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(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on _____

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Product Communications Act of 2017''.

SEC. 2. COMMUNICATIONS REGARDING INTENDED USES OF DRUGS AND DEVICES; SCIENTIFIC EXCHANGE.

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 201 of such Act (21 U.S.C. 321) the following:

"SEC. 201A. INTENDED USES OF DRUGS AND DEVICES.

''(a) INTENDED USE.—For purposes of this Act, including sections 301(d), 502(f)(1), 505, 510, and 515 and for purposes of section 351 of the Public Health Service Act, the intended use of a drug, biological product, or device—

''(1) shall be determined by reference to the objective intent of the manufacturer and sponsor of such drug, biological product, or device, or persons acting on the manufacturer's or sponsor's behalf, as demonstrated by statements contained in labeling, advertising, or analogous oral statements; and

''(2) shall not be determined by reference to—

''(A) actual or constructive knowledge of the manufacturer or sponsor that such drug, biological product, or device will be used in a manner that varies from the use approved for marketing under section 505, 510, or 515 of this Act or section 351 of the Public Health Service Act; or

''(B) scientific exchange as described in subsection (b).

''(b) SCIENTIFIC EXCHANGE.—

''(1) IN GENERAL.—For purposes of this Act, including sections 301(d), 502(f)(1), 505, 510(k), and 515 and for purposes of section 351 of the Public Health Service Act, the scientific exchange of information about a drug, biological product, or device, as described in paragraph (2), shall not constitute labeling, advertising, or evidence of a new intended use.

''(2) REQUIREMENTS FOR SCIENTIFIC EXCHANGE.—A communication by a manufacturer or sponsor, or a person acting on behalf of a manufacturer or sponsor, about the manufacturer's or sponsor's drug, biological product, or device, or use of such drug, biological product, or device, that has not been approved for marketing under section 505, 510, or 515 of this Act or section 351 of the Public Health Service Act, about a device or use of such device that has not been approved or cleared for marketing under section 510 or 515 of this Act, or about information that is not included in the drug, biological product, or device labeling, constitutes scientific exchange when—

''(A) the communication is supported by scientifically appropriate and statistically sound data, studies, or analyses;

''(B) the communication includes a conspicuous and prominent statement that the drug, biological product, or device, or use of such drug, biological product, or device, that is the subject of the communication, has not been approved for marketing under section 505, 510, or 515 of this Act or section 351 of the Public Health Service Act, or that such communication includes information that is not contained in the drug, biological product, or device labeling, as applicable; and

''(C) for communications relating to a drug, biological product, or device that has not been approved for marketing under section 505, 510, or 515 of this Act or section 351 of the Public Health Service Act, or relating to a use of a drug, biological product, or device that has not been so approved, the manufacturer and sponsor make no claims that such product or use has been demonstrated to be safe or effective.

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

''(A) dissemination of scientific findings in scientific or lay media;

''(B) publication of results of scientific studies;

''(C) letters to the editor in defense of public challenges;

''(D) communications at scientific or medical conferences or meetings;

''(E) dissemination of medical or scientific publications, reference texts, or clinical practice guidelines;

''(F) communication, both proactive and reactive, of information regarding a manufacturer's research and development efforts;

''(G) communication, both proactive and reactive, of scientific, medical, or technical information or findings, including communication of such information by personnel in scientific, medical, or clinical development departments of manufacturers; and

''(H) communication, both proactive and reactive, of health care economic and health

outcomes information, including communication of such information delivered by or on behalf of the health care economic or health outcomes departments of manufacturers to an individual, group of individuals, or entity responsible for contributing toward, advising, or facilitating decisionmaking related to health care resource or utilization management, including decisions about the selection of drugs, biological products, or devices for a population of patients.

''(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

''(A) to authorize the Secretary to require that a manufacturer or sponsor submit an application, certification, or other such submission, or to seek the Secretary's review or approval, before, during, or subsequent to engaging in scientific exchange; or

''(B) to limit the ability of manufacturers or sponsors to engage in communications or activities that properly constitute scientific exchange as that term is described in paragraph (2) but that are not specified in paragraph (3).''.