



AMERICAN
EPILEPSY
SOCIETY

Position statement on the substitution of different formulations of antiepileptic drugs for the treatment of epilepsy

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The American Epilepsy Society (AES) is one of the oldest neurological professional organizations in the U.S. comprised of multi-specialty and multi-disciplinary members. The Society seeks to promote interdisciplinary communication, scientific investigation, the exchange of clinical information about epilepsy, and optimal care of people with epilepsy.

There is equipoise about the therapeutic equivalence of the various formulations of Antiepileptic Drugs (AEDs) when used to treat people with epilepsy. The U.S. Food and Drug Administration (U.S. FDA) states that the current regulations guarantee that the approved AED formulations of each specific AED can be used interchangeably without concern for safety or efficacy and that no additional testing is needed when formulations of the same AED are interchanged. However, physicians and patients, in several surveys including one performed of AES members in 2007, express a majority opinion that the various formulations of the same AED are not always therapeutically equivalent in every patient. Positions taken by several organizations including the American Academy of Neurology, the Epilepsy Foundation and the International League Against Epilepsy (French Chapter) reflect this equipoise and advocate for physician and patient consent prior to switching formulations. The AES recognizes that controlled, prospective data on therapeutic equivalence of different AED formulations in people with epilepsy is not available because appropriate studies have not been conducted.

The American Epilepsy Society offers its support of the following principles concerning the continuity of Antiepileptic Drugs for adults and children with epilepsy:

- The American Epilepsy Society supports the development and completion of a valid controlled, prospective clinical trial, with protocol approval by the U.S. FDA, studying the impact of differences between the same AED formulations of different manufacturers. Until such data becomes available, the following positions are adopted:
- Physicians who treat people with epilepsy are skilled in choosing appropriate AEDs at appropriate dosages to reduce or eliminate seizures and avoid adverse effects. Physicians are trained to do this by using the best available scientific evidence in combination with clinical expertise. As such, the Society opposes formulation substitution of antiepileptic drugs for the treatment of epilepsy without physician and patient approval.
- The American Epilepsy Society believes that ensuring appropriate access and financial coverage of AEDs for the treatment of epilepsy contributes to ethical, high-quality care. The Society opposes all state and federal legislation and formularies that limit the ability of physicians to determine which AED formulations, to prescribe for the treatment of patients with epilepsy.
- The American Epilepsy Society strongly supports the development of federal regulations validated in people with epilepsy that ensure that the various formulations of each AED are therapeutically equivalent and can be used interchangeably without concern for safety or efficacy.