SENATE BILL REPORT
SB 6550

As Reported by Senate Committee On:
Health Care, February 4, 2016

Title: An act relating to allowing access to investigational products by terminally ill patients participating in clinical trials.

Brief Description: Allowing access to investigational products by terminally ill patients participating in clinical trials.

Sponsors: Senators Pedersen, Becker, Cleveland, Keiser, Frockt, Conway, Chase, Carlyle and Roach.

Brief History:
Committee Activity: Health Care: 2/02/16, 2/04/16 [DPS-WM].

SENATE COMMITTEE ON HEALTH CARE

Majority Report: That Substitute Senate Bill No. 6550 be substituted therefor, and the substitute bill do pass and be referred to Committee on Ways & Means.

Signed by Senators Becker, Chair; Dammeier, Vice Chair; Cleveland, Ranking Minority Member; Angel, Bailey, Baumgartner, Brown, Conway, Frockt, Jayapal, Keiser, Parlette and Rivers.

Staff: Kathleen Buchli (786-7488)

Background: The United States Food and Drug Administration (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

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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 Bill: The bill as referred to committee not considered.

Summary of Bill (Recommended Substitute): An eligible patient is a person who: is 18 years of age or older, is a Washington State resident, has a treating physician who attests to the patient's serious or immediately life-threatening disease or condition and recommends treatment with the investigational product, has been informed of other FDA approved treatment options, and has provided 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 that the patients 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 his or her 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 and 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, except 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.

Committee/Commission/Task Force Created: No.

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

Staff Summary of Public Testimony on First Substitute: PRO: This is about providing hope for people who are battling terminal diseases and they may not have access to a treatment that may help them. Similar legislation has been enacted in about 20 other states. It is not a cure for their disease but it is a useful tool for these people. People need to be given a chance to save their own lives. People go out of the state to seek these treatments. The FDA approval process is long; it may take up to fifteen years. The FDA compassionate use pathway involves a lengthy paperwork battle; this is a way to access developing drugs without spending the time to play out the process. This could be the difference between life and death. Some people do not have access to clinical trials.

OTHER: Protections against liability should be in place to protector physicians who administer and recommend investigational products.

Persons Testifying on First Substitute: PRO: Senator Pedersen, prime sponsor; Ann Donovan.

OTHER: Sean Graham, Washington State Medical Association.

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