Drug Companies Seek to Invoke Shield Law of Preemption

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(Vocus) May 15, 2008 -- An anticipated US Supreme Court ruling may prevent victims injured by the Ortho Evra patch and other harmful drugs from having their day in court, according to Hissey Kientz, LLP.

Manufacturers of the Ortho Evra patch and other drug companies have argued that they should be shielded from responsibility for the injuries caused by their products. If the drugs were approved by the Food and Drug Administration, these corporations argue that a legal doctrine known as "preemption" should protect them from this responsibility.

"Such a ruling would abolish our constitutional guarantee to hold corporations responsible for wrongdoing in a court of law," according to Michael Hissey, an attorney with Hissey Kientz, LLP in Austin, Texas.

The U.S. Supreme Court will soon rule in the case of Wyeth v. Levin, No. 06-1249. The issue to be decided is whether FDA approval shields a drug company from responsibility, even when known risks were concealed. Such a corporate shield would prevent victims injured by the Ortho Evra patch and other dangerous drugs from holding corporations responsible for medical bills and the serious injuries they have suffered.

Many are unaware that the Food and Drug Administration does not perform safety studies or clinical trials on any drugs. Instead, the drug companies themselves fund these studies privately and submit select studies for the FDA to review.

The FDA's former top lawyer, Daniel Troy, has a long history of working for the very drug companies he was sworn to regulate. Under Troy, the FDA actually filed briefs as "friends of the court" in support of the corporate shield law against many victims injured by dangerous or defective drugs. "We can't rely on drug companies to tell us whether their own products are safe. We should not ask the fox to count the chickens for us," says attorney Rob Kientz.

According to Professor Tom McGarity, author of the forthcoming book The Preemption War (Yale University Press, October 2008), "Federal agency preemption puts the victims of corporate malfeasance in the worst of all possible worlds -- unprotected by the overworked and underfunded federal bureaucracies and uncompensated by corporate wrongdoers because they have lost their right to a day in court."

Even in cases where drug companies concealed risks of dangerous drugs, they argue that they should not bear any responsibility. When the Ortho Evra patch was approved by the FDA in 2001, studies conducted by Johnson & Johnson showed that the patch releases a much higher dose of estrogen into the bloodstream than traditional birth control pills. Because estrogen increases the risk of blood clots, Ortho Evra users are much more likely to suffer heart attacks, strokes and deep vein thrombosis.

J&J initially failed to reveal to the FDA that the Ortho Evra patch delivered too much estrogen. Several years passed before the agency became aware of the true dangers of the birth control patch. Thousands of patients who were unaware of these risks suffered blood clots, heart attacks or strokes, and many died, before the first time that J&J changed the patch's label. Instead of voluntarily recalling this dangerous product, J&J simply decided to change the warning label on the Ortho Evra patch, which it has now done three times. Unfortunately, the warning is still as inadequate as the drug is dangerous.

More than 3,000 women and their families have filed lawsuits to hold drug companies responsible for the serious or fatal injuries they suffered after using the Ortho Evra patch. If the drug companies get their way, thousands of others who were unaware of the health risks they faced from the Ortho Evra patch and other "approved" drugs may soon be left with no means to hold companies responsible for their wrongdoing.

About Hissey Kientz, LLP

Hissey Kientz, LLP is currently handling cases involving people injured by the Ortho Evra Patch. Hissey Kientz LLP also represents those who contracted mesothelioma or lung cancer as a result of asbestos exposure, those injured by dangerous drugs and medical devices including Heparin allergic reactions, Trasylol, the Composix Kugel mesh patch and other defective drugs and devices. To learn more about the firm and other drug cases, visit Hissey Kientz, LLP (www.hkllp.com) or call toll-free at (866) 275-4454.

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