AN ACT relating to liability shield products and declaring an emergency.

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

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Allergenicity" means the ability to provoke an allergic reaction in an individual;

(b) "Cabinet" means the Cabinet for Health and Family Services;

(c) "Carcinogenicity" means the ability to cause cancer in an individual;

(d) "Fertility impact" means the ability to adversely affect the reproductive health or fertility of an individual;

(e) "Immunogenicity" means the ability to cause an immune response in an individual;

(f) "Liability shield product" means a medical, pharmaceutical, biological, or technological product that has been designated as immune from liability under federal law;

(g) "Mutagenicity" means the ability to cause a genetic mutation in an individual;

(h) "Placebo" means a substance used as a control in a placebo-controlled study that:

1. Is administered to a study participant; and

2. Should not have a pharmacological effect on the participant;

(i) "Placebo-controlled study" means a scientific study that randomly assigns a participant to receive either a product that is being studied or a placebo to measure health effects and the safety outcome metrics of the product on participants;

(j) "Reactogenicity" means the symptoms or the outcome of a vaccine that is

administered to an individual; and

(k) "Safety outcome metrics" means data that is collected and analyzed on a product concerning the following aspects of the product:

1. Allergenicity;

2. Carcinogenicity;

3. Fertility impact;

4. Immunogenicity;

5. Mutagenicity; and

6. Reactogenicity.

(2) (a) A manufacturer of a liability shield product shall ensure that a placebo-controlled study of the liability shield product has been completed before it is manufactured, marketed, distributed, or administered in Kentucky.

(b) The placebo-controlled study required in paragraph (a) of this subsection shall be continued for at least five (5) years and continuously collect safety outcome metrics during the five (5) years.

(c) The results of the placebo-controlled study and the safety outcome metrics required under this subsection shall be made publicly available and accessible to the public including patients, health care providers, and state agencies, on the cabinet's website.

(3) The cabinet shall:

(a) Monitor and track adverse outcomes of liability shield products using:

1. The Kentucky Health Information Exchange; and

2. The Vaccine Adverse Event Reporting System cosponsored by the Centers for Disease Control and Prevention and the Food and Drug Administration in the United States Department of Health and Human Services; and

(b) Publish any post-market surveillance data that reports an adverse

consequence of a liability shield product.

(4) The cabinet shall issue an alert and bulletin with information about any adverse consequences of a liability shield product identified under subsection (3) of this section.

(5) By January 1, 2026, the cabinet shall establish and make public a policy to monitor and publish data as required under this section.

(6) (a) By July 1, 2028, all manufacturers of liability shield products that are distributed, manufactured, marketed, or administered in Kentucky shall submit documentation to the cabinet confirming that a placebo-controlled study has been initiated on the liability shield product and listing the safety outcome metrics being collected.

(b) Not later than December 31, 2030, all manufacturers of liability shield products that are distributed, manufactured, marketed, or administered in Kentucky shall submit a compliance report to the cabinet confirming that a required placebo-controlled study has been completed and describing the placebo-controlled study results.

(7) An individual has the right to refuse a liability shield product and shall not be subject to coercion or threat to use a liability shield product.

(8) Beginning January 1, 2031, if an entity violates subsection (2), (6), or (7) of this section, the Attorney General may bring an action to obtain the following:

(a) Injunctive relief;

(b) A civil penalty of not more than one hundred thousand dollars ($100,000) for each violation; and

(c) Reasonable attorney's fees and costs.

(9) (a) An individual who suffers an injury due to a violation of subsection (3), (4), or (7) of this section may bring an action to obtain the following:

1. Injunctive relief;

2. Compensatory damages; and

3. Reasonable attorney's fees and costs.

(b) A suit brought under this section may be filed by the individual or a personal representative on behalf of the individual.

➔Section 2. Whereas it is essential to public health that the citizens of the Commonwealth be aware and informed of the safety of liability shield products, an emergency is declared to exist, and this Act takes effect upon its passage and approval by the Governor or upon its otherwise becoming a law.