



ARIZONA STATE SENATE
Fifty-Fifth Legislature, Second Regular Session

AMENDED
FACT SHEET FOR S.B. 1163

individualized investigational treatment; availability; prohibitions

Purpose

Allows eligible manufacturers to make individualized investigational treatment (IIT) available to patients with a life-threatening disease or severely debilitating illness, including individualized gene therapy or any drug, biological product or device produced specifically for the patient's own genetic profile.

Background

Before a drug manufacturer can market a drug in the United States, the drug must first be tested and approved by the Food and Drug Administration (FDA). After a manufacturer tests a drug in a laboratory to determine its effectiveness and likelihood of safe outcomes in humans, the manufacturer submits an Investigational New Drug application to the FDA for review. The drug then goes through three phases of clinical trials in humans, after which the manufacturer sends the data to the FDA for review by experts including chemists, physicians, statisticians, pharmacologists and other scientists. While the drug is being studied in a clinical trial it is called an investigational drug. If it is determined that the drug's benefits outweigh the risks for the proposed use, the drug is approved for sale ([FDA](#)).

In 2014, Arizona voters approved the Terminal Patients' Right to Try Act to allow manufacturers, health care institutions and physicians to make investigational drugs, biological products and devices that have completed phase one of a clinical trial but have not been FDA-approved available to eligible patients that have: 1) a terminal illness; 2) no comparable or satisfactory FDA-approved treatment options available; 3) received a prescription or recommendation from a physician; 4) provided written consent for use of the investigational drug, biological product or device; and 5) received documentation from a physician that each of these requirements are met. 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 ([AZSOS](#); [A.R.S. Title 36, Chapter 11.1, Article 1](#)).

Human gene therapy is the modification or manipulation of the expression of a gene or the alteration of the biological properties of living cells for therapeutic use to treat or cure disease, including cancer, genetic diseases and infectious diseases ([FDA](#)).

There is no anticipated fiscal impact to the state General Fund associated with this legislation.

Provisions

1. Permits manufacturers operating within an eligible facility to make IIT available to eligible patients, including individualized gene therapy, antisense oligonucleotides, individualized

neoantigen vaccines or any drug, biological product or device produced specifically for the patient's own genetic profile.

2. Allows an eligible patient's physician to request an individualized investigational drug, biological product or device from an eligible manufacturer.
3. Specifies that manufacturers are not required to make IIT available to patients.
4. Permits an eligible facility or manufacturer to:
 - a) provide IIT to a patient without receiving compensation; and
 - b) require an eligible patient to pay the cost of manufacturing IIT.
5. Specifies that a health plan, third party administrator or other third-party payor may, but is not required to, provide coverage for the cost of IIT.
6. States that hospitals and other health care institutions are not required to provide any new or additional services associated with IIT, unless approved by the institution.
7. Specifies that the heirs of a patient that dies while receiving IIT are not liable for any outstanding debt related to the treatment.
8. Restricts an official, employee or agent of the state from blocking an eligible patient's access to IIT.
9. Specifies that providing counseling, advice or recommendations consistent with medical standards is not considered blocking a patient's access to IIT.
10. Specifies that this legislation does not create a private cause of action against an IIT manufacturer or any other person involved in the care of a patient receiving IIT for any patient harm resulting from IIT if the manufacturer or person is complying with the law in good faith and has exercised reasonable care.
11. Defines *eligible facility*, *eligible patient*, *individualized investigational treatment*, *severely debilitating illness* and *written informed consent*.
12. Becomes effective on the general effective date.

Amendments Adopted by Committee

- Removes the prohibition on health profession regulatory board licensure revocation or suspension for physicians that recommend IIT to an eligible patient.

Senate Action

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Prepared by Senate Research

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