

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.

---

## 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

---

## 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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Act to Ban Zohydro”.

5 **SEC. 2. FINDINGS.**

6 Congress finds as follows:

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

1 schedule II of section 202(c) of the Controlled Sub-  
2 stances Act (21 U.S.C. 812(c)).

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

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

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

14 (5) The Analgesic Drug Products Advisory  
15 Committee concluded that, if approved and mar-  
16 keted, Zohydro ER will be abused, possibly at a rate  
17 greater than that of currently available hydrocodone  
18 combination products.

19 (6) The Anesthetic and Analgesic Drug Prod-  
20 ucts Advisory Committee voted 11 to 2 against ap-  
21 proval of Zohydro ER, citing the high possibility for  
22 addiction.

23 (7) The Food and Drug Administration ap-  
24 proved Zohydro ER without an abuse deterrent for-  
25 mulation despite the fact that the Anesthetic and

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

3 (8) The Food and Drug Administration has ac-  
4 knowledged that the widespread abuse of opioid  
5 drugs across the country has reached epidemic pro-  
6 portions in some parts of the country.

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

12 (10) The Centers for Disease Control and Pre-  
13 vention has identified reducing deaths attributable to  
14 prescription painkiller abuse and overdose as a top  
15 health priority for 2014.

16 (11) Attorneys General from 28 States have  
17 asked the Food and Drug Administration to recon-  
18 sider its approval of Zohydro ER.

19 (12) Health care professionals, addiction treat-  
20 ment providers, and community-based drug and al-  
21 cohol prevention programs are groups opposed to the  
22 approval of Zohydro ER.

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

1 are widely available, approval of Zohydro ER should  
2 be withdrawn until such time that there is available  
3 a Food and Drug Administration-approved abuse de-  
4 terrent formulation.

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

7 (a) WITHDRAWAL OF APPROVAL.—Effective begin-  
8 ning on the day that is 45 days after the date of enact-  
9 ment of this Act, approval of the application with respect  
10 to pure hydrocodone bitartrate extended-release capsules  
11 (marketed as the drug Zohydro ER) under section 505(c)  
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 355(c)) is deemed to have been withdrawn under section  
14 505(e) of such Act (21 U.S.C. 355(e)).

15 (b) NO APPROVAL OF ANY FORMULATION THAT IS  
16 NOT ABUSE DETERRENT.—The Commissioner of Food  
17 and Drugs shall not approve any application under section  
18 505 of the Federal Food, Drug, and Cosmetic Act (21  
19 U.S.C. 355) for pure hydrocodone bitartrate extended-re-  
20 lease capsules unless such drug is formulated to prevent  
21 abuse.

○