

116TH CONGRESS
1ST SESSION

S. 419

To require the Food and Drug Administration to revoke the approval of one opioid pain medication for each new opioid pain medication approved.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 7, 2019

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

A BILL

To require the Food and Drug Administration to revoke the approval of one opioid pain medication for each new opioid pain medication approved.

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 “Protecting Americans
5 from Dangerous Opioids Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) Opioids killed more than 33,000 people in
9 the United States in 2015, more than any year on

1 record. Nearly half of all opioid overdose deaths in-
2 volve a prescription opioid.

3 (2) According to the Centers for Disease Con-
4 trol, 3 out of 4 new heroin users abused prescription
5 opioids before moving to heroin.

6 (3) The United States makes up only 4.6 per-
7 cent of the world's population, but consumes 80 per-
8 cent of its opioid pain medications.

9 (4) In 2012, health care providers wrote
10 259,000,000 prescriptions for painkillers, enough for
11 every individual in the United States to have a bottle
12 of pills.

13 (5) The amount of prescription opioids sold in
14 the United States has nearly quadrupled since 1999
15 without a reported increase in pain. At the same
16 time overdose deaths involving opioids have also
17 quadrupled since 1999.

18 **SEC. 3. REQUIREMENT TO REVOKE APPROVAL.**

19 (a) IN GENERAL.—Notwithstanding any other provi-
20 sion of law, if the Secretary of Health and Human Serv-
21 ices (referred to in this section as the “Secretary”) ap-
22 proves an application under subsection (b) or (j) of section
23 505 of the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 355) for an opioid drug, the Secretary shall revoke

1 the approval of another opioid drug previously approved
2 under such subsection (b) or (j).

3 (b) CONSIDERATIONS.—In determining the drug for
4 which the Secretary will revoke approval pursuant to sub-
5 section (a), the Secretary shall—

6 (1) prioritize revocation of non-abuse deterrent
7 formulations of opioid drugs; and

8 (2) consider the public health impact of the
9 opioid drug being on the market.

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