ORIGINAL SENATE **ENGROSSED**
FILE NO. SF0003

ENROLLED ACT NO. 76, SENATE

SIXTY-THIRD LEGISLATURE OF THE STATE OF WYOMING
2015 GENERAL SESSION

AN ACT relating to public health and safety; authorizing provision of certain investigational drugs, biological products and devices by manufacturers; providing for availability and coverage of investigational drugs, biological products and prohibiting actions against licenses of physicians as specified; specifying that no private cause of action against manufacturers and other entities is created; providing definitions; exempting conflicting provisions; and providing for an effective date.

Be It Enacted by the Legislature of the State of Wyoming:

Section 1. W.S. 35-7-1801 through 35-7-1806 are created to read:

ARTICLE 18
RIGHT TO TRY ACT

35-7-1801. Short title.

This article is known and may be cited as the "Right To Try Act."

35-7-1802. Definitions.

(a) As used in this article:

(i) "Eligible patient" means a person who has:

(A) A terminal illness;

(B) Considered all other treatment options currently approved by the United States food and drug administration;

(C) Received a recommendation from a physician for an investigational drug, biological product or device;

(D) Given written, informed consent for the use of the investigational drug, biological product or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf; and

(E) Documentation from a physician that the person meets the requirements of this paragraph.

(ii) "Investigational drug, biological product or device" means a drug, biological product or device that has successfully completed phase one of a 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 clinical trial;

(iii) "Terminal illness" means a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

35-7-1803. Availability of investigational drugs, biological products or devices; insurance coverage.

(a) A manufacturer of an investigational drug, biological product or device may make the drug, product or device available to eligible patients in accordance with the provisions of this section. Nothing in this section

shall be construed to require a manufacturer to make available any drug, product or device.

(b) A health care insurer may, but is not required to, provide coverage for the cost of an investigational drug, biological product or device.

(c) Nothing in this section expands the coverage provided in W.S. 26-20-301.

35-7-1804. Action against physician license prohibited.

Notwithstanding any other provision of law, the Wyoming state board of medicine shall not revoke, fail to renew, suspend or take any other action against a physician's license issued pursuant to W.S. 33-26-101 et seq., based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or device, as long as the recommendations are consistent with medical standards of care.

35-7-1805. Access to investigational drugs, biological products and devices.

An official, employee or agent of this state shall not block or attempt to block an eligible patient's access to an investigational drug, biological product or device. Counseling, advice or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

35-7-1806. No cause of action created.

This article does not create a private cause of action against a manufacturer of an investigational drug, biological product or device, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this article.

Section 2. W.S. 35-7-118 is amended to read:

35-7-118. New drugs.

(a) No person shall sell, offer for sale, hold for sale or give away any new drug unless an application with respect thereto has been approved and the approval has not been withdrawn under section 505 of the federal act.

(b) This section does not apply to a drug intended solely for investigational use by physicians pursuant to W.S. 35-7-1802(a)(i)(C).

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Section 3. This act is effective July 1, 2015.

(END)

Speaker of the House

President of the Senate

Governor

TIME APPROVED: _____

DATE APPROVED: _____

I hereby certify that this act originated in the Senate.

Chief Clerk