

115TH CONGRESS  
1ST SESSION

# S. 2260

To establish and fund an Opioids and STOP Pain Initiative to expand, intensify, and coordinate fundamental, translational, and clinical research of the National Institutes of Health with respect to opioid abuse, the understanding of pain, and the discovery and development of safer and more effective treatments and preventive interventions for pain.

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## IN THE SENATE OF THE UNITED STATES

DECEMBER 21, 2017

Mr. SCHATZ introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To establish and fund an Opioids and STOP Pain Initiative to expand, intensify, and coordinate fundamental, translational, and clinical research of the National Institutes of Health with respect to opioid abuse, the understanding of pain, and the discovery and development of safer and more effective treatments and preventive interventions for pain.

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 “Opioids and STOP  
5 Pain Initiative Act”.

1 **SEC. 2. ESTABLISHMENT.**

2       There is established an Opioids and STOP Pain Ini-  
3 tiative, to be administered by the Director of the National  
4 Institutes of Health, in coordination with other agencies,  
5 as appropriate, which shall include efforts to support re-  
6 search on the following:

7           (1) Section 108 of the Comprehensive Addiction  
8 and Recovery Act of 2016 (42 U.S.C. 284q–1),  
9 known as the STOP Pain Act, which directs the Na-  
10 tional Institutes of Health to intensify and coordi-  
11 nate fundamental, translational, and clinical re-  
12 search with respect to—

13                   (A) the understanding of pain;

14                   (B) the discovery and development of  
15 therapies for chronic pain; and

16                   (C) the development of alternatives to  
17 opioids for effective pain treatments.

18       (2) Developing improved options and evidence  
19 for medication-assisted treatment.

20       (3) Developing improved options and evidence  
21 for opioid overdose reversal treatments.

22       (4) The Federal Pain Research Strategy, in-  
23 cluding research that focuses on—

24                   (A) novel drugs, non-addictive, and non-  
25 pharmacological treatments for pain;

- 1 (B) screening tools and outcome measures  
 2 for assessments across the continuum of pain;  
 3 (C) national registries, datasets, and re-  
 4 search networks;  
 5 (D) effective models of care delivery for  
 6 pain management; and  
 7 (E) precision medicine methodology to pre-  
 8 vent and treat pain.

9 (5) The components of the Department of  
 10 Health and Human Services five-point strategy to  
 11 address the opioid crisis that states: “Providing sup-  
 12 port for cutting edge research on pain and addic-  
 13 tion”.

14 (6) The pain therapy screening program estab-  
 15 lished under section 4.

16 (7) Other elements that the Secretary of Health  
 17 and Human Services may designate, in consultation  
 18 with the Director of the National Institutes of  
 19 Health.

20 **SEC. 3. FUNDING FOR THE OPIOIDS AND STOP PAIN INITIA-**  
 21 **TIVE.**

22 (a) IN GENERAL.—There is authorized to be appro-  
 23 priated, and there is appropriated, \$5,000,000,000, to be  
 24 used during the 5-fiscal year period beginning in the fiscal  
 25 year in which such funds are appropriated, to the National

1 Institutes of Health Innovation Account to be used to ad-  
 2 minister the Opioids and STOP Pain Initiative established  
 3 under section 2.

4 (b) EMERGENCY SPENDING.—

5 (1) IN GENERAL.—Amounts appropriated under  
 6 subsection (a) are designated as an emergency re-  
 7 quirement pursuant to section 4(g) of the Statutory  
 8 Pay-As-You-Go Act of 2010 (2 U.S.C. 933(g)).

9 (2) DESIGNATION IN THE SENATE.—In the  
 10 Senate, amounts appropriated under subsection (a)  
 11 are designated as an emergency requirement pursu-  
 12 ant to section 403(a) of S. Con. Res. 13 (111th  
 13 Congress), the concurrent resolution on the budget  
 14 for fiscal year 2010.

15 **SEC. 4. PAIN THERAPY SCREENING PROGRAM.**

16 (a) IN GENERAL.—The Secretary of Health and  
 17 Human Services (referred to in this section as the “Sec-  
 18 retary”) shall carry out through the National Institutes  
 19 of Health a program to be known as the “Pain Therapy  
 20 Screening Program” that focuses on the development of  
 21 pain therapeutics.

22 (b) GRANTS.—The Secretary shall award grants  
 23 under the program under subsection (a) to eligible public  
 24 and private nonprofit entities to support the development  
 25 of new pre-clinical models for pain disorders, and the ap-

1 plication of these models in drug, device, or other therapy  
2 screening.

3 (c) MODEL.—The program under this section shall  
4 be modeled after the Epilepsy Therapy Screening Program  
5 carried out by the National Institute of Neurological Dis-  
6 orders and Stroke.

7 (d) FEES.—The Secretary of Health and Human  
8 Services may assess reasonable fees on private pharma-  
9 ceutical or medical device industry entities that utilize the  
10 program under this section to screen proprietary molec-  
11 ular compounds and devices. Such fees shall be paid to  
12 the Foundation for the National Institutes of Health and  
13 transferred to the NIH Innovation Account to be used for  
14 the Opioids and STOP Pain Initiative established under  
15 section 2.

16 (e) FUNDING.—The Director of the National Insti-  
17 tutes of Health shall determine the amount, and allocate,  
18 funds from the amount appropriated under section 3, to  
19 carry out this section.

20 **SEC. 5. FUNDING PROVISIONS.**

21 (a) SUPPLEMENT NOT SUPPLANT.—Amounts appro-  
22 priated in this Act (including the amendments made by  
23 this Act) shall be used to supplement, not supplant, cur-  
24 rent funding for pain and opioid research at the National  
25 Institutes of Health.

1       (b) ACCEPTANCE OF DONATIONS.—Notwithstanding  
2 section 1342 of title 31, United States Code, the Secretary  
3 of Health and Human Services may accept donations (in-  
4 cluding from the pharmaceutical and medical device indus-  
5 tries) to be used to assist in carrying out programs and  
6 activities under this Act (and the amendments made by  
7 this Act). Such donations shall be paid to the Foundation  
8 for the National Institutes of Health and transferred to  
9 the NIH Innovation Account to be used for the Opioids  
10 and STOP Pain Initiative established under section 2.

11       (c) INCLUSION OF CONTRIBUTION AMOUNTS IN  
12 BASIC RESEARCH FOR PURPOSES OF RESEARCH CRED-  
13 IT.—

14               (1) IN GENERAL.—Paragraph (6) of section  
15 41(e) of the Internal Revenue Code of 1986 is  
16 amended by adding at the end the following new  
17 subparagraph:

18               “(E) OPIOIDS AND STOP PAIN INITIA-  
19 TIVE.—The National Institutes of Health, if the  
20 payment is made in support of the Opioids and  
21 STOP Pain Initiative, as established by the  
22 Opioids and STOP Pain Initiative Act.”.

23               (2) EFFECTIVE DATE.—The amendments made  
24 by this subsection shall apply to taxable years begin-  
25 ning after the date of the enactment of this Act.

1 **SEC. 6. AUTHORITY.**

2       Notwithstanding any other provision of the law, the  
3 Director of the National Institutes of Health may use  
4 funds available under section 3 to enter into transactions  
5 (other than contracts, cooperative agreements, or grants)  
6 to carry out research identified pursuant to the Opioids  
7 and STOP Pain Initiative established under section 2.

8 **SEC. 7. REPORTS.**

9       (a) ANNUAL REPORTS.—Not later than October 1 of  
10 each of fiscal years 2019 through 2026, the Director of  
11 the National Institutes of Health shall submit to the Com-  
12 mittee on Health, Education, Labor, and Pensions and the  
13 Committee on Appropriations of the Senate and the Com-  
14 mittee on Energy and Commerce and the Committee on  
15 Appropriations of the House of Representatives, a report  
16 that includes—

17           (1) the amount obligated or expended in the fis-  
18 cal year prior to the fiscal year in which the report  
19 is being submitted for each program or activity de-  
20 scribed in this Act (or an amendment made by this  
21 Act);

22           (2) a description of all such programs or activi-  
23 ties carried out using funds provided under this Act  
24 (or amendments); and

25           (3) a description of how such programs or ac-  
26 tivities are advancing public health, including the

1        impact on treating pain and addressing opioid mis-  
2        use in the United States.

3        (b) ADDITIONAL REPORTS.—At the request of the  
4        Committee on Health, Education, Labor, and Pensions or  
5        the Committee on Appropriations of the Senate, or the  
6        Committee on Energy and Commerce or the Committee  
7        on Appropriations of the House of Representatives, the  
8        Director of the National Institutes of Health shall provide  
9        to the relevant Committee an update in the form of testi-  
10       mony and additional reports concerning the allocation of  
11       funding under this Act (or the amendments made by this  
12       Act) or the description of the programs and activities car-  
13       ried out with such funding.

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