EPILEPSY FOUNDATION
Colorado

5889 Greenwood Plaza Blvd, Suite 404 • Greenwood Village, CO 80111

Epilepsy Foundation Calls on Drug Enforcement Agency to Improve Review Process for New Treatments

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DEA Delays Threaten to Hurt People Living with Seizures

The Epilepsy Foundation calls on the Drug Enforcement Administration (DEA) to revise its process for reviewing new treatments. The current method dampens innovation and lacks transparency for both consumers and industry.

Currently when a new treatment with abuse potential is approved by the Food and Drug Administration (FDA), the sponsors may not commercially market the drug until it has been scheduled by the DEA and labeled with the controlled substance schedule. This delay between FDA approval and DEA scheduling has no set time limit, and there is no formal deadline or requirement that a timeline for agency action be provided to patients or physicians. During this interim timeframe, patients may not access these new therapies, regardless of FDA approval. The unpredictable DEA process results in patients being denied access to important medicines that can improve, and in some cases save, their lives.

“People with epilepsy, their caregivers, or parents of children with epilepsy find it very frustrating to wait for an additional treatment option for seizure control due to DEA delay,” said Phil Gattone, president and CEO of the Epilepsy Foundation. “It is even more disheartening to know that the system is not required to have a clear timeline for consumers.”

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 effects 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 antiepileptic drug schedules (whether as monotherapies or in combination), can develop brain damage or experience other life threatening effects.

The Epilepsy Foundation agrees on the need to be vigilant regarding the serious problem of prescription drug abuse, but an open ended regulatory barrier for new products that have met FDA standards for efficacy and safety is not the answer. The Epilepsy Foundation is concerned about the lack of transparency and certainty in the DEA review process and welcomes changes that would bring hope to those living with epilepsy, especially those currently living with uncontrolled seizures.

The Foundation recently sent a letter to DEA Administrator Michele Leonhart requesting that the agency review its policies, processes, and timelines so patients and their physicians can know with more certainty a timeline for availability of these needed treatments. Such a timeline would provide hope and certainty, and could also provide more safety and stability for access to FDA approved therapies.

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