119TH CONGRESS
1ST SESSION

S. 2513

To amend the Federal Food, Drug, and Cosmetic Act with respect to transparency and reporting regarding over-the-counter drug monograph activities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 29, 2025

Mr. KAINE 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 amend the Federal Food, Drug, and Cosmetic Act with respect to transparency and reporting regarding over-the-counter drug monograph activities, 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 ''OTC Monograph Drug User Fee Transparency Act''.

SEC. 2. OTC MONOGRAPH DRUG PERFORMANCE REPORTS.

(a) PERFORMANCE REPORT.—Section 744N of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–73) is amended—

(1) in subsection (a)—

(A) by striking ''Beginning with'' and inserting the following:

''(1) IN GENERAL.—Beginning with'';

(B) by striking ''section 3861(b)'' and inserting ''section 3861''; and

(C) by adding at the end the following:

''(2) ADDITIONAL INFORMATION.—Beginning with fiscal year 2026, the annual report under this subsection shall include—

''(A) the progress of the Food and Drug Administration in achieving the goals, and future plans for meeting the goals, including—

''(i) the number of Tier 1 OTC monograph order requests for which a proposed order was issued, and the number of such requests for which a final order was issued, in the previous fiscal year;

''(ii) the number of Tier 2 OTC monograph order requests for which a proposed order was issued, and the number of

such requests for which a final order was issued, in the previous fiscal year;

''(iii) the number of specified safety OTC monograph order requests for which a proposed order was issued, and the number of such requests for which a final order was issued, in the previous fiscal year;

''(iv) the number of generally recognized as safe and effective finalization OTC monograph order requests for which a proposed order was issued, and the number of such requests for which a final order was issued, in the previous fiscal year;

''(v) the average timeline for processing OTC monograph order requests, in the aggregate and by submission type, in the previous fiscal year; and

''(vi) postmarket safety activities with respect to OTC monograph drugs, including—

''(I) collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports;

"(II) developing and using improved analytical tools, adverse event data-collection systems, including information technology systems, to assess potential safety problems, including access to external databases; and

"(III) activities under section 760; and

"(B) information regarding registration of OTC monograph drug facilities and contract manufacturing organization facilities and payment of registration fees by such facilities, including—

"(i) the OTC monograph drug facilities and contract manufacturing organization facilities that were first registered under section 510(c) or 510(i) in the fiscal year; and

"(ii) for each OTC monograph drug facility and contract manufacturing organization facility that was assessed a facility fee under section 744M(a) in the fiscal year, whether the facility paid such fee.

"(3) CONFIDENTIALITY.—Nothing in paragraph (2) shall be construed to authorize the disclo-

sure of information that is prohibited from disclosure under section 301(j) of this Act or section 1905 of title 18, United States Code, or that is subject to withholding under section 552(b)(4) of title 5, United States Code.''; and

(2) by adding at the end of subsection (d) the following:

''(4) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the public website of the Food and Drug Administration, robust written minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry, not later than 30 days after each such negotiation meeting.

''(B) CONTENT.—The robust written minutes described under subparagraph (A) shall contain, in detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

(b) GAO REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report assessing the supply chain of over-the-counter monograph drugs.

(2) CONTENTS.—The report required under paragraph (1) shall include an assessment of—

(A) information the Food and Drug Administration and others have reported about the overall stability of the supply chain of over-the-counter monograph drugs;

(B) what information is collected by the Food and Drug Administration with respect to the supply chain of over-the-counter monograph drugs;

(C) how the Food and Drug Administration uses information collected on the supply chain of over-the-counter monograph drugs to inform regulatory decisions;

(D) how the Food and Drug Administration coordinates with other Federal agencies to

monitor and mitigate disruptions to the supply chain of over-the-counter monograph drugs; and

(E) the unique characteristics of the over-the-counter monograph drug marketplace and what additional authorities or information, if any, the Food and Drug Administration and others have identified as being necessary to ensure the stability of the supply chain of over-the-counter monograph drugs.

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