

I WANT A NEW DRUG
(Pharmaceutical Litigation Update)

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*Wyeth v. Diana Levine*¹

In what is likely the biggest news in pharmaceutical law in the last 12 months, on March 4, 2009, the U.S. Supreme Court rendered its opinion in the case of Wyeth versus Diana Levine. Wyeth claimed that their drug had an FDA approved label, and thus no suit could be brought for a defective label; the U.S. Supreme Court disagreed. The decision put to rest (at least for the time-being) the full-on assault drug-maker defendants had lodged against those they have injured based on federal preemption. The heart of Wyeth's argument in the case, which was echoed in virtually every other failure-to-warn drug case in the country, was that state-law claims such as Ms. Levine's make it impossible for drug-makers to comply with both state-law duties underlying those claims and federal labeling duties imposed by the Food and Drug Administration (FDA). This irreconcilable conflict, according to Wyeth, meant that injured parties should be prohibited from filing state-law claims based on FDA-approved warnings. The Supreme Court wholly rejected Wyeth's argument.

Ms. Levine lost her arm because Wyeth's drug Phenergan was incorrectly administered to her through the IV-push method. Ms. Levine sued Wyeth in Vermont state court, claiming that the label on Wyeth's drug Phenergan did not contain an adequate warning about the risks associated with IV-push administration of the drug. A Vermont jury agreed and awarded Ms. Levine \$7,400,000.00 in damages. The Vermont Supreme Court affirmed, and Wyeth then appealed to the U.S. Supreme Court. Wyeth's arguments on appeal were essentially two-fold. First, Wyeth argued that it would have been impossible to comply with the court-imposed state-law duty to modify the drug's label without violating federal law. Second, Wyeth claimed that such state action created an obstacle to the purposes and objectives of Congress because it substituted the expert judgment of the FDA with that of a lay jury.

In a 6-3 opinion,² the Court held that federal law did not preempt Ms. Levine's failure to warn claims. Addressing Wyeth's first point, the majority found that a manufacturer can indeed change its labeling to add or strengthen warnings for safety purposes without running afoul of

¹ 129 S.Ct. 1187 (2009).

² Justice Stevens delivered the opinion, joined by Kennedy, Souter, Ginsburg and Breyer. Justice Breyer filed a concurring opinion and Justice Thomas filed an opinion concurring in the judgment. Justices Alito, Roberts and Scalia dissented.

federal regulation. The Court went on to state that “absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.” *Id.* At 1199. In rejecting Wyeth’s second argument, the Court first pointed out that state law claims do not obstruct Congressional purposes and objectives as set forth in drug labeling regulation because “all evidence of Congress’ purposes is to the contrary.” *Id.* In the 70-year history of the FDCA, Congress neither provided a federal remedy for those harmed by unsafe drugs nor expressly preempted state-law suits. “Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers.” *Id.* The Court further rejected Wyeth’s reliance on the preamble to a 2006 FDA regulation which stated that FDA approval of a drug’s label preempted conflicting or contrary state law. Not only were the statements included in violation of rule-making procedures, the Court said, but also reversed the FDA’s own long-standing position on the issue without explanation. Therefore, the FDA’s position warranted no deference.³

In sum, the Court preserved an injured consumer’s right to sue a drug company for failure to adequately warn, indicating that “state law offers an additional, and important, layer of consumer protection that complements FDA regulation.” *Id.* At 1202. There might still be narrow circumstances that could legitimately support a preemption argument, but the likelihood is now quite rare. Of course, drug companies are surely analyzing the case in detail attempting to fashion arguments around the holdings and it is unlikely we have seen the last of preemption motions in drug cases.

***Gladys Mensing v. Julie Wyeth*⁴ and *Julie Demahy v. Actavis*⁵**

Mensing and *Demahy* are both cases involving the drug Reglan, and its generic equivalent metoclopramide (MCP). Both were decided in the last year regarding generic manufacturers’ claim of federal preemption – efforts by the generic drug companies to seek immunity from liability. In both cases the generic manufacturers argued that at the time of first approval of the generic drug, their drugs’ label had to follow an FDA requirement that it be

³ In essence, the dissent simply finds that there is an irreconcilable conflict between state tort actions and FDA labeling regulations; that the FDA did weigh the risks of IV-push administration and approved the labeling and warnings about that risk; and that the FDA, rather than a lay jury, should be making these cost-benefit balancing functions.

⁴ *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009)

⁵ *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir.2010)

identical to the brand name label, therefore, state law failure-to-warn tort claims were preempted. In *Mensing* and *Demahy*, the Eighth and Fifth Circuit Courts of Appeal, respectively, rejected that argument. Both courts acknowledged that although *Levine* concerned a brand name manufacturer, the holding in *Levine* did carry “important implications, regarding the courts’ consideration of preemption in relation to the duties of generic drug manufacturers”. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 433 (5th Cir.2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

In *Mensing*, the Eighth Circuit pointed out that Congress has the ability to pass specific preemptive laws regarding generic drugs but has not done so to date. [p7]. The Eight Circuit identified a number of different ways for generic manufacturers to comply with FDA regulations, yet still effect changes in their labels to make the label accurate. [p 8]. For example, the generic manufacturers’ could request new label language, could petition the FDA for corrections, and could send warning letters to health care professionals. [p11]. The *Demahy* court echoed the findings of *Mensing*. [p12]. The Fifth Circuit Court of Appeals pointed out that once the drug is approved, the FDA regulations do not prevent ongoing changes to the label by generic manufacturers; in fact, brand name and generic manufacturers alike have a duty to warn customers when the hazards of a drug come to light. [p14].

The courts in *Mensing* and *Demahy* make clear state tort failure to warn claims against generic manufacturers are not preempted by FDA regulations. To the contrary, a generic manufacturer has the same duty to warn end users of its products harmful side effects.

Reglan®

Reglan, or its generic equivalent metoclopramide (MCP), is a dopamine antagonist/neuroleptic⁶ drug indicated for patients with gastroesophageal reflux (GERD), diabetic gastroparesis, to prevent nausea and vomiting associated with chemotherapy or post-operatively and to aid in other limited medical procedures. Although Reglan is only indicated for short-term use (4 to 12 weeks), the medical conditions are all long-term problems. This creates a problem, as after 12 weeks of use, the risks of serious side effects increase dramatically. Most notable of these side effects are Tardive Dyskinesia, which can include involuntary movements of limbs and facial grimacing, torticollis, rhythmic protrusion of the tongue, bulbar

⁶ Most dopamine antagonist/neuroleptics are indicated to treat psychosis and include Haldol®, Risperdol®, Seroquel®, Zyprexa® and others. They also carry the risk of development of tardive dyskinesia and other EPS.

speech, dystonic reactions, tremors, akathisia and other abnormal movements. In certain cases, these symptoms can be irreversible and there is no widely effective treatment at this time.

In light of the serious risks associated with the drug, one would expect careful administration for only those patients who fail to respond to safer alternatives. Unfortunately, studies have consistently shown that over one-third of all prescriptions are written for use in excess of 12 weeks. Further, those most likely to prescribe the drug - gastroenterologists and primary care doctors - are typically neither aware of the potential side effects nor properly trained to identify them. Not surprisingly, the labeling provided little assistance for several reasons: (1) Reglan/MCP has not been listed in the Physicians' Desk Reference since 2001; (2) the labeling grossly underestimates the risk of TD associated with all use and most notably long-term use and (3) it implies that most TD can be reversed and are easily treatable.

Recognizing the inadequate nature of the label and warnings, in February 2009 the FDA issued an advisory requiring the addition of a **Boxed Warning** for Reglan/MCP. This new warning spells out that "Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible" Additionally, the new Boxed Warning now tells physicians and patients that "Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases" Finally, the FDA is now requiring that manufacturers implement a Risk Evaluation and Mitigation Strategy (that each patient be given a Medication Guide) because the FDA has determined that the use of Reglan/MCP "pose[s] a serious and significant public health concern requiring the distribution of a Medication Guide." This Medication Guide, setting out all the risks of the drug and to be given to all users "is necessary for the patients' safe use of Reglan (metoclopramide)" See www.fda.gov/bbs/topics/NEWS/2009/NEW01963.

Although a handful of cases have been and are being prosecuted across the country, the addition of the Boxed Warning has brought to the forefront the serious issues associated with this drug. Many more cases have been filed across the country in the months since the Boxed Warning was issued by the FDA. In anticipation of this increase in litigation, a motion was made with the Judicial Panel on Multidistrict Litigation for the formation of a MDL. Ultimately, the Federal Judicial Panel ruled against the formation of a MDL. Since that time, a coordinating court has been established in Philadelphia, PA for Reglan litigation. Lastly, numerous suits against generic manufacturers across the nation are set to begin trial in the next few months.

Hormone Therapy Litigation

In July of 2002, a landmark study commissioned by the National Institutes of Health was suddenly halted after the safety board monitoring the study determined that the risks of combination hormone therapy (synthetic estrogen and progestin) exceeded the benefits after approximately 5 years of follow-up. *See* Writing Group for the Women's Health Initiative Investigators, Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women, JAMA 2002;288:321-333. These risks include invasive breast cancer, heart attack, stroke, and venous thromboembolism.

The study participants were randomized to placebo, Premarin® (an estrogen-only drug), and Prempro® (combination estrogen and progestin), the latter drugs being manufactured by Wyeth Pharmaceuticals (formerly Ayerst, or Wyeth-Ayerst). Premarin, which is made from the urine of pregnant mares, was first introduced on the market by Ayerst in the early 1940s to alleviate symptoms associated with menopause and aging. By the late 1960s and 1970s, use of the drug became increasingly popular (and profitable) until it was determined that use of unopposed estrogen lead to the development of hormone-dependent uterine cancer. Thereafter, a synthetic form of progesterone, or a progestin, manufactured by Upjohn and sold under the trade name Provera®, was added to significantly reduce the risk of this deadly form of uterine cancer. In 1995, Wyeth received FDA approval to combine the two drugs in one pill, Prempro.

Unfortunately, until the NIH undertook to study this combination, its safety was never fully investigated by the manufacturers of the products. Instead, manufacturers such as Wyeth-Ayerst, Upjohn and others focused their attention on gaining additional indications for the products so as to further profit from these drugs. Although the FDA approved the drugs for the treatment of vasomotor symptoms (such as hot flashes and night sweats) and the prevention of osteoporosis, the manufacturers wanted more. They repeatedly sought additional indications such as the prevention of heart disease, prevention of dementia/Alzheimer's, and the like. When the FDA refused to endorse these unproven indications, the companies nonetheless marketed these alleged benefits off-label in order to convince physicians and the women they treated that combination therapy could cure a host of age-related ailments.

Much of this was suspended after the Women's Health Initiative study (WHI) was halted, however. Since that time, more and more evidence has come to light to show the strong

association between the use of combination hormone therapy and a number of serious health conditions, most notably, invasive breast cancer. The FDA required significant label changes to give physicians and women more information about the true risks and benefits of combination hormone therapy use – particularly in the long-term. Additionally, more and more information is coming to light about safer alternatives such as estradiol patches used in combination with natural progesterone.

Wyeth, Pfizer (as successor to Upjohn) and others are facing thousands of lawsuits around the country. The majority of these cases are pending in the federal MDL in the Eastern District of Arkansas before Hon. William R. Wilson (MDL-1507).

The court has recently ordered that case-specific discovery begin in approximately 200 other cases. That discovery is essentially complete, and virtually all of those cases have now been remanded to their originating court to begin preparation for a trial. Moreover, the court remanded other cases where case-specific discovery was completed or the plaintiffs were in *extremis*. In addition, the court plans to release 200 cases per month for the additional case specific discovery, with the intention of remanding all the cases to their originating courts.

Litigation has also been active in various state courts. Several trials have gone forward in the Pennsylvania consolidated action – almost all with positive jury findings and verdicts ranging from 1.7 million to 3.5 million.

Two other state courts have also been active in the litigation – Nevada and New Jersey. Both jurisdictions have provided some of the best rulings in the litigation to date; particularly concerning the admissibility of documents related to marketing. Not surprisingly, several cases set for trial in the respective jurisdictions have settled on the eve of trial. The settlement amounts are confidential, but counsel in those cases were said to be pleased with the results. On the trial side, in October of 2007 a Reno jury returned a plaintiffs' verdict for three women against Wyeth totaling \$134.5 million (included compensatory and punitive findings). Needless to say, Wyeth has appealed and the appeal is currently pending.

The Minnesota Supreme Court heard arguments on May 5, 2009 on an issue important to many already involved in this litigation – statute of limitations. Because of the lack of accurate information about the risks of hormone therapy until the publication of the Women's Health Initiative study, a number of cases were filed in Minnesota (with a six-year statute of limitations) to ensure valid claims would not be unfairly time-barred. Many of these women were not from

Minnesota and the defendants asked that Judge Wilson (in the MDL) certify a question to the Minnesota Supreme Court regarding this issue – can a non-Minnesota woman take advantage of the Minnesota statute of limitations? He did so and the court ruled in the plaintiffs favor.

Fentanyl Patch

Fentanyl transdermal patches, also known under the brand name Duragesic®, contain extremely strong narcotic analgesics used to treat chronic pain. The drug is contained in a gel which is embedded in a patch, and applied directly to the skin. In theory, the patch slowly releases the pain medication directly into the body through the skin in a slow, measured manner. In reality, the patch often releases the drug in varied doses – sometimes in large, fatal doses. This potential for overdose led to a recall of a number of patches by Janssen in 2004, two FDA safety advisories and another round of recalls beginning in February of 2008. At that time, several companies (PriCara, Sandoz and Alza) recalled their patches due to gel leakage and overdosing risks. All of these patches were made by PriCara, a division of Ortho-McNeil-Janssen Pharmaceuticals. Shortly thereafter, Actavis recalled its patches as well. Numerous problems exist with the patches including poor design, manufacturing defects, inadequate warnings and poor quality control. Although overdose can involve trouble breathing or shallow breathing, extreme sleepiness or sedation, an inability to walk or talk normally, and feeling faint, dizzy, and confused, tragically it often leads to death.

The case against the makers of these patches is well developed with a number of cases having gone to trial over the last several years – many with multi-million dollar verdicts including a \$5.5 million verdict for the family of Adam Hendleson in Florida federal court, a \$13.3 million verdict for the family of Susan Hodgemire in Florida state court and a \$16.5 million verdict for the family of Janice DiCosolo in Illinois state court. In *DiCosolo* the defendants have appealed and the appeal is still pending. Thus far, no multidistrict litigation regarding this drug has been established, but cases continue to proceed in various state and federal courts around the country.

Fosamax®

Fosamax, Merck & Co., Inc.'s brand name for its compound alendronate, was approved by the FDA in September of 1995 for the treatment of osteoporosis and Paget's Disease (a disease affecting the growth rate of bone). It belongs to a class of drugs called bisphosphonates;

a class which includes a number of drugs indicated for use as chemotherapy – particularly to battle bone cancers. Beginning in the 1990s, studies began revealing the frequent and common occurrence of osteonecrosis (bone death) of the jaw with the bisphosphonates used for chemotherapy.

Bisphosphonates, including Fosamax, work by slowing the natural process whereby dead bone cells are removed and replaced by new ones. Unfortunately, if the process is slowed too much or stopped altogether, the affected bone will suffer from ischemia or restriction of the blood supply. As a result, a minor injury or disease, or normal bone trauma (such as a simple tooth extraction) can turn into a non-healing wound, which in turn, can progress to widespread bone death (osteonecrosis) and inflammation of bone marrow (osteomyelitis). Once this process begins and becomes symptomatic, it is very difficult to treat and typically is not reversible. There is much dispute about other causes of osteonecrosis of the jaw. *See* L. Ruggiero, *et al.* Osteonecrosis of the Jaws Associated with the use of Bisphosphonates: A review of 63 cases, 62 ORAL MAXILLOFAC. SURG. 527-34 (2004).

Rather than fully study these adverse events or warn patients, Merck instead focused its attention on obtaining new indications for Fosamax from the FDA and extending the exclusivity period. The potential for phosphates to cause significant problems has been known all the way back to the 1700s when match factories were shut down because of the significant injuries suffered by those working with phosphate.

In mid-2006, a federal MDL for Fosamax cases was established in the Southern District of New York under the direction of Hon. John F. Keenan (MDL-1789). Discovery began in late 2006 with an eye toward the selection of 25 cases for pre-trial work up with the ultimate goal of selecting three cases for trial. In June of 2007, the 25 cases were selected. In late 2008, the judge set three individual cases for trials to be held in late 2009 and early 2010. With these settings, he also set deadlines for generic expert discovery and *Daubert* challenges. The first of the three trials, the *Boles* case, went to trial in August of 2009 and resulted in a mistrial in September after the jury was deadlocked; reportedly there were physical threats amongst the jurors and a chair was thrown in the jury room. *Boles* is set for retrial later this year. The second case, *Maley v. Merck*, is set for trial on April 19, 2010, after Merck's motion summary judgment was denied by the court.

Avandia®

In May of 2007, the FDA issued a safety alert on Avandia (rosiglitazone), a treatment for type 2 diabetes. The alert indicated that data has shown a potentially significant increase in the risk of heart attack and heart-related deaths in patients taking Avandia. This alert came on the heels of an article published in the *New England Journal of Medicine* co-authored by Steven E. Nissen, M.D., a highly-respected cardiologist at the Cleveland Clinic. Dr. Nissen undertook his own meta-analysis of Avandia clinical studies after noting an increase in cardiovascular events for patients taking the drug in at least two post-marketing trials. Dr. Nissen's findings, of an approximately 40% increased risk of cardiovascular events, coincide with the findings of two analyses by the manufacturer and one by the FDA.

Avandia is a product of GlaxoSmithKline and was originally approved by the FDA in 1999. Although litigation is heating up, some caution is in order. Dr. Nissen himself has disclosed the limitations of his meta-analysis and the fact that little good information about the risks of the drug exists at this time. More conclusive information should be available in the coming years when results from ongoing clinical trials specifically designed to assess risks, including heart risks, are completed.

Hundreds of suits have been filed regarding Avandia, with the majority being consolidated into an MDL in the U.S. District Court for the Eastern District of Pennsylvania (MDL 1871). The Hon. Cynthia M. Rufe is overseeing the consolidated litigation. The MDL was established in late 2007 and to date, its work has focused on discovery. Specifically, in November of 2009, defendant GlaxoSmithKline claimed that about 90,000 documents were privileged based upon attorney-client privilege and attorney work-product. The Plaintiffs' Steering Committee (PSC) filed motions seeking discovery of those documents with trials set this summer. Glaxo ultimately reduced the number of documents it claimed were privileged to only 25. Judge Rufe then ruled that most of the remaining 25 documents were in fact not privileged.

There are also a number of cases proceeding in various state courts, but no firm trial dates have yet been set in the MDL or elsewhere. The MDL has established an informative website at www.paed.uscourts.gov/mdl1871. This includes copies of all pretrial orders, approved forms, and transcripts of proceedings.

CHANTIX

Chantix is a smoking cessation drug by Pfizer. This litigation is in the early stages. On July 1, 2009, the FDA mandated that Chantix include a Black Box warning. The warning concerns the increased risk of neuropsychiatric symptoms, including hostility, depressed mood, suicidal behavior and thoughts of and attempted suicide. The Black Box warning was born out of the volume of adverse event reports received by the FDA regarding Chantix as well as another smoking cessation drug, Zyban and its generic equivalents. Since the issuance of the Black Box warning, it is anticipated that even more lawsuits will be filed regarding Chantix. It is also interesting to note that Pfizer is still marketing Chantix via varying mediums, including television advertisements with new extended warnings regarding mood changes. On October 1, 2009, thirty-seven (37) federal lawsuits were consolidated in a MDL before Judge Inge P. Johnson in the Northern District of Alabama. Most recently, on February 2, 2010, Judge Johnson appointed plaintiff and defendant counsel to leadership positions in the MDL. Counsel were appointed as plaintiffs' lead counsel, the Plaintiffs' Executive Committee and Plaintiffs' Steering Committee. With the leadership established it is anticipated that discovery will begin in earnest.

SHOULDER PAIN PUMPS

There are numerous suits across the country against the manufactures of shoulder pain pumps alleging shoulder chondrolysis. The manufacturers include Stryker, Breg, Inc. and AstraZeneca PLC to name a few. Shoulder chondrolysis is also known as post-arthroscopic glenohumeral chondrolysis (PAGCL). PAGCL results in the loss of cartilage limiting the range of motion in the shoulder and in certain cases necessitating shoulder replacement surgery.

In August 2008, the Judicial Panel on Multi-District Litigation ruled against creating a MDL for post surgical shoulder pain pump litigation. At the time the Judicial Panel declined to create a MDL there were over thirty (30) cases nationwide. Cases are in varying stages of litigation and pending in various jurisdictions from Florida to Oregon

In November of 2009, the FDA said that local anesthetics and pumps are not approved for treating post-surgical pain related to shoulder surgery. The FDA issued the statement after receiving numerous reports of PAGCL. More than half the patients reporting problems to the FDA required additional corrective surgery.

On November 30, 2009 an application was made to New Jersey's director of courts seeking to centralize fifteen New Jersey state court shoulder pump cases. On December 11, 2009, the New Jersey Supreme Court issued a notice seeking comment regarding the request for centralization. However, the plaintiffs are only seeking centralization and not designation of pain pump litigation as a mass tort in New Jersey. Similarly, the motion to create a federal MDL was renewed and is once again pending before the federal Judicial Panel on MDL.

On January 22, 2010, in what has been reported as the first pain pump case to go to verdict, an Oregon jury awarded 35 year old Matthew Beale \$5.4 million.

ACUTANE

Accutane, manufactured by Hoffman La Roche, is an acne treatment drug. Plaintiffs assert claims alleging Accutane causes inflammatory bowel disease (IBD) and suicide. In New Jersey Accutane cases have been centralized as a mass tort. Since centralization in New Jersey there have been three trials that have resulted in multi-million dollar verdicts related to IBD injuries. One of those cases is currently scheduled for retrial this summer. The other two verdicts have been appealed. Federal cases are in a MDL in the U.S. District Court for the Middle District of Florida. The Federal MDL judge has to date excluded plaintiffs' causation testimony. For example, the general causation testimony of plaintiffs' expert, Dr. Ronald Gold, was excluded on Aug. 11, 2009 for a second time by the MDL judge.

In a high profile case, U.S. Representative Bart Stupak's son, Bartholomew J. Stupak, committed suicide after being on Accutane for about six months. Laurie Stupak, wife of Rep. Stupak and mother to Bartholomew, filed suit against Hoffman La Roche asserting claims of negligence and strict liability. In 2007, the court granted Hoffman La Roche's summary judgment on Stupak's negligence and strict liability claims. Mrs. Stupak appealed. The 11th Circuit upheld the court's summary judgment last year.

Discovery is ongoing. For example, in September and October of 2009, ongoing discovery in New Jersey revealed that manufacturers of Accutane and generic forms of Accutane as well as their law firms have paid more than half a million dollars to a university researcher. Not surprisingly, that researcher's study was favorable to defendants in the litigation and has been proffered as evidence by the defendants.

More recently, in October of 2009, a \$7 million Florida state court trial verdict against Accutane for damages related to IBD was reversed on appeal. The Florida appeals court said that the plaintiff had failed to prove his failure to warn claim and causation, and further added that the plaintiff's claims were barred by the learned intermediary doctrine. Also in October of last year, A New Jersey verdict against Accutane in the amount of \$12.8 million was cut by \$450,000, but otherwise the verdict was allowed to stand. And more recently, on February 16, 2010, another New Jersey jury awarded over \$25 million to a man in a retrial of a case from 2007. (*McCarrell v. Hoffman-La Roche, Inc.*, No. ATL-L-1951-03-MT, J.J. Super., Atlantic Co.) The verdict is nearly ten times what a jury awarded the plaintiff in his first trial.

Yaz and Yasmin

Yaz and Yasmin (Yaz/Yasmin) are oral contraceptives made by Bayer and Berlex Laboratories International, Inc. that can cause heart attacks and strokes. Yaz/Yasmin use the same hormone, drospirenone. The only difference between the two drugs is that Yaz contains a slightly lesser amount of ethinyl estradiol. Plaintiffs allege their injuries are caused by exposure to drospirenone, the progestin in Yaz/Yasmin. Yaz/Yasmin are the only birth control pills to contain drospirenone, the 4th generation of progestin. Yaz/Yasmin are also approved as a treatment for premenstrual dysphoric disorder (PMDD) and moderate to severe acne. In 2008 the FDA cited Bayer for television advertisements that overstated what Yaz/Yasmin was approved for. Plus, according the FDA, Bayer failed to state the risks of Yaz/Yasmin. The FDA required new advertisements to correct prior misstatements.

Yaz/Yasmin have been associated with heart attacks and strokes as well as causing the need for victims to have their gall bladder removed, thrombotic events and pulmonary embolisms. Plaintiffs allege that defendants failed to warn users about the possibility of terrible side effects as well as over promoting the drugs.

Last summer a petition was filed before the Federal Judicial Panel of Multidistrict Litigation seeking that Yaz/Yasmin cases be centralized. At the time, thirty-two (32) cases were pending in various federal courts. On October 1, 2009, the Judicial Panel created a MDL for Yaz/Yasmin cases in the Southern District of Illinois, Judge David Hendron presiding.