REFERENCE TITLE: investigational drugs; biological products; devices

State of Arizona
House of Representatives
Fifty-first Legislature
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Introduced by
Representatives Lovas, Allen, Borrelli, Boyer, Forese, Kwasman, Livingston, Orr, Otondo, Seel: Brophy McGee, Cardenas, Dial, Lesko, Mesnard, Petersen, Shope, Townsend, Wheeler

A CONCURRENT RESOLUTION

ENACTING AND ORDERING THE SUBMISSION TO THE PEOPLE OF A MEASURE RELATING TO THE USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it resolved by the House of Representatives of the State of Arizona, the Senate concurring:

1. Under the power of the referendum, as vested in the legislature, the following measure, relating to the use of investigational drugs, biological products or devices, is enacted to become valid as a law if approved by the voters and on proclamation of the Governor:

AN ACT

AMENDING TITLE 36, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 11.1; RELATING TO THE USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS OR DEVICES.

Be it enacted by the Legislature of the State of Arizona:

Section 1. Title 36, Arizona Revised Statutes, is amended by adding chapter 11.1, to read:

CHAPTER 11.1

TERMINAL PATIENTS' COMPASSIONATE CARE ACT

ARTICLE 1. GENERAL PROVISIONS

36-1311. Definitions

IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

1. "ELIGIBLE PATIENT" MEANS A PERSON WHO MEETS ALL OF THE FOLLOWING:

(a) HAS A TERMINAL ILLNESS.

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

(c) HAS RECEIVED A PRESCRIPTION OR RECOMMENDATION FROM THE PERSON'S PHYSICIAN 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 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.

(e) HAS DOCUMENTATION FROM THE PERSON'S PHYSICIAN THAT THE PERSON HAS MET THE REQUIREMENTS OF THIS PARAGRAPH.

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 CLINICAL TRIAL.

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

36-1312. Availability of investigational drugs, biological products or devices; costs; insurance coverage

A. 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.

B. A MANUFACTURER MAY:

1. PROVIDE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION.

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

C. THIS ARTICLE DOES NOT REQUIRE A HEALTH CARE INSURER TO PROVIDE COVERAGE FOR THE COST OF ANY INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE. A HEALTH CARE INSURER MAY PROVIDE COVERAGE FOR AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

36-1313. Action against physician license; prohibition

NOTWITHSTANDING ANY OTHER LAW, A STATE REGULATORY BOARD MAY NOT REVOKE, FAIL TO RENEW OR TAKE ANY OTHER ACTION AGAINST A PHYSICIAN'S LICENSE ISSUED PURSUANT TO TITLE 32, CHAPTER 13 OR 17 BASED SOLELY ON A PHYSICIAN'S RECOMMENDATION TO AN ELIGIBLE PATIENT REGARDING OR PRESCRIPTION FOR OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

36-1314. Violation; classification

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 IS GUILTY OF A CLASS 1 MISDEMEANOR.

Sec. 2. Findings; intent

A. The legislature finds and declares that:

1. The process of approval for investigational drugs, biological products and devices in the United States often takes many years.

2. 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.

3. 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.

4. 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.

5. 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 and is not a decision to be made by the government.

B. It is the intent of the legislature that allowing for the terminal patients' compassionate care act to apply to patients with nonterminal illnesses furthers the purpose of this act.

Sec. 3. Severability

If a provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

2. The Secretary of State shall submit this proposition to the voters at the next general election as provided by article IV, part 1, section 1, Constitution of Arizona.