

118TH CONGRESS  
1ST SESSION

# S. 606

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 1, 2023

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

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## 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) Drug overdoses killed more than 107,000  
9 people in the United States in 2021. Nearly two-

1 thirds of all drug overdose deaths involved a pre-  
2 scription opioid or synthetic opioid.

3 (2) According to the National Institute on Drug  
4 Abuse, 80 percent of new heroin users abused pre-  
5 scription opioids before moving to heroin.

6 (3) The United States makes up only 4.25 per-  
7 cent of the world’s population, but consumes 80 per-  
8 cent of its opioid pain medications.

9 (4) In 2020, health care providers in the United  
10 States wrote nearly 143,000,000 prescriptions for  
11 painkillers, which is 43 prescriptions per 100 people.

12 (5) The amount of prescription opioids sold in  
13 the United States has increased without a reported  
14 increase in pain. At the same time, overdose deaths  
15 involving opioids have quadrupled since 1999, with  
16 more than 932,000 people having died from a drug  
17 overdose.

18 (6) Although overdose death rates are begin-  
19 ning to see a slow decline, over 106,000 people are  
20 predicted to have died of drug overdose in 2022.

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

22 (a) IN GENERAL.—Notwithstanding any other provi-  
23 sion of law, if the Secretary of Health and Human Serv-  
24 ices (referred to in this section as the “Secretary”) ap-  
25 proves an application under subsection (b) or (j) of section

1 505 of the Federal Food, Drug, and Cosmetic Act (21  
2 U.S.C. 355) for an opioid drug, the Secretary shall revoke  
3 the approval of another opioid drug previously approved  
4 under subsection (c) or (j) of such section 505.

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

8 (1) prioritize revocation of non-abuse deterrent  
9 formulations of opioid drugs; and

10 (2) consider the public health impact of the  
11 opioid drug being on the market.

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