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.

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

---

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Conditional Approval Act''.

SEC. 2. CONDITIONAL APPROVAL OF NEW HUMAN DRUGS.

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

"SEC. 524B. CONDITIONAL AND TIME LIMITED APPROVAL PATHWAY FOR NEW DRUGS.

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

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

"(2) such drug is intended for the treatment, prevention, or medical diagnosis of a seriously debilitating disease, a life-threatening disease, or a chronic condition;

"(3) the expected benefits of the drug outweigh the potential risks to patients, taking into account the fact that additional data are still required to assess the drug and the severity of the underlying disease or condition the drug is intended to treat;

"(4) there are no existing meaningful treatments for the disease or condition that the drug is intended to treat;

''(5) confirmatory clinical trials are difficult or costly to conduct; and

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

''(b) APPROVAL REQUIREMENTS.—

''(1) IN GENERAL.—Not later than 180 days after the date on which the Secretary receives a request for conditional approval under subsection (a) with respect to a new drug, the Secretary shall require the sponsor of such drug to—

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

''(B) conduct clinical trials other than confirmatory trials, to demonstrate a certain degree of safety and efficacy of the drug; and

''(C) demonstrate that necessary post-market surveillance and risk-management tools are in place with respect to the drug.

''(2) PERIOD OF CONDITIONAL APPROVAL.—The period of conditional approval for a drug under

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

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

''(4) REQUIREMENTS.—As a condition on receipt of conditional approval under this section, the Secretary shall require the sponsor of the drug to agree to the following:

''(A) Complete in a timely manner such clinical investigations to provide a full demonstration of effectiveness as the Secretary determines to be necessary for approval of the drug under section 505 of this Act or section 351 of the Public Health Service Act, as applicable.

''(B) Submit to the Secretary an annual report on the progress of the sponsor in conducting the clinical investigations required under this section.

"(C) Ensure that all labeling and promotional materials for the drug bear the statement 'conditionally approved by the FDA pending a full demonstration of effectiveness under applicable _____' (specifying the application number assigned by the Secretary in place of the blank).

"(5) APPLYING FOR FULL APPROVAL.—The sponsor of a drug granted conditional approval pursuant to this subsection may, at any point, submit an application for full approval as described under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, as applicable.

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

"(c) LIMITATION ON LIABILITY.—

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

wise made available pursuant to a grant of conditional approval under this subsection is unsafe or ineffective, no liability in a cause of action shall lie against a sponsor or manufacturer, unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intention tort under any applicable State law.

''(2) RULE OF CONSTRUCTION.—Except as set forth in subparagraph (A), nothing in this subsection shall be construed to modify or otherwise affect the right of any person to bring private action under any Federal or State product liability, tort, consumer protection, or warranty law.

''(d) DEFINITIONS.—In this section:

''(1) SERIOUSLY DEBILITATING DISEASE.—The term 'severely debilitating disease' means a disease or condition that causes major irreversible morbidity.

''(2) LIFE-THREATENING DISEASE.—The term 'life-threatening disease' means—

''(A) a disease or condition where the likelihood of death is high unless the course of the disease is interrupted; or

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

"(3) CHRONIC CONDITION.—The term 'chronic condition' means a disease or condition that—

"(A) usually lasts for 3 months or longer; and

"(B)(i) requires ongoing medical attention; or

"(ii) limits activities of daily living.".

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

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

○