**House File 2203 - Introduced**

HOUSE FILE 2203
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HF 2010)

## A BILL FOR

An Act relating to experimental treatments for terminally ill persons, and including effective date provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 144E.2, subsection 1, paragraphs a, c, and e, Code 2022, are amended to read as follows:

*a.* Has a terminal illness, attested to by ~~the patient's~~ a treating physician, or is receiving mechanical ventilation to prolong life.

*c.* Has received a recommendation from ~~the individual's~~ a physician for an investigational drug, biological product, or device.

*e.* Has documentation from ~~the individual's~~ a physician that the individual meets the requirements of this subsection.

Sec. 2. Section 144E.2, subsection 2, Code 2022, is amended to read as follows:

2. *"Investigational drug, biological product, or device"* means ~~a~~ any of the following:

*a.* A drug, biological product, or device that has successfully completed phase 1 of a United States food and drug administration-approved clinical trial but has not yet been approved for general use by the United States food and drug administration and remains under investigation in a United States food and drug administration-approved clinical trial.

*b.* An off-label use of a drug.

Sec. 3. Section 144E.2, Code 2022, is amended by adding the following new subsection:

NEW SUBSECTION. 2A. *"Off-label use of a drug"* means the legal, prescribed use of a drug in a manner different from that described on the United States food and drug administration-approved drug label, including the use of a drug for a different disease or medical condition or giving a drug at a different dose or through a different route of administration other than that approved by the United States food and drug administration.

Sec. 4. Section 144E.2, subsection 4, unnumbered paragraph 1, Code 2022, is amended to read as follows:

*"Written informed consent"* means a written document that is signed by the patient, a parent of a minor patient, or a

legal guardian or other legal representative of the patient and attested to by ~~the patient's~~ a treating physician and a witness and that includes all of the following:

Sec. 5. Section 144E.2, subsection 4, paragraphs b and d, Code 2022, are amended to read as follows:

*b.* An attestation that the patient concurs with ~~the patient's~~ a treating physician in believing that all products and treatments approved by the United States food and drug administration are unlikely to prolong the patient's life.

*d.* A description of the best and worst potential outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by use of the proposed investigational drug, biological product, or device. The description shall be based on ~~the~~ a treating physician's knowledge of the proposed investigational drug, biological product, or device in conjunction with an awareness of the patient's condition.

Sec. 6. Section 144E.8, subsection 1, Code 2022, is amended to read as follows:

1. This chapter shall not create a private cause of action against a manufacturer of an investigational drug, biological product, or device, against a physician, health care practitioner, or facility that provides necessary follow-up care, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, if the manufacturer or other person or entity is complying in good faith with the terms of this chapter and has exercised reasonable care.

Sec. 7. Section 144E.9, Code 2022, is amended to read as follows:

**144E.9 Assisting suicide.**

This chapter shall not be construed to allow a ~~patient's treating~~ physician to assist ~~the~~ a patient in committing or attempting to commit suicide as prohibited in section 707A.2.

Sec. 8. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

EXPLANATION

**The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.**

This bill relates to experimental treatments for terminally ill persons.

The bill expands the definition of "eligible patient" to include a person who is receiving mechanical ventilation to prolong life. The bill also expands the definition of an "investigational drug, biological product, or device" to include the off-label use of a drug as defined in the bill.

The bill replaces the current required involvement of the patient's physician or the patient's treating physician to instead require involvement from a physician or a treating physician to fulfill certain duties. The bill expands protections relating to a private cause of action for certain persons complying in good faith with and exercising reasonable care under the bill.

The bill takes effect upon enactment.