The Honorable Kemp Hannon
New York State Senate
The Capitol- Room 420
Albany, NY 12247

April 3, 2017

RE: Rescheduling of FDA-approved cannabidiol (CBD) in the state of New York

Dear Chairman Hannon:

The intractable childhood epilepsies begin early in life and most often result in persistent seizures, intellectual impairment, significant morbidity, and need for continued care into adulthood. These lifelong epilepsies are catastrophic and devastating, both to the patients and their families. Two-income families are many times forced to decide which parent leaves their employment to stay home and care for the afflicted child since the child spends much of his or her life in the hospital or emergency room, in a doctors' office, home from school recovering from prolonged or cluster seizures, or at therapy appointments.

Families find it difficult or impossible to find caregivers to take care of such a medically fragile child who may have intellectual and/or behavioral comorbidities and are often denied nursing services by their insurance carrier, Medicaid or Medicare. Divorce rates are high and the parents we see are often without hope when their child continues to fail to achieve acceptable seizure control from combinations of multiple FDA-approved medications, devices, surgeries, and/or restrictive diets, while suffering significant adverse effects from the polypharmacy that is required to keep them out of the hospital and in some cases, alive.

These children deserve an opportunity to try a new FDA-approved anticonvulsant as soon as it is available. In some cases, minimizing seizures significantly improves the cognitive and behavioral outcome for the child. Further, seizure frequency is the risk factor with the strongest link to Sudden Unexpected Death in Epilepsy (SUDEP). SUDEP causes approximately 17% of deaths in people with epilepsy. Children with intractable epilepsy are at the highest risk.

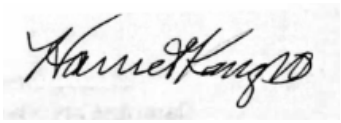
Cannabidiol (CBD) is being developed for the treatment of intractable childhood epilepsies and the results have been very encouraging. We have seen these results first hand because we have served as investigators in studies in this state. Our patients with treatment-resistant epilepsy desperately need access to any new treatment option as soon as those treatments have been proven safe and effective to the FDA's satisfaction. We have never before heard of a delay in patient access to an FDA-approved drug because of additional state procedural obstacles. If this product is approved as safe and efficacious by the FDA, and the DEA has reassigned it to an appropriate schedule, we believe that there should be no gap in access for patients. This is particularly true for patients with intractable types of epilepsy --and their families--who suffer greatly from the burden and stress of these conditions and for whom a delay will cause further suffering and potential harm, that could be prevented or mitigated by a new treatment option.

We therefore urge you to act with urgency to take the necessary steps to ensure that FDA-approved cannabidiol products are rescheduled within this state at the earliest opportunity so our patients will be able to try this exciting new treatment option without delay.

Sincerely yours,

Orrin Devinsky, MD
NYU Comprehensive Epilepsy Center

Sheryl Haut, MD
Montefiore Medical Center



Harriet Kang, MD
Mount Sinai Beth Israel

David Wang, MD
University of Rochester Medical Center

Laurie Seltzer, DO
University of Rochester Medical Center

Arie Weinstock, MD
Women and Children's Hospital of Buffalo