HOUSE COMMITTEE OF REFERENCE REPORT

_____ March 25, 2014
Chairman of Committee Date

Committee on Health, Insurance, & Environment.

After consideration on the merits, the Committee recommends the following:

HB14-1281 be amended as follows, and as so amended, be referred to the Committee of the Whole with favorable recommendation:

Amend printed bill, strike everything below the enacting clause and substitute the following:

"**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) 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;

(d) 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 HEALTH CARE PROVIDER AND THE PATIENT'S HEALTH CARE TEAM, IF APPLICABLE; AND

(e) THE DECISION TO USE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE SHOULD BE MADE WITH FULL AWARENESS OF THE POTENTIAL RISKS, BENEFITS, AND CONSEQUENCES TO THE PATIENT AND THE PATIENT'S FAMILY.

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

(I) A TERMINAL ILLNESS, ATTESTED TO BY THE PATIENT'S TREATING PHYSICIAN;

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

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

(IV) 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

(V) DOCUMENTATION FROM HIS OR HER PHYSICIAN THAT HE OR SHE MEETS THE REQUIREMENTS OF THIS PARAGRAPH (a).

(b) "ELIGIBLE PATIENT" DOES NOT INCLUDE A PERSON BEING TREATED AS AN INPATIENT IN A HOSPITAL LICENSED OR CERTIFIED PURSUANT TO SECTION 25-3-101.

(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 YET 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.

(4) "WRITTEN, INFORMED CONSENT" MEANS A WRITTEN DOCUMENT SIGNED BY THE PATIENT AND ATTESTED TO BY THE PATIENT'S PHYSICIAN AND A WITNESS THAT, AT A MINIMUM:

(a) EXPLAINS THE CURRENTLY APPROVED PRODUCTS AND TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT SUFFERS;

(b) ATTESTS TO THE FACT THAT THE PATIENT CONCURS WITH HIS OR HER PHYSICIAN IN BELIEVING THAT ALL CURRENTLY APPROVED AND CONVENTIONALLY RECOGNIZED TREATMENTS ARE UNLIKELY TO PROLONG THE PATIENT'S LIFE;

(c) CLEARLY IDENTIFIES THE SPECIFIC PROPOSED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT THE PATIENT IS SEEKING TO USE;

(d) DESCRIBES THE POTENTIALLY BEST AND WORST OUTCOMES OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME, BASED ON THE PHYSICIAN'S KNOWLEDGE OF THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT'S CONDITION;

(e) MAKES CLEAR THAT THE PATIENT'S HEALTH INSURER AND PROVIDER ARE NOT OBLIGATED TO PAY FOR ANY CARE OR TREATMENTS CONSEQUENT TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

(f) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT AND CARE MAY BE REINSTATED IF THE CURATIVE TREATMENT ENDS AND THE PATIENT MEETS HOSPICE ELIGIBILITY REQUIREMENTS;

(g) MAKES CLEAR THAT IN-HOME HEALTH CARE AND INPATIENT SERVICES MAY BE DENIED IF TREATMENT BEGINS; AND

(h) STATES THAT THE PATIENT UNDERSTANDS THAT HE OR SHE IS LIABLE FOR ALL EXPENSES CONSEQUENT TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, AND THAT THIS LIABILITY EXTENDS TO THE PATIENT'S SUCCESSORS AND ESTATE.

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; OR

(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:

(a) PROVIDE COVERAGE FOR THE COST OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

(b) PAY FOR ANY CARE OR TREATMENT CONSEQUENT TO THE USE OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT DIFFER FROM THE COSTS OF THE COURSE OF CARE OR TREATMENT THAT WOULD BE COVERED BY THE INSURED'S HEALTH CARE POLICY IN THE ABSENCE OF THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

25-45-105. Action against health care provider's license or medicare certification prohibited. NOTWITHSTANDING ANY OTHER LAW, A LICENSING BOARD MAY NOT REVOKE, FAIL TO RENEW, SUSPEND, OR TAKE ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE ISSUED PURSUANT TO TITLE 12, C.R.S., BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. ACTION AGAINST A HEALTH CARE PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATION THAT A PATIENT HAVE ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE IS PROHIBITED.

25-45-106. Access to investigational drugs, biological products, and devices. AN OFFICIAL, EMPLOYEE, OR AGENT OF THIS STATE SHALL NOT BLOCK OR ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. COUNSELING, ADVICE, OR A RECOMMENDATION FROM A LICENSED HEALTH CARE PROVIDER IS NOT A VIOLATION OF THIS SECTION.

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 THE CARE OF AN ELIGIBLE PATIENT USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, FOR ANY HARM DONE TO THE ELIGIBLE PATIENT RESULTING FROM THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, SO LONG AS THE MANUFACTURER OR OTHER PERSON OR ENTITY IS COMPLYING IN GOOD FAITH WITH THE TERMS OF THIS PART 1.

25-45-108. Affect on health care coverage. NOTHING IN THIS SECTION AFFECTS THE MANDATORY HEALTH CARE COVERAGE FOR PARTICIPATION IN CLINICAL TRIALS PURSUANT TO SECTION 10-16-106 (20),

C.R.S.

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.".

Page 1, line 101, after "**TO**" insert "**HAVE ACCESS TO INVESTIGATIONAL PRODUCTS THAT HAVE NOT BEEN APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION THAT OTHER PATIENTS HAVE ACCESS TO WHEN THEY**".

Page 1, lines 102 and 103, strike "**TRIALS USING INVESTIGATIONAL PRODUCTS.**" and substitute "**TRIALS.**".

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