MINUTES

SENATE HEALTH & WELFARE COMMITTEE

DATE:	Monday, January 26, 2015
TIME:	3:00 P.M.
PLACE:	Room WW54
MEMBERS PRESENT:	Chairman Heider, Vice Chairman Martin, Senators Johnson (Lodge), Nuxoll, Hagedorn, Tippets, Lee and Schmidt
ABSENT/ EXCUSED:	Senator Lacey
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 Heider** called the meeting of the Health and Welfare Committee (Committee) to order at 3:00 p.m. and welcomed Senator Kim Johnson, sitting in for Senator Lodge.
PASSED THE GAVEL:	Chairman Heider passed the gavel to Vice Chairman Martin for rules review.
DOCKET NO. 27-0101-1401	**Mark Johnston**, Executive Director of the Board of Pharmacy (Board), addressed **Docket No. 27-0101-1401**, Rules of the Idaho State Board of Pharmacy. The proposed rule would allow biosimilar products to be substituted for a prescribed biological product in order to be consistent with federal law. There is no negative fiscal impact on the General Fund. Negotiated rulemaking was conducted, and the rule is consistent with the Board's authority under Idaho Code § 54-1717. **Mr. Johnston** explained that Congress has created a new pathway for drug approval, collectively known as biosimilars, and outlined the makeup of biological products compared to most drugs. He said federal law allows for a provision that goes beyond simply approving a biosimilar, by determining that the licensed biosimilar is interchangeable with the referenced biological product. **Mr. Johnston** said if this rule is defeated via concurrent resolution, biosimilar substitution will not be allowed in Idaho, thus making Idaho more restrictive than the federal government. He said this promulgation establishes the Idaho parameters for biosimilar interchange and is supported by groups such as Blue Cross of Idaho, Regence Blue Shield of Idaho, Select Health Plans, and others. **Mr. Johnston** read the changes to the rule word for word and said the Board has received no opposition to the language. He said notification requirements have been raised, but he emphasized Idaho has years to determine if notification should be required and what such a requirement might look like. He concluded by asking the Committee to approve **Docket No. 27-0101-1401** and stood for questions. Questions from the Committee centered mostly on notification requirements and cost savings, all of which were answered fully by Mr. Johnston. **Vice Chairman Martin** called on those wishing to testify on **Docket No. 27-0101-1401.**
TESTIMONY:	**Dr. Troy Rohn**, Professor, Boise State University, testified in opposition to **Docket No. 27-0101-1401**. He said he was in favor of biosimilars because of their therapeutic value and cost savings for consumers. However, he was in opposition to the rule as written because the wording did not contain notification requirements, which he said were necessary for patient safety, transparency and treatment plans.

Susan Holladay from Meridian, representing herself, testified in opposition to the rule because of lack of notification requirements to the physician. She said five family members are on biologics, and her experience confirms the patient and physician need to know if a prescription is substituted because of the potentially harmful consequences.

Tony Holladay from Meridian, representing himself, testified in opposition to the rule. He said as a person with rheumatoid arthritis, he has been pain-free for over a year because of biologics. He said, however, that it is vitally important for his physician to know when a substitution has been made.

Ken McClure, an attorney with Givens-Pursley, representing the Idaho Medical Association (IMA) and AmGen, testified in opposition to the rule. He distributed letters of opposition and graphs (see attachment 1). He said that IMA has urged the Board to give the physicians full knowledge about what is going on. He believes this is an important aspect missing from the rule.

Mr. McClure said biologics are used mostly in oncology, rheumatology, and dermatology. He said all national specialty societies of these physician groups have written letters to Legislators. All have asked that a mechanism be required for the substitution to be placed in the patient's medical chart.

Mr. McClure referred to the charts distributed to the Committee, which illustrated information on top biologics and biologic adverse event attribution without complete patient records. He said most biologic drugs are either injected or infused by a clinic or hospital but some do come from pharmacies, which can result in lack of information needed by the doctor. He referred to the handout from the Generic Pharmaceutical Association, which also supports the communication requirement.

Shad Priest, Director of Government Affairs, Regence Blue Shield and also representing Bridge Pan Health, Cambia Health Solutions, and Oneida County Rx, testified in support of **Docket No. 27-0101-1401**. He said these companies care about health care costs, and biosimilars are a tool to control prices through competition. He said the United States has one of the most stringent rules for new drugs and, because this is a class of medication that does not yet exist, there is time to refine the rule at a later date.

Pam Eaton, President and CEO, Idaho Retailers Association and Retail Pharmacy Council, testified in support of the rule. She said the FDA is extremely cautious, and biosimilars will help get costs under control.

TESTIMONY: **Stacey Satterlee**, Director of Government Relations in Idaho, American Cancer Society, testified in opposition to the rule. She said the rule does not contain a requirement for patient and prescriber notification when a biosimilar substitution is made. She stressed that patients need to be more actively engaged in their treatments, and they can only be as effective as the information provided to them.

TESTIMONY: **Maral Farsi**, representing CVS Health, Blue Cross of Idaho, and Pacific Source Health, testified in support of the rule, as adopted by the Board. She said notification is unnecessary and undermines the FDA exhaustive approval process.

Throughout all testimonies, the Committee asked questions and received detailed answers in response. The primary objection to the rule was the lack of wording that would require notification to a patient's physician when a biosimilar substitution is made. **Senator Hagedorn** also expressed concern about the wording "patient's medical records", which appeared to be at variance with the actual meaning "patient's medication records." **Mr. McClure** said this was a misprint, and it would be corrected.

Vice Chairman Martin reminded the Committee the vote would be on the wording as written.

MOTION:	**Senator Nuxol**l moved to approve **Docket No. 27-0101-1401**. **Chairman Heider** seconded the motion. The motion passed by **voice vote**.
PASSED THE GAVEL:	Vice Chairman Martin passed the gavel back to Chairman Heider.
ADJOURNED:	**Chairman Heider** notified the Committee and audience the remaining dockets on the agenda would be rescheduled. He adjourned the meeting at 5:00 p.m.

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Senator Heider
Chair

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Erin Denker
Secretary

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Jeanne´ Clayton
Assistant Secretary