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## *Healthcare*

Comprehensive counseling for healthcare providers, insurers and the companies that supply them with products and services.

The healthcare industry accounts for nearly one-fifth of the US economy. In the EU, healthcare spending is expected to rise to nearly 15% of GDP by 2030. Our lawyers—who include the former general counsel of one of the largest health insurers in the United States and senior in-house lawyers from an array of life sciences companies—know this industry from the inside.

Our team also has a nuanced understanding of the constantly evolving legal regime that governs healthcare policy, thanks to the many lawyers who have served in the US Department of Justice (DOJ), the Federal Trade Commission, the White House, and on the staffs of senators who have been the leading voices on healthcare policy issues.

This experienced team offers a broad range of exceptional counseling to healthcare providers, healthcare insurers, and the companies that supply them with products and services, including in fraud investigations and litigation, data protection and privacy, patent and trademark prosecution and litigation, transactions, antitrust, public policy, and commercial litigation.

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## *Key Contacts*



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## *Related Solutions*

Life Sciences

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## *Areas of Focus*

Healthcare Investigations and Enforcement Litigation

Healthcare Patent and Trademark Prosecution and Litigation

Commercial Litigation and Healthcare

Public Policy and Congressional and Executive Branch Investigations in Healthcare

Healthcare Data Security and Privacy

Healthcare in the European Union and Germany

Healthcare Transactions and Corporate Counseling

Antitrust and Healthcare

Healthcare in China

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## *Experience*

Leading an independent compliance monitorship for a major healthcare provider in the wake of a Department of Justice settlement.

Secured an arbitration award of more than \$100 million on behalf of a major medical device manufacturer asserting breach of contract.

Advised in a landmark court proceeding in the European Union regarding commissioned data processing of patient data.

## HEALTHCARE INVESTIGATIONS AND ENFORCEMENT LITIGATION

- Represented medical device companies, senior executives, and sales and marketing personnel in numerous criminal and civil False Claims Act investigations of alleged off-label marketing and kickbacks.
- Represented a medical device manufacturer in the defense and resolution of government claims that it had breached a deferred prosecution agreement.
- For a lab company, provided counsel in a government investigation of allegations of Medicare and Medicaid fraud.
- Represented a company in an inquiry by Senator Chuck Grassley into whether several companies in a particular healthcare sector engaged in Medicaid fraud or otherwise failed to comply with applicable laws.
- For an internet search and technology company, handled a grand jury investigation of alleged aiding and abetting of unlawful conduct by Canadian online pharmacies and the negotiation of a non-prosecution agreement that resulted in the closing of the investigation and a release of claims.
- Defended a company in a grand jury investigation of alleged kickbacks and obstruction in which the government declined prosecution.
- Defended a medical device manufacturer in a grand jury investigation of allegations that it had violated the Anti-Kickback Statute, and negotiated a global resolution of the government's criminal, civil and administrative claims.
- On behalf of a healthcare company, persuaded the Justice Department not to proceed against the company in an False Claims Act matter, and negotiated a favorable settlement with the Department of Health and Human Services.
- Represented a third-party billing company in the civil resolution of parallel criminal and civil investigations of alleged Medicare and Medi-Cal fraud.
- For a medical device manufacturer, obtained a global civil resolution in an investigation by a US attorney's office arising from a former employee's allegations that the company had maintained an inadequate complaint reporting system under the Food, Drug, and Cosmetic Act and had misrepresented the quality of numerous medical devices.
- Secured the government's dismissal of all criminal charges against a biomedical sales manager after opening statements and less than one day of trial testimony.
- Represented a device manufacturer in a grand jury investigation in which the government ultimately declined to pursue any criminal charges.
- Handled numerous internal investigations—including internal investigations of activities in the United States, China, Korea, India, Japan, Mexico, Russia and Poland—on behalf of medical device and other life sciences companies facing alleged violations of the Food, Drug, and Cosmetic Act; the Anti-Kickback Statute; and the Foreign Corrupt Practices Act.
- Offered compliance counseling to multiple clients, including a clinical research organization and a health insurance company, regarding anti-bribery risk assessments, compliance policies and compliance training.
- Represented a global medical device manufacturer in an Foreign Corrupt Practices Act investigation by the Justice Department and the Securities and Exchange Commission.

## **PUBLIC POLICY AND CONGRESSIONAL AND EXECUTIVE BRANCH INVESTIGATIONS**

- For a major insurance company, advised on constitutional, substantive and strategic issues associated with efforts to achieve a global legislative solution to the national asbestos crisis.
- Assisted in a successful effort to obtain legislation protecting the confidentiality of sensitive business information provided to the government to assist in the protection of critical infrastructure.
- For a director of a major US healthcare corporation, advised in an investigation by the House Energy and Commerce Committee.
- Guided a medical device company in its response to congressional inquiries about its marketing practices.
- Represented a medical device company in hearings concerning dual-use technology issues.

## **HEALTHCARE TRANSACTIONS AND CORPORATE COUNSELING**

- Represented TransMedics, a medical technology company dedicated to improving quality, assessing viability and increasing the utilization of donor organs for transplantation, in its closing of \$51.2 million growth equity financing.
- For healthcare IT provider Caradigm, provided licensing and general corporate advice.
- Represented aesthetic laser treatment developer Cynosure in its acquisition by Hologic for \$1.6 billion.
- Represented the underwriters in the initial public offering for IT security company Impriva and represented medical equipment company Medtronic in a Rule 144A placement of convertible note offerings, among many other transactions handled for life sciences companies.

## **PATENT AND TRADEMARK PROSECUTION AND LITIGATION**

- For Roche Molecular Systems, argued and won against Stanford University in a closely watched case regarding the effect of the Bayh-Dole Act on patent rights to inventions developed using federal funds (the first patent case in which the US Supreme Court affirmed the Federal Circuit, despite the fact that the solicitor general urged reversal).
- Represented Medtronic in its appeals of adverse judgments in three cases (*DePuy*, *Spine Solutions* and *Brainlab*), obtaining rulings reversing the district court's judgments against the company, including awards of sanctions in *DePuy* and *Brainlab*. We also represented Medtronic at the trial level in *Globus Medical*, where we obtained a ruling, affirmed on appeal, that Globus Medical had infringed two Medtronic patents.

## **DATA SECURITY AND PRIVACY**

- Negotiate data-sharing agreements among collaborators in life sciences research projects.
- Advise covered entities and business associates on HIPAA privacy, security and breach notification compliance requirements.
- For a provider of a direct-to-consumer personal health record solution, advised on the regulatory considerations affecting such entities that operate outside of the

HIPAA regulatory regime.

- Counseled a state-sponsored operator of a health information exchange on its federal Department of Health and Human Services grant funding agreement and related compliance requirements.
- Advise biotech clients on licensing of data and technology from federal agencies, such as the Centers for Medicare and Medicaid Services and the National Institutes of Health.
- Counsel software developers operating as business associates on the contractual, intellectual property and regulatory considerations involved in conducting data aggregation and de-identifying and using health information for secondary purposes.
- Have advised on the patent eligibility of algorithms, software and methods of analysis relating to genetic data.
- For software startups in the healthcare sector, developed standards for ensuring that HIPAA-covered information is secured, while ensuring that information is de-identified in accordance with HIPAA standards.
- For a large account servicing organization, conducted regulatory due diligence review in the acquisition of a health claims processing company.
- For a nonprofit healthcare provider, investigated and coordinated the remediation, individual notification and regulatory reporting stemming from a loss of computer media containing unsecured health data.

#### **ANTITRUST**

- Represented a major insurance carrier in the Insurance Brokerage Antitrust Litigation, successfully securing the dismissal of all federal antitrust, RICO and ERISA claims in the consolidated class action complaint against employee benefits insurers, as well as the related state law claims.
- Represented the second-largest provider of regulated medical waste services in obtaining clearance for its acquisition by the largest provider of those services.

#### **COMMERCIAL LITIGATION**

- Prevailed on all issues in a three-week trial before the American Arbitration Association involving license rights to molecular diagnostic probes.
- For affiliates of an internet-based health information firm, provided representation in several consumer class actions brought by physicians.
- Representation of a national medical billing system company in arbitration against developers of software.
- For a pharmacy benefits manager, provided representation in numerous litigation matters.
- Represented a medical device manufacturer in arbitration against a European distributor.
- Represented several hospitals in billing disputes with the Commonwealth of Massachusetts.

#### **EUROPEAN UNION AND GERMANY**

- For a Boston-based medical device producer, advised on a contract with DSO, the

German federal foundation for organ transplantation, regarding the financing of a heart transplant device.

- Counseled US companies in medical devices industries on market access and reimbursement in the EU, as well as on regulatory product approval and labeling and requirements.
- For associations of German physicians, negotiated selective agreements on standards for primary medical care and doctor's fees, including the groundbreaking first selective agreement affecting approximately 5,000 general practitioners, almost 4 million patients and a major public health insurance fund. According to the German Federal Minister of Health, the arrangement serves as a role model for similar agreements.
- Advised and represented associations of general practitioners in more than 350 arbitration proceedings with public health insurance funds and 155 litigation proceedings before the social courts in connection with various arbitral awards in Germany.

## **CHINA**

- Advised on the development of housing and healthcare facilities for seniors.
- Counseled a Beijing-based owner and operator of private hospitals and clinics.
- For an operator of specialty care hospitals, advised on the provision of services in China.
- To facilitate foreign investment, advised on the restructuring of a Chinese hospital management company.