

HOUSE BILL NO. HB0145

Pharmaceutical manufacturers-promotion of off label use.

Sponsored by: Representative(s) Clem, Barlow, Hallinan,
Halverson, Jennings and Lone and Senator(s)
Bouchard

A BILL

for

1 AN ACT relating to food and drugs; allowing pharmaceutical
2 manufacturers to engage in truthful promotion of an off
3 label use of a drug, biological product or device;
4 specifying that truthful promotion of an off label use is
5 not misbranding; disallowing action by a licensing board
6 against a licensee solely for engaging in truthful
7 promotion or prescribing of an off label use of a drug,
8 biological product or device; specifying that this act does
9 not require a health care insurer to cover the cost of off
10 label use; specifying that the off label promotion or
11 prescribing of a drug does not create a cause of action;
12 providing definitions; and providing for an effective date.

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

15

1 **Section 1.** W.S. 33-24-101(b) by creating a new
2 paragraph (v), 35-7-110(a) by creating new paragraphs
3 (xxxii) through (xxxiv) and by renumbering (xxxii) as
4 (xxxv), 35-7-111 by creating a new subsection (d), 35-7-116
5 and 35-7-118 by creating a new subsection (c) are amended
6 to read:

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8 **33-24-101. Short title; definitions.**

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10 (b) As used in this act:

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12 (v) "Misbranding" does not include the truthful
13 promotion of an off label use of a drug, biological product
14 or device as defined in W.S. 35-7-110(a) (xxxii) through
15 (xxxiv).

16

17 **35-7-110. Definitions.**

18

19 (a) As used in this act:

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21 (xxxii) "Misbranding" does not include the
22 truthful promotion of an off label use of a drug,
23 biological product or device;

1

2 (xxxiii) "Off label use" means the use of a
3 United States food and drug administration approved drug,
4 biological product or device in a manner other than the use
5 the United States food and drug administration approved;

6

7 (xxxiv) "Truthful promotion" means the sharing
8 between a pharmaceutical manufacturer and a licensed
9 professional who can prescribe medication within the
10 professional's scope of practice of information that is not
11 misleading, not contrary to fact and consistent with
12 generally accepted scientific principles;

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14 ~~(xxxii)~~ (xxxv) "This act" means W.S. 35-7-109
15 through 35-7-127.

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17 **35-7-111. Prohibited acts.**

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19 (d) The truthful promotion of an off label use of a
20 drug, biological product or device shall not be considered
21 a violation of this act.

22

1 **35-7-116. Food, drugs and cosmetics; adulteration and**
2 **misbranding.**

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4 A food, cosmetic or a drug or device is adulterated if it
5 is adulterated under the federal act. A food, cosmetic or
6 a drug or device is misbranded if it is misbranded under
7 the federal act, except that the truthful promotion of an
8 off label use of a drug, biological product or device shall
9 not constitute misbranding.

10
11 **35-7-118. New drugs; off label use of approved drugs.**

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13 (c) The truthful promotion of an off label use of an
14 existing approved drug shall not be considered a new drug.
15 The following shall apply:

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17 (i) A health care insurer may, but is not
18 required to, cover the cost of off label use of a drug,
19 biological product or device;

20
21 (ii) No board or commission shall revoke, fail
22 to renew, suspend or take any other action against a
23 licensee, certificate holder or registrant based solely on

1 the person's truthful promotion or prescribing of an off
2 label use of a drug, biological product or device;

3
4 (iii) The off label truthful promotion or
5 prescribing of a drug, biological product or device shall
6 not create a cause of action against a pharmaceutical
7 manufacturer or against any licensed professional who can
8 prescribe or dispense medication within the professional's
9 scope of practice, so long as the manufacturer or other
10 person's actions are not misleading, not contrary to fact
11 and consistent with generally accepted scientific
12 principles.

13
14 **Section 2.** This act is effective July 1, 2018.

15
16 (END)