

114TH CONGRESS
1ST SESSION

H. R. 2479

To amend the Federal Food, Drug, and Cosmetic Act to provide for the issuance of up-to-date regulations and guidance applying to the dissemination by means of the Internet of information about medical products.

IN THE HOUSE OF REPRESENTATIVES

MAY 20, 2015

Mr. LONG 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 to provide for the issuance of up-to-date regulations and guidance applying to the dissemination by means of the Internet of information about medical products.

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. DISSEMINATION OF INFORMATION ABOUT**
4 **MEDICAL PRODUCTS USING THE INTERNET.**

5 (a) IN GENERAL.—The Federal, Food, Drug, and
6 Cosmetic Act is amended by inserting after section 715
7 of such Act (21 U.S.C. 379d–4) the following:

1 **“SEC. 716. DISSEMINATION OF INFORMATION ABOUT MED-**
2 **ICAL PRODUCTS USING THE INTERNET.**

3 “(a) PROPOSED REVISIONS.—Not later than 6
4 months after the date of enactment of this section, the
5 Secretary shall—

6 “(1) review each regulation and guidance that
7 applies to the dissemination by means of the Inter-
8 net (including social media platforms and character-
9 limited applications) of information about medical
10 products; and

11 “(2) propose revisions to such regulations and
12 guidance (in the form of proposed amended regula-
13 tions and draft guidance, respectively) that—

14 “(A) facilitate meaningful use, by the
15 sponsors of medical products, of the Internet,
16 including Internet applications and social
17 media, for dissemination of truthful, non-mis-
18 leading information about medical products;

19 “(B) recognize that such sponsors may use
20 the Internet—

21 “(i) to disseminate, in character-lim-
22 ited applications, truthful, introductory in-
23 formation about medical products, includ-
24 ing the name of such products and their
25 approved uses; and

1 “(ii) to provide additional information
2 about the safety and effectiveness of the
3 medical products using information that is
4 hyperlinked to such introductory informa-
5 tion; and

6 “(C) for regulatory purposes, treat
7 hyperlinked information described in subpara-
8 graph (B)(ii) as if the information appeared in
9 introductory information described in subpara-
10 graph (B)(i).

11 “(b) FINAL REGULATIONS AND GUIDANCE; UP-
12 DATES.—The Secretary shall, after providing notice and
13 an opportunity for public comment—

14 “(1) not later than 18 months after publication
15 of proposed regulations and guidance pursuant to
16 subsection (a), publish final regulations and guid-
17 ance addressing the matters described in subsection
18 (a); and

19 “(2) periodically thereafter, review and, as ap-
20 propriate, update such regulations and guidance.

21 “(c) MEDICAL PRODUCT DEFINED.—In this section,
22 the term ‘medical product’ means a drug, biological prod-
23 uct, or device.”.

1 (b) CONFORMING REPEAL.—Section 1121 of the
2 Food and Drug Administration Safety and Innovation Act
3 (Public Law 112–144; 21 U.S.C. 379d–5) is repealed.

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