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Neutral Testimony on SB250
Senate Committee on Public Health & Welfare
Kansas State Board of Healing Arts
February 14, 2025

Chair Gossage and Honorable Committee Members,

Thank you for the opportunity to provide this neutral testimony concerning SB250, the Kansas Right to Try Act. My name is Susan Gile, and I am the Executive Director for the Kansas State Board of Healing Arts ("KSBHA" or "Board"). The Board is the executive body tasked with licensing and regulating 16 different healthcare professions in Kansas. *See* K.S.A. 65-2801 *et seq*. The Board is composed of 15 members, 12 of whom are licensed healthcare professionals from various professions, including eight licensed physicians, three chiropractors, one podiatrist, and three public members. **The statutory mission of the Board is patient protection**. *See* K.S.A. 65-2801.

SB250 as written would permit manufacturers of individualized investigational treatments to make available said treatments to eligible patients. Though the Board remains neutral as to the passage of this legislation, I would like to highlight several areas of consideration for the committee.

First, clarification on the scope of the bill's definitions is necessary.

"Individualized investigational treatment", as used in this act, means:

> "Drugs, biological products or devices that are unique to and produced exclusively for use on an individual patient, based on the patient's own genetic profile. Individualized investigational treatment includes, but is not limited to, individualized gene therapy antisense oligonucleotides (ASO) and individualized neoantigen vaccines"

The full scope of this definition is not immediately clear. Would this extend to drugs, biological products, or devices that have yet to pass any clinical trials? Is there a requirement that the treatment has been tested on humans before being administered to an eligible patient?

"Eligible patient", as used in this act, means individuals with life-threatening or severely debilitating diseases, defined under federal law as:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and
(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.
(3) Diseases or conditions that cause major irreversible morbidity.

To be eligible to receive treatment, the eligible patients are required to consider all other available treatment options, obtain a recommendation from their physician, and provide *written informed consent*. Within this section, we would appreciate additional clarification on who may serve as the physician's witness (a)(5) line 36. There are ethical concerns if said witness is an employee of the physician, a manufacturer, nurse, etc.

One of the requirements for written informed consent, as used in this act, is that the eligible patient provides:

> "(B) an attestation that the patient concurs with such patient's physician that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life."

It is an unreasonable expectation that an eligible patient would possess the medical knowledge required to attest to this.

Further clarification on (5)(G) would be greatly appreciated. This language appears to state that the cost of these treatments *will* extend to the patient's estate, which implies that the eligible patient has passed away. But (e) mentions that the patient's heirs shall not be liable if a patient dies while being treated by an individual investigational treatment. Do these provisions contradict one another?

It would also be beneficial to include the language under (b)(1) within the requirements for informed consent as used in this act. Patient acknowledgement that SB250 does not require that a manufacturer make available the treatment to the patient can help ensure that consent is provided in an informed manner, can prevent confusion from patients, and can maintain trust between provider and patient.

One of our major concerns is that this bill would interfere with the Board's ongoing efforts to protect patients from fraudulent practices. Such providers and clinics have been known to apply, prescribe or recommend therapies inappropriately, over-promise without sufficient data to support claims, and exploit patients who are often in desperate circumstances and willing to try any proposed therapy as a last resort, even if there is excessive cost or scant evidence of efficacy. Obtaining informed consent and engaging in shared decision making with patients involves conveying information about the reasonable effectiveness of a proposed treatment, as well as its risks and benefits. This may be particularly difficult with respect to the nature of individualized investigational treatments as defined by SB250.

Section (f)(1) would prevent the Board from taking disciplinary action against a physician's license based solely on their recommendation to an eligible (terminally ill) patient regarding treatment with individualized investigational treatments; drugs, biological products or devices that are unique to and produced exclusively for use on said patient. This section could potentially prevent the Board from taking disciplinary action against licensees who inappropriately recommend individualized investigational treatments based on a vested financial interest, without sufficient evidence to support their claims, or who obtain informed consent illegitimately.

Section (f)(2) causes further confusion. Would "individual investigational treatments" - that ostensibly are still under development, not considered standard practice, and may lack sufficient data on efficacy – be consistent with medical standards of care? If SB250 is passed, would the Board lose the ability to investigate and determine whether the eligible patient's physician met the standard of care?

If the Board were to lose its ability to take reasonable disciplinary action, patients are left with no recourse in the event of abuse. Section (i) would expressly prohibit an eligible patient from seeking restitution from the manufacturer of an individualized investigational treatment, nor "any other person or entity involved in the care of an eligible patient using the individualized investigational treatment. This raises major questions from a patient safety perspective, especially given the vulnerable state of these eligible patients.

The Board remains neutral on the passage of SB250 and we would welcome further discussion of the above items. Should you have any questions, please feel free to contact me at 785-296-3680.

Sincerely,

Susan Gile

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Executive Director

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