

MINUTES
SENATE STATE AFFAIRS COMMITTEE

DATE: Wednesday, March 04, 2015

TIME: 8:00 A.M.

PLACE: Lincoln Auditorium - WW02

MEMBERS PRESENT: Chairman McKenzie, Vice Chairman Lodge, Senators Davis, Hill, Winder, Siddoway, Lakey, Stennett and Buckner-Webb

ABSENT/ EXCUSED: None

NOTE: The sign-in sheet, testimonies and other related materials will be retained with the minutes in the committee's office until the end of the session and will then be located on file with the minutes in the Legislative Services Library.

CONVENED: **Chairman McKenzie** called the Senate State Affairs Committee (Committee) to order at 8:03 a.m.

GUBERNATORIAL APPOINTMENT: **The Reappointment of Jeff Anderson as Director of the Idaho State Liquor Division.**

MOTION: **Senator Davis** moved to send the gubernatorial appointment of Jeff Anderson as Director of the Idaho State Liquor Division to the floor with the recommendation that he be confirmed by the Senate. **Senator Winder** seconded the motion. The motion carried by **voice vote**.

PASSED THE GAVEL: Chairman McKenzie passed the gavel to Senator Lakey.

S 1106 **Relating to Controlled Substances to Revise and Define Definitions Related to "Cannabidiol Oil" (CBD oil).**

Chairman McKenzie explained that he has been working on a form of this legislation for two years after the mother of a child with Dravet Syndrome, a form of intractable epilepsy, came to him for help. He explained that these small children have multiple seizures daily that can last for hours. They are treated and prescribed with medications that, very often, have been tested for adults but not for children of their age or in the combinations prescribed; this can cause extreme side effects. Thus, Alexis' Law was born.

Chairman McKenzie described CBD oil as a non-pyschoactive component of hemp that has been shown to have beneficial effects on seizure activity. Parents have found CBD oil to be effective in controlling their children's seizures without the extreme side effects of current medications. If this bill is approved, it would define CBD oil as having no more than 0.3 percent tetrahydrocannabinol (THC). That is the most restrictive definition compared to any of the 12 states that have passed legislation legalizing CBD oil. He summarized the quotes of several Idaho neurologists. They are in agreement with the definition that allows only trace amounts of THC; it would have virtually zero potential for abuse or dependence. They have recommended that the parents be given the CBD oil for their children who are suffering from severe and intractable epilepsy.

Chairman McKenzie listed the 12 states that currently allow the use of CBD oil but have rejected medical marijuana. Georgia is also looking at legalizing some form of use of CBD oil. These states have used multiple approaches: growing marijuana plants at state universities, registration

programs, distribution centers, limiting the percentage of THC contained in CBD oil, and limiting the type of medical conditions that would qualify for its use. The definitions of CBD oil with trace THC range from 0.3 percent to 0.9 percent and some don't have a limit. All but one state limits the conditions, mostly to epilepsy or seizure disorders.

If Idaho approves the use of CBD oil, how should it be done so that the size of government doesn't increase? There should not be marijuana grown at state universities. Government registration, monitoring or distribution programs should not be implemented. The State should use the most restrictive level of THC under state or federal law. Federal law defines industrial hemp as having no more than 0.3 percent THC. This bill adds CBD oil to the current list of exemptions under Idaho's definition of marijuana. There are a number of marijuana plant derivatives that are currently legal under Idaho law. The use is self-regulating because a person cannot get "high" from it, and it is much more expensive than hemp oil; hemp oil is legal. The only markets for CBD oil are parents of children suffering from intractable epilepsy or the sufferers themselves.

Chairman McKenzie outlined the concerns stated by government agencies.

- Legalizing CBD oil will invalidate the drug dogs and there would be a high cost to replace them.
- New equipment will be required at the state laboratory.
- Legalizing CBD oil will make it difficult to prosecute various crimes.
- Costs in every area of law enforcement where CBD oil is involved will increase.
- Prosecutors will need to hire expert witnesses to testify if there are psychoactive substances in the CBD oil.

The State has a policy that is tough on drugs and this legislation isn't going to change that. As a nation, the U.S. is tougher on crime than any other nation in the world. CBD oil laws have been passed in 12 states; 24 states have medical marijuana laws. They still use drug dogs and prosecute drug crimes. A study, *The Effect of Medical Marijuana Laws on Crime: Evidence from State Panel Data, 1990-2006*, by Robert G. Morris, Michael TenEyck, J. C. Barnes and Tomislav V. Kovandzic, found that there is no positive association between medical marijuana and any crime type. Even hemp oil, which is legal in Idaho, has trace elements of THC that can't be removed. Because of the concerns, it was decided to do this by statute that would limit the availability to those seizure disorders where it seems to have an effect. The amendments the sponsor is considering would require FDA compliant labeling that would state that it fits the definition of CBD oil under Idaho law.

Chairman McKenzie was ready to stand for questions, but he asked if the Committee would allow the bill to be held at the Chairman's discretion until he could come back with the actual proposed amendments. These would not be Committee amendments, but it would be important for the Committee to see the proposed amendments.

Senator Hill thanked the Chairman for his work on this worthy cause. He asked how the FDA labeling would be monitored to determine if it is correct.

Chairman McKenzie responded that it would be like any prescription that is used. **Chairman McKenzie** described a scenario about where a parent was stopped while driving and the car was searched with drug dogs and

CBD oil was found. There would probably be a citation, court appearance and testing to prove it contained the proper components. A drug dog has no way of knowing amounts or the type of a drug, only the existence of a drug.

Senator Siddoway asked what would happen if CBD oil was identified when a car was stopped and at the same time, there was evidence of another criminal action. Why would the presence of the CBD oil negate the investigation of the other crime? **Chairman McKenzie** stated that the original search would be for CBD oil and the second crime would fall under the "fruit of the poisonous tree" theory. **Senator Siddoway** gave another scenario using a traffic violation; would that also stop law enforcement from proceeding if they discovered another criminal action? **Chairman McKenzie** answered that he couldn't definitely answer that question.

Senator Lakey asked for any additional questions.

**PASSED THE
GAVEL:**

Senator Lakey passed the gavel to Chairman McKenzie.

Testimony in Support of S 1106:

Clair Carey testified for herself in support of the bill. At the age of 1 month, Alexis had her first seizure that lasted 15 minutes. Clair went on to detail the history of Alexis' life living with intractable epilepsy. She showed a film of her infant baby girl having seizures. Her seizures continued to occur even with heavy doses of medication. Even with the seizures, Alexis was developing and meeting all of the growth milestones. They hoped the seizures were of the type that she would outgrow. Instead, the seizures increased, and she began having multiple types of seizures. At 17 months, she began to regress developmentally. Alexis was then diagnosed with Dravet seizure disorder for which there is no effective treatment. Alexis is now 10, takes multiple medications and continues to have seizures nearly every day. **Ms. Carey** went on to tell the story of Alexis' life.

In recent years, families in the Dravet community have been able to access CBD oil for their children and many have had a positive response. Families have moved to other states or separated their family to access CBD oil. **Ms. Carey** outlined what CBD oil is and what it will and will not do.

Diane Foote, Executive Director, Epilepsy Foundation of Idaho (Foundation), stated that the Foundation feels an urgency to respond and take action on this issue; those they serve need safe and legal access to CBD oil. The Foundation supports their activities with advice from the advisory board of the national office and support from a range of other leading epilepsy professionals. It is estimated that there are about 1,000 children in Idaho who suffer from epileptic seizures. The Foundation supports the rights of individuals and families to access CBD oil. Nothing should stand in the way of access to a potentially life-saving treatment; they need it now, not in 5 or 10 years. The Foundation applauds the CBD trials that have begun in several states; hopefully, also in Idaho. Despite the progress in epilepsy therapy over the last decade, it remains slow and disappointing. The Foundation believes that treatment for these seizures should not be determined by someone's zip code.

Natalie Stevens testified for herself in support of **S 1106**. Ms. Stevens and her daughter Marley came before the Committee. Marley does not have Dravet Syndrome but has another condition that is a mutation of the 17th chromosome in which seizures are very common. They have a daily struggle not knowing when a seizure could go wrong. They have tried every drug combination on

the market that has been deemed safe, but they have horrible side effects. These families are trying to access CBD oil as a low risk, non-invasive option to improve the quality of life for their children.

Senator Siddoway stated that everyone in the room would do anything to relieve the pain of their child. He spoke of his friend who has a child with Pallister-Killian Syndrome. This man has gone out of state to get CBD oil because it is the only thing that brings relief to his child. **Senator Siddoway** asked Ms. Stevens if they have tried CBD oil. **Ms. Stevens** said that living in Idaho makes it hard to access CBD oil. She has investigated options to obtain the oil in order to do whatever is necessary to save the life of her child. They all agree that further testing to have a standardized product that ensures a low level of THC and a specific ratio of CBD to THC, is a good course of action, as well as, the ability to access a physician that could prescribe a proper dosage. **Ms. Stevens** said they have considered moving to another state where they would have the option of using CBD oil.

Hollie Bunderson testified for herself in support of the bill. She talked about her son Scout, known as Ironman, who is seven and has a condition known as cortical dysplasia, which is formed in the womb. He had his first seizure at ten months and it lasted one and one-half hours. She told her personal story of living with a child suffering from seizures. Scout has now had four brain surgeries, and last July, three crucial parts of his brain were removed. At first there were no seizures but slowly they have started to return. She explained the brain process when that happens. At this point they cannot do more surgery and there are no FDA medications that can help him. They have heard good reports about CBD oil from others that have used it, and they would like to try it although they don't know if it will work. They are generational Idahoans and they don't want to leave their home. They believe Idaho will do the right thing by these children.

Dr. David Bettis, a pediatric neurologist whose life's work has been caring for children with epilepsy, stated that he, as a doctor has failed, the current drugs have failed, his profession has failed and medical science has failed to help these children with epilepsy. There is evidence in animal and clinical studies that this drug has promise. **Dr. Bettis** indicated that his friend's, Dr. Martin, stance on the trial is wrong. **Dr. Bettis** said he has worked on eight trials, the process is very slow and cumbersome but very important. He predicted that CBD oil will not be approved by this process in less than three to five years. He is in favor of the studies proceeding, but the time clock is ticking for these families.

Dr. Bettis explained that the American Epilepsy Society met in December and had an entire session devoted to CBD and cannabinoid derivatives to treat epilepsy. Physicians do not deny there is a need for more study; it does not work for everybody, no drug does. CBD oil is plant-based and many of the current drugs that have been prescribed are much more concerning. **Dr. Bettis** explained that, in the past, he has used non-FDA approved drugs on a compassionate plea basis; some have gone on to be FDA approved. He asked the Committee to craft legislation with reasonable regulation.

Senator Stennett asked if there were side effects for CBD oil that were worrisome to Dr. Bettis in comparison to the current medications. **Dr. Bettis** responded that there were none that were concerning, but until it is studied, those are unknown.

Morgan Gonzalez, a student, testified for himself in support of **S 1106**. He explained his support as well as his concerns with the bill. There is a stigma with the word marijuana, the definition should be changed.

Ron Gambassi spoke for himself and described his personal experience. They have twin daughters who are 13 and who have a rare disease called Cardio-Facio-Cutaneous Syndrome. **Mr. Gambassi** told Dr. Bettis that he hadn't failed them, he is their hope. His kids have seizures with this rare disease; there are only about 400 cases around the world. He respectfully asked the Committee to pass this bill.

Julia Davis testified for herself in support of the bill. She gave her personal story. They have followed the same paths as the stories the Committee has already heard. She pointed out that Dovecote has been around since the 1800s and is considered the best FDA approved drug for children. It is known to cause liver and bone density issues and it slows brain growth development. No drugs approved by the FDA have been tested for children with seizures. CBD oil with the same THC level, 0.3 percent, was approved in the Federal Farm Bill Act of 2014 and is now sold across the counter at the Co-op and Whole Foods. The lab results for the oil coming out of Colorado are given to any parent who requests them. This bill only asks that responsible parents have a guarantee that they won't go to jail for doing what they should do to help their children.

Austin Watson testified on her own behalf. She talked about her son Owen who, at 16 months, has seizures that are out of control. At one point in time, he was on six FDA approved medicines that were not controlling his seizures. She talked about her experience. CBD oil may not work for Austin, but they need to be able to try it. **Ms. Watson** implored the Committee to consider **S 1106**.

Katie Donnahue testified for herself. She is a cannabis patient; she has a rare disease called Parry-Romberg Syndrome. This disease destroys tissue in the face, head and brain. She commended the writers of the legislation, and she acknowledged that Idaho's finest can sit down and come up with an answer for law enforcement. This bill allows parents to do what they need to do and it doesn't stop Idaho's finest from carrying out the law. They know how to tell the difference between a Clair Carey and a Michael Dauber.

Stuart Sandall, from Twin Falls, with his son Isaac, testified in support of the bill. They have gone through all the battles. He asked the Committee to do something with this bill quickly and not drag out the process because there are many people who will benefit.

Gerry Morris testified for herself in favor of the bill. It is important to legalize CBD oil. Her granddaughter Liliana (Lily) is six and suffers from intractable epilepsy. She was not there that morning because this is the time she generally has her seizures. She currently takes three seizure medicines twice a day plus other controls. She has dropped from 30 to 40 seizures a day to 6 to 8 a day which is still too many, and they are of many types. She described how Lily's development has stopped and even deteriorated.

Ms. Morris said that studies have shown that CBD oil has been very successful in controlling seizures, it is not a psychotic drug, and it would be an additional supplement just like the others she takes each day. Cost has been discussed here today. Lily's care is paid by the State through Medicaid, as are most of the children here, either as a primary or secondary payor. Lily's medicines cost about \$2,500 a month (\$30,000 a year). She listed all the other items Medicaid pays for: neurologists, multiple trips to the emergency room, and admissions when the seizures can't be stopped; she is just one child. CBD oil would be a cost to the families, not to the State, and they are willing to do that. She asked that the bill be sent to the floor with a do pass recommendation.

Bryce Bunderson said the young man, Scout, that could be seen crawling around does not look like a child who has spent months in the intensive care

unit (ICU) or close to 40 hours in several brain surgeries. He discussed the Epidiolex study. Scout's neurologist in Utah participated in that study, and when asked, said it was disappointing. It isn't getting the results they had hoped for compared to the whole plant extract. Although, this may not help these children now, this bill will help those children in the future. **Mr. Bunderson** said he doesn't know the answers for law enforcement.

Testimony in Opposition to S 1106:

William Martin, retired emergency room physician, testified in opposition to the bill. He stated he was very hopeful for CBD oil as a medication. Although he hopes the CBD oil is successful, he does not agree with the bill on how to approach the issue. There is a system in medicine for evaluating drugs for their effectiveness, public safety and protecting the medical community. Currently, physicians practice using evidence-based medicine. He stated his heartfelt concern for the families, but the use of this substance should be approached in a scientific fashion. **Dr. Martin** stated that he has high hopes for CBD oil.

Senator Stennett asked if Dr. Martin agreed that pharmaceuticals could have many side effects, even those that have been tested. **Dr. Martin** responded that there are no pharmaceuticals that don't have side effects. **Senator Stennett** asked if drugs have a particularly bad effect on children's brains. **Dr. Martin** agreed. **Senator Stennett** questioned the difference between using CBD oil as an option and the drugs they are currently using that are not working. **Dr. Martin** said his issue is not with CBD oil, it is with using medicine that is not evaluated for dosage, toxins, and other parameters through scientific study.

Senator Lakey asked Dr. Martin to expound on the studies that could be available. **Dr. Martin** said a CBD study will be available soon.

Senator Davis asked if Dr. Martin was aware of any liver issues that have occurred in the 12 states that have CBD oil but do not have medical marijuana. **Dr. Martin** stated he did not know of any.

Jeff Levey, Chief of Police, City of Meridian, and board member of the Idaho Chiefs of Police Association (Association), who he was representing, testified in opposition to **S 1106**. **Chief Levey** stated that they oppose the bill as written because of the approach and the potential for unintended consequences. They view the issue in two parts: 1) compassion for the kids and help for the families, and 2) the unintended consequences for the State. Controls must be put in place. There is the potential for abuse and the effects it may have for law enforcement, the courts and the crime labs. CBD oil is available from multiple outlets. There must be some regulations in place to ensure the outcomes they are looking for.

Senator Davis noted that Chief Levey said that "as written" he couldn't support the legislation. How would you write the legislation? **Chief Levey** said they have looked at 13 states that have some form of regulations in place. They all have some controls; Idaho is the only one that has no controls. They should be able to come up with some kind of compromise in line with other states. The Office of Drug Policy is prepared to offer some suggestions.

Shane Turman, Chief of Police for Rexburg and President of the Association, spoke in opposition to the bill. **Chief Turman** said their hearts go out to these children that are suffering. It would be a great injustice not to allow them to get treatments that would help them. However, it would be a great injustice to all the children in the State if this bill was passed the way it is written today because

it allows carte blanche use of this substance and makes it almost impossible to stop illegal drugs within Idaho communities. The bill needs to include who should have CBD oil and ensure that only those who need it are getting it. Other states have had to retrain the drug dogs so they won't hit on marijuana. Officers will not be able to tell the percentage of THC in the container. There need to be safeguards in place.

Senator Hill stated that CBD oil has a very low concentration of THC, but it must have some effect on the brain or it wouldn't do any good. Why would someone want to use this oil for vapor or other illegal purposes? **Chief Turman** responded that they wouldn't know if it is the 0.3 percent or less or if it was something else without sending it off to a state lab.

Elisha Figueroa, Administrator of the Governor's Office of Drug Policy (ODP), agreed that these intractable seizure disorders are devastating and these children need real, viable solutions for their health concerns while ensuring the public safety; **S 1106** is not the right option. She talked about the number of states that have legislated the use of CBD oil with high CBD and low THC marijuana oil.

Senator Davis asked Ms. Figueroa how she would write this bill. **Ms. Figueroa** stated that they have many concerns about this bill as it is written including law enforcement concerns that equal a \$6 million fiscal impact. She thinks that the primary, good, positive and viable option is the Federal Drug Administration (FDA) trial set to begin later this month. **Ms. Figueroa** outlined the FDA trial process.

- It is a way for patients to obtain CBD oil.
- It is a natural, plant based CBD medication called Epidiolex.
- The trial will be conducted by a local neurologist and will start at the end of the month.
- There is no limit to the number of patients who can participate in the trial.
- Some of the recipients will be given a placebo during the first few weeks.
- Once the open label study begins after the initial trial period, all participants will be given the medication free of charge until the FDA makes a determination about the drug.

The object of the study is to determine the efficacy and the proper dosage of the medication. The quality of the medication will also be consistent. **Ms. Figueroa** said that lawmakers have requested additional information about this study. They have worked closely with the Idaho State Police, the Department of Health and Welfare, and the Board of Pharmacy. This is a complicated issue, the regulations are complicated and they are sorting through those things so they are not prepared to make a recommendation.

Senator Davis inquired if all families in Idaho will be part of that trial. **Ms. Figueroa** explained that there are certain qualifications the participants must meet and those aren't published. It is likely that not everyone will be enrolled in the trial.

Senator Stennett asked for the name of the pharmaceutical company controlling the study of Epidiolex. **Ms. Figueroa** responded that it is through GW Pharmaceuticals (GWP), a British company. **Senator Stennett** asked if Epidiolex is a completely plant-based oil or is it a derivative of the original plant. **Ms. Figueroa** answered that it is an oil, and as far as she knows, it is plant based. This is not public information because of some of the legalities associated with a new product.

Senator Buckner-Webb requested information on the time period for the first segment of the study where a placebo would be given and the delay before all participants would be given the Epidiolex. **Ms. Figueroa** said her understanding was that it will be 12 to 14 weeks with the placebo and the Epidiolex will begin immediately after that time period.

Senator Winder asked if there was anything like an Idaho or federal law that would prevent this study from going forward. **Ms. Figueroa** said that laws do not have to change; this is a FDA process that is used to approve every medication.

Senator Davis recalled that universities had been listed as a source for CBD oil. Have any of them lost federal funding as a result of that activity? **Ms. Figueroa** stated that she was unaware of any issues, but these are very new laws; the first was in 2013. **Chairman McKenzie** said 7 U.S.C. § 5940(b)(2) defines and allows for universities to research industrial hemp at 0.3 percent THC. **Ms. Figueroa** said it allows for research, but she does not know if it allows for consumption of the product.

Senator Winder asked for a time period when they could have an alternative to this bill. **Ms. Figueroa** indicated that they would need at least a week although others thought it would take six months.

Ms. Figueroa referred to the canines mentioned by Chiefs Lehey and Turman. Randy Arthur, a canine handler, is here to testify about the canines and the issues associated with them. Nik testing is another tool that this bill affects. The Nik tests are used in the field but they can't determine the amount of THC, only that it is there. As a result, any questionable substance would have to be sent to the state lab. There are also problems with search and seizure. Heather Riley from the Prosecutor's office will speak to those. **Ms. Figueroa** alluded to other questions that will be covered in other testimonies: the abuse of an illegal substance and the inaccuracy and abuse of labeling.

Ms. Figueroa closed her comments by saying that everyone must be very careful when laws are passed regulating things that are in violation of federal law. This opens the door to an incremental process; the number of illnesses increase as does the level of THC.

Senator Lakey asked if the bill passes with the 0.3 percent of THC, does that violate federal law. **Ms. Figueroa** confirmed that it does. **Chairman McKenzie** agreed that most of the states are in violation of federal law. In August 2013, the Department of Justice came out with a statement that they are not going to interfere with states' rights on this issue.

Bryan Taylor, Canyon County Prosecuting Attorney and President of the Idaho Prosecuting Attorneys Association, spoke in opposition to **S 1106** as it is currently written. On behalf of the prosecutors, he extends their empathy to the children who suffer from these rare forms of medical issues. However, they have to take all of the other children into consideration. This bill is the most liberal CBD bill in the country; there are no regulations or safeguards.

Senator Davis asked him how the bill should be written.

Mr. Taylor noted that there is no specific medical issue in this bill as it is currently written. He outlined some suggested requirements:

- There should be a definition of the specific medical condition.
- There should be patient registration and identification.
- There should be physician recommendation components.

- There should be oversight by state regulators such as the Office of Drug Policy.
- Product labels and certificates should be intact as well as product analysis.
- Drugs should come from licensed laboratories.

These are only his ideas and have not been approved by others. On behalf of the prosecutors, **Mr. Taylor** strongly opposes this bill as it is written. It is going to have issues and there are those that will exploit this bill.

Senator Davis asked if Mr. Taylor had talked with his colleagues from other states. Are they having the types of legal complications that have been expressed here? **Mr. Taylor** said he had not spoken to anyone in the other 13 states.

Senator Hill asked if any parents have been prosecuted in Idaho for the use of the CBD oil discussed in this bill. **Mr. Taylor** answered that there have been none in Canyon County but could not speak for anywhere else.

Senator Stennett observed that some very rare illnesses have been discussed. How would you suggest the Committee formulate the list of diseases? **Mr. Taylor** suggested that Idaho should investigate what other states have done. They have parameters on certain illnesses. Also, the medical profession should be heavily relied upon.

Senator Lakey asked for information that should be built into the code as it relates to search and seizure. **Mr. Taylor** said he couldn't really answer the question without doing some research.

Jan Bennetts, Ada County Prosecuting Attorney, addressed the comments already made relating to Senator Davis' request as to how they would write the bill. She would like to sit with the medical professionals and design something that would do no harm. There still is the problem with the dogs and how to help them do their jobs under these circumstances.

Randy Arthur, Idaho Fraternal Order of the Police, stated that he has been a canine handler since 1996. He is a state certified trainer for drug dogs. He emphasized that the people here today are not who they are concerned about. In the case of CBD oil, the dogs only distinguish by odor no matter what the drug is. The concern is the lack of parameters in this bill, which could invalidate all of the dogs.

**UNANIMOUS
CONSENT
REQUEST:**

Chairman McKenzie asked for unanimous consent to hold **S 1106** to a date certain which is anticipated to be Monday, March 9th, when there will be amendments for the Committee to consider before making a decision on the bill.

Before sending the bill to the Amending Order, the Committee will have the opportunity to see the potential amendments from the sponsor addressing the concerns that have been heard.

Senator Hill added his support for the request. He challenged the stakeholders who have concerns to come back with some answers next week.

Senator Lakey agreed and appreciated the opportunity to see the amendments in Committee rather than in the Amending Order; that is a good approach and he supports it.

There were no objections.

ADJOURNED:

Chairman McKenzie adjourned the meeting at 10:20 a.m.

Senator McKenzie, Chair

Twyla Melton, Secretary