CCS#2 SS HCS HB 1685 -- INVESTIGATIONAL DRUGS

This bill allows, but does not require, a manufacturer of an investigational drug, biological product, or device to make the drug, product, or device available to an eligible patient who has a terminal illness, has considered all other treatment options currently approved by the United States Food and Drug Administration, has received a prescription or recommendation from his or her physician, and has given his or her written informed consent for the use of the drug, product, or device.

A manufacturer may:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(2) Require an eligible patient to pay the costs of or associated with the manufacture of the drug, product, or device.

These provisions do not require a health care insurer or the Department of Corrections to provide coverage for the cost of any investigational drug, biological product, or device but a health care insurer may provide the coverage.

A state agency or regulatory board cannot revoke, fail to renew, or take any other action against a physician’s license issued under Chapter 334, RSMo, based solely on the physician’s recommendation to an eligible patient regarding prescription for or treatment with an investigational drug, biological product, or device. Action against a health care provider's Medicare certification based solely on his or her recommendation that a patient have access to a drug, product, or device is prohibited.

These provisions contain a severability clause and if a provision or its application to any person or circumstance is held invalid, the invalidity does not affect the other provisions or applications.

If the clinical trial is closed due to the lack of efficacy or toxicity, the drug must not be offered. If notice is given on a drug, product, or device taken by a patient outside of a clinical trial, the pharmaceutical company or patient's physician must notify the patient of the information from the safety committee of the clinical trial.

Except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug or device to an eligible patient must not be liable in any action under state law

for any loss, damage, or injury arising out of, relating to, or resulting from:

(1) The design, development clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, prescription, administration, or use of the drug or devise; or

(2) The safety or effectiveness of the drug or device.