



November 11, 2013

To whom it may concern

RE: "Alepsia" or Cannabidiol Oil for Utah children with severe epilepsy

Dear Colleague:

I am writing to express my strong support for Utah families seeking to make a specialized cannabis-oil product available to their children here in Utah. I am a pediatric neurologist who has cared for children with epilepsy in Utah for more than 25 years. I am the Division Director of Pediatric Neurology at the University of Utah and a member of the Child Neurology Society. Every day of my professional life I care for numerous children with uncontrolled epilepsy and specifically I care for several children with Dravet syndrome, a type of severe childhood epilepsy that has been in the news in Utah recently relevant to the medical use of cannabidiol. Therefore, I believe I am well qualified to provide an objective medical and neurological opinion on this matter.

Cannabidiol (CBD) is one of the "cannabinoids" or naturally occurring chemical elements found in the natural product Cannabis, or Marijuana. There is extensive "pre-clinical" data (meaning experimental data in animals and laboratory studies) that indicates that CBD as a chemical is effective in reducing epileptic activity, electrophysiologic disturbances analogous to epilepsy or in blocking molecular pathways that are involved in the generation of seizures or epilepsy. Thus, there is extensive and reproducible data demonstrating that, from an experimental point of view, CBD holds great promise as an antiepileptic agent.

In addition to this, there have been recently publicized cases of children with severe epilepsy who have experienced extraordinary seizure control and improvement in their quality of life from natural substances that contain high content of CBD. These substances are purposefully manufactured with high content of CBD (a non-psychoactive component of cannabis) and very low or nearly undetectable levels of tetrahydrocannabinol (THC) which is the "psychoactive" ingredient of cannabis or marijuana. However, due to the manner in which existing regulation regarding availability of cannabis products is interpreted in the United States and Utah, these non-psychoactive products

are not currently available to our Utah patients with severe epilepsy. As a pediatric neurologist who cares for many children with severe epilepsy, I believe any product that is actually legally available in the United States and is legally taken by some of our citizens should be available to United States citizens whether they be residents of Colorado (where the CBD product is legally available) or of Utah (where currently it is not available). In this discussion, the following key points should be considered:

- **CBD oil is a natural product that is not regulated by the FDA**
- **CBD oil ("Alepsia" or "Realm Oil" and similar preparations) is very high in CBD but has THC content that is as low as or lower than other natural substances** such as hemp-based creams that currently can be legally purchased in Utah
- **CBD oil is not a psychoactive substance**; it does not "produce a high" and is not "mind-altering" in its effect.
- **CBD may be extremely effective in some cases:** The anecdotal experience of many patients and families is that CBD oil results in remarkable seizure control with improvement in quality of life. (This is despite the fact that all these children have previously been on numerous antiseizure medications with minimal benefit).
- **CBD appears to be safe:** So far, experience with CBD oil and related products containing CBD indicates that side effects are very limited or non-existent. This alone is a very unusual property for a substance that may produce remarkable seizure control.
- **CBD is not available currently in the US as a pharmaceutical product.** Thus, our patients in Utah currently cannot access this potentially extremely helpful treatment with CBD without physically moving to a state where they can be legally treated with CBD oil or where they can participate in one of two limited medium sized IND trials (which are only available currently at UCSF [California] or NYU [New York])
- **Pediatric neurologists and physicians routinely recommend substances to their patients that are not FDA-approved medications. There is no logical reason that CBD oil should not be similarly available.**

In summary, I would like to express my strong belief that CBD-based oils (referred to here in Utah as "Alepsia") should be available as soon as possible to Utah children with severe epilepsy. The substance is not psychoactive or hallucinogenic, it contains less THC than do other materials that can be legally purchased in Utah, and it has absolutely no abuse potential. In Utah its use would be supervised by careful and knowledgeable physicians for the benefit of their patients. It is critical that safe and reasonable options for the treatment of children with severe epilepsy be available in Utah as they are in other states.

Otherwise, as a community we would be making the decision to limit access of our children to a potentially life-improving therapy.

Please feel free to contact me if I can provide additional information.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'Helen Barkan', written in a cursive style.

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