

Last Sunday, April 6th, *The New York Times* ran a front-page story that prominently featured ORTHO EVRA® (norelgestromin/ethinyl estradiol transdermal system), our transdermal contraceptive patch. As I said in a brief note sent to employees that same evening, while the story largely addressed a legal doctrine known as pre-emption, it also called into question our own practices and interactions with health authorities. In that communication, I mentioned that we chose to actively engage with *The Times'* reporters and that we answered all of their questions in a lengthy interview. Unfortunately, the article did not include many of the significant facts our representatives relayed to them during the interview, but I want to provide to you what we shared with them, to give you a more complete picture of our actions.

Let me assure you of this: First, we deny any assertion that we “obscured evidence” from the FDA, the medical community and the public. The opening paragraph in *The Times* comes directly from briefs filed by plaintiff’s attorneys suing the Company, which does not qualify as an objective presentation of the facts. Second, we take very seriously our responsibility to provide current and accurate information about our products so that health authorities, physicians and patients can make the most-informed choices about treatment options.

Below I hope to clarify four points we discussed at length with *The Times* reporters, which they did not fairly portray in the article.

1) Why was a correction factor used in our analysis and did the FDA know about it?

The correction factor is part of a mathematic calculation used to estimate the average amount of medicine that enters the blood from the patch on a daily basis. The “correction factor” was not a change made to the amount of estrogen actually received by women wearing the patch. Study 014 was included in the ORTHO EVRA New Drug Application. The study report is 42 pages, not 400 pages (there are approximately 350 pages of “supporting data” - tables, charts and appendices attached to the file report). The correction factor is discussed and described in three places -- the body of the report, the summary and discussion of the report and an attached Appendix.

Hormonal birth control pills deliver a specific daily dose of medication to the body. Approximately half of that amount of medication goes into the blood stream and is ultimately cleared from the body within a specified timeframe (also known as systemic clearance). Calculating the daily dose from the patch cannot be done in the same fashion as with the pill.

In a 1999 pharmacokinetic study (called 014), we set out to measure the levels of estrogen in women’s bodies after wearing the patch for a week, and to determine the amount of estrogen reaching the blood each day.

At no time were the actual measured levels of estrogen in the patch wearers lowered by the “correction factor.” The use of the “correction factor” did not change the overall level of estrogen reported to the FDA.

2) When did you know about the 60% increased estrogen exposure using ORTHO EVRA vs. the pill?

After ORTHO EVRA was approved by the FDA, a pharmacokinetic study (called NED-1) was conducted in the Netherlands to further characterize the pharmacokinetic profiles of ORTHO EVRA and the birth control pill, CILEST (Ortho-Cyclen). NED-1 reported that women using ORTHO EVRA had peak concentrations of estrogen, which were 25% lower than women using the pill. The study also found that women using ORTHO EVRA had

average concentrations of estrogen at steady state, which was 60% higher than women using the pill.

These data were sent to the FDA within 90 days of the report being finalized, as part of an annual submission and added to the label after discussion with the FDA in November 2005.

The FDA approved label clearly states that it is not known whether these differences in the pharmacokinetic profiles increase the risk of serious adverse events.

The approved ORTHO EVRA product label has always stated the known risks associated with the use of ORTHO EVRA. When new data advanced our understanding of the risks of the product's use, we proactively approached the FDA and updated the label.

3) Did we obscure evidence from the FDA?

Absolutely not. We have always acted appropriately and responsibly in developing and making available ORTHO EVRA as a hormonal birth control option for women. We have regularly disclosed data to the FDA, the medical community and the public in a timely manner.

4) Is pre-emption a legal shield for companies?

Pre-emption is a legal doctrine that says the FDA is exclusively authorized to make decisions about the safety and effectiveness of medical devices and pharmaceutical products. Put more simply, pre-emption respects the FDA's expertise to carefully review safety and efficacy data and ensure that appropriate risk-benefit determinations are made for pharmaceutical products. Our Company has regularly disclosed data to the FDA, the medical community and the public in a timely manner.

In closing, I know that you share my concerns when our Company and the actions of our people are unjustly portrayed. Therefore, it is important for me to present you with these facts, as they were presented to their reporters. In the months ahead, the media will likely continue to cover ORTHO EVRA as lawsuits move forward, and we will provide information to the media, as appropriate, to ensure that our point of view is conveyed.

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