

CREATING AND RESTORING EQUAL ACCESS TO
EQUIVALENT SAMPLES ACT OF 2019

MAY 10, 2019.—Committed to the Committee of the Whole House on the State of
the Union and ordered to be printed

Mr. NADLER, from the Committee on the Judiciary,
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 the Judiciary, 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 without amendment and recommend that the bill do pass.

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Purpose and Summary

H.R. 965, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019,” is designed to address the soaring cost of prescription drugs. The CREATES Act targets abusive delay tactics that are used to block the development of more

affordable generic and biosimilar medicines. The legislation establishes a private right of action against branded drug companies for generic drug companies that are unreasonably denied access to drug samples they require to conduct bioequivalence testing for Food and Drug Administration (FDA) approval. H.R. 965 also authorizes a court to award damages to deter misconduct by branded drug companies that withhold samples without a legitimate business justification. This legislation is supported by a broad coalition of healthcare providers, patient groups, and public-interest organizations, including AARP, Consumer Reports, and Public Citizen, among many others.¹

Background and Need for the Legislation

BACKGROUND

The CREATES Act addresses two delay tactics used by branded drug companies to block or delay entry by generic competitors. The first delay tactic occurs when brand-name drug companies prevent potential biosimilar and generic competitors from obtaining samples of branded drugs covered by the FDA’s Risk, Evaluation, and Mitigation Strategy (REMS) program—samples that the generics and biosimilar drug makers need to develop more affordable alternatives to brand-name products. The second delay tactic occurs when brand-name drug companies refuse to allow competitors to participate in a required safety protocol, which also may be intended to block generic or biosimilar competition. According to the non-partisan Congressional Budget Office (CBO), these delays impose significant costs in the form of higher Medicare expenses.²

The FDA’s Risk, Evaluation, and Mitigation Strategy (REMS) Program

The Food and Drug Administration Amendments Act of 2007 granted the FDA authority to require a REMS from drug manufacturers to ensure that a certain drug’s benefits outweigh its risks.³ The FDA has defined REMS as “required risk management plans that use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks.”⁴ Through REMS safety protocols, the FDA restricts the distribution of drugs with dangerous characteristics, such as high toxicities and severe side effects, to qualified medical professionals.⁵ Examples of REMS requirements include education

¹ See, e.g., Letter from AARP to Representative Jerrold Nadler (D–NY), Chair, H. Comm. on the Judiciary & Representative Doug Collins (R–GA), Ranking Member, H. Comm. on the Judiciary (Apr. 30, 2019); Letter from Consumer Reports to Representative Jerrold Nadler (D–NY), Chair, H. Comm. on the Judiciary & Representative Doug Collins (R–GA), Ranking Member, H. Comm. on the Judiciary (Apr. 29, 2019); Letter from Public Citizen to Representative Jerrold Nadler (D–NY), Chair, H. Comm. on the Judiciary & Representative Doug Collins (R–GA), Ranking Member, H. Comm. on the Judiciary (Apr. 29, 2019) (all on file with H. Comm. on the Judiciary Democratic staff).

² CONG. BUDGET OFFICE, H.R. 965 CREATING AND RESTORING EQUAL ACCESS TO EQUIVALENT SAMPLES ACT OF 2019 (2019), https://www.cbo.gov/system/files/2019-05/hr965_Judiciary.pdf.

³ AGATA DABROWSKA & SUSAN THAUL, CONG. RESEARCH SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 19 (2018), <https://fas.org/sgp/crs/misc/R41983.pdf>.

⁴ U.S. FOOD & DRUG ADMIN., A BRIEF OVERVIEW OF RISK EVALUATION & MITIGATION STRATEGIES (REMS) 2, <https://wayback.archive-it.org/7993/20190425135753/https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf>.

⁵ U.S. FOOD & DRUG ADMIN., REMS: FDA’S APPLICATION OF STATUTORY FACTORS IN DETERMINING WHEN A REMS IS NECESSARY 2–5 (2019), <https://www.fda.gov/media/100307/download>.

addressing possible risks of serious infection, certification and training of prescribers and dispensers, continued monitoring for liver damage, and required negative pregnancy tests before dispensing the drug to avoid severe birth defects.⁶

More restrictive REMS programs have “Elements to Assure Safe Use” (ETASU), which can include prescriber experience requirements, certification systems, patient monitoring or registration, and controlled distribution. These requirements restrict a drug’s distribution and affect how it can be sold to consumers.⁷ ETASU measures are “designed to be compatible with established distribution, procurement, and dispensing systems for drugs.”⁸ Since their initiation in 2007, REMS programs have become an increasingly prominent part of the FDA approval process.⁹ In 2014, nearly 40% of new drugs had REMS programs.¹⁰ Currently, over 60% of existing REMS include ETASU requirements.¹¹

In order to develop generic versions of branded drugs, generic manufacturers must acquire samples to conduct testing. ETASU restrictions, however, can limit the ability of generic manufacturers to obtain samples of REMS-restricted drugs for bioequivalence testing for an ANDA.¹² Without the ability to demonstrate bioequivalence in the ANDAs, potential generic entrants are unable to obtain FDA approval of drugs that would eventually compete with the REMS drugs.¹³

Unlike typical drugs that can be purchased easily on the marketplace, drugs covered by these safety protocols require direct negotiations with the branded manufacturer.¹⁴ While these negotiations generally center on ensuring safe testing and limiting liability, allegations have been made that branded drug companies are using REMS restrictions as excuses not to sell samples of their branded drugs to generic manufacturers.¹⁵

The FDA’s Single Shared REMS Program

After the generic has completed the necessary testing and is ready to seek FDA approval to enter the market with a generic version of a branded drug containing a REMS with ETASU program, the REMS statute requires the generic and branded manu-

⁶U.S. FOOD & DRUG ADMIN., RISK EVALUATION AND MITIGATION STRATEGIES (REMS) 4, <https://www.fda.gov/media/105565/download>.

⁷U.S. FOOD & DRUG ADMIN., A BRIEF OVERVIEW OF RISK EVALUATION & MITIGATION STRATEGIES (REMS) 13, <https://wayback.archive-it.org/7993/20190425135753/https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf>.

⁸ U.S.C. § 355–1(f)(2)(D)(ii) (2019).

⁹ALEX BRILL, LOST PRESCRIPTION DRUG SAVINGS FROM USE OF REMS PROGRAMS TO DELAY GENERIC MARKET ENTRY 1 (2014), https://static1.1.sqspcdn.com/static/f/460582/25228342/1406034596510/REMS_Study_July.pdf.

¹⁰*Id.*

¹¹ALEX BRILL, UNREALIZED SAVINGS FROM THE MISUSE OF REMS AND NON-REMS BARRIERS 2 (2018), https://accessiblemeds.org/sites/default/files/2018-09/REMS_WhitePaper_September2018%5B2%5D.pdf.

¹²*Id.*

¹³*Id.*

¹⁴Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Policies to Reduce the Ability of Brand Drugs Makers to Use REMS Programs as a Way to Block Timely Generic Drug Entry, Helping Promote Competition and Access (May 31, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policies-reduce-ability-brand-drug-makers-use-rems>.

¹⁵*See, e.g.*, Fed. Trade Comm’n Brief as Amicus Curiae at 2, Mylan Pharm. Inc. v. Celgene Corp., No. 14–cv–2094 (D.N.J. June 17, 2014), http://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf; Fed. Trade Comm’n Brief as Amicus Curiae at 2, Actelion Pharm. Ltd. v. Apotex Inc., No. 12–cv–05743 (D.N.J. Mar. 11, 2013), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et.al.v.apotex-inc./130311actelionamicusbrief.pdf.

facturers to work together to create a Single Shared REMS program (“SSRS”).¹⁶ The FDA may waive this shared-system requirement and allow a generic to file its own REMS in two situations. The first applies when the burden of creating a single, shared system outweighs the benefits.¹⁷ The second occurs when an aspect of the ETASU 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 generic certifies that it has taken (unsuccessful) steps to obtain a license.¹⁸

NEED FOR THE LEGISLATION

Branded drug manufacturers have allegedly abused the REMS process to block or delay entry by price-reducing generic competitors.¹⁹ One study estimates that American consumers have lost \$5.4 billion in annual savings due to delays in accessing drug samples caused by REMS misuse or other restricted access programs.²⁰ The CBO estimates that these delays cost taxpayers \$3.9 billion in direct government spending over a ten-year period.²¹

In response, potential generic entrants have attempted to use the antitrust laws to force manufacturers of REMS-restricted drugs to provide them with samples.²² Without these samples, generic manufacturers are unable to conduct necessary tests to demonstrate their products are “bioequivalent” to, or work in the same way as, their branded counterparts.

Antitrust litigation, however, is both immensely time-consuming and uncertain. As the non-partisan Congressional Research Service has noted, a “generic product developer’s ability to obtain relief for sample denial under antitrust law is currently uncertain. Under longstanding antitrust precedents, a company—even a monopolist—generally does not have a duty to deal with its competitors.”²³ Furthermore, even successful litigation may not provide complete relief for abusive delays. Markus Meier, then-Acting Director of the Federal Trade Commission’s (FTC’s) Bureau of Competition, testified before the Subcommittee on Regulatory Reform, Commercial, and Antitrust Law²⁴ last Congress that

even if a generic firm is ultimately able to prevail in an antitrust action and all subsequent appeals therefrom, such litigation can create substantial delays in obtaining the needed samples and a corresponding delay in generic

¹⁶ 21 U.S.C. 335-1(i)(1)(B).

¹⁷ *Id.* 335-1(i)(1)(B)(i).

¹⁸ *Id.* 335-1(i)(1)(B)(ii).

¹⁹ *See, e.g.*, Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Agency Efforts to Shine Light on Situations Where Drug Makers May Be Pursuing Gaming Tactics to Delay Generic Competition (May 17, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm>.

²⁰ ALEX BRILL, LOST PRESCRIPTION DRUG SAVINGS FROM USE OF REMS PROGRAMS TO DELAY GENERIC MARKET ENTRY 1 (2014), <https://static1.l.sqspcdn.com/static/f/460582/25228342/1406034596510/REMS Study July.pdf>.

²¹ CONG. BUDGET OFFICE, H.R. 965 CREATING AND RESTORING EQUAL ACCESS TO EQUIVALENT SAMPLES ACT OF 2019 (2019), https://www.cbo.gov/system/files/2019-05/hr965_Judiciary.pdf.

²² *See, e.g.*, Complaint at 4, Mylan Pharm. Inc. v. Celgene Corp., No. 14-cv-2094 (D.N.J. Apr. 3, 2014); Complaint for Declaratory Judgment at 7-8, Actelion Pharm. Ltd. v. Apotex Inc., No. 12-cv-05743 (D.N.J. Sept. 14, 2012).

²³ CONG. RESEARCH SERV., THE CREATES ACT OF 2019 AND LOWERING DRUG PRICES: LEGAL BACKGROUND & OVERVIEW 3 (2019), <https://fas.org/spp/crs/misc/LSB10272.pdf>.

²⁴ The Subcommittee on Regulatory Reform, Commercial, and Antitrust Law was renamed the Subcommittee on Antitrust, Commercial, and Administrative Law in the 116th Congress.

approval. Accordingly, even a successful antitrust challenge is unlikely to provide immediate redress.²⁵

Branded drug companies may also use the requirement of a SSRS to block generic entry. The generic drug manufacturer has to negotiate with the branded manufacturer to enter into a shared REMS programs before the generic drug can be approved.²⁶ The negotiations to reach agreement on a SSRS can extend for long periods of time, delaying market entry of a generic drug.²⁷ Under current law, branded companies have an opportunity to delay generic entry not only on the front end by denying access to samples, but also “on the back end of the [Abbreviated New Drug Application] process, by denying the generic firm access to the existing REMS distribution system so that the FDA cannot approve the generic firm’s ANDA application and labelling.”²⁸

Hearings

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to consider H.R. 965: Hearing on “Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive conduct in Health Care Markets,”²⁹ held before the Subcommittee on Antitrust, Commercial, and Administrative Law, on March 7, 2019.³⁰ At this hearing, several witnesses testified about competition issues in health care markets, including Dr. Fiona Scott Morton, Professor of Economics at Yale School of Management; Dr. Martin Gaynor, Professor of Economics and Health Policy at Carnegie Mellon University; Michael Kades, Director of Markets and Competition Policy at Washington Center for Equitable Growth; and Dr. Craig Garthwaite, Herman R. Smith Research Professor at Northwestern University’s Kellogg School of Management. In particular, Professor Scott Morton and Messrs. Kades and Garthwaite all expressed support for the CREATES Act.

In the 115th Congress, H.R. 2212, the CREATES Act of 2017, was introduced by then-Subcommittee Chair Tom Marino (R-PA) and then-Ranking Member David N. Cicilline (D-RI).³¹ The Senate companion, S. 974, was introduced by Senator Patrick Leahy (D-

²⁵ *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (2017) (statement of Mr. Markus Meier at 10), https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf.

²⁶ Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Policies to Reduce the Ability of Brand Drugs Makers to Use REMS Programs as a Way to Block Timely Generic Drug Entry, Helping Promote Competition and Access (May 31, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policies-reduce-ability-brand-drug-makers-use-rems>.

²⁷ *Id.*

²⁸ *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (2017) (statement of Mr. Markus Meier at 6–7), https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf.

²⁹ *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets, Hearing Before the Subcomm. on Antitrust, Commercial, and Administrative Law of the H. Comm. on the Judiciary*, 116th Cong. (2019).

³⁰ *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets, Hearing Before the Subcomm. on Antitrust, Commercial, and Administrative Law of the H. Comm. on the Judiciary*, 116th Cong. (2019).

³¹ Creating and Restoring Equal Access to Equivalent Samples Act of 2017, H.R. 2212, 115th Cong. (2017).

VT) and reported out of the Senate Judiciary Committee favorably.³²

In 2017, the Subcommittee held a two-paneled hearing on “Antitrust Concerns and the FDA Approval Process.”³³ On the first panel, the Subcommittee heard testimony from Dr. Scott Gottlieb, M.D., Commissioner of the FDA, and Markus Meier, Acting Director, Bureau of Competition at the Federal Trade Commission. On the second panel, the Subcommittee heard testimony from Professor David Olson, Boston College Law School; Professor Erika Lietzan, University of Missouri School of Law; Alden Abbott, the Heritage Foundation; and Professor Aaron Kesselheim, M.D., M.P.H., Harvard Medical School. At the hearing, Commissioner Gottlieb identified REMS abuse as an ongoing concern for the FDA, and Messrs. Meier and Abbott, Dr. Kesselheim, and Professor Olson all expressed support for the 2017 version of the CREATES Act, which is substantively identical to H.R. 965 in the 116th Congress.

Committee Consideration

On April 30, 2019, the Committee met in open session and ordered the bill, H.R. 965, favorably reported, without amendment, by voice vote, a quorum being present.

Committee Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that no rollcall votes occurred during the Committee’s consideration of H.R. 965.

Committee Oversight Findings

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

New Budget Authority and Tax Expenditures

Clause 3(c)(2) of rule XIII of the Rules of the House of Representatives is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

Congressional Budget Office Cost Estimate

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 965, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

³² Creating and Restoring Equal Access to Equivalent Samples Act of 2018, S. 974, 115th Cong. (as reported by S. Comm. on the Judiciary, June 21, 2018).

³³ *Antitrust Concerns and the FDA Approval Process, Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary, 115th Cong.* (2017).

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 8, 2019.

Hon. JERROLD NADLER,
*Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2375, the Preserve Access to Affordable Generics and Biosimilars Act.

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

Sincerely,

KEITH HALL,
Director.

Enclosure.

cc: Honorable Doug Collins
Ranking Member

H.R. 2375, Preserve Access to Affordable Generics and Biosimilars Act			
As ordered reported by the House Committee on the Judiciary on April 30, 2019			
By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-193	-520
Revenues	0	34	93
Deficit Effect	0	-227	-613
Spending Subject to Appropriation (Outlays)	0	-24	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?	Yes, Over Threshold
n.e. = not estimated.			

H.R. 2375 would make certain agreements—used to settle claims of patent infringement between sponsors of brand-name, generic, or biosimilar drugs and relating to the sale of a drug or biological product—presumptively illegal under antitrust law. The bill would require particular types of agreements arising from proceedings conducted by the Patent Trial and Appeal Board (PTAB) to be reported to Federal Trade Commission (FTC) and the Department of Justice (DOJ). H.R. 2375 also would establish the authority to impose civil penalties when a party to a settlement is found to have violated the bill's requirements.

CBO expects that the bill would accelerate the availability of lower-priced generic or biosimilar drugs that would have been affected by agreements targeted by the bill and reduce the average price of drugs paid by federal health programs that purchase drugs or provide health insurance that covers drugs. In total, CBO estimates that enacting H.R. 2375 would decrease the deficit by \$613 million over the 2019–2029 period. That amount includes a \$520 million reduction in direct spending and a \$93 million increase in revenues.

CBO also estimates that implementing H.R. 2375 would decrease spending subject to appropriation by \$24 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.

Details of the estimated budgetary effect of H.R. 2375 are shown in Table 1. Those effects fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 2375

	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	-21	-53	-63	-56	-58	-61	-65	-74	-69	-193	-520
Estimated Outlays	0	0	-21	-53	-63	-56	-58	-61	-65	-74	-69	-193	-520
On-Budget	0	0	-21	-53	-63	-56	-58	-61	-65	-74	-69	-192	-518
Off-Budget ^a	0	0	*	*	*	*	*	*	*	*	*	-1	-2
Increases in Revenues													
Estimated Revenues	0	0	3	9	11	11	10	11	12	12	13	34	93
On-Budget	0	0	3	6	8	8	7	8	9	9	10	25	69
Off-Budget	0	0	1	2	3	3	3	3	3	3	3	9	24
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	0	-24	-62	-74	-67	-68	-72	-77	-86	-82	-227	-613
On-Budget	0	0	-23	-59	-71	-64	-66	-69	-74	-83	-78	-217	-587
Off-Budget	0	0	-1	-3	-3	-3	-3	-3	-3	-3	-4	-10	-26
Increases or Decreases (-) in Spending Subject to Appropriation													
Estimated Authorization	0	*	-3	-6	-8	-7	n.e.	n.e.	n.e.	n.e.	n.e.	-24	n.e.
Estimated Outlays	0	*	-3	-6	-8	-7	n.e.	n.e.	n.e.	n.e.	n.e.	-24	n.e.

Components may not sum to totals because of rounding; n.e. = not estimated. * = between -\$500,000 and zero.

^aIncludes off-budget effects on the operating costs of the U.S. Postal Service.

By enhancing FTC authority to restrict certain agreements between sponsors of brand-name, generic, or biosimilar drugs, H.R. 2375 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). The bill also would impose a private-sector mandate by requiring those manufacturers to notify the FTC of agreements that resolve PTAB proceedings. CBO estimates the cost of the mandate, particularly in the form of lost revenues, would exceed the threshold for private-sector mandates established in UMRA (\$164 million in 2019, adjusted annually for inflation) in at least two of the first five years the mandate is in effect.

On April 26, 2019, CBO transmitted an estimate for H.R. 1499, the Protecting Consumer Access to Generic Drugs Act of 2019, as ordered reported by the House Committee on Energy and Commerce on April 3, 2019. CBO's estimates of the effect on the deficit through 2029 for the two bills are the same. In different ways, both H.R. 2375 and H.R. 1499 would modify the conduct of enforcement actions by FTC against parties to certain agreements to settle a claim of patent infringement and would impose significant restrictions on the terms of compensation in affected agreements. H.R. 2375 also would require particular types of agreements relating to PTAB proceedings to be filed with FTC and the DOJ; H.R. 1499 does not contain a comparable provision. CBO expects that both bills would accelerate, on average, the availability of lower-priced generic and biosimilar drugs to a similar extent and would generate an equivalent amount of budgetary savings from 2020 through 2029.

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

Duplication of Federal Programs

No provision of H.R. 965 establishes or reauthorizes a program of the Federal government known to be duplicative of another federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

Performance Goals and Objectives

The Committee states that pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 965 would substantially lower drug prices by making it easier for generic pharmaceutical companies to obtain drug samples from branded companies, which they require in order to perform testing necessary to enter the market. The CREATES Act seeks to end the abusive delay in the provision of samples by providing generic and biosimilar competitors with tailored relief to obtain samples necessary to enter the market.

Advisory on Earmarks

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 965 does not contain any congressional

earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

Section 1. Short Title. Section 1 sets forth the short title of the legislation as the “Creating and Restoring Equal Access to Equivalent Samples Act of 2019” or the “CREATES Act of 2019”.

Section 2. Findings. Section 2 sets forth congressional findings relating to drugs and biological products that are subject to REMS.

Section 3. Actions for Delays of Generic Drugs and Biosimilar Biological Products. Section 3(a) sets forth various definitions.

Section 3(b) establishes a private right of action for prospective generic or biosimilar applicants who are denied samples of the brand product needed for tests to support approval of the generic or biosimilar application. An eligible product developer may bring a civil action against the license holder for a covered product in an appropriate U.S. district court 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.

To prevail in a civil action brought under the CREATES Act, an eligible product developer must prove, by a preponderance of the evidence, the following elements: (1) the covered product is not subject to a risk evaluation and mitigation strategy with elements to assure safe use (REMS with ETASU); or if the covered product is subject to a REMS with ETASU, the eligible product developer has obtained a “covered product authorization” from the Secretary of Health and Human Services (the Secretary) and provided a copy of that authorization to the license holder; (2) the product developer has not been able to obtain sufficient quantities of the covered product on commercially reasonable, market-based terms (as of the date on which the civil action is filed); (3) the product developer has requested to purchase such quantities from the license holder; and (4) the license holder has not delivered such quantities on commercially reasonable, market-based terms within 31 days after receiving the request for products not subject to REMS with ETASU, or within 31 days after receiving the request or a copy of the covered product authorization, whichever is later, for products subject to REMS with ETASU.

Section 3(b)(3) establishes an affirmative defense to a civil action brought under the Act if the license holder can establish, by a preponderance of the evidence, that: (1) it was not engaged in manufacturing the covered product and did not have access to inventory of the covered product when the product developer made the request; or (2) the license holder sells the product through agents, distributors, or wholesalers; the license holder has placed no implicit or explicit restrictions on the sale of the covered product; and the product developer can purchase the product from agents, distributors, or wholesalers of the license holder on commercially reasonable, market-based terms.

Section 3(b)(2)(B) establishes a process for a product developer to submit a request for and receive an authorization from the Department of Health and Human Services to obtain sufficient quantities

of a covered product subject to a REMS with ETASU. This section requires that the Secretary must issue a written authorization within 120 days of receiving an appropriate request. For development and testing not involving clinical trials, the product developer must agree to comply with any conditions the Secretary determines necessary. For development and testing involving clinical trials, the product developer must submit protocols, informed consent documents, and other informational materials about the testing that contain safety protections comparable to those provided by the REMS for the covered product—or otherwise satisfy the Secretary that such protections will be provided—and meet any other requirements the Secretary may establish. The authorization shall state that the license holder’s provision of the product will not be a violation of the REMS for the covered product.

Section 3(b)(4) sets forth remedies for a product developer that prevails in a civil action established by this section. These include ordering the license holder to provide sufficient quantities of the product without delay, on commercially reasonable, market-based terms, and awarding the product developer reasonable attorney’s fees. Additionally, if the court finds that the license holder delayed providing sufficient quantities of the product “without a legitimate business justification” or failed to comply with the court’s order to provide the product, the court may award the product developer damages “sufficient to deter” the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms. These damages may not be greater than the revenue the license holder earned on the product during the period beginning on the date 31 days after receiving the request or 31 days after receiving a copy of the covered product authorization (depending on whether the covered product is subject to a REMS with ETASU) and ending on the date the product developer ultimately received sufficient quantities of the covered product. To avoid delay, the court may issue an order requiring the provision of samples of the covered product before conducting further proceedings that may be necessary to determine whether a monetary award or attorney’s fees are appropriate.

Section 3(c) limits the liability of license holders for any claims under state, federal, or local law arising out of the eligible product developer’s failure to follow adequate safeguards during any product development or testing activities, such as the transportation, handling, use, or disposal of the product.

Section 3(d) clarifies that providing samples of the product under a covered product authorization will not be considered a violation of any REMS requirements that may be in place for the product.

Section 3(e) establishes a rule of construction that nothing in this Act shall be construed to limit the operation of the antitrust laws.

Section 4. REMS Approval Process for Subsequent Filers. Section 4 amends section 505–1 of the Federal Food, Drug, and Cosmetic Act (FDCA) to: (1) authorize the Secretary to require a drug manufacturer to submit a proposed modification to a REMS strategy that has already been approved by the Secretary in order to accommodate different, comparable approved REMS strategies for generic drug applicants; and (2) establish that a generic drug applicant may use a single, shared ETASU system with the listed drug, or

a different, comparable aspect of ETASU. Section 4 further amends the FDCA to provide that the Secretary may require a generic drug to use a single, shared ETASU system if the Secretary determines that no different, comparable aspect of ETASU satisfies the statutory requirements. Finally, Section 4 amends the FDCA to define the terms “different, comparable aspect of the elements to assure safe use” and “different, comparable approved risk evaluation and mitigation strategies” to mean a REMS “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.”

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, H.R. 965, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no changes are proposed is shown in roman):

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 italic, 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

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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 formulations 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.

(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 approved risk evaluation and mitigation strategies for a drug that is the subject of an application under section 505(j), and the applicable listed drug.

(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 exempted 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 recommenda-

tion, 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.

(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) *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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