

# Alaska State Legislature

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## Senator Shelley Hughes

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### **SB 32 Interchangeable Biological Products**

#### **Clarification on Questions Asked in Senate Health and Social Services Committee**

**Question 1:** Why is prior authorization by prescriber not required in this bill for interchangeable?

This would conflict with federal law. The Biological Price Competition and Innovation Act (BPCIA) provides that interchangeable biological products “may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.” Act (42 U.S.C. 262(i)) (3)

**Question 2:** Why this bill at this time?

To address biosimilars available now

Right now the law does not prevent a pharmacist from substituting a biosimilar that has not been approved as “interchangeable” for an originally prescribed biological product, even though the Ketchikan pharmacist, who testified on February 10th, testified that a pharmacist in Alaska would not. AS 08.80.295 (a) currently states “Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product.” In Section 4 of Senate Bill 32, language is added to clarify ‘drug’ and ‘biological product’, and the bill further clarifies that only FDA approved “interchangeables” can be substituted for the original prescription.

To address interchangeable biologics soon to be approved by FDA and soon to be available in Alaska.

The FDA could designate a biosimilar product as interchangeable tomorrow. The Federal law that created the biosimilar pathway provides the FDA the ability to progress the pathway without the need for guidance. Although, at this time, we can’t say with accuracy when the first interchangeable will be approved, we do believe that there are a couple of signals that may point towards an approval sooner, rather than later.

Some companies have publicly disclosed their active pursuit of interchangeability. There are also a number of companies that have completed studies with one or more switches that could support an interchangeable designation, but at this time any pending interchangeable application is confidential. The FDA will not disclose a submitted application unless the company that submits an application publically discloses. Last year, in a House, Energy, and Commerce Committee hearing, Janet Woodcock (FDA CDER Director) shared that she expected the approval of the first interchangeable before the release of a draft interchangeability guidance. The draft guidance was released this year.

Once there ARE interchangeable products approved by the FDA, we don’t want suffering patients to wait what could be a year or more for legislation to pass to fix the statute. A cancer patient may not have the luxury of a year or more to wait.