



December 3, 2018

Quentin Scholtz
Office of Senator Mitch McConnell
317 Russell Senate Office Building
Washington, DC 20510

Dear Mr. Scholtz,

On behalf of the Epilepsy Foundation and people living with epilepsy, we appreciate the role of the Food and Drug Administration (FDA) in monitoring the safety and efficacy of cannabidiol (CBD) products available to consumers. We urge you to include language in the Farm Bill conference report to preserve the FDA's oversight authority and specifically, to produce a report on the potential impacts of CBD on public health. Proposed language to achieve this is as follows:

The managers believe that FDA has an important role in protecting public safety. To that end, it is the intention of the managers that USDA and FDA carefully monitor implementation of this section so as to verify that consumer products that become available through the bill's enactment pose a minimal risk to consumers. CBD products are available in a wide variety of forms and are being used by the public for a variety of health and wellness purposes. Many products are promoted for medical use and some are marketed to vulnerable populations. Research indicates that CBD products (or products purporting to contain CBD), available without a prescription and administered without close physician supervision, may pose risks through harmful drug-interactions, adulteration, or liver toxicity. The managers expect that within 12 months after the enactment of this Act, that FDA submit to Congress a report detailing the types of CBD products being marketed, the purposes for which they are marketed, the potential for drug-interactions or related toxicity, and the effects that such products may have on the health and wellbeing of consumers in the United States, including, but not limited to, children, adolescents, and vulnerable populations; and any recommendation for additional authorities or resources needed to help further mitigate these effects.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the at least 3.4 million Americans with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. There is no "one size fits all" treatment for epilepsy, and about a third of people living with epilepsy suffer from uncontrolled or intractable seizures, with many more living with significant side-effects, despite available treatments. Uncontrolled seizures can lead to disability, injury, and even early death. This is why people living with uncontrolled seizures turn to medical cannabis when other options have failed.

The Epilepsy Foundation is committed to supporting physician-directed care, and to exploring and advocating for all potential treatment options for epilepsy, including CBD. People living with



uncontrolled seizures live with the continual risk of serious injuries and loss of life. Currently, the medical use of cannabis is legal per state law in the majority of the states. In these states, a number of people living with epilepsy report beneficial effects, including decrease in seizure activity, when using a cannabis strain rich in CBD. If an individual and their health care professionals feel that the potential benefits of medical cannabis for epilepsy outweigh the risks, then families need to have that option and there must be processes in place to ensure the safety of the substance. The FDA plays a critical role in ensuring that access to CBD is safe and reliable.

The Epilepsy Foundation is committed to supporting physician-directed care, and to ensuring the safety and reliability of potential treatment options for people living with epilepsy. We urge you to include language in the Farm Bill conference report to preserve FDA jurisdiction and allow them to assess the potential impacts on public health so that individuals living with epilepsy and their physicians may be better informed about this treatment option. Please do not hesitate to contact Laura Weidner, Esq., Vice President of Government Relations & Advocacy at lweidner@efa.org or 301-918-3766 with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Philip M. Gattone".

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