Epilepsy Community Seeks Redefinition of Bioequivalence from FDA

Two studies presented at American Epilepsy Society meeting underscore need for change

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Washington, D.C., December 9, 2013— For several years, epilepsy practitioners have questioned the U.S. Food and Drug Administration’s (FDA) definition of bioequivalence as it applies to narrow therapeutic index (NTI) drugs, such as those used for epilepsy. In response to these concerns, the FDA has sponsored 3 studies of antiepileptic drugs and also convened an advisory board to help determine which drugs are NTI. The new NTI definition and new bioequivalence guidelines and their impact will be a major point of discussion during a town hall session held with leaders from the FDA during the American Epilepsy Society's 67th annual meeting in Washington D.C.

Bioequivalence, a term used by the FDA to define specific criteria used to approve generic variations of brand drugs means that the versions of a drug produced by various manufacturers are expected to be used interchangeably without safety or efficacy concerns. A generic drug must produce blood levels within 80-120% of the brand drug in order to receive FDA approval. For drugs with a narrow therapeutic index, there are significant concerns among the epilepsy and neurology community that 80-120% may allow too much variability to ensure patient safety. Countless anecdotal reports suggest that manufacturer variations of antiepileptic drugs may cause changes in blood concentrations leading to loss of seizure control or other adverse effects, leading to serious mental, physical and social consequences for the person with epilepsy.

“Clinicians are concerned about balancing the need to control medication costs while ensuring the safety of generic drug switches. We are grateful that the FDA has listened to concerns and funded these critical studies on generic drug safety,” said Michael Privitera, MD, Director of the Epilepsy Center at the University of Cincinnati Neuroscience Institute and Vice President for the American Epilepsy Society.

In addition to the town hall session two other new studies about manufacturer variations and bioequivalence were presented at the meeting.

One of the studies is part of the national FDA-funded clinical trial EQUIGEN (Equivalence Among Antiepileptic Drug Generic and Brand Products in People with Epilepsy). This particular series of experiments, led by researchers at the University of Wisconsin is an in-vitro screening of generic versions of the antiepileptic drug, lamotrigine. The goal was to find the two most different generic products to use in the human testing portion of EQUIGEN, which is using rigorous blood level testing in both single dose and multiple dose studies. The methodology
identified disparate generic products for the EQUIGEN studies by demonstrating variations in dissolution time. (Posters 1.229 and 3.212/ Abstracts 1750371)

In a separate study, a survey of retail pharmacist knowledge and attitudes about antiepileptic drugs was conducted by Cincinnati Children’s Hospital Medical Center and the University of Cincinnati. The study found that most pharmacists (73%) reported reservations when switching from brand to generic manufacturers for antiepileptic drugs. Pharmacists (80%) reported trying to keep the same antiepileptic drug manufacturer in stock for patients if possible. Most pharmacists (63%) believed the range used by the FDA to determine bioequivalence to be stricter than actual requirements. Of the pharmacists surveyed, nearly a third (30%) were aware of patients that experienced breakthrough seizures or side effects associated with manufacturer change. (Poster 2.170/ Abstract 1748970)

“Pharmacists play an important role in the care of people with epilepsy,” said Lisa Garrity, PharmD, Clinical Pharmacy Specialist, Cincinnati Children’s Hospital. “Our study reveals retail pharmacists share concerns surrounding manufacturer changes of antiepileptic drugs and highlights a need for additional education on issues associated with antiepileptic manufacturer changes for pharmacists. Communication between retail pharmacists, patients and epilepsy care providers is essential to safely utilize generic medications in patients with epilepsy.”

Editors Note: Authors of the above studies will be available at a press briefing at 8:15am (EST) in the press room at the American Epilepsy Society meeting, Room 209A, upper level of the Walter E. Washington Convention Center. To join the briefing by phone: 605-475-4000 code 521653#

About Epilepsy
The epilepsies affect 50 million people worldwide, including three million in the United States. The disorder can have a single specific, well-defined cause, such as a head injury, or manifest as a syndrome with a complex of symptoms. It is the third most common neurological disorder after Alzheimer’s disease and stroke.

About the American Epilepsy Society (AES)
The American Epilepsy Society, based in West Hartford, Conn., seeks to advance and improve the treatment of epilepsy through the promotion of research and education for healthcare professionals. Society membership includes epileptologists and other medical professionals, allied healthcare professionals, and scientists concerned with the care of people who have seizure disorders.

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