AN ACT relating to gene therapy.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Expose" means transmit to another person through skin-to-skin contact, sexual activity, introduction into the blood stream or food supply, or any other means;

(b) "Gene therapy product" means any product with any capacity to alter, interfere with, or otherwise act in any manner similar or equivalent to genetic material;

(c) "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; and

(d) "Product" means any product that is:

1. A food, cosmetic, drug, or other substance intended to be ingested into, introduced into, or applied to the human body or intended to induce physiological effects; and

2. Made available for sale in the Commonwealth to the general public at retail.

(2) (a) Any product that has been created to act as a process that could result in the product potentially acting as a gene therapy product or that could otherwise impact, alter, or introduce genetic material or genetic change into the individual using the product, individuals exposed to the product, or individuals exposed to others who have used the product, shall be conspicuously labeled with the words: "Potential Gene Therapy Product," unless the product is known to be a gene therapy product. Reasonable steps

shall 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 shall be conspicuously labeled with the words: "Gene Therapy Product."

(3) (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 products, including but not limited to vaccines, gene therapies, drugs, and medical interventions, shall provide any and all information related to the ways in which individuals who did not directly obtain or use the product may be exposed to the product or a component of the product.

(b) Any product manufacturer, government agency, or organization of any type that has any interest or involvement in the production, sale, or distribution of a product described in paragraph (a) of this subsection shall be subject to a disclosure request made under this subsection and shall provide all relevant reports, research, and knowledge upon request.

(4) Any entity described in subsection (3) of this section shall provide the information requested under that subsection as soon as reasonably practicable, and no later than twenty-one (21) days after receipt of the written request.

(5) 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 informed consent from all individuals who could be exposed to that product before exposure could occur. Informed consent requires, at a minimum, that an individual is made aware of all benefits and risks, including side effects of the product, any adverse events of special interest, and any other reasonably possibly impacts of the product.