II

115TH CONGRESS
2D SESSION

S. 2669

To provide for accelerated approval of pain and addiction therapies.

IN THE SENATE OF THE UNITED STATES

APRIL 16, 2018

Mr. HATCH (for himself, Mr. BENNET, Mr. DONNELLY, and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for accelerated approval of pain and addiction therapies.

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 ''Advancing Innovation in Alternative Pain and Addiction Therapies Act''.

SEC. 2. ACCELERATED APPROVAL OF PAIN AND ADDICTION THERAPIES.

(a) PURPOSE.—It is the purpose of this section to clarify the appropriate processes for encouraging and expediting the review of non-opioid or non-addictive medical

products to treat chronic or acute pain or substance use disorders.

(b) DRAFT GUIDANCE.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall issue draft guidance, clarifying the methods and processes by which the Food and Drug Administration may provide accelerated approval for non-opioid or non-addictive drugs developed to treat chronic or acute pain or substance use disorders.

(2) CONTENTS.—The guidance under paragraph (1) shall address—

(A) eligibility requirements for such drugs to receive accelerated approval;

(B) opportunities for engagement with the Food and Drug Administration with respect to the accelerated approval pathway;

(C) considerations for different types of pain and product mechanism of action; and

(D) potential criteria for novel surrogate or intermediate clinical endpoints or biomarkers to assess pain.

(c) FINAL GUIDANCE.—Not later than 6 months after the close of the period for public comment on the draft guidance under subsection (b), the Secretary shall finalize such guidance.

(d) DATA IN PERFORMANCE REPORTS.—

(1) IN GENERAL.—As a component of the annual performance report under section 736B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)), the Secretary shall include information, as appropriate, on policies and processes of the Division of Anesthesia, Analgesia, and Addiction Products of the Food and Drug Administration (referred to in this section as the ''DAAAP'') for the accelerated approval pathway with respect to drugs developed to treat pain or substance use disorders, during the previous fiscal year.

(2) CONTENTS.—Information submitted as a part of the performance reports under section 736B(a) of the Federal Food, Drug, and Cosmetic Act may address—

(A) the number of requests for accelerated approval submitted to the DAAAP for non-opioid or non-addictive medical products;

(B) the number of applications for accelerated approval that the DAAAP granted, and a

description of the common reasons for granting applications for accelerated approval;

(C) the number of applications for accelerated approval that the DAAAP denied, and a description of the common reasons for denying applications for accelerated approval;

(D) the percentage of products in such review division which met the review goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 (Public Law 115–52);

(E) agency efforts to ensure consistency across review divisions in the metrics and processes by which new drug applications for non-addictive or non-opioid products intended to treat pain are reviewed;

(F) a discussion and summary of the common reasons for applications which did not meet the review goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 (Public Law 115–52), as applicable and appropriate; and

(G) recommendations to better enable utilization of the accelerated approval pathway.

SEC. 3. BREAKTHROUGH THERAPY STATUS FOR PAIN AND ADDICTION THERAPIES.

(a) DRAFT GUIDANCE.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall issue draft guidance, clarifying the methods and processes by which the Food and Drug Administration may provide a breakthrough therapy designation for non-opioid or non-addictive drugs or devices developed to treat chronic or acute pain or substance use disorders.

(2) CONTENTS.—The guidance under paragraph (1) shall address—

(A) eligibility requirements for such drugs and devices to receive breakthrough therapy designation;

(B) opportunities for engagement with the Food and Drug Administration with respect to the breakthrough therapy pathway;

(C) specific actions to ensure that the design of the clinical trials is as efficient as practicable, when applicable and scientifically appropriate, for such drugs and devices; and

(D) the application of organizational commitment of the Food and Drug Administration to facilitating breakthrough designation for qualified drugs and devices, including involvement of senior managers of the Food and Drug Administration for such drugs and devices.

(b) FINAL GUIDANCE.—Not later than 6 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary shall finalize such guidance.

(c) DATA IN PERFORMANCE REPORTS.—

(1) IN GENERAL.—As a component of the performance reports under sections 736B(a) and 738A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2, 379j–1), the Secretary shall include information, as appropriate, on policies and processes of the Division of Anesthesia, Analgesia, and Addiction Products of the Food and Drug Administration (referred to in this section as the ''DAAAP'') for the breakthrough therapy pathway, with respect to drugs and devices developed to treat chronic or acute pain or substance use disorders, during the previous fiscal year.

(2) CONTENTS.—Information provided as a component of the performance reports under sec-

tions 736B(a) and 738A(a) of the Federal Food, Drug, and Cosmetic Act may address—

(A) the number of requests for breakthrough therapy designation submitted to the DAAAP;

(B) the number of applications for breakthrough therapy designation that the DAAAP granted, and a description of the common reasons for granting applications for breakthrough therapy designation;

(C) the number of applications for breakthrough therapy designation that the DAAAP denied, and a description of the common reasons for denying applications for breakthrough therapy designation; and

(D) recommendations to better enable utilization of the breakthrough therapy designation pathway for non-addictive or non-opioid products intended to treat pain.

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