Second Regular Session
Sixty-ninth General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 14-0892.01 Kristen Forrestal x4217 **HOUSE BILL 14-1281**

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A BILL FOR AN ACT

CONCERNING THE ALLOWANCE FOR TERMINALLY ILL PATIENTS TO PARTICIPATE IN CLINICAL TRIALS USING INVESTIGATIONAL PRODUCTS.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://www.leg.state.co.us/billsummaries.)

The bill allows, but does not require, eligible patients to participate in clinical trials and use investigational drugs, biological products, and devices. The bill defines an eligible patient as a person who has:

! A terminal illness;

- Considered all other treatment options currently approved by the United States food and drug administration;
- Received a prescription or recommendation from his or her physician;
- Given written, informed consent for the use of the investigational drug, biological product, or device; and
- Documentation from his or her physician that he or she meets the definition of "eligible patient".

The bill clarifies that a health insurance carrier is not required to pay for the investigational drug, biological product, or device.

The bill prohibits any action against a physician's license for his or her recommendations regarding the use of investigational drugs, biological products, or devices.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, **add** article 45 to title 25 as follows:

ARTICLE 45

Terminal Patients' Compassionate Care Act

25-45-101. Short title. THIS ARTICLE SHALL BE KNOWN AND MAY BE CITED AS THE "RIGHT TO TRY ACT".

25-45-102. Legislative declaration. (1) THE GENERAL ASSEMBLY FINDS AND DECLARES THAT:

(a) THE PROCESS OF APPROVAL FOR INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES IN THE UNITED STATES OFTEN TAKES MANY YEARS;

(b) PATIENTS WHO HAVE A TERMINAL ILLNESS DO NOT HAVE THE LUXURY OF WAITING UNTIL AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE RECEIVES FINAL APPROVAL FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

(c) THE STANDARDS OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR THE USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL

PRODUCTS, AND DEVICES MAY DENY THE BENEFITS OF POTENTIALLY LIFE-SAVING TREATMENTS TO TERMINALLY ILL PATIENTS;

(d) PATIENTS WHO HAVE A TERMINAL ILLNESS HAVE A FUNDAMENTAL RIGHT TO ATTEMPT TO PURSUE THE PRESERVATION OF THEIR OWN LIVES BY ACCESSING AVAILABLE INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES; AND

(e) THE USE OF AVAILABLE INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES IS A DECISION THAT SHOULD BE MADE BY THE PATIENT WITH A TERMINAL ILLNESS IN CONSULTATION WITH THE PATIENT'S PHYSICIAN.

(2) IT IS THE INTENT OF THE GENERAL ASSEMBLY TO ALLOW FOR TERMINALLY ILL PATIENTS TO USE POTENTIALLY LIFE-SAVING INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

25-45-103. Definitions. AS USED IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "ELIGIBLE PATIENT" MEANS A PERSON WHO HAS:

(a) A TERMINAL ILLNESS;

(b) CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

(c) RECEIVED A PRESCRIPTION OR RECOMMENDATION FROM HIS OR HER PHYSICIAN FOR AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

(d) GIVEN WRITTEN, INFORMED CONSENT FOR THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE OR, IF THE PATIENT IS A MINOR OR LACKS THE MENTAL CAPACITY TO PROVIDE INFORMED CONSENT, A PARENT OR LEGAL GUARDIAN HAS GIVEN WRITTEN, INFORMED CONSENT ON THE PATIENT'S BEHALF; AND

(e) DOCUMENTATION FROM HIS OR HER PHYSICIAN THAT HE OR SHE MEETS THE REQUIREMENTS OF THIS SUBSECTION (1).

(2) "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE" MEANS A DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT HAS SUCCESSFULLY COMPLETED PHASE ONE OF A CLINICAL TRIAL BUT HAS NOT BEEN APPROVED FOR GENERAL USE BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND REMAINS UNDER INVESTIGATION IN A UNITED STATES FOOD AND DRUG ADMINISTRATION-APPROVED CLINICAL TRIAL.

(3) "TERMINAL ILLNESS" MEANS A DISEASE THAT, WITHOUT LIFE-SUSTAINING PROCEDURES, WILL SOON RESULT IN DEATH OR A STATE OF PERMANENT UNCONSCIOUSNESS FROM WHICH RECOVERY IS UNLIKELY.

25-45-104. Drug manufacturers - availability of investigational drugs, biological products, or devices - costs - insurance coverage. (1) A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE MAY MAKE AVAILABLE THE MANUFACTURER'S INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO ELIGIBLE PATIENTS PURSUANT TO THIS ARTICLE. THIS ARTICLE DOES NOT REQUIRE THAT A MANUFACTURER MAKE AVAILABLE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT.

(2) A MANUFACTURER MAY:

(a) PROVIDE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION; AND

(b) REQUIRE AN ELIGIBLE PATIENT TO PAY THE COSTS OF, OR THE COSTS ASSOCIATED WITH, THE MANUFACTURE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

(3) A HEALTH INSURANCE CARRIER MAY, BUT IS NOT REQUIRED TO,

PROVIDE COVERAGE FOR THE COST OF ANY INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

25-45-105. Action against physician license - prohibited. NOTWITHSTANDING ANY OTHER LAW, THE COLORADO MEDICAL BOARD MAY NOT REVOKE, FAIL TO RENEW, SUSPEND, OR TAKE ANY ACTION AGAINST A PHYSICIAN'S LICENSE ISSUED PURSUANT TO ARTICLE 36 OF TITLE 12, C.R.S., BASED SOLELY ON A PHYSICIAN'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING A PRESCRIPTION FOR OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

25-45-106. Violation - penalty. AN OFFICIAL, EMPLOYEE, OR AGENT OF THIS STATE WHO BLOCKS OR ATTEMPTS TO BLOCK ACCESS OF AN ELIGIBLE PATIENT TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE COMMITS A CLASS 1 MISDEMEANOR AND SHALL BE PUNISHED AS PROVIDED IN SECTION 18-1.3-501, C.R.S.

25-45-107. No cause of action created. THIS ARTICLE DOES NOT CREATE A PRIVATE CAUSE OF ACTION AGAINST A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, OR AGAINST ANY OTHER PERSON OR ENTITY INVOLVED IN A CLINICAL TRIAL, FOR ANY HARM DONE TO AN ELIGIBLE PATIENT RESULTING FROM PARTICIPATION IN A CLINICAL TRIAL SO LONG AS THE MANUFACTURER OR OTHER PERSON OR ENTITY IS COMPLYING IN GOOD FAITH WITH THE TERMS OF THE CLINICAL TRIAL.

SECTION 2. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, and safety.