Below is information on a newly discovered risk that is associated with Lamictal (lamotrigine) use; so far there have been only 8 known cases of this reaction in 24 years. Psychiatrists are still trying to assess this new risk. In patients currently taking the medication not experiencing this reaction, the likelihood of the reaction occurring seems very small, though it's not yet possible to know how small. I encourage folks on Lamictal to discuss this further with their doctor. Below is an article on the risk from the website Medscape:

"The anticonvulsant medication lamotrigine can cause the rare but serious immune system reaction hemophagocytic lymphohistiocytosis (HLH), the US and Food and Drug Administration said today in a safety communication. The FDA said a warning about the risk for HLH will be added to the prescribing information on lamotrigine drug labels.

Lamotrigine is used alone or with other medicines to treat seizures in patients age 2 years and older. It is also indicated for maintenance treatment in patients with bipolar disorder to help stave off mood episodes (depression, mania or hypomania, and mixed episodes). HLH is a hyperinflammatory syndrome that can lead to hospitalization and death, especially if not diagnosed and treated quickly. Diagnosis is often complicated because early signs and symptoms, such as fever and rash, are not specific, the FDA notes. HLH may also be confused with other serious immune-related adverse reactions, such as drug reaction with eosinophilia and systemic symptoms (DRESS).

Lamotrigine was approved in 1994 and is available under the brand name *Lamictal* (GlaxoSmithKline) and in generic forms. In the 24 years since approval, the FDA has identified eight cases (two in the United States and six abroad) of confirmed or suspected HLH associated with lamotrigine in children and adults but says there are "likely additional cases" that they are unaware of. There is "reasonable evidence" that lamotrigine was the cause of HLH in these

eight cases, based on the timing of events and the order in which they occurred, the agency said. All eight patients required hospitalization and received drug and other medical treatments. One patient died.

The FDA recommends that patients taking lamotrigine who develop fever or rash be evaluated promptly; the drug should be stopped if HLH or another serious immune-related adverse reaction is suspected and an alternative cause for the signs and symptoms cannot be established.

Patients receiving lamotrigine should be advised to seek immediate medical attention if they experience symptoms of HLH. HLH can be diagnosed if a patient has at least five of the following eight signs or symptoms:

- Fever and rash;
- Enlarged spleen;
- Cytopenias;
- Elevated levels of triglycerides or low blood levels of fibrinogen;
- High levels of blood ferritin;
- Hemophagocytosis identified through bone marrow, spleen, or lymph node biopsy;
- Decreased or absent natural killer cell activity; and
- Elevated blood levels of CD25 showing prolonged immune cell activation.

Healthcare professionals are encouraged to report adverse events related to use of lamotrigine to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.