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119TH CONGRESS
2D SESSION

H. R. 9661

To amend the Public Health Service Act to codify that the default expectation for licensure of biological products as biosimilar does not include clinical studies assessing pharmacodynamics or comparative clinical efficacy, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2026

Mr. LANGWORTHY (for himself and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to codify that the default expectation for licensure of biological products as biosimilar does not include clinical studies assessing pharmacodynamics or comparative clinical efficacy, 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 ''Expedited Access to Biosimilars Act''.

SEC. 2. ASSESSMENT OF PHARMACODYNAMICS OR EFFICACY IN CLINICAL STUDIES REQUIRED FOR LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR.

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

(1) in clause (i)(I)—

(A) in item (bb)—

(i) by striking ''item (aa) or (cc)'' and inserting ''item (aa), (cc), or (dd)''; and

(ii) by striking ''and'' at the end; and

(B) by striking item (cc) and inserting the following:

''(cc) an assessment of pharmacokinetics and immunogenicity (which may rely on, or consist of, a clinical pharmacokinetics study or studies or a study or studies described in item (aa) or (dd), as appropriate); and

''(dd) subject to clause (iv), an additional clinical study or studies in 1 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) LIMITATION ON REQUIRING ADDITIONAL CLINICAL STUDY OR STUDIES.—The Secretary may only require an additional clinical study or studies described in clause (i)(I)(dd), including a study or studies that include an assessment of pharmacodynamics or efficacy, if the Secretary determines that such study or studies are necessary, in combination with the other studies described in clause (i)(I), to demonstrate biosimilarity and provides written notice of such determination to the sponsor of the proposed biosimilar biological product. Such written notice shall be provided not later than—

''(I) the date on which the Secretary grants a request for a biosimilar biological product development meeting from such sponsor, unless the Secretary describes in writing why an assessment of the need for such study

or studies cannot be made at that time; or

"(II) if no request for a biosimilar biological product development meeting is submitted or if the Secretary was unable to make the assessment under subclause (I), the date that is 60 days after the date of the submission of an application under this subsection.".

(b) REPEAL OF REQUIREMENT RELATING TO CONDUCT OF REVIEWS.—Section 351(k)(5) of the Public Health Service Act (42 U.S.C. 262(k)(5)) is amended—

(1) by striking subparagraph (B); and

(2) by redesignating subparagraph (C) as subparagraph (B).

(c) APPLICABILITY.—The amendments made by subsection (a) shall apply with respect to an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) on or after the date of enactment of this Act.

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