

## LIFE SCIENCES & MEDICAL DEVICES

### AT A GLANCE

Your business is life sciences, pharmaceuticals and medical devices. Our business is to provide legal services to advance your business and product lines. Our lawyers on two continents guide your company, financiers, partners and customers to resolution of the critical legal issues involved in product development and marketing. Whether you develop or market branded products, or support, finance or acquire life science and device companies, we work with you to shape strategies that are realistic, effective and compliant.

### Experience

Our team focuses on your product. Through each stage of your company's business and product development, our approach is to match our lawyers and skills to your specific product development needs.

*Pre-clinical development:* New companies need corporate structuring and financing as well as tax, executive compensation and operating advice. Securing and developing intellectual property rights are critical. Our extensive work with scientific entrepreneurs both in and out of academia, serving as regulatory, patent and finance counsel, distinguishes our life sciences services from those of other firms. We are especially attuned to the sensitive economic and political issues associated with technology and other inventions originating in a university or medical center, and are uniquely equipped to effectively advance, protect and capitalize on those inventions as your company engages in pre-clinical research and development.

*Clinical trial development:* While planning and conducting global phase I-IV clinical trials, life sciences and device companies face business challenges with complex legal and regulatory implications. These include subject recruitment, privacy, informed consent practices, study design and Institutional Review Board management, conflicts of interest, and U.S. Food and Drug Administration (FDA) classification and approval requirements for emerging products. Our lawyers support you with practical legal advice consistent with your business objectives. Also during this development phase, we advise life science and device companies, private equity firms and investment banks as they embark on initial public offerings and secondary offerings. Our corporate/securities law experience, combined with our intellectual property, FDA and health regulatory experience, uniquely positions us to advise on disclosure matters and corporate governance issues, as well as regulatory issues and related contracting matters with clinical trial research sites.

*Post-approval development and marketing:* To carry your product to the market, we develop strategies for a successful product launch. Our experience includes identifying and securing product reimbursement codes; regulatory post-product approval compliance; implementing effective and compliant sales and marketing programs; and developing relationships with third-party insurers, wholesalers, pharmacies and physicians. We defend against enforcement challenges in these matters, including investigations by the U.S. Department of Justice, the Office of the Inspector General and associated *qui tam* suits. We further enforce your intellectual property and defend your product against challenges. Our trial lawyers handle complex litigation including class actions and product liability suits, and we simultaneously handle your ever-present financing, corporate and international tax needs.

### Scope of Services

#### CORPORATE, FINANCE AND TAX

- Mergers and acquisitions
- Licensing and collaborative arrangements
- Cross-border and transfer tax planning

#### HEALTH CARE STRATEGY, REGULATION AND POLICY

- Compliance planning
- Reimbursement counseling
- False claims and anti-kickback defense (civil and criminal)
- Regulatory agency representation

#### INTELLECTUAL PROPERTY

- Protection and enforcement litigation
- Portfolio strategy
- Patent prosecution and interference
- Trademark, copyright and trade secret protection

#### RESEARCH

- Clinical trial structuring and coordination
- Research strategies and compliance
- Database and outcomes analysis

### Our Team

75+ lawyers

### Contacts

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## International Reach

McDermott offers fully integrated services in Europe and the United States. Our clients range in size from the world's largest pharmaceutical, medical device and biotechnology companies to start-ups. We also serve academic medical centers and other institutional providers, physician groups, universities and investment banking and venture capital firms involved in life science product development and marketing. We practice before the Supreme Court of the United States and other courts of appeal, and before European national courts (including the European Court of Justice), the International Trade Commission, international arbitration forums and panels, the European Commission, the European Medicines Agency, and EU Member State and U.S. regulatory agencies. We work with EU colleagues on cross-border data matters in the context of clinical trials, research and post-approval observational registries.

## Hot Topics

Our life sciences team regularly assesses trends in the industry.

- Stem cell procurement, reproductive technologies and related processes
- Defense of civil and criminal false claims actions involving marketing and pricing practices
- Biologic generics
- Research program development, reform and compliance
- Bioinformatics and associated data mining in accordance with U.S. and European privacy laws
- Tissue and data repository development and procurement, and related secondary research
- Managing recalls for implantable medical devices
- Royalty stream private equity financing techniques
- Tax treatment of milestone payments and cross-licensing arrangements

## Awards & Recognition

Our life science and biotechnology practice is globally recognized.

- Ranked among the top firms in the United States in the area of life sciences – *Chambers USA* 2009
- Among the world's top biotechnology and life sciences patent firms – *Managing Intellectual Property* 2009
- McDermott partners ranked as leaders in biotechnology law – *The Best Lawyers in America* 2009
- Recognized for life sciences in the United States – *PLC Which Lawyer? Yearbook* 2008
- Top-tier health care practice in California, Florida, Illinois, Massachusetts and Washington, D.C. – *Chambers USA* 2009.

## Our Firm

McDermott Will & Emery is a leading international law firm with a diversified business practice. We represent a wide range of commercial, industrial and financial enterprises, both publicly and privately held. Our clientele include some of the world's largest corporations, small and medium-sized businesses, and individuals.

Currently numbering 1,000 lawyers, we have offices in Boston, Brussels, Chicago, Düsseldorf, Houston, London, Los Angeles, Miami, Milan, Munich, New York, Orange County, Rome, San Diego, Silicon Valley and Washington, D.C. McDermott Will & Emery has a strategic alliance with MWE China Law Offices (Shanghai).