Qnexa Weight-Loss Drug Makes a Comeback

March 1, 2012 by Patrick A. Malone

It's as if they're playing hokey-pokey over at the FDA.

The Endocrinologic and Metabolic Drugs Advisory Committee recently gave a thumbs-up to Qnexa fewer than two years after recommending against it. It's the first time since 1999 that an advisory panel for the federal agency has approved a weight-loss drug.

The FDA doesn't have to accept the panel's advice, but usually does.

The side effects that prompted the initial rejection of Qnexa are still of concern, but experts believe that if the drug is used only by a certain segment of the obese population and if trials study its performance after approval, the benefits for that population supersede the risks.
Like all the expansive media coverage of the Qnexa announcement, MedPage Today reported that concern centers around the increased risk of an elevated heart rate and of birth defects, specifically oral clefts.

Cardiovascular issues arise because Qnexa contains phentermine, the second member of Fen-Phen (fenfluramine/phentermine), an obesity drug yanked from the market six months after its introduction in 1997 because it increased the risk of valvular heart disease, posed a risk for birth defects and compromised mental acuity.

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The drug combines phentermine, an appetite suppressant, with topiramate, an anti-seizure medication that increases the feeling of having eaten enough. Both drugs already are FDA-approved.

FDA panelists reviewed three studies that were conducted after the first advisory committee review of Qnexa and concluded that they did not show an association of topiramate exposure and risk of major congenital malformations. They warned, however, that topiramate exposure in pregnancy was likely to be associated with increased incidence of oral clefts.

Vivus, manufacturer of Qnexa, agreed to develop a risk-mitigation strategy that provides:

- labeling that states the drug should be discontinued if the patient becomes pregnant;
- distribution of Qnexa only through 10 certified mail-order pharmacies that agree to train pharmacists in use of the drug and submit to internal audits;
- targeted education programs aimed at providers and patients, including a brochure on contraception and recommendations for monthly pregnancy testing;
- development of a pregnancy registry to track pregnancy outcomes.

In addition, Qnexa is intended for use only by people with a body mass index (BMI) 30 or higher, or a BMI of 27 or above for people who also have weight-related health problems, such as diabetes. A BMI of 25 to 29 signifies overweight, and 30 or greater is considered obese.

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