Bill Cassidy, M.D.

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.**

# 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.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Expedited Access to Biosimilars Act".

**SEC. 2. DATA 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 "or (cc)" and inserting ", (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 described in item (aa) or (dd)), as appropriate; and

"(dd) a clinical study or studies, if required by the Secretary pursuant to clause (ii)(II), to support a demonstration that there is no clinically meaningful difference between the biological product and the reference product in terms of safety, purity, and potency of such product;"; and

(2) in clause (ii)—

(A) in the clause heading, by striking "DETERMINATION" and inserting "DETERMINATIONS";

(B) by striking "The Secretary may" and inserting the following:

"(I) IN GENERAL.—The Secretary may"; and

(C) by adding at the end the following:

"(II) PROCEDURE FOR CERTAIN STUDIES.—

"(aa) IN GENERAL.—For an application for licensure of a biosimilar biological product submitted under this subsection, the Secretary may require a clinical study that includes an assessment of pharmacodynamics or efficacy, as described in clause (i)(I)(dd), only if the Secretary provides a written determination, as described in item (bb) or (cc), to the sponsor of the biosimilar biological product that such assessments or studies are necessary, in combination with other

information required pursuant to clause (i)(I), to demonstrate biosimilarity.

"(bb) WRITTEN DETERMINATION.—The Secretary shall—

"(AA) when the Secretary issues meeting minutes of a biosimilar biological product development meeting (as such term is defined in section 744G(5) of the Federal Food, Drug, and Cosmetic Act), provide a written determination described in item (aa), or provide written notice to the sponsor that describes why such a determination can not be made at such time; and

"(BB) if the Secretary is unable to make a written determination described in item (aa) at the time de-

scribed in subitem (AA), provide such determination not later than 60 days after the date of submission of an application for licensure under this section.

"(cc) AMENDMENT TO A DETERMINATION.—A written determination under this subclause shall not be amended to require a clinical study or studies described in clause (i)(I)(dd) after the date on which such a determination is made, except—

"(AA) by written agreement with the sponsor; or

"(BB) in the case that the Secretary determines there is a scientific justification to amend the determination, provides a detailed written justification to the sponsor as soon as practicable, and, upon the request of the sponsor, holds a

biosimilar biological product development meeting (as such term is defined in section 744G(5) of the Federal Food, Drug, and Cosmetic Act) to discuss the amendment.".

(b) STREAMLINING BIOSIMILAR 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 subsections (a) and (b) 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.