

114TH CONGRESS
2D SESSION

S. 1878

AN ACT

To extend the pediatric priority review voucher program.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Advancing Hope Act
3 of 2016”.

4 **SEC. 2. REAUTHORIZATION OF PROGRAM FOR PRIORITY**
5 **REVIEW TO ENCOURAGE TREATMENTS FOR**
6 **RARE PEDIATRIC DISEASES.**

7 (a) IN GENERAL.—Section 529 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

9 (1) in subsection (a)—

10 (A) in paragraph (3), by amending sub-
11 paragraph (A) to read as follows:

12 “(A) The disease is a serious or life-threat-
13 ening disease in which the serious or life-threat-
14 ening manifestations primarily affect individ-
15 uals aged from birth to 18 years, including age
16 groups often called neonates, infants, children,
17 and adolescents.”; and

18 (B) in paragraph (4)(F), by striking “Pre-
19 scription Drug User Fee Amendments of 2012”
20 and inserting “Advancing Hope Act of 2016”;
21 (2) in subsection (b)—

22 (A) by striking paragraph (4) and insert-
23 ing the following:

24 “(4) NOTIFICATION.—

25 “(A) SPONSOR OF A RARE PEDIATRIC DIS-
26 EASE PRODUCT.—

1 “(i) IN GENERAL.—Beginning on the
2 date that is 90 days after the date of en-
3 actment of the Advancing Hope Act of
4 2016, the sponsor of a rare pediatric dis-
5 ease product application that intends to re-
6 quest a priority review voucher under this
7 section shall notify the Secretary of such
8 intent upon submission of the rare pedi-
9 atric disease product application that is the
10 basis of the request for a priority review
11 voucher.

12 “(ii) APPLICATIONS SUBMITTED BUT
13 NOT YET APPROVED.—The sponsor of a
14 rare pediatric disease product application
15 that was submitted and that has not been
16 approved as of the date of enactment of
17 the Advancing Hope Act of 2016 shall be
18 considered eligible for a priority review
19 voucher, if—

20 “(I) such sponsor has submitted
21 such rare pediatric disease product
22 application—

23 “(aa) on or after the date
24 that is 90 days after the date of
25 enactment of the Prescription

1 Drug User Fee Amendments of
2 2012; and

3 “(bb) on or before the date
4 of enactment of the Advancing
5 Hope Act of 2016; and

6 “(II) such application otherwise
7 meets the criteria for a priority review
8 voucher under this section.

9 “(B) SPONSOR OF A DRUG APPLICATION
10 USING A PRIORITY REVIEW VOUCHER.—

11 “(i) IN GENERAL.—The sponsor of a
12 human drug application shall notify the
13 Secretary not later than 90 days prior to
14 submission of the human drug application
15 that is the subject of a priority review
16 voucher of an intent to submit the human
17 drug application, including the date on
18 which the sponsor intends to submit the
19 application. Such notification shall be a le-
20 gally binding commitment to pay the user
21 fee to be assessed in accordance with this
22 section.

23 “(ii) TRANSFER AFTER NOTICE.—The
24 sponsor of a human drug application that
25 provides notification of the intent of such

1 sponsor to use the voucher for the human
2 drug application under clause (i) may
3 transfer the voucher after such notification
4 is provided, if such sponsor has not yet
5 submitted the human drug application de-
6 scribed in the notification.”; and

7 (B) by striking paragraph (5) and insert-
8 ing the following:

9 “(5) TERMINATION OF AUTHORITY.—The Sec-
10 retary may not award any priority review vouchers
11 under paragraph (1) after December 31, 2016.”;
12 and

13 (3) in subsection (g), by inserting before the pe-
14 riod “, except that no sponsor of a rare pediatric
15 disease product application may receive more than
16 one priority review voucher issued under any section
17 of this Act with respect to the drug for which the
18 application is made.”

19 (b) RULE OF CONSTRUCTION.—Nothing in this Act,
20 or the amendments made by this Act, shall be construed
21 to affect the validity of a priority review voucher that was
22 issued under section 529 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360ff) before the date of enact-
24 ment of this Act.

1 **SEC. 3. GAO REPORT.**

2 (a) STUDY.—The Comptroller General of the United
3 States shall conduct a study on the effectiveness of award-
4 ing priority review vouchers under section 529 of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) in
6 providing incentives for the development of drugs that
7 treat or prevent rare pediatric diseases (as defined in sub-
8 section (a)(3) of such section) that would not otherwise
9 have been developed. In conducting such study, the Comp-
10 troller General shall examine the following:

11 (1) The indications for which each drug for
12 which a priority review voucher was awarded under
13 such section 529 was approved under section
14 505(b)(1) of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 355(b)(1)) or section 351(a) of the
16 Public Health Service Act (42 U.S.C. 262(a)).

17 (2) Whether the priority review voucher im-
18 pacted sponsors' decisions to invest in developing a
19 drug to treat or prevent a rare pediatric disease.

20 (3) An analysis of the drugs for which such pri-
21 ority review vouchers were used, which shall in-
22 clude—

23 (A) the indications for which such drugs
24 were approved under section 505(b)(1) of the
25 Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 355(b)(1)) or section 351(a) of the Pub-
2 lic Health Service Act (42 U.S.C. 262(a));

3 (B) whether unmet medical needs were ad-
4 dressed through the approval of such drugs, in-
5 cluding, for each such drug—

6 (i) if an alternative therapy was pre-
7 viously available to treat the indication;
8 and

9 (ii) if the drug provided a benefit or
10 advantage over another available therapy;

11 (C) the number of patients potentially
12 treated by such drugs;

13 (D) the value of the priority review vouch-
14 er if transferred; and

15 (E) the length of time between the date on
16 which a priority review voucher was awarded
17 and the date on which it was used.

18 (4) With respect to the priority review voucher
19 program under section 529 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360ff)—

21 (A) the resources used by the Food and
22 Drug Administration in implementing such pro-
23 gram, including the effect of such program on
24 the Food and Drug Administration's review of

1 drugs for which a priority review voucher was
2 not awarded or used;

3 (B) the impact of the program on the pub-
4 lic health as a result of the review and approval
5 of drugs that received a priority review voucher
6 and products that were the subject of a re-
7 deemed priority review voucher; and

8 (C) alternative approaches to improving
9 such program so that the program is appro-
10 priately targeted toward providing incentives for
11 the development of clinically important drugs
12 that—

13 (i) prevent or treat rare pediatric dis-
14 eases; and

15 (ii) would likely not otherwise have
16 been developed to prevent or treat such
17 diseases.

18 (b) REPORT.—Not later than January 31, 2022, the
19 Comptroller General of the United States shall submit to
20 the Committee on Health, Education, Labor, and Pen-
21 sions of the Senate and the Committee on Energy and
22 Commerce of the House of Representatives a report con-

- 1 taining the results of the study of conducted under sub-
- 2 section (a).

Passed the Senate September 22, 2016.

Attest:

Secretary.

114TH CONGRESS
2^D Session

S. 1878

AN ACT

To extend the pediatric priority review voucher
program.