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116TH CONGRESS
1ST SESSION

H. R. 4404

To amend the Federal Food, Drug, and Cosmetic Act to require that the label of drugs with an increased risk of suicide or depression present such increased risk prominently, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 2019

Mr. RUSH 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 require that the label of drugs with an increased risk of suicide or depression present such increased risk prominently, 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 ''Depression Side Effect Labeling Awareness Act of 2019''.

SEC. 2. PROMINENT DRUG LABELING FOR INCREASED RISK OF SUICIDE OR DEPRESSION.

(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:

''(ee) If the warnings and precautions in the drug's label include an increased risk of suicide or depression, unless such increased risk is presented prominently.''.

(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 promulgate final regulations to carry out section 502(ee) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a). Before promulgating such regulations, the Secretary shall consult with stakeholders, including manufacturers of drugs.

(c) DELAYED APPLICABILITY.—Such section 502(ee) shall not apply until the Secretary of Health and Human Services has issued a final regulation under subsection (b).

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