

115TH CONGRESS
2D SESSION

S. _____

To provide for accelerated approval of pain and addiction therapies.

IN THE SENATE OF THE UNITED STATES

Mr. HATCH (for himself, Mr. BENNET, Mr. DONNELLY, and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To provide for accelerated approval of pain and addiction therapies.

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 “Advancing Innovation
5 in Alternative Pain and Addiction Therapies Act”.

6 **SEC. 2. ACCELERATED APPROVAL OF PAIN AND ADDICTION**
7 **THERAPIES.**

8 (a) PURPOSE.—It is the purpose of this section to
9 clarify the appropriate processes for encouraging and ex-
10 pediting the review of non-opioid or non-addictive medical

1 products to treat chronic or acute pain or substance use
2 disorders.

3 (b) DRAFT GUIDANCE.—

4 (1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of this Act, the Secretary of
6 Health and Human Services (referred to in this sec-
7 tion as the “Secretary”), acting through the Com-
8 missioner of Food and Drugs, shall issue draft guid-
9 ance, clarifying the methods and processes by which
10 the Food and Drug Administration may provide ac-
11 celerated approval for non-opioid or non-addictive
12 drugs developed to treat chronic or acute pain or
13 substance use disorders.

14 (2) CONTENTS.—The guidance under para-
15 graph (1) shall address—

16 (A) eligibility requirements for such drugs
17 to receive accelerated approval;

18 (B) opportunities for engagement with the
19 Food and Drug Administration with respect to
20 the accelerated approval pathway;

21 (C) considerations for different types of
22 pain and product mechanism of action; and

23 (D) potential criteria for novel surrogate or
24 intermediate clinical endpoints or biomarkers to
25 assess pain.

1 (c) FINAL GUIDANCE.—Not later than 6 months
2 after the close of the period for public comment on the
3 draft guidance under subsection (b), the Secretary shall
4 finalize such guidance.

5 (d) DATA IN PERFORMANCE REPORTS.—

6 (1) IN GENERAL.—As a component of the an-
7 nual performance report under section 736B(a) of
8 the Federal Food Drug and Cosmetic Act (21
9 U.S.C. 379h-2(a)), the Secretary shall include infor-
10 mation, as appropriate, on policies and processes of
11 the Division of Anesthesia, Analgesia, and Addiction
12 Products of the Food and Drug Administration (re-
13 ferred to in this section as the “DAAAP”) for the
14 accelerated approval pathway with respect to drugs
15 developed to treat pain or substance use disorders,
16 during the previous fiscal year.

17 (2) CONTENTS.—Information submitted as a
18 part of the performance reports under section
19 736B(a) of the Federal Food, Drug and Cosmetic
20 Act may address—

21 (A) the number of requests for accelerated
22 approval submitted to the DAAAP for non-
23 opioid or non-addictive medical products;

24 (B) the number of applications for acceler-
25 ated approval that the DAAAP granted, and a

1 description of the common reasons for granting
2 applications for accelerated approval;

3 (C) the number of applications for acceler-
4 ated approval that the DAAAP denied, and a
5 description of the common reasons for denying
6 applications for accelerated approval;

7 (D) the percentage of products in such re-
8 view division which met the review goals identi-
9 fied in the letters described in section 101(b) of
10 the Prescription Drug User Fee Amendments
11 of 2017 (Public Law 115–52);

12 (E) agency efforts to ensure consistency
13 across review divisions in the metrics and proc-
14 esses by which new drug applications for non-
15 addictive or non-opioid products intended to
16 treat pain are reviewed;

17 (F) a discussion and summary of the com-
18 mon reasons for applications which did not
19 meet the review goals identified in the letters
20 described in section 101(b) of the Prescription
21 Drug User Fee Amendments of 2017 (Public
22 Law 115–52), as applicable and appropriate;
23 and

24 (G) recommendations to better enable utili-
25 zation of the accelerated approval pathway.

1 **SEC. 3. BREAKTHROUGH THERAPY STATUS FOR PAIN AND**
2 **ADDICTION THERAPIES.**

3 (a) DRAFT GUIDANCE.—

4 (1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of this Act, the Secretary of
6 Health and Human Services (referred to in this sec-
7 tion as the “Secretary”), acting through the Com-
8 missioner of Food and Drugs, shall issue draft guid-
9 ance, clarifying the methods and processes by which
10 the Food and Drug Administration may provide a
11 breakthrough therapy designation for non-opioid or
12 non-addictive drugs or devices developed to treat
13 chronic or acute pain or substance use disorders.

14 (2) CONTENTS.—The guidance under para-
15 graph (1) shall address—

16 (A) eligibility requirements for such drugs
17 and devices to receive breakthrough therapy
18 designation;

19 (B) opportunities for engagement with the
20 Food and Drug Administration with respect to
21 the breakthrough therapy pathway;

22 (C) specific actions to ensure that the de-
23 sign of the clinical trials is as efficient as prac-
24 ticable, when applicable and scientifically appro-
25 priate, for such drugs and devices; and

1 (D) the application of organizational com-
2 mitment of the Food and Drug Administration
3 to facilitating breakthrough designation for
4 qualified drugs and devices, including involve-
5 ment of senior managers of the Food and Drug
6 Administration for such drugs and devices.

7 (b) FINAL GUIDANCE.—Not later than 6 months
8 after the close of the period for public comment on the
9 draft guidance under subsection (a), the Secretary shall
10 finalize such guidance.

11 (c) DATA IN PERFORMANCE REPORTS.—

12 (1) IN GENERAL.—As a component of the per-
13 formance reports under sections 736B(a) and
14 738A(a) of the Federal Food, Drug and Cosmetic
15 Act (21 U.S.C. 379h–2, 379j–1), the Secretary shall
16 include information, as appropriate, on policies and
17 processes of the Division of Anesthesia, Analgesia,
18 and Addiction Products of the Food and Drug Ad-
19 ministration (referred to in this section as the
20 “DAAAP”) for the breakthrough therapy pathway,
21 with respect to drugs and devices developed to treat
22 chronic or acute pain or substance use disorders,
23 during the previous fiscal year.

24 (2) CONTENTS.—Information provided as a
25 component of the performance reports under sec-

1 tions 736B(a) and 738A(a) of the Federal Food,
2 Drug and Cosmetic Act may address—

3 (A) the number of requests for break-
4 through therapy designation submitted to the
5 DAAAP;

6 (B) the number of applications for break-
7 through therapy designation that the DAAAP
8 granted, and a description of the common rea-
9 sons for granting applications for breakthrough
10 therapy designation;

11 (C) the number of applications for break-
12 through therapy designation that the DAAAP
13 denied, and a description of the common rea-
14 sons for denying applications for breakthrough
15 therapy designation;

16 (D) recommendations to better enable uti-
17 lization of the breakthrough therapy designa-
18 tion pathway for non-addictive or non-opioid
19 products intended to treat pain.