AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 974

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

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 ''Creating and Restoring Equal Access to Equivalent Samples Act of 2018'' or the ''CREATES Act of 2018''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) It is the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of

low-cost generic and biosimilar versions of those drugs and biological products.

(2) Since their enactment in 1984 and 2010, respectively, the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417; 98 Stat. 1585) and the Biologics Price Competition and Innovation Act of 2009 (Subtitle A of title VII of Public Law 111–148; 124 Stat. 804), have provided pathways for making lower-cost versions of previously approved drugs and previously licensed biological products available to the people of the United States in a timely manner, thereby lowering overall prescription drug costs for patients and taxpayers by billions of dollars each year.

(3) In order for these pathways to function as intended, developers of generic drugs and biosimilar biological products (referred to in this section as ''generic product developers'') must be able to obtain quantities of the reference listed drug or biological product with which the generic drug or biosimilar biological product is intended to compete (referred to in this section as a ''covered product'') for purposes of supporting an application for approval by the Food and Drug Administration, including for testing to show that—

(A) a prospective generic drug is bioequivalent to the covered product in accordance with subsection (j) of section 505 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355), or meets the requirements for approval of an application submitted under subsection (b)(2) of that section; or

(B) a prospective biosimilar biological product is biosimilar to or interchangeable with its reference biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as applicable.

(4) For drugs and biological products that are subject to a risk evaluation and mitigation strategy, another essential component in the creation of low-cost generic and biosimilar versions of covered products is the ability of generic product developers to join the manufacturer of the covered product (referred to in this section as the ''license holder'') in a single, shared system of elements to assure safe use and supporting agreements, or secure a variance therefrom, as required by section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

(5) Contrary to the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, certain license holders are preventing generic product developers from obtaining quantities of the covered product necessary for the generic product developer to support an application for approval by the Food and Drug Administration, including testing to show bioequivalence, biosimilarity, or interchangeability to the covered product, in some instances based on the justification that the covered product is subject to a risk evaluation and mitigation strategy with elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

(6) The Director of the Center for Drug Evaluation and Research at the Food and Drug Administration has testified that some manufacturers of covered products have used REMS and distribution restrictions adopted by the manufacturer on their own behalf as reasons to not sell quantities of a covered product to generic product developers, causing barriers and delays in getting generic products on the market. The Food and Drug Administration has

reported receiving significant numbers of inquiries from generic product developers who were unable to obtain samples of covered products to conduct necessary testing and otherwise meet requirements for approval of generic drugs.

(7) The Chairwoman of the Federal Trade Commission has testified that the Federal Trade Commission continues to be very concerned about potential abuses by manufacturers of brand drugs of REMS or other closed distribution systems to impede generic competition.

(8) Also contrary to the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, certain license holders are impeding the prompt negotiation and development on commercially reasonable terms of a single, shared system of elements to assure safe use, which may be necessary for the generic product developer to gain approval for its drug or licensing for its biological product.

(9) While the antitrust laws may address the refusal by some license holders to provide quantities of a covered product to a generic product developer,

a more tailored legal pathway would help ensure that generic product developers can obtain necessary quantities of a covered product in a timely way for purposes of developing a generic drug or biosimilar biological product, facilitating competition in the marketplace for drugs and biological products.

(10) The antitrust laws may address actions by license holders who impede the prompt negotiation and development of a single, shared system of elements to assure safe use, and the Food and Drug Administration has some authority to waive the requirement of a single, shared system. Clearer regulatory authority to approve different systems that meet the statutory requirements to ensure patient safety, however, would limit the effectiveness of bad faith negotiations over single, shared systems to delay generic approval. At the same time, clearer regulatory authority would ensure all systems protect patient safety.

SEC. 3. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''commercially reasonable, market-based terms'' means—

(A) a non-discriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under

section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that the Secretary has determined to be currently in shortage and that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless the shortage will not be promptly resolved—

(i) as demonstrated by the fact that the drug or biological product has been in shortage for more than 6 months; or

(ii) as otherwise determined by the Secretary;

(3) the term ''device'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(4) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

(6) the term ''REMS'' means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(8) the term ''Secretary'' means the Secretary of Health and Human Services;

(9) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1); and

(10) the term ''sufficient quantities'' means an amount of a covered product that allows the eligible product developer to—

(A) conduct testing to support an application—

(i) for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) for licensing under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to such an application for approval or licensing.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this sub-

section in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has requested to purchase sufficient quantities of the covered product from the license holder; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered

product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms; or

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible

product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) NO VIOLATION OF REMS.—The provision of samples of a drug pursuant to an authorization under subsection (b)(2)(B) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for such drug.

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different, comparable approved risk evaluation and mitigation strategies for a drug that is the subject of an abbreviated new drug application, and its reference drug product.'';

(2) in subsection (i)(1), by striking subparagraph (B) and inserting the following:

''(B) Elements to assure safe use, if required under subsection (f) for the listed drug.

''(i) Subject to clause (ii), a drug that is the subject of an abbreviated new drug application may use—

''(I) a single, shared system with the listed drug under subsection (f); or

''(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

''(ii) The Secretary may require a drug that is the subject of an abbreviated new drug application and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).''; and

(3) by adding at the end the following:

''(l) SEPARATE REMS.—When used in this section, the terms ''different, comparable aspect of the elements to assure safe use'' or ''different, comparable approved risk evaluation and mitigation strategies'' means a risk evaluation and mitigation strategy for a drug that is the

subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable reference drug, or other application under section 505(j) with the same such reference listed drug, but achieves the same level of safety as such strategy.''.