SENATE BILL REPORT
SSB 5035

As Amended by House, April 6, 2017

Title: An act relating to patients' access to investigational medical products.

Brief Description: Concerning patients' access to investigational medical products.

Sponsors: Senate Committee on Health Care (originally sponsored by Senators Pedersen, Rivers, Cleveland, Becker, Keiser, Walsh, Conway, Bailey, O'Ban, Mullet, Kuderer, Darneille and Wellman).

Brief History:
Committee Activity: Health Care: 1/23/17, 2/02/17 [DPS, w/oRec].
Floor Activity:
Passed Senate: 2/28/17, 49-0.
Passed House: 4/06/17, 97-0.

Brief Summary of First Substitute Bill

- Permits patients who are suffering from a serious or immediately life-threatening disease to use investigational medical products that have been partially tested by the Food and Drug Administration (FDA), but are not available for patient use.
- Provides that the patient's health insurance provider is not required to provide coverage for the investigational medical product or harm caused to the patient as a result of product use.

SENATE COMMITTEE ON HEALTH CARE

Majority Report: That Substitute Senate Bill No. 5035 be substituted therefor, and the substitute bill do pass.

Signed by Senators Rivers, Chair; Cleveland, Ranking Minority Member; Kuderer, Assistant Ranking Minority Member; Bailey, Conway, Keiser, Miloscia, Mullet, O'Ban and Walsh.

Minority Report: That it be referred without recommendation.

Signed by Senator Becker, Vice Chair.

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.

Staff: Kathleen Buchli (786-7488)

Background: The United States FDA enforces the federal regulatory pathway for approval of medical therapies, including drugs. Until the FDA approves the drug for medical use, the drug may not be sold or distributed. Drugs typically undergo multiple phases of clinical trials to establish the drug's safety and efficacy. In Phase I, researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. Phase I clinical trials may last several months to a year. Phases II and III involve larger groups of people to further evaluate its safety, confirm its effectiveness, and collect new information to allow the drug to be used safely. Phases II and III may each take two or more years to complete.

If individuals do not qualify for a clinical trial but may benefit from treatment with an investigational drug, the FDA has an expanded access pathway that permits access to these drugs if: the individual has a serious or immediately life-threatening condition and there is no satisfactory alternative therapy, the potential benefit outweighs the treatment risks, and providing the investigational drug will not interfere with the clinical trial's process or compromise the product's development.

Right to try laws enable terminally ill patients to access experimental drugs, biologics, and devices that are still in a research phase and have not yet been approved for use by the FDA. In general, right to try laws permit patient access to an investigational drug if: the patient is terminally ill, a physician recommends use of the treatment, the patient provides informed consent, and the treatment has completed a Phase 1 clinical safety/dose limitation trial. They do not require that the patient be in a clinical trial or be otherwise approved by the FDA to use the drug.

Summary of First Substitute Bill: Patients who are suffering from a serious or immediately life-threatening disease or condition may request a pharmaceutical manufacturer to make an investigational product available to the patient. In order to qualify for an investigational product, the patient must be at least 18 years old and be a Washington resident. The patient's treating physician must recommend treatment with the investigational product after informing the patient of FDA-approved treatment options. Finally, the patient must provide written, informed consent for the use of the investigational product.

Written, informed consent must include the following:

- an assertion that the patient has a serious or immediately life-threatening disease and currently approved treatments are unlikely to prolong the patient's life;
- potentially best and worst outcomes of the investigational product;
- a statement that the patient’s health benefit plan is not obligated to pay for the investigational product or harm caused to the patient by the product; and
- that the patient is liable for all expenses consequent to the use of the investigational product.

The eligible patient and their treating physician may request that a drug manufacturer make an investigational product available for treatment of the patient. The manufacturer may, but is not required to, make the product available to the patient.

Health carriers may, but are not required to, provide coverage for the cost or the administration of an investigational product. The health carrier may deny coverage to an eligible patient who is treated with an investigational product from harm caused by the treatment. The health carrier is not required to cover costs associated with receiving the investigational product or costs associated with an adverse effect resulting from the product. The health carrier may not deny coverage for: the eligible patient's serious or immediately life-threatening disease or condition, benefits that accrued before the day on which the patient was treated with the investigational product, or palliative care for a patient who ceases treatment of the investigational product.

It is not an act of professional misconduct for a health care practitioner to recommend or administer an investigational product to an eligible patient.

Physicians who recommend investigational products and manufacturers who provide the product are immune from civil liability arising from treatment with the product; this does not apply if either performs acts or omissions constituting gross negligence or willful or wanton misconduct. Physicians are also provided civil immunity if the physician denies a patient's request for an investigational product.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Original Bill: *The committee recommended a different version of the bill than what was heard.* PRO: This bill is about providing hope for people who have run out of alternatives. We are open to the discussion with the hospitals about clarifying their immunity under the bill. There is a need for terminal patients to access treatment outside clinical trials. The standards of care drive treatment options and clinical trials do not work for all patients because they require people be in the early stage of their disease and are set to drive drugs to the market; patients who are sick now cannot wait for the results.

OTHER: This bill could create false hope and that could impede access to hospice because hospice is not permitted with concurrent care. Advanced registered nurse practitioners should be added to the providers permitted to participate under the bill. We are concerned about potential liability to hospitals. Carrier concerns have been addressed.

Persons Testifying: PRO: Senator Jamie Pedersen, Prime Sponsor; Ann Donovan, citizen.

OTHER: Leslie Emerick, ARNPs United of WA; Chris Bandoli, Washington State Hospital Association; David Knutson, Association of Washington Health Plans.

Persons Signed In To Testify But Not Testifying: No one.

EFFECT OF HOUSE AMENDMENT(S):

- Establishes protection from unprofessional conduct for health care practitioners who refuse to recommend, request, prescribe, or provide an investigational product.
- Expands the immunity from civil, criminal, and administrative actions for health care practitioners who refuse to recommend or request an investigational product by removing the limitation on the practitioner's denial being based on a belief that there are more effective treatments or the treatment is not likely to be effective.