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FDA Critical Path comments  
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### The Impact of Epilepsy

Epilepsy is a neurological condition and is also known as a seizure disorder. It is usually diagnosed after a person has had at least two seizures that were not caused by some known medical condition. The seizures in epilepsy may be related to a brain injury or a family tendency, but most of the time the cause is unknown.

There are over 2.3 million people in the United States at any one time who are diagnosed with epilepsy. The population affected by epilepsy is constantly changing, reflecting the fact that epilepsy can strike people of all ages, although the disease is most prevalent in the very young and the very old. In fact, it is estimated that at least 1 in 10 people will suffer at least one seizure in their lifetime.

More than one-third of the 2.3 million epilepsy patients in the United States have persistent seizures despite using existing therapies. Many others tolerate serious side effects, including diminished cognition, as a price for seizure control. New therapies introduced over the last decade offer fewer side effects but have done little to bring effective seizure control to the significant population living with active and uncontrolled epilepsy. Despite this serious unmet medical need, research funding for epilepsy is scarce and existing philanthropic support limited. Further, many major pharmaceutical companies have scaled back epilepsy development programs. Even after a promising new treatment is discovered, the prohibitive cost and the uncertainty and length of time required for a new treatment to go through clinical trials are hurdles that only the largest pharmaceutical companies can afford to overcome. As a result, successful lab research and new findings are rarely translated into new epilepsy therapy.

There are several different approaches that can be taken to remove some of the roadblocks and result in additional new treatments for epilepsy. One possible solution is to create a clinical trials consortium for epilepsy. This consortium could be done under the umbrella of several academic centers with input and support from industry as well. The result of a well coordinated clinical trials consortium would be a comprehensive patient database, which could help speed and improve the quality of clinical trials as well as being a repository of information for researchers looking to unlock the secrets of epilepsy.

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Another hurdle inhibiting the development of new antiepileptic drugs is the issue of monotherapy. Currently, the FDA requires a company to demonstrate the efficacy of a drug for monotherapy by utilizing placebos during the clinical trial process. Because of the obvious ethical issues regarding giving a patient with uncontrolled seizures a placebo, it is no surprise that of the nine antiepileptic drugs approved by the FDA since 1990, only one has been approved for monotherapy. The lack of monotherapy approval for new antiepileptic drugs, which have significantly decreased side effects, prevents many patients from receiving the most effective treatment possible for controlling their seizures. The number of antiepileptic drugs that can be used for monotherapy could be greatly increased if the FDA accepted the European standard of active control equivalence trials to approve drugs for monotherapy use. A possible alternative standard would be the use of historical placebo controls to determine the efficacy and safety of a drug for use as monotherapy. It is clearly within the FDA's power to streamline the standards for approving drugs for epilepsy and, by doing so, result in newer and less toxic antiepileptic drugs becoming available for patients suffering this debilitating disease.

The devastating effects of epilepsy on not only those who suffer from the disease but on their loved ones is indescribable. In addition, those suffering from seizures also suffer from societal stigma that can make the disease doubly difficult to bear. The FDA has the opportunity to elevate the visibility of this debilitating disease and take steps to encourage and accelerate research into new treatments for epilepsy. For the millions who are living with epilepsy, new treatments—and, ultimately, a cure—cannot come soon enough.

### About The Epilepsy Project

The Epilepsy Project is a non-profit organization whose mission is to advance new therapies for people living with epilepsy. Founded in 2002 by a group of parents, distinguished physicians and researchers, The Epilepsy Project supports the research and development of more effective therapies and serves as a catalyst for moving new therapies from the lab to the patient. Since its founding, The Epilepsy Project has raised over five million dollars towards its mission. For further information on The Epilepsy Project, please visit [www.epilepsyproject.org](http://www.epilepsyproject.org).

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