

Calendar No. 520

119TH CONGRESS
2^D SESSION

S. 1414

To amend the Public Health Service Act to provide that clinical studies required for licensure of biological products as biosimilar shall not be required to include the assessment of immunogenicity, pharmacodynamics, or comparative clinical efficacy.

IN THE SENATE OF THE UNITED STATES

APRIL 10, 2025

Mr. PAUL (for himself, Mr. LEE, and Ms. HASSAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 27, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Public Health Service Act to provide that clinical studies required for licensure of biological products as biosimilar shall not be required to include the assessment of immunogenicity, pharmacodynamics, or comparative clinical efficacy.

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 “Expedited Access to
3 Biosimilars Act”.

4 **SEC. 2. ASSESSMENT OF IMMUNOGENICITY,**
5 **PHARMACODYNAMICS, OR COMPARATIVE**
6 **CLINICAL EFFICACY IN CLINICAL STUDIES**
7 **REQUIRED FOR LICENSURE OF BIOLOGICAL**
8 **PRODUCTS AS BIOSIMILAR.**

9 (a) IN GENERAL.—Section 351(k)(2)(A) of the Pub-
10 lic Health Service Act (42 U.S.C. 262(k)(2)(A)) is amend-
11 ed—

12 (1) in clause (i)(I)—

13 (A) in item (bb), by striking “and” at the
14 end; and

15 (B) by striking item (cc) and inserting the
16 following

17 “(cc) a clinical study or
18 studies assessing pharmaco-
19 kinetics that are sufficient to
20 demonstrate safety, purity, and
21 potency; and

22 “(dd) subject to clause (iv),
23 a clinical study or studies that
24 are sufficient to demonstrate
25 safety, purity, and potency in 1
26 or more appropriate conditions of

use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;” and

(2) by adding at the end the following:

“(iv) CLINICAL STUDIES.—

“(I) IN GENERAL.—Subject to subclause (II), the Secretary may determine, in the Secretary’s discretion, that a clinical study required under clause (i)(I)(dd) shall include the assessment of immunogenicity, pharmacodynamics, or comparative clinical efficacy.

“(II) REQUIREMENT.—The Secretary may only require the assessment of immunogenicity, pharmacodynamics, or comparative clinical efficacy pursuant to a determination under subclause (I) if the Secretary provides to the applicant notice of the requirement, including a written justification of the basis for such determination, not later than the

1 earliest date on which the applicant
 2 may file the application under this
 3 subsection.”.

4 (b) **APPLICABILITY.**—The amendments made by sub-
 5 section (a) shall apply with respect to an application sub-
 6 mitted under section 351(k) of the Public Health Service
 7 Act (42 U.S.C. 262(k)) on or after the date of enactment
 8 of this Act.

9 **SECTION 1. SHORT TITLE.**

10 *This Act may be cited as the “Expedited Access to*
 11 *Biosimilars Act”.*

12 **SEC. 2. DATA REQUIRED FOR LICENSURE OF BIOLOGICAL**
 13 **PRODUCTS AS BIOSIMILAR.**

14 (a) **IN GENERAL.**—Section 351(k)(2)(A) of the Public
 15 Health Service Act (42 U.S.C. 262(k)(2)(A)) is amended—

16 (1) in clause (i)(I)—

17 (A) in item (bb)—

18 (i) by striking “or (cc)” and inserting

19 “, (cc), or (dd)”;

20 (ii) by striking “and” at the end; and

21 (B) by striking item (cc) and inserting the

22 following

23 “(cc) an assessment of phar-

24 macokinetics and immunogenicity

25 (which may rely on, or consist of,

1 *a clinical pharmacokinetics study*
 2 *or studies described in item (aa)*
 3 *or (dd)), as appropriate; and*

4 “*(dd) a clinical study or*
 5 *studies, if required by the Sec-*
 6 *retary pursuant to clause (ii)(II),*
 7 *to support a demonstration that*
 8 *there is no clinically meaningful*
 9 *difference between the biological*
 10 *product and the reference product*
 11 *in terms of safety, purity, and po-*
 12 *tency of such product;”*; and

13 *(2) in clause (ii)—*

14 *(A) in the clause heading, by striking “DE-*
 15 *TERMINATION” and inserting “DETERMINA-*
 16 *TIONS”;*

17 *(B) by striking “The Secretary may” and*
 18 *inserting the following:*

19 “*(I) IN GENERAL.—The Secretary*
 20 *may”*; and

21 *(C) by adding at the end the following:*

22 “*(II) PROCEDURE FOR CERTAIN*
 23 *STUDIES.—*

24 “*(aa) IN GENERAL.—For an*
 25 *application for licensure of a bio-*

1 similar biological product sub-
2 mitted under this subsection, the
3 Secretary may require a clinical
4 study that includes an assessment
5 of pharmacodynamics or efficacy,
6 as described in clause (i)(I)(dd),
7 only if the Secretary provides a
8 written determination, as de-
9 scribed in item (bb) or (cc), to the
10 sponsor of the biosimilar biological
11 product that such assessments
12 or studies are necessary, in com-
13 bination with other information
14 required pursuant to clause (i)(I),
15 to demonstrate biosimilarity.

16 “(bb) WRITTEN DETERMINA-
17 TION.—The Secretary shall—

18 “(AA) when the Sec-
19 retary issues meeting min-
20 utes of a biosimilar biological
21 product development meeting
22 (as such term is defined in
23 section 744G(5) of the Fed-
24 eral Food, Drug, and Cos-
25 metic Act), provide a written

1 *determination described in*
 2 *item (aa), or provide written*
 3 *notice to the sponsor that de-*
 4 *scribes why such a deter-*
 5 *mination can not be made at*
 6 *such time; and*

7 “(BB) if the Secretary
 8 *is unable to make a written*
 9 *determination described in*
 10 *item (aa) at the time de-*
 11 *scribed in subitem (AA), pro-*
 12 *vide such determination not*
 13 *later than 60 days after the*
 14 *date of submission of an ap-*
 15 *plication for licensure under*
 16 *this section.*

17 “(cc) AMENDMENT TO A DE-
 18 *TERMINATION.—A written deter-*
 19 *mination under this subclause*
 20 *shall not be amended to require a*
 21 *clinical study or studies described*
 22 *in clause (i)(I)(dd) after the date*
 23 *on which such a determination is*
 24 *made, except—*

1 “(AA) by written agree-
2 ment with the sponsor; or

3 “(BB) in the case that
4 the Secretary determines
5 there is a scientific justifica-
6 tion to amend the determina-
7 tion, provides a detailed
8 written justification to the
9 sponsor as soon as prac-
10 ticable, and, upon the request
11 of the sponsor, holds a bio-
12 similar biological product de-
13 velopment meeting (as such
14 term is defined in section
15 744G(5) of the Federal Food,
16 Drug, and Cosmetic Act) to
17 discuss the amendment.”.

18 (b) *STREAMLINING BIOSIMILAR REVIEWS*.—Section
19 351(k)(5) of the Public Health Service Act (42 U.S.C.
20 262(k)(5)) is amended—

21 (1) by striking subparagraph (B); and

22 (2) by redesignating subparagraph (C) as sub-
23 paragraph (B).

24 (c) *APPLICABILITY*.—The amendments made by sub-
25 sections (a) and (b) shall apply with respect to an applica-

1 *tion submitted under section 351(k) of the Public Health*
2 *Service Act (42 U.S.C. 262(k)) on or after the date of enact-*
3 *ment of this Act.*

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