

EMPLOYMENT LAW

## Suits build over birth patch

Hundreds of actions allege clots, strokes; MDL pending in Ohio.

**Tresa Baldas/Staff reporter**  
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A birth control patch has triggered a major legal migraine for Johnson & Johnson, which has been hit with a slew of lawsuits over its patented contraceptive device.

As many as 500 suits have been filed over the Ortho Evra patch in the last two years, claiming it has caused clots, strokes and in several cases, death, according to court records and plaintiffs' lawyers.

At least one lawsuit has been filed every month. Two were filed in California this week on behalf of more than 50 women, including one wrongful death case. Three more were filed in Texas last week, and a multidistrict litigation (MDL) is pending in Ohio on behalf of more than 100 women nationwide. *In re Ortho Evra Products Liability Litigation*, No. MDL-1742 (N.D. Ohio).

Ortho Evra, which was approved by the the U.S. Food and Drug Administration (FDA) in 2001, is a once-a-week birth control patch worn on the skin. It releases estrogen and progestin directly into the bloodstream.

In September, the FDA approved new label information for Ortho Evra following a study that showed women using the patch were twice as likely to experience blood clots as were those who took the pill. The FDA also required Ortho Evra last year to carry a new warning that the drug exposed women to 60% higher levels of estrogen than oral contraceptives.

### Warnings not enough?

For plaintiffs' attorneys, however, the warning in bold and label updates aren't enough.

"This drug should be off the market," said attorney John David Hart of The Law Offices of John David Hart in Fort Worth, Texas, who represents more than 40 women in four suits over the patch.

"The Ortho Evra patch is great for Johnson & Johnson, which is selling 20 million prescriptions for this," Hart said. "But for the women who are using this, they're never told that they're trading safety for convenience."

Officials at Johnson & Johnson, which owns Ortho-McNeil Pharmaceutical Co., the patch's developer and manufacturer, declined to comment. A company spokesperson referred *The National Law Journal* to the Ortho Evra Web site, in which the company addressed the two recent studies that prompted the FDA to mandate the label warning.

"Agreements are in place to continue data collection for both studies and we will continue to provide new information to [the] FDA," the company stated in a September news release.

With regard to safety information, the company states on its Web site: "Serious as well as minor side effects have been reported with the use of the Patch. Serious risks, which can be life threatening, include blood clots, stroke and heart attacks and are increased if you smoke cigarettes."

Lawyers at Tucker & Ellis in Cleveland, which is representing Ortho-McNeil in the Ohio MDL, as well as in other lawsuits, declined to comment.

According to court documents filed in Texas, between April 2002 and December 2004, nearly 28,000 adverse events were reported to the FDA regarding Ortho Evra. In comparison, for that same time period, about 5,500 adverse events were reported by women taking the Ortho-Tricyclin birth control pill, another Johnson & Johnson product.

California plaintiffs' attorney Shawn Khorrami, who is representing more than 400 women in numerous Ortho Evra lawsuits, wants the product yanked off the market.

"I'm fine with making something more convenient, but safety is what's got to be paramount here," said Khorrami of the Law Offices of Shawn Khorrami in Los Angeles.

Khorrami's law firm last week filed a wrongful death suit involving a 26-year-old woman who died while using the patch, and a mass action suit on behalf of 55 women nationwide suffering from blood clots and other serious illnesses. *Angelle v. Ortho-Evra*, No. CGC-06-458631 (San Francisco Co., Calif., Super. Ct.).

"The company should seriously think about settling these claims," Khorrami said.