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REPORT
114–557

OPIOID REVIEW MODERNIZATION ACT OF 2016

MAY 10, 2016.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 4976]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4976) to require the Commissioner of Food and Drugs to seek recommendations from an advisory committee of the Food and Drug Administration before approval of certain new drugs that are opioids without abuse-deterrent properties, and for other purposes, 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. 4976 would require the Food and Drug Administration (FDA) to refer certain applications for new opioid drug products to an advisory committee before approval; seek advisory committee recommendations regarding a framework for including information about pediatric use on an opioid label prior to making any labeling decisions for opioids intended for use in pediatric populations; develop recommendations on education programs for prescribers of certain opioids; and finalize guidance on the evaluation of abuse deterrence in generic opioids.

BACKGROUND AND NEED FOR LEGISLATION

The number of prescriptions for opioid pain medications has significantly increased in recent years. Further, opioid use disorder and overdose deaths have reached epidemic levels. While a comprehensive approach to address this crisis is needed, FDA does play a critical role in reviewing opioid pain medications to determine whether their benefits outweigh their risks. It is important that FDA seeks the advice of the agency's expert advisory committees prior to making key product approval and labeling decisions, particularly to ensure that such risks are effectively communicated and mitigated. Further, the agency can play a role in ensuring prescribers have access to education regarding pain management and safe prescribing of opioids so as to decrease inappropriate prescribing.

HEARINGS

The Committee on Energy and Commerce did not hold a hearing on this legislation.

COMMITTEE CONSIDERATION

On April 20, 2016, the Subcommittee on Health met in open markup session and forwarded H.R. 4976, without amendment, to the full Committee by a voice vote. On April 26, 27, and 28, 2016, the Committee on Energy and Commerce met in open markup session and ordered H.R. 4976, without amendment, favorably reported to the House by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4976 reported.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee did not hold a hearing on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of this act is to ensure that an advisory committee of FDA provides input regarding the approval of new opioids that

do not utilize abuse deterrent properties and obtain recommendations regarding a framework for labeling any opioid intended for pediatric use. Additionally, this act requires FDA to develop recommendations regarding prescriber opioid education and finalize guidance on evaluating abuse deterrence in generic opioids.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4976 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 4976 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

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.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 6, 2016.

Hon. FRED UPTON,
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. 4976, the Opioid Review Modernization Act of 2016.

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.

Enclosure.

H.R. 4976—Opioid Review Modernization Act of 2016

H.R. 4976 would require the Food and Drug Administration (FDA) to seek recommendations from an expert advisory committee before approving any new drug that contains an opioid that does not have abuse-deterrent properties. The bill would also require that the Pediatric Advisory Committee recommend labeling information for opioid use by children. In addition, the bill would require FDA to develop recommendations for educating prescribers of

opioids and to publish final guidance on evaluating efforts to deter abuse of generic opioid drugs.

CBO estimates that enacting H.R. 4976 would not have a significant budgetary effect because FDA is currently implementing similar requirements through their action plan on opioids. Enacting H.R. 4976 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. CBO estimates that enacting H.R. 4976 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

H.R. 4976 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

The CBO staff contact for this estimate is Ellen Werble. The estimate was approved by Holly Harvey, 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.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4976 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.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4976 does not direct any specific rule making within the meaning of 5 U.S.C. 551.

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 provides the short title of "Opioid Review Modernization Act of 2016."

Section 2. FDA Opioid Action Plan

This section requires FDA to refer any new drug application for an opioid that does not have abuse-deterrent properties to an advi-

sory committee prior to making an approval decision. Such a referral is not required if FDA determines that it is not in the interest of the public health or based on a review of the relevant scientific information. If such an application is not referred to an advisory committee based on one of these factors, FDA must submit a notice containing the rationale for this decision to the Congressional authorizing committees.

In addition, this section requires FDA to convene the Pediatric Advisory Committee before to provide recommendations regarding the framework for including any information about pediatric use on an opioid label before approving any labeling or labeling change for a drug that is an opioid intended for use in a pediatric population.

Section 3. Prescriber education

This section would require FDA, within one year of enactment, to evaluate the Risk Evaluation and Mitigation Strategy (REMS) program currently in place for extended-release and long-acting opioids and develop recommendations, in consultation with relevant stakeholders, regarding education programs for prescribers of opioids, including which prescribers should participate in such programs and how often.

Section 4. Guidance on Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Products

This section would require FDA, not later than two years after the close of the comment period for the draft guidance entitled "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products" to issue a final version of the guidance.

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 (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

SECTION 569–1 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

SEC. 569–1. OPIOID ACTION PLAN.

(a) NEW DRUG APPLICATION.—

(1) IN GENERAL.—Subject to paragraph (2), prior to the approval pursuant to an application under section 505(b) of a new drug that is an opioid and does not have abuse-deterrent properties, the Secretary shall refer the application to an advisory committee of the Food and Drug Administration to seek recommendations from such advisory committee.

(2) PUBLIC HEALTH EXEMPTION.—A referral to an advisory committee under paragraph (1) is not required with respect to a new drug if the Secretary—

(A) finds that such a referral is not in the interest of protecting and promoting public health;

(B) finds that such a referral is not necessary based on a review of the relevant scientific information; and

(C) submits a notice containing the rationale for such findings to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(b) PEDIATRIC OPIOID LABELING.—The Secretary shall convene the Pediatric Advisory Committee of the Food and Drug Administration to seek recommendations from such Committee regarding a framework for the inclusion of information in the labeling of drugs that are opioids relating to the use of such drugs in pediatric populations before the Secretary approves any labeling or change to labeling for any drug that is an opioid intended for use in a pediatric population.

(c) SUNSET.—The requirements of subsections (a) and (b) shall cease to be effective on October 1, 2022.

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