(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. 6996

To amend the Federal Food, Drug, and Cosmetic Act with respect to the accelerated approval of a product for a serious or life-threatening disease or condition, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the accelerated approval of a product for a serious or life-threatening disease or condition, 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 "Accelerating Access for Patients Act of 2022".

SEC. 2. ACCELERATED APPROVAL.

(a) IN GENERAL.—Subsection (c) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended to read as follows:

"(c) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—

"(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) of this Act or section 351(a) of the Public Health Service Act upon a determination—

"(i) that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments; or

"(ii) of the safety and effectiveness of the product based on the known benefit-risk profile of such product in the intended population, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments.

"(B) COMPREHENSIVE CLINICAL DEVELOPMENT PLAN.—The Secretary shall establish procedures by which a sponsor of a product seeking approval described in subparagraph (A) may meet with appropriate officials of the Food and Drug Administration to develop a plan to provide clarity and certainty for the sponsor regarding the applicability of the requirements of this subsection. Such a plan shall include—

"(i) a determination as to whether the product subject to such approval is intended to treat an unmet medical need;

"(ii) an agreement on the surrogate or intermediate clinical endpoint to be assessed, if applicable;

"(iii) an agreement on the design of the studies to be conducted to support the approval;

"(iv) a plan for a postapproval study to satisfy paragraph (2)(A), if required, including a plan for reaching agreement on the design of any such study;

"(v) a plan for reaching agreement on the types of developmental milestones to be met; and

"(vi) a strategy for the inclusion of diverse populations.

"(C) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A)(i) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

"(D) REFERENCES.—In this section, approval described in subparagraph (A) is referred to as 'accelerated approval'.

"(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

"(A) That the sponsor conduct appropriate postapproval studies (which may include clinical evidence, patient registries, or other sources of

real world evidence) to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

"(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

"(3) GUIDANCE.—The Secretary shall issue—

"(A) guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of drugs submitted for approval described in paragraph (1)(A)(ii); and

"(B) guidance on the use of novel clinical trial designs that may be used to conduct appropriate postapproval studies as may be required under paragraph (2)(A).

"(4) APPROVAL OF STUDY PROTOCOL.—Not later than 60 calendar days after the submission by the sponsor of a product of a proposed protocol for a postapproval study required under paragraph (2)(A), the Secretary shall—

"(A) approve the protocol; or

"(B) specify changes to the protocol that would enable such approval.

"(5) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

"(A) the sponsor fails to conduct any required postapproval study of the product with due diligence;

"(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

"(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(6) REPORTING.—Not later than 180 days after the date of enactment of the Accelerating Ac-

cess for Patients Act of 2022, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Labor, Pensions, and Education of the Senate a report describing—

"(A) the circumstances and number of applications submitted for approval described in paragraph (1)(A) for which real world evidence was deemed appropriate to support or fulfill postapproval studies required under this subsection; and

"(B) the circumstances and number of applications submitted for approval described in paragraph (1)(A) for which real world evidence was submitted for such postapproval studies.".

(b) INITIAL GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) shall issue draft guidance pursuant to section 506(c)(3) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a), not later than 18 months after the date of enactment of this Act;

(2) shall promulgate final guidance pursuant to such section 506(c)(3) not later than 18 months after the close of the public comment period on such draft guidance; and

(3) may approve products as described in section 506(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a), prior to issuing initial draft or final guidance under this subsection.