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**Statement on CBD for Severe Epilepsy**

As a private practice neurologist in our community, Medical Director of the Epilepsy Center at St. Luke's, Board President of the Epilepsy Foundation of Idaho, the only full-time epileptologist in Idaho, and an active clinical researcher, I have followed with great interest the process seeking access to CBD for children with severe epilepsy both here in Idaho and across the nation. While I treat patients with severe epilepsy every clinic day, often with some success, I cannot imagine how difficult it must be to be the parent of one of these kids. Just watching the process has been heart wrenching and my thoughts and prayers are with them.

However, the emotions surrounding these terrible circumstances should not be allowed to cloud our thinking regarding good clinical care. As physicians, one of the first things we are taught in medical school is that physicians should not treat themselves or their immediate family members because good judgement can be clouded under such emotional circumstances. This is of particular concern when parents of desperately ill children are enticed by unproven therapies.

In the United States, the FDA requires that therapies must be proven superior to a placebo or other comparator in order to gain approval. They must also show a favorable safety and tolerability profile. Such studies are conducted under carefully controlled circumstances, often involving hundreds and sometimes thousands of patient volunteers. These studies are organized by the companies, but are conducted by trained independent physicians with close oversight from institutional review boards, ethics committees, study monitors and, sometimes, FDA monitors, with all observed safety and efficacy data reported to the FDA.

CBD has not been tested in this way. Much of the "evidence" of its efficacy comes from retrospective questionnaires completed by desperate parents of children with dire illnesses or through retrospective physician chart reviews. These two approaches have revealed an interesting pattern. While most physician retrospective reviews report a success rate of about 30% on average with CBD for epilepsy, parent questionnaires report a success rate closer to 80%. A similar pattern was recently reported in a retrospective study of children being treated with CBD for severe epilepsy in Colorado. Families who moved to Colorado to gain access to CBD for their ill children were three times more likely to report being positive responders than families who were already living in Colorado when treatment was started. I cannot imagine that families in such dire circumstances would deliberately provide false information. Nor does it seem likely that the mere act of moving to Colorado resulted in improved seizure control. It seems more likely that the emotional nature of such a relocation clouded their perception.

At best we can say that an unbiased review of currently available studies suggests that CBD may work in some cases, with an overall chance of success on par with other currently approved therapies. It is important to study it further because not every therapy will work in every patient, so the more therapies we have available the greater our chance of success. However, CBD should be studied in a controlled way to better define its safety and efficacy

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profile before being made widely available. Does it really work? Does it have long-term negative cognitive consequences, as some studies have already suggested? Does it have interactions with other medications? Is it safe to use on its own or is it better in combination with existing therapy? These questions must be answered.

I have seen several instances of desperate parents and the media referencing the “dangerous side effects” posed by pharmaceutical agents. I would urge everyone to keep in mind that pharmaceutical medications and unapproved supplements are all chemical agents. The difference is that the pharmaceutical medications are chemicals that have been carefully tested whereas supplements are chemicals that have not been carefully tested. It is only with careful testing that side effects can be identified. CBD has not been tested carefully. This does not mean that it does not have side effects, it just means the side effect profile has not been fully defined.

My fear is that, if CBD is made widely available in an uncontrolled way, families will run to it because of the hype, often using it to replace rather than augment current therapy. Some children might benefit. But it will not work for everyone and, if it is used as a stand alone therapy in children for whom it does not work, then some of those children will die. These children need to be protected from uncontrolled seizures but they also need to be protected from unproven therapies. Sadly, the good intentions of their desperate, loving parents have the potential to put some of these children in harm’s way.

At least two different pharmaceutical companies have undertaken controlled clinical trials of purified CBD. These trials are being expedited, in part due to the media attention that has come to bear on this issue in the past year. Results are months, not years, away. The epilepsy research community is fully committed to getting good data published as quickly as possible. While I cannot speak for the legislature, our governor or the FDA, I am certain we all want to do everything we can to help these kids. But when it comes to CBD, wishing does not make it so. We need the data. If the legislature choses to allow access to CBD in the absence of data, then my hope is that is will be in a carefully controlled and regulated way, under the care of a skilled and licensed physician who can weigh the risks and benefits of therapy and can ensure that all other appropriate, approved therapeutic avenues have been exhausted before this unapproved therapy is undertaken.

Respectfully,



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