

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “OTC Monograph Drug
5 User Fee Transparency Act”.

1 **SEC. 2. OTC MONOGRAPH DRUG PERFORMANCE REPORTS.**

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

5 (1) in subsection (a)—

6 (A) by striking “Beginning with” and in-
7 serting the following:

8 “(1) IN GENERAL.—Beginning with”;

9 (B) by striking “section 3861(b)” and in-
10 serting “section 3861”; and

11 (C) by adding at the end the following:

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

15 “(A) the progress of the Food and Drug
16 Administration in achieving the goals, and fu-
17 ture plans for meeting the goals, including—

18 “(i) the number of Tier 1 OTC mono-
19 graph order requests for which a proposed
20 order was issued, and the number of such
21 requests for which a final order was issued,
22 in the previous fiscal year;

23 “(ii) the number of Tier 2 OTC
24 monograph order requests for which a pro-
25 posed order was issued, and the number of

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

3 “(iii) the number of specified safety
4 OTC monograph order requests for which
5 a proposed order was issued, and the num-
6 ber of such requests for which a final order
7 was issued, in the previous fiscal year;

8 “(iv) the number of generally recog-
9 nized as safe and effective finalization
10 OTC monograph order requests for which
11 a proposed order was issued, and the num-
12 ber of such requests for which a final order
13 was issued, in the previous fiscal year;

14 “(v) the average timeline for proc-
15 essing OTC monograph order requests, in
16 the aggregate and by submission type, in
17 the previous fiscal year; and

18 “(vi) postmarket safety activities with
19 respect to OTC monograph drugs, includ-
20 ing—

21 “(I) collecting, developing, and
22 reviewing safety information on OTC
23 monograph drugs, including adverse
24 event reports;

1 “(II) developing and using im-
2 proved analytical tools, adverse event
3 data-collection systems, including in-
4 formation technology systems, to as-
5 sess potential safety problems, includ-
6 ing access to external databases; and

7 “(III) activities under section
8 760; and

9 “(B) information regarding registration of
10 OTC monograph drug facilities and contract
11 manufacturing organization facilities and pay-
12 ment of registration fees by such facilities, in-
13 cluding—

14 “(i) the OTC monograph drug facili-
15 ties and contract manufacturing organiza-
16 tion facilities that were first registered
17 under section 510(c) or 510(i) in the fiscal
18 year; and

19 “(ii) for each OTC monograph drug
20 facility and contract manufacturing organi-
21 zation facility that was assessed a facility
22 fee under section 744M(a) in the fiscal
23 year, whether the facility paid such fee.

24 “(3) CONFIDENTIALITY.—Nothing in para-
25 graph (2) shall be construed to authorize the disclo-

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

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

8 “(4) MINUTES OF NEGOTIATION MEETINGS.—

9 “(A) PUBLIC AVAILABILITY.—The Sec-
10 retary shall make publicly available, on the pub-
11 lic website of the Food and Drug Administra-
12 tion, robust written minutes of all negotiation
13 meetings conducted under this subsection be-
14 tween the Food and Drug Administration and
15 the regulated industry, not later than 30 days
16 after each such negotiation meeting.

17 “(B) CONTENT.—The robust written min-
18 utes described under subparagraph (A) shall
19 contain, in detail, any substantive proposal
20 made by any party to the negotiations as well
21 as significant controversies or differences of
22 opinion during the negotiations and their reso-
23 lution.”.

24 (b) GAO REPORT.—

1 (1) IN GENERAL.—Not later than 2 years after
2 the date of enactment of this Act, the Comptroller
3 General of the United States shall submit to the
4 Committee on Health, Education, Labor, and Pen-
5 sions of the Senate and the Committee on Energy
6 and Commerce of the House of Representatives a re-
7 port assessing the supply chain of over-the-counter
8 monograph drugs.

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

11 (A) information the Food and Drug Ad-
12 ministration and others have reported about the
13 overall stability of the supply chain of over-the-
14 counter monograph drugs;

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

19 (C) how the Food and Drug Administra-
20 tion uses information collected on the supply
21 chain of over-the-counter monograph drugs to
22 inform regulatory decisions;

23 (D) how the Food and Drug Administra-
24 tion coordinates with other Federal agencies to

1 monitor and mitigate disruptions to the supply
2 chain of over-the-counter monograph drugs; and
3 (E) the unique characteristics of the over-
4 the-counter monograph drug marketplace and
5 what additional authorities or information, if
6 any, the Food and Drug Administration and
7 others have identified as being necessary to en-
8 sure the stability of the supply chain of over-
9 the-counter monograph drugs.

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