

115TH CONGRESS
1ST SESSION

H. R. 1703

To amend the Federal Food, Drug, and Cosmetic Act with respect to determining the intended use of drugs and devices.

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2017

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to determining the intended use of drugs and devices.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Product Com-
5 munications Act of 2017”.

1 **SEC. 2. COMMUNICATIONS REGARDING INTENDED USES OF**
2 **DRUGS AND DEVICES; SCIENTIFIC EX-**
3 **CHANGE.**

4 The Federal Food, Drug, and Cosmetic Act is amend-
5 ed by inserting after section 201 of such Act (21 U.S.C.
6 321) the following:

7 **“SEC. 201A. INTENDED USES OF DRUGS AND DEVICES.**

8 “(a) INTENDED USE.—For purposes of this Act, in-
9 cluding sections 301(d), 502(f)(1), 505, 510, and 515 and
10 for purposes of section 351 of the Public Health Service
11 Act, the intended use of a drug, biological product, or de-
12 vice—

13 “(1) shall be determined by reference to the ob-
14 jective intent of the manufacturer and sponsor of
15 such drug, biological product, or device, or persons
16 acting on the manufacturer’s or sponsor’s behalf, as
17 demonstrated by statements contained in labeling,
18 advertising, or analogous oral statements; and

19 “(2) shall not be determined by reference to—

20 “(A) actual or constructive knowledge of
21 the manufacturer or sponsor that such drug, bi-
22 ological product, or device will be used in a
23 manner that varies from the use approved for
24 marketing under section 505, 510, or 515 of
25 this Act or section 351 of the Public Health
26 Service Act; or

1 “(B) scientific exchange as described in
2 subsection (b).

3 “(b) SCIENTIFIC EXCHANGE.—

4 “(1) IN GENERAL.—For purposes of this Act,
5 including sections 301(d), 502(f)(1), 505, 510(k),
6 and 515 and for purposes of section 351 of the Pub-
7 lic Health Service Act, the scientific exchange of in-
8 formation about a drug, biological product, or de-
9 vice, as described in paragraph (2), shall not con-
10 stitute labeling, advertising, or evidence of a new in-
11 tended use.

12 “(2) REQUIREMENTS FOR SCIENTIFIC EX-
13 CHANGE.—A communication by a manufacturer or
14 sponsor, or a person acting on behalf of a manufac-
15 turer or sponsor, about the manufacturer’s or spon-
16 sor’s drug, biological product, or device, or use of
17 such drug, biological product, or device, that has not
18 been approved for marketing under section 505,
19 510, or 515 of this Act or section 351 of the Public
20 Health Service Act, about a device or use of such de-
21 vice that has not been approved or cleared for mar-
22 keting under section 510 or 515 of this Act, or
23 about information that is not included in the drug,
24 biological product, or device labeling, constitutes sci-
25 entific exchange when—

1 “(A) the communication is supported by
2 scientifically appropriate and statistically sound
3 data, studies, or analyses;

4 “(B) the communication includes a con-
5 spicuous and prominent statement that the
6 drug, biological product, or device, or use of
7 such drug, biological product, or device, that is
8 the subject of the communication, has not been
9 approved for marketing under section 505, 510,
10 or 515 of this Act or section 351 of the Public
11 Health Service Act, or that such communication
12 includes information that is not contained in
13 the drug, biological product, or device labeling,
14 as applicable; and

15 “(C) for communications relating to a
16 drug, biological product, or device that has not
17 been approved for marketing under section 505,
18 510, or 515 of this Act or section 351 of the
19 Public Health Service Act, or relating to a use
20 of a drug, biological product, or device that has
21 not been so approved, the manufacturer and
22 sponsor make no claims that such product or
23 use has been demonstrated to be safe or effec-
24 tive.

1 “(3) SCIENTIFIC EXCHANGE DESCRIBED.—The
2 scientific exchange of information under paragraph
3 (2) may include—

4 “(A) dissemination of scientific findings in
5 scientific or lay media;

6 “(B) publication of results of scientific
7 studies;

8 “(C) letters to the editor in defense of pub-
9 lic challenges;

10 “(D) communications at scientific or med-
11 ical conferences or meetings;

12 “(E) dissemination of medical or scientific
13 publications, reference texts, or clinical practice
14 guidelines;

15 “(F) communication, both proactive and
16 reactive, of information regarding a manufac-
17 turer’s research and development efforts;

18 “(G) communication, both proactive and
19 reactive, of scientific, medical, or technical in-
20 formation or findings, including communication
21 of such information by personnel in scientific,
22 medical, or clinical development departments of
23 manufacturers; and

24 “(H) communication, both proactive and
25 reactive, of health care economic and health

1 outcomes information, including communication
2 of such information delivered by or on behalf of
3 the health care economic or health outcomes de-
4 partments of manufacturers to an individual,
5 group of individuals, or entity responsible for
6 contributing toward, advising, or facilitating de-
7 cisionmaking related to health care resource or
8 utilization management, including decisions
9 about the selection of drugs, biological products,
10 or devices for a population of patients.

11 “(4) RULE OF CONSTRUCTION.—Nothing in
12 this subsection shall be construed—

13 “(A) to authorize the Secretary to require
14 that a manufacturer or sponsor submit an ap-
15 plication, certification, or other such submis-
16 sion, or to seek the Secretary’s review or ap-
17 proval, before, during, or subsequent to engag-
18 ing in scientific exchange; or

19 “(B) to limit the ability of manufacturers
20 or sponsors to engage in communications or ac-
21 tivities that properly constitute scientific ex-
22 change as that term is described in paragraph
23 (2) but that are not specified in paragraph
24 (3).”.

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