

117TH CONGRESS
2D SESSION

S. 4026

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 SENATE OF THE UNITED STATES

APRIL 7, 2022

Ms. SMITH (for herself and Ms. STABENOW) 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 grant eligible researchers access to eligible products at a discounted price for qualified research, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Discounted Drugs for
5 Clinical Trials Act”.

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

3 (a) IN GENERAL.—Chapter V of the Federal Food,
 4 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 5 ed by inserting after section 505–1 of such Act (21 U.S.C.
 6 355–1) the following new section:

7 **“SEC. 505–2. DISCOUNTED SALES OF ELIGIBLE PRODUCTS**
 8 **FOR QUALIFIED RESEARCH PURPOSES.**

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

13 “(1) the individual or entity is an eligible re-
 14 searcher;

15 “(2) the product being sought is an eligible
 16 product;

17 “(3) the researcher seeks to use the eligible
 18 product for qualified research; and

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

21 “(b) DUTIES OF SECRETARY.—The Secretary shall—

22 “(1) review each application submitted under
 23 subsection (a) in a timely manner;

24 “(2) provide to the applicant, within a reason-
 25 able time of such submission—

1 “(A) a written order specifying the suffi-
2 cient quantity of the eligible product approved
3 to be purchased by the eligible researcher at the
4 discounted price; or

5 “(B) a written denial of the application;

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

10 “(4) annually publish information on the num-
11 ber and types of applications granted and denied
12 under this section.

13 “(c) ACQUISITION OF DISCOUNTED DRUG.—Upon
14 receipt from an eligible researcher of an order obtained
15 under subsection (b)(2)(A) for the acquisition of an eligi-
16 ble product for qualified research, the manufacturer or li-
17 cense holder of the eligible product shall sell to the eligible
18 researcher the quantity specified in the order at the dis-
19 counted price.

20 “(d) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-
21 CIENT QUANTITY OF AN ELIGIBLE PRODUCT.—

22 “(1) IN GENERAL.—An eligible researcher may
23 bring a civil action against the manufacturer or li-
24 cense holder of an eligible product seeking relief
25 under this subsection in an appropriate district

1 court of the United States alleging that the manu-
2 facturer or license holder has declined to provide the
3 quantity of the eligible product specified in a written
4 order from the Secretary to the eligible researcher
5 for the discounted price.

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

10 “(A) the eligible researcher has—

11 “(i) obtained a written order for the
12 specified quantity of the eligible product
13 from the Secretary in accordance with sub-
14 section (b)(2)(A); and

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

17 “(B) as of the date on which the civil ac-
18 tion is filed, the eligible researcher has not ob-
19 tained the specified quantity of the eligible
20 product at the discounted price by 31 days
21 after the date on which the manufacturer or li-
22 cense holder received the eligible researcher’s
23 request for the eligible product, including a
24 copy of the written order.

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

5 “(A) that, on the date on which the eligible
6 researcher requested to purchase the specified
7 quantity of the eligible product from the manu-
8 facturer or license holder—

9 “(i) neither the manufacturer, license
10 holder, nor any of their agents, whole-
11 salers, or distributors, was engaged in the
12 manufacturing or commercial marketing of
13 the eligible product; and

14 “(ii) neither the manufacturer, license
15 holder, nor any of their agents, whole-
16 salers, or distributors, otherwise had access
17 to inventory of the eligible product to sup-
18 ply the specified quantity to the eligible re-
19 searcher at the discounted price;

20 “(B) that—

21 “(i) the manufacturer or license hold-
22 er sells the eligible product through agents,
23 distributors, or wholesalers;

24 “(ii) the manufacturer has placed no
25 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

1 “(C) electronic means.

2 “(5) REMEDIES.—If an eligible researcher pre-
3 vails in a civil action brought under paragraph (1),
4 the court shall—

5 “(A) order the manufacturer or license
6 holder to provide to the eligible researcher with-
7 out delay the specified quantity of the eligible
8 product at the discounted price;

9 “(B) award to the eligible researcher rea-
10 sonable attorney’s fees and costs of the civil ac-
11 tion; and

12 “(C) award to the eligible researcher a
13 monetary amount sufficient to deter the manu-
14 facturer or license holder from failing to provide
15 eligible researchers with a sufficient quantity of
16 an eligible product at the discounted price, if
17 the court finds, by a preponderance of the evi-
18 dence, that the manufacturer or license holder,
19 without a legitimate business justification—

20 “(i) delayed providing the specified
21 quantity to the eligible researcher; or

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

24 “(6) MAXIMUM MONETARY AMOUNT.—A mone-
25 tary amount awarded under paragraph (5) shall not

1 be greater than the revenue that the manufacturer
 2 or license holder earned on the eligible product be-
 3 ginning on the date that is 31 days after the date
 4 on which the manufacturer or license holder received
 5 the request and ending on the date on which the eli-
 6 gible researcher received the specified quantity of
 7 the eligible product.

8 “(7) AVOIDANCE OF DELAY.—The court may
 9 issue an order under paragraph (5)(A) before con-
 10 ducting further proceedings that may be necessary
 11 to determine—

12 “(A) whether the eligible researcher is en-
 13 titled to an award under subparagraph (B) or
 14 (C) of paragraph (5); or

15 “(B) the amount of any such award.

16 “(e) LIMITATION OF LIABILITY.—A manufacturer or
 17 license holder of an eligible product obtained by an eligible
 18 researcher pursuant to this section shall not be liable for
 19 any claim under Federal, State, or local law arising out
 20 of the failure of the eligible researcher to follow adequate
 21 safeguards to assure safe use of the eligible product, in-
 22 cluding with respect to transportation, handling, use, or
 23 disposal.

24 “(f) RULE OF CONSTRUCTION.—This section shall
 25 not be construed to—

1 “(1) undermine or abrogate any requirement
 2 imposed pursuant to a risk evaluation and mitiga-
 3 tion strategy under section 505–1; or

4 “(2) interfere with the private right of action
 5 afforded under section 610 of division N of the Fur-
 6 ther Consolidated Appropriations Act, 2020 (Public
 7 Law 116–94) (21 U.S.C. 355–2; commonly referred
 8 to as the ‘CREATES Act’).

9 “(g) DEFINITIONS.—In this section:

10 “(1) COMMISSIONER.—The term ‘Commis-
 11 sioner’ means the Commissioner of Food and Drugs.

12 “(2) COMBINATION PRODUCT.—The term ‘com-
 13 bination product’ means a combination product de-
 14 scribed in section 503(g).

15 “(3) DISCOUNTED PRICE.—The term ‘dis-
 16 counted price’ means the direct costs to the manu-
 17 facturer or license holder of producing the eligible
 18 product.

19 “(4) ELIGIBLE PRODUCT.—The term ‘eligible
 20 product’ means—

21 “(A) any—

22 “(i) drug approved under section
 23 505(c) of this Act or biological product li-
 24 censed under section 351(a) of the Public
 25 Health Service Act;

1 “(ii) combination product including
2 such a drug or biological product; or

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

6 “(B) any product that is—

7 “(i) a covered part D drug (as defined
8 in section 1860D–2(e) of the Social Secu-
9 rity Act) eligible for placement on, with re-
10 spect to a plan year, a specialty tier (as de-
11 fined in section 423.560 of title 42, Code
12 of Federal Regulations) of a formulary for
13 such plan year of a prescription drug plan
14 under part D of title XVIII of such Act or
15 an MA–PD plan under part C of such
16 title; or

17 “(ii) a drug (including any biological
18 product), or combination product, whose
19 cost is determined by the Commissioner to
20 be prohibitive to the advancement of quali-
21 fied research.

22 “(5) ELIGIBLE RESEARCHER.—The term ‘eligi-
23 ble researcher’ means any individual seeking to ob-
24 tain an eligible product for qualified research.

1 “(6) LICENSE HOLDER.—The term ‘license
2 holder’ means the holder of an application approved
3 under subsection (c) or (j) of section 505 of this Act,
4 or a license under subsection (a) or (k) of section
5 351 of the Public Health Service Act, for an eligible
6 product.

7 “(7) QUALIFIED RESEARCH.—The term ‘quali-
8 fied research’ means any of the following:

9 “(A) Research in furtherance of an appli-
10 cation under subsection (c) or (j) of section 505
11 of this Act.

12 “(B) Research in furtherance of an appli-
13 cation for a license under subsection (a) or (k)
14 of section 351 of the Public Health Service Act.

15 “(C) Research for which an exemption for
16 investigational use is granted pursuant to sec-
17 tion 505(i) of this Act or section 351(a) of the
18 Public Health Service Act.

19 “(D) Research using an approved drug for
20 an approved indication with the purpose of eval-
21 uating and comparing the clinical effectiveness,
22 risks, or benefits of 2 or more of any of the fol-
23 lowing:

24 “(i) Health care interventions, proto-
25 cols for treatment, care management, de-

1 livery procedures, diagnostic tools, or inte-
2 grative practices.

3 “(ii) Drugs (including biological prod-
4 ucts), devices, or combination products.

5 “(iii) Any other treatments, services,
6 practices, or items being used in the treat-
7 ment, management, or diagnosis of, or pre-
8 vention of, illness or injury in individuals.

9 “(8) SUFFICIENT QUANTITY.—The term ‘suffi-
10 cient quantity’ means an amount of an eligible prod-
11 uct no greater than the eligible researcher deter-
12 mines to be necessary to accomplish the qualified re-
13 search and fulfill any related regulatory require-
14 ments.”.

15 (b) REGULATIONS.—Not later than 180 days of the
16 date of enactment of this Act, the Secretary of Health and
17 Human Services, acting through the Commissioner of
18 Food and Drugs, shall promulgate final regulations to
19 carry out section 505–2 of the Federal Food, Drug, and
20 Cosmetic Act, as added by subsection (a), including regu-
21 lations—

22 (1) to appropriately calculate the discounted
23 price applicable with respect to an eligible product
24 (as such terms are defined in such section 505–2);
25 and

- 1 (2) with respect to civil actions under sub-
- 2 section (d) of such section 505–2.

