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**EDITORIAL**

## **The Dangers in Pre-emption**

The pharmaceutical industry and its good friends in the Bush administration are working hard to prevent consumers from filing damage suits for injuries caused by federally approved drug products. They may soon get a helping hand from the Supreme Court, which has already barred many suits over faulty medical devices.

If this perverse legal doctrine, known as federal pre-emption, continues to spread, the public will be deprived of a vital tool for policing companies and unearthing documents that reveal their machinations.

The dangers were made clear in an article by Gardiner Harris and Alex Berenson in *The Times* on April 6. Their report described how Johnson & Johnson obscured the fact that its Ortho Evra birth control patch delivered much more estrogen than standard birth control pills, thereby increasing the risk of blood clots and strokes. More than 3,000 women and their families have sued the company.

The company is arguing in court that the women can't sue because the patch and its labeling were approved by the Food and Drug Administration, the presumed authority on drug safety. But the disturbing element is that the company seems to have done its best to mislead the F.D.A., as revealed in company documents made public as a result of the lawsuits.

The company's primary study on Ortho Evra, completed in 1999, found that the patch delivered a relatively high amount of estrogen into the bloodstream. A company official dealt with that uncomfortable and unexpected fact by applying a "correction factor" to lower the numbers by 40 percent. He rationalized that the correction was justified because the body metabolizes hormones from pills and patches in different ways. But the company was not eager to acknowledge what it had done. The correction factor was mentioned only once in a 435-page report to the F.D.A. and even then only in a complex mathematical formula. Nor was it mentioned when the study was published in 2002.

The F.D.A. has since required label changes citing evidence that patch users are at higher risk of developing serious blood clots than women using birth control pills. Even so, the agency

continues to insist that Ortho Evra is a safe and effective method of contraception.

Whatever the merits of this case, it would be a mistake to rely solely on the F.D.A.'s judgment. The agency is short of skilled scientists. If a company buries important information deep in the bowels of a report, the agency may not detect it or appreciate its significance. Injured patients should not lose the right to sue if they are harmed by duplicitous manufacturers.

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