

113TH CONGRESS
2^D SESSION

S. 2134

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 SENATE OF THE UNITED STATES

MARCH 13, 2014

Mr. MANCHIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 Anes-
4 thetic and Analgesic Drug Products Advisory Com-
5 mittee report cited available dosages of Zohydro ER
6 that, according to health care and substance abuse
7 professionals, have up to 10 times more hydrocodone
8 than any hydrocodone painkiller currently on the
9 market.

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

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

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

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

24 (7) The Food and Drug Administration ap-
25 proved Zohydro ER without an abuse deterrent for-

1 mulation despite the fact that the Anesthetic and
2 Analgesic Drug Products Advisory Committee voted
3 11 to 2 against doing so.

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

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

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

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

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

24 (13) The burdens of Zohydro ER to the public
25 health outweigh its potential therapeutic benefits.

