HOUSE BILL 98:
Right to Try Individualized Treatments.

2023-2024 General Assembly

Committee:	Senate Rules and Operations of the Senate	**Date:**	June 26, 2024
Introduced by:	Reps. Biggs, Hardister, N. Jackson, Lambeth	**Prepared by:**	Kristen L. Harris* Staff Attorney
Analysis of:	Fourth Edition		

OVERVIEW: House Bill 98 would allow eligible patients with life-threatening or severely debilitating illnesses the right to try individualized investigational drugs, biological products, and devices.

CURRENT LAW: S.L. 2015-137 (HB 652) created Article 23A (Right to Try Act), Chapter 90 of the General Statutes, which established a process for terminally ill eligible patients to obtain access to investigational drugs, biological products, and devices when various criteria are met.

S.L. 2019-70 (HB 934) labeled the initial language from S.L. 2015-137 as "Part 1. Experimental Treatments" and created "Part 2. Investigational Adult Stem Cell Treatments" to authorize access to and use of investigational adult stem cell treatments for patients with certain severe chronic diseases.

BILL ANALYSIS: House Bill 98 would create "Part 3. Individualized Treatments" under Article 23A of Chapter 90 of the General Statutes to allow an eligible patient access to an individualized investigational drug, biological product, or device.

The bill contains the elements outlined below.

- Creates a definitions section (G.S. 90-325.30) containing definitions for: "eligible facility;" "eligible patient;" "individualized investigational drug, biological product, or device;" "institution;" "life-threatening or severely debilitating illness;" and "written, informed consent." Information on select definitions is provided below.
    - *Eligible facility* – An institution operating under Federalwide Assurance for the Protection of Human Subjects, in accordance with 45 C.F.R § 46 and 42 U.S.C. §289(a).
    - *Eligible patient* – Must meet all of the following criteria: an individual with a physician-attested life-threatening or severely debilitating illness; has considered all FDA treatment options in consultation with a treating physician; received a recommendation from the treating physician for use of the individualized investigational drug, biological product, or device; has given informed consent in writing; and has documentation from the treating physician that the individual meets all of the criteria.
    - *Individualized investigational drug, biological product, or device* - A drug, biological product, or device that is unique and produced exclusively for an individual patient based on their own genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.
    - *Life-threatening or severely debilitation illness* – As the term is defined in 21 C.F.R. §312.81. Life-threatening means: "(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and (2) Diseases or conditions with

potentially fatal outcomes, where the end point of clinical trial analysis is survival." Severely debilitating means "diseases or conditions that cause major irreversible morbidity."

- *Written informed consent* – Must meet all of the following criteria: an explanation of the currently approved treatments for the eligible patient's illness; patient's attestation that he or she concurs with the treating physician that currently approved treatments are unlikely to prolong the patient's life; clear identification of the proposed treatment; description of the potential best and worst outcomes resulting from the treatment; statement regarding eligibility for hospice care; statements regarding insurance coverage and patient's liability for expenses related to proposed treatment; patient's signed consent to use the proposed treatment.

- Authorizes access to and use of individualized investigational drugs, biological products, or devices by providing that a manufacturer operating within an eligible facility and in accordance with federal law, may make, but is not required to make, the manufacturer's product available to an eligible patient with or without compensation. (G.S. 90-325.31)
- Prohibits liability for the eligible patient's heirs for outstanding debt related to the use of the individualized investigational drug, biological product, or device if the eligible patient dies while being treated. (G.S. 90-325.32)
- Prohibits sanctions (revocation, failure to renew, suspension, or other disciplinary action) against a health care provider based solely on the provider's recommendation to an eligible patient related to the individualized investigational drug, biological product, or device. (G.S. 90-325.33)
- Prohibits an official, employee, or agent of the State from blocking access to an individualized investigational drug, biological product, or device. However, counseling, advice, or recommendations consistent with medical standards of care from a licensed health care provider or denial of coverage by Medicaid are not violations. (G.S. 90-325.34)
- Prohibits a private right of action against manufacturers of individualized investigational drugs, biological products, or devices resulting from use, if the manufacturer, person, or entity made a good-faith effort to comply with the provisions of this Part and exercised reasonable care. (G.S. 90-325.35)
- A health benefit plan is not required to cover an insured's participation in a clinical trial. (G.S. 90-325.26)

EFFECTIVE DATE: Section 1 would become effective October 1, 2024. The remainder of this act would become effective when it becomes law.

** Theresa Matula, Legislative Analysis Division, substantially contributed to this summary.*