MINUTES

SENATE STATE AFFAIRS COMMITTEE

DATE:	Friday, March 20, 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.
RS 23614	**A Unanimous Consent Request From the Commerce and Human Resources Committee For a Senate Concurrent Resolution to Encourage Congress to Support Federal Legislation to Create a Health Care Cost Support Choice**.
MOTION:	**Senator Siddoway** moved to print **RS 23614**. **Vice Chairman Lodge** seconded the motion. The motion carried by **voice vote**.
H 184	**Relating to Beer to Clarify Provisions Relating to Small Brewer Self-Distribution**.
	Jeremy Pisca, Risch Pisca Law Firm, representing the Idaho Beer & Wine Distributors Association, began his explanation of the bill on page 3. This bill clarifies the small brewers exemption in Idaho Code § 23-1003 relating to distribution. In Idaho, small brewers have the ability to be their own retailer and distributor. This ties the distribution back to their own manufactured product. Other changes make the statute gender neutral. The last change on page 1, line 16 relates to a Certificate of Approval for a business outside the State to sell to wholesalers, not brewers, located within the State.
	Senator Siddoway asked if this bill would prevent two brewers from purchasing and using a truck together to make their deliveries. He also inquired about the brewers' association. **Mr. Pisca** replied that if this was a cooperative arrangement between multiple brewers, it would be restricted. Idaho Brewers United is the trade association for small brewers. The brewers in the Teton Valley are prominent members of that association.
MOTION:	**Vice Chairman Lodge** moved to send **H 184** to the floor with a **do pass** recommendation. **Senator Buckner-Webb** seconded the motion. The motion carried by **voice vote**.
S 1167	**Relating to Hemp Extract to Define Hemp Extract and Allow the Use and Possession of Such Substance for Children with Intractable Epilepsy**.
	Senator Winder asked for **unanimous consent** to withdraw **S 1167**.
	Senator Hill asked if the bill could be held in Committee instead of withdrawn. **Senator Winder** responded that if it is the will of the Committee and the Chairman to hold the bill and make it subject to the call of the Chair, he would be in agreement rather than totally withdrawing it.

UNANIMOUS CONSENT REQUEST:

Chairman McKenzie said there is a unanimous consent request to withdraw **S 1167** from consideration today and it would be subject to the call of the Chair if the sponsor changes that request. There being no objections, **S 1167** will not be considered on the agenda today.

S 1156

Relating to Investigational Drugs to Authorize the Department of Health and Welfare to Administer an Expanded Access Program.

Senator Heider stated he has been approached on numerous occasions about the use of a marijuana extract to help children with intractable seizures. There is a drug called Epidiolex that is being tested in clinical trials. It is manufactured in England and can be purchased in the United States (US) legally. Dr. Robert Wechsler, a neurologist specializing in epilepsy with St. Lukes Hospital, will be conducting a clinical trial. Initially, 25 children or more can be enrolled in that trial. The State has authorized $223,500 for this trial and has been approved by the Director of Health and Welfare. **Senator Heider** introduced Dr. Hahn to explain the bill.

Dr. Christine Hahn, Medical Director, Division of Public Health, Department of Health and Welfare (Department), said the Department supports **S 1156**. It will allow children with intractable epilepsy to access a promising cannaniboid that is in clinical trials in the US and can be obtained through this process in line with current state and federal law.

The bill authorizes the Department to enter into agreements for the administration and supervision of the Federal Drug Administration (FDA) approved expanded access programs, sometimes called compassionate use programs. Those are set aside programs for rare diseases or diseases where drugs are still being tested and where the demand is great because of the urgency of the situation. Epidiolex is such a drug. It is a plant-based, non-synthetic cannabidoid that comes in an oil form. It has no tetrahydrocannabinol (THC). Epidiolex is produced by GW Pharmaceuticals (GWP) in London and is considered a Schedule 1 substance by the FDA; it has been authorized by the FDA and the Drug Enforcement Administration (DEA). She listed some of the locations that are doing these trials across the US. Dr. Wechsler has been approved to begin a clinical trial for four to ten patients and has agreed to apply for the expanded program for people not currently in the trial. All children in the expanded program would receive the drug under the oversight of a neurologist.

Dr. Hahn explained that GWP cannot commit to the expanded access program until they see Dr. Wechsler's application, but his program would be looked upon favorably. There are 21 expanded programs around the country; the number of participants in each one has been 25-50. Since Idaho is a small state with a relatively small population, it would probably qualify for 25.

The funding the Department would receive would be used to reimburse the medical costs for the children enrolled in the study and to reimburse the study investigator. GWP provides the drug fee of charge. They receive beneficial information about the drug to identify the advantages and disadvantages of its use. Enrollment is expected to begin in May.

Senator Stennett asked what certifications and licensing Dr. Wechsler is required to have. **Dr. Hahn** said he is a board certified neurologist and an epileptologist licensed to practice medicine in Idaho, he has a DEA license that authorizes him to prescribe scheduled substances and he has special approval by the FDA and DEA to handle Schedule 1 substances. **Senator Stennett** asked how the $223,500 for the 25 children that the Department receives

annually would be spent, and how long would this program continue. What happens to the participants when they get off the trial? **Dr. Hahn** answered that the funding goes to the doctor on a per child basis. The FDA hopes to enroll enough children to make the program robust, and the drug will be licensed in a few years.

Senator Stennett asked how law enforcement will be affected and if there are any safeguards outside the doctor's office. **Dr. Hahn** couldn't guarantee what would happen in a given situation. This product and these families should not be treated any differently than anyone else involved in an experimental drug trial.

Senator Hill referred to the CBD oil that had to be less than 0.3 percent THC. It was the assumption that there had to be some THC to make the drug effective. Is there a need for THC and if there is, why isn't it in the Epidiolex? **Dr. Hahn** explained that the cannabis plant contains a variety of chemicals, and GWP has separated those chemicals removing any THC. There are some individuals that believe THC is the active, curing, ingredient, but scientists and medical providers believe it is not necessarily the THC that provides the benefit. It is yet unknown and that is the reason for the trials.

Senator Hill asked if this legislation leaves the option, in case it is found that THC is an important component, to initiate clinical trials using drugs with THC. **Dr. Hahn** said this legislation would not allow anyone to overstep the FDA. Anything that was found with THC would have to go through all the application and approval process.

Senator Buckner-Webb inquired if patients from outside of Ada County could participate in the study. **Dr. Hahn** said the neurologist that is approved is in Boise, but they would reach out to other neurologists around the State and they could apply to be an approved site. **Senator Buckner-Webb** asked how long the application process takes. **Dr Hahn** said it could take up to six months.

Chairman McKenzie noted that the bill says the Department is being authorized to enter into FDA expanded access programs not necessarily limited to this one. Is this something that has been needed in the past, is the State paying for those, and will there be additional people coming into the State to have a program paid for? **Dr. Hahn** answered that they haven't had the funding, authority or requests in the past but if they apply, they have to be considered no matter where they are from.

Senator Winder asked to circulate a letter from Dr. Wechsler when the time is appropriate, that would answer some questions.

Elisha Figueroa, Administrator, Office of Drug Policy, stated their support of **S 1156**. After the initial hearing on this topic a few weeks ago, they were charged with finding a solution that would address the parents' concerns and the concerns of law enforcement. This plan provides access to plant-based CBD oil in a manner in keeping with state and federal law. She stated that the parents' points of concern with the FDA were:

1. They wanted a plant based product. Epidiolex is a plant-based product.
2. The time frame was an issue. The children cannot wait for years for medications to be approved. The expanded access programs provide access to investigational new drugs.
3. There was concern with the efficacy of Epidiolex. The initial reports from three studies show some effectiveness.

This solution addresses the concerns of law enforcement. The product would be like a prescription with a label that indicated the physician's name and it could be verified that they were a program participant.

This provides an immediate and long-term solution. It provides information and research on the issue of epilepsy. **Ms. Figueroa** read a paragraph from Dr. Wechsler's letter explaining how they came to the number of 25 patients and what the need in Idaho is. She said they are confident this program will meet the need of the families suffering from this disease.

This program would be free of charge to the families, and the medication is free to the State. There are no age limits although it is focused on children. There are no limits on the type of epilepsy. There is no placebo group. It provides a consistent, purified product that is administered with the oversight of a neurologist. It does not violate state or federal law and it is available in Idaho.

Senator Stennett remarked that she had a conversation with Dr. Wechsler and sometimes there was a need to be on more than one drug regimen. She asked if the patients can stay on their current regimens and still do this. **Ms. Figueroa** said the regimen had to be stabilized then the new drug would be added.

Senator Siddoway asked how many people in the State may be potential users of this drug if it proves to be effective. **Ms. Figueroa** said they don't have exact numbers. The determination is made by using an equation. There is a difference in the total number of people with epilepsy and the number with intractable epilepsy, which is what the trial is for.

Senator Stennett inquired if all seizure disorders are considered epilepsy. **Dr. Hahn** answered that there are seizure disorders that are not classified as epilepsy. **Senator Stennett** asked how efficacy could be determined if the current medical regimens were continued or if they were interrupted. **Dr. Hahn** said the new drug is added for a period of time and then taken away, then the number of seizures per day and what changes occur are monitored

Chairman McKenzie asked if there is a gap in time from when they get the drug through the test program and when it is approved; or will there be a time when the drug is not approved and the families would not have access to it? **Ms. Figueroa** said that GWP is committed to providing the medication as long as necessary for those who are responding positively to it. **Chairman McKenzie** inquired if the State would continue to pay the $15,000 to $20,000 after the study. **Ms Figueroa** said that once the FDA has completed the study, then the medication could be accessed through a pharmacy like all other medications.

MOTION: **Senator Hill** moved to send **S 1156** to the floor with a **do pass** recommendation. **Senator Lodge** seconded the motion. The motion carried by **voice vote**.

SCR 115 **A Senate Concurrent Resolution Regarding Federal Lands to Request the Department of Lands to Perform Certain Duties with the Federal Government Regarding Federal Lands**.

Senator Winder stated that this resolution is the result of a recommendation from the Interim Committee on Federal and Public Lands (Interim Committee). Senator Winder distributed a copy of some suggested amendments to **SCR 115**. He explained that the amendments are the culmination of changes that occurred after working with a variety of stakeholders including the Department of Lands and members of the House and Senate that were on the Interim Committee. **Senator Stennett** commented on the good work and language.

Vice Chairman Lodge suggested that this may help with the situation at Lake Lowell. She acknowledged her appreciation to Senator Winder.

MOTION:	**Senator Lakey** moved to send **SCR 115** to the 14th Order for possible amendment. **Senator Stennett** seconded the motion. The motion carried by **voice vote**.
MINUTES APPROVAL:	**Senator Winder** moved to accept the Minutes of February 11, 2015. **Senator Davis** seconded the motion. The motion carried by **voice vote**.
MINUTES APPROVAL:	**Senator Stennett** moved to accept the Minutes of February 16, 2015. **Senator Lakey** seconded the motion. The motion carried by **voice vote**.
MINUTES APPROVAL:	**Senator Hill** moved to accept the Minutes of February 18, 2015. **Senator Siddoway** seconded the motion. The motion carried by **voice vote**.
MINUTES APPROVAL:	**Vice Chairman Lodge** moved to accept the Minutes of March 6, 2015. **Senator Buckner-Webb** seconded the motion. The motion carried by **voice vote**.
	Senator Davis referred to Senate Rule 36(c), Non Amendable Measures; Senate resolutions, concurrent resolutions and joint memorials shall not be subject to amendment.
UNANIMOUS CONSENT REQUEST:	**Senator Davis** made a Unanimous Consent Request that the prior decision of the Committee to send **SCR 115** to the 14th Order for possible amendment be withdrawn. There were no objections.
	Senator Davis suggested that the new legislation could be buck slipped and introduced no later than Monday. **Chairman McKenzie** said he would defer the decision to Senator Winder.
ADJOURNED:	**Chairman McKenzie** adjourned the meeting at 8:58 a.m.

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Senator McKenzie
Chair

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Twyla Melton
Secretary