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118TH CONGRESS
1ST SESSION

H. R. 1805

To mitigate the effects of the COVID–19 pandemic on incentives under the Federal Food, Drug, and Cosmetic Act for the development of orphan drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 27, 2023

Mr. GOTTHEIMER (for himself and Mr. BACON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To mitigate the effects of the COVID–19 pandemic on incentives under the Federal Food, Drug, and Cosmetic Act for the development of orphan 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 ''Leo's Law''.

SEC. 2. MITIGATION OF EFFECTS OF COVID–19 PANDEMIC ON ORPHAN-DRUG DEVELOPMENT INCENTIVES.

(a) IN GENERAL.—In the case of a covered orphan drug, each of the following exclusivity periods is deemed to be extended by 180 days, so long as such period is not expired:

(1) The 12-year period referred to in subparagraph (A) of section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)).

(2) The 5-year period referred to in subsection (c)(3)(E)(ii) and subsection (j)(5)(F)(ii) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(3) The 3-year period referred to in each of clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(4) The 7-year period referred to in section 527(a) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360cc).

(5) In the case of a covered orphan drug with one or more certifications specified in clauses (ii), (iii), and (iv) of section 505(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(b)(2)(A)), or in subclauses (II), (III), and (IV) of section 505(j)(2)(A)(vii) of such Act (21 U.S.C. 355(j)(2)(A)(vii)), each corresponding patent-related approval-delay period (other than a patent for which the information required pursuant to subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) has not been filed).

(b) CONFORMING EXTENSIONS.—In addition to the periods extended under subsection (a) for a covered orphan drug, the following periods are each deemed to be extended by 180 days:

(1) The 4-year period referred to in subparagraph (B) of section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)).

(2) The 4-year, 48-month, and 7 and one-half-year periods referred to in subsection (c)(3)(E)(ii) and subsection (j)(5)(F)(ii) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(c) DEFINITIONS.—In this section:

(1) The term ''covered orphan drug'' means an orphan drug for which—

(A) an application is submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) during the

COVID–19 emergency period (without regard to whether the same applicant has submitted such applications for the same drug before December 1, 2019, for a different rare disease or condition);

(B) an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or under section 351(a) of the Public Health Service Act (or a supplemental application, as the case may be) is approved pursuant to the investigational new drug application referred to in paragraph (1); and

(C) there is no approved indication that is not for a rare disease or condition.

(2) The term ''corresponding patent-related approval delay period'', with respect to a covered orphan drug, means the period ending with the last applicable date for the approval of an application within the meaning of subparagraph (A), (B), or (C) of section 505(c)(3) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)), or clause (i), (ii), or (iii) of section 505(j)(5)(B) of such Act (21 U.S.C. 355(j)(5)(B)), whichever applies pursuant to the applicable patent certification.

(3) The term ''orphan drug'' means a drug that the Secretary has designated as a drug for a rare disease or condition under section 526(a) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)).

(4) The term ''COVID–19 emergency period'' means the period beginning on December 1, 2019, and ending on the date that is not later than 120 days before the date on which the emergency period (as defined in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B))) terminates.

(5) The term ''rare disease or condition'' has the meaning given such term in section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb).

(d) EFFECTIVE DATE.—This section takes effect upon the date of the enactment of this Act, without regard to whether the Secretary has issued guidance or regulations regarding the implementation of this Act.

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