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August 20, 2010

NEWS RELEASE

U.S. APPEALS COURT REINSTATES CLAIM THAT CONTROVERSIAL DIET DRUG REDUX SHOULD NEVER HAVE BEEN OFFERED TO AMERICAN PEOPLE

Holds that Federal regulation does not preempt Ohio state consumer-protection law

Cincinnati, Ohio (August 19, 2010) – An Ohio Federal Court of Appeals ruling issued yesterday is reinstating the late victim's claim that the recalled diet drug Redux (commonly called fen-phen) linked to her death should never have been marketed to the American people by Wyeth due in part to its pre-approval concerns about potentially lethal side effects. The Court, in remanding the case to the trial court, held that Federal drug regulations do not preempt Ohio negligence claims, and indicated that the Supreme Court's 2009 landmark pharmaceutical manufacturer preemption decision (*Wyeth v. Levine*) may apply beyond inadequate warning-label claims.

Benjamin H. Anderson, Esq., of Anderson Law Offices, LLC of Cleveland, Ohio, counsel for the plaintiff, said, "Mary Buchanan, like so many others, turned to a drug to help her lose weight and as a result she lost her life. She and her surviving family members deserve justice; this is an important decision in her case and for the harms and losses she sustained, as well as the many millions of Americans taking prescription medications who have long been concerned about drug companies being shielded from appropriate state negligence laws. Significantly, the appeals court has also reinstated and remanded to the trial court our claim for punitive damages."

In reversing key sections of the trial court's finding for the defendant on summary judgment in *Wimbush v. Wyeth et.al.*, 6th Cir. No. 09-3380, the three-judge appeals panel held that the trial judge erred in concluding that the U.S. Food and Drug Administration (FDA) preempted the Buchanan family's negligence claims that the drug should never have been made available to Americans given Wyeth-Redux's known health risks, particularly Primary Pulmonary

Hypertension (PPH). Mrs. Buchanan, a hard-working and dedicated 66- year-old nurse from Maple Heights, Ohio who took the weight-loss drug during 1996 and 1997, lost her life to PPH in 2003 within a few months after filing the complaint. The drug company, which spent more than \$50 million marketing the wildly popular and profitable drug after its launch in April 1996, pulled it on September 15, 1997 at the request of the FDA and under mounting criticism by independent researchers and reports in respected medical journals.

Though Redux was only on the market for a relatively short period, to date it is estimated that Wyeth has paid thousands of victims of Redux and its predecessor, Pondimin – and/or their survivors – more than \$20 billion in damages. In evaluating the potential side effects of Redux, researchers noted that PPH is a devastating pulmonary disease for which there is still no cure, and the associated heart-valve problems may and often did require high-risk heart surgery. The controversial, high-risk diet drug had previously been evaluated and pulled from pharmacies overseas and it was banned in some individual states before the total recall.

In its decision, the appeals Court stated, “. . . we are not persuaded that it is always impossible to comply with both state law duties and FDA regulations in the process leading up to FDA approval.” It added, “. . . we cannot agree with the district court’s conclusion as, not only is there a presumption against preemption, but the case law supports the conclusion that Congress did not intend to preempt state tort law claims when it passed the Food, Drug, and Cosmetics Act (FDCA).”

In a footnote, it commented “. . . the overwhelming take-away from the *Levine* majority opinion is that state tort law has historically played a substantial role in the regulation of drug manufacturers and that Congress has never indicated an intent to change this role. Thus, while *Levine* did leave open the possibility that there may be some state law claims that would conflict with the FDA’s regulatory authority and function, the claim at issue in *Levine* was not one of them. We do not believe that Buchanan’s pre-approval negligence claims are, either.”

Attorney Anderson, commenting on the interpretation of the *Levine* ruling in the case, said, “Drug companies are now on notice that they cannot lie to and conceal from the FDA crucial information in the pre-approval process and then expect to be held harmless once their drugs are responsible for causing pain, suffering and, as in Mrs. Buchanan’s case, death.”

The Court affirmed the dismissal of the balance of the plaintiff’s claims, and Attorney Anderson said he will evaluate with appellate counsel Paul Flowers, Esq., and Mrs. Buchanan’s family all appropriate legal options.

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