



June 12, 2018

The Honorable Pat Roberts
Chairman
Senate Agriculture Committee
109 Hart Senate Office Building
Washington, DC 20510

The Honorable Lamar Alexander
Chairman
Senate Health, Education, Labor, and Pensions Committee
428 Dirksen Office Building
Washington, DC 20515

The Honorable Debbie Stabenow
Ranking Member
Senate Agriculture Committee
328A Russell Senate Office Bldg.
Washington, DC 20515

The Honorable Patty Murray
Ranking Member
Senate Health, Education, Labor, and Pensions Committee
428 Senate Dirksen Office Building
Washington, DC 20515

Dear Chair Roberts, Chair Alexander, Ranking Member Stabenow, and Ranking Member Murray:

On behalf of the Epilepsy Foundation, we urge you to amend the 2018 Farm Bill to include language preserving the Food and Drug Administration's (FDA) jurisdiction over cannabidiol (CBD) products. Access to new and safe therapies is particularly important for the one third of people living with uncontrolled seizures or who experience significant adverse effects from their current medication.

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 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 with uncontrolled seizures live with the continual risk of serious injuries and loss of life. If an individual and their health care professionals feel that the potential benefits of medical cannabis for uncontrolled 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.

Currently, the medical use of CBD is legal per state law in the majority of 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. The FDA plays a critical role in ensuring

that access to CBD is safe and reliable. The 2018 Farm Bill would remove FDA’s jurisdiction over CBD and place oversight and regulatory authority within the United States Department of Agriculture (USDA). We are concerned with this proposed change in jurisdiction because the USDA is not equipped to monitor the labeling requirements and medical claims made by companies selling CBD. FDA testing and Warning Letters indicate the need for proper oversight in this space.¹ The FDA has found that some CBD products on the market misrepresent the amount of CBD contained in the tincture—which sometimes contain no CBD at all. Because some individuals with epilepsy rely on CBD mixtures as a treatment option for their seizures, it is imperative to have an oversight agency that can monitor and enforce truth in labeling. Additionally, some vendors make unsupported medical claims intended to reach vulnerable populations. Not everyone with epilepsy should or would consider CBD as a treatment option, and further research is needed, but CBD, when recommended by a treating physician, may be the best alternative for some individuals living with drug resistant epilepsy and uncontrolled seizures. As individuals with epilepsy turn to CBD as a potential treatment option, it is crucial to preserve FDA’s proactive oversight to ensure the safety and efficacy of these products.

The Epilepsy Foundation and the Epilepsy Foundation is committed to supporting physician-directed care, and to ensuring the safety and reliability of potential treatment options for people with epilepsy. We urge you to amend the 2018 Farm Bill to preserve the FDA’s authority over CBD compounds, which is a potential treatment option for many people living with epilepsy. Please do not hesitate to contact Abbey Roudebush, Government Relations Manager, at 301-918-3784 or aroudebush@efa.org with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Philip M. Gattone". The signature is written in a cursive, flowing style.

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

¹ <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm>