HOUSE BILL REPORT
SSB 5035

As Passed House - Amended:
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 & Wellness: 3/15/17, 3/22/17 [DPA].
Floor Activity:
Passed House - Amended: 4/6/17, 97-0.

Brief Summary of Substitute Bill
(As Amended by House)

- Allows patients with a serious or life-threatening disease or condition who are unable to participate in clinical trials for investigational drugs or devices to request that a drug or device manufacturer make investigational products available to the patients for treatment.
- Establishes additional informed consent requirements that treating physicians must meet prior to treating an eligible patient with an investigational product.
- Establishes immunity from civil, criminal, administrative, and professional liability for health care providers, manufacturers of investigational products, hospitals, and health care facilities.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass as amended. Signed by 17 members: Representatives Cody, Chair; Macri, Vice Chair; Schmick, Ranking Minority Member; Graves, Assistant Ranking Minority Member; Caldier, Clibborn, DeBolt, Harris, Jinkins, MacEwen, Maycumber, Riccelli, Robinson, Rodne, Slatter, Stonier and Tharinger.

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: Chris Blake (786-7392).

Background:

Prior to selling a drug to the public, a drug manufacturer must receive approval from the federal Food and Drug Administration (FDA). Before the FDA approves a drug or treatment, the manufacturer must complete three phases of testing. In phase I, the drug or treatment is tested in a small group to determine safety, dosage range, and side effects. In phase II, the drug or treatment is tested on a larger group of people. Phase III focuses on the drug or treatment's effectiveness, side effects, and comparison to other commonly used treatments.

The FDA has an expanded access program that allows patients to access drugs that have not yet been approved for sale to the public. Under the general expanded access criteria, the FDA must find that:

- the patient has a serious or immediately life-threatening disease or condition and that there is no comparable alternative therapy;
- the potential benefit justifies the potential risks of the treatment use and those risks are not unreasonable; and
- providing the investigational drug for the requested use will not interfere with the clinical investigations related to drug approval.

In the case of an individual patient seeking expanded access, two additional criteria must be met. First, the physician must find that the probable risk to the patient from the investigational drug is not greater than the probable risk from the disease or condition. Second, the FDA must find that the patient cannot obtain the drug under another investigational new drug protocol.

Recent federal legislation requires that manufacturers and distributors of investigational drugs make available their policies on evaluating and responding to requests for investigational drugs under the expanded access program. The policies must include contact information about expanded access requests, procedures for making such a request, the criteria used by the manufacturer or distributor to evaluate requests, the time required to acknowledge receipt of a request, and a hyperlink or reference to the clinical trial record with information about expanded access to the drug. The federal law specifies that the posting of a policy is not to be considered a guarantee of access to a specific investigational drug.

Summary of Amended Bill:

Certain patients and their treating physicians may request that a manufacturer of drugs, biological products, or devices make investigational products available to the patients for treatment. Upon receiving a request and informed consent statement from a physician or eligible patient, a manufacturer may make an investigational product available to eligible patients. The term "investigational products" includes any drugs, biological products, or devices that have completed Phase I clinical trials and are in a subsequent phase of the federal Food and Drug Administration (FDA) approval process.

A patient may become eligible for access to investigational products if he or she is at least 18 years old and a Washington resident and meets other criteria related to his or her medical

condition, treatment options, and informed consent. First, the patient's treating physician must attest that the patient has a "serious or immediately life-threatening disease or condition," which is defined as a stage of disease in which there is a reasonable likelihood that death will occur within six months or that premature death is likely without early treatment. Second, the patient's treating physician must inform the patient of all FDA-approved treatment options and recommend that the patient be treated with an investigational product. Third, the patient's physician must determine that the patient is unable to participate in a clinical trial for the investigational product because there are no clinical trials available, the patient would not qualify for a clinical trial, or waiting to join a clinical trial may further harm the patient. Lastly, the patient or the patient's legally authorized representative must provide written informed consent that is signed, dated, and witnessed by at least one adult.

The substance of the informed consent requirement must meet common standards, including a description of the nature and character of the treatment, the anticipated results, possible alternatives, and serious possible risks and anticipated benefits of the treatment and the alternatives. The physician must also provide the following specific information:

- that the patient has been diagnosed with a serious or immediately life-threatening disease or condition and currently approved product and treatment options have been explained to the patient;
- that currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;
- clear identification of the investigational product being sought;
- the potentially best and worst outcomes of using the investigational product and a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms may result and that death could be hastened;
- that the patient's health plan is not required to pay for the investigational drug or any harm resulting from its use; and
- that the patient is liable for all expenses related to the use of the investigational product.

Insurers are not required to cover the cost of either the investigational product or the administration of the investigational product. Insurers may deny coverage to eligible patients for harm to the patient resulting from the investigational product or the costs associated with an adverse effect from its use. Insurers, however, may not deny coverage for the patient's serious or immediately life-threatening disease or condition, benefits that accrued prior to the use of the investigational product, or palliative care or hospice care for a patient who had been treated with an investigational product, but has stopped using it.

Hospitals and health care facilities may allow health care providers to treat a patient with an investigational product. Hospitals and health care facilities are not required to pay for an investigational product, any harm that an investigational product may cause a patient, or any care, including charity care, that is required as a result of a patient having used an investigational product.

Obtaining, administering, or treating a patient with an investigational product does not constitute unprofessional conduct on the part of a health care provider. In addition, it is not unprofessional conduct for a health care provider to refuse to recommend, request, or

prescribe an investigational product. Except in cases of gross negligence or willful misconduct, there is no criminal, civil, or administrative liability for:

- a health care provider who recommends or requests an investigational product for a patient;
- a health care provider who refuses to recommend or request an investigational product for a patient;
- a manufacturer that provides an investigational product;
- a hospital or health care facility in which an investigational product is either administered or provided to a patient; or
- a hospital or health care facility that refuses to allow health care providers to treat patients with an investigational product on the premises.

Legislative findings are made regarding the time required for the FDA to complete its approval process for investigational products and the need to allow patients with terminal illnesses and their physicians to decide whether or not to use an investigational product. The Legislature's intent is declared to allow terminally ill patients to use investigational products.

Appropriation: None.

Fiscal Note: Available.

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

Staff Summary of Public Testimony:

(In support) Terminal patients in Washington have an urgent need to access life-saving treatment outside of clinical trials. There are too few options for many patients with life-threatening conditions. The clinical trial program offers hope to patients, but it is most easily accessed by those patients who are early in their treatment. Patients with a terminal disease do not have time to wait for drugs to be brought to market. Patients need to be able to have the option of accessing drugs outside of the clinical trial program so they have the opportunity to try them. Thirty-three states have decided that drugs that have been through the federal Food and Drug Administration's safety testing, but have not received final approval for market, should be available to people who might find some benefit from their use.

(Opposed) None.

Persons Testifying: Senator Pedersen, prime sponsor; and Ann Donovan.

Persons Signed In To Testify But Not Testifying: None.