Union Calendar No. 431

114TH CONGRESS
2D SESSION

H. R. 4976

[Report No. 114–557]

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.

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2016

Mr. SEAN PATRICK MALONEY of New York (for himself and Mr. LANCE) introduced the following bill; which was referred to the Committee on Energy and Commerce

MAY 10, 2016

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

A BILL

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Opioid Review Modernization Act of 2016''.

SEC. 2. FDA OPIOID ACTION PLAN.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 569 of such Act (21 U.S.C. 350bbb–8) the following:

''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.".

SEC. 3. PRESCRIBER EDUCATION.

Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services,

acting through the Commissioner of Food and Drugs, as part of the Food and Drug Administration's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, and in consultation with relevant stakeholders, shall develop recommendations regarding education programs for prescribers of opioids pursuant to section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), including recommendations on—

(1) which prescribers should participate in such programs; and

(2) how often participation in such programs is necessary.

SEC. 4. GUIDANCE ON EVALUATING THE ABUSE DETERRENCE OF GENERIC SOLID ORAL OPIOID DRUG PRODUCTS.

Not later than 2 years after the end of the period for public comment on the draft guidance entitled ''General Principals for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products'' issued by the Center for Drug Evaluation and Research of the Food and Drug Administration in March 2016, the Commissioner of Food and Drugs shall publish in the Federal Register a final version of such guidance.

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