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117TH CONGRESS
2D SESSION

H. R. 7472

To amend the Federal Food, Drug, and Cosmetic Act to grant eligible researchers access to eligible products at a discounted price for qualified research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 7, 2022

Mrs. CAROLYN B. MALONEY of New York (for herself, Mr. WELCH, Ms. SCHAKOWSKY, Ms. PORTER, Mr. DESAULNIER, and Mr. RASKIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to grant eligible researchers access to eligible products at a discounted price for qualified research, 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 ''Discounted Drugs for Clinical Trials Act''.

SEC. 2. DISCOUNTED SALES OF ELIGIBLE PRODUCTS FOR QUALIFIED RESEARCH PURPOSES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505–2 of such Act (21 U.S.C. 355–1) the following new section:

"SEC. 505–3. DISCOUNTED SALES OF ELIGIBLE PRODUCTS FOR QUALIFIED RESEARCH PURPOSES.

''(a) APPLICATION BY RESEARCHER.—To obtain an eligible product for qualified research at the discounted price, an individual or entity shall submit to the Secretary an application certifying and demonstrating that—

''(1) the individual or entity is an eligible researcher;

''(2) the product being sought is an eligible product;

''(3) the researcher seeks to use the eligible product for qualified research; and

''(4) the amount of the eligible product sought is reasonable for completing the qualified research.

''(b) DUTIES OF SECRETARY.—The Secretary shall—

''(1) review each application submitted under paragraph (1) in a timely manner;

''(2) provide to the applicant, within a reasonable time of such submission—

''(A) a written order specifying the sufficient quantity of the eligible product approved to be purchased by the eligible researcher at the discounted price; or

''(B) a written denial of the application;

''(3) require manufacturers and license holders to report to the Secretary any additional information determined by the Secretary to be necessary to carry out this section; and

''(4) annually publish information on the number and types of applications granted and denied under this section.

''(c) ACQUISITION OF DISCOUNTED DRUG.—Upon receipt from an eligible researcher of an order obtained under subsection (b)(2)(A) for the acquisition of an eligible product for qualified research, the manufacturer or license holder of the eligible product shall sell to the eligible researcher the quantity specified in the order at the discounted price.

''(d) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITY OF AN ELIGIBLE PRODUCT.—

''(1) IN GENERAL.—An eligible researcher may bring a civil action against the manufacturer or license holder of an eligible product seeking relief under this subsection in an appropriate district

court of the United States alleging that the manufacturer or license holder has declined to provide the quantity of the eligible product specified in a written order from the Secretary to the eligible researcher for the discounted price.

''(2) ELEMENTS.—To prevail in a civil action brought under paragraph (1), an eligible researcher shall prove, by a preponderance of the evidence, that—

''(A) the eligible researcher has—

''(i) obtained a written order for the specified quantity of the eligible product from the Secretary in accordance with subsection (b)(2)(A); and

''(ii) provided a copy of the order to the manufacturer or license holder; and

''(B) as of the date on which the civil action is filed, the eligible researcher has not obtained the specified quantity of the eligible product at the discounted price by 31 days after the date on which the manufacturer or license holder received the eligible researcher's request for the eligible product, including a copy of the written order.

''(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

''(A) that, on the date on which the eligible researcher requested to purchase the specified quantity of the eligible product from the manufacturer or license holder—

''(i) neither the manufacturer, license holder, nor any of their agents, wholesalers, or distributors, was engaged in the manufacturing or commercial marketing of the eligible product; and

''(ii) neither the manufacturer, license holder, nor any of their agents, wholesalers, or distributors, otherwise had access to inventory of the eligible product to supply the specified quantity to the eligible researcher at the discounted price;

''(B) that—

''(i) the manufacturer or license holder sells the eligible product through agents, distributors, or wholesalers;

''(ii) the manufacturer has placed no restrictions, explicit or implicit, on its

agents, distributors, or wholesalers on selling the eligible product to eligible researchers; and

''(iii) the eligible product can be purchased by the eligible researcher in the specified quantity at the discounted price or a lower price from the agents, distributors, or wholesalers of the manufacturer or license holder; or

''(C) that the manufacturer or license holder made an offer to sell the specified quantity of the eligible product to the eligible researcher for the discounted price and the eligible researcher did not accept such offer by the date that is 14 days after the date on which the eligible product researcher received such offer.

''(4) METHODS FOR TRANSMISSION OF REQUESTS FOR ELIGIBLE PRODUCTS.—A written request for an eligible product, offer to sell an eligible product, or acceptance of such an offer between the eligible researcher and the manufacturer or license holder of the eligible product shall be made by—

''(A) certified or registered mail with return receipt requested;

''(B) personal delivery; or

"(C) electronic means.

"(5) REMEDIES.—If an eligible researcher prevails in a civil action brought under paragraph (1), the court shall—

"(A) order the manufacturer or license holder to provide to the eligible researcher without delay the specified quantity of the eligible product at the discounted price;

"(B) award to the eligible researcher reasonable attorney's fees and costs of the civil action; and

"(C) award to the eligible researcher a monetary amount sufficient to deter the manufacturer or license holder from failing to provide eligible researchers with a sufficient quantity of an eligible product at the discounted price, if the court finds, by a preponderance of the evidence, that the manufacturer or license holder, without a legitimate business justification—

"(i) delayed providing the specified quantity to the eligible researcher; or

"(ii) failed to comply with a written order under subsection (b)(2)(A).

"(6) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under paragraph (5) shall not

be greater than the revenue that the manufacturer or license holder earned on the eligible product beginning on the date that is 31 days after the date on which the manufacturer or license holder received the request and ending on the date on which the eligible researcher received the specified quantity of the eligible product.

''(7) AVOIDANCE OF DELAY.—The court may issue an order under paragraph (5)(A) before conducting further proceedings that may be necessary to determine—

''(A) whether the eligible researcher is entitled to an award under subparagraph (B) or (C) of paragraph (5); or

''(B) the amount of any such award.

''(e) LIMITATION OF LIABILITY.—A manufacturer or license holder of an eligible product obtained by an eligible researcher pursuant to this section shall not be liable for any claim under Federal, State, or local law arising out of the failure of the eligible researcher to follow adequate safeguards to assure safe use of the eligible product, including with respect to transportation, handling, use, or disposal.

''(f) RULE OF CONSTRUCTION.—This section shall not be construed to—

''(1) undermine or abrogate any requirement imposed pursuant to a risk evaluation and mitigation strategy under section 505–1; or

''(2) interfere with the private right of action afforded under section 610 of division N of the Further Consolidated Appropriations Act, 2020 (Public Law 116–94) (21 U.S.C. 355–2 note; commonly referred to as the 'CREATES Act').

''(g) DEFINITIONS.—In this section:

''(1) COMMISSIONER.—The term 'Commissioner' means the Commissioner of Food and Drugs.

''(2) COMBINATION PRODUCT.—The term 'combination product' means a combination product described in section 503(g).

''(3) DISCOUNTED PRICE.—The term 'discounted price' means the direct costs to the manufacturer or license holder of producing the eligible product.

''(4) ELIGIBLE PRODUCT.—The term 'eligible product' means—

''(A) any—

''(i) drug approved under section 505(c) of this Act or biological product licensed under section 351(a) of the Public Health Service Act;

"(ii) combination product including such a drug or biological product; or

"(iii) product, including any device, that is marketed or intended for use with such a drug or biological product; and

"(B) any product that is—

"(i) a covered part D drug (as defined in section 1860D–2(e) of the Social Security Act) eligible for placement on, with respect to a plan year, a specialty tier (as defined in section 423.560 of title 42, Code of Federal Regulations) of a formulary for such plan year of a prescription drug plan under part D of title XVIII of such Act or an MA–PD plan under part C of such title; or

"(ii) a drug (including any biological product), or combination product, whose cost is determined by the Commissioner to be prohibitive to the advancement of qualified research.

"(5) ELIGIBLE RESEARCHER.—The term 'eligible researcher' means any individual or entity seeking to obtain an eligible product for qualified research.

''(6) LICENSE HOLDER.—The term 'license holder' means the holder of an application approved under section subsection (c) or (j) of section 505 of this Act, or a license under subsection (a) or (k) of section 351 of the Public Health Service Act, for an eligible product.

''(7) QUALIFIED RESEARCH.—The term 'qualified research' means—

''(A) research in furtherance of an application under section 505(b) or (j) of this Act;

''(B) research in furtherance of an application for a license under section 351(a) or (k) of the Public Health Service Act;

''(C) research for which an exemption for investigational use is granted pursuant to section 505(i) of this Act or section 351(a) of the Public Health Service Act; or

''(D) research using an approved drug for an approved indication with the purpose of evaluating and comparing the clinical effectiveness, risks, or benefits of 2 or more of any of the following:

''(i) Health care interventions, protocols for treatment, care management, de-

livery procedures, diagnostic tools, or integrative practices.

"(ii) Drugs (including biological products), devices, or combination products.

"(iii) Any other treatments, services, practices, or items being used in the treatment, management, or diagnosis of, or prevention of, illness or injury in individuals.

"(8) SUFFICIENT QUANTITY.—The term 'sufficient quantity' means an amount of an eligible product no greater than the eligible researcher determines to be necessary to accomplish the qualified research and fulfill any related regulatory requirements.".

(b) REGULATIONS.—Not later than 180 days of the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations to carry out section 505–3 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), including regulations to appropriately calculate the discounted price applicable with respect to an eligible product (as such terms are defined in such section 505–3).

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