ONE HUNDRED FIFTH LEGISLATURE - FIRST SESSION - 2017
COMMITTEE STATEMENT
LB117

Hearing Date: Friday January 27, 2017
Committee On: Health and Human Services
Introducer: Hilkemann
One Liner: Adopt the Investigational Drug Use Act

Roll Call Vote - Final Committee Action:
Advanced to General File with amendment(s)

Vote Results:

Aye:	7	Senators Crawford, Erdman, Howard, Linehan, Kolterman, Riepe, Williams
Nay:		
Absent:		
Present Not Voting:		

Verbal Testimony:

Proponents:	**Representing:**
Senator Robert Hilkemann	Introducer
Matt Schaefer	Nebraska Medical Association
Opponents:	**Representing:**
Neutral:	**Representing:**
John Lindsay	Nebraska Association of Trial Attorneys

Summary of purpose and/or changes:
LB 117 creates the Investigational Drug Use Act and allows eligible patients to be treated with any drug, biological product or device that has successfully completed Phase 1 of a clinic trial but has not yet been approved for general use by the United States Food and Drug Administration.

SECTION BY SECTION:

Section 1: Creates the Investigational Drug Use Act.

Section 2: Definitions: "advanced illness", "eligible patient", "health care provider", "investigational drug", "physician", "written, informed consent".

Section 3: Creates a list of criteria to be a patient eligible under the Act, including having an advanced illness, having considered all other treatment options, recommendation from the treating physician, informed consent for the use of an investigational drug.

Section 4: Provides requirements for informed consent.

Section 5: Allows manufacturers of investigational drugs, biological products, or devices to make the treatment available to patients.

Section 6: State the manufacturer does not have to require compensation from the patient.

Section 7: Manufacturer may not seek reimbursement for outstanding debt relating to treatment if patient dies while being treated.

Section 8: Disallows the Director of Public Health of the Division of Public Health and the Chief Medical Officer from taking action against a health care provider based solely on the provider's recommendation of the use of an investigational drug, biological product or device to a patient. Disallows a Medicaid certification entity from taking action against a provider's Medicaid certification.

Section 9: Disallows a treating physician in compliance with the Act from arrest, prosecution, penalty, or denial of any right.

Section 10: Disallows any state employee or agent of the state from blocking a patient's access to an investigational drug, biological product, or device. Allows licensed health care providers employed by or an agent of the state to provide counseling, advice or recommendations without violating this section.

Section 11: Clarifies this Act does not create a private right of action against a manufacturer of an investigational drug, biological product, or device or against those involved in the care of the patient using such for any harm done to the patient when the manufacturer or person or entity has complied in good faith with the Act.

Explanation of amendments:
AM 46 strikes the term "certification" and replaces it with "enrollment".

Merv Riepe, Chairperson