

Theodore Weltzin, MD
Pathway Clinic
560 4th Street
Prairie du Sac, WI 53578

October 5, 2006

Dear Dr. Weltzin,

On September 29, 2006, the FDA notified healthcare professionals and patients regarding preliminary information from the North American Antiepileptic Drug Pregnancy (NAAED) Registry that suggests that babies exposed to Lamictal (lamotrigine) during the first three months of pregnancy may have a higher chance of being born with a cleft lip or cleft palate. The oral clefts reported were few and were not part of a syndrome that included other birth defects.

- In the NAAED registry, 564 pregnant women were treated with lamotrigine monotherapy, and 5 oral cleft cases (2 isolated cleft lip, 3 isolated cleft palate) occurred (total prevalence of **8.9 per 1000**).
- Prevalence of non-syndromic oral clefts among infants of nonepileptic mothers not taking lamotrigine in other studies from the U.S., Australia and Europe range from **0.50 to 2.16 per 1000**.

The clinical significance of the currently unconfirmed association between lamotrigine and oral clefts remains uncertain pending further data collection in pregnancy registries or through other research. Additional information is available at: <http://www.fda.gov/cder/drug/infopage/lamotrigine/default.htm>.

Unity Health Insurance wishes to assist you in caring for your patients affected by this recent action. **Unity records indicate the patients (female and age as of 10/4/06 between 13 and 50) in the enclosed report received a prescription for Lamictal from your practice since 7/1/2006.** Please be advised that this is only as accurate as the prescription claim submitted. Unity is not making a recommendation to discontinue therapy but to consider the benefits and risks for the individual patient, keeping in mind that pregnant women and unborn children may face significant health risks from untreated epilepsy or bipolar disorder.

If you have any questions about this letter please call the Unity Pharmacy Program at 1-888-450-4884.