PHARMACEUTICAL DRUG LITIGATION – A NOVEMBER 2003 OVERVIEW

Ted G. Meadows
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
Post Office Box 4160
Montgomery, Alabama 36103-4160
(334) 269-2343
www.beasleyallen.com

For decades pharmaceutical companies have received profits in their industry that now make it the most profitable in the world. Seizing the opportunity created by the public outcry for the concern over the HIV/AIDS epidemic, big pharmaceutical companies lobbied for and crafted legislation to allow for the fast tracking of drugs. The Prescription Drug User Fee Act (PDUFA), with its fast tracking drug approval provisions has accounted for the increasing introduction of new drugs into the marketplace over the last nine years. A natural result of shortening the time period in which to investigate is the dizzying number of drugs recalled from the market, and those for which the Food and Drug Administration must require more stringent warnings than the companies are willing to provide on their own. Additionally, the number of consumers injured by pharmaceutical products has risen since the change of fast tracking drugs. Hence, the growth of mass tort litigation in the pharmaceutical context.

A Brief History of Mass Torts

From asbestos to tobacco to pharmaceutical products, mass tort litigation has become a powerful form of litigation in both state and federal courts. Mass tort litigation is a growing area of the law, which shows no signs of slowing down in the near future. Mass tort claims find their origins barely twenty-five years ago.[1] Some scholars trace true mass tort cases back even further to the late 1960's and early 1970's. In the 60's lawyers began to represent passengers in plane crashes on a structured basis. They represented a multitude of plaintiffs and victims against a myriad of defendants including manufacturers, suppliers and the airline companies themselves. These cases, referred to as "mass accident" claims, where a catastrophic event results in a number of serious and fatal injuries, are usually followed by mass litigation.[2] In mass accident litigation, injuries generally occur at a central location and usually manifest themselves immediately.

We also employ the term "mass torts" to refer to cases of mass exposure where claims arise from product use or exposure to toxic substances, including pharmaceutical products like Baycol, Rezulin, and Meridia. In some jurisdictions, mass tort claims

[1] Peggy Lane, 159 Bodies recovered in club fire, Wash. Post, May 30, 1977, at A1. (A fire in the Beverly Hills Supper Club in Southgate, KY killed 159 people and injured 100 more. The fire resulted in the first tort class action suit.)
[2] Deborah R. Hensler & Mark A. Peterson, Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis, 59 Brook. L. Rev. 961 at 1014 (1993).

stemming from exposure to products or toxins "account for over twenty-five percent of the entire civil caseload."[3] In mass exposure cases, injuries may occur in numerous, widely dispersed locations, at different times and their full effect may be unknown for years. With the implementation of the "fast-track" system of new drugs by the FDA, pharmaceutical mass exposure cases have been prevalent in recent times. The FDA has recalled eleven drugs since 1997, the latest of which is Baycol. This figure represents only one fewer than the total number of drugs recalled in the past twenty years.[4] Critics of the FDA and this "fast-track" program claim that they have become a rubber stamp for the pharmaceutical industry.

Pharmaceutical Mass Torts – A Product of Our Times

There are certainly a number of factors that would contribute to all of these drugs being withdrawn in the last several years. Most people point to a march on Washington in the early 1990's by those suffering from the AIDS epidemic. The Food and Drug Administration, has long been considered the protector of our citizenry by requiring drug companies to meet very strict safety standards before drugs are sold to the American public. Before, it could take years to get a prescription medication to the market. Therefore, people suffering from AIDS marched on Washington and demanded they be allowed quicker access to medication. The pharmaceutical industry responded and legislation was passed called the Prescription Drug User Fee Act ("PDUFA"). The pharmaceutical industry lobbyists were successful in obtaining a "fast track" review of drugs that treated life threatening and "serious" health conditions. The insertion of the word "serious" has led to the fast track approval of far too many unnecessary and under tested medications.

The act did work in decreasing the time in approving the drugs. From 1993 to 2001, approval times for standard drugs have dropped by nearly half, from a median of 27 months to 14 months. Approval for new drugs has dropped more than two-thirds from 21 months to about 6 months. At the same time, there has been a rise in the percentage of drugs that have been withdrawn from the market after approval because of safety related reasons. By requiring the FDA to speed up their process, the pharmaceutical companies may also be increasing their speed to market and markedly increasing the FDA's work load. Some writers believe that in order to meet it's performance goals, the FDA has had to markedly increase reviewer's work loads, leaving their staff little time for training and development. The FDA has a staff turnover rate among its scientists far higher than among scientists working in other government agencies.

[3] John C. Coffee, Jr., Class Wars: The Dilemma of the Mass Tort Class Action, 95 Colum. L. Rev. 1343 at 1363 (1995).
[4] Paul Durman*, Sunday Times* (London), August 12, 2001.

We are also seeing concerns from the standpoint of funding of the FDA. Over half of the funding of the FDA now is pursuant to PDUFA and the payment of large fees by the pharmaceutical industry to the FDA. Many people argue that this creates a conflict of interest. The FDA is the best resource drug approval agency in the world. However, it is operating in a world with considerable legislative oversight by congress and heavy funding from the companies who are looking for approval of their drugs. In 2001, an internal inquiry into the review of regulatory staff at the FDA's Center for Drug Evaluation and Review reported that one third of respondents did not feel comfortable expressing their scientific opinions with some reporting pressure to favor the wishes of manufacturers over the interest of science and public health and receiving requests from senior agency officials to alter their opinions.[5]

In the late 1990's, when some FDA scientists released documents to congress because of their concerns about the risk of Rezulin while it was on the U.S. market, they received threats of disciplinary action from agency management.[6] In 2000, when an FDA doctor recommended the withdrawal of Lotronex, he was ignored and ultimately "frozen out" of the administration.

Litigating the Pharma Mass Tort Case

In the past, mass tort litigation was an alternative view to the traditional notions of the civil litigation system. Courts have long recognized the need for special procedures in litigation involving multiple tort claims arising from mass disaster or mass exposure cases. Mass tort cases, like that of Baycol, have now emerged to the forefront of modern civil litigation.

Due to the complexity of mass tort litigation, it is an area of the law which requires attorneys to handle several major issues simultaneously. Cases may be filed in either state or federal court with multiple named plaintiffs and defendants. Plaintiffs must also deal with defendants who may be in bankruptcy, which obviously affects their ability to collect a judgment. Plaintiff's counsel must also navigate through various state laws which may effect a variety of issues such as compensatory and punitive damages, potential statute of limitations problems, standards of liability, rights of contribution, indemnification and subrogation. Third party complaints may also arise, further complicating the process. Of course, expert testimony is critical. The use of an expert and admissibility of testimony and evidence can develop into a fierce adversarial battle. This issue requires the judge to act as the "gatekeeper" in reviewing scientific evidence as set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 113 S. Ct. 2786 (1993).[7] Defendants have used the *Daubert* decision to deny admission of expert evidence.

[5] Horton, R. The FDA and Lancet; In Exchange. Lancet 2001; 358: 417.
[6] Gale Eam. Lessons from the Glitazones: A Story of Drug Development. Lancet 2001; 357: 1870-75.
[7] The Court noted that the trial judge is responsible for determining the relevance of expert testimony and the reliability of the methodology upon which the expert relies.

For an attorney unfamiliar with mass tort litigation, it can be confusing and intimidating territory. The plaintiff must constantly be on the offense, pushing discovery issues and securing trial settings. Trial settings in mass tort litigation are crucial in discovery issues and vital in initiating settlement negotiations.

Discovery

Discovery in mass tort litigation is often a long, uphill battle from the plaintiff's perspective. The defendant's strategy to stall and release discovery as slowly as possible has become a common theme among defense counsel. This type of behavior is often the source for motions to compel and motions for sanctions filed by plaintiffs.

With mass tort litigation, discovery may become delayed from the outset of the case based on the sheer volume of documents and materials required. This makes it even more vital that requests for discovery be served immediately. It is preferable to serve discovery with the summons and complaint in order to help ensure a timely response by your adversary. It is also worth noting that proper documentation should be kept of the defendant's failure to comply with discovery request. While it is ill advised to engage in a "battle of letters", which can amount to a complete waste of time, it is wise to have documentation, such as a letter to reconsider defendant's objections, to support a motion to compel.

Remember that defense counsel can play within the rules and force the plaintiffs to "work" to obtain discovery. Defendants can require plaintiffs to state, with reasonable accuracy, the documents that they are requesting, rather than responding to a request for "all" records. The opposite strategy is to overwhelm the plaintiff with documents by "burying them in paperwork". Courts have held that this type of response is improper where specific inquires have been made. The rule is clear that a "responding party has the duty to specify, by category and location, the records from which answers to the interrogatories can be derived."[8] Although this type of conduct is inappropriate, a diligent lawyer may discover valuable information that he or she would not have otherwise specifically requested. Also remember that the "uncooperative client" is not a valid excuse available to defense counsel for failure to produce.[9]

Mass tort discovery does not involve any different or special discovery. They simply require traditional, standard discovery methods applied to a large inventory of cases. The main discovery tools utilized include interrogatories, document discovery, depositions and request for admissions. The defendants will use the same discovery tools for the most part in addition to requesting disclosure of medical records and possible physical examinations. The order of discovery is determined on a case-by-case basis or by preference of the attorney. Different strategies may be employed here depending on the companies, executives, and personnel involved.

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[8] Advisory Committee's notes on amendment to FED. R. CIV. E 33 (c) (1987).

[9] Federal Rule of Civil Procedure 26(g): The lawyer must make a "reasonable effort to assure that the client has provided all the information and documents responsive to the discovery demand."

Digital Data

Today, computers are a must for both large and small corporations. Computers are used to store large amounts of data as well as an efficient way to communicate. For the most part, corporations do a less than adequate job of preserving information and data related to litigation. For most companies the lack luster maintenance of records is an innocent act as opposed to an intentional wrong. However, because the majority of relevant information in pharmaceutical litigation is stored electronically, the services of a skilled computer professional may be required. Requests for discovery include disclosure of electronically stored data, the most prevalent being e-mail. This data may not have ever been transformed into a hard copy and even though "deleted" may still be retrievable.[10] This "digital data", electronically stored information, is discoverable, if relevant.[11] Plaintiffs should be entitled to discover any material related to the record holder's computer hardware, programming techniques associated with relevant data, structure of the stored data and the operation of the data processing system.[12]

"Given the work that computers can do today, it is probable that the parties to mass litigation will index and store documents so that they can be readily searched and retrieved. At a minimum one would want to be able to search by the names in the document (sender, recipient, name in the text), date, subject and the document's assigned number, tying into use later at trial."[13]

Generally, mass tort cases have a higher rate of settlement than do most individual tort cases.[14] Often defendants find it safer to settle rather than "role the dice" in front of a jury of their peers. Aggregating cases may increase the plaintiff's opportunity for a large group settlement.

Trial settings drive settlements; this is true for both mass tort and individual tort cases. For this very reason, judges may pressure the parties to complete **discovery in a** timely fashion knowing settlement is always a possibility. Mass tort cases have settled on the day of or day before trial, i.e. – Agent Orange.

Another type of settlement often discussed in mass tort circles are "global settlements". Global settlements occur where all claims are resolved in one fail swoop. This type of settlement can be beneficial to the plaintiff, the defendant and the court system in general. The plaintiff has the opportunity to be compensated in a reasonably

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[10] Simon Property Group L.P. v. mySimon, Inc., 194 F.R.D. 639 (S.D. Ind. 2000); Linnen v. A.H. Robins Co., Inc., 10 Mass L. Rptr. 189, 1999 WL 462015 (Mass Super. Ct. 1999). Motions for discovery of electronic data may also seek injunctive relief for non-destruction of electronic files, see Illinois Tool Works, Inc. v. Metro Mark Products, Ltd., 43 F. Supp. 2d 951 (N.D. ILL. 1999), and a duty to preserve may arise without any such order, Baliotis v. McNeil, 870 F. Supp. 1285 (M.D. Pa. 1994).

[11] Anti-Monopoly, Inc. v. Hasbro, Inc., No. 94-Civ. 2120 (S.D.N.Y. 1995), 1995 WL 649934; Seattle Audubon Soc. v. Lyons, 871 F. Supp. 1291 (W.D. Wash. 1994).

[12] Manual for Complex Litigation § 2.715, at 120 (5th ed.)

[13] Thomas E. Willging, "Beyond Maturity: Mass Tort Case Management in The Manual for Complex Litigation," 147 U.Pa.L.Rev. 2225 (2000)

[14] *Manual for Complex Litigation* (3rd ed.)

efficient time without further expense and the defendant is able to resolve all claims against them as well as have a clear picture of their future financial position. This type of settlement also clears room on the court docket and promotes judicial economy. These types of settlements usually occur with weaker cases where the plaintiff's position is not as strong as desired.

Update On Drugs Withdrawn in the Last Several Years

- Phen-Fen
- Propulsid
- Rezulin
- Baycol
- PPA
- Lotronex (placed back on market in limited program)

Questionable Medications

- Meridia
- Serzone
- Arava

Where Do We Go From Here – Mass "Tort Reform"

The pharmaceutical industry and those large corporations making it up have more lobbyists in Washington, D.C. than any other industry. They are some of the most profitable companies in the world. The current framework and approval process with the FDA stands little chance of change because of the power and influence that they have over our legislators. If patient health and safety were truly their main concern, wouldn't a process allowing for more effective testing and review of drugs be the answer that we need to stop injuring and killing citizens for the sake of profits? It is doubtful we will see the pharmaceutical industry step back. Instead, they will take a more aggressive approach and attack those who represent persons injured and killed using these medications.[15]

The U.S. House of Representatives has passed legislation that would preempt state laws designed to protect consumers and patients from medical malpractice, defective drugs and medical devices and other egregious acts by health care providers. That the Republican party, who preaches a large federal government being downsized and returning rights to the states, would attempt to pass laws that would preempt state's rights is hypocrisy. If such legislation is eventually passed by the senate it would likely accomplish its goals of foreclosing people's rights by federalizing the system and capping recoveries.

[15] HR 4600

Supporters of this argue that the legislation is designed to address rising medical malpractice insurance premiums. Nevertheless, proposed bills include provisions that protect pharmaceutical and medical device manufacturers from products liability claims involving defective products. Recently, mass "tort reform" was snuck into a class action reform bill at the last minute. As proposed, it is the opinion of the writer that this legislation would allow the company to profit from the sale of a defective product, which injures or kills, and increases the burden on an injured consumer in who seeks to punish the wrongdoer for causing permanent and debilitating injuries and would limit the amount of damages the injured consumer can recover regardless of the egregiousness of the conduct causing the injury. Is there any doubt that this bill is intended to benefit the pharmaceutical industry and not individual consumers?

Conclusion

The review process at the FDA has not changed since 1998. If anything, things have gotten worse. New legislation continues to weaken the review process, erode the power of the FDA, and gives more control to the pharmaceutical industry. As Peter Lurie, MD, MPH, deputy director of Public Citizen's Health Research Group stated, "[t]he FDA is supposed to rigorously screen all new drugs and ensure that they are safe and effective before they are sold to millions of people. Unless the agency gets out of the snug bed it is currently sharing with the industry, unsafe drugs will continue to slip through the safety net." In 1998, Public Citizen quoted one Medical Officer at the FDA who stated, "[m]y feeling after more than twenty years at FDA is that unless drugs can not be shown to 'kill patients' outright then they will be approved with revised labeling and box warning." It appears that consumers continue to take a back seat in an FDA vehicle being driven wherever Big Pharma wants to go. This makes it all the more important for us to have a strong civil justice system, with plaintiff's lawyers up to the task.

