Hollingsworth LLP
Litigation Matters.®

Pharmaceutical & Medical Device

Handling high-stakes cases for the most prominent pharmaceutical and medical device manufacturing companies in the world.

With product liability lawsuits escalating the past two decades, Hollingsworth LLP has represented pharmaceutical and medical device manufacturing clients in some of the most challenging and high-stakes litigation in the country, and, as a result, our clients have enjoyed broad and widely-recognized success. Our lawyers are among some of the most experienced in the nation—they write articles, give speeches, and teach—but mostly, they litigate and *try* cases.

We handled some of the leading published federal trial-level and appellate-level cases on issues critical to the pharmaceutical industry, such as those involving the admissibility of expert testimony. *The National Law Journal* has recognized three of those cases as Top Defense Wins:

- *Crowson v. Davol, Inc.*—the first jury trial in the U.S. involving allegations that hernia-repair mesh can cause infertility.
- *Glastetter v. Novartis Pharm. Corp.*—one of our *Daubert* summary judgment victories recognized as a top win without trial (and subsequently affirmed by the Eighth Circuit, it stands as one of the industry's most important *Daubert* rulings to date).
- *Warren v. Sandoz Pharm. Corp.*—our defense verdict in a jury trial in southern Mississippi.

Our work on behalf of our pharmaceutical and medical device clients has given us significant experience handling complex issues such as:

- rapidly evolving medical literature
- scientific and medical fields of epidemiology, toxicology, neurology, cardiovascular disease, and obstetrics
- chemical structure analyses
- biochemical mechanisms of action
- anecdotal evidence
- putative corporate admissions
- broad regulatory oversight
- international and domestic adverse drug reaction reporting
- withdrawal of indicated use in the United States

With strong support systems that enable us to successfully handle large-scale cases, we coordinate and control massive discovery efforts of international scope through our in-house, lawyer-managed technology and related staff. We track world literature through Washington's National Institutes of Health and National Library of Medicine; we assemble teams of renowned, world-class experts; and we have developed an outstanding network of regional and local counsel in jurisdictions all over the country.

Since 1988, we have hosted our highly regarded Annual Seminar on Complex Litigation Defense, which showcases leading defense practitioners who share cutting-edge legal theories and strategies developed while defending high-stakes cases.

PHARMACEUTICAL PRODUCTS LITIGATION
Hollingsworth LLP is national trial counsel to one of the world's largest pharmaceutical manufacturers in nationwide products liability claims involving cancer therapies and drugs treating a variety of non-cancer conditions, including ophthalmologic and obstetrical drugs. Notable cases we have handled include:

- The successful defense of the cancer medicines Zometa® and Aredia® in federal multidistrict litigation (*In re Zometa® and Aredia® Products Liability Litigation*, MDL No. 1760) and state court consolidation in New Jersey (*In re: Zometa®/Aredia®*, MCL No. 278). At one point, more than 1,000 claims were pending against our client alleging that these medicines—used to strengthen the bones of patients with metastatic cancer—caused a "signature injury." During our decade-long defense of these cases, we obtained complete defense verdicts in nine of the fourteen cases taken to trial, with juries awarding modest amounts to plaintiffs in several of the cases where we did not prevail outright. Those trial victories occurred all over the country from Florida to California. Two of those trials, both complete defense verdicts, were the only cases tried in the New Jersey state court proceedings: *Bessemer v. Novartis Pharm. Corp.*, No. MID-L-1835-08-MT and *Meng v. Novartis Pharm. Corp.*, *Meng v. Novartis Pharmaceuticals Corp.*, No. MID-L-7670-07-MT. Hollingsworth LLP disposed of more than 110 cases pre-trial; more than 40 cases settled under the weight of upcoming trials, pending discovery motions, or pending dispositive motions; and plaintiffs dismissed more than 150 cases voluntarily during the consolidated proceedings. On appeal, the firm prevailed on behalf of its client in thirty of thirty-five appeals pursued by the parties. After a decade of litigation, the firm was able to procure favorable confidential resolution of all remaining claims.
- The successful defense of the medicine Parlodel®. The claims—which generally involved severe neurological or cardiovascular injuries, including stroke, seizure, and myocardial infarction—provoked intense media coverage and presented complex issues of medical causation, liability, and FDA regulation. We successfully tried casesin diverse, difficult forums from coast to coast and succeeded in upholding our defense verdicts on appeal. We also won many significant cases on summary judgment,successfully defended those judgments on appeal, and successfully litigated in the context of extensive Rule 706 proceedings. We prevailed on appeal in three cases that fleshed out the application of *Daubert* in the specific factual context of those cases—*Glastetter v. Novartis Pharm. Corp.*, *Rider/Siharath v. Sandoz Pharm. Corp.*, *Hollander v. Sandoz Pharm. Corp.*—known collectively as "The Parlodel® Trilogy." Additionally, our team intensely litigated non-medical issues in these cases, such as *Buckman* federal preemption, off-label use, and essential corporate document confidentiality.

Our pharmaceutical products liability work also involves such products as anti-fungals, anti-cholesterols, migraine treatments, anti-depressants and anti-coagulants for clients, including manufacturers and distributors of prescription drugs, as well as many *amici curiae* whose interests parallel those of our pharmaceutical clients. Our representations include both national trial counsel service in serial litigation and defense of single-plaintiff cases.

MEDICAL DEVICE LITIGATION

Our long-standing expertise in pharmaceutical products liability litigation also positions us well for handling product liability suits involving FDA-regulated medical devices. Our attorneys have represented numerous manufacturers of medical devices, including contraceptive devices and various mesh products. The *National Law Journal* recognized as one of its "Top Ten Defense Wins" in 2004 our complete defense verdict, after less than an hour of deliberations, in a trial involving mesh used to repair inguinal hernias (*Crowson v. Davol*).

REGULATORY COUNSELING

Hollingsworth LLP counsels clients regarding food, drug, and medical device law with an emphasis on U.S. Food and Drug Administration regulation of pharmaceuticals, medical devices, biologics, and food chemical additives. We represent manufacturers, distributors, and suppliers of finished and bulk products regarding FDA regulation, inspections, and enforcement actions.

Our attorneys prepare compliance programs, conduct internal corporate investigations and due diligence reviews, and have represented clients in connection with FDA hearings, advisory committee proceedings, citizen petitions, clinical trial investigations and reviews, FDA civil and criminal investigations, and Congressional investigations. We counsel clients on FDA regulation of prescription and over-the-counter drugs, biologics (including blood plasma derivatives), medical devices, dietary supplements, and food additives, and on pioneer and generic drug marketing exclusivity claims under the Drug Price Competition and Patent Term Restoration Act.