116TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPT. 116–55
Part 1

CREATING AND RESTORING EQUAL ACCESS TO EQUIVALENT SAMPLES ACT OF 2019

MAY 10, 2019.—Ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 965]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 965) 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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

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 2019" or the "CREATES Act of 2019".

SEC. 2. 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(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 (c) 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—

(i) the drug or biological product has been on the drug shortage list in effect under such section 506E continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage.

(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(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 the eligible product developer determines allows it 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 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;

(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; or

(C) that the license holder made an offer to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product developer received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) METHODS FOR TRANSMISSION OF REQUESTS FOR COVERED PRODUCTS.—A written request for a covered product, offer to sell a covered product, or acceptance of such an offer between the eligible product developer and the license holder shall be made by—

(A) certified or registered mail with return receipt requested;

(B) personal delivery; or

(C) electronic means.

(5) 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 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.—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:

"(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 2(a) of the Creating and Restoring Equal Access to Equivalent Samples Act of 2019) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under this section 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. 3. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic 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

(C) by adding at the end the following:

"(iii) accommodate different, comparable aspects of the elements to assure safe use 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).";

(3) in subsection (i), by adding at the end the following:

"(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use

under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug."; and

(4) by adding at the end the following:

"(m) 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.".

SEC. 4. RULE OF CONSTRUCTION.

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

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

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

PURPOSE AND SUMMARY

H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples Act of 2019", was introduced on February 5, 2019, by Reps. Cicilline (D–RI), Sensenbrenner (R–WI), Nadler (D–NY), Collins (R–GA), Welch (D–VT), and McKinley (R–WV), and referred to the Committee on Energy and Commerce and the Committee on the Judiciary. H.R. 965 clarifies the process by which a generic manufacturer could seek Food and Drug Administration (FDA) authorization to obtain sufficient quantities of samples for testing. The bill would also allow a generic manufacturer facing delays in receiving the requested samples to bring an action in federal court to obtain the samples it needs. Courts would be authorized to award monetary damages sufficient to deter future gaming. It would also clarify the FDA's discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system instead of entering a shared safety protocol with brand manufacturers, provided that such separate protocol meets the same safety standard as the original system.

BACKGROUND AND NEED FOR LEGISLATION

Drug prices in the United States see considerable reductions through market availability of multiple generic drugs following expiration of market exclusivity.[1] FDA found that generic competition helps decrease prices most significantly when a third competing product is introduced into the market. Drug prices also continue to decrease with additional market entry—even up to the seventh competing product.[2]

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[1] AS Kesselheim, J Avorn, & A Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform* (2016) (https://www.ncbi.nlm.nih.gov/pubmed/27552619).

[2] Food and Drug Administration (FDA), *"Generic Competition and Drug Prices."* (https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm).

Access to brand drug samples is integral to the competition contemplated by the Hatch-Waxman Act.[3] Some branded drug manufacturers use restricted distribution systems—including safety protocols called Risk Evaluation and Mitigation Strategies or REMS—to delay or impede generic competition through the delay or denial of the sale of samples needed to conduct testing necessary for purposes of FDA approval, or through the delay of negotiations on single, shared protocols.[4] [5]

The CREATES Act seeks to discourage the delay or denial of the sale of samples needed for purposes of submitting an application to the FDA by allowing a manufacturer facing delay tactics to bring an action in federal court for injunctive relief. Courts would be authorized to award monetary damages in an amount sufficient to deter gaming by brand manufacturers. FDA would also be given clarified discretion to allow generic manufacturers to operationalize equivalent safety protocols in a different separate system rather than enter a shared safety protocol with brand manufacturers.

COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 965:

The Subcommittee on Health held a legislative hearing entitled, "Lowing the Cost of Prescription Drugs: Reducing Barriers to Market Competition" on March 13, 2019, to consider H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" and six other bills. The Subcommittee received testimony from the following witnesses:

(1) Lou Kennedy, Chief Executive Officer and Owner, Nephron Pharmaceuticals;

(2) Anthony Barrueta, Senior Vice President for Government Relations, Kaiser Permanente;

(3) Michael Carrier, Distinguished Professor, Rutgers Law School;

(4) Kurt Karst, Director, Hyman, Phelps & McNamara, P.C.;

(5) Jeff Kushan, Partner, Sidley Austin LLP;

(6) Marc M. Boutin, JD, Chief Executive Officer, National Health Council; and

(7) Chester "Chip" Davis, Jr., President and Chief Executive Officer, Association for Accessible Medicines.

COMMITTEE CONSIDERATION

H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" or the "CREATES Act of 2019", was introduced on February 5, 2019, by Rep. David N. Cicilline (D–RI), and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on February 6, 2019. Following legislative hearings, the Subcommittee met in open markup session, pursuant to notice, on H.R. 965 on

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[3] Michael Carrier, *Sharing, Samples, and Generics: An Antitrust Framework* (2017) (http://cornelllawreview.org/files/2017/11/1.Carrierfinal.pdf).

[4] Alex Brill, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers* (2018) (https://accessiblemeds.org/sites/default/files/201809/REMS_WhitePaper_September2018%5B2%5D.pdf).

[5] Id. 3

March 26, 2019, for consideration of the bill. An amendment was offered by Mr. Welch (D–VT) was agreed to by a voice vote. An amendment by Mr. Gianforte (R–MT) and an amendment by Mr. Buchson (R–IN) were each defeated by a voice vote. Subsequently, the Subcommittee on Health agreed to a motion by Ms. Eshoo, Chairwoman of the Subcommittee, to favorably forward H.R. 965, amended, to the full Committee on Energy and Commerce by a voice vote.

On April 3, 2019, the full Committee met in open markup session, pursuant to notice, to consider H.R. 965. During markup of the bill, an amendment in the nature of a substitute offered by Mr. Pallone (D–NJ) was adopted by a voice vote. At the conclusion of consideration of the bill, the full Committee agreed to a motion by Mr. Pallone, Chairman of the Committee, to order H.R. 965 favorably reported to the House, amended, by a record vote of 51 yeas to 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that a record vote was taken on final passage of H.R. 965. A motion by Mr. Pallone to order H.R. 965 favorably reported to the House, amended, was agreed to by a record vote of 51 yeas to 0 nays. The following is that record vote taken during Committee consideration, including the names of those members voting for and against:

COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 14

BILL: H.R. 965, the "CREATES Act of 2019"

MOTION: A motion by Mr. Pallone to order H.R. 965 favorably reported to the House, amended. (Final Passage)

DISPOSITION: AGREED TO by a roll call vote of 51 yeas to 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone	X			Rep. Walden	X		
Rep. Rush	X			Rep. Upton	X		
Rep. Eshoo	X			Rep. Shimkus	X		
Rep. Engel				Rep. Burgess	X		
Rep. DeGette	X			Rep. Scalise			
Rep. Doyle	X			Rep. Latta	X		
Rep. Schakowsky	X			Rep. Rodgers	X		
Rep. Butterfield	X			Rep. Guthrie	X		
Rep. Matsui	X			Rep. Olson	X		
Rep. Castor	X			Rep. McKinley	X		
Rep. Sarbanes	X			Rep. Kinzinger	X		
Rep. McNerney	X			Rep. Griffith	X		
Rep. Welch	X			Rep. Bilirakis	X		
Rep. Lujan	X			Rep. Johnson	X		
Rep. Tonko	X			Rep. Long	X		
Rep. Clarke	X			Rep. Buschon	X		
Rep. Loebsack	X			Rep. Flores	X		
Rep. Schrader	X			Rep. Brooks	X		
Rep. Kennedy	X			Rep. Mullin			
Rep. Cardenas	X			Rep. Hudson	X		
Rep. Ruiz	X			Rep. Walberg	X		
Rep. Peters	X			Rep. Carter	X		
Rep. Dingell	X			Rep. Duncan	X		
Rep. Veasey	X			Rep. Gianforte	X		
Rep. Kuster	X						
Rep. Kelly	X						
Rep. Barragan	X						
Rep. McEachin							
Rep. Blunt Rochester	X						
Rep. Soto	X						
Rep. O'Halleran	X						

04/03/2019

OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 965 from the Director of the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 25, 2019.

Hon. FRANK PALLONE, Jr.,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 965, the CREATES Act of 2019.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

KEITH HALL,
Director.

Enclosure.

H.R. 965, the CREATES Act of 2019

As ordered reported by the House Committee on Energy and Commerce on April 3, 2019

Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-901	-3,299
Revenues	0	165	609
Deficit Effect	0	-1,066	-3,908
Spending Subject to Appropriation (Outlays)	0	-118	n.e.

Pay-as-you-go procedures apply?	Yes	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

n.e. = not estimated.

H.R. 965 would create a private right of action that would allow developers of generic drugs or biosimilar products to bring civil lawsuits against manufacturers of brand-name drugs if sufficient quantities of reference samples of a branded product are not made available for premarket testing. (To obtain marketing approval of their products from the Food and Drug Administration (FDA), developers of generic or biosimilar drugs currently must purchase reference samples to conduct the testing required to demonstrate that their drugs meet the FDA's approval criteria.)

The bill also would remove a statutory requirement that manufacturers of generic or biosimilar versions of certain drugs that carry a significant risk of serious side effects use the same risk management system as the brand-name reference drug to ensure safe use of the product. Instead, it would provide the FDA with more discretion to allow those manufacturers to use comparable safety systems on a case-by-case basis.

CBO expects that the bill's provisions would allow generic drugs (including biosimilar versions of biologics) to enter the market earlier, on average, than they would under current law. Because of the earlier entry of lower-priced generic drugs, CBO estimates, enacting the legislation would reduce federal spending on prescription drugs and subsidies for health insurance. In total, CBO estimates that enacting H.R. 965 would decrease the deficit by $3.9 billion over the 2019–2029 period. That amount includes a $3.3 billion reduction in direct spending and a $0.6 billion increase in revenues.

CBO also estimates that implementing H.R. 965 would decrease spending subject to appropriation by $118 million over the 2019–2024 period, assuming appropriation actions consistent with the bill. That decrease would result primarily because lower estimated drug prices would reduce costs for discretionary health programs.

The estimated budgetary effect of H.R 965 is shown in Table 1. The effects of the legislation fall primarily within budget functions 550 (health), and 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 965

	By Fiscal Year, Millions of Dollars—												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019–2024	2019–2029
Decreases (−) in Direct Spending													
Estimated Budget Authority	0	0	−47	−179	−310	−365	−424	−450	−478	−542	−503	−901	−3,299
Estimated Outlays	0	0	−47	−179	−310	−365	−424	−450	−478	−542	−503	−901	−3,299
On-budget	0	0	−47	−178	−308	−363	−423	−448	−476	−540	−501	−897	−3,284
Off-budget[a]	0	0	*	−1	−2	−2	−2	−2	−2	−2	−2	−5	−15
Increases in Revenues													
Estimated Revenues	0	0	9	31	56	70	76	85	91	95	99	165	609
On-budget	0	0	6	22	40	50	55	63	68	71	74	119	448
Off-budget	0	0	2	9	16	20	21	22	23	24	25	46	161
Net Decrease (−) in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	0	−55	−210	−366	−435	−500	−535	−568	−637	−602	−1,066	−3,908
On-budget	0	0	−53	−200	−348	−414	−477	−511	−544	−611	−575	−1,015	−3,732
Off-budget	0	0	−3	−9	−17	−21	−23	−24	−25	−26	−27	−51	−175
Increases or Decreases (−) in Spending Subject to Appropriation													
Estimated Authorization	0	1	−7	−23	−41	−47	n.e.	n.e.	n.e.	n.e.	n.e.	−118	n.e.
Estimated Outlays	0	1	−7	−23	−41	−47	n.e.	n.e.	n.e.	n.e.	n.e.	−118	n.e.

Components may not sum to totals because of rounding; n.e. = not estimated; * = between −$500,000 and zero.
[a] Includes off-budget effects on the operating costs of the U.S. Postal Service.

The CBO staff contact for this estimate is Ellen Werble. The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is 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.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 965 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 965 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 states that the Act may be cited as the "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" or the "CREATES Act of 2019".

Section 2. Actions for delays of generic drugs and biosimilar biological products

Subsection (a) clarifies the meaning of key terms used in the legislation. Such terms include:

- "Commercially Reasonable, Market-Based Terms" to include only the following: a non-discriminatory price that is at or below the most recent wholesale acquisition cost for that drug product and a schedule for delivery that meets the required timelines outlined in the bill.
- "Covered Product" as any drug approved under section 505 or any biological product that is licensed under section 351 of the Public Health Services Act (PHSA), including any combination of products and when reasonably necessary to demonstrate sameness, biosimilarity, or interchangeability, any product, including any device, that is marketed or intended for use with such drug or biological product. This definition is intended to include all drug products and biologics with the exception of products that are on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act, unless the product has been on the shortage list continuously for more than 6 months or the Secretary determines that inclusion of the drug in the covered product definition is likely to contribute to alleviating or preventing a shortage.
- "Eligible Product Developer" as a person that seeks to develop an application for the approval of a drug under section 505(b) or 505(j) or the licensing of a biological product under section 351 of the PHSA. This definition is intended to include developers of generic products, 505(b)(2) drug products, and biosimilars.
- "License Holder" refers to the holder of an application or a license for a covered product (including the holder's agents, wholesalers, distributors, assigns, and corporate affiliates).
- "Sufficient Quantities" refers to an amount of the covered product that the eligible product developer determines allows it to conduct the necessary testing to support their application and meet any additional regulatory requirements.

Subsection (b) allows an eligible product developer to bring a civil action against a license holder if the license holder has refused to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

Paragraph (b)(2) sets out a series of elements that the eligible product developer must prove by a preponderance of evidence to prevail in their case. Evidence for such a case would include: as of the date the civil action is filed that the eligible product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms; that the eligible product developer had made a request; and that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms.

Further, paragraph (b)(2) allows eligible product developers to request authorization to access products subject to REMS with elements to assure safe use (ETASU) if they meet certain safety conditions or otherwise satisfy the FDA that such protections will be

provided, to receive from FDA authorization to obtain an individual covered product for development and testing purposes. The committee intends this subparagraph to require the FDA to make an authorization decision within 120 days of receiving such request. It further provides that the contents of such request must meet FDA requirements to provide safety protections comparable to those provided by the REMS for the covered product, including specific conditions related to protections for any clinical trial protocols.

Paragraph (b)(3) establishes several affirmative defenses for the license holder, including to show that it has placed no restrictions on its agents, distributors, or wholesalers to sell covered products to generic manufacturers; that the product can be purchased by the generic manufacturer in sufficient quantities on commercially reasonable, market-based terms; or that the license holder made an offer via appropriate means to sell sufficient quantities of the covered product to the eligible product developer at commercially-reasonable, market-based terms and that the eligible product developer did not accept the offer within a reasonable timeframe.

Paragraph (b)(4) specifies that a written request, offer to sell, or acceptive of such offer of a covered product between the eligible product developer and license holder shall be made by certified or registered mail with return receipt requests; personal delivery; or electronic means.

Paragraph (b)(5) provides three remedies available to the court if the eligible product developer prevails. First, the court shall order that the license holder provide without delay sufficient quantities of the covered product on commercially reasonable, market-based terms to the eligible product developer. Second, the court shall also award reasonable attorney's fees and costs of the civil action to the eligible product developer. And finally, the court shall also award a monetary amount sufficient to deter the license holder from failing to provide sufficient quantities of a covered product on commercially reasonable, market-based terms.

Subsection (c) provides that a license holder shall not be liable for any claim 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.

Subsection (d) clarifies that the provision of samples from a license holder to an eligible product developer is not a violation of REMS requirements.

Subsection (e) clarifies the term "antitrust laws" and specifies that nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

Section 3. REMS approval process for subsequent filers

Section 3 provides the FDA with the authority to waive the requirement that brand and generic developers participate in a shared safety protocol and clarifies that a generic drug developer would only be allowed to develop their own protocol if the FDA determines to their satisfaction that the generic protocol, while different, provides the same level of patient safety protections as the previously approved brand protocol.

Section 4. Rule of construction

Section 4 clarifies that this legislation does not require eligible product developers to obtain an authorization before seeking access to samples, and that the bill does not negate any requirements related to REMS with ETASU.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * * * *

SEC. 505–1. RISK EVALUATION AND MITIGATION STRATEGIES.

(a) SUBMISSION OF PROPOSED STRATEGY.—

(1) INITIAL APPROVAL.—If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

(A) The estimated size of the population likely to use the drug involved.

(B) The seriousness of the disease or condition that is to be treated with the drug.

(C) The expected benefit of the drug with respect to such disease or condition.

(D) The expected or actual duration of treatment with the drug.

(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

(F) Whether the drug is a new molecular entity.

(2) POSTAPPROVAL REQUIREMENT.—

(A) IN GENERAL.—If the Secretary has approved a covered application (including an application approved before the effective date of this section) and did not when approving the application require a risk evaluation and mitigation strategy under paragraph (1), the Secretary, in consultation with the offices described in paragraph (1), may

subsequently require such a strategy for the drug involved (including when acting on a supplemental application seeking approval of a new indication for use of the drug) if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

(B) SUBMISSION OF PROPOSED STRATEGY.—Not later than 120 days after the Secretary notifies the holder of an approved covered application that the Secretary has made a determination under subparagraph (A) with respect to the drug involved, or within such other reasonable time as the Secretary requires to protect the public health, the holder shall submit to the Secretary a proposed risk evaluation and mitigation strategy.

(3) ABBREVIATED NEW DRUG APPLICATIONS.—The applicability of this section to an application under section 505(j) is subject to subsection (i).

(4) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(b) DEFINITIONS.—For purposes of this section:

(1) ADVERSE DRUG EXPERIENCE.—The term "adverse drug experience" means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—

(A) an adverse event occurring in the course of the use of the drug in professional practice;

(B) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

(C) an adverse event occurring from abuse of the drug;

(D) an adverse event occurring from withdrawal of the drug; and

(E) any failure of expected pharmacological action of the drug, which may include reduced effectiveness under the conditions of use prescribed in the labeling of such drug, but which may not include reduced effectiveness that is in accordance with such labeling.

(2) COVERED APPLICATION.—The term "covered application" means an application referred to in section 505(p)(1)(A).

(3) NEW SAFETY INFORMATION.—The term "new safety information", with respect to a drug, means information derived from a clinical trial, an adverse event report, a postapproval study (including a study under section 505(o)(3)), or peer-reviewed biomedical literature; data derived from the postmarket risk identification and analysis system under section 505(k); or other scientific data deemed appropriate by the Secretary about—

(A) a serious risk or an unexpected serious risk associated with use of the drug that the Secretary has become aware of (that may be based on a new analysis of existing information) since the drug was approved, since the risk evaluation and mitigation strategy was required, or since

the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

(B) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the last assessment of such strategy.

(4) SERIOUS ADVERSE DRUG EXPERIENCE.—The term "serious adverse drug experience" is an adverse drug experience that—

(A) results in—

(i) death;

(ii) an adverse drug experience that places the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form);

(iii) inpatient hospitalization or prolongation of existing hospitalization;

(iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

(v) a congenital anomaly or birth defect; or

(B) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(5) SERIOUS RISK.—The term "serious risk" means a risk of a serious adverse drug experience.

(6) SIGNAL OF A SERIOUS RISK.—The term "signal of a serious risk" means information related to a serious adverse drug experience associated with use of a drug and derived from—

(A) a clinical trial;

(B) adverse event reports;

(C) a postapproval study, including a study under section 505(o)(3);

(D) peer-reviewed biomedical literature;

(E) data derived from the postmarket risk identification and analysis system under section 505(k)(4); or

(F) other scientific data deemed appropriate by the Secretary.

(7) RESPONSIBLE PERSON.—The term "responsible person" means the person submitting a covered application or the holder of the approved such application.

(8) UNEXPECTED SERIOUS RISK.—The term "unexpected serious risk" means a serious adverse drug experience that is not listed in the labeling of a drug, or that may be symptomatically and pathophysiologically related to an adverse drug experience identified in the labeling, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

(c) CONTENTS.—A proposed risk evaluation and mitigation strategy under subsection (a) shall—

(1) include the timetable required under subsection (d); and

(2) to the extent required by the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, include additional elements described in subsections (e) and (f).

(d) MINIMAL STRATEGY.—For purposes of subsection (c)(1), the risk evaluation and mitigation strategy for a drug shall require a timetable for submission of assessments of the strategy that—

(1) includes an assessment, by the date that is 18 months after the strategy is initially approved;

(2) includes an assessment by the date that is 3 years after the strategy is initially approved;

(3) includes an assessment in the seventh year after the strategy is so approved; and

(4) subject to paragraphs (1), (2), and (3)—

(A) is at a frequency specified in the strategy;

(B) is increased or reduced in frequency as necessary as provided for in subsection (g)(4)(A); and

(C) is eliminated after the 3-year period described in paragraph (1) if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed.

(e) ADDITIONAL POTENTIAL ELEMENTS OF STRATEGY.—

(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), may under such subsection require that the risk evaluation and mitigation strategy for a drug include 1 or more of the additional elements described in this subsection if the Secretary makes the determination required with respect to each element involved.

(2) MEDICATION GUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that, as applicable, the responsible person develop for distribution to each patient when the drug is dispensed—

(A) a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations); and

(B) a patient package insert, if the Secretary determines that such insert may help mitigate a serious risk of the drug.

(3) COMMUNICATION PLAN.—The risk evaluation and mitigation strategy for a drug may require that the responsible person conduct a communication plan to health care providers, if, with respect to such drug, the Secretary determines that such plan may support implementation of an element of the strategy (including under this paragraph). Such plan may include—

(A) sending letters to health care providers;

(B) disseminating information about the elements of the risk evaluation and mitigation strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests)

(C) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use; or

(D) disseminating information to health care providers about drug formulations or properties, including information about the limitations or patient care implications of such formulations or properties, and how such formula-

tions or properties may be related to serious adverse drug events associated with use of the drug.

(4) PACKAGING AND DISPOSAL.—The Secretary may require a risk evaluation mitigation strategy for a drug for which there is a serious risk of an adverse drug experience described in subparagraph (B) or (C) of subsection (b)(1), taking into consideration the factors described in subparagraphs (C) and (D) of subsection (f)(2) and in consultation with other relevant Federal agencies with authorities over drug disposal packaging, which may include requiring that—

(A) the drug be made available for dispensing to certain patients in unit dose packaging, packaging that provides a set duration, or another packaging system that the Secretary determines may mitigate such serious risk; or

(B) the drug be dispensed to certain patients with a safe disposal packaging or safe disposal system for purposes of rendering drugs nonretrievable (as defined in section 1300.05 of title 21, Code of Federal Regulations (or any successor regulation)) if the Secretary determines that such safe disposal packaging or system may mitigate such serious risk and is sufficiently available.

(f) PROVIDING SAFE ACCESS FOR PATIENTS TO DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD OTHERWISE BE UNAVAILABLE.—

(1) ALLOWING SAFE ACCESS TO DRUGS WITH KNOWN SERIOUS RISKS.—The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

(A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and

(B) for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

(2) ASSURING ACCESS AND MINIMIZING BURDEN.—Such elements to assure safe use under paragraph (1) shall—

(A) be commensurate with the specific serious risk listed in the labeling of the drug;

(B) within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

(C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

(i) patients with serious or life-threatening diseases or conditions;

(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

(iii) patients with functional limitations; and

(D) to the extent practicable, so as to minimize the burden on the health care delivery system—

(i) conform with elements to assure safe use for other drugs with similar, serious risks; and

(ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

(3) ELEMENTS TO ASSURE SAFE USE.—The elements to assure safe use under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

(A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider);

(B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification shall be available to any willing provider from a frontier area);

(C) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

(E) each patient using the drug be subject to certain monitoring; or

(F) each patient using the drug be enrolled in a registry.

(4) IMPLEMENTATION SYSTEM.—The elements to assure safe use under paragraph (1) that are described in subparagraphs (B), (C), and (D) of paragraph (3) may include a system through which the applicant is able to take reasonable steps to—

(A) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

(B) work to improve implementation of such elements by such persons.

(5) EVALUATION OF ELEMENTS TO ASSURE SAFE USE.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) or other advisory committee of the Food and Drug Administration, shall—

(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection for 1 or more drugs may be standardized so as not to be—

(i) unduly burdensome on patient access to the drug; and

(ii) to the extent practicable, minimize the burden on the health care delivery system;

(B) periodically evaluate, for 1 or more drugs, the elements to assure safe use of such drug to assess whether the elements—

(i) assure safe use of the drug;

(ii) are not unduly burdensome on patient access to the drug; and

(iii) to the extent practicable, minimize the burden on the health care delivery system; and

(C) considering such input and evaluations—

(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

(ii) modify elements under this subsection for 1 or more drugs as appropriate.

(6) ADDITIONAL MECHANISMS TO ASSURE ACCESS.—The mechanisms under section 561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this subsection. The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 561.

(7)

(8) LIMITATION.—No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 505(b)(2) or (j) or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.

(g) ASSESSMENT AND MODIFICATION OF APPROVED STRATEGY.—

(1) VOLUNTARY ASSESSMENTS.—After the approval of a risk evaluation and mitigation strategy under subsection (a), the responsible person involved may, subject to paragraph (2), submit to the Secretary an assessment of the approved strategy for the drug involved at any time.

(2) REQUIRED ASSESSMENTS.—A responsible person shall submit an assessment of the approved risk evaluation and mitigation strategy for a drug—

(A) when submitting a supplemental application for a new indication for use under section 505(b) or under section 351 of the Public Health Service Act, unless the drug is not subject to section 503(b) and the risk evaluation and mitigation strategy for the drug includes only the timetable under subsection (d);

(B) when required by the strategy, as provided for in such timetable under subsection (d);

(C) within a time period to be determined by the Secretary, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that an assessment is needed to evaluate whether the approved strategy should be modified to—

(i) ensure the benefits of the drug outweigh the risks of the drug; or

(ii) minimize the burden on the health care delivery system of complying with the strategy.

(3) REQUIREMENTS FOR ASSESSMENTS.—An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include, with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

(4) MODIFICATION.—

(A) ON INITIATIVE OF RESPONSIBLE PERSON.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. Such proposal may propose the addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support such proposed addition, modification, or removal of any goal or element of the strategy.

(B) ON INITIATIVE OF SECRETARY.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

(i) ensure the benefits of the drug outweigh the risks of the drug; **[**or**]**

(ii) minimize the burden on the health care delivery system of complying with the strategy**[**.**]***; or*

(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 505(j), and the applicable listed drug.

(h) REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS AND MODIFICATIONS OF APPROVED STRATEGIES.—

(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), shall promptly review each proposed risk evaluation and mitigation strategy for a drug submitted under subsection (a) and each assessment of and proposed modification to an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g), and, if necessary, promptly initiate discussions with the responsible person about such proposed strategy, assessment, or modification.

(2) ACTION.—

(A) IN GENERAL.—

(i) TIMEFRAME.—Unless the dispute resolution process described under paragraph (3) or (4) applies, and, except as provided in clause (ii) or clause (iii) below, the Secretary, in consultation with the offices described in subsection (c)(2), shall review and act on the proposed risk evaluation and mitigation strategy for a drug or any proposed modification to any required

strategy within 180 days of receipt of the proposed strategy or modification.

(ii) MINOR MODIFICATIONS.—The Secretary shall review and act on a proposed minor modification, as defined by the Secretary in guidance, within 60 days of receipt of such modification.

(iii) REMS MODIFICATION DUE TO SAFETY LABELING CHANGES.—Not later than 60 days after the Secretary receives a proposed modification to an approved risk evaluation and mitigation strategy to conform the strategy to approved safety labeling changes, including safety labeling changes initiated by the responsible person in accordance with FDA regulatory requirements, or to a safety labeling change that the Secretary has directed the holder of the application to make pursuant to section 505(o)(4), the Secretary shall review and act on such proposed modification to the approved strategy.

(iv) GUIDANCE.—The Secretary shall establish, through guidance, that responsible persons may implement certain modifications to an approved risk evaluation and mitigation strategy following notification to the Secretary.

(B) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under subparagraph (A).

(C) PUBLIC AVAILABILITY.—Upon acting on a proposed risk evaluation and mitigation strategy or proposed modification to a risk evaluation and mitigation strategy under subparagraph (A), the Secretary shall make publicly available an action letter describing the actions taken by the Secretary under such subparagraph (A).

(3) DISPUTE RESOLUTION AT INITIAL APPROVAL.—If a proposed risk evaluation and mitigation strategy is submitted under subsection (a)(1) in an application for initial approval of a drug and there is a dispute about the strategy, the responsible person shall use the major dispute resolution procedures as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(4) DISPUTE RESOLUTION IN ALL OTHER CASES.—

(A) REQUEST FOR REVIEW.—

(i) IN GENERAL.—The responsible person may, after the sponsor is required to make a submission under subsection (a)(2) or (g), request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board under subsection (j), except that the determination of the Secretary to require a risk evaluation and mitigation strategy is not subject to review under this paragraph. The preceding sentence does not prohibit review under this paragraph of the particular elements of such a strategy.

(ii) SCHEDULING.—Upon receipt of a request under clause (i), the Secretary shall schedule the dispute involved for review under subparagraph (B) and, not

later than 5 business days of scheduling the dispute for review, shall publish by posting on the Internet or otherwise a notice that the dispute will be reviewed by the Drug Safety Oversight Board.

(B) SCHEDULING REVIEW.—If a responsible person requests review under subparagraph (A), the Secretary—

(i) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

(ii) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application).

(C) AGREEMENT AFTER DISCUSSION OR ADMINISTRATIVE APPEALS.—

(i) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under subparagraph (A) shall not preclude further discussions to reach agreement on the risk evaluation and mitigation strategy, and such a request shall not preclude the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including appeals as described in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 for procedural or scientific matters involving the review of human drug applications and supplemental applications that cannot be resolved at the divisional level. At the time a review has been scheduled under subparagraph (B) and notice of such review has been posted, the responsible person shall either withdraw the request under subparagraph (A) or terminate the use of such administrative appeals.

(ii) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under subparagraph (G), the Secretary (in consultation with the offices described in subsection (c)(2)) and the responsible person may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

(D) MEETING OF THE BOARD.—At a meeting of the Drug Safety Oversight Board described in subparagraph (B), the Board shall—

(i) hear from both parties via written or oral presentation; and

(ii) review the dispute.

(E) RECORD OF PROCEEDINGS.—The Secretary shall ensure that the proceedings of any such meeting are recorded, transcribed, and made public within 90 days of the meeting. The Secretary shall redact the transcript to protect any trade secrets and other information that is ex-

empted from disclosure under section 552 of title 5, United States Code, or section 552a of title 5, United States Code.

(F) RECOMMENDATION OF THE BOARD.—Not later than 5 days after any such meeting, the Drug Safety Oversight Board shall provide a written recommendation on resolving the dispute to the Secretary. Not later than 5 days after the Board provides such written recommendation to the Secretary, the Secretary shall make the recommendation available to the public.

(G) ACTION BY THE SECRETARY.—

(i) ACTION LETTER.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

(I) the action deadline for the action letter on the application; or

(II) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

(ii) ORDER.—With respect to an assessment of an approved risk evaluation and mitigation strategy under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2), the Secretary shall issue an order, which shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

(H) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under subparagraph (G).

(I) EFFECT ON ACTION DEADLINE.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall be considered to have met the action deadline for the action letter on the application if the responsible person requests the dispute resolution process described in this paragraph and if the Secretary has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under subparagraphs (B), (F), and (G), respectively.

(J) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who reviews a drug or who participated in an administrative appeal under subparagraph (C)(i) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under subparagraph (D) to review a dispute about the risk evaluation and mitigation strategy for such drug.

(K) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under subparagraph (D) of the Drug Safety Oversight Board.

(5) USE OF ADVISORY COMMITTEES.—The Secretary may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

(A) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under subparagraph (B) or (C) of subsection (g)(2);

(B) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

(C) review a dispute under paragraph (3) or (4).

(6) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

(A) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary, in consultation with the offices described in subsection (c)(2), may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has convened 1 or more public meetings to consider possible responses to such concern.

(B) NOTICE.—If the Secretary defers an assessment under subparagraph (A), the Secretary shall—

(i) give notice of the deferral to the holder of the approved covered application not later than 5 days after the deferral;

(ii) publish the deferral in the Federal Register; and

(iii) give notice to the public of any public meetings to be convened under subparagraph (A), including a description of the deferral.

(C) PUBLIC MEETINGS.—Such public meetings may include—

(i) 1 or more meetings of the responsible person for such drugs;

(ii) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under paragraph (6); or

(iii) 1 or more workshops of scientific experts and other stakeholders.

(D) ACTION.—After considering the discussions from any meetings under subparagraph (A), the Secretary may—

(i) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

(ii) seek public comment about such action; and

(iii) after seeking such comment, issue an order addressing such regulatory action.

(7) INTERNATIONAL COORDINATION.—The Secretary, in consultation with the offices described in subsection (c)(2), may coordinate the timetable for submission of assessments under subsection (d), or a study or clinical trial under section 505(o)(3), with efforts to identify and assess the serious risks of such drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States. If the Secretary takes

action to coordinate such timetable, the Secretary shall give notice to the responsible person.

(8) EFFECT.—Use of the processes described in paragraphs (6) and (7) shall not be the sole source of delay of action on an application or a supplement to an application for a drug.

(i) ABBREVIATED NEW DRUG APPLICATIONS.—

(1) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under section 505(j) is subject to only the following elements of the risk evaluation and mitigation strategy required under subsection (a) for the applicable listed drug:

(A) A Medication Guide or patient package insert, if required under subsection (e) for the applicable listed drug.

(B) A packaging or disposal requirement, if required under subsection (e)(4) for the applicable listed drug.

[(C) Elements to assure safe use, if required under subsection (f) for the listed drug. A drug that is the subject of an abbreviated new drug application and the listed drug shall use a single, shared system under subsection (f). The Secretary may waive the requirement under the preceding sentence for a drug that is the subject of an abbreviated new drug application, and permit the applicant to use a different, comparable aspect of the elements to assure safe use, if the Secretary determines that—

[(i) the burden of creating a single, shared system outweighs the benefit of a single, system, taking into consideration the impact on health care providers, patients, the applicant for the abbreviated new drug application, and the holder of the reference drug product; or

[(ii) an aspect of the elements to assure safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that, as a trade secret, is entitled to protection, and the applicant for the abbreviated new drug application certifies that it has sought a license for use of an aspect of the elements to assure safe use for the applicable listed drug and that it was unable to obtain a license.

A certification under clause (ii) shall include a description of the efforts made by the applicant for the abbreviated new drug application to obtain a license. In a case described in clause (ii), the Secretary may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such abbreviated new drug application may use an aspect of the elements to assure safe use, if required under subsection (f) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.**]**

(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).

(2) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under section 505(j), the Secretary—

(A) shall undertake any communication plan to health care providers required under subsection (e)(3) for the applicable listed drug;

(B) shall permit packaging systems and safe disposal packaging or safe disposal systems that are different from those required for the applicable listed drug under subsection (e)(4); and

(C) shall inform the responsible person for the drug that is so approved if the risk evaluation and mitigation strategy for the applicable listed drug is modified.

(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug.

(j) DRUG SAFETY OVERSIGHT BOARD.—

(1) IN GENERAL.—There is established a Drug Safety Oversight Board.

(2) COMPOSITION; MEETINGS.—The Drug Safety Oversight Board shall—

(A) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

(B) include representatives from offices throughout the Food and Drug Administration, including the offices responsible for postapproval safety of drugs;

(C) include at least 1 representative each from the National Institutes of Health and the Department of Health and Human Services (other than the Food and Drug Administration);

(D) include such representatives as the Secretary shall designate from other appropriate agencies that wish to provide representatives; and

(E) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.

(k) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this section with respect to a qualified countermeasure (as defined in section 319F–1(a)(2) of the Public Health Service Act) to which a requirement under this section has been applied, if the Secretary determines that such waiver is

required to mitigate the effects of, or reduce the severity of, the circumstances under which—

(1) a determination described in subparagraph (A), (B), or (C) of section 564(b)(1) has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(2) the identification of a material threat described in subparagraph (D) of section 564(b)(1) has been made pursuant to section 319F–2 of the Public Health Service Act.

(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 2(a) of the Creating and Restoring Equal Access to Equivalent Samples Act of 2019) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under this section for such drug.

(m) 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.

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