MINUTES

HOUSE HEALTH & WELFARE COMMITTEE

DATE: Monday, January 19, 2015

TIME: 9:00 A.M.

PLACE: Room EW20

MEMBERS: Chairman Wood, Vice Chairman Packer, Representatives Hixon, Perry, Romrell, Vander Woude, Beyeler, Redman, Troy, Rusche, Chew

ABSENT/ EXCUSED: Representative(s) Chew

GUESTS: The sign-in sheet will be retained in the committee secretary's office until the end of the session. Following the end of the session, the sign-in sheet will be filed with the minutes in the Legislative Services Library.

Chairman Wood called the meeting to order at 9:00 a.m.

MOTION: **Rep. Perry** made a motion to approve the minutes of January 14, 2015. **Motion carried by voice vote.**

DOCKET NO. 27-0101-1401: **Mark Johnston**, Executive Director, Idaho Board of Pharmacy (IBOP), presented **Docket No. 27-0101-1401**. New drugs known as biosimilars have been recognized by Congress and the Federal Drug Administration (FDA). Biological products are produced by living cells, with slight batch variations possible. These are complicated molecules, cannot be exactly replicated, and have no generic equivalent. An exact copy is unnecessary since only the part adhering to the receptor site must fit. The FDA can approve biosimilars, after a rigorous process, and stipulates provisions by law. Idaho Rule promulgation is required to allow FDA approved interchangeable biosimilars substitution.

Dr. Johnston described public concerns that biosimilars will not work as well and may cause harmful side effects. He shared the Board's confidence in the FDA process, previous existence of biosimilars on the European market, and the impact of reduced costs over the next decade. The first biosimilar approved by an FDA panel, still to be accepted by the FDA, is not yet determined to be interchangeable. The FDA approval process is taking 15 to 24 months.

Dr. Johnston said rejection of this Pending Rule would mean biosimilar substitution will not be allowed in Idaho and we would be without the ability to realize the savings. He explained opponents desire provisions for prescriber substitution notification.

Eric Cannon, Vice President, Pharmacy Benefit Services, Select Health, Board of Director, Academy of Managed Care Pharmacy, testified **in support** of **Docket No. 27-0101-1401**, stating any notification requirement places an undue burden on pharmacists. If the physician deems any interchange inappropriate, it can be indicated on the prescription.

Responding to questions, **Mr. Cannon** stated the majority of biologic products require prior authorization. After reviewing prescriber information, a notification letter goes to the prescribing physician, patient, and pharmacist. It lists the approved products, approval duration, and any duration requirements.

Dr. Troy Rohn, Professor, Boise State University, Ph.D. Pharmacology, testified **in opposition** to **Docket No. 27-0101-1401**. He is involved in a research program that regularly makes and applies biologics in his study. These are complex molecules, not small chemical generics, are produced in living systems, and cannot be replicated. If a biosimilar substitute caused an adverse event, how would the physician be able to pinpoint the event without knowledge of the change? Eight other states with similar legislation require patient or physician notification when a substitution is made.

Answering questions, **Dr. Rohn** said the process of making the biologic in a living cell can take hundreds of steps, all patent protected. Any company making one will have to start from scratch, leading to a product that will be different from the biologic. Very different results occur with even slight alterations that are perceived as identical. Information, perhaps from the European marketing of the product, helps determine if there is anything to connect an adverse reaction to a patient. He described the FDA drug approval process as the most stringent and safest in the world.

Mark Guimond, Arthritis Foundation, testified **in opposition** to **Docket No. 27-0101-1401**. This Rule provides an opportunity to bring a substantially less expensive medication to market. Biologics will not be found at corner drugstores. For those with crippling illnesses, the biologics give them back their lives.

One hundred percent of the biologics are either intravenous (IV) or injected, requiring special handling and special patient instructions. When something goes wrong, the patient may ruin their adherence, which the physician must know immediately. Twenty-six percent of all biologics are handled by mail. Restrictions put into place now could be removed in the future.

Responding to questions, **Mark Guimond** commented that variations of the same biosimilar could exist, such as version one, two, or three. Without notification, the prescriber would have no way of knowing which version was substituted. When such a fragile patient fails with the substitution, a complete new drug regiment is required. "Dispense as written" notations protect physicians, but do not allow the opportunity for cost reduction.

Chairman Wood commented that Idaho law assures the prescribing community has the authority to allow substitution because they know the most about the patient and can provide prescription safeguards.

Bruce Lott, Vice President, Global Biologics, Mylan Specialty Medicines, testified **in support** of **Docket No. 27-0101-1401**. His company has marketed five biosimilars inside and one outside the United States. Biologics are without competition and have an average daily cost twenty-two times a traditional drug. This Rule is about allowing substitution of interchangeable biosimilars. The biosimilars must work the same way as the referenced product and are expected to produce the same clinical result in any given patient. No applications for interchangeable biologics have been filed with the FDA, so it could be several years before one is on the market. IBOP got the Rule right and will assure patients have access to safe, more affordable products when they are available.

Stacy Satterlee, Director, Government Relations, American Cancer Society - Cancer Action Network, testified **in opposition** to **Docket No. 27-0101-1401**. Interchangeables are not necessarily the same product. Patient safety and transparency of information outweigh concerns about timing and opportunity. Until patient medication and electronic medical health record integration, it is critical that the prescribing physician and patient record be quickly updated and as accurate as possible. Phone or E-mail notification would be sufficient.

In answer to a question, **Ms. Satterlee** said this type of prescription is filled through mail order, not at a corner pharmacy, which makes it harder for a doctor to determine where it came from and what was dispensed.

Shad Priest, Regence Blue Shield, Can Do Health Solutions, testified **in support** of **Docket No. 27-0101-1401**. The past generic introduction addressed sky rocketing costs, with similar notification concerns. States who changed their Rules to include the notification had fewer generic drugs issued at pharmacies, resulting in continued higher customer costs. The FDA requirements are very high, stringent, and the safest in the world. The IBOP negotiated rule making process was excellent, with robust open deliberation, and a unanimous decision not to impose restrictions higher than the federal government.

Answering questions, **Mr. Priest** said access to affordable medication is key to getting the medication. Generics provide cost savings to employers, the public, and taxpayers, since they are paid for by Medicaid, Medicare, and State or Employee health plans. This Rule does not require substitution. The physician can choose to write the "dispense as prescribed" notation.

Pam Eaton, President, Chief Executive Officer, Idaho, Retailers Association, Retail Pharmacy Council, testified **in support** of **Docket No. 27-0101-1401**. The FDA is extremely cautious and conservative. For patients with delicate conditions, physicians can mark "dispense as written."

Angela Richards, American Health Insurance Plan, testified **in support** of **Docket No. 27-0101-1401**, stating interchangeability will be thoroughly studied before anything is approved. Insurance companies and doctors will maintain records. Adoption of this Rule will allow safe and effective interchangeable biosimilars when the FDA has approved them.

Ken McClure, Amgen, testified **in opposition** to **Docket No. 27-0101-1401**. Their request is for notification to assure complete medical records and does not discourage substitution. Problems with biologics and substitutions can take time to appear in a patient. Biologics are infused or injected and usually done in a clinical setting where the doctor knows what was actually dispensed. The doctor is left unaware of a change when out-of-state specialty pharmacies deliver directly to the patient or the insurer changes the formulary. After-the-fact notification will not prohibit uptake of the biosimilars.

Julie Taylor, Pharmacy Benefit Management Company, CVS Caremark, testified **in support** of **Docket No. 27-0101-1401**. She read a letter from **Maral Farsi**, Regional Director, Government Affairs, CVS Health. In her letter, Ms. Farsi stated her **support** of **Docket No. 27-0101-1401** which removes barriers and facilitates the approval of biosimilars, increasing lifesaving medication accessibility and affordability. (See attachment 1)

For the record, no one else indicated their desire to testify.

Responding to further comment, **Mark Johnston** said six states have notification requirements and eight states have refused to introduce such communication. Idaho's Health Information Exchange (HIX) could be an electronic source of notification. The counseling statute for all new medications provides patients the opportunity to be informed, consult about cost options, and reject any therapy. He stated the IBOP does not legislate to the fear of a future possibility, reversing it when the need does not mature. They believe communication already exists, with no benefit to go through a process of notification.

Responding to questions, **Dr. Johnston** said rejection of this rule would eliminate the possibility of substitution of any interchangeable drug that becomes available.

MOTION: **Rep. Perry** made a motion to approve **Docket No. 27-0101-1401.**

Rep. Perry said the expressed concern is about notification, which needs to be addressed in a separate rule making process that could occur later.

Responding to further questions, **Dr. Johnston** said pharmacists are a defense and safety valve with corresponding liability and responsibility. A separate rule requires pharmacies keep stipulated information on every patient and prescription. Physician E-mail addresses are not on prescriptions or available to pharmacies. Any electronic notification can become an issue of privacy and Health Insurance Portability and Accountability Act (HIPAA) compliancy.

Rep. Beyeler commented on the importance of communication after the fact and encouraged development in that direction.

Rep. Rusche said the committee is being asked to vote on something that doesn't exist.

Rep. Vander Woude stated his opposition to the motion. Realizing that every medication is different with each patient makes it critical that doctors know if the actual drug or something similar is being used. Such notification seems a simple opposition remedy.

Rep. Perry stated that there is time to determine how notifications happen since the drugs are not on the market. The Rule covers the possible approval of one biosimilar later this year. Concerns can be addressed at a later date.

Chairman Wood commented in support of the motion, stating all the testimony was very true. In his experience with the FDA, they are a most cautious, conservative drug regulation entity that emphasizes patient protection. Since they did not include a notification requirement, we need to look at that extra step very carefully. A physician using the "dispense as written" provision takes responsibility that nothing can be substituted. Idaho's rules and laws make sure the prescribing community is solely in charge of what the patient gets. Because there are no pending interchangeable biosimilars, we have time to decide about notification.

VOTE ON MOTION: **Chairman Wood** called for a vote on the motion to approve **Docket No. 27-0101-1401. Motion carried by voice vote. Reps. Rusche** and **Vander Woude** asked to be recorded as voting Nay.

Chairman Wood put the committee at ease at 10:56 a.m.

Chairman Wood called the meeting back to order at 11:04 a.m.

RS 23196: **Mark Johnston**, Executive Director, IBOP, presented **RS 23196**, proposed legislation to grant the IBOP authority to restrict controlled substance registrations and enforce stipulated agreements. Other housekeeping changes are included in the legislation.

MOTION: **Rep. Perry** made a motion to introduce **RS 23196. Motion carried by voice vote.**

RS 23197: **Mark Johnston**, Executive Director, IBOP, presented **RS 23197**. Recognizing the public safety issue inherent in the current six-week delay with the Idaho background checking process, this proposed legislation waives the fingerprint requirement for reinstatement of applicants whose licenses have lapsed for less than a year.

MOTION: **Vice Chairman Packer** made a motion to introduce **RS 23197. Motion carried by voice vote.**

RS 23208: **Mark Johnston**, Executive Director, IBOP, presented **RS 23208**, proposed legislation to allow electronic prescription drug transmission from nursing homes to their pharmacy, as is already used by hospitals.

MOTION: **Rep. Hixon** made a motion to introduce **RS 23208. Motion carried by voice vote.**

RS 23222: **Mark Johnston**, Executive Director, IBOP, presented **RS 23222**, proposed legislation requiring a presiding judge to issue a subpoena for Prescription Monitory Program (PMP) data.

MOTION: **Rep. Hixon** made a motion to introduce **RS 23222. Motion carried by voice vote.**

RS 23223: **Mark Johnston**, Executive Director, IBOP, presented **RS 23223**. The proposed legislation is a result of the Drug Quality and Security Act preempting the state tracking of prescription drug product distribution by striking the normal distribution channel definition. Pursuant to the Idaho Wholesale Drug Distribution Act, additional changes have been made to address grey wholesaling and controlled substance wholesale distributor duties.

MOTION: **Rep. Romrell** made a motion to introduce **RS 23223. Motion carried by voice vote.**

RS 23248: **Mark Johnston**, Executive Director, IBOP, presented **RS 23248**, proposed legislation to update Idaho's Schedules of Controlled Substances in accordance with the Drug Enforcement Administration (DEA).

MOTION: **Rep. Redman** made a motion to introduce **RS 23248. Motion carried by voice vote.**

ADJOURN: There being no further business to come before the committee, the meeting was adjourned at 11:22 a.m.

Representative Wood
Chair

Irene Moore
Secretary