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113TH CONGRESS
2D SESSION

# H. R. 4241

To withdraw approval for the drug Zohydro ER and prohibit the Food and Drug Administration from approving such drug unless it is reformulated to prevent abuse.

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IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2014

Mr. LYNCH (for himself, Mr. ROGERS of Kentucky, Mr. GRIMM, Ms. DELAURO, Mr. KEATING, Mr. WOLF, Mr. FITZPATRICK, Mr. MICHAUD, Ms. SHEA-PORTER, Mr. KENNEDY, Mr. TONKO, Mr. HIGGINS, and Ms. CLARK of Massachusetts) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To withdraw approval for the drug Zohydro ER and prohibit the Food and Drug Administration from approving such drug unless it is reformulated to prevent abuse.

*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 ''Act to Ban Zohydro''.

**SEC. 2. FINDINGS.**

Congress finds as follows:

(1) The drug Zohydro ER is a high-dose hydrocone-only opioid narcotic painkiller listed in

schedule II of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).

(2) The Food and Drug Administration Analgesic Drug Products Advisory Committee report cited available dosages of Zohydro ER that, according to health care and substance abuse professionals, have up to 10 times more hydrocodone than any hydrocodone painkiller currently on the market.

(3) Zohydro ER is manufactured without an abuse deterrent formulation.

(4) Zohydro's time-released effect, an important element of its pharmaceutical use, is easily negated by abusers to achieve a heroin-like effect.

(5) The Analgesic Drug Products Advisory Committee concluded that, if approved and marketed, Zohydro ER will be abused, possibly at a rate greater than that of currently available hydrocodone combination products.

(6) The Anesthetic and Analgesic Drug Products Advisory Committee voted 11 to 2 against approval of Zohydro ER, citing the high possibility for addiction.

(7) The Food and Drug Administration approved Zohydro ER without an abuse deterrent formulation despite the fact that the Anesthetic and

Analgesic Drug Products Advisory Committee voted 11 to 2 against doing so.

(8) The Food and Drug Administration has acknowledged that the widespread abuse of opioid drugs across the country has reached epidemic proportions in some parts of the country.

(9) According to the Centers for Disease Control and Prevention, deaths connected to prescription opioids have more than quadrupled in the United States, from 4,030 deaths involving the painkillers in 1999 to 16,651 deaths in 2010.

(10) The Centers for Disease Control and Prevention has identified reducing deaths attributable to prescription painkiller abuse and overdose as a top health priority for 2014.

(11) Attorneys General from 28 States have asked the Food and Drug Administration to reconsider its approval of Zohydro ER.

(12) Health care professionals, addiction treatment providers, and community-based drug and alcohol prevention programs are groups opposed to the approval of Zohydro ER.

(13) The burdens of Zohydro ER to the public health outweigh its potential therapeutic benefits. Given that alternative pain medicines and methods

are widely available, approval of Zohydro ER should be withdrawn until such time that there is available a Food and Drug Administration-approved abuse deterrent formulation.

**SEC. 3. WITHDRAWAL OF APPROVAL OF DRUG ZOHYDRO ER.**

(a) WITHDRAWAL OF APPROVAL.—Effective beginning on the day that is 45 days after the date of enactment of this Act, approval of the application with respect to pure hydrocodone bitartrate extended-release capsules (marketed as the drug Zohydro ER) under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is deemed to have been withdrawn under section 505(e) of such Act (21 U.S.C. 355(e)).

(b) NO APPROVAL OF ANY FORMULATION THAT IS NOT ABUSE DETERRENT.—The Commissioner of Food and Drugs shall not approve any application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for pure hydrocodone bitartrate extended-release capsules unless such drug is formulated to prevent abuse.

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