S T A T E O F N E W Y O R K

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2015-2016 Regular Sessions

I N A S S E M B L Y

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Introduced by M. of A. ROSENTHAL, GUNTHER, GALEF, ZEBROWSKI, BENEDETTO, BROOK-KRASNY, ARROYO, DUPREY, COLTON, MILLER, COOK -- Multi-Sponsored by -- M. of A. BLAKE, SIMON -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing the "right to try act"

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. This act shall be known and may be cited as the "right to try act".

S 2. The public health law is amended by adding a new article 29-CCCC to read as follows:

ARTICLE 29-CCCC
RIGHT TO TRY ACT

SECTION 2994-AAA. DEFINITIONS.
2994-BBB. MANUFACTURERS' OBLIGATIONS.
2994-CCC. COVERAGE.
2994-DDD. LIABILITY FOR PATIENT DEBT.
2994-EEE. ACTIONS AGAINST LICENSE OR CERTIFICATION.
2994-FFF. IMMUNITY.
2994-GGG. ACCESS TO TREATMENT.
2994-HHH. CAUSE OF ACTION.

S 2994-AAA. DEFINITIONS. THE FOLLOWING WORDS AND TERMS WITHIN THIS ARTICLE SHALL HAVE THE FOLLOWING MEANINGS, UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE.

1. "TERMINAL ILLNESS", FOR PURPOSES OF THIS ARTICLE ONLY, MEANS A PROGRESSIVE DISEASE OR MEDICAL OR SURGICAL CONDITION THAT ENTAILS SIGNIFICANT FUNCTIONAL IMPAIRMENT, THAT IS NOT CONSIDERED BY A TREATING HEALTH CARE PROVIDER TO BE REVERSIBLE EVEN WITH ADMINISTRATION OF CURRENT UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED AND AVAIL-

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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ABLE TREATMENTS AND THAT, WITHOUT LIFE-SUSTAINING PROCEDURES, WILL SOON RESULT IN DEATH.

2. "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WHO MEETS ALL OF THE FOLLOWING CONDITIONS:

(A) HAS A TERMINAL ILLNESS, ATTESTED TO BY THE PATIENT'S TREATING HEALTH CARE PROVIDER.

(B) HAS CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(C) HAS RECEIVED A RECOMMENDATION FROM HIS OR HER TREATING HEALTH CARE PROVIDER FOR AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

(D) HAS GIVEN WRITTEN, INFORMED CONSENT FOR THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

(E) HAS DOCUMENTATION FROM HIS OR HER TREATING HEALTH CARE PROVIDER THAT HE OR SHE MEETS THE REQUIREMENTS OF THIS SUBDIVISION.

3. "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.

4. "WRITTEN, INFORMED CONSENT" MEANS A WRITTEN DOCUMENT THAT IS SIGNED BY THE PATIENT; PARENT, IF THE PATIENT IS A MINOR; LEGAL GUARDIAN; OR HEALTH CARE AGENT DESIGNATED BY THE PATIENT UNDER ARTICLE TWENTY-NINE-C OF THIS CHAPTER AND ATTESTED TO BY THE PATIENT'S TREATING HEALTH CARE PROVIDER AND A WITNESS AND THAT, AT A MINIMUM, INCLUDES ALL OF THE FOLLOWING:

(A) AN EXPLANATION OF THE CURRENTLY APPROVED PRODUCTS AND TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT SUFFERS.

(B) AN ATTESTATION THAT THE PATIENT CONCURS WITH HIS OR HER TREATING HEALTH CARE PROVIDER IN BELIEVING THAT ALL CURRENTLY APPROVED AND CONVENTIONALLY RECOGNIZED TREATMENTS ARE UNLIKELY TO PROLONG THE PATIENT'S LIFE.

(C) CLEAR IDENTIFICATION OF THE SPECIFIC PROPOSED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE THAT THE PATIENT IS SEEKING TO USE.

(D) A DESCRIPTION OF THE POTENTIALLY BEST AND WORST OUTCOMES OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE AND A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME. THE DESCRIPTION SHALL INCLUDE THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT OR WORSE SYMPTOMS MIGHT RESULT AND THAT DEATH COULD BE HASTENED BY THE PROPOSED TREATMENT. THE DESCRIPTION SHALL BE BASED ON THE HEALTH CARE PROVIDER'S KNOWLEDGE OF THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT'S CONDITION.

(E) A STATEMENT THAT THE PATIENT'S HEALTH PLAN OR THIRD PARTY ADMINISTRATOR AND PROVIDER ARE NOT OBLIGATED TO PAY FOR ANY CARE OR TREATMENTS CONSEQUENT TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE, UNLESS THEY ARE SPECIFICALLY REQUIRED TO DO SO BY LAW OR CONTRACT.

(F) A STATEMENT THAT THE PATIENT'S ELIGIBILITY FOR HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE AND THAT CARE MAY BE REINSTATED IF THIS TREATMENT ENDS AND THE PATIENT MEETS HOSPICE ELIGIBILITY REQUIREMENTS.

(G) A STATEMENT 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 ESTATE, UNLESS A CONTRACT BETWEEN THE PATIENT AND THE MANUFACTURER OF THE DRUG, BIOLOGICAL PRODUCT OR DEVICE STATES OTHERWISE.

S 2994-BBB. MANUFACTURERS' OBLIGATIONS. 1. A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE MAY MAKE AVAILABLE AND AN ELIGIBLE PATIENT MAY REQUEST THE MANUFACTURER'S INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE UNDER THIS SECTION. THIS SECTION 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.

S 2994-CCC. COVERAGE. 1. THIS ARTICLE DOES NOT EXPAND THE COVERAGE REQUIRED OF AN INSURER UNDER THE INSURANCE LAW OR ANY OTHER APPLICABLE LAWS.

2. A HEALTH PLAN, THIRD PARTY ADMINISTRATOR, OR GOVERNMENTAL AGENCY MAY, BUT IS NOT REQUIRED TO, PROVIDE COVERAGE FOR THE COST OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE OR THE COST OF SERVICES RELATED TO THE USE OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE UNDER THIS ARTICLE.

3. THIS ARTICLE DOES NOT REQUIRE ANY GOVERNMENTAL AGENCY TO PAY COSTS ASSOCIATED WITH THE USE, CARE OR TREATMENT OF A PATIENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

4. THIS ARTICLE DOES NOT REQUIRE A HOSPITAL OR FACILITY ESTABLISHED UNDER ARTICLE TWENTY-EIGHT OF THIS CHAPTER TO PROVIDE NEW OR ADDITIONAL SERVICES, UNLESS APPROVED BY THE HOSPITAL OR FACILITY.

5. THIS ARTICLE DOES NOT AFFECT ANY MANDATORY HEALTH CARE COVERAGE FOR PARTICIPATION IN CLINICAL TRIALS UNDER THE INSURANCE LAW OR OTHER APPLICABLE LAWS.

S 2994-DDD. LIABILITY FOR PATIENT DEBT. IF A PATIENT DIES WHILE BEING TREATED BY AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE, THE PATIENT'S HEIRS ARE NOT LIABLE FOR ANY OUTSTANDING DEBT RELATED TO THE TREATMENT OR LACK OF INSURANCE DUE TO THE TREATMENT.

S 2994-EEE. ACTIONS AGAINST LICENSE OR CERTIFICATION. A LICENSING BOARD OR DISCIPLINARY SUBCOMMITTEE SHALL NOT REVOKE, FAIL TO RENEW, SUSPEND OR TAKE ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE BASED SOLELY ON THE PROVIDER'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE. AN ENTITY RESPONSIBLE FOR MEDICARE CERTIFICATION SHALL NOT TAKE ACTION AGAINST A HEALTH CARE PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATION THAT AN ELIGIBLE PATIENT HAVE ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

S 2994-FFF. IMMUNITY. IF AS A RESULT OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE, A PATIENT'S SYMPTOMS WORSEN OR CHANGE OR A PATIENT DIES, NO HEALTH CARE PROVIDER SHALL BE SUBJECT TO CIVIL LIABILITY PROVIDED THAT SUCH HEALTH CARE PROVIDER PARTICIPATED IN GOOD FAITH COMPLIANCE WITH THE PROVISIONS OF THIS ARTICLE AND OBTAINED WRITTEN, INFORMED CONSENT FROM THE PATIENT.

S 2994-GGG. ACCESS TO TREATMENT. 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 CONSISTENT WITH MEDICAL STANDARDS OF

CARE FROM A LICENSED HEALTH CARE PROVIDER IS NOT A VIOLATION OF THIS SECTION.

S 2994-HHH. CAUSE OF ACTION. THIS SECTION 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, IF THE MANUFACTURER OR OTHER PERSON OR ENTITY IS COMPLYING IN GOOD FAITH WITH THE TERMS OF THIS ARTICLE AND HAS EXERCISED REASONABLE CARE.

S 3. This act shall take effect on the ninetieth day after it shall have become a law.