

Bill No.: SF0003 **Effective:** 7/1/2015

LSO No.: 15LSO-0129

Enrolled Act No.: SEA 76

Chapter No.: 174

Prime Sponsor: Burns

Catch Title: Right to try.

Subject: Authorizing the use of investigational drugs, biological products or devices by eligible patients.

Summary/Major Elements:

- This bill authorizes a manufacturer of an investigational drug, biological product or device to make the drug, product or device available to a person who has:
 - A disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely;
 - Considered all other treatment options currently approved by the United States Food and Drug Administration;
 - Received a recommendation from a physician for an investigational drug, biological product or device;
 - Given written, informed consent for the use of the investigational drug, biological product or device; and
 - Documentation from a physician that the person meets all these requirements.
- This bill defines an investigational drug, biological product or device as a drug, biological product or device that has successfully completed phase one of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial.
- This bill prohibits the state Board of Medicine from revoking, failing to renew, suspending or taking any other action against a physician's license based solely on that physician's recommendation that an eligible person use an investigational drug, biological product or device.
- This bill prohibits an official, employee or agent of the State from blocking or attempting to block an eligible person's access to an investigational drug, biological product or device.
- This bill specifies no private cause of action is created against manufacturers of an investigational drug, biological product or device or any other person or entity involved in the care of an eligible person using such a drug, biological product or device so long as the manufacturer or other person or entity is complying in good faith with the terms of the act.