GlobalResearch
Center for Research on Globalization

Big Pharma May be Handed Blanket Immunity for All Drug Side Effects, Deaths

By David Gutierrez
Global Research, November 09, 2008
NaturalNews 3 November 2008

Region: USA
Theme: Science and Medicine

The Supreme Court may rule that pharmaceutical companies cannot be sued for dangerous or even deadly side effects from their drugs if those side effects arise from an FDA-approved use.

Under a legal argument known as “pre-emption,” the FDA’s approval of a drug absolves companies of any responsibility if that drug later turns out to be dangerous, even if information was concealed from the FDA during the approval process. While courts have rejected this argument for decades, the winds appear to be shifting.

In February, the Supreme Court ruled that makers of medical devices were indeed immune from state lawsuits if their devices had received FDA approval. But that decision hinged on the specific wording of the law that gives the FDA authority over medical devices, and the laws relating to drug regulation are not worded the same way.

Even so, the Bush administration has been actively urging the courts to apply the same principle to drugs. The administration argues that only the FDA is equipped to regulate drugs and decide whether a product is safe, and that judges or juries are not able to make informed decisions on those matters.

The FDA has also recently thrown its support behind pre-emption, reversing a longstanding, de-facto policy of viewing lawsuits as an extra layer of oversight to make up for the agency’s time and budget constraints. Now the agency says that lawsuits over drug side effects could lead to a confusing state-by-state regulatory patchwork that would cause hardship to drug companies and discourage patients from taking certain medications.

Drug companies are using the pre-emption argument as a legal defense in a wide variety of lawsuits, and the Supreme Court is expected to hear such a case, concerning the company Wyeth, in the fall. Before that, however, a lower federal court is expected to rule on whether pre-emption can be used to dismiss lawsuits by more than 3,000 women who claim that they were injured by using Johnson & Johnson’s OrthoEvra birth control patch according to the instructions on the label.

When Johnson & Johnson announced its plans for a birth control patch in 1996, one of the main benefits it claimed the product would provide was the ability to prevent pregnancies through lower doses of estrogen than birth control pills. High doses of estrogen are known to increase women’s risks of blood clots, heart attacks, strokes and death.

But company documents publicized as part of the lawsuits show that in 1999, the company

discovered that the patch actually exposed women to significantly more estrogen than the pill, a total of 30 to 38 micrograms per day. Because only about half of the estrogen in a birth control pill actually enters the bloodstream, this means that women using the patch were getting as much estrogen each day as if they were taking a 76 microgram birth control pill.

The FDA banned birth control pills containing more than 50 micrograms of estrogen in 1988.

Rather than reporting this data to the FDA, however, the study's author instead applied a "correction factor," reducing the estrogen figures by 40 percent. Although the author claimed this was meant to adjust for differing rates of estrogen absorption, such a "correction" was a deviation from the study procedure previously submitted to the FDA.

In the final report submitted to the FDA, Johnson & Johnson claimed that OrthoEvra exposed women to only 20 micrograms of estrogen per day. The "correction factor" was referenced only once in the 435-page study report, buried in a complex mathematical formula.

According to internal company emails, other clinical trials conducted before approval suggested that women were experiencing side effects such as breast soreness and nausea due to high estrogen doses, but the company did not warn the FDA that the patch might be delivering more estrogen than advertised. Nor did it tell the agency about other studies, in 1999 and 2003, showing that the patch exposed women to more estrogen than the pill.

When the FDA approved the product in 2001, Johnson & Johnson marketed it as releasing less estrogen than the pill, containing 20 micrograms per day.

The label was not revised until a 2005 investigation by the FDA, following reports of deaths resulting from use of the drug. At that point, the FDA made Johnson & Johnson add a warning that the product "exposes women to higher levels of estrogen than most birth control pills."

But the company always knew this to be the case, several lawsuits now allege, and is thus responsible for the side effects that resulted: heart attacks, strokes, and even deaths in those who used the patch as directed. Studies have since confirmed that women on the patch may have twice the blood clot risk of women taking birth control pills, and prescriptions have fallen 80 percent, from a high of 900,000 in March 2004 to only 187,000 in February 2007.

But Johnson & Johnson claims that because the FDA approved the drug, the company cannot be held responsible for its effects.

Janet Abaray, a lawyer for one of the plaintiffs, disagrees, saying the company took advantage of the agency's shortcomings.

"Johnson & Johnson knew that FDA. does not have the funding or the manpower to police drug companies," Abaray said.

David Vladeck of Georgetown Law School agrees that the FDA has no ability to verify that drug companies are being truthful in their reports.

"These are scientists, not cops," he said.

Chris Seeger, another plaintiffs' lawyer, said it would be a mistake to allow pre-emption to let the drug companies off the hook.

"Our lawsuits are the ultimate check against the mistake made by the government, or fraud made by the companies against the government, or just an underfunded bureaucracy stretched thin," he said.

Sources for this story include: www.nytimes.com.

Articles by: David Gutierrez