

116TH CONGRESS  
1ST SESSION

# S. 3133

To amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited conditional approval pathway, subject to specific obligations, for certain drugs, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

DECEMBER 19, 2019

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 amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited conditional approval pathway, subject to specific obligations, for certain drugs, and for other purposes.

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 “Conditional Approval  
5 Act”.

1 **SEC. 2. CONDITIONAL APPROVAL OF NEW HUMAN DRUGS.**

2 (a) IN GENERAL.—Subchapter A of chapter V of the  
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
4 et seq.) is amended by adding at the end of the following:

5 **“SEC. 524B. CONDITIONAL AND TIME LIMITED APPROVAL**  
6 **PATHWAY FOR NEW DRUGS.**

7 “(a) PATHWAY REQUIREMENTS.—The Secretary  
8 shall, at the request of the sponsor of a new drug, grant  
9 provisional and time-limited approval of such drug under  
10 this section, if the Secretary determines that—

11 “(1) it is likely that the sponsor will be able to  
12 provide comprehensive clinical data after such drug  
13 is conditionally approved;

14 “(2) such drug is intended for the treatment,  
15 prevention, or medical diagnosis of a seriously debili-  
16 tating disease, a life-threatening disease, or a chron-  
17 ic condition;

18 “(3) the expected benefits of the drug outweigh  
19 the potential risks to patients, taking into account  
20 the fact that additional data are still required to as-  
21 sess the drug and the severity of the underlying dis-  
22 ease or condition the drug is intended to treat;

23 “(4) there are no existing meaningful treat-  
24 ments for the disease or condition that the drug is  
25 intended to treat;

1           “(5) confirmatory clinical trials are difficult or  
2           costly to conduct; and

3           “(6) such drug is intended to treat a disease or  
4           condition for which no more than 2 meaningful  
5           treatments currently exist.

6           “(b) APPROVAL REQUIREMENTS.—

7           “(1) IN GENERAL.—Not later than 180 days  
8           after the date on which the Secretary receives a re-  
9           quest for conditional approval under subsection (a)  
10          with respect to a new drug, the Secretary shall re-  
11          quire the sponsor of such drug to—

12                   “(A) complete in a timely manner clinical  
13                   investigations to provide full demonstration of  
14                   safety and effectiveness as described in section  
15                   505 of the Federal Food, Drug, and Cosmetic  
16                   Act or section 351 of the Public Health Service  
17                   Act, as applicable;

18                   “(B) conduct clinical trials other than con-  
19                   firmatory trials, to demonstrate a certain de-  
20                   gree of safety and efficacy of the drug; and

21                   “(C) demonstrate that necessary post-mar-  
22                   ket surveillance and risk-management tools are  
23                   in place with respect to the drug.

24           “(2) PERIOD OF CONDITIONAL APPROVAL.—

25          The period of conditional approval for a drug under

1 this subsection is effective for 1 year, and is renew-  
2 able by the Secretary for up to 4 additional 1-year  
3 terms. A conditional approval shall be in effect for  
4 not more than 5 years from the date on which condi-  
5 tional approval is first granted.

6 “(3) TIME LIMITATION.—If any conditionally  
7 drug approved under this section is not brought to  
8 market within 3 years of the conditional approval,  
9 any conditional approval granted under this section  
10 with respect to such drug shall be deemed invalid.

11 “(4) REQUIREMENTS.—As a condition on re-  
12 ceipt of conditional approval under this section, the  
13 Secretary shall require the sponsor of the drug to  
14 agree to the following:

15 “(A) Complete in a timely manner such  
16 clinical investigations to provide a full dem-  
17 onstration of effectiveness as the Secretary de-  
18 termines to be necessary for approval of the  
19 drug under section 505 of this Act or section  
20 351 of the Public Health Service Act, as appli-  
21 cable.

22 “(B) Submit to the Secretary an annual  
23 report on the progress of the sponsor in con-  
24 ducting the clinical investigations required  
25 under this section.

1           “(C) Ensure that all labeling and pro-  
2           motional materials for the drug bear the state-  
3           ment ‘conditionally approved by the FDA pend-  
4           ing a full demonstration of effectiveness under  
5           applicable \_\_\_\_\_’ (specifying the application  
6           number assigned by the Secretary in place of  
7           the blank).

8           “(5) APPLYING FOR FULL APPROVAL.—The  
9           sponsor of a drug granted conditional approval pur-  
10          suant to this subsection may, at any point, submit  
11          an application for full approval as described under  
12          section 505 of the Federal Food, Drug, and Cos-  
13          metic Act or section 351 of the Public Health Serv-  
14          ice Act, as applicable.

15          “(6) UTILIZATION OF REAL WORLD EVIDENCE  
16          TO SUPPORT FULL APPROVAL.—The Secretary shall  
17          allow the use of real world evidence, as defined in  
18          section 505F(b), and collected by the sponsor of a  
19          drug during the duration of conditional approval  
20          granted approval to this subsection, to supplement  
21          an application for full approval, in addition to other  
22          post-approval studies.

23          “(c) LIMITATION ON LIABILITY.—

24                 “(1) IN GENERAL.—With respect to any claim  
25                 under State law alleging that a drug sold or other-

1 wise made available pursuant to a grant of condi-  
2 tional approval under this subsection is unsafe or in-  
3 effective, no liability in a cause of action shall lie  
4 against a sponsor or manufacturer, unless the rel-  
5 evant conduct constitutes reckless or willful mis-  
6 conduct, gross negligence, or an intention tort under  
7 any applicable State law.

8 “(2) RULE OF CONSTRUCTION.—Except as set  
9 forth in subparagraph (A), nothing in this sub-  
10 section shall be construed to modify or otherwise af-  
11 fect the right of any person to bring private action  
12 under any Federal or State product liability, tort,  
13 consumer protection, or warranty law.

14 “(d) DEFINITIONS.—In this section:

15 “(1) SERIOUSLY DEBILITATING DISEASE.—The  
16 term ‘severely debilitating disease’ means a disease  
17 or condition that causes major irreversible mor-  
18 bidity.

19 “(2) LIFE-THREATENING DISEASE.—The term  
20 ‘life-threatening disease’ means—

21 “(A) a disease or condition where the like-  
22 lihood of death is high unless the course of the  
23 disease is interrupted; or

1           “(B) a disease or condition with potentially  
2           fatal outcomes, where the end point of clinical  
3           trial analysis is survival.

4           “(3) CHRONIC CONDITION.—The term ‘chronic  
5           condition’ means a disease or condition that—

6                   “(A) usually lasts for 3 months or longer;

7                   and

8                   “(B)(i) requires ongoing medical attention;

9                   or

10                   “(ii) limits activities of daily living.”.

11           (b) REGULATIONS AND GUIDANCE.—Not later than  
12 1 year after the date of the enactment of this Act, the  
13 Secretary of Health and Human Services shall issue final  
14 regulations and guidance for carrying out section 524B  
15 of the Federal Food, Drug, and Cosmetic Act, as added  
16 by subsection (a).

17           (c) CONFORMING AMENDMENT.—Section 505(a) of  
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 355(a)) is amended by inserting “, or there is in effect  
20 a conditional approval under section 524B with respect  
21 to such drug” before the period.

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