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118TH CONGRESS
1ST SESSION

H. R. 6664

To encourage innovation in the development of pediatric drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 7, 2023

Ms. ESHOO (for herself and Mr. MCCAUL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To encourage innovation in the development of pediatric 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 ''Innovation in Pediatric Drugs Act of 2023''.

SEC. 2. PEDIATRIC STUDIES OF ORPHAN DRUGS.

(a) APPLICATION OF PEDIATRIC RESEARCH REQUIREMENTS TO ORPHAN DRUGS.—

(1) IN GENERAL.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended by striking subsection (k).

(2) APPLICABILITY.—The amendment made by paragraph (1) applies only to applications described in subparagraph (A) or (B) of section 505B(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(1)) that are submitted on or after the date that is 18 months after the date of enactment of this Act.

(b) GUIDANCE.—The Secretary of Health and Human Services (referred to in this Act as the ''Secretary'') shall—

(1) not later than 6 months after the date of enactment of this Act, issue draft guidance describing how, upon the applicability of the amendment made by subsection (a)(1), the requirements of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) will apply with respect to any drug or biological product for an indication for which orphan designation has been granted under section 526 of such Act (21 U.S.C. 360bb); and

(2) not later than 18 months after the date of enactment of this Act, finalize such draft guidance.

(c) CONTENT OF GUIDANCE.—The guidance under subsection (b) shall address the following:

(1) Information regarding how full and partial waivers under subsections (a)(5)(A), (a)(5)(B), and (b)(2) of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) for any drug or biological product for an indication for which orphan designation has been granted under section 526 of such Act (21 U.S.C. 360bb) will be granted (including a description of impossible or highly impracticable studies for indications for which orphan designation has been granted under such section 526).

(2) Application of the requirements of section 505B(e) of such Act (21 U.S.C. 355c(e)) to drugs or biological products for an indication for which orphan designation has been granted under section 526 of such Act (21 U.S.C. 360bb), including submission and timing of planned requests for full or partial waivers and responses by the Food and Drug Administration to those requests.

(3) Process for regularly updating conditions that automatically qualify for a waiver under subsection (a)(5)(A) or (b)(2)(A) of section 505B of such Act (21 U.S.C. 355c).

(4) Situations where the initial pediatric study plan under section 505B(e) of such Act (21 U.S.C. 355c(e)) includes a plan to study the drug or biological product in all relevant pediatric age groups.

(5) Consideration of how the Secretary of Health and Human Services will balance the unique scientific challenges of rare disease drug development with the need for improved pediatric labeling of drugs and biological products for indications for which orphan designation has been granted under section 526 of such Act (21 U.S.C. 360bb).

(6) Applicability of real-world evidence in the fulfillment of requirements under section 505B of such Act (21 U.S.C. 355c).

(7) Consideration of input received from the public meeting set forth in subsection (d).

(d) PUBLIC MEETING.—The Secretary shall—

(1) not later than 1 year after the date of enactment of this Act, hold a public meeting to inform the final guidance to be issued under subsection (b)(2); and

(2) publish prior notice of such meeting in the Federal Register.

(e) GAO STUDY.—Not later than 4 years after the date of enactment of this Act, the Comptroller General

of the United States shall submit to the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that—

(1) addresses the impacts of this Act on—

(A) rare disease drug development in the United States; and

(B) the increased availability of pediatric information on drugs and biological products for indications for which orphan designation has been granted under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb); and

(2) includes—

(A) the findings of a survey of companies of varying sizes engaged in the development of orphan drugs; and

(B) input from patient groups and medical provider associations.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit requirements for investigations, as described in section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)), of molecularly targeted pediatric cancer drugs for which or-

phan designation has been granted under section 526 of such Act (21 U.S.C. 360bb).

SEC. 3. REAUTHORIZING THE PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended in paragraph (1) by striking ''$25,000,000 for each of fiscal years 2023 through 2027'' and inserting ''$50,000,000 for each of fiscal years 2023 through 2027''.

SEC. 4. ENSURING COMPLETION OF PEDIATRIC STUDY REQUIREMENTS.

(a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY REQUIREMENTS.—Section 505B(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)(2)) is amended by striking ''(except that the drug or biological product shall not be subject to action under section 303)''.

(b) CONFORMING AMENDMENTS.—Section 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(4)(A)) is amended by striking ''or 505–1'' and inserting ''505–1, or 505B''.

(c) TRANSITION RULE.—The Secretary of Health and Human Services shall take no enforcement actions under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) for failures described in section

505B(d) of such Act (21 U.S.C. 355c(d)) before the date this is 180 days after the date of enactment of this Act.

SEC. 5. FDA REPORT ON PREA ENFORCEMENT.

Section 508(b) of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 355c–1(b)) is amended—

(1) in paragraph (11), by striking the semicolon at the end and inserting ", including an assessment of the appropriateness of deferrals and deferral extensions granted for such products and an evaluation of compliance with deadlines provided for in such deferrals and deferral extensions;";

(2) in paragraph (15), by striking "and" at the end;

(3) in paragraph (16), by striking the period at the end and inserting "; and"; and

(4) by adding at the end the following:

"(17) a listing of penalties, settlements, or payments under section 303 of the Federal Food, Drug, and Cosmetic Act for failure to comply with requirements under section 505B of such Act, including for each penalty, settlement, or payment the name of the drug, the sponsor thereof, and the amount of the penalty, settlement, or payment imposed.".

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