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PROPOSITION 303

HOUSE CONCURRENT RESOLUTION 2005

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.

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' RIGHT TO TRY ACT

ARTICLE 1. GENERAL PROVISIONS

36-1311. Definitions

IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

1. "ELIGIBLE PATIENT" MEANS A PERSON TO WHOM ALL OF THE FOLLOWING APPLY:

(a) THE PERSON HAS A TERMINAL ILLNESS AS DETERMINED BY THE PERSON'S PHYSICIAN AND A CONSULTING PHYSICIAN.

(b) THE PERSON'S PHYSICIAN HAS DETERMINED THAT THE PERSON HAS NO COMPARABLE OR SATISFACTORY UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED TREATMENT OPTIONS AVAILABLE TO DIAGNOSE, MONITOR OR TREAT THE DISEASE OR CONDITION INVOLVED AND THAT THE PROBABLE RISK TO THE PERSON FROM THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE IS NOT GREATER THAN THE PROBABLE RISK FROM THE DISEASE OR CONDITION.

(c) THE PERSON HAS RECEIVED A PRESCRIPTION OR RECOMMENDATION FROM THE PERSON'S PHYSICIAN FOR AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

(d) THE PERSON 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) THE PERSON 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. "PHYSICIAN" MEANS THE PHYSICIAN WHO IS PROVIDING MEDICAL CARE OR TREATMENT TO THE ELIGIBLE PATIENT FOR THE TERMINAL ILLNESS BUT DOES NOT INCLUDE A PRIMARY CARE PHYSICIAN.

4. "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.

3. REQUIRE AN ELIGIBLE PATIENT TO PARTICIPATE IN DATA COLLECTION RELATING TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

C. THIS ARTICLE DOES NOT REQUIRE A HEALTH CARE INSURER OR ANY STATE AGENCY 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 or health care institution license; prohibition

A. 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.

B. NOTWITHSTANDING ANY OTHER LAW, A STATE AGENCY MAY NOT TAKE ANY ACTION AGAINST A HEALTH CARE INSTITUTION'S LICENSE BASED SOLELY ON THE INSTITUTION'S PARTICIPATION IN THE TREATMENT OR USE OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE UNDER THIS CHAPTER.

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' right to try 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.

ANALYSIS BY LEGISLATIVE COUNCIL

Proposition 303, the "Right To Try Act", would allow a terminally ill patient, with the recommendation of the patient's physician and a determination by the patient's physician that no comparable or satisfactory United States Food and Drug Administration approved treatment options are available, access to medications or treatments made available by a manufacturer that have not completed the full United States Food and Drug Administration approval process. In consultation with the patient, the patient's physician must determine that the probable risk to the patient from the medication or treatment is not greater than the probable risk from the disease or condition prior to recommending the medication or treatment. The eligible patient must give 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 must give written informed consent on the patient's behalf.

An "investigational drug, biological product or device" is defined as 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.

The manufacturer may provide the investigational drug, biological product or device with or without charge to the eligible patient and may require the eligible patient to participate in data collection relating to the use of the investigational drug, biological product or device. A health care insurer may provide coverage for an investigational drug, biological product or device, but neither a health care insurer nor any state agency is required to provide such coverage.

A state regulatory board may not take any action against a physician's license based solely on the physician's recommendation for, prescription for or treatment with the investigational drug, biological product or device. A state agency may not take any action against a health care institution's license based solely on the institution's participation in the treatment or use of the investigational drug, biological product or device.

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.

ARGUMENTS "FOR" PROPOSITION 303

Please support Prop 303!

As the sponsor of this ballot measure, I am writing to ask for your support.

I was proud to sponsor this proposal in the legislature because I believe that a terminally ill patient should have every opportunity to try and save their own life.

What will this ballot measure do?

It will remove a federal government barrier and give those who are terminally ill access to investigational drugs prior to FDA approval because these patients often can't wait 7-10 years for the FDA to approve a potentially life-saving drug.

Here's an example. Let's say you or a loved one has cancer. You have exhausted all FDA approved options and your prognosis is dire. What can you do?

Right now you have two choices: Either get into a clinical trial or get approval from the FDA expanded access program in order to use these non-approved but promising drugs.

But here's the problem. Only about 3% of terminally ill patients can qualify for clinical trials. And if you can even get into a clinical trial, you still have a 50% chance of receiving a placebo.

And when it comes to expanded access being granted, for the last year of available data, less than 1200 patients were approved by the FDA. Remember 500,000 people die of cancer each year.

Similar bills have been signed into law in Colorado and Louisiana. We in Arizona are sending it to the ballot because getting your approval is important for this historic change in medical policy.

If you or a loved one had a terminally ill disease, wouldn't you want every option available to try and save your life or theirs?

Vote yes on Prop 303.

State Representative Phil Lovas, Legislative District 22, Lovas for Arizona, Peoria

Paid for by Lovas for Arizona

Vote yes for Prop 303, Right to Try

As a recent cancer survivor, I have met many cancer patients along my journey. Some were not as fortunate as me. I was recently saddened with the news that one of my fellow cancer acquaintances passed away. She was denied approval from the FDA for compassionate use of an experimental drug. My friend could tell you that by passing Prop 303 it could have possibly saved her life, but she can't because she is no longer here to tell her story.

I support Proposition 303, because it gives people the opportunity to make their own choice, the choice to try investigational treatments that may save their life.

Cara Bilinski, Avondale

Voters should vote yes on Prop 303

I support Proposition 303, Arizona's Right to Try, because I see that it will give those with no other alternatives hope for a chance at an extended life.

As a health provider I have seen people not only physically, but mentally devastated when all treatment options have been exhausted. As a son, I have personally felt the pain as my mother left the country she loved in order to seek treatments that were not yet approved by our Federal Food and Drug Administration.

Problems within our countries drug regulatory system quickly become apparent as you watch your sick loved ones board a plane, solely for treatment abroad.

The Federal Food and Drug Administration, and the regulatory process that they abide by, force new drugs through such rigorous standards that drug testing can take as long as fifteen years from inception to production. We should never bypass safety standards, but the federal bureaucracy is unbelievable.

From my own personal experience, I know that this can be far too long and cumbersome of a process when there are people with no other options who are ready to try to save or extend their lives.

Proposition 303 will help bring these patients and these possibly lifesaving or extending drugs together in a manner that will be supported and supervised by the patients' physician. This will maintain the integrity and security of our medical process, while giving hope to patients like my mother who had tried everything else.

I whole-heartedly support Proposition 303, Arizona's Right to Try.

Dr. Michael A. Smith, Phoenix

Sheriff Babeu Supports Families and Safe Healthcare Treatments

I support Proposition 303, *Right to Try*

Thursday, July 03, 2014

Dear Friends,

As a County Sheriff I understand the importance of public safety, especially when it comes to prescription drugs and treatments that can safely help patients. Ensuring a safe environment where a patient can work with their physicians to get the healthcare options they need, is vitally important not only to our citizens - but to our families who won't have to leave the United States to find the lifesaving treatments.

Proposition 303 *Right to Try*, will do just that. After having dealt with the federal government as I have, allowing terminal patients the Right to Try as opposed to the Food and Drug Administration dictating the end of your life can be frustrating, if not downright cruel.

It will allow terminally ill patients access to FDA Phase I lifesaving treatments while under the supervision of a licensed physician. These are NOT illicit drugs; these are legitimate investigational research treatments. Close supervision will ensure that no drugs are misused and that the citizens of Arizona are safe while receiving much needed healthcare treatment.

I proudly support Proposition 303, Arizona's *Right to Try*, for the public safety and supervision it provides while allowing Arizona citizens to take control of their own healthcare.

Paul Babeu, Sheriff, Pinal County Arizona, Florence

Support Prop 303, Right to Try

Being in the pharmaceutical industry, I know firsthand the benefits that many drugs can have on patients. I also know that there are many treatments that could be used to help very sick patients, including children, but they are not utilized since they are still in their clinical trials. I support Prop 303 because allowing terminally ill patients access to experimental treatments give them one fundamental component for survival; hope. Access needs to be expanded to these patients to give them a second chance at life.

Spelling, grammar and punctuation were reproduced as submitted in the "for" and "against" arguments.

I'm also a mom to two young children. Passing the Right to Try proposition, gives me a level of reassurance that we would have every possible option if they ever became terminally ill. Please support Prop 303 to give families access to experimental medicine, as well as a sense of hope. No one should ever be told they have run out of options to try to save their life or the life of a loved one.

Patricia Noack, Scottsdale

Vote YES on Prop 303 to give hope to those who need it most.

My daughter Kristina is living with Stage IV cancer. She was pregnant when she was diagnosed last year, which made her ineligible for any trials involving potentially life-saving treatments. As a doctor, I wanted her to have the best care possible. As a father, I wanted to do everything I could to help save my daughter. But the drugs that might save her life won't be approved for several more years, which is time I fear she might not have to wait.

That's why I introduced and helped pass Right to Try in Missouri, and now it's time for you to bring hope to Arizona. This is hope through access. Hope for the possibilities. The terminal deserve the Right to Try.

Rep. Jim Neely M.D., Cameron, MO

Please vote Yes on 303. Our whole family supports it...

Dear Voters,

When our child was diagnosed with a grave illness, the diagnosis was only one part of the difficulty we endured as a family. The second comes when hope for treatment is held out of our reach.

When doctors told us our 11-year-old son, Diego, had a rare form of bone cancer called osteosarcoma, we were devastated. You can't imagine how stunned we were when the doctor told us the treatments our son needed were not available here.

We soon learned that the potentially life-saving drug was approved and available outside of the United States. We felt our only option to save our child's life was to uproot our entire family and move to another continent 5000 miles away. This was not only difficult for Diego; this was difficult on our entire family.

Voting yes on Proposition 303 would allow terminally ill patients to access investigational treatments before the Federal Government has approved it. It would allow families to stay home where we belong. Vote yes on Proposition 303 and give families the hope, comfort and health choices they so desperately deserve. Thank God Diego is alive and well today and living in Phoenix, Arizona with us. We are blessed.

Jason & Paulina Morris, Phoenix

Dear Friends:

Please vote yes on Proposition 303. Nothing could be more important or humane than ensuring terminally ill patients have the right to try to save their own lives. Sadly, these individuals now have to spend more time fighting government red tape than their disease. This is simply not fair. Proposition 303, Right to Try, gives these patients a fighting chance at life.

Please remember when you're voting that these are not nameless, faceless strangers. These terminally ill people are our neighbors, friends and family. Let's pass this measure for them. Please vote yes on Proposition 303.

Phoenix Councilman Sal DiCiccio, Phoenix

Support Prop 303 - It Can Save Lives

As a mother with two young children, I cannot imagine hearing a doctor tell me my child has a terminal illness and there is nothing else that can be done. How could you not try to fight to find other treatments that could save your dying child's life? When I heard about Prop 303, I knew this was something that I had to support. Right to Try gives the opportunity for patients to receive potentially life-saving drugs before they have FDA approval. I hope that no one ever has to encounter this tragic situation, but voting yes for Prop 303 could one day save your child's life.

Kelly Vaughn, Chandler

I Support Proposition 303

As the proud Grandmother of 6, my grandchildren are the light of my life. They are the continuation of my family, as well as our future. Like so many children they have amazing things to offer our world and I cannot wait to see the people they grow up to be. However, the tragic fact is that for many families, thinking long term like this is nothing but a fantasy. When you have children with life threatening illnesses, all you have is right now. Patients need hope in order to have the strength to keep fighting every day. The sad reality is that for many people, their chances for this hope are frequently crushed when they are denied access to experimental medicine that could give them a second chance. When I learned about Prop 303 and that it aims to grant patients the right to try experimental treatments, I knew it was something I had to get behind. No patient, of any age should be denied the chance for hope and the opportunity to try every single option that might exist in an effort to get well. Please join me and vote yes on Prop 303.

Len Noack, Overgaard

Vote YES on Prop 303 for my Momma Toni and all the Mothers who deserve to live.

My Momma Toni was a respected local artist who enjoyed life and always saw the beauty in things. Sadly, she would leave this world and the people she loved too early because of an aggressive form of breast cancer.

She went to get a mammogram, not because she was worried, but because it was the responsible thing to do. That day everything changed. That's when she discovered she had cancer.

We immediately pulled together to help my Mother, who had a warrior's mentality, fight her cancer. After six years, exhausting all of the available treatments, her doctor recommended she try to get into a trial for TDM-1. Unlike most people, my Mom got into her trial, but it was hundreds of miles away in California. My Mom couldn't afford to move or fly or rent an apartment there, so she had to drive round trip every few weeks with family for treatment. The miles and the battle wore on her. She and her broken body eventually became too tired to continue and had to stop the trial. She died in Aug. 2011.

If Right to Try had been law in Arizona, my Momma would have received her treatment in a timely manner right here in Tucson, and she probably would still be alive like many of the other women who benefited from TDM-1, which is now approved. Please vote yes so more Mommas can spend time here with their loved ones.

Tracy Beach, Tucson

Vote Yes for Prop 303

I have been a teacher for the past 21 years. My passion is putting children on the path towards whom they will grow up to be. I teach my kids about the wonders of math and science, as well as the benefits of positivity and working hard. I work hard to instill the belief that anything is possible and there are no limits to what can be accomplished. However, when I hear that for many terminally ill

children, limitations are a part of life because they don't have access to certain experimental treatments, it's difficult to believe. How can we teach kids that anything is possible in life, and yet for some that life is only possible if medicines they need have finished their clinical trials? Join me in backing Prop 303 to give families the Right To Try experimental medications and renew our children's belief that anything is possible.

Jeré Oakley, Phoenix

Each year American pharmaceutical companies create hundreds of breakthrough drugs that can save millions of lives. But because of the federal government's cumbersome, 10+ year approval process, millions of Americans die waiting. The same drugs that are denied to American patients are often available to foreign patients oversees, or to Americans wealthy enough to leave the country for treatment. This is insane. American patients facing terminal illness should have the right to try any drug that has passed FDA Phase One clearance.

Federal overreach is a threat to every Arizonan. That's why we encourage you to vote yes on Props 122 and 303. Arizonans deserve the Right to Try.

Jack Biltis, Chairman, Yes On 122, Phoenix

Imagine that you're facing a terminal illness and you've been told there's no hope…not because there isn't a cure, but because a government bureaucrat has decided that you don't have a right to try the cure.

There are new medications out there that are already approved in different countries but the FDA hasn't gotten around to approving. These drugs have had years of tests and success. If your doctor recommends these medications and you're certain to die without the medication, what right does the FDA have to deny you the chance? I strongly support Prop 303 and the right to try

Jack Biltis, Phoenix

ARGUMENTS "AGAINST" PROPOSITION 303

There were no arguments "against" Proposition 303.

PROPOSITION 303 ~ BALLOT FORMAT

BALLOT FORMAT

PROPOSITION 303

REFERRED TO THE PEOPLE BY THE LEGISLATURE RELATING TO THE USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS OR DEVICES [HCR 2005]

PROPOSITION 303 ENACTING AND ORDERING THE SUBMISSION TO THE PEOPLE OF A MEASURE RELATING TO THE USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES.
DESCRIPTIVE TITLE ALLOWS A MANUFACTURER TO MAKE AVAILABLE TO AN ELIGIBLE TERMINALLY ILL PATIENT 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.

A "yes" vote shall have the effect of allowing a manufacturer to make available an investigational drug, biological product or device to an eligible terminally ill patient. It exempts a physician from regulatory action based solely on the physician's recommendation of the drug, product or device to the eligible terminally ill patient and classifies, as a class 1 misdemeanor, any attempt by a state official, employee or agent to block access of the investigational drug, biological product or device to an eligible terminally ill patient.	**YES** ☐
A "no" vote shall have the effect of retaining the current law regarding the availability of an investigational drug, biological product or device that has not been approved for general use by the United States Food and Drug Administration.	**NO** ☐