WINSTON & STRAWN LLP

Medical Devices

The medical device industry is currently undergoing monumental change—from supply chain challenges to disruptive technologies and economic fluctuations. To pave the way for a more accessible and innovative health care landscape—including advances in wearables, implants, diagnostics, mobility, drug delivery—the evolving and expansive medical device industry faces wide-ranging legal needs. Clients in this sector can tap the remarkable depth and breadth of our sector-focused and skilled attorneys in the U.S. and abroad. Our Health Care & Life Sciences Industry Group engages clients at all points in the product development life cycle to provide sound advice and practical solutions regardless of the client's size or the complexity of their need. We help clients navigate today's complex regulatory landscape, defend products and reputations in the face of high-profile product liability and mass tort claims, protect innovative intellectual property (IP), and leverage cross-border experience to advise on commercial transactions.

Key Contacts

Charles B. Klein

T. Reed Stephens

Nimalka Wickramasekera

Areas of Focus

Medtech Patent Litigation

With more than 100 attorneys, our IP Practice is one of the most active and highly regarded in the U.S. In this legal discipline, very few firms offer as wide a spectrum as that of our life sciences and technology experience. Technologies Covered by Our Practice

- Mechanical & Systems Engineering – products and devices designed to carry out specific functions, manufacturing, or process steps (e.g., medical devices, heat transfer, fluid control, and industrial process equipment)
- Life Sciences & Biotechnology – genetically engineered and DNA-based technology; implantable devices; diagnostics, vaccines, probes, vectors, and cell lines; and related discoveries for application in compositions, treatments, and therapeutics
- Electrical Engineering & Electronics— computer hardware, peripherals, and software; artificial intelligence; and digital devices

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Product Life Cycle Compliance

Our Health Care & Life Sciences Industry Group stands ready to meet our clients wherever they may be in the product development life cycle—research, commercialization, or distribution—to provide advice and practical solutions to clients, whatever the complexity of the need. We routinely draw from our extensive business and regulatory knowledge to help sector participants navigate the complete product life cycle, including:

- clinical research and development programs, including HIPAA privacy and consent;
- sales and marketing compliance, including employee training on fraud and abuse and Code of Ethics;
- marketing application strategies for drugs, biologics, and medical devices and U.S. state licensing requirements;
- government Price Reporting obligations for Medicare, Medicaid, the Department of Veterans Affairs, and 340B;
- the negotiation of customer and distributor supply agreements for both pharmaceutical manufacturers and medical device companies, including government purchasers under the Federal Supply Schedule (FSS);
- design and execution of Patient Access programs (e.g., kickstart, patient assistance and co-pay assistance programs for pharmaceutical manufacturers, limited pharmacy distribution networks, and hub service vendors); and
- international trade compliance, including country of origin.

Mergers & Acquisitions

We have extensive experience advising clients on risk management concerns involving mergers and acquisitions, public policy, IP protection, and an array of regulatory compliance matters relating to product marketing, foreign bribery, and import/export controls.

Internal & Governmental Investigations & Related Litigation

With former DOJ attorneys and in-house attorneys embedded in our Health Care & Life Sciences Industry Group, our attorneys have extensive experience in matters involving state and federal government law enforcement and investigations, including federal False Claims Act (FCA) defense, internal investigations, fraud and abuse compliance training, congressional investigations, and health care litigation.

Related Capabilities

Commercial Litigation & Disputes | Employee Benefits & Executive Compensation | Environmental | Government Program Fraud, False Claims Act & Qui Tam Litigation | Intellectual Property | International Trade | Labor & Employment | Litigation/Trials | Mergers & Acquisitions | Patent Litigation | Private Equity | Privacy & Data Security | Trade Secrets, Non Competes & Restrictive Covenants | Health Care | Life Sciences

Recent Experience

- Picard Medical...
- Culper Capital...
- Surgical Science...
- Won Rare...
- Incodema Holdings'...
- Hospice Source's...
- United American...

Resources

Product Liability & Mass Torts Digest

PTAB Perspectives

Related Insights & News

BLOG

Eleventh Circuit Affirms CoolSculpting Device Manufacturer Win on Warning and Defect Claims

AUGUST 11, 2023

SPEAKING ENGAGEMENT

Ivan Poullaos Discusses How the Supreme Court's Enablement Ruling in *Amgen v. Sanofi* Will Affect Biologic Patent Portfolio Strategies

JUNE 27-28, 2023

CLIENT ALERT

Clarifying the Enabling Obligation of the Patent Act: *Amgen Inc. v. Sanofi*

JUNE 21, 2023

SEMINAR/CLE

Winston & Strawn's Product & Mass Torts Summit 2023

JUNE 14, 2023

BLOG

The FTC Attempts (Again) to Lay the Groundwork for Use of Its Penalty Offense Authority: This Time for Deceptive Product Claims

MAY 8, 2023

SPEAKING ENGAGEMENT

Kurt Mathas Speaks on Pharmaceutical Patent Litigation Settlements at Paragraph IV Disputes Conference

APRIL 19-20, 2023

RECOGNITIONS

Winston & Strawn Recognized in *Chambers Europe* 2023

MARCH 16, 2023

BLOG

Cherry-Picking Epidemiological Data Proves Fruitless for Zantac MDL Plaintiffs

MARCH 14, 2023

BLOG

Zantac MDL Decision Highlights Need for Rigorous and Objective Approach in Bradford Hill Analyses

FEBRUARY 15, 2023

BLOG

Zantac MDL Decision Reinforces Principle that Lack of General Acceptance of an Expert's Conclusions Raises a Red Flag

FEBRUARY 14, 2023

NEWS

Winston Team Accelerates Path to Market for Generic Cancer Drug

JANUARY 26, 2023

RECOGNITIONS

Winston Attorneys Recognized in Litigator of the Week Column

JANUARY 6, 2023