**South Carolina General Assembly**

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**H. 3096**

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General Bill

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Summary: Gene Therapy

**HISTORY OF LEGISLATIVE ACTIONS**

Date Body Action Description with journal page number

12/5/2024 House Prefiled

12/5/2024 House Referred to Committee on **Labor, Commerce and Industry**

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**VERSIONS OF THIS BILL**

[12/05/2024](https://www.scstatehouse.gov/sess126_2025-2026/prever/3096_20241205.docx)

A bill

TO AMEND THE SOUTH CAROLINA CODE OF LAWS BY ADDING CHAPTER 141 TO TITLE 44 SO AS TO PROVIDE FOR THE REGULATION OF GENE THERAPY BY REQUIRING CERTAIN LABELING OF GENE THERAPY PRODUCTS, DISCLOSURE OF INFORMATION, AND INFORMED CONSENT.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Title 44 of the S.C. Code is amended by adding:

CHAPTER 141

Gene Therapy

Section 44‑141‑10. For purposes of this chapter:

(1) “Cosmetic” has the same meaning as defined in Section 39‑25‑20, except that the term “cosmetic” shall include soap.

(2) “Expose” means transmit to another through skin‑to‑skin contact, sexual activity, droplets or aerosols suspended in the air, introduction into the blood supply or food supply, or any other means.

(3) “Food” has the same meaning as defined in Section 39‑35‑20.

(4) “Gene therapy product” means any product with any capacity to alter, interfere with, or otherwise act in any manner similar or equivalent to genes.

(5) “Genetically modified” means the alteration of genetic material through modern biotechnology, directed evolution, or any other mechanism in a way that does not occur naturally or that does not occur at its natural rate.

(6) “Product” means any product that is:

(a) a food, cosmetic, or other substance intended to be ingested, introduced into, or applied to the human body or intended to induce physiological effects; and

(b) made available for sale in this State to the general public at retail.

Section 44‑141‑20. (A) Any product that has been created to act as, or exposed to processes that could result in the product potentially acting as, a gene therapy or that could otherwise possibly impact, alter, or introduce genetic material or a genetic change into the user of the product, individuals exposed to the product, or individuals exposed to others who have used the product must be conspicuously labeled with the words “Potential Gene Therapy Product” unless the product is known to be a gene therapy product. Reasonable steps must be taken to ensure the potential purchaser or user of the product is made aware of the presence of this label.

(B) If a product is known to be a gene therapy product, the product must be conspicuously labeled with the words “Gene Therapy Product.”

(C) The provisions of this section must be liberally construed in favor of disclosure of any potential gene therapy product.

Section 44‑141‑30. (A) Upon the written request of any resident of this State, any entity that produces, sells, or distributes a product in this State with the capacity to infect an individual with a disease or to expose an individual to genetically modified material including, but not limited to, vaccines, gene therapy products, drugs, and medical interventions, shall provide any and all information related to the ways in which individuals who did not directly obtain or use such product may be exposed to the product or a component of the product. Any product manufacturer, governmental agency, or organization of any type that has an interest in the production, sale, or distribution of such product shall be subject to the disclosure requirement of this section and shall provide all relevant reports, research, and knowledge upon request under this section.

(B) Any entity described in subsection (A) shall provide the information requested under subsection (A) as soon as reasonably practicable, but at least within twenty‑one days, after receipt of the written request to the resident who made the request.

(C) Any entity that makes a product available in this State that could infect, transmit to, or be absorbed in any individual in any way that would act as a medical intervention, vaccine, drug, or genetic modification shall obtain fully informed consent from all individuals who could be exposed to such product before exposure could occur. Fully informed consent requires, at a minimum, that an individual is made aware of all benefits and risks of the product, including side effects, any adverse events of special interest, and any other reasonably possible impacts of the product.

SECTION 2. This act takes effect upon approval by the Governor.

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