***ESA Position Statement:* Alleged increased risk of suicidal behaviour and suicidal ideation with anti-epileptic drugs**

The Food and Drug Administration (FDA) of the United States of America issued an alert in January 2008 advising that a retrospective analysis of anti-epileptic add-on drug trials showed an increased risk of "suicidal behaviour and suicidal ideation". The FDA alleged that this may be a "class effect" applicable to all anti-epileptic drugs. The estimate of the size of the risk was small, corresponding to an extra two patients per 1,000 in the drug treatment arms experiencing suicidality. It is difficult to envisage a biological mechanism affecting all anti-epileptic drugs in add-on trials.

Because of this FDA alert, clinicians may feel need to inform their patients of this preliminary and retrospective finding and, raise the issue in trials of new anti-epileptic drugs. The ESA Committee's opinion, at this time, is that the currently available, preliminary data do not require specific action from Australian clinicians or researchers The increased risk of depression, suicide and other psychiatric co-morbidities in epilepsy is well known. It is felt that drawing attention to the FDA alert may be counter productive for the well-being and quality of life of patients and their families, potentially detracting from the importance of seizure control with antiepileptic drugs.

It should be noted that the Therapeutic Goods Administration of Australia has not made a directive regarding this issue to date. The ESA will continue to monitor this matter and review its position should new data become available.

Created and approved by the ESA Committee 3/10/2008

Further Reading

- FDA Alert 31/1/2008
- American Epilepsy Society position statement
- Avorn, J. (2008). Drug Warnings That Can Cause Fits — Communicating Risks in a Data-Poor Environment. *New England Journal of Medicine,* 359(10):991-994