## Amendment in the Nature of a Substitute to H.R. 965 Offered by M .

Strike all after the enacting clause and insert the following:

### 1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the "Creating and Restoring
3 Equal Access to Equivalent Samples Act of 2019" or the
4 "CREATES Act of 2019".

5 SEC. 2. ACTIONS FOR DELAYS OF GENERIC DRUGS AND

**BIOSIMILAR BIOLOGICAL PRODUCTS.** 

# 7 (a) DEFINITIONS.—In this section— 8 (1) the term "commercially reasonable, market-

9 based terms" means—

10 (A) a nondiscriminatory price for the sale
11 of the covered product at or below, but not
12 greater than, the most recent wholesale acquisi13 tion cost for the drug, as defined in section
14 1847A(c)(6)(B) of the Social Security Act (42)
15 U.S.C. 1395w-3a(c)(6)(B));

16 (B) a schedule for delivery that results in17 the transfer of the covered product to the eligi-

1	ble product developer consistent with the timing
2	under subsection $(b)(2)(A)(iv)$ ; and
3	(C) no additional conditions are imposed
4	on the sale of the covered product;
5	(2) the term "covered product"—
6	(A) means—
7	(i) any drug approved under sub-
8	section (c) or (j) of section 505 of the Fed-
9	eral Food, Drug, and Cosmetic Act (21
10	U.S.C. 355) or biological product licensed
11	under subsection (a) or (k) of section 351
12	of the Public Health Service Act (42
13	U.S.C. 262);
14	(ii) any combination of a drug or bio-
15	logical product described in clause (i); or
16	(iii) when reasonably necessary to
17	support approval of an application under
18	section 505 of the Federal Food, Drug,
19	and Cosmetic Act (21 U.S.C. 355), or sec-
20	tion 351 of the Public Health Service Act
21	(42 U.S.C. 262), as applicable, or other-
22	wise meet the requirements for approval
23	under either such section, any product, in-
24	cluding any device, that is marketed or in-

1	tended for use with such a drug or biologi-
2	cal product; and
3	(B) does not include any drug or biological
4	product that appears on the drug shortage list
5	in effect under section 506E of the Federal
6	Food, Drug, and Cosmetic Act (21 U.S.C.
7	356e), unless—
8	(i) the drug or biological product has
9	been on the drug shortage list in effect
10	under such section 506E continuously for
11	more than 6 months; or
12	(ii) the Secretary determines that in-
13	clusion of the drug or biological product as
14	a covered product is likely to contribute to
15	alleviating or preventing a shortage.
16	(3) the term "device" has the meaning given
17	the term in section 201 of the Federal Food, Drug,
18	and Cosmetic Act (21 U.S.C. 321);
19	(4) the term "eligible product developer" means
20	a person that seeks to develop a product for ap-
21	proval pursuant to an application for approval under
22	subsection (b)(2) or (j) of section 505 of the Federal
23	Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
24	for licensing pursuant to an application under sec-

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1	tion $351(k)$ of the Public Health Service Act (42
2	U.S.C. 262(k));
3	(5) the term "license holder" means the holder
4	of an application approved under subsection (c) or
5	(j) of section 505 of the Federal Food, Drug, and
6	Cosmetic Act (21 U.S.C. 355) or the holder of a li-
7	cense under subsection (a) or (k) of section 351 of
8	the Public Health Service Act (42 U.S.C. 262) for
9	a covered product;
10	(6) the term "REMS" means a risk evaluation
11	and mitigation strategy under section 505–1 of the
12	Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13	355–1);
14	(7) the term "REMS with ETASU" means a
15	REMS that contains elements to assure safe use
16	under section 505–1(f) of the Federal Food, Drug,

17 and Cosmetic Act (21 U.S.C. 355-1(f));

18 (8) the term "Secretary" means the Secretary19 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

1	(10) the term "sufficient quantities" means an
2	amount of a covered product that the eligible prod-
3	uct developer determines allows it to—
4	(A) conduct testing to support an applica-
5	tion under—
6	(i) subsection $(b)(2)$ or $(j)$ of section
7	505 of the Federal Food, Drug, and Cos-
8	metic Act (21 U.S.C. 355); or
9	(ii) section 351(k) of the Public
10	Health Service Act (42 U.S.C. 262(k));
11	and
12	(B) fulfill any regulatory requirements re-
13	lating to approval of such an application.
14	(b) Civil Action for Failure To Provide Suffi-
15	CIENT QUANTITIES OF A COVERED PRODUCT.—
16	(1) IN GENERAL.—An eligible product developer
17	may bring a civil action against the license holder
18	for a covered product seeking relief under this sub-
19	section in an appropriate district court of the United
20	States alleging that the license holder has declined
21	to provide sufficient quantities of the covered prod-
22	uct to the eligible product developer on commercially
23	reasonable, market-based terms.
24	(2) Elements.—

1	(A) IN GENERAL.—To prevail in a civil ac-
2	tion brought under paragraph (1), an eligible
3	product developer shall prove, by a preponder-
4	ance of the evidence—
5	(i) that—
6	(I) the covered product is not
7	subject to a REMS with ETASU; or
8	(II) if the covered product is sub-
9	ject to a REMS with ETASU—
10	(aa) the eligible product de-
11	veloper has obtained a covered
12	product authorization from the
13	Secretary in accordance with sub-
14	paragraph (B); and
15	(bb) the eligible product de-
16	veloper has provided a copy of
17	the covered product authorization
18	to the license holder;
19	(ii) that, as of the date on which the
20	civil action is filed, the product developer
21	has not obtained sufficient quantities of
22	the covered product on commercially rea-
23	sonable, market-based terms;
24	(iii) that the eligible product developer
25	has requested to purchase sufficient quan-

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1	tities of the covered product from the li-
2	cense holder; and
3	(iv) that the license holder has not de-
4	livered to the eligible product developer
5	sufficient quantities of the covered product
6	on commercially reasonable, market-based
7	terms—
8	(I) for a covered product that is
9	not subject to a REMS with ETASU,
10	by the date that is 31 days after the
11	date on which the license holder re-
12	ceived the request for the covered
13	product; and
14	(II) for a covered product that is
15	subject to a REMS with ETASU, by
16	31 days after the later of—
17	(aa) the date on which the
18	license holder received the re-
19	quest for the covered product; or
20	(bb) the date on which the
21	license holder received a copy of
22	the covered product authorization
23	issued by the Secretary in ac-
24	cordance with subparagraph (B).

1	(B) Authorization for covered prod-
2	UCT SUBJECT TO A REMS WITH ETASU.—
3	(i) REQUEST.—An eligible product de-
4	veloper may submit to the Secretary a
5	written request for the eligible product de-
6	veloper to be authorized to obtain suffi-
7	cient quantities of an individual covered
8	product subject to a REMS with ETASU.
9	(ii) AUTHORIZATION.—Not later than
10	120 days after the date on which a request
11	under clause (i) is received, the Secretary
12	shall, by written notice, authorize the eligi-
13	ble product developer to obtain sufficient
14	quantities of an individual covered product
15	subject to a REMS with ETASU for pur-
16	poses of—
17	(I) development and testing that
18	does not involve human clinical trials,
19	if the eligible product developer has
20	agreed to comply with any conditions
21	the Secretary determines necessary; or
22	(II) development and testing that
23	involves human clinical trials, if the
24	eligible product developer has—

1	(aa)(AA) submitted proto-
2	cols, informed consent docu-
3	ments, and informational mate-
4	rials for testing that include pro-
5	tections that provide safety pro-
6	tections comparable to those pro-
7	vided by the REMS for the cov-
8	ered product; or
9	(BB) otherwise satisfied the
10	Secretary that such protections
11	will be provided; and
12	(bb) met any other require-
13	ments the Secretary may estab-
14	lish.
15	(iii) NOTICE.—A covered product au-
16	thorization issued under this subparagraph
17	shall state that the provision of the covered
18	product by the license holder under the
19	terms of the authorization will not be a
20	violation of the REMS for the covered
21	product.
22	(3) AFFIRMATIVE DEFENSE.—In a civil action
23	brought under paragraph (1), it shall be an affirma-
24	tive defense, on which the defendant has the burden
25	of persuasion by a preponderance of the evidence—

1	(A) that, on the date on which the eligible
2	product developer requested to purchase suffi-
3	cient quantities of the covered product from the
4	license holder—
5	(i) neither the license holder nor any
6	of its agents, wholesalers, or distributors
7	was engaged in the manufacturing or com-
8	mercial marketing of the covered product;
9	and
10	(ii) neither the license holder nor any
11	of its agents, wholesalers, or distributors
12	otherwise had access to inventory of the
13	covered product to supply to the eligible
14	product developer on commercially reason-
15	able, market-based terms;
16	(B) that—
17	(i) the license holder sells the covered
18	product through agents, distributors, or
19	wholesalers;
20	(ii) the license holder has placed no
21	restrictions, explicit or implicit, on its
22	agents, distributors, or wholesalers to sell
23	covered products to eligible product devel-
29	covered products to engine product dever

1	(iii) the covered product can be pur-
2	chased by the eligible product developer in
3	sufficient quantities on commercially rea-
4	sonable, market-based terms from the
5	agents, distributors, or wholesalers of the
6	license holder; or
7	(C) that the license holder made an offer
8	to sell sufficient quantities of the covered prod-
9	uct to the eligible product developer at commer-
10	cially reasonable market-based terms—
11	(i) for a covered product that is not
12	subject to a REMS with ETASU, by the
13	date that is 14 days after the date on
14	which the license holder received the re-
15	quest for the covered product, and the eli-
16	gible product developer did not accept such
17	offer by the date that is 7 days after the
18	date on which the eligible product devel-
19	oper received such offer from the license
20	holder; or
21	(ii) for a covered product that is sub-
22	ject to a REMS with ETASU, by the date
23	that is 20 days after the date on which the
24	license holder received the request for the
25	covered product, and the eligible product

1	developer did not accept such offer by the
2	date that is 10 days after the date on
3	which the eligible product developer re-
4	ceived such offer from the license holder.
5	(4) Methods for transmission of Re-
6	QUESTS FOR COVERED PRODUCTS.—A written re-
7	quest for a covered product, offer to sell a covered
8	product, or acceptance of such an offer between the
9	eligible product developer and the license holder
10	shall be made by—
11	(A) certified or registered mail with return
12	receipt requested;
13	(B) personal delivery; or
14	(C) electronic means.
15	(5) Remedies.—
16	(A) IN GENERAL.—If an eligible product
17	developer prevails in a civil action brought
18	under paragraph (1), the court shall—
19	(i) order the license holder to provide
20	to the eligible product developer without
21	delay sufficient quantities of the covered
22	product on commercially reasonable, mar-
23	ket-based terms;

1	(ii) award to the eligible product de-
2	veloper reasonable attorney's fees and costs
3	of the civil action; and
4	(iii) award to the eligible product de-
5	veloper a monetary amount sufficient to
6	deter the license holder from failing to pro-
7	vide eligible product developers with suffi-
8	cient quantities of a covered product on
9	commercially reasonable, market-based
10	terms, if the court finds, by a preponder-
11	ance of the evidence—
12	(I) that the license holder delayed
13	providing sufficient quantities of the
14	covered product to the eligible product
15	developer without a legitimate busi-
16	ness justification; or
17	(II) that the license holder failed
18	to comply with an order issued under
19	clause (i).
20	(B) MAXIMUM MONETARY AMOUNT.—A
21	monetary amount awarded under subparagraph
22	(A)(iii) shall not be greater than the revenue
23	that the license holder earned on the covered
24	product during the period—

(i) beginning on—

1	(I) for a covered product that is
2	not subject to a REMS with ETASU,
3	the date that is 31 days after the date
4	on which the license holder received
5	the request; or
6	(II) for a covered product that is
7	subject to a REMS with ETASU, the
8	date that is 31 days after the later
9	of—
10	(aa) the date on which the
11	license holder received the re-
12	quest; or
13	(bb) the date on which the
14	license holder received a copy of
15	the covered product authorization
16	issued by the Secretary in ac-
17	cordance with paragraph $(2)(B)$ ;
18	and
19	(ii) ending on the date on which the
20	eligible product developer received suffi-
21	cient quantities of the covered product.
22	(C) AVOIDANCE OF DELAY.—The court
23	may issue an order under subparagraph (A)(i)
24	before conducting further proceedings that may
25	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.

4 (c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under 5 Federal, State, or local law arising out of the failure of 6 7 an eligible product developer to follow adequate safeguards 8 to assure safe use of the covered product during develop-9 ment or testing activities described in this section, including transportation, handling, use, or disposal of the cov-10 ered product by the eligible product developer. 11

(d) NO VIOLATION OF REMS.—Section 505–1 of the
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–
1) is amended by adding at the end the following new subsection:

16 "(1) Provision of Samples Not a Violation of STRATEGY.—The provision of samples of a covered prod-17 uct to an eligible product developer (as those terms are 18 19 defined in section 2(a) of the Creating and Restoring Equal Access to Equivalent Samples Act of 2019) shall 2021 not be considered a violation of the requirements of any 22 risk evaluation and mitigation strategy that may be in 23 place under this section for such drug.".

24 (e) RULE OF CONSTRUCTION.—

1	(1) DEFINITION.—In this subsection, the term
2	"antitrust laws"—
3	(A) has the meaning given the term in
4	subsection (a) of the first section of the Clayton
5	Act (15 U.S.C. 12); and
6	(B) includes section 5 of the Federal
7	Trade Commission Act (15 U.S.C. 45) to the
8	extent that such section applies to unfair meth-
9	ods of competition.
10	(2) ANTITRUST LAWS.—Nothing in this section
11	shall be construed to limit the operation of any pro-
12	vision of the antitrust laws.
13	SEC. 3. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-
13 14	SEC. 3. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL- ERS.
14	ERS.
14 15	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2,
14 15 16	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2,
14 15 16 17	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2, is further amended—
14 15 16 17 18	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2, is further amended— (1) in subsection (g)(4)(B)—
14 15 16 17 18 19	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2, is further amended— (1) in subsection (g)(4)(B)— (A) in clause (i) by striking "or" after the
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> </ol>	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2, is further amended— (1) in subsection (g)(4)(B)— (A) in clause (i) by striking "or" after the semicolon;
14 15 16 17 18 19 20 21	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2, is further 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
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	ERS. Section 505–1 of the Federal Food, Drug, and Cos- metic Act (21 U.S.C. 355–1), as amended by section 2, is further 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

1	safe use for a drug that is the subject of
2	an application under section 505(j), and
3	the applicable listed drug.";
4	(2) in subsection (i)(1), by striking subpara-
5	graph (C) and inserting the following:
6	"(C)(i) Elements to assure safe use, if re-
7	quired under subsection (f) for the listed drug,
8	which, subject to clause (ii), for a drug that is
9	the subject of an application under section
10	505(j) may use—
11	"(I) a single, shared system with the
12	listed drug under subsection (f); or
13	"(II) a different, comparable aspect of
14	the elements to assure safe use under sub-
15	section (f).
16	"(ii) The Secretary may require a drug
17	that is the subject of an application under sec-
18	tion 505(j) and the listed drug to use a single,
19	shared system under subsection (f), if the Sec-
20	retary determines that no different, comparable
21	aspect of the elements to assure safe use could
22	satisfy the requirements of subsection (f).";
23	(3) in subsection (i), by adding at the end the
24	following:

1 "(3) SHARED REMS.—If the Secretary ap-2 proves, in accordance with paragraph (1)(C)(i)(II), a 3 different, comparable aspect of the elements to as-4 sure safe use under subsection (f) for a drug that 5 is the subject of an abbreviated new drug application 6 under section 505(j), the Secretary may require that 7 such different comparable aspect of the elements to 8 assure safe use can be used with respect to any 9 other drug that is the subject of an application 10 under section 505(j) or 505(b) that references the 11 same listed drug."; and

12 (4) by adding at the end the following:

13 "(m) SEPARATE REMS.—When used in this section, 14 the terms "different, comparable aspect of the elements to assure safe use" or "different, comparable approved 15 risk evaluation and mitigation strategies" means a risk 16 17 evaluation and mitigation strategy for a drug that is the 18 subject of an application under section 505(j) that uses 19 different methods or operational means than the strategy 20 required under subsection (a) for the applicable listed 21 drug, or other application under section 505(j) with the 22 same such listed drug, but achieves the same level of safe-23 ty as such strategy.".

#### 1 SEC. 4. RULE OF CONSTRUCTION.

2 (a) IN GENERAL.—Nothing in this Act, the amend3 ments made by this Act, or in section 505–1 of the Fed4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–1),
5 shall be construed as—

6 (1) prohibiting a license holder from providing
7 an eligible product developer access to a covered
8 product in the absence of an authorization under
9 this Act; or

10 (2) in any way negating the applicability of a
11 REMS with ETASU, as otherwise required under
12 such section 505–1, with respect to such covered
13 product.

(b) DEFINITIONS.—In this section, the terms "covered product", "eligible product developer", "license holder", and "REMS with ETASU" have the meanings given
such terms in section 3(a).

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