KING & SPALDING

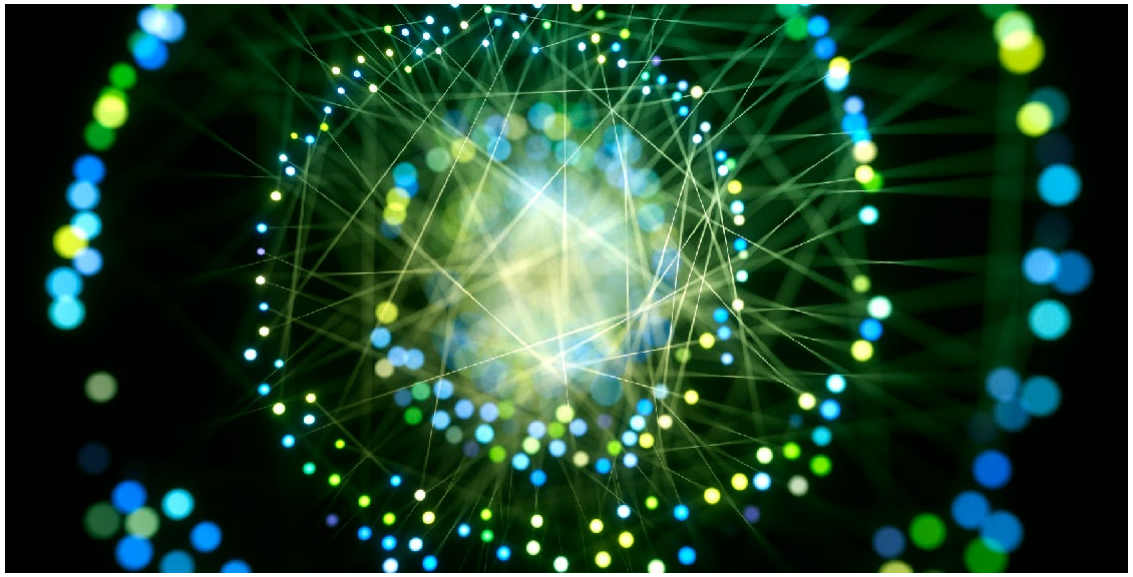
Helping Clients Improve Patient Health and Realize Commercial Objectives Through Life Sciences

Serving the Goals of a Powerhouse Industry.

The life sciences industry connects breakthrough science, vast commercial momentum and complex compliance obligations.

Our integrated life sciences capabilities are designed to support and protect the success and strategic growth of companies in this highly specialized, accelerating and multibillion-dollar global industry.

Serving clients in every segment of the life sciences sector, we leverage our broad experience to achieve outcomes that best protect and advance their interests. This includes helping establish startups developing breakthrough drugs, defending the world's largest pharmaceutical manufacturers in precedent-setting legal challenges and providing counsel on strategic acquisitions as well as along the full spectrum of regulatory matters.



A "firm that dominated" by "successfully securing wins in bet-the-company matters and closing high-profile, big-ticket deals for clients" and for "delivering value to their clients by cultivating world-class expertise and working across different groups to develop holistic solutions to complex problems."

— LAW360

360° Insights. Integrated Solutions.

ACING REGULATORY AND COMPLIANCE

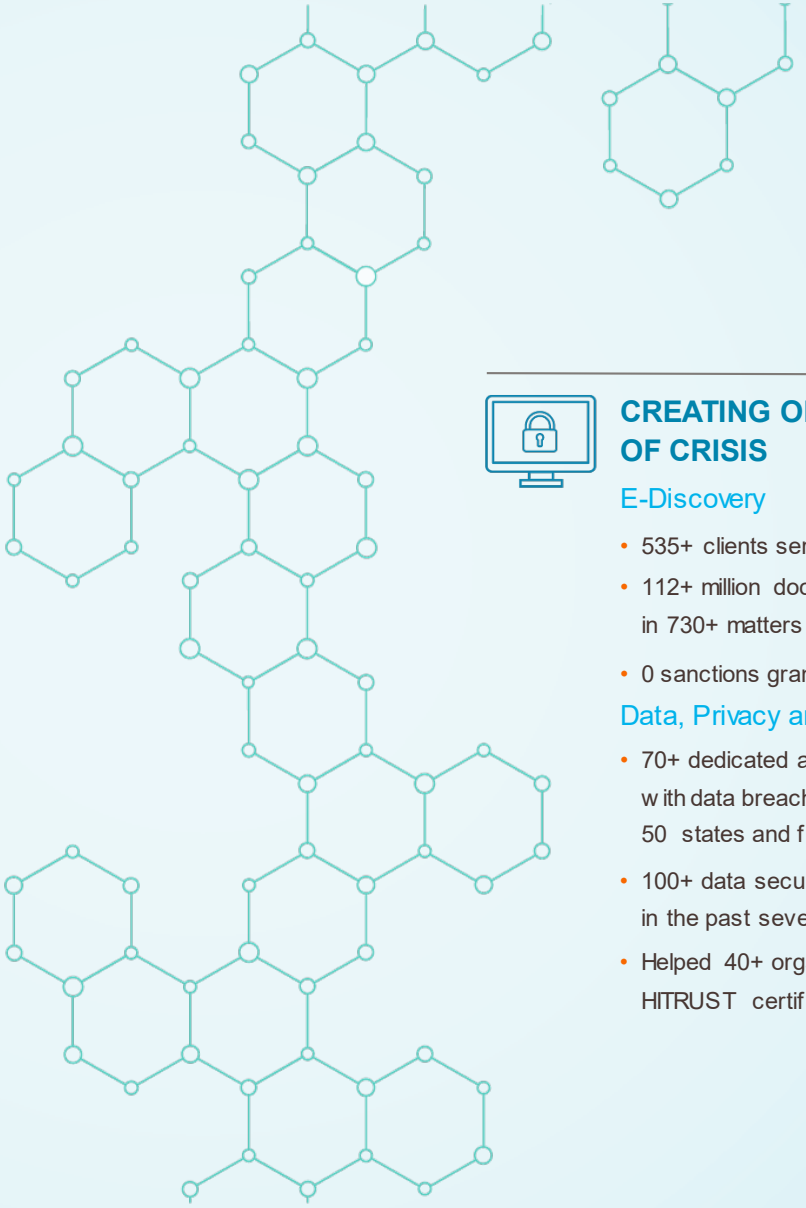
FDA and Life Sciences

- 40+ attorneys and professionals in the U.S. and EU devoted full time to regulatory work, including clients with a presence in the EU as well as in France, Belgium and Germany
- Industry-leading consultants, including physicians and former senior FDA officials
- Extensive footprint in regulatory and legislative affairs, with a focus on FDA and the Centers for Medicare & Medicaid Services

PREPARING FOR SCRUTINY

Special Matters and Government Investigations

- 125+ professionals with prior government experience
- Conducted investigations in 80+ countries
- Appeared before 73 of the 93 U.S. attorneys offices and all 12 SEC field offices
- Resolved more than 170+ False Claims Act (FCA) matters and investigations in the past 10 years; 45+ FCA-related matters over the past 5 years
- Negotiated 45 corporate integrity agreements for life sciences and healthcare industry clients



CREATING ORDER IN TIMES OF CRISIS

E-Discovery

- 535+ clients served
- 112+ million documents reviewed in 730+ matters since 2008
- 0 sanctions granted against clients

Data, Privacy and Security

- 70+ dedicated attorneys and professionals with data breach experience across all 50 states and five continents
- 100+ data security incidents managed in the past several years
- Helped 40+ organizations become HITRUST certified

360° Insights. Integrated Solutions. (continued)

MITIGATING RISKS

National Security and Corporate Espionage

- 125+ former senior U.S. government officials with decades of experience in national security legal positions at agencies including the FBI), CIA, Office of the Director of National Intelligence, USTR and Department of Justice
- Experience at the most senior levels of government, including a former FBI chief of staff and a former director of national intelligence
- Certified ethical hackers and computer hacking forensic investigators

NAVIGATING UNCHARTERED TERRITORY GLOBALLY

International Trade

- 30+ dedicated lawyers and professionals, including former general counsel to the United States Trade Representative (USTR), with in-depth knowledge of the latest trade policies and actions
- 130+ collective years of firsthand government experience at the Department of Commerce, USTR, World Trade Organization, Office of Foreign Assets Control and European Commission

ADVANCING POLITICAL STRATEGY

Government Advocacy and Public Policy

- Lawyers with direct Capitol Hill experience, including 5 former members of Congress, 12 former congressional staffers and 6 former members of the executive branch
- Experience on both sides of the aisle to leverage bipartisan relationships
- Decades of experience navigating legal and public relations challenges in congressional investigations

360° Insights. Integrated Solutions. (continued)

CONTAINING VIRAL LITIGATION

Class Action Defense

- Involved in hundreds of class actions in the past seven years
- Defeated class certification in 30+ jurisdictions
- One of few firms that try class actions to verdict

MOUNTING STRATEGIC AND CREATIVE DEFENSES

Product Liability Litigation

- 175+ lawyers across the world leveraging knowledge of complex science and technology
- High-stakes product cases tried every year in the most challenging jurisdictions
- Regularly serve as national coordinating counsel in mass tort litigation

PROTECTING WHAT'S YOURS

Intellectual Property Licensing, Approvals and Litigation

- First-chair trial and business lawyers; respected scientific consultants
- 200 trials before the Patent Trial and Appeal Board since 2012
- Dozens of Hatch-Waxman ANDA trials, 0 losses
- Trial and inter partes review record: 21-0
- 40+ attorneys with technical degrees

360° Insights. Integrated Solutions. (continued)

STRUCTURING GLOBAL GROWTH

Mergers and Acquisitions

- Over 150 M&A lawyers located throughout global offices
- Advise on company and product acquisitions and dispositions, financings, complex licenses, and collaboration and development agreements
- Navigate activist shareholders

SERVING THE TECHNOLOGY SECTOR, SPONSORS AND OTHER INVESTORS

- 25 lawyers working on matters involving mergers and acquisitions, venture capital and government contracts
- Advise from initial formation and fundraising, to VC and debt financing structures, IP and product licensing agreements, commercial contracts and outsourcing, acquisition and exit opportunities, and day-to-day corporate governance
- Cover all phases of outsourcing lifecycle, from strategy development and RFPs through executive, go-live and post-closing relationship management

OPTIMIZING FEDERAL CONTRACTS

Government Contracts

- Dedicated attorneys with 55+ years of government contracts experience
- Extensive experience with procurement contracts, grants, cooperative agreements, and government-unique compliance, risk mitigation, IP protection and investigations
- Represent life sciences companies in opportunities and risks related to pandemic emergency activities and issues

ABOVE AND BEYOND

- Combining financial restructuring skills with industry experience
- Securing supply chains
- Supporting companies with products that target or impact women with our Focus on Women's Health initiative

High Stakes. Disciplined Industry Solutions.

Safeguarding Markets and Products

Fast-Tracking Market Protections for Allergan

Allergan USA Inc., in partnership with King & Spalding, challenged the promotional practices of purported compounders Imprimis Pharmaceuticals Inc. (now Tennessee-based Harrow Health Inc.) and Prescriber's Choice. Using first-of-their-kind legal arguments developed by K&S, Allergan brought unfair competition and false advertising lawsuits against the entities. After its motion to dismiss failed, Prescriber's Choice consented to judgment on the eve of trial. In the Imprimis matter, restrictive rulings for compounders ensued: a summary judgment that Imprimis had misled consumers and physicians; a ruling that Imprimis had violated the Sherman Act by selling unapproved drugs; monetary damages awarded to Allergan in a jury trial of the false advertising claim; and a permanent injunction barring Imprimis from selling any drug in California except under rare circumstances.

Mitigating Serial Liability Claims for GlaxoSmithKline

For well over a decade, GlaxoSmithKline (GSK) has partnered with King & Spalding to reach favorable resolutions of product liability cases related to its antidepressant Paxil®. Serving as national coordinating and lead trial counsel, K&S has sustained an informed defense against allegations that maternal use of Paxil causes in utero injuries. Through meticulous, voluminous discovery and deposition-taking, K&S has worked with GSK to successfully manage cases in some of the most challenging U.S. jurisdictions, including preventing unfair results and avoiding trial consolidation.

Erecting a Product Bulwark for Johnson & Johnson

Johnson & Johnson (J&J) has worked with King & Spalding as its California coordinating and trial counsel to mount a consistent defense and accrue wins related to claims against its talc-based powder products. Bringing cases in the plaintiff-friendly jurisdiction of California and staffing multiple trials concurrently, K&S has coordinated with J&J to win two complete defense verdicts, two mistrials, a summary judgment and a voluntary dismissal since 2017 alone.

High Stakes. Disciplined Industry Solutions. (continued)

Launching Smart Growth

Adding Alzheimer's Muscle for Eisai Pharmaceuticals

Eisai Pharmaceuticals, advised by King & Spalding, successfully expanded its collaboration with Biogen to jointly develop and commercialize investigational treatments for Alzheimer's disease. Integrating multi-office capabilities in corporate, tax, intellectual property and regulatory law, as well as litigation, K&S worked with Eisai to restructure the parties' development and promotional responsibilities, ownership of development and commercialization costs, and sharing of operating profits in line with Eisai's business model and growth strategy. Eisai also gained the right to co-promote Biogen products in lucrative Asia-Pacific markets.

Launching a Next-Gen Dental Practice Toolkit for Henry Schein

Filling an integrated-technology gap in dental practice management and marketing, Henry Schein Inc., a global distributor of medical, dental and veterinary supplies, partnered with King & Spalding FDA and life sciences lawyers to structure and close a joint venture deal with Internet Brands. Working closely with Henry Schein, K&S thoroughly vetted the California-based new media company, defined criteria for establishing "Henry Schein One" and continuing each entity's operations, and addressed complex state licensing requirements. By integrating with Internet Brands, whose premium websites include WebMD, Fodor's Travel and CarsDirect, the healthcare products and services major significantly expanded its product portfolio and customer base while strengthening its core business.

Propelling a Diagnostics Platform for Telomere

To automate and streamline its diagnostic informatics workflow and solutions, Telomere Inc., advised by King & Spalding, acquired UNIConnect L.C. Bringing UNIConnect's process management software in-house, the combination also integrates these efficiencies with the capabilities of recently acquired GeneInsight. Telomere, a subsidiary of Sunquest Information Systems and Roper Technologies, now offers a complete, automated diagnostics and genetics platform to its 1,700+ global laboratory customers.

Protecting a Billion-Dollar Market With New IP Guardrails for Galderma

To protect a franchise generating billions since its launch, Galderma Laboratories LP looked to stop generic manufacturers from marketing a generic form of its flagship rosacea product, Oracea®, positing that the generic infringed on the Swiss pharmaceutical's patents. In a rare application of the statute, King & Spalding coordinated with Galderma to argue that Amneal Pharmaceutical's "design around" product infringed under the equitable Doctrine of Equivalents. A federal judge agreed, ratifying Galderma's equivalents argument— a veritable unicorn ruling in patent litigation. In a recent order, it was determined that Sun Pharmaceutical also directly infringed Galderma's patents despite claiming to have a different formulation. These wins continue to protect the exclusivity of Galderma's Oracea product through December 24, 2020.

High Stakes. Disciplined Industry Solutions. (continued)

Empowering Business Continuity

Challenging a High-Value ITC Decision for Amarin Corporation

King & Spalding coordinated with Amarin Corporation to challenge the International Trade Commission's decision not to investigate trade practices by importers of certain drugs labeled as dietary supplements. K&S worked with Amarin to file a complaint under the Tariff Act of 1930 and the Lanham Act with the Federal Circuit, followed by a petition for certiorari with the U.S. Supreme Court. The case is expected to decide a significant, recurring issue of trade law and the authority of two government agencies related to importer rights and U.S. market share.

Securing No Wrongdoing in Daunting Probe for Takeda Pharmaceuticals

Takeda Pharmaceuticals (formerly Shire) successfully reached a civil-only settlement under the FCA, with no admission of wrongdoing or liability, in parallel civil and criminal investigations brought by multiple government authorities. Takeda worked with King & Spalding to manage inquiries related to the sales and marketing practices of the former Advanced BioHealing business, which Shire had acquired in 2011 and divested in 2014. Following the US$350 million settlement, Takeda was also dismissed from the ongoing FCA litigation.

Winning a High-Profile Investigation

In a widely publicized ongoing and industrywide DOJ investigation focused on Anti-Kickback Statute and FCA issues, King & Spalding helped Actelion Pharmaceuticals (since acquired by J&J) to reach a civil-only settlement and pay US$360 million to resolve government claims. Focused on donations made by pharmaceutical manufacturers to charitable patient- assistance foundations, the investigations subpoenaed 20+ pharmaceutical manufacturers, for whom K&S has led a joint defense group. Defended by K&S, Actelion admitted to no wrongdoing and was not required to implement a corporate integrity agreement.

Driving Breakthrough Drugs to Market for TherapeuticsMD

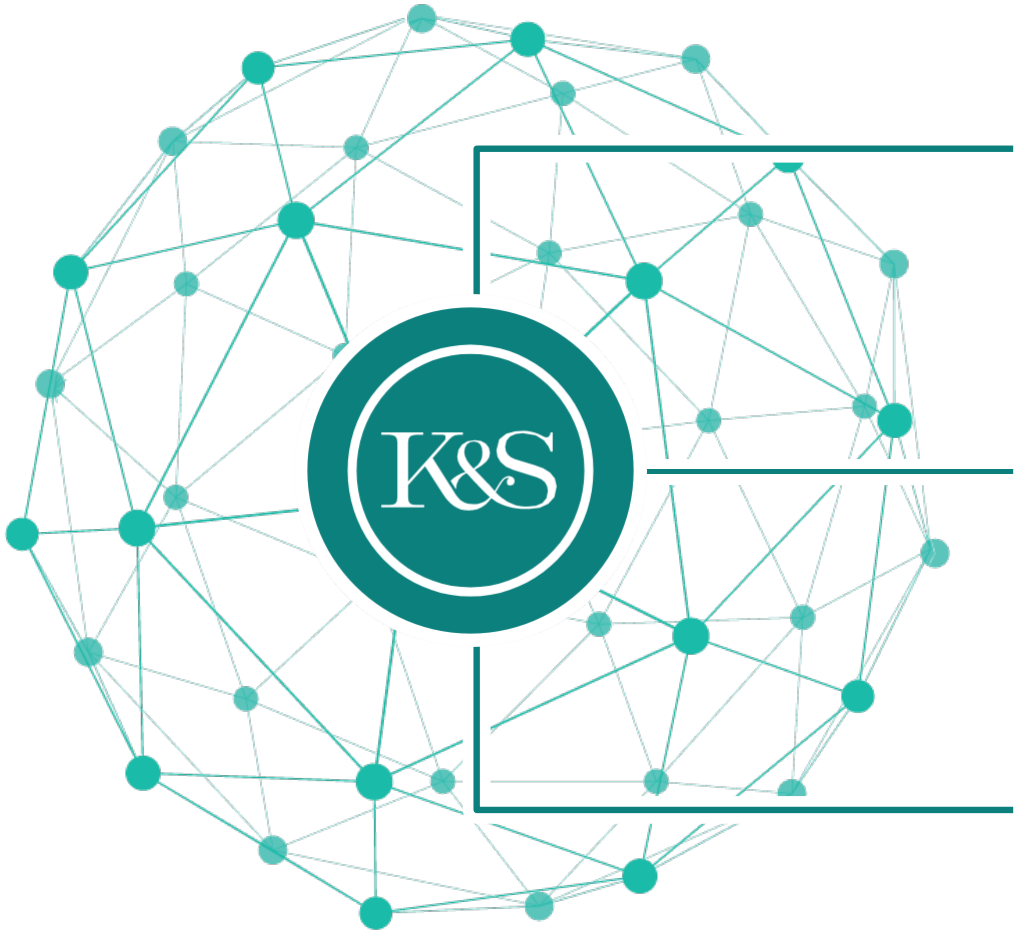
Clearing considerable safety hurdles in hormone replacement therapy (HRT), TherapeuticsMD, an emerging pharmaceutical company, partnered with King & Spalding to obtain FDA approval and commercially launch its first two products. One is the very first FDA-approved bioidentical combination hormone therapy, for which demand is significant. K&S has also assisted the company with in-licensing a commercially complementary contraceptive and out-licensing its HRT products, adding a significant revenue stream in global markets.

Resuming Infusion Pump Sales Post-Probe for Medtronic

Restoring its compliance profile and representing a significant milestone, the most significant restrictions imposed by an FDA Consent Decree of Injunction related to Medtronic's SynchroMed II Infusion Pump were lifted, following a coordinated effort by Medtronic and King & Spalding to address the decree's numerous restrictions and requirements. Serving as lead counsel, K&S negotiated the highly publicized decree to resolve alleged manufacturing and quality system deficiencies concerning the pump, and managed all related FDA communications and decree-required activities. Resolving all major concerns, Medtronic resumed normal operations and the unrestricted manufacture and distribution of its infusion pump devices.

Life Sciences: Strength at a Glance.

Industry Knowledge + 360 Insights + Global Platform = Better Client Solutions



INDUSTRY LEADERS

- 250+ life sciences clients
- Representing the top 50 U.S. pharma, biotech and medical device manufacturers

+

DEDICATED PRACTITIONERS

- 350+ cross-practice lawyers collaborating to serve industry goals
- 125+ lawyers with prior government experience; 30+ M.D.'s, Ph.D.'s and others with advanced medical, scientific, and technical credentials

+

COMPREHENSIVE GLOBAL PLATFORM

- Capabilities at each stage of the product and corporate life cycles
- Integrated regulatory, litigation, and transactional solutions

Industry Events Advancing Thought Leadership.

Medical Device Summit

- Sought-after compass for rapidly evolving regulatory landscape for 150+ industry stakeholders
- Senior government officials and others mapping upcoming challenges

West Coast Pharmaceutical and Medical Device University

- Strategic networking with 100+ West Coast counsel, execs, compliance pros and other stakeholders

Pharmaceutical University

- 10+ years-strong, pharma law summit
- 350+ sophisticated industry speakers and participants

Life Sciences Roundtable

- Webinars on cutting-edge topics impacting life sciences clients
- Industry-leading practitioners with deep knowledge offering 360-degree perspectives

Recognized Achievement in Life Sciences and Healthcare.

The firm and our lawyers and practices consistently garner market recognition for our work with and on behalf of life sciences clients.

Practice Group of the Year (Multiyear)

- Life Sciences
- Healthcare
- Product Liability

King & Spalding: Firm of the Year

— LAW360

Corporate Crime & Investigations
Government Relations
Healthcare: Pharmaceutical/Medical Products Regulatory
Product Liability & Mass Torts

— CHAMBERS USA

FDA Law
Healthcare Law

— U.S. NEWS & WORLD REPORT BEST RANKINGS

Corporate Investigations and White-Collar Criminal Defense
Life Sciences
Product Liability, Mass Tort and Class Actions: Pharmaceuticals and Medical Devices - Defense

— LEGAL 500 US

Healthcare: Pricing & Reimbursement
Licensing & Collaboration
Medical Devices Regulatory
Pharmaceuticals Regulatory
Product Liability & Recall
White-Collar/Government Investigations

— LMG LIFE SCIENCES

Coronavirus Task Force.

King & Spalding mobilized the Coronavirus Task Force as the 2019 Novel Coronavirus (COVID-19) continues its rapid proliferation across the globe with complex and widening implications. The FDA and Life Sciences practice has advised clients on a range of issues, including:

Emergency Use Authorization ("EUA")

Navigating FDA expectations and preparing applications regarding the urgent development of novel products for potential treatment of COVID-19, including blood-related therapies, as well as medical devices for rapid diagnosis of SARS-CoV-2 infection under EUA

Contracts

Counseling on contractual issues relating to supply chain impacts, such as enforceability of force majeure agreements

Operational Issues

Counseling clients on FDA Quality System and GMP-related issues

Clinical Trials

Expediting the conduct of clinical trials related to potential COVID-19 therapeutics and vaccines, including the potential interface with NIH and BARDA

Regulatory and Public Health Compliance

Assisting with compliance of FDA regulations during the Coronavirus pandemic; compliance with shelter-in-place orders and qualification as essential infrastructure

Supply Chain

Advising on supply chain disruptions impacting manufacturing, product distribution and U.S. and EU regulatory compliance

Coronavirus Task Force: Experience.

- Counseling life sciences clients on FDA expectations and preparing applications regarding the development of novel products for potential treatment of COVID-19, including blood-related therapies.
- Assisting global medical device manufacturers in obtaining Emergency Use Authorizations pursuant to FDA enforcement policy for invitro diagnostic for the detection and/or diagnosis of COVID-19.
- Advising global clients from other industries on obtaining Emergency Use Authorization and the manufacturing of Personal Protective Equipment and ventilators under FDA enforcement policies.
- Analyzing potential tort immunity for swabs, face shields and potentially face masks for a teledentistry company under the PREP Act.
- Advising and assisting a medical equipment manufacturer with CARES Act and the SBA loan process.
- Assisting a global pharmaceutical manufacturer with legal and regulatory counseling on matters relating to the Coronavirus epidemic.
- Counseling a medical technology company involving DPA requirements following the White House announcement.
- Representing a blood collection and distribution center on federal contracting issues related to COVID-19—namely, invoking a provision in its federal contract ("Excusable Delays") that excuses non-performance of the contract in certain extreme circumstances, including epidemics.
- Advising numerous manufacturers, distributors and other life sciences companies on federal and state government procurement issues in the context of the COVID-19 pandemic, including the assessment of and development of responses to government solicitations (*i.e.*, RFPs) and other funding opportunities, negotiation of federal and state government contracts under emergency procurement procedures, compliance considerations related to pandemic contracting, operation and application of the Defense Production Act and the intersection between FDA regulatory requirements and government procurement opportunities.

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