

IN THE SENATE

SENATE BILL NO. 1346

BY JUDICIARY AND RULES COMMITTEE

AN ACT

1 RELATING TO HUMAN GENE THERAPY PRODUCTS; PROVIDING LEGISLATIVE INTENT;
2 AMENDING CHAPTER 48, TITLE 39, IDAHO CODE, BY THE ADDITION OF A NEW SEC-
3 TION 39-4810, IDAHO CODE, TO ESTABLISH A MORATORIUM ON CERTAIN USES OF
4 HUMAN GENE THERAPY PRODUCTS; AND DECLARING AN EMERGENCY.
5

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

7 SECTION 1. LEGISLATIVE INTENT. It is the intent of the Legislature to
8 protect Idaho children from the adverse effects of experimental gene ther-
9 apy and biologic products utilized as immunizations. Given the thousands of
10 reports of harm in the Centers for Disease Control and Prevention Vaccin Ad-
11 verse Event Reporting System, and given that the long-term consequences of
12 gene therapy immunizations are unknown, the Legislature seeks to stand in
13 the gap where regulatory agencies have failed to protect children from ex-
14 perimentation. The Legislature establishes a two-year moratorium on gene
15 therapy immunizations for children under the age of eighteen years, includ-
16 ing children in the womb, and pregnant women to ensure the safety, cellular
17 integrity, and well-being of Idaho children.

18 SECTION 2. That Chapter 48, Title 39, Idaho Code, be, and the same is
19 hereby amended by the addition thereto of a NEW SECTION, to be known and des-
20 ignated as Section 39-4810, Idaho Code, and to read as follows:

21 39-4810. MORATORIUM ON CERTAIN USE OF HUMAN GENE THERAPY PRODUCTS. (1)
22 This section shall be known and may be cited as the "Maintaining Idaho Chil-
23 dren's Health Act."

24 (2) The legislature finds that in order to protect the health and safety
25 of Idaho children, including those in the womb, a moratorium on the admin-
26 istration of human gene therapy products in certain cases is necessary. No
27 person in Idaho shall administer, by any route or modality, any human gene
28 therapy product for any infectious disease indication to a child under eigh-
29 teen (18) years of age or a woman who is pregnant, regardless of whether such
30 administration is termed an immunization, vaccine, or any other term.

31 (3) For the purpose of this section, "human gene therapy products"
32 means all products that mediate their effects by transcription or transla-
33 tion of transferred genetic material or by specifically altering human ge-
34 netic sequences. Human gene therapy products include but are not limited to:

- 35 (a) Nucleic acids, such as plasmids and in vitro-transcribed ribonu-
36 cleic acid;
- 37 (b) Genetically modified microorganisms, such as viruses, bacteria,
38 and fungi;
- 39 (c) Engineered site-specific nucleases used for human genome editing;
40 and
- 41 (d) Ex vivo genetically modified human cells.

1 (4) The provisions of this section shall not apply to human gene therapy
2 products utilized for treatment or therapy of cancer or genetic disorders.

3 (5) The moratorium described in this section shall remain in effect for
4 two (2) years after the effective date of this section, subject to legisla-
5 tive review of available safety data.

6 (6) An individual human gene therapy product may be exempted from the
7 provisions of this section if the legislature determines, after reviewing
8 the available safety data for such individual human gene therapy product,
9 that:

10 (a) (i) The available safety data indicates that the product has
11 been proven safe;

12 (ii) Proper informed consent procedures exist for the administra-
13 tion of the product; and

14 (iii) Compensation for an individual who experiences an adverse
15 outcome from the product has been assured by the manufacturer or
16 person who administers the product; or

17 (b) The human gene therapy product is part of a clinical trial that is
18 covered under an active institutional review board protocol; or

19 (c) The human gene therapy product is provided under expanded access,
20 also known as compassionate use, for a patient with a serious or immedi-
21 ately life-threatening disease or condition.

22 SECTION 3. An emergency existing therefor, which emergency is hereby
23 declared to exist, this act shall be in full force and effect on and after its
24 passage and approval.