

Morgan Lewis

advancing life sciences and
healthcare innovation

life sciences and healthcare



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morgan lewis fast facts

firmwide

Among the top 20 largest law firms in the world

Ranked as one of the top law firms in *Corporate Counsel* magazine's 2010 listing of "Who Represents America's Biggest Companies?"

life sciences/healthcare industry

More than 150 partners and counsel focused on the life sciences/healthcare industry

Nearly 50 professionals with advanced scientific degrees

Nearly 900 active life sciences/healthcare clients

honors

PLC *Cross-border Quarterly* 2011 Life Sciences Legal Market Review: **Regulatory Super League** – Ranked #10 among law firms worldwide

PLC *Cross-border Life Sciences Handbook* 2011
U.S. – recognized for commercial/partnering, competition/antitrust, corporate, government enforcement/investigations, regulatory, regulatory (medical devices)
England – recognized for regulatory
Japan – recognized for corporate/commercial

Chambers USA 2011: Ranked nationwide for Life Sciences and ranked in Washington, D.C. for Healthcare and Pharmaceuticals/Medical Device Regulatory

UK Legal 500: London: Pharmaceuticals and Biotechnology – highest tier

BioPharm Insight: Top five ranking in the North American, European, and global licensing agreements categories

clients

16 of the top 20 pharmaceutical companies

7 of the top 20 biotechnology companies

9 of the top 20 medical device companies



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what does our experience mean to your company?

Morgan Lewis has become a comprehensive resource for companies developing and marketing life sciences and healthcare products and services.

We are consistently ranked among the top 20 life sciences/healthcare practices in the world.

What sets us apart is our capability to serve clients throughout the complete product life cycle and in all aspects of the healthcare industry.

Nearly 900 life sciences/healthcare clients profit from insights that can be gained only in a practice that touches all aspects of the industry. Clients include every type of company regulated by the Food and Drug Administration and the Centers for Medicare and Medicaid Services.

More than 150 Morgan Lewis partners and counsel – together with nearly 50 professionals with advanced scientific degrees – devote their practices to helping life sciences and healthcare companies achieve their business goals.

FDA and healthcare regulatory capability is a core strength of our practice – from obtaining product approvals to teaming with our lawyers in other practice areas on domestic and global transactions and litigation.

Our international reach touches the United States, Asia, and Europe, enabling us to assist in European and, together with our joint venture firm TMI Associates, Asian life sciences matters.

Representing all facets of the life sciences/healthcare industry – including established and emerging companies, product manufacturers and healthcare providers, and U.S. and non-U.S. entities – gives us a breadth of experience that benefits all of our clients.



17% of the firm's practice is devoted to the life sciences/healthcare industry

protecting the complete product life cycle

For life sciences companies, business, science, and law are inextricably linked. Our practice recognizes that regulatory compliance, intellectual property protection, and business and litigation strategies must move together, or none will succeed. Our lawyers work together seamlessly to ensure that when you have a question, our answer addresses the needs of our clients on all fronts.

Emerging Growth and Finance

- Corporate Structuring
- Tax Structuring
- Financing Arrangements
- Equity Investments
- Venture Capital
- Private Placements
- Public Offerings
- Royalty Monetizations

Intellectual Property Strategy

- Patent, Trademark, and Copyright Protection
- FDA and European Market Exclusivity, Including Orphan Drug/Pediatric
- IP Portfolio Strategic Management
- Technology Transfer
- Due Diligence
- Freedom to Operate Opinions
- Oppositions
- Infringement and Design-Around Counseling

Research and Development

- Good Laboratory Practices
- Clinical Trials Strategy
- Good Clinical Practices/Audits
- Sponsored Research Agreements
- Informed Consents
- IRB Review/Negotiation
- IND/IDE and CTA Submissions and Regulatory Meetings
- Codevelopment Agreements
- Clinical Trial Agreements
- Material Transfer Agreements
- Trade Name Approval
- Reimbursement/Coverage Issues

Regulatory Approval

- NDA, BLA, 505(b)(2), Biosimilars, PMA, 510(k), GRAS, FCN, and European Product Approval/Clearance Submissions
- Regulatory Pathway Strategy
- Scientific/Regulatory Disputes
- Legislative/Patient Group Advocacy
- FDA Panel Review Strategy
- International Product Approval Strategy



Pricing and Reimbursement

Global Marketing and Operations

Litigation and Investigations

Collaborations and M&A

- Medicare/Medicaid/DoD/VA/TRICARE Procurement Requirements
- CMS/State Coding/Coverage/Reimbursement (Products and Services)
- CMS Hearings and Appeals
- Government Program Exclusion, Debarment, and Penalties
- Price Discrimination
- Market Competition Issues/Pricing
- CMS Program and Compliance Integrity Agreements

- Advertising/Promotion/Labeling/Sampling
- Patent Extension
- Distribution Arrangements
- Social Media
- Product Modifications
- Postmarketing Studies
- Good Manufacturing Practices
- Postmarketing Reporting
- Recalls and Crisis Management
- Compliance Programs/Enforcement
- Labor and Employment
- Employee Benefits
- Immigration
- Real Estate Transactions
- HIPAA Privacy and Security

- Fraud and Abuse/False Claims Act Investigations/Litigation (Internal and OIG/DOJ)
- Payor/Insurer Litigation
- IP Litigation
- Commercial Litigation
- Competition/Pricing Investigations and Litigation
- Hatch-Waxman Patent Litigation
- Product Liability Counseling and Litigation
- Unfair and Deceptive Practices Litigation
- FTC/State Consumer Protection Investigations
- False Advertising Litigation/NAD Proceedings
- Insurance Recovery Litigation
- Employment Litigation
- Foreign Corrupt Practices Act/Anti-bribery investigations

- Mergers and Acquisitions
- Joint Ventures
- Collaboration Agreements
- Corporate Partnering Agreements
- Copromotion and Comarketing Agreements
- Contract Sales Agreements
- Manufacturing and Supply/Quality Agreements
- Outsourcing Agreements
- Tax/Transfer Payments

serving all aspects of the healthcare industry

Our multisector focus enables us to serve all aspects of the healthcare industry in all areas: regulatory, compliance, enforcement, transactions, investigations, and litigation. We regularly work with all types of healthcare providers, including hospitals and healthcare systems; health plans and insurers; pharmacies; physician practices; specialty, rehabilitation, and long-term care facilities; academic medical centers; GPOs; and ACOs; as well as suppliers and distributors.

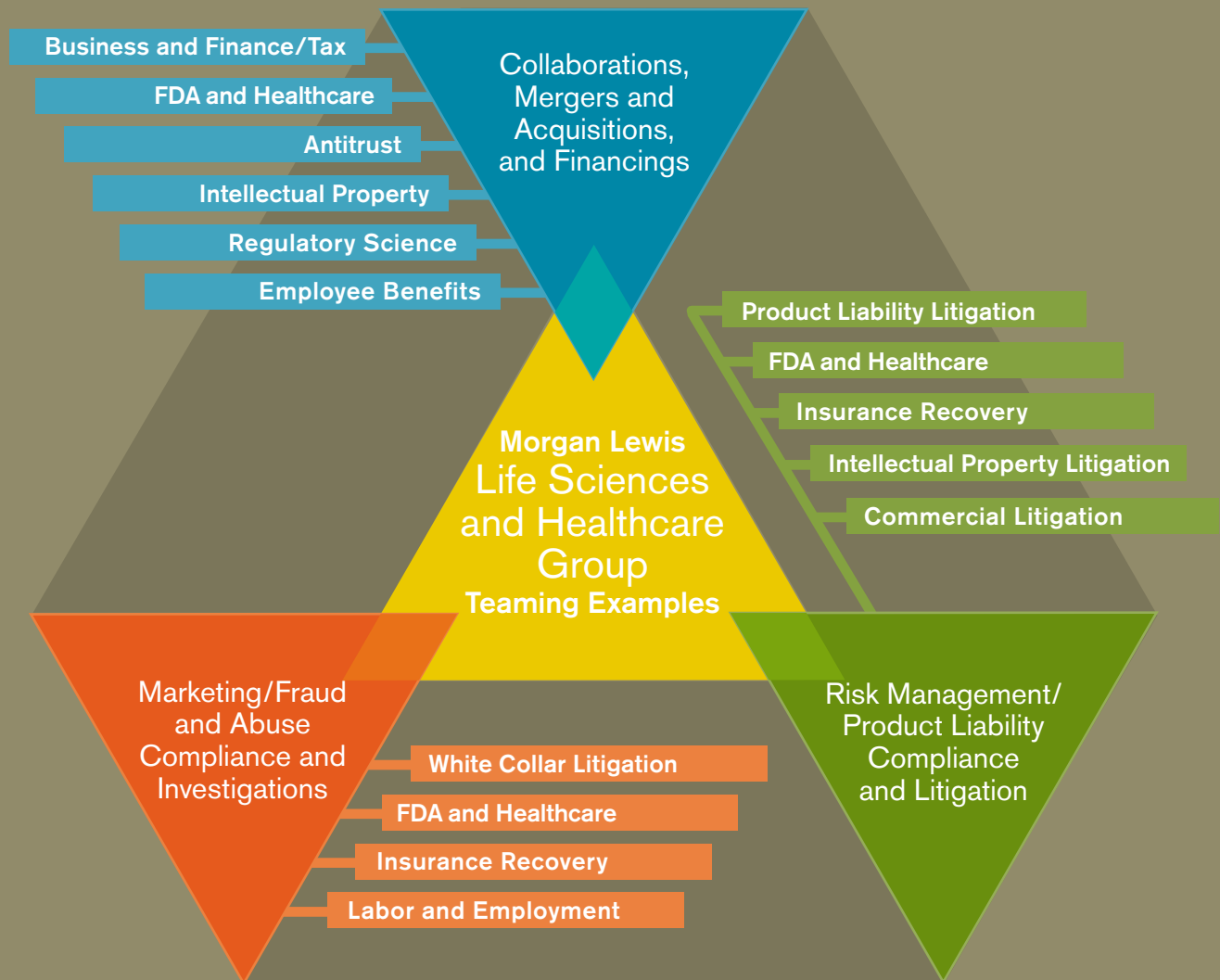




By 2019, healthcare is expected to account for 19.6% of the U.S. gross domestic product.
source: CMS

our multipractice teaming approach

The scale and scope of our Life Sciences and Healthcare Group allow us to respond efficiently by integrating all relevant practice areas.



together

international

Beijing
Boston
Brussels
Chicago
Dallas
Frankfurt
Harrisburg
Houston
Irvine
London
Los Angeles
Miami
New York
Palo Alto
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Tokyo
Washington, D.C.
Wilmington

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