

DyKEMA

Exceptional service. Dykema delivers.



As innovative as the industry itself
Pharmaceutical and Medical
Products Industry Group

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California | Illinois | Michigan | Minnesota | Texas | Washington, D.C.

Overview

Pharmaceutical and medical products industry participants are faced with an unusually diverse set of legal challenges. For this reason, Dykema draws the members of its Pharmaceutical and Medical Products Industry Group from across the major practice areas of the Firm—providing drug, device, medical facility, provider, diagnostic and biotechnology companies, whether public or private, large or small, the comprehensive legal counsel they need to succeed. The lawyers in Dykema’s Pharmaceutical and Medical Products Industry Group always proceed with a full appreciation and understanding of how the various practice areas can and do influence and affect one another—providing pharmaceutical and medical products clients with a legal partner upon whom they can confidently rely.

Bringing together a deep technical, scientific and legal understanding of the complexities of the various industry sectors, we are uniquely positioned to help pharmaceutical and medical products clients identify opportunities and innovative ventures that allow companies to grow and prosper while, at the same time, fending off litigation risks and legal challenges that can impair a company’s focus and deprive it of critical resources. Dykema’s “excellent breadth and depth of knowledge” of client business objectives (*Chambers USA*) enables the Firm to provide the full range of strategic, cost-effective and customized business services to our clients. Dykema’s team of “tremendous” and “well prepared” litigators (*Chambers USA*) provides our pharmaceutical and medical products clients with high quality and high value litigation, trial, and appellate, and risk counseling services.

Dedication to client service and attention to detail have made Dykema a firm of choice to industry leaders, including prescription and OTC drug manufacturers, device manufacturers, biotechnology companies, medical facilities and others. Covering the industry, our representation includes: product liability defense; antitrust and trade regulation; commercial litigation; consumer protection; governmental investigations and white collar defense; corporate and finance; employment related matters; government policy; intellectual property; real estate; and regulatory and

compliance counsel. In addition, our litigators have extensive and deep experience defending bet-the-company class actions—from inception through multiple levels of appeal—and serving in the role of national or regional counsel for pharmaceutical companies and other clients facing potential nationwide liability in mass tort litigation.

National/Regional Litigation Counsel Services

Dykema has a leading practice as national and regional coordinating, trial and discovery counsel. With 12 offices in California, Illinois, Michigan, Minnesota, Texas and Washington, D.C., a fully mobile workforce and lawyers licensed to practice in multiple jurisdictions, Dykema is well positioned to handle legal work throughout the United States. Dykema trial lawyers have tried cases and arbitrated disputes in more than 35 states and the District of Columbia—from coast to coast—and beyond to Hawaii and Alaska.

We know that our clients’ business objectives must drive strategy decisions and that even the best strategy, if inconsistently or blindly followed, is a poor one. For these reasons we work closely with our clients to understand fully their businesses, goals, litigation histories and risk profiles to develop strategies that best further their specific interests. In the role of national or regional counsel, we standardize work product to the furthest extent feasible, and learn how and where our clients maintain discoverable documents, ultimately culling out, organizing and storing electronically a master document repository for all related lawsuits, eliminating redundant activities that can disrupt business and drive up legal costs.

Product Liability and Related Claims

We have a long history with the industry, providing a legal and a scientific perspective that is crucial when it comes to high-profile product liability matters that may impact a company’s reputation and bottom line. Having been repeatedly retained as national counsel for science



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and expert witnesses, Dykema attorneys combine a thorough understanding of the medical and scientific issues with exceptional legal judgment to develop proactive and creative steps to anticipate, avoid and minimize the potential impact of litigation. Should litigation ensue, the Dykema team is well positioned to analyze and formulate a comprehensive science-based strategy and to identify, retain and prepare the highly qualified expert witnesses necessary to mount the best possible defense.

When trial proves to be the best path to resolution, Dykema lawyers have deep first chair trial experience that few firms can match.

From the initial threat of mass tort litigation involving a drug or medical device to the resolution of the final pending case, Dykema attorneys know the science, the law and the strategies necessary to minimize risk and to maximize results.

Commercial Litigation

With decades of experience in commercial litigation—from administrative actions to complex multistate matters—Dykema’s trial attorneys bring seasoned professionalism

to the courtroom in business and commercial matters. Our strong commercial litigation practice includes arbitrators, mediators, trial and appellate counsel, and consultants. We have litigated matters pertaining to business breakups, contracts, warranties, Uniform Commercial Code issues, securities, real estate and virtually every other type of commercial or business dispute imaginable.

Helping our clients stay out of court by limiting or preventing liability is a key element of our approach to business disputes. To support fully our clients and their business needs, Dykema attorneys always explore with clients the risks and benefits of all available strategies, such as creative alternative dispute resolution methods, mediation, arbitration and/or settlement.



Consumer Protection, Fraud and Abuse

In recent years, pharmaceutical and medical product companies have been faced with a growing number of consumer protection and fraud claims, both by governmental agencies and civil complainants, often in the form of class actions. All too often pharmaceutical companies and other clients are confronted with government investigations and challenges running parallel to class actions and *qui tam* suits. When faced with these intense situations, Dykema attorneys knowledgeable in regulatory and administrative law team with our healthcare, government policy and litigation attorneys covering all the bases. We represent our clients in all aspects of these redundant proceedings, working closely with our clients to make this often harrowing experience bearable and short-lived.

Class Actions

While defending any lawsuit can place a strain on a business, class actions magnify this risk. That’s why when a business is hit with a class action lawsuit, it needs Dykema—a leading class action defense firm with an enviable record of success in defending high-stakes pharmaceutical class actions.

Our lawyers excel in effectively and efficiently handling all aspects of class action defense—from initial analysis and investigation to pleading challenges, pre-emptive motions to strike, discovery, opposing certification, trial and appeal. Dykema lawyers have a proven record of developing and employing strategies to resolve class actions before certification and trial. For those matters not resolved on the pleadings, our lawyers use solid strategies to achieve settlements favorable to our clients, while keeping client expense at a minimum. When it is not possible to end a class action before trial on terms satisfactory to our clients, we have “tremendous” and “very skilled” litigators (*Chambers USA*, 2011 and 2012) with strong first chair jury trial experience that few firms can match. It is no surprise that we have obtained positive outcomes in many class actions against major drug and medical product manufacturers, as well as biotechnology companies.

Intellectual Property, Technology, Licensing and Related Litigation

Business success and growth in the pharmaceutical and medical products field often depends on a company's ability to safeguard invaluable intellectual property (IP).

Dykema's IP attorneys have the breadth of legal, technical and scientific knowledge and experience to counsel clients in all aspects of the procurement, management and enforcement of IP rights. Considered a "go-to" law firm for intellectual property by General Counsel at America's top companies, Dykema delivers strategically focused solutions across the life cycle of intangible IP assets.



By helping our pharmaceutical and medical products clients protect their IP assets, we help them achieve and maintain competitive market advantages. Our attorneys—many of whom are registered with the U.S. Patent and Trademark Office—draw on technical backgrounds in fields such as chemistry, biochemistry and molecular biology to provide exceptional representation to industry clients.

Our comprehensive services include preparing and prosecuting U.S. and foreign patent applications, copyrights and trademarks; drafting and negotiating confidentiality, proprietary rights, distribution, manufacturing, sales, licensing, collaboration and technology transfer agreements; and representing both plaintiffs and defendants in IP litigation.

Antitrust and Trade Regulation

Dykema's antitrust and trade regulation lawyers help our pharmaceutical and medical products clients avoid antitrust and trade regulation problems and, where unavoidable, resolve them as expeditiously as possible. To this end, we help clients structure their transactions, business relationships, sales practices and internal processes to steer clear of all antitrust and trade regulation problems.

When challenged, we represent clients in state and federal regulatory investigations and related proceedings—knowledgeably interacting with regulators to bring such matters to successful closure. And our experienced

litigators handle all aspects of antitrust and trade regulation cases—having first-chaired major antitrust and trade regulation actions—including precedent-setting cases in state and federal trial and appellate courts across the United States involving issues of international jurisdiction, monopolization, mergers and various restraints of trade.

Our attorneys have held leadership positions with the U.S. Department of Justice, the Federal Trade Commission (FTC), the staff of the United States Senate Judiciary Subcommittee on Antitrust and Monopolies, and in state and national professional associations. Our experience within the regulatory environment provides an enhanced perspective, benefiting our pharmaceutical and medical products clients through more effective regulatory negotiations, litigation tactics and strategic advice.

Corporate Finance

We represent pharmaceutical, medical products, diagnostic and biotechnology company clients on the full spectrum of transactional matters, from initial entity formation, mergers, acquisitions and IPOs to venture capital, angel, and other debt and equity financings. We are as creative as the pharmaceutical and medical products industry when it comes to helping our clients explore innovative strategic alliances, joint ventures, partnering arrangements, and research and development collaborations.

Employment and Operational Matters

We provide complete employment, labor, employee benefits and executive compensation counsel to our clients—from executive contracts and compensation to employee stock option plans, and from confidentiality and non-competition agreements to compliance with federal and state employment and labor laws. For clients facing immigration issues, we can help with the issuance of H1-B visas to foreign professionals.

We also can help clients with their general operational legal needs, such as corporate governance, tax, insurance and contracting issues.

From the initial threat of mass tort litigation involving a drug or medical device to the resolution of the final pending case, Dykema attorneys know the science, the law and the strategies necessary to minimize risk and to maximize results.

Government Policy

Dykema can help clients formulate and execute efficient government policy strategies that get real world results. Our government policy lawyers and regulatory advisors offer guidance on state and national legislative matters that impact the pharmaceutical and medical products industry, as well as on such issues as government contracts, grants, research agreements, export control and technology transfers.

Through our many years on Capitol Hill and working with many federal and state agencies, we have developed a deep and solid understanding of the inner workings of both federal and state governments, and formed close relationships with many high-ranking officials, lawmakers and staff. We maintain those relationships with integrity and credibility—which translates into substantial value to our clients.

Real Estate and Facilities

Our Pharmaceutical and Medical Products Industry Group includes members from Dykema's nationally-recognized real estate practice (*Chambers USA* and *Midwest Real Estate News*) to help our clients with their facility projects—providing both legal and strategic guidance to ensure projects are timely completed in a cost-effective manner. Clients wishing to expand and grow their companies benefit from solutions that address their building, construction and leasing and/or equipment purchase and leasing needs. In addition, the wide ranging experience of Dykema's professionals in the real estate, environmental, health care and tax groups allows our pharmaceutical and medical products clients to confidently rely on Dykema as their sole source of legal services for all aspects of their important projects.

Regulatory and Compliance

Pharmaceutical and medical product manufacturers are among the most highly regulated and closely scrutinized industries today—making regulatory compliance and documentation of such compliance a priority for every industry participant. Experienced in the wide range of health care issues that impact the pharmaceutical and medical products industry, we help our clients to file applications for FDA approval and address complex FDA compliance issues; comply with Medical Device Reporting requirements; resolve clinical research issues, including preparation and negotiation of clinical trial agreements and informed consents; obtain licenses; and

resolve HIPAA issues. If the need arises, we also advise clients with adverse event reporting issues.

Dykema lawyers are well versed in the federal and state consumer protection statutes and other laws governing product marketing in the pharmaceutical and medical products industry. Along with compliance advice in this area, we provide our clients preventative counseling and proactive risk avoidance strategies that save clients not only time and money, but business disruption and anguish.

When the need arises, we competently represent clients in state and federal agency investigations, as well as defend them throughout enforcement and other regulatory proceedings. We work closely with our clients to bring such matters to an expeditious, cost-effective resolution. We also have an exemplary track record defending clients against allegations of white-collar crime that can arise in this closely watched industry.

The Dykema Difference

What distinguishes Dykema is our unparalleled commitment to client service delivered through our “my client, my partner” approach to the practice of law. Dykema hires and retains the best and the brightest talents and instills in all Dykema attorneys and every other employee our signature unyielding commitment to client satisfaction. When we say we “partner with our clients,” we do it. Our attorneys are passionate about knowing and understanding our clients' businesses, markets and challenges. If it keeps you up at night, we don't sleep either. Through focused industry groups—such as the Pharmaceutical and Medical Products Industry Group—our attorneys study all aspects of their clients' industries. Bottom line: we make it our business to know your business.



From the courtroom to the boardroom and beyond, our lawyers deliver unparalleled client service, outstanding results and exceptional value in every engagement.



Exceptional service. Dykema delivers.

Dykema is a leading national law firm, serving businesses worldwide on a wide range of complex business issues. For outstanding results, unparalleled service and exceptional value: Dykema delivers.

Unparalleled Client Service

We stand behind our promise of superior service with a comprehensive set of principles and approaches developed consistent with the Association of Corporate Counsel's Value Challenge and our own century of experience. Dykema's Client Service Standards represent our pledge not to meet, but to exceed, client expectations.

Outstanding Results

At the first sign of possible product liability claims, Dykema attorneys have repeatedly demonstrated their ability to quickly develop a thorough understanding of the complicated medical and scientific issues and to use this knowledge to help clients anticipate, avoid and minimize the threat and potential impact of litigation. This knowledge base also allows Dykema attorneys, working in partnership with the client, to formulate the best factual and science-based defense strategy and to be ready to implement this strategy should litigation ensue.

Our litigators are widely known as fierce and successful advocates. They are the "go-to" trial lawyers for business, and have successfully handled virtually every type of civil dispute and white collar criminal defense. Our transactional lawyers are equally as well known for their tenacity, practicality and excellence in achieving client goals.

Exceptional Value

Our vast experience, sophisticated level of practice and industry-leading technology synergize to provide Dykema the ability to give our clients the fullest range of services at exceptional value without jeopardizing quality or effectiveness. Our professionals, in turn, turn that ability into reality, delivering extraordinary value to every client in every engagement.

Dykema is committed to delivering clients the best in service, results and value, and that is what Dykema delivers: our best, today, tomorrow and every day. That is the Dykema difference.