

By: Representative Brown

To: Public Health and Human Services

HOUSE BILL NO. 1226

1 AN ACT TO ADOPT THE FREE SPEECH IN MEDICINE MODEL ACT; TO
2 PROVIDE DEFINITIONS FOR THE ACT; TO AUTHORIZE, AND PROHIBIT THE
3 PROSECUTION OF, THE TRUTHFUL PROMOTION OF OFF-LABEL USES OF
4 PHARMACEUTICAL PRODUCTS; AND FOR RELATED PURPOSES.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

6 **SECTION 1.** As used in this act, and unless the context
7 otherwise requires:

8 (a) "Off-label" means the use of an United States Food
9 and Drug Administration-approved drug, biological product, or
10 device other than the use or uses approved by the United States
11 Food and Drug Administration.

12 (b) "Misbranding" shall have the meaning as the term is
13 defined under federal law in 21 U.S.C. Section 352.

14 **SECTION 2.** (1) A pharmaceutical manufacturer or its
15 representatives may engage in truthful promotion of off-label
16 uses.

17 (2) This article does not require a health insurance
18 carrier, other third-party payer, or other health plan sponsor to
19 provide coverage for the cost of any off-label treatment. A health



20 insurance carrier, other third-party payer or other health plan
21 sponsor may provide coverage for an off-label treatment.

22 **SECTION 3.** (1) Notwithstanding any other law to the
23 contrary, no official, employee or agent of this state shall
24 enforce or apply any state law against or otherwise prosecute a
25 pharmaceutical manufacturer or its representatives for engaging in
26 truthful promotion of off-label uses.

27 (2) Notwithstanding any other law to the contrary, no state
28 regulatory board may revoke, fail to renew or take any other
29 action against a pharmaceutical manufacturer's or
30 representative's, health care institution's, or physician's
31 license solely for engaging in truthful promotion of off-label
32 uses.

33 **SECTION 4.** This state and all political subdivisions of this
34 state are prohibited from using any personnel or financial
35 resources to enforce or cooperate with federal attempts to enforce
36 or apply 21 U.S.C. Section 331 or 352 against or otherwise
37 prosecute a pharmaceutical manufacturer or its representatives
38 solely for engaging in truthful promotion of off-label uses.

39 **SECTION 5.** This act shall take effect and be in force from
40 and after July 1, 2018.

