EPILEPSY FOUNDATION

September 14, 2018

The Honorable Jeff Sessions
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Attorney General Sessions:

The Epilepsy Foundation represents more than 3.4 million Americans suffering from various Epilepsy conditions. We work to prevent, control, and cure epilepsy through community services, public education, federal and local advocacy, and supporting research into new treatments and therapies. At its core, our mission is to ensure that people with seizures have the opportunity to live their lives to their fullest potential.

An integral part of that mission is working to remove barriers preventing or delaying our patients from accessing innovative new therapies. It's been almost three months since the Food and Drug Administration approved Epidiolex for the treatment of seizures associated with Dravet and Lennox-Gastaut (LGS) Syndromes and we are growing increasingly concerned by the delay in rescheduling Epidiolex and authorizing its distribution to patients. People living with epilepsy who are unable to obtain seizure control with existing treatments are at a higher risk of accident, injury, hospitalization, and even death. Until the DEA makes a rescheduling determination, Epidiolex remains Schedule I and out of reach for the patients who need it most. We urge you to reschedule Epidiolex in line with the Food and Drug Administration's scheduling recommendation so that some of these most vulnerable individuals may have the hope of gaining better seizure control.

Although we recognize that DEA can by statute take up to 90 days to reschedule a drug after FDA approval, DEA's prolonged consideration of Epidiolex is particularly concerning in light of the fact that:

- Dravet and LGS are rare, severe, and life-threatening forms of epilepsy
- Both conditions disproportionately affect children
- Epidiolex is the first FDA-approved treatment for seizures associated with Dravet
- Both conditions are considered refractory epilepsies, meaning that many patients cannot achieve adequate disease control with existing therapies
- FDA granted Epidiolex Priority Review, a program intended to "expedite the review of drugs to treat serious conditions and fill an unmet medical need," and Fast-Track designation, which is reserved for drugs that "would be significant improvements in the safety or effectiveness compared to" available therapies.
- FDA concluded that Epidiolex has "negligible abuse potential."

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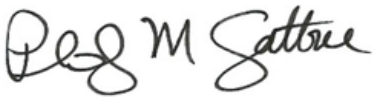
As the 90-day deadline approaches, we ask that the DEA promptly take action to reschedule Epidiolex so that patients can finally gain access to this important new therapy. The epilepsy community has for many years been awaiting access to Epidiolex because it offers hope to patients with refractory disease searching for new treatment options. Every day counts for individuals we serve who are at greatest risk for death and injury due to uncontrolled seizures.

Sincerely,



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