

[in the news] BY TERRI D'ARRIGO

Avandia Update

Committee urges caution on heart risks

By now, you have probably seen the headlines about heart attack and the popular type 2 diabetes drug Avandia. That drug has been the subject of controversy and widespread news coverage since an analysis published in the June 14 issue of the *New England Journal of Medicine* suggested that those who use Avandia face up to a 43 percent greater risk of heart attack than those who don't. (See "Avandia and Your Heart," July 2007, p.16.) Now a Food and Drug Administration (FDA) advisory committee has recommended that Avandia remain on the market but with strong warnings on the label describing the heart attack risk.

Although the FDA committee agreed that Avandia appears to increase the risk of heart attack, it also felt that the benefits of taking the drug for blood glucose control warranted keeping it on the market. The committee of independent medical experts acknowledged the complexity of studies concerning Avandia as well as the controversy surrounding the studies, how they were carried out, and whether the results could be interpreted different ways using different methods of calculating statis-



tics. Several committee members noted that other diabetes drugs have risks, too.

The FDA is not required to follow advisory committee recommendations but usually does so. In this case, the committee recommended the strongest caution possible, a "black box" warning. Black box warnings are added to the paper insert in drug packaging to highlight particular risks as well as symptoms that could indicate problems associated with a medication.

If You Take Avandia

So what does this mean for people currently taking Avandia, and the similar drug Actos? "First, don't do anything rash, like stopping your medications without telling your doctor," says Paris Roach, MD, associate professor of clinical medicine in the Division of Endocrinology at the Indiana University School

of Medicine in Indianapolis.

He adds that the decision to continue the drug should be one you and your doctor make together. "If someone already has [heart] risk factors, [their doctor] might shy away from Avandia," he says.

But if you've been taking the drug, you're healthy, and your blood glucose is in good control, those are also things to consider. Although heart disease risk is something to consider during treatment with Avandia, it is well-established in the medical community that uncontrolled diabetes can raise your risk, too. And remember, doctors regularly weigh the risks of any medications they prescribe. "You have to seek your physician's input," says Roach. "Your doctor will consider the [study] data and your level of control when discussing your alternatives."

Terri D'Arrigo is an associate editor of Diabetes Forecast.

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