

**Senate Caucus on
International Narcotics Control
Hearing on “Cannabidiol: Barriers to Research and
Potential Medical Benefits”
Wednesday, June 24, 2015**

**Prepared Statement of
Chairman Chuck Grassley of Iowa**

Today’s hearing addresses a timely and important topic. Thousands of children throughout our country suffer from rare, extreme types of intractable epilepsy. Some of these children experience hundreds of seizures a week that prevent them from living anything close to a normal life. Parents fear that the next seizure may be their child’s last.

These children are often treated with multiple drugs to control their seizures. However, these drugs are very

powerful, and some have strong side effects which may also incapacitate the child's ability to function and develop normally.

But in recent years, evidence has come to light suggesting that a substance called cannabidiol (canna-bi-DIE-awl), or CBD, may help these children.

CBD is a compound derived from the marijuana plant that can be administered in the form of an oil. It's not smoked, and it can't be used to get high. Even though all the leading medical organizations reject the idea of smoked marijuana as medicine, many of them have called for further research into the potential medical use of CBD.

These aren't inconsistent positions – they simply reflect the fact that sometimes medicines can be developed from raw plants that shouldn't be smoked or

otherwise ingested. For example, doctors prescribe morphine to manage pain -- but they don't recommend that a patient smoke raw opium or heroin, which also come from the poppy plant.

Right now, there's still much we don't know about CBD and its effect on the human body, especially on children. But in recent years, as word of its potential medical benefit has spread, more and more parents, out of understandable desperation, have turned to what is essentially a black market to get it.

These parents are buying CBD products that haven't undergone the usual testing for safety and efficacy associated with new medicines, and in many cases haven't been evaluated for concentration or purity. And

sometimes these products may be helping children, but sometimes they have no effect, or may even cause harm.

Out of concern for the situation, last October and again in May, Senator Feinstein and I wrote to the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) about this issue. The purpose of our letters was two-fold.

First, we asked these agencies to consider revising regulations that may be inhibiting research into the potential medical applications of CBD. Some, but not all, of these regulations are related to CBD's status as a Schedule I substance. Encouraging responsible research on CBD is a goal I think we all share, and I expect we'll talk more about these regulations today.

But I'm happy that it appears our letter has already made a difference on this front. Earlier this week, HHS announced that it was eliminating the extra layer of review for non-government funded CBD research that it previously required its Public Health Service (PHS) to complete. Doing away with the PHS review, which wasn't required for any other Schedule I substance, is a step in the right direction.

At the same time, it's also worth recognizing that research on CBD is proceeding, even under the current regulations. A highly concentrated CBD drug called Epidiolex (Ep-ah-DIOL-lex) is currently undergoing FDA-approved clinical trials to treat two rare forms of pediatric epilepsy. I'm glad that one of the sites at which it's being tested is the University of Iowa. In addition, hundreds of

children are currently being treated with Epidiolex (EpidioleX) through Expanded Access Investigational New Drug programs.

So far, the data emerging from these efforts is promising. In fact, the company developing the drug plans to submit a New Drug Application to the FDA next year. So even though more research is needed, there is reason to hope that at least one FDA-approved CBD medicine may be more widely available soon.

The second purpose of our May letter to DOJ and HHS was to ask these agencies to evaluate CBD using the appropriate scientific and medical factors to make a scheduling determination for it that is separate from the whole marijuana plant. If it turns out that CBD may be classified on a lower schedule than the entire marijuana

plant, then research on it may proceed somewhat more easily.

I'm also pleased to report that in a response to our letter we received yesterday, DOJ and HHS agreed to undertake this evaluation. This is a significant breakthrough, and I commend those agencies for agreeing to take this step. I certainly don't know what the results of the evaluation will be. But the important thing is that it's made on the basis of a careful, rigorous review of the science associated with CBD by medical professionals.

I look forward to discussing with our witnesses the ways in which we can work together to facilitate research on CBD that can result in safe, effective FDA-approved medicines to help children who suffer from these rare

conditions. I now recognize Senator Feinstein for her opening statement.