

IN THE SENATE

SENATE BILL NO. 1189

BY JUDICIARY AND RULES COMMITTEE

AN ACT

RELATING TO IMMUNIZATIONS; AMENDING CHAPTER 48, TITLE 39, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 39-4806, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING LIMITATION OF DISTRIBUTION AND WAIVER OF IMMUNITY FOR CERTAIN HUMAN GENE THERAPY PRODUCTS; AND DECLARING AN EMERGENCY AND PROVIDING AN EFFECTIVE DATE.

Be It Enacted by the Legislature of the State of Idaho:

SECTION 1. That Chapter 48, Title 39, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 39-4806, Idaho Code, and to read as follows:

39-4806. LIMITATION OF DISTRIBUTION -- WAIVER OF IMMUNITY. (1) Notwithstanding any provision of law to the contrary, a human gene therapy product for any infectious disease indication shall not be distributed, sold, or administered in this state unless the manufacturer of such human gene therapy product affirmatively waives any immunity from suit for an injury arising from a design defect of the human gene therapy product, including immunity granted pursuant to 42 U.S.C. 300aa-1, et seq.

(2) A manufacturer of a human gene therapy product for any infectious disease indication that is distributed, sold, or administered within this state shall be deemed to have waived any immunity from suit for injuries caused by a design defect of the human gene therapy product, including immunity granted pursuant to 42 U.S.C. 300aa-1, et seq.

(3) For the purpose of this section, "human gene therapy product" means all products that mediate their effects by transcription or translation of transferred genetic material or by specifically altering human genetic sequences. Human gene therapy products include but are not limited to:

- (a) Nucleic acids, such as plasmids and in vitro transcribed ribonucleic acid;
- (b) Genetically modified microorganisms, such as viruses, bacteria, and fungi;
- (c) Engineered site-specific nucleases used for human genome editing; and
- (d) Ex vivo genetically modified human cells.

SECTION 2. An emergency existing therefor, which emergency is hereby declared to exist, this act shall be in full force and effect on and after July 1, 2025.