EPILEPSY FOUNDATION®
epilepsy therapy project
Stronger Together

8301 Professional Place, Landover, MD 20785-2353

May 28, 2014

The Honorable Joe Pitts
United States House of Representatives
420 Cannon House Office Building
Washington, DC 20515

Dear Chairman Pitts,

On behalf of the Epilepsy Foundation, I write to thank you for your leadership and sponsorship of H.R. 4299, the *Improving Regulatory Transparency for New Medical Therapies Act*, which would help bring new treatments to market in a timely and transparent manner.

The Epilepsy Foundation is the leading non-profit patient organization providing a voice for over 2.8 million Americans with epilepsy and their families. We work to ensure that people with seizures are able to participate in all life experiences, and maintaining seizure control, often achieved through the use of medication, is an important part of having these experiences. Your bipartisan legislation will give those living with epilepsy and other chronic conditions access to new and promising treatments without unnecessary delays.

People with epilepsy, their caregivers, or parents of children with epilepsy should not wait an undetermined amount of time for the new hope of seizure control. Access to new therapies is particularly important for the 20 to 30 percent of people living with epilepsy who experience intractable or uncontrolled seizures, or have significant adverse reactions to medication. Patients who have drug resistant epilepsy – defined as a failure to achieve seizure freedom, after adequate trials of two tolerated, appropriately chosen, and used anti-epilepsy drug schedules (whether as mono therapies or in combination) – can develop brain damage or experience other life threatening effects.

As you know and recognized through your championing of this legislation, the existing delays are the result of a flaw in the Controlled Substances Act which requires new medicines with abuse potential, approved by the Food and Drug Administration (FDA), to undergo a controlled substance "scheduling" by the Drug Enforcement Administration (DEA) before they can be marketed. Before this scheduling, the FDA provides a recommended schedule to the DEA based on the extensive medical and scientific research performed on the medication during the approval process. The recommended schedule is designed to ensure patients with legitimate health needs have access to necessary

medications, while keeping them from people who could abuse them. We at the Epilepsy Foundation understand and applaud these public health concerns, but this process is flawed and these delays are harming patients with critical health needs.

Upon receiving the FDA's recommendation for scheduling, the DEA then undertakes its own unpredictable and often lengthy review. The DEA is under no time limit to act, and this has led to increasing delays between FDA approval and DEA scheduling. Between 1997-1999 and 2009-2013, the time between FDA approval of a medicine and DEA's final scheduling increased from an average of 49 days to an average of 238 days, an almost five-fold increase.

H.R. 4299 would rectify this problem by mandating DEA scheduling within 45 days of FDA approval of new therapies. The current process lacks transparency and timelines, and the unpredictable and unexplainable delays are dangerous for patients who are in need of new treatment options.

The Epilepsy Foundation applauds the committee for moving H.R. 4299 forward. Your actions will help bring new treatments to market in a timely and transparent manner. Please do not hesitate to contact Angela Ostrom, Vice President of Public Policy and Advocacy, at aostrom@efa.org, with any questions or concerns.

Sincerely,

Philip M. Gattone, M.Ed.
President & CEO
Epilepsy Foundation