118TH CONGRESS
1ST SESSION

S. 3557

To require the Secretary of Health and Human Services to prepare a report that outlines a plan for completing a review of approved opioid analgesic drugs that considers the public health effects of such opioid drugs.

IN THE SENATE OF THE UNITED STATES

DECEMBER 19, 2023

Mr. MURPHY (for himself and Mr. BRAUN) 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 require the Secretary of Health and Human Services to prepare a report that outlines a plan for completing a review of approved opioid analgesic drugs that considers the public health effects of such opioid drugs.

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

SECTION 1. REVIEW OF OPIOID DRUGS AND ACTIONS.

Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall publish on the website of the Food and Drug Administration (referred to in this section as the ''FDA'') a report that

outlines a plan for completing a review of opioid analgesic drugs that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that considers the public health effects of such opioid drugs as part of the benefit-risk assessment, and that addresses the activities of the FDA that relate to increasing the development of non-addictive medical products intended to treat pain or addiction. Such report shall include—

(1) an opportunity for public input concerning the regulation by the FDA of opioid analgesic drugs, including scientific evidence that relates to conditions of use, safety, or benefit-risk assessment (including consideration of the public health effects) of such opioid drugs;

(2) an update on the actions taken by the FDA to review the effectiveness, safety, benefit-risk profile (which may include public health effects), and use of approved opioid analgesic drugs;

(3) a timeline for an assessment of the potential need, as appropriate, for labeling changes, revised or additional postmarketing requirements, enforcement actions, or withdrawals for opioid analgesic drugs;

(4) an overview of the steps that the FDA has taken to support the development and approval of non-addictive medical products intended to treat

pain or addiction, and actions planned to further support the development and approval of such products; and

(5) an overview of the consideration by the FDA of clinical trial methodologies for analgesic drugs, including the enriched enrollment randomized withdrawal methodology, and the benefits and drawbacks associated with different trial methodologies for such drugs, incorporating any public input received under paragraph (1).

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