

116TH CONGRESS
1ST SESSION

H. R. 5497

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.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 19, 2019

Mr. WESTERMAN (for himself, Mr. GALLAGHER, and Mr. BURCHETT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 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—

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 under sec-
15 tion 505 of the Federal Food, Drug, and Cos-
16 metic Act or section 351 of the Public Health
17 Service 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 section is effective for a 1-year period and is
2 thereafter renewable by the Secretary annually for
3 up to 4 additional 1-year terms. A conditional ap-
4 proval shall be in effect for no more than 5 years
5 from the date of approval under this section.

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 section may, at any point, submit an
11 application for full approval as described under sec-
12 tion 505 of the Federal Food, Drug, and Cosmetic
13 Act or section 351 of the Public Health Service Act,
14 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 section is unsafe or ineffecti-
3 ve, 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 Act:

15 “(1) SERIOUSLY DEBILITATING DISEASES.—
16 The term ‘severely debilitating diseases’ means dis-
17 eases or conditions that cause major irreversible
18 morbidity.

19 “(2) LIFE-THREATENING DISEASES.—The term
20 ‘life-threatening diseases’ 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.

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

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