

The April 6th edition of *The New York Times* published an article entitled, “Drug Makers Near Old Goal: A Legal Shield.” The article is about a legal doctrine, called pre-emption, and featured prominently is ORTHO EVRA® (norelgestromin/ethinyl estradiol transdermal system), the birth control patch marketed in the U.S. by Ortho-McNeil.

While the 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.

We chose to participate in an interview on this subject with *The New York Times* late last week to ensure their reporters understood the actions we took, and when we took them, as new data on ORTHO EVRA became available. Some of the information we shared was incorporated into the story, but certainly not all.

ORTHO EVRA is a safe and effective birth control method when used according to the approved product label. As with all of our hormonal contraceptive products, we have always suggested that women consult their healthcare professionals to make choices that best meet their individual needs.

Throughout the development of ORTHO EVRA, and since its availability on the U.S. market, we have regularly disclosed data to the FDA in an appropriate manner. The FDA-approved product label states the known risks associated with the use of the product, and the label has been updated appropriately, always following FDA review and input.

We anticipate that there could be ongoing media coverage about the legal doctrine of pre-emption and ORTHO EVRA, and it is important to remember that we have acted responsibly in reporting scientific data to the FDA throughout the product’s development and post-marketing availability.

The men and women of our pharmaceutical companies remain committed to the safe use of all of our products, and patient safety is of primary concern to all of us. Our responsibility has been, and remains, focused on helping people live healthier lives while meeting the needs of health care professionals and patients. We will continue our work in that spirit.

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