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.

IN THE HOUSE OF REPRESENTATIVES

February 5, 2019

Mr. Cicilline (for himself, Mr. Sensenbrenner, Mr. Nadler, Mr. Collins of Georgia, Mr. Welch, and Mr. McKinley) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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.

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 “Creating and Restoring Equal Access to Equivalent Samples Act of 2019” or the “CREATES Act of 2019”.

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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 bioequiva-
 lent 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 prod-
ucts is the ability of generic product developers to
join the manufacturer of the covered product (re-
ferred to in this section as the “license holder”) in
a single, shared system of elements to assure safe
use and supporting agreements as required by sec-

(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 of the Food and Drug Administration has testified that some manufacturers of covered products have used risk evaluation and mitigation strategies 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 sig-
nificant numbers of inquiries from generic product
developers who were unable to obtain samples of cov-
ered products to conduct necessary testing and oth-
erwise meet requirements for approval of generic
drugs.

(7) In 2018, the Acting Chairman of the Fed-
eral Trade Commission testified that the Federal
Trade Commission continues to be very concerned
about potential abuses by manufacturers of brand
drugs of risk evaluation and mitigation strategies 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, cer-
tain license holders are impeding the prompt nego-
tiation and development on commercially reasonable
terms of a single, shared system of elements to as-
sure safe use, which may be necessary for the ge-
eneric 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 ele-
ments to assure safe use, and the Food and Drug
Administration has some authority to waive the re-
quirement of a single, shared system. Clearer regu-
ulatory 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 pro-
tect 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 nondiscriminatory 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(e)(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 (e) 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 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 ap-
proval 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 sec-
tion 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 li-
cense 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
355–1);

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

(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(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); 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 under—

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

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

(B) fulfill any regulatory requirements relating to approval of such an application.

(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 subsection 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 re-
quest 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 ac-
cordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PROD-
UCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product de-
veloper may submit to the Secretary a
written request for the eligible product de-
veloper to be authorized to obtain suffi-
cient 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 eligi-
ble product developer to obtain sufficient
quantities of an individual covered product
subject to a REMS with ETASU for pur-
poses 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’s 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 FILLERS.

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 application under section 505(j), and the applicable listed drug.”;

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:
“(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 505(j) 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 application under section 505(j) 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 listed drug, or other application under section 505(j) with the same such listed drug, but achieves the same level of safety as such strategy.”.