

119TH CONGRESS  
1ST 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.

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## IN THE SENATE OF THE UNITED STATES

APRIL 10, 2025

Mr. PAUL introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Expedited Access to  
5 Biosimilars Act”.

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

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

9 (1) in clause (i)(I)—

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

12 (B) by striking item (cc) and inserting the  
 13 following

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

19 “(dd) subject to clause (iv),  
 20 a clinical study or studies that  
 21 are sufficient to demonstrate  
 22 safety, purity, and potency in 1  
 23 or more appropriate conditions of  
 24 use for which the reference prod-  
 25 uct is licensed and intended to be  
 26 used and for which licensure is

1 sought for the biological prod-  
2 uct;”; and

3 (2) by adding at the end the following:

4 “(iv) CLINICAL STUDIES.—

5 “(I) IN GENERAL.—Subject to  
6 subclause (II), the Secretary may de-  
7 termine, in the Secretary’s discretion,  
8 that a clinical study required under  
9 clause (i)(I)(dd) shall include the as-  
10 sessment of immunogenicity,  
11 pharmacodynamics, or comparative  
12 clinical efficacy.

13 “(II) REQUIREMENT.—The Sec-  
14 retary may only require the assess-  
15 ment of immunogenicity,  
16 pharmacodynamics, or comparative  
17 clinical efficacy pursuant to a deter-  
18 mination under subclause (I) if the  
19 Secretary provides to the applicant  
20 notice of the requirement, including a  
21 written justification of the basis for  
22 such determination, not later than the  
23 earliest date on which the applicant  
24 may file the application under this  
25 subsection.”.

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

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