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## Ortho-McNeil's Response To April 2008 NYT Article About Ortho Evra And FDA / Federal Preemption

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FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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### New York Times Reporters Gardiner Harris and Alex Berenson Bring Attention To How This Emerging Legal Issue Would Affect Drug Injury Cases

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

To our pleasant surprise, we saw lots of notice and reaction being given to the April 6, 2008 *New York Times* (NYT) article, "[Drug Makers Near Old Goal: A Legal Shield](#)", wherein *Times* reporters Gardiner Harris and Alex Berenson explore the concept of "federal preemption" as regards some pending Ortho Evra lawsuits.

The Harris - Berenson NYT "Ortho Evra" article is worth a read, especially if you have an interest in either the preemption issue or this particular drug injury litigation:

For years, Johnson & Johnson obscured evidence that its popular Ortho Evra birth control patch delivered much more estrogen than standard birth control pills, potentially increasing the risk of blood clots and strokes, according to internal company documents.

But because the Food and Drug Administration approved the patch, the company is arguing in court that it cannot be sued by women who claim that they were injured by the product — even though its old label inaccurately described the amount of estrogen it released.

This legal argument is called pre-emption. After decades of being dismissed by courts, the tactic now appears to be on the verge of success, lawyers for plaintiffs and drug companies say.

The Bush administration has argued strongly in favor of the doctrine, which holds that the F.D.A. is the only agency with enough expertise to regulate drug makers and that its decisions should not be second-guessed by courts. The Supreme Court is to rule on a case next term that could make pre-emption a legal standard for drug cases. The court already ruled in February that many suits against the makers of medical devices like pacemakers are pre-empted....

What had not gotten as much attention was Ortho-McNeil's written response to this April 6 *NYT* article that the drug company published on their website. One reason for the lower profile might be that the company-statement item is a bit difficult to find: It goes by the obscure title of "April 2008 Employee Communication", and the link is found on [what appears to be a new, specially created web page](#), *i.e.*, it had no page title nor was it listed on the Sitemap when accessed at 4:20 p.m. on April 7, 2008.

Perhaps wanting to make sure that the word got out, however, the Ortho McNeil "retort" was the subject of an April 7 post, "[The New York Times, Pre-Emption and ORTHO EVRA](#)", found over at "About JNJ BTW" -- the in-house blog for Johnson & Johnson (Editor: Marc Monseau).

As for [the text of Ortho McNeil's retort to this Ortho Evra - federal preemption story](#), here's the gist:

While the [April 6 *NYT*] article deals predominantly with the issue of pre-emption, it also questions our commitment to patient safety and scientific integrity. And in so doing, it inaccurately depicts our actions leading up to approval of the patch by the U.S. Food and Drug Administration (FDA) in 2001, and the data reporting procedures we have followed since. I want to make sure you have our point of view, in part because some of the characterizations in the article, including references to internal company documents, are taken clearly out of context.


This April 2008 *NYT* report demonstrates how important it is to learn more about this issue of federal preemption. As I wrote recently on this site, in this post, "[Issue: Should We Be Prohibited From Filing Product Liability Lawsuits Against Medical Device Manufacturers And Pharmaceutical Companies?](#)":

According to some critics, the prohibition of drug injury lawsuits by operation of the federal preemption doctrine may have some merit in an ideal world where the FDA was performing its drug-safety regulatory functions at 100%. But that has not been the situation in the past, nor is it the case today.

Our thanks to two of the leading Pharma reporters, Gardiner Harris and Alex Berenson, for shining a light on this critical legal issue of preemption in the context of drug injury claims.

[Read more from this blogger at Drug Injury Watch](#) | [Let us know what you think of this feature](#)

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