Suits over Yaz surpass 10,000 mark

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With the number of Yaz lawsuits (and also suits involving similar drugs Yasmin and Ocella) recently surpassing the 10,000 mark, this popular birth control pill remains one of the most copious pieces of mass-tort litigation of 2012.[1] The federal court system consolidated all of the federal Yaz, Yasmin and Ocella cases in 2009. *In re Yasmin & Yaz Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, 2009 WL 3163531 (J.P.M.L. Oct. 1, 2009) (see *Pharmaceutical Litigation Reporter*, Vol. 25, Iss. 9).

Because MDL cases involve similar issues of fact, it is an efficient way to proceed with the large number of actions, for pretrial and discovery proceedings. Consolidation of these thousands of cases for pretrial litigation ultimately conserves limited judicial resources and saves all parties both time and money. The MDL is pending in the U.S. District Court of the Southern District of Illinois before Judge David R. Herndon.

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In early 2012, Bayer Corp. began settling hundreds of these cases, and according to an analyst at JPMorgan Chase, Bayer could pay some $2.65 billion to settle the remaining lawsuits.[2] Earlier in 2012, Judge Herndon postponed bellwether trials to allow Bayer time to mediate claims with thousands of women claiming injury.

Bayer continues to market and sell these drugs despite the identified risks. In 2010 alone, Bayer reaped $1.62 billion in sales from these drugs.[4] Part of the drugs' smashing success when released in 2006 can be attributed to Bayer's marketing strategy.

In addition to its use as a contraceptive, Yaz was promoted as a drug that improved

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Part of the reason for the skyrocketing number of claims involving more than 12,000 women is the drug's own immediate success. (By way of full disclosure, Langdon & Emison has an active mass-torts practice and currently represents numerous women across the country in Yaz litigation.) A masterful marketing plan made this Bayer product America's top-selling birth-control pill, touted as a drug that performed wonders beyond mere contraception.

YAZ IN THE MARKETPLACE

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Drospirenone has been tied to serious side effects including blood clots, heart attack, stroke, pulmonary embolism and deep vein thrombosis. In a recently released government-funded study that compared several different types of oral contraceptives, those containing drospirenone were shown to increase blood clot risks by 75 percent.[3]

conditions as disparate as bloating, fatigue, acne, and moodiness.[5] While Bayer successfully widened the drug's target audience, it also drew the attention of the Food and Drug Administration, which called the company's ads "misleading" because they "broaden the drug's indication, overstate the efficacy of Yaz and minimize serious risks associated with the use of the drug."[6]

In January 2012 an FDA advisory panel confirmed that Yaz and Yasmin do pose a blood clot risk, though the panel narrowly voted that the increased risk was acceptable in order to prevent pregnancy. However, it turned out that three of the 26 panel advisers had either research or financial ties to Bayer. A fourth adviser had ties to Teva Pharmaceuticals Industries and Barr Pharmaceuticals, which make generic versions of Yaz. According to the Project on Government Oversight, all four of these advisers voted in support of Yaz and Bayer, saying that Yaz's benefits outweighed its risks.

"The American public must be able to trust the FDA and its advisory committees are making decisions based on science, not industry influence," POGO Executive Director Danielle Brian told Reuters.[7] POGO asked the FDA to throw out the vote and convene

a new, truly independent advisory panel without ties to Bayer or the generics makers.

While the dangerous side effects of Yaz persist, it remains a best seller. Although Bayer contends that the drugs are safe and the risks are overstated, it voluntarily enhanced the safety warnings on Yaz labeling in March 2011.[8]

THE HEALTH ISSUES AT THE CORE OF THE MDL

The problem with Yaz, Yasmin and Ocella lies with the synthetic hormone drospirenone, which can cause increased blood levels of potassium. As the MDL lawsuits contend, the high potassium levels mean that the health risks associated with these drugs are greater than those associated with any number of non-drospirenone birth control pills such as Alesse, Tri-Levlen and Ortho-Cyclen. Studies in Germany and Great Britain have found that health risks from taking Yaz, Yasmin and Ocella are double those from taking other birth control pills.

The risks that the plaintiffs in these suits allegedly have suffered include:

- Stroke.
- Heart attack.
- Gall bladder disease.
- Blood clots in the legs (deep vein thrombosis).
- Blood clots in the lungs (pulmonary embolisms).
- Pancreatitis.
- Death (usually as a result of a blood clot, stroke or heart attack).

BAYER WAS WARNED

In 2008 the FDA sent a warning letter to Bayer's president and CEO, centering on the company's Yaz television commercials. It stated in part:

> The Division of Drug Marketing, Advertising, and Communications has reviewed two 60-second direct-to-consumer broadcast television advertisements (TV ads) entitled "Not Gonna Take It" (ZYRA-6323) and "Balloons" (ZYRA-6567) for YAZ (drospirenone and ethinyl estradiol) tablets (YAZ) submitted by Bayer HealthCare Pharmaceuticals Inc. under cover of separate Forms FDA-2253. The ads are misleading because they broaden the drug's indication, overstate the efficacy of YAZ, and minimize serious risks associated with the use of the drug. Thus, the ads misbrand the drug in violation of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 352(n), 352(f)(1) & 321 (n), and FDA's implementing regulations, 21 CFR 201.1 OO(c)(1); 201.128; 202.1 (e)(5)(iii) & (e)(6)(i). These violations are concerning from a public health perspective because they encourage use of YAZ in circumstances other than those in which the drug has been approved, over-promise the benefits and minimize the risks associated with YAZ.

The 2008 warning letter spoke to the drug's successful marketing to that point and noted that the commercial suggests Yaz can treat acne of all severities and such common symptoms as "irritability" and "moodiness."

Since the commercial fails to distinguish between premenstrual syndrome and the more serious premenstrual dysphoric disorder, viewers are led to believe that Yaz is effective at treating PMS, the FDA said.

The FDA letter said the ads were misleading because they suggested that the contraceptive relieves PMS symptoms and helps treat all types of acne, not just moderate acne. After receipt of the FDA letter, Bayer pulled the ads from the air.

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Public Citizen, a nonprofit consumer advocacy group, began warning of the drug's dangers and placed Yasmin on its list of "do not use" pills.

In April 2010, the FDA then required Bayer in to include additional information on package inserts. The new inserts specifically warn consumers of the risks of developing blood clots and having a stroke.

However, the current litigation claims Bayer failed to adequately disclose the risks of taking Yaz and should have informed doctors and patients that the risk of developing a blood clot or having a stroke while taking Yaz was much higher than if patients took non-drospirenone birth control pills. Patient advocates also maintain that Bayer did not fully disclose its research to the FDA, research that was more comprehensive on the drug's side effects and risks.

OFF-LABEL MARKETING EFFORTS

Yaz plaintiffs also contend Bayer engaged in off-label promotion of Yaz and related birth control drugs. They have called former FDA Commissioner David Kessler as an expert witness in the MDL. In a recently unsealed expert's report, Kessler said:

- "Bayer violated its duties under FDA regulations and state law by selectively presenting data as to thromboembolic events, which did not adequately inform FDA, doctors or consumers of the thromboembolic risks, from premarketing to the present."
- "Bayer engaged in extensive off-label promotion of Yasmin and Yaz for unapproved uses, in violation of FDA regulations, to increase sales."
- "That off-label promotion increased the risk of thromboembolic events in patients in violation of state law duties."

According to internal Bayer emails disclosed as part of the litigation, Bayer officials discussed how to promote the contraceptive as a treatment for a wide range of PMS, even though U.S. regulators had only approved the drug to treat its most severe form, PMDD. Salespeople were sent an email saying that they should cite a Woman's Day magazine article when extolling the birth control drug as a safe PMS treatment.

A False Claims Act *qui tam* suit against Bayer was dismissed on Aug. 31, 2012. The *qui tam* case was brought by Pharma Watch LLC and centered on Bayer's off-label marketing of Yaz and Yasmin, in turn leading to distribution of Medicaid payments based on the company's false claims for the products.[9]

The marketing was initially disclosed in a patent infringement case Bayer brought against other drug companies that sought FDA approval to market generic versions of the two drugs. As part of its legal claims in the patent suit, Bayer submitted materials showing that it had marketed the drugs for uses other than oral contraception.[10] In September 2010, it lost the patent case when the court found that its marketing methods were not FDA-approved.

On July 31, 2012, Bloomberg News reported that Bayer had resolved nearly 2,000 Yaz suits in settlements averaging $212,000 each. It appears that Bayer has taken seriously the bevy of lawsuits filed against the company over the drug. The same Bloomberg article said Bayer had also reserved up to $610 million to settle more cases, but that — for now — is only settling claims related to blood clots. Bellwether trials will keep the litigation moving forward, and it is hoped by those on the plaintiffs' side that Bayer will learn from this episode as it develops future products. WJ

NOTES

[1] *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100 (S.D. Ill.).

[2] Jef Feeley & Margaret Cronin Fisk, Bayer Yasmin Lawsuit Settlements Climb to $142 Million, Bloomberg News, Apr. 26, 2012.

[3] Naomi Gronich, Idit Lavi & Gad Rennert, Higher risk of venous thrombosis associated with drospirenone-containing oral contraceptives: a population-based cohort study, CMAJ (Nov. 7, 2011).

[4] Bayer Supports Yaz and Yasmin, Despite Possible Increased Blood Clot Risk, Drug Indus. Daily, Apr. 25, 2011.

[5] Natasha Singer, Health Concerns over Popular Contraceptive, N.Y. Times, Sept. 26, 2009.

[6] Letter from Thomas Abrams, Director, Division of Drug Marketing, Advertising, and Communications, FDA, to Reinhard Franzen, President & CEO, Bayer HealthCare Pharmaceuticals (Oct. 3, 2008) (*available at* http://r.reuters.com/cap45t.)

[7] Anna Yukhananov, U.S. Group Seeks Re-Vote on Birth Control Clot Risk, Reuters, Jan. 12, 2012.

[8] Andrew Bradt, The Shortest Distance: Direct Filing and Choice of Law in Multidistrict Litigation, 88 Notre Dame L. Rev. (July 26, 2012), *available at* http://ssrn.com/abstract=2118219.

[9] *United States ex rel. Pharma Fraud Watch LLC v. Bayer,* No. 1:10-CV-669, *complaint filed* (E.D. Tex. Aug. 31, 2012).

[10] Ellyn Sternfield, Articles In Legal Industry Publications Continue To Qualify As Public Disclosure Under The False Claims Act, Mondaq, Sept. 14, 2012.

Pfizer

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The case was prosecuted by the health care fraud unit of the office of the U.S. attorney in Massachusetts and the Justice Department's consumer protection branch.

The complaint and settlement were filed Dec. 12 in the U.S. District Court for the District of Massachusetts.

"Wyeth tried to cheat the system by obtaining a limited [Food and Drug Administration] approval for Protonix, fully intending to promote this drug for additional, unapproved uses," Massachusetts U.S. Attorney Carmen M. Ortiz said in a statement released by the Department of Justice.

According to the complaint, Protonix is a type of drug known as a proton pump inhibitor, which blocks the production of acid in the stomach.

PPIs are used to treat gastroesophageal reflux disease, commonly known as heartburn, caused by excess acid flowing from the stomach to the esophagus. Symptomatic GERD that does not cause damage to the esophagus is referred to as non-erosive reflux disease.

Erosive esophagitis occurs when a patient has heartburn and damage to the esophagus.

The FDA treats the two types of GERD as separate indications, according to the complaint.

According to the complaint, Wyeth obtained approval of Protonix in February 2000, for short-term treatment of erosive esophagitis, although it anticipated that the drug would be accepted by doctors as treatment for all types of GERD.

In its initial marketing campaign in March 2000, Wyeth said Protonix should be taken to treat GERD.

After receiving admonishments from the FDA, Wyeth changed its marketing materials to use the phrase "erosive GERD" instead of "GERD," the complaint says.

Although Wyeth changed its marketing materials, from February 2000 through June 2001, it trained its sales force to convince doctors to prescribe Protonix for all forms of GERD, not just erosive esophagitis, the complaint alleges. The marketing plan was approved at the highest levels of the company.

Wyeth also promoted Protonix for unapproved uses through continuing medical education programs for doctors. Through its illegal promotion and distribution of misbranded Protonix tablets, the company was unjustly enriched, the complaint alleged.

"Drug manufacturers should not be permitted to profit from misbranding their products," Stuart Delery, principal deputy assistant attorney general, said in the Department of Justice press release.

"The disgorgement remedy here ensures that this does not happen in this case," he added. WJ

Related Court Document:
Complaint: 2012 WL 6801533

See Document Section A (P. 19) for the complaint.