

By: Bettencourt

S.B. No. 1820

A BILL TO BE ENTITLED

AN ACT

relating to the promotion of off-label uses of certain drugs,  
biological products, and devices.

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

SECTION 1. Subtitle A, Title 6, Health and Safety Code, is  
amended by adding Chapter 444 to read as follows:

CHAPTER 444. OFF-LABEL USE OF CERTAIN DRUGS, BIOLOGICAL PRODUCTS,  
AND DEVICES

Sec. 444.001. DEFINITIONS. In this chapter:

(1) "Health care provider" means a person other than a  
physician who is licensed, certified, or otherwise authorized by  
the laws of this state to dispense or prescribe a prescription drug  
in the ordinary course of business or practice of a profession.

(2) "Off-label use" means the use of a drug,  
biological product, or device approved for use by the United States  
Food and Drug Administration in a manner other than the use for  
which it is approved by the United States Food and Drug  
Administration.

(3) "Physician" means a person licensed to practice  
medicine in this state.

Sec. 444.002. PROMOTION OF OFF-LABEL USE OF CERTAIN DRUGS,  
BIOLOGICAL PRODUCTS, OR DEVICES. (a) Notwithstanding other law, a  
pharmaceutical manufacturer or a representative of a  
pharmaceutical manufacturer may promote, in the manufacturer's

1 advertising or marketing materials or directly to a physician or  
2 health care provider, a medically truthful and accurate off-label  
3 use of a drug, biological product, or device.

4 (b) A physician or health care provider may communicate or  
5 otherwise promote to a patient an off-label use of a drug,  
6 biological product, or device consistent with the off-label use  
7 promoted for that drug, product, or device, as applicable, by a  
8 pharmaceutical manufacturer under Subsection (a).

9 Sec. 444.003. DISCIPLINARY ACTION PROHIBITED FOR PROMOTION  
10 OF OFF-LABEL USE. (a) A pharmaceutical manufacturer or a  
11 representative of a pharmaceutical manufacturer may not be  
12 prosecuted or be subject to disciplinary action, including a  
13 revocation of or refusal to renew a license or certification, for  
14 promoting an off-label use of a drug, biological product, or device  
15 under Section 444.002.

16 (b) The state regulatory authority of a physician or health  
17 care provider may not revoke or refuse to renew the license or  
18 certificate of or otherwise impose a disciplinary action against a  
19 physician or health care provider who communicates or otherwise  
20 promotes an off-label use of a drug, biological product, or device  
21 under Section 444.002.

22 Sec. 444.004. HEALTH BENEFIT PLAN COVERAGE FOR OFF-LABEL  
23 USE NOT REQUIRED. This chapter does not require a health benefit  
24 plan to provide health benefit coverage for an off-label use of a  
25 drug, biological product, or device.

26 Sec. 444.005. USE OF STATE MONEY FOR CERTAIN PURPOSES  
27 PROHIBITED. This state or a local governmental entity may not use

1 public money to enforce or to cooperate with the federal government  
2 in enforcing 21 U.S.C. Sections 331 and 335 against a  
3 pharmaceutical manufacturer or a representative of a  
4 pharmaceutical manufacturer for promoting an off-label use under  
5 Section 444.002.

6 SECTION 2. Section 444.003, Health and Safety Code, as  
7 added by this Act, applies to a prosecution or disciplinary action  
8 initiated or pending on or after the effective date of this Act.

9 SECTION 3. This Act takes effect September 1, 2021.