I

113TH CONGRESS
2D SESSION

H. R. 5613

To amend the Federal Food, Drug, and Cosmetic Act to ensure that liquid over-the-counter medications are packaged with appropriate dosage delivery devices and, in the case of such medications labeled for pediatric use, appropriate flow restrictors, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2014

Mr. ISRAEL 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 ensure that liquid over-the-counter medications are packaged with appropriate dosage delivery devices and, in the case of such medications labeled for pediatric use, appropriate flow restrictors, 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 ''Protecting Our Kids' Medicine Act of 2014''.

SEC. 2. DOSAGE DELIVERY DEVICES FOR LIQUID OTC DRUGS AND FLOW RESTRICTORS FOR SUCH DRUGS LABELED FOR PEDIATRIC USE.

(a) IN GENERAL.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(dd)(1) If it is a liquid formulation of a drug that is not subject to section 503(b) and—

''(A) it is not packaged with a dosage delivery device in accordance with specifications to be determined by the Secretary by regulation;

''(B) in the case of such a liquid formulation that is labeled for pediatric use, it is not packaged with a dosage delivery device, as described in subparagraph (A), and—

''(i) a flow restrictor; or

''(ii) another mechanism to reduce the frequency and volume of accidental ingestion that provides a level of safety that is equivalent to or greater than the level of safety that would be provided by a flow restrictor, as determined by the Secretary by regulation; or

''(C) its labeling is in violation of subparagraph (2).

''(2) The Secretary shall require that any measurement in the labeling of a liquid formulation of a drug that

is not subject to section 503(b), including any measurement in the labeling of a dosage delivery device packaged with the liquid formulation, be expressed exclusively in metric units. The Secretary may waive the requirement in the preceding sentence with respect to one or more liquid formulations if the Secretary determines that, with respect to such formulations, implementation of such requirement would not benefit the public health.

''(3) In this paragraph:

''(A) The term 'dosage delivery device'—

''(i) means an object that is designed to measure the dosage of a drug in liquid form and deliver that drug to an individual; and

''(ii) includes calibrated cups, droppers, syringes, and spoons.

''(B) The term 'flow restrictor' has such meaning as the Secretary may prescribe by regulation.''.

(b) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) promulgate a final rule implementing the amendment made by subsection (a); and

(2) include in such rule a definition of the term ''flow restrictor''.

(c) APPLICABILITY.—The amendment made by subsection (a) applies beginning on the date that is 1 year after the date of enactment of this Act.

○