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119TH CONGRESS
1ST SESSION

H. R. 1539

To amend the Federal Food, Drug, and Cosmetic Act to expand the types of devices for which required labeling may be made available solely by electronic means, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 24, 2025

Mr. OBERNOLTE (for himself, Mr. MULLIN, Mr. CRENSHAW, and Ms. CRAIG) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to expand the types of devices for which required labeling may be made available solely by electronic means, and for other purposes.

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 Device Electronic Labeling Act''.

SEC. 2. ALLOWING REQUIRED LABELING OF DEVICES TO BE MADE AVAILABLE SOLELY BY ELECTRONIC MEANS.

Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended to read as follows:

''(f)(1) Unless its labeling bears (A) adequate directions for use; and (B) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (A) of this subparagraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

''(2) Subject to subparagraph (3), required labeling for devices (including in vitro diagnostic devices) may be made available solely by electronic means, provided that—

''(A) such required labeling is readily accessible to intended users of such devices;

''(B) the manufacturer affords intended users of such devices the opportunity to request the required labeling in paper form, and upon such re-

quest, promptly provides the requested information in paper form without additional cost; and

''(C) the label affixed to the device or its immediate container includes all information in compliance with this Act and the regulations thereunder or any applicable order of the Secretary under subparagraph (3)(A).

''(3)(A) With respect to devices for which labeling is made available solely by electronic means, the Secretary may issue an order establishing requirements in addition to, or exceptions from, the requirements under subparagraph (2) for the label affixed to a device type.

''(B) Notwithstanding subchapter II of chapter 5 of title 5, United States Code, such order shall be published in the Federal Register, following publication of a proposed order in the Federal Register and consideration of comments to a public docket.

''(C) Such order may require the label of a device to contain certain information or comply with certain conditions only if the Secretary determines such requirement is necessary to provide a reasonable assurance of the safety and effectiveness of the device.''.

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