

HOUSE COMMITTEE SUBSTITUTE

FOR

HOUSE BILL NO. 1169

AN ACT

To amend chapter 196, RSMo, by adding thereto one new section relating to required disclosures for certain products.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI, AS FOLLOWS:

Section A. Chapter 196, RSMo, is amended by adding thereto one new section, to be known as section 196.1400, to read as follows:

196.1400. 1. As used in this section, the term "gene therapy product" means any product or other substance ingested, introduced into, or applied to the human body that is made through or has undergone any human-made process intended to change the DNA of the consumer. The term "gene therapy product" shall also include messenger RNA constructed in order to genetically instruct the consumer's cells to produce a protein.

2. Gene therapy products shall be conspicuously labeled with the words "gene therapy product" by the manufacturer.

3. Any entity that makes a gene therapy 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 fully informed consent from all individuals who could be exposed to such product before exposure could occur. Fully informed consent requires, at a

16 minimum, that an individual is made aware of all benefits and
17 risks, including side effects, of the product, any adverse events
18 of special interest, and any other reasonably possible impacts of
19 the product.

20 4. The attorney general or any potential consumer of an
21 unlabeled gene therapy product may bring suit to enjoin any party
22 from distributing a gene therapy product that is not conspicuously
23 labeled as required under this section.