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.

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

SECTION 1. DISSEMINATION OF INFORMATION ABOUT MEDICAL PRODUCTS USING THE INTERNET.

(a) In General.—The Federal, Food, Drug, and Cosmetic Act is amended by inserting after section 715 of such Act (21 U.S.C. 379d–4) the following:
“SEC. 716. DISSEMINATION OF INFORMATION ABOUT MEDICAL PRODUCTS USING THE INTERNET.

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

“(1) review each regulation and guidance that applies to the dissemination by means of the Internet (including social media platforms and character-limited applications) of information about medical products; and

“(2) propose revisions to such regulations and guidance (in the form of proposed amended regulations and draft guidance, respectively) that—

“(A) facilitate meaningful use, by the sponsors of medical products, of the Internet, including Internet applications and social media, for dissemination of truthful, non-misleading information about medical products;

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

“(i) to disseminate, in character-limited applications, truthful, introductory information about medical products, including the name of such products and their approved uses; and
“(ii) to provide additional information about the safety and effectiveness of the medical products using information that is hyperlinked to such introductory information; and

“(C) for regulatory purposes, treat hyperlinked information described in subparagraph (B)(ii) as if the information appeared in introductory information described in subparagraph (B)(i).

“(b) Final Regulations and Guidance; Updates.—The Secretary shall, after providing notice and an opportunity for public comment—

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

“(2) periodically thereafter, review and, as appropriate, update such regulations and guidance.

“(c) Medical Product Defined.—In this section, the term ‘medical product’ means a drug, biological product, or device.”.
(b) CONFORMING REPEAL.—Section 1121 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 21 U.S.C. 379d–5) is repealed.