

By: Shofner

H.B. No. 3455

A BILL TO BE ENTITLED

AN ACT

relating to manufacturer disclosure requirements and liability for
experimental drugs and devices.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter E, Chapter 431, Health and Safety
Code, is amended by adding Section 431.118 to read as follows:

Sec. 431.118. EXPERIMENTAL DRUG OR DEVICE DISCLOSURE
REQUIREMENTS; LIABILITY. (a) In this section, "experimental drug
or device" means a drug or device that:

(1) is experimental or investigational; or

(2) has been approved by the United States Food and
Drug Administration for emergency use.

(b) A manufacturer of an experimental drug or device shall
provide to a purchaser of the drug or device a disclosure form that
provides a consumer all information reasonably necessary for the
consumer to make an informed decision on whether to use the drug or
device, including possible adverse health effects of the drug or
device, in a clear and coherent summary.

(c) A purchaser of an experimental drug or device shall
provide the disclosure form described by Subsection (b) to a person
to whom the purchaser sells the drug or device. A health care
provider or retailer providing or selling the drug or device to a
consumer:

(1) shall provide the disclosure form in person to the

1 consumer; and

2 (2) may provide or sell the drug or device to the
3 consumer only if a person capable of providing informed consent for
4 the ultimate consumer of the drug or device signs the disclosure.

5 (d) A consumer who receives an experimental drug or device
6 in violation of this section may bring an action against the
7 manufacturer of the drug or device for damages arising from an
8 adverse effect of the drug or device.

9 (e) A prevailing claimant in an action brought under
10 Subsection (d) may recover:

11 (1) compensatory damages, including damages for
12 physical and emotional pain and suffering;

13 (2) exemplary damages; and

14 (3) reasonable attorney's fees and costs incurred in
15 bringing the action.

16 SECTION 2. Section 431.118, Health and Safety Code, as
17 added by this Act, applies only to a cause of action that accrues on
18 or after the effective date of this Act.

19 SECTION 3. This Act takes effect September 1, 2025.