HOUSE BILL NO. 216

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - SECOND SESSION

BY REPRESENTATIVE EASTMAN

Introduced: 1/16/24
Referred: Health and Social Services, Labor and Commerce

A BILL

FOR AN ACT ENTITLED

"An Act relating to required disclosures for gene therapy products."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 18.13 is amended by adding a new section to read:

Article 2. Gene Therapy Products.

Sec. 18.13.100. Required disclosures. (a) An entity that makes a gene therapy product available in the state that could possibly affect, alter, or introduce genetic material or genetic change into the user of the product, individuals exposed to the product, or individuals exposed to others who have used the product, shall conspicuously label the product with the words "Potential Gene Therapy Product," unless the product is commonly known to be a gene therapy product. The entity shall take reasonable steps to ensure the potential purchaser or user of the product is made aware of the presence of this label.

(b) Upon written request of a resident of this state, an entity that produces, sells, or distributes a product in this state with the capacity to expose the individual to genetically modified material, including vaccines, gene therapies, drugs, and medical

interventions, or a product manufacturer, government agency, or organization that has an interest in the production, sale, or distribution of a gene therapy product, shall provide all information, including all relevant reports, research, and knowledge, regarding the ways in which an individual who did not directly obtain or use the product may be exposed to the product or a component of the product. An entity is not required to disclose proprietary materials or information protected under state or federal intellectual property laws.

(c) An entity that makes a product available in the state that could transmit to or be absorbed into an individual in any way that could result in genetic modification shall obtain informed consent from all individuals who could be exposed to the product before exposure could occur. An entity unable to obtain informed consent under this subsection may not make the product available in the state.

(d) In this section,

(1) "cosmetic" means articles and the components of articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part of the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance;

(2) "food" has the meaning given in AS 17.20.370;

(3) "gene therapy product" means a product with capacity to alter, interfere with, or otherwise act in a manner similar or equivalent to genes;

(4) "genetically modified" means the alteration of the genetic material of an individual through biotechnology or any other mechanism in a way that does not occur naturally or that does not occur at a natural rate;

(5) "genetic change" is the measurable and irreversible alteration of a natural person's genes;

(6) "product" means 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 is made available for retail sale to the general public.