HOUSE BILL REPORT
HB 2326

As of Second Reading

Title: An act relating to the prescription of biological products and interchangeable biological products.

Brief Description: Concerning the prescription of biological products.

Sponsors: Representatives Cody, Schmick, Harris, Morrell, Ross, Manweller, Sullivan, Ryu and Jinkins.

Brief History:
Committee Activity:
Health Care & Wellness: 1/20/14, 2/3/14, 2/5/14.

Brief Summary of Bill

- Authorizes biosimilar products to be substituted in the place of a biological product if the United States Food and Drug Administration has determined that the biosimilar product is interchangeable with the biological product.
- Requires pharmacists dispensing biological products to record the name of the product and the manufacturer in an interoperable health records system that is shared with the prescribing provider or to communicate it directly to the prescribing provider.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Staff: Chris Blake (786-7392).

Background:

Biological and Biosimilar products.
Biological drug products replicate natural bodily substances and are often produced in living systems, such as microorganisms or plant or animal cells. Compared to small molecule drugs, which are generally pure chemical substances that can be entirely reproduced, these products are usually larger, more complex, and unlikely to be structurally identical in their production.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Federal law defines "biological products" to include the following items when used for the prevention, treatment, or cure of a disease: a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, an allergenic product, a protein, or an arsphenamine. Federal law prohibits the introduction of biological products into interstate commerce unless the product has been licensed by the United States Food and Drug Administration (FDA). To receive a license, an applicant must demonstrate that the biological product is safe, pure, and potent and the manufacturing facility maintains those qualities. The law establishes standards for labeling, inspecting manufacturing processes, and recalls of hazardous biological products.

A "biosimilar product" is defined as an item that is highly similar to a biological reference product and has no clinically meaningful differences with the biological reference product in terms of safety, purity, and potency. A "biological reference product" is a biological product to which another biological product is compared. The FDA considers applications to determine whether a product either meets: (1) the definition of a biosimilar; or (2) the safety standard of an interchangeable biological product. The FDA's safety standards for interchangeability require that the biological product be determined to be: (1) biosimilar to a reference product; and (2) expected to produce the same clinical result as the reference product to any given patient. In the case of biological products that are administered to patients in multiple doses, the product must also demonstrate that the safety risks and risks of reduced efficacy when alternating between the biological product and a biological reference product are no different between doses of the same biological reference product.

Substitution of Drugs.
Drug prescriptions must contain an instruction as to whether or not a therapeutically equivalent generic drug may be substituted, unless a prior-consent authorization allows for substitutions. A prescription is not valid unless the prescribing practitioner has signed whether the prescription must be dispensed as written or if a substitution is permitted.

When filling a prescription under a state-purchased health care program, including Medical Assistance programs, the Public Employee Benefits Board's self-insured program, and Labor and Industries programs, a pharmacist must substitute a preferred drug for a non-preferred drug in a therapeutic class. This requirement does not apply in cases in which the prescribing practitioner has noted on the prescription that the non-preferred drug must be dispensed as written.

Summary of Bill:

"Biological products" are defined as any of the following items when used for the prevention, treatment, or cure of a disease: a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, an allergenic product, a protein, or an arsphenamine. "Biosimilar products" are items that are highly similar to a biological product and have no clinically meaningful differences with the biological product in terms of safety, purity, and potency.

Prescriptions for biological products must include instructions on whether or not an interchangeable biological product may be substituted in its place. If a pharmacist substitutes a biological product in the place of a different biological product, he or she must record the

brand name or nonpropriety name of the substitute. The records must be maintained for at least two years.

If the cost of an interchangeable biological product is less than the price of the prescribed product, the pharmacist must substitute the interchangeable biological product unless the patient requests the brand name product.

When a pharmacist dispenses a biological product, he or she must record the name of the product and manufacturer of the product in an interoperable health records system shared with the prescribing practitioner within 10 days. If there is no such health records system in place, the pharmacist must communicate the name of the product to the prescribing practitioner within 10 days. The communication requirement does not apply if there is no interchangeable biological product for the prescribed product or a refill is provided for the product that had been originally dispensed. The Pharmacy Quality Assurance Commission is required to maintain a list of all biological products that the United States Food and Drug Administration has determined to be interchangeable and the associated reference product.

Pharmacists assume the same responsibility for selecting an interchangeable biological product as the pharmacist has when filling that product as prescribed by name. Prescribing practitioners are not liable for a pharmacist's decisions regarding the selection, preparation, or dispensing of an interchangeable biological product.

Pharmacy signage requirements notifying patients of substitutions of equivalent drugs must also reference interchangeable biological products. The name of the manufacturer of a drug product must be stated on the drug's label.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) This bill creates a pathway to safe biologics and biosimilars. Biological drugs are formulated differently from other drugs and if there is an adverse reaction both the manufacturer and the physician should have that information.

The bill's focus on electronic medical records will streamline communication on all biological medicines dispensed to maintain a consistent and complete medical record. This bill ensures transparency and communication between patients and their treatment team. Providing information about biologics that have been dispensed in the past allow patients and health care providers to discuss past treatment experiences to ensure patient safety in the event of an unexplained side effect. Other states that have worked on this issue have had a notification period like the one in this bill. This bill has no effect on the ability of payors to

manage drug benefits. This bill represents a safe and standard process, but the 10-day notification period may not be quick enough. It is reasonable to expect that notification occur within 24 hours.

Without this bill, the drugs that are being approved by the United States Food and Drug Administration (FDA) might not be made available to patients in Washington as soon as possible. For many people, biologic drugs are the difference between disability and full participation in society. Biosimilars may reduce the cost of these drugs to allow access for more patients. Biosimilars are medicines that are a high quality, safe, effective, and more affordable version of an existing biological medicine that has lost patent protection. Biological drugs have revolutionized medicine. Biosimilars have been available abroad for seven years and have benefitted tens of thousands of patients and resulted in significant savings for the health care system. This legislation will update state law to allow for the substitution of biologic products with FDA-approved interchangeable biologic products.

(Opposed) Biologic drugs are very expensive and their use is growing dramatically. Interchangeable biosimilar drugs offer the possibility of offering patients an alternative drug at better prices with large savings to purchasers. The FDA, however, is still developing its guidance for biosimilars and interchangeable biologics; once these regulatory pathways have been created, the states will have the information needed to move forward with legislation to make the products available in the state. Branded biologic companies are pushing this legislation to undermine the authority of the FDA and reduce competition by creating barriers for the use of these products. Federal law already allows for the substitution of an interchangeable biologic product for the reference product without the intervention of the prescribing health care provider. The FDA has stated that efforts to undermine the trust in interchangeable biologic products are worrisome and a disservice to patients who could benefit from lower cost treatments. It will likely be some time before any products are approved by the FDA as interchangeable biological products.

Notification requirements create barriers to the substitution of various kinds of therapeutic classes and this is the same thing. There is little data about the impact of notification because few states have done this, however, in Tennessee's Medicaid program the notification requirement for anti-epileptic drugs resulted in a large increase in brand dispensing. Placing a manufacturer's name of the label will be a systems change for many pharmacists and could lead to patient confusion and reduced readability. This bill changes the definition of "substitute" and the definition of "therapeutically equivalent" and requires research into the impact on other regulations. Without FDA guidance, pharmacists will be left to guess as to what the appropriate safety requirements are.

Persons Testifying: (In support) Chris Rivera, Washington Biotechnology and Biomedical Association; Susie Tracy and Johanna Lindsay, Washington State Medical Association; Dr. William Yoon, Sandoz; and Geoff Eich, Amgen.

(Opposed) Sydney Smith Zvara, Association of Washington Healthcare Plans; Cynthia Laubacher, Express Scripts; Bruce Lott, Mylan; and Jeff Rochon, Washington State Pharmacy Association.

Persons Signed In To Testify But Not Testifying: None.