wide variety of U.S. and international corporations on regulatory, civil and criminal matters involving U.S. and European Union economic sanctions laws, including those administered by the U.S. Department of the Treasury's Office of Foreign Assets Control and other federal and state regulators, among others. We advise multinational companies from all industries, including life sciences and health care companies, in all aspects of global economic sanctions. Our work includes counseling on compliance, voluntary disclosures, transactional due diligence, implementation of remedial measures and compliance programs, and defense of federal and state government investigations.

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.

Compliance Programs and Corporate Governance
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.

Industry Sectors

Life Sciences
Our attorneys represent pharmaceutical, biotechnology, medical device and food companies across all aspects of their businesses. We counsel on transactions, litigation and enforcement, regulation, intellectual property, tax, antitrust, finance and other matters. We advise on FDA and health care regulatory issues, including investigations by law enforcement agencies, U.S. attorney's offices, the Criminal and Civil Divisions of the DOJ and state attorneys general. Our attorneys also handle federal securities class actions. We have represented numerous global pharmaceutical and medical device companies in government investigations into alleged violations of various laws, including the Federal Food, Drug and Cosmetic Act. Additionally,

our team has extensive experience managing mass tort litigation for medical device clients and other FDA-regulated companies.

Hospital and Health Systems and Other Providers
We advise a wide variety of hospitals, academic medical centers, health care systems, managed care organizations, pharmacies, home health care agencies, clinical laboratories and skilled nursing and senior living facilities. We counsel these clients in responding to government investigations, FDA enforcement challenges, mergers and acquisitions, restructurings, antitrust matters and tax issues, among other matters. Additionally, our attorneys represent health care providers and corporations in response to civil and criminal investigations and litigation brought under the provisions of the False Claims Act and other statutes.

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 Plans and Insurers
Skadden counsels on numerous issues for health plan and insurance providers, including reinsurance matters, mergers and acquisitions, corporate finance matters, insurance fraud and class action litigation.