

# **DRUG LITIGATION PRIMER**

## ***ZOLL, KRANZ & BORGESS, LLC***

### **Q. How does drug litigation work generally?**

When a person initiates a civil lawsuit, the person enters into a process called litigation. Product liability claims against a pharmaceutical manufacturer can range from one to thousands of claims across the country. If the number of cases is large, there is always a possibility that they will be transferred to a single, national proceeding known as multidistrict litigation (an "MDL") and/or become part of a consolidated state court action(s). Thus, drug litigation is often nationwide in scope, and clients should understand how coordination of drug litigation occurs and why.

### **Q. What is an MDL?**

You may have heard of the Vioxx, Bextra, Celebrex and Heparin "MDLs" in the media recently. So what exactly is an "MDL"? MDL is an abbreviation for Multidistrict Litigation. The first thing you should understand is that it is not the same thing as a class action.

In a class action, one or more people or entities, called "Class Representatives," sue on behalf of people who have similar claims. These latter people, called the "Class" or "Class Members," are not individually named in the suit. For example, one person might sue on behalf of thousands of other people who were overcharged for a product as a result of an illegal price-fixing conspiracy, or by a member of a company for illegal hiring or salary practices. In a class action, if the named plaintiff (the "Class Representative") wins at trial or resolves his/her claims, then all of the claims of the un-named Class members are likewise resolved, with the exception of those that exclude themselves from the Class.

Multidistrict litigation is very different from a class action. Although MDLs may involve a host of categories, such as airplane crashes, train wrecks, hotel fires, asbestos, fraud, and price fixing, many MDLs involve defective medical drugs and devices. To understand how multidistrict litigation works, it is best to give an example. Assume that a dangerous drug has just been pulled from the market because it was contaminated or manufactured improperly, resulting in hundreds of injuries and/or deaths. As the news of the disaster spreads, attorneys begin filing suits all across the country on behalf of the victims. If enough suits are filed in federal court against the same manufacturer for the same drug and for the same or similar injury, a federal court, manufacturer, and/or plaintiff's lawyer might ask the Judicial Panel on Multidistrict Litigation to "consolidate" all of the cases in an "MDL" before a single judge.

Although the Clerk of the Judicial Panel on Multidistrict Litigation is permanently stationed in Washington, D.C., the panel meets in different cities in the United States, on a periodic basis, to review requests that cases be consolidated. After an MDL request is made, a hearing will be held to determine whether to create the MDL proceeding.

If the panel agrees after the hearing to create an MDL, it will also decide where the MDL will be located. The judge who gets all the federal cases assigned to him is known as the "transferee judge." The judges throughout the United States who send cases to the MDL judge are known as

the "transferor judges" or "transferor courts." The panel's selection of the transferee court that is in charge of the MDL may affect the outcome of the litigation. There are friendly jurisdictions and not-so-friendly ones. Parties try to influence the panel by proposing, when they can, a single, consensus choice for the transferee court, or at least one offered by all plaintiffs and one by all defendants.

Generally, the transferee court (also called the "MDL court") will then set standing orders or pretrial orders informing the lawyers involved of the ground rules, deadlines and procedures that the Court expects the litigants to follow. Although there may be hundreds or even thousands of cases in an MDL, if the Court makes a ruling, it generally applies to all of the cases. Indeed, this is one of the purposes of the MDL, as it is much more efficient to have one ruling on a general issue than possibly hundreds of conflicting rulings by many judges on the exact same issue.

Typically, hierarchies of plaintiff "executive" and/or "steering" committees made of leading and experienced drug litigation lawyers, such as our firm, are then appointed. These committees are often referred to simply as the "PEC" and/or the "PSC." The PEC and/or PSC are responsible for representing all the claimants in the MDL and managing the substance of the litigation. Under the supervision and direction of the PEC and/or PSC, volunteer lawyers will assist in reviewing documents, taking depositions, writing briefs, and developing and prosecuting the common aspects of the litigation. Ultimately, they will prepare and provide to all MDL plaintiffs a trial package consisting of documents that the plaintiff's attorney will need to try his or her case.

In an MDL, all of the information-gathering and investigation is done at the same time on behalf of all of the plaintiffs. This is referred to as the "discovery" process and is designed to obtain the basic facts of the case. The MDL Judge also rules on discovery disputes and decides critical issues, including whether there is sufficient evidence for the claims to proceed to a jury trial.

During and/or at the conclusion of this process, the MDL Judge often works with both sides in an attempt to reach a global settlement (which if successful, is often a matrix based on various factors involved in each specific case and decided by neutral masters or arbiters who have experience in this area). To assist in trying to reach a settlement, the MDL Judge may even have a few jury trials on cases that were actually filed in his or her own court. Some MDL cases are settled individually, others as a group. Each claimant is typically free to accept or reject the award, but if they accept it, then they give up their claim and release the manufacturer of any further liability.

**It is important to understand, however, that a settlement does not always occur in an MDL.** If settlement cannot be reached, each of the cases is sent back for trial, to the court where it was originally filed. The only cases that would not be remanded are those cases originally filed in the court with the MDL Judge is seated. Unlike a class action where there is only one trial, MDL cases are tried individually. That is, each plaintiff gets his or her day in court.

**Q. What are the pros and cons of multi-district litigation?**

Suing a billion dollar drug company with almost unlimited resources who will fight at every turn is expensive. A single victim would unlikely be able to finance such litigation alone. The

combination of claims in a single forum increases the plaintiffs' leverage by permitting counsel to pool their resources and to work for the plaintiffs' common benefit. Thus, one purpose of an MDL is to make it cheaper for individual plaintiffs by spreading the costs of information gathering and trial preparation among hundreds or even thousands of plaintiffs. Although Zoll, Kranz & Borgess, LLC does not require its clients to reimburse it for costs if the case does not result in settlement or a favorable verdict, if there is a settlement or favorable verdict, costs come out of the settlement or verdict amount and an assessment is paid to the MDL. Thus, an MDL allows each plaintiff's costs to be substantially reduced and avoids one client bearing a disproportionate share of the costs that benefit all such clients.

An MDL also promotes efficiency and consistency of rulings. Instead of 10, 100 or 1,000 cases pending in different courts across the county, the litigation is coordinated and important decisions are made by a single court saving substantial time and expenses.

However, there are disadvantages, too. The primary disadvantage is the length of time it takes to resolve an MDL. Although certainly litigation can resolve at any point, MDL litigation can often drag out for 4-5 years, or even more. Thus, MDL claimants should not have an expectation of a quick or guaranteed resolution of their case.

**Q. Are there any options other than the MDL?**

Most plaintiff attorneys filing a case in state court against an out-of-state drug manufacturer may have no choice but to become part of an MDL proceeding, as the case will likely be pulled to federal court by the drug manufacturer.

However, if the attorney believes it is in his or her client's best interests, there may be some appropriate state jurisdictions as well. (Although some state court judges may insist on close coordination nonetheless.)

In every litigation, Zoll, Kranz & Borgess, LLC carefully considers all federal and state jurisdictional options to determine which is in their clients' best interests.

**Q. What experience does Zoll, Kranz & Borgess, LLC have with Drug Litigation/MDLs?**

Zoll, Kranz & Borgess, LLC has been recognized on a national level for its work in MDLs. As a recent example, on February 14, 2008, Zoll, Kranz & Borgess, LLC was the first law firm in the nation to file suit against Baxter Healthcare Corporation and other related companies regarding contaminated batches of its drug, Heparin, and is now leading Heparin MDL 1953 in its position as Liaison Counsel and Chair of the Plaintiffs' Executive Committee. In April of 2008, the firm was honored to have three of its clients speak before Congress at an investigational hearing on tainted Heparin entitled, "The Heparin Disaster: Chinese Counterfeits and American Failures." Their stories have also been featured in news media, including on ABC Nightly News, Nightline, CNN, Bloomberg News and in Time Magazine.

Zoll, Kranz & Borgess, LLC was also one of the first firms to file suit in 2009 regarding the birth control drugs, Yasmin and Yaz, and have obtained leadership roles in both the MDL and state court consolidated actions. Other MDL involvement includes, but is not limited to, the Plaintiffs' Steering Committee for In Re: Yamaha Motor Corp. Rhino ATV, MDL No. 2016, acting as special counsel on behalf of Plaintiffs in In re: Inter-Op Hip Prosthesis Liability Litigation (Sulzer) MDL Docket No. 01-CV-9000, on the Discovery Committee in In re: Vioxx® Products Liability Litigation MDL Docket No. 1657, and involvement in Ford Crown Victoria, Bextra/Celebrex, and other mass tort litigation projects.

**Q. What is the basis of the Metoclopramide/Reglan Litigation?**

Metoclopramide (also referred to by the brand names Reglan, Reglan ODT, Metozol ODT or Octamide) is a "prokinetic" drug that increases muscle contractions in the upper digestive tract (i.e. the lower esophageal sphincter, stomach, and small intestine). This speeds up the rate at which the stomach empties into the intestines.

Metoclopramide is primarily used to treat heartburn caused by gastroesophageal reflux disease (GERD) in people who have used other medications without relief of symptoms. GERD is a disorder that allows hydrochloric acid, pepsin, and bile in the stomach to flow back into the esophagus. This backflow causes a burning sensation in the chest (known as "heartburn").

Reglan also has other uses, including treatment of slow gastric emptying in people with diabetes (also called diabetic gastroparesis), which can cause nausea, vomiting, heartburn, loss of appetite, and a feeling of fullness after meals.

According to the FDA, there are over 2 million people in the U.S. taking these drugs, including Reglan tablets, Reglan injections, and oral solutions. Many of them are using these drugs as a long-term treatment.

In February 2009, the FDA released a boxed warning on all metoclopramide products. A "black box" warning is the FDA's strongest warning. The warning specifically highlights the risk of developing a condition called tardive dyskinesia, as a result of using the drug.

Tardive Dyskinesia is a very serious disorder that causes involuntary, repetitive tic-like movements primarily in the facial muscles or (less commonly) the limbs, fingers and toes. The hips and torso may also be affected. Tardive means "delayed" and dyskinesia means "abnormal movement." Symptoms may include involuntary facial grimacing, jaw swinging, repetitive chewing and tongue thrusting. Tardive dyskinesia can appear similar to other types of disorders, most notably Tourette's syndrome.

You can view a video of symptoms of tardive dyskinesia at:

[http://www.youtube.com/watch?v=W\\_3bbpFjI68](http://www.youtube.com/watch?v=W_3bbpFjI68)

Symptoms of tardive dyskinesia can develop and persist long after use of the medication causing the disorder has been discontinued. There is no known cure.

Unfortunately, many individuals and their doctors didn't realize this substantial risk when they took or were prescribed metoclopramide. Lawsuits have been filed against the manufacturers of these drugs, alleging that although the drug companies knew or should have known of this serious risk, they failed to adequately warn about the potential risk associated with long-term use of the drugs.

**Q. What is the status of the Metoclopramide/Reglan Litigation?**

MDL status was originally requested, but denied on June 3, 2009. So for the time being, the cases will proceed individually. However, federal or state court consolidation still could occur at some point in the future.

On Friday, January 8, 2010, the United States Court of Appeals for the Fifth Circuit handed down a very important decision in this litigation, upholding the rights of those suffering from tardive dyskinesia, a neurological movement disorder, to pursue claims against the generic manufacturers of Metoclopramide/Reglan.

The decision is available at:

<http://www.ca5.uscourts.gov/opinions%5Cpub%5C08/08-31204-CV0.wpd.pdf>

The case, Demahy v. Actavis, held that the federal regulatory regime governing pharmaceuticals does NOT preempt state-law failure-to-warn claims against manufacturers of generic drugs.

Here are some highlights from the decision, which built on the Supreme Court case of Wyeth v. Levine:

*On the contrary, "through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." As for maintaining an adequate label, the regulatory framework makes plain that manufacturers—name brand and generic alike—must act to warn customers when they learn that they may be marketing an unsafe drug. For their part, generic manufacturers are subject to the requirement that their labeling "be revised . . . as soon as there is reasonable evidence of an association of a serious hazard with a drug." Demahy claims that Actavis failed to comply with this requirement despite reasonable evidence that long-term use of metoclopramide poses a serious hazard.*

...

*Of the three avenues for complying with both state and federal law that Demahy identifies—the CBE process, the prior approval process, and letters sent directly to healthcare providers—each shares the same fundamental attributes: the manufacturer bears primary responsibility for maintaining its label consistent with safe and effective use of its product; when reports indicate that a label requires revision, the manufacturer must alert the FDA and provide supporting scientific data; and the FDA then makes the decision whether such a labeling change is supported by science.*

...

*At least in the case of metoclopramide, it seems, the allegedly higher risk of long-term use was noted in medical literature beginning in the 1980s and 1990s. Even if state law prompts Actavis to alert the FDA to this information, Actavis has provided no evidence that such collection and analysis of existing data and conclusions would result in significant additional expenditures.*

This case will have important repercussions for generic drug manufacturers, including those in other cases. In the case of those clients and our future clients injured by metoclopramide and who have been diagnosed with tardive dyskinesia, there is now solid ground that we can successfully hold these generic manufacturers responsible for the serious harm caused by their drugs.