ALASKA STATE LEGISLATURE

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SENATOR BILL WIELECHOWSKI

Senate Bill 113 – Explanation of Changes
Version A to Version H

1. **Page 1, Lines 11 following "illness;":** Inserts a new subsection to read "is ineligible or unable to participate in a current clinical trial for the investigational drug, biological product, or device;"

   The intent of this subsection is to prevent damage to clinical trial participation. By ensuring patients have already attempted to enter a clinical trial, this protects both the trial and helps to better target the 97% of patients who do not meet strict clinical trial requirements, and thus have no other recourse.

2. **Removes former Section 1(d) of the prior version A:** "A hospital or health facility may not interfere with the physician-patient relationship by restricting or forbidding the use of investigational drugs, biological products, or devices when prescribed, dispensed, or administered by a physician under (c) of this section."

3. **Page 2, Line 9 following "investigation":** Inserts "and remains in ongoing clinical trials under Phase 2 or Phase 3"

   Amends the definition of "investigational drug, biological product, or device" to require the investigational drug be in an *ongoing* clinical trial. This change protects patients by preventing manufacturers from stopping trials after Phase 1 simply to push their product. Remaining in ongoing trials through Phase 2 or 3 means that the investigational drug is moving toward approval, results are proving beneficial, and a company is investing money into the process because they believe it will eventually get to market.

4. **Page 2, Line 21 following "physician":** Inserts "or member of the medical team"

   Extends immunity protections to a physician's medical team members, as they may be involved in administering the investigational drug along with the physician.

5. **Page 3, Line 11 following "AS 08.64.367(c)":** Inserts Section 4 to read "The department may not require a licensed entity to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient. In this subsection, 'investigational drug, biological product, or device' has the meaning given in AS 08.64.367."

   Amends statute to prohibit the Department of Health and Social Services from requiring a licensed health care facility to increase its services solely to accommodate physicians prescribing, dispensing or administering investigational drugs to a patient.