

With respect to the summaries of post-marketing adverse experience reports, which have been prepared by FDA's Division of Drug Risk Evaluation I (Office of Post-Marketing Drug Risk Assessment), please note that these summaries provide qualitative and descriptive information about reports that have been received for individual drugs. These summaries should not be interpreted as supporting conclusions about the comparative safety of the different drugs. Variations in adverse event reporting practices make quantitative safety comparisons of different drugs problematic. Sources of variation may include manufacturer reporting practices, time on market, calendar year, and publicity. These and other factors may result in substantial variations in the types and numbers of reports for individual drugs in the spontaneous Adverse Event Reporting System.