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. 1954

To improve the requirements for making a determination of interchangeability of a biological product and its reference product.

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 "Biosimilar Red Tape Elimination Act".

SEC. 2. BIOSIMILAR BIOLOGICAL PRODUCTS.

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

(1) in the subsection heading, by striking "OR INTERCHANGEABLE";

(2) in paragraph (2)—

(A) by striking subparagraph (B);

(B) by redesignating clauses (ii) and (iii) of subparagraph (A) as subparagraphs (B) and (C), respectively, and adjusting the margins accordingly;

(C) in subparagraph (A)—

(i) in clause (i), by redesignating subclauses (I) through (V) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (i), as so redesignated by clause (i) of this subparagraph, by redesignating items (aa) through (cc) as subclauses (I) through (III), respectively, and adjusting the margins accordingly;

(iii) by striking "(A) IN GENERAL" and all that follows through "An application submitted under this subsection shall include information" and inserting the following:

"(A) IN GENERAL.—An application submitted under this subsection shall include information"; and

(iv) in clause (i)(II), as so redesignated by subparagraph (C) of this para-

graph, by striking "item (aa) or (cc)" and inserting "subclause (I) or (III)";

(D) in subparagraph (B), as so redesignated by subparagraph (B) of this paragraph, by striking "clause (i)(I)" and inserting "subparagraph (A)(i)"; and

(E) in subparagraph (C), as so redesignated by subparagraph (B) of this paragraph—

(i) by redesignating subclauses (I) through (III) as clauses (i) through (iii), respectively, and adjusting the margins accordingly; and

(ii) by striking "publicly-available" each place it appears and inserting "publicly available";

(3) by amending subparagraph (A) of paragraph (3) to read as follows:

"(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product is biosimilar to the reference product; and";

(4) by amending paragraph (4) to read as follows:

"(4) INTERCHANGEABILITY.—

"(A) IN GENERAL.—A biological product licensed under this subsection shall be deemed to be interchangeable with the reference product, subject to subparagraph (B).

"(B) TIMING OF DEEMED INTERCHANGEABILITY.—A biological product licensed under this subsection (referred to in this subparagraph as the 'applicable biological product') shall be deemed to be interchangeable with the reference product upon such licensure (or, in the case of a biological product so licensed before the transition date described in subparagraph (C), on such transition date), unless the applicable biological product relied on the same reference product as another biological product for which—

"(i) licensure under this subsection was in effect on the date of enactment of the Biosimilar Red Tape Elimination Act; and

"(ii) a first interchangeable exclusivity period under paragraph (6) (as in effect on the day before the date of enactment of the Biosimilar Red Tape Elimination Act) is in effect on the date of licensure of the appli-

cable biological product (or on the transition date described in subparagraph (C), in the case of a biological product licensed before the transition date),

in which case the applicable biological product shall be deemed interchangeable with the reference product under this paragraph on the date on which the exclusivity period described in clause (ii) ends.

"(C) TRANSITION DATE.—The transition date described in this subparagraph is the date that is 60 days after the date of enactment of the Biosimilar Red Tape Elimination Act.";

(5) by amending paragraph (6) to read as follows:

"(6) TRANSITION WITH RESPECT TO PRESERVING FIRST INTERCHANGEABILITY EXCLUSIVITY WITH RESPECT TO CERTAIN BIOLOGICAL PRODUCTS.—With respect to a biological product licensed under this subsection before the date of enactment of the Biosimilar Red Tape Elimination Act, for which there was an unexpired period of first interchangeable exclusivity under this subsection (as then in effect), such unexpired exclusivity period shall remain in effect for the duration of such period."; and

(6) in paragraph (8)(D)—

(A) in clause (i), by striking "class; and" and inserting "class.";

(B) by striking clause (ii); and

(C) by striking "description of—" and all that follows through "criteria that the Secretary" and inserting "description of the criteria that the Secretary".

(b) CONFORMING AMENDMENTS.—

(1) Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(A) in subsection (i)(3), by striking "that is shown to meet the standards described in subsection (k)(4)" and inserting "licensed under subsection (k)"; and

(B) in subsection (l)(1)(F), by striking "publicly-available" and inserting "publicly available";

(2) Section 352A of the Public Health Service Act (42 U.S.C. 263–1) is amended by striking "and interchangeable biosimilar biological products" each place it appears.

(3) Section 744G(14) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(14)) is amended by striking ", including a supplement re-

questing that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act".

(4) Subsection (l) of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:

"(l) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biological product for which an application, including a supplement to an application, is submitted under section 351(k) of the Public Health Service Act shall not be considered to have a new active ingredient for purposes of this section, unless—

"(1) the application seeks licensure for a claimed indication that has been approved for the reference product in a relevant pediatric population or for which there is a deferral of the pediatric assessment under subsection (a)(4) for the reference product; and

"(2) the assessment or investigation described in subsection (a) would not involve the development of a biological product with a strength, dosage form, route of administration, or condition of use that could not be licensed under such section 351(k).".

(c) GUIDANCE.—The Secretary of Health and Human Services may issue or revise guidance, as appropriate, regarding the data and information that an applicant may be required to submit to support a determination of biosimilarity in an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as amended by this Act, including any additional information related to the device constituent part of a biosimilar biological product that is a combination product. The issuance or non-issuance of such guidance shall not preclude the review of, or action on, an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as amended by this Act.