

1 AN ACT relating to human gene therapy products and declaring an emergency.

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

3 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 214 IS CREATED TO  
4 READ AS FOLLOWS:

5 *(1) It is the intent of the General Assembly to protect Kentucky adults and children*  
6 *from the adverse effects of experimental gene therapy and biologic products*  
7 *utilized as immunizations. The General Assembly seeks to establish a moratorium*  
8 *on gene therapy immunizations to ensure the safety and well-being of all*  
9 *Kentuckians.*

10 *(2) As used in this section, "human gene therapy product":*

11 *(a) Means all products that mediate their effects by transcription or translation*  
12 *of transferred genetic material or by specifically altering human genetic*  
13 *sequences; and*

14 *(b) Includes but is not limited to:*

15 *1. Nucleic acids, such as plasmids and in vitro transcribed ribonucleic*  
16 *acid (RNA);*

17 *2. Genetically modified microorganisms, such as viruses, bacteria, and*  
18 *fungi;*

19 *3. Engineered site-specific nucleases used for human genome editing;*  
20 *and*

21 *4. Ex vivo genetically modified human cells.*

22 *(3) A person in the Commonwealth shall not administer, by any route or modality,*  
23 *any human gene therapy product for any infectious disease indication, regardless*  
24 *of whether the administration is termed an immunization, vaccine, or any other*  
25 *term.*

26 *(4) The provisions of this section:*

27 *(a) Shall not apply to human gene therapy products utilized for treatment or*

1                    *therapy of cancer or genetic disorders; and*  
2                    *(b) Shall expire on July 1, 2035, unless extended by an act of the General*  
3                    *Assembly following legislative review of available safety data.*

4                    ➔Section 2. Whereas it is essential that the General Assembly promptly provide  
5 for safety in public health settings in the Commonwealth, an emergency is declared to  
6 exist, and this Act takes effect upon its passage and approval by the Governor or upon its  
7 otherwise becoming a law.