Calendar No. 152

119TH CONGRESS
1ST SESSION

S. 2292

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-the-counter monograph drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 15, 2025

Mr. BANKS (for himself, Mr. KAINE, Mr. KIM, and Mr. HUSTED) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 8, 2025

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-the-counter monograph drugs, 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 "Over-the-Counter Monograph Drug User Fee Amendments".~~

SEC. 2. FINDING.

Congress finds that the fees authorized by the amendments made in this Act will be dedicated to OTC monograph drug activities, as set forth in the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71 et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record.

SEC. 3. DEFINITIONS.

Section 744L(9)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71(9)(A)) is amended—

(1) in clause (v), by striking ''; or'' and inserting a semicolon;

(2) in clause (vi)—

(A) by striking ''addition'' and inserting ''the addition''; and

(B) by striking the period and inserting ''; or''; and

(3) by adding at the end the following:

''(vii) the addition or modification of a testing procedure applicable to one or more OTC monograph drugs, provided that such ad-

ditional or modified testing procedure reflects a voluntary consensus standard with respect to pharmaceutical quality that is—

"(I) established by a national or international standards development organization; and

"(II) recognized by the Secretary through a process described in guidance for industry, initially published in July 2023, or any successor guidance, publicly available on the website of the Food and Drug Administration, which addresses voluntary consensus standards for pharmaceutical quality.".

SEC. 4. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH FEES.

(a) TYPES OF FEES.—Section 744M(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(a)(1)) is amended—

(1) in subparagraph (A)—

(A) by striking "on December 31 of the fiscal year or at any time during the preceding 12-month period" and inserting "at any time during the applicable period specified in clause (ii) for a fiscal year";

(B) by striking ''Each person'' and inserting the following:

''(i) ASSESSMENT OF FEES.—Each person''; and

(C) by adding at the end the following:

''(ii) APPLICABLE PERIOD.—For purposes of clause (i), the applicable period is—

''(I) for fiscal year 2026, the 12-month period ending on December 31, 2025;

''(II) for fiscal year 2027, the 9-month period ending on September 30, 2026; and

''(III) for fiscal year 2028 and each subsequent fiscal year, the 12-month period ending on September 30 of the preceding fiscal year.'';

(2) in subparagraph (B)(i), by amending subclause (I) to read as follows:

''(I) has ceased all activities related to OTC monograph drugs prior to—

''(aa) for purposes of fiscal year 2026, January 1, 2025;

"(bb) for purposes of fiscal year 2027, January 1, 2026; and

"(cc) for purposes of fiscal year 2028 and each subsequent fiscal year, October 1 of the preceding fiscal year; and"; and

(3) by amending subparagraph (D) to read as follows:

"(D) DUE DATE.—

"(i) FISCAL YEAR 2026.—For fiscal year 2026, the facility fees required under subparagraph (A) shall be due on the later of—

"(I) the first business day of June of such year; or

"(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

"(ii) FISCAL YEAR 2027.—For fiscal year 2027, the facility fees required under subparagraph (A) shall be due—

"(I) in a first installment representing 50 percent of such fee, on the later of—

"(aa) October 1, 2026; or

"(bb) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year; and

"(II) in a second installment representing the remaining 50 percent of such fee, on—

"(aa) February 1, 2027; or

"(bb) if an appropriations Act described in subclause (I)(bb) is not in effect on February 1, 2027, the first business day after enactment of such an appropriations Act.

"(iii) SUBSEQUENT FISCAL YEARS.—For fiscal year 2028 and each subsequent fiscal year, the facility fees required under subparagraph (A) shall be due on the later of—

"(I) the first business day on or after October 1 of the fiscal year; or

"(II) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section for the fiscal year.".

(b) FEE REVENUE AMOUNTS.—Section 744M(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(b)) is amended to read as follows:

"(b) FEE REVENUE AMOUNTS.—

"(1) IN GENERAL.—For each of the fiscal years 2026 through 2030, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

"(A) the annual base revenue for the fiscal year (as determined under paragraph (2));

"(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

"(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2));

"(D) additional direct cost adjustments (as determined under subsection (c)(3));

"(E) an additional dollar amount equal to—

"(i) $2,373,000 for fiscal year 2026;

"(ii) $1,233,000 for fiscal year 2027; and

"(iii) $854,000 for fiscal year 2028; and

"(F) in the case of a fiscal year for which the Secretary applies the one-time facility fee workload adjustment under subsection (c)(4), the dollar amount equal to such adjustment.

"(2) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

"(A) for fiscal year 2026, the dollar amount of the total revenue amount established for fiscal year 2025 under this subsection as in effect on the day before the date of enactment of the Over-the-Counter Monograph Drug User Fee Amendments, not including any adjustments made for such fiscal year 2025 under subsection (c)(2), as so in effect; and

''(B) for fiscal years 2027 through 2030, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(2) or (c)(3).''.

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section 744M(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), in the matter preceding clause (i)—

(i) by striking ''subsection (b)(2)(B)'' and inserting ''subsection (b)(1)(B)''; and

(ii) by striking ''fiscal year 2022 and each subsequent fiscal year'' and inserting ''each fiscal year'';

(B) in subparagraph (B), by striking ''fiscal year 2022'' and all that follows through the period at the end and inserting the following: ''a fiscal year shall be equal to the product of—

''(i) for fiscal year 2026—

''(I) the fee for fiscal year 2025 under subsection (a)(2); and

"(II) the inflation adjustment percentage under subparagraph (C); and

"(ii) for each of fiscal years 2027 through 2030—

"(I) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

"(II) the inflation adjustment percentage under subparagraph (C)."; and

(C) in subparagraph (C)—

(i) in the matter preceding clause (i), by inserting "the sum of" after "is equal to";

(ii) by striking clause (i);

(iii) by redesignating subclauses (I) and (II) of clause (ii) as clauses (i) and (ii), respectively, and adjusting the margins accordingly;

(iv) by striking "(ii) for each of fiscal years 2024 and 2025, the sum of—"; and

(v) in clause (ii), as so redesignated, by striking "Washington-Baltimore, DC–

MD–VA–WV'' and inserting ''Washington–Arlington–Alexandria–DC–VA–MD–WV'';

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) by striking ''fiscal year 2021 and subsequent fiscal years'' and inserting ''each fiscal year'';

(ii) by striking ''subsections (b)(1)(B) and (b)(2)(C)'' and inserting ''subsection (b)(1)(C)''; and

(iii) by striking ''the number of weeks specified in subparagraph (B)'' and inserting ''10 weeks'';

(B) by striking subparagraph (B);

(C) by redesignating subparagraphs (C) and (D) as subparagraphs (B) and (C), respectively; and

(D) in subparagraph (C), as so redesignated, by striking ''paragraph (4) establishing'' and inserting ''paragraph (5) publishing'';

(3) in paragraph (3)—

(A) in the matter preceding subparagraph (A), by striking ''subsection (b)(2)(D)'' and inserting ''subsection (b)(1)(D)''; and

(B) by striking subparagraphs (A) through (E) and inserting the following:

"(A) $135,000 for fiscal year 2026;

"(B) $300,000 for fiscal year 2027;

"(C) $55,000 for fiscal year 2028;

"(D) $30,000 for fiscal year 2029; and

"(E) $0 for fiscal year 2030."; and

(4) by striking paragraph (4) and inserting the following:

"(4) ONE-TIME FACILITY FEE WORKLOAD ADJUSTMENT.—

"(A) IN GENERAL.—In addition to the adjustments under paragraphs (1), (2), and (3), the Secretary may further increase the fee revenues and fees through a one-time adjustment made for fiscal year 2028, 2029, or 2030, in accordance with this paragraph.

"(B) ADJUSTMENT DESCRIBED.—

"(i) CONDITIONS FOR ADJUSTMENT.—An adjustment under this paragraph may be made for a fiscal year only if—

"(I) an adjustment under this paragraph had not been made for any prior fiscal year;

"(II) the average number of OTC monograph drug facilities subject to a facility fee under subsection (a)(1) over the period of the preceding 3 fiscal years exceeds 1,625; and

"(III) with respect to facilities described in subclause (II), the average number of such facilities (expressed as a percentage) that appeared on the arrears lists pursuant to subsection (c)(1)(A)(i) over the period of the preceding 3 fiscal years is less than 30 percent.

"(ii) AMOUNT OF ADJUSTMENT.—An adjustment under this paragraph for a fiscal year shall equal the product of—

"(I) the total facility revenue amount determined under subsection (b) for the fiscal year, exclusive of the adjustment under this paragraph for such fiscal year; and

"(II) the excess facility percentage described in clause (iii).

"(iii) EXCESS FACILITY PERCENTAGE.—The excess facility percentage described in this clause is—

"(I) the amount by which the average number of OTC monograph drug facilities subject to a facility fee under subsection (a)(1) over the preceding 3 fiscal years exceeds 1,625; divided by

"(II) 1,625.

"(5) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the first day of each fiscal year—

"(A) establish for such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

"(i) OTC monograph drug facility fees under subsection (a)(1); and

"(ii) OTC monograph order request fees under subsection (a)(2); and

"(B) publish such fee revenue amounts, facility fees, and OTC monograph order request fees in the Federal Register.".

(d) CREDITING AND AVAILABILITY OF FEES.—Section 744M(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(f)) is amended—

(1) in paragraph (2)(D)—

(A) in the subparagraph heading, by striking "IN SUBSEQUENT YEARS"; and

(B) by striking "(after fiscal year 2021)"; and

(2) in paragraph (3), by striking "2021 through 2025" and inserting "2026 through 2030".

SEC. 5. REAUTHORIZATION; REPORTING REQUIREMENTS.

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 fiscal year 2021, and not later than 120 calendar days after the end of each fiscal year thereafter" and inserting "Not later than 120 calendar days after the end of each fiscal year"; and

(B) by striking "section 3861(b) of the CARES Act" and inserting "section 2 of the Over-the-Counter Monograph Drug User Fee Amendments";

(2) in subsection (b), by striking ''fiscal year 2021 and each subsequent fiscal year'' and inserting ''each fiscal year''; and

(3) in subsection (d), by striking ''2025'' each place it appears and inserting ''2030''.

SEC. 6. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744L and 744M of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71; 379j–72) shall cease to be effective October 1, 2030.

(b) REPORTING REQUIREMENTS.—Section 744N of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–73) shall cease to be effective January 31, 2031.

SEC. 7. EFFECTIVE DATE.

The amendments made by this Act shall take effect on October 1, 2025, or the date of the enactment of this Act, whichever is later, except that fees under part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71 et seq.) shall be assessed beginning October 1, 2025, regardless of the date of the enactment of this Act.

SEC. 8. SAVINGS CLAUSE.

Notwithstanding the amendments made by this Act, part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71 et

~~seq.),~~ ~~as~~ ~~in~~ ~~effect~~ ~~on~~ ~~the~~ ~~day~~ ~~before~~ ~~the~~ ~~date~~ ~~of~~ ~~enactment~~ ~~of~~ ~~this~~ ~~Act,~~ ~~shall~~ ~~continue~~ ~~to~~ ~~be~~ ~~in~~ ~~effect~~ ~~with~~ ~~respect~~ ~~to~~ ~~assessing~~ ~~and~~ ~~collecting~~ ~~any~~ ~~fee~~ ~~required~~ ~~by~~ ~~such~~ ~~part~~ ~~for~~ ~~a~~ ~~fiscal~~ ~~year~~ ~~prior~~ ~~to~~ ~~fiscal~~ ~~year~~ ~~2026.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Over-the-Counter Monograph Drug User Fee Amendments".

SEC. 2. FINDING.

Congress finds that the fees authorized by the amendments made in this Act will be dedicated to OTC monograph drug activities, as set forth in the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71 et seq.) in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record.

SEC. 3. DEFINITIONS.

Section 744L(9)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71(9)(A)) is amended—

(1) in clause (v), by striking "; or" and inserting a semicolon;

(2) in clause (vi)—

(A) by striking "addition" and inserting "the addition"; and

(B) by striking the period and inserting "; or"; and

(3) by adding at the end the following:

"(vii) the addition or modification of a testing procedure applicable to one or more OTC monograph drugs, provided that such additional or modified testing procedure reflects a voluntary consensus standard with respect to pharmaceutical quality that is—

"(I) established by a national or international standards development organization; and

"(II) recognized by the Secretary through a process described in guidance for industry, initially published in July 2023, or any successor guidance, publicly available on the website of the Food and Drug Administration, which addresses voluntary consensus standards for pharmaceutical quality.".

SEC. 4. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH FEES.

(a) TYPES OF FEES.—Section 744M(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(a)(1)) is amended—

(1) in subparagraph (A)—

(A) by striking "on December 31 of the fiscal year or at any time during the preceding 12-month period" and inserting "at any time during the applicable period specified in clause (ii) for a fiscal year";

(B) by striking "Each person" and inserting the following:

"(i) ASSESSMENT OF FEES.—Each person"; and

(C) by adding at the end the following:

"(ii) APPLICABLE PERIOD.—For purposes of clause (i), the applicable period is—

"(I) for fiscal year 2026, the 12-month period ending on December 31, 2025;

"(II) for fiscal year 2027, the 9-month period ending on September 30, 2026; and

"(III) for fiscal year 2028 and each subsequent fiscal year, the 12-month period ending on September 30 of the preceding fiscal year.";

(2) in subparagraph (B)(i), by amending subclause (I) to read as follows:

"(I) has ceased all activities related to OTC monograph drugs prior to—

"(aa) for purposes of fiscal year 2026, January 1, 2025;

"(bb) for purposes of fiscal year 2027, January 1, 2026; and

"(cc) for purposes of fiscal year 2028 and each subsequent fiscal year, October 1 of the preceding fiscal year; and"; and

(3) by amending subparagraph (D) to read as follows:

"(D) DUE DATE.—

"(i) FISCAL YEAR 2026.—For fiscal year 2026, the facility fees required under subparagraph (A) shall be due on the later of—

"(I) the first business day of June of such year; or

"(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

"(ii) FISCAL YEAR 2027.—For fiscal year 2027, the facility fees required under subparagraph (A) shall be due—

"(I) in a first installment representing 50 percent of such fee, on the later of—

"(aa) October 1, 2026; or

"(bb) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year; and

"(II) in a second installment representing the remaining 50 percent of such fee, on—

"(aa) February 1, 2027; or

"(bb) if an appropriations Act described in subclause (I)(bb) is not in effect on February 1, 2027, the first business day after enactment of such an appropriations Act.

"(iii) SUBSEQUENT FISCAL YEARS.—For fiscal year 2028 and each subsequent fiscal year, the facility fees required under subparagraph (A) shall be due on the later of—

"(I) the first business day on or after October 1 of the fiscal year; or

"(II) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section for the fiscal year.".

(b) FEE REVENUE AMOUNTS.—Section 744M(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(b)) is amended to read as follows:

"(b) FEE REVENUE AMOUNTS.—

"(1) IN GENERAL.—For each of the fiscal years 2026 through 2030, fees under subsection (a)(1) shall

be established to generate a total facility fee revenue amount equal to the sum of—

"(A) the annual base revenue for the fiscal year (as determined under paragraph (2));

"(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

"(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2));

"(D) additional direct cost adjustments (as determined under subsection (c)(3));

"(E) an additional dollar amount equal to—

"(i) $2,373,000 for fiscal year 2026;

"(ii) $1,233,000 for fiscal year 2027; and

"(iii) $854,000 for fiscal year 2028; and

"(F) in the case of a fiscal year for which the Secretary applies the one-time facility fee workload adjustment under subsection (c)(4), the dollar amount equal to such adjustment.

"(2) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

"(A) for fiscal year 2026, the dollar amount of the total revenue amount established for fiscal year 2025 under this subsection as in effect on the day before the date of enactment of the Over-the-Counter Monograph Drug User Fee Amendments, not including any adjustments made for such fiscal year 2025 under subsection (c)(2), as so in effect; and

"(B) for fiscal years 2027 through 2030, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(2) or (c)(3).".

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section 744M(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), in the matter preceding clause (i)—

(i) by striking "subsection (b)(2)(B)" and inserting "subsection (b)(1)(B)"; and

(ii) by striking "fiscal year 2022 and each subsequent fiscal year" and inserting "each fiscal year";

(B) in subparagraph (B), by striking "fiscal year 2022" and all that follows through the period at the end and inserting the following: "a fiscal year shall be equal to the product of—

"(i) for fiscal year 2026—

"(I) the fee for fiscal year 2025 under subsection (a)(2); and

"(II) the inflation adjustment percentage under subparagraph (C); and

"(ii) for each of fiscal years 2027 through 2030—

"(I) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

"(II) the inflation adjustment percentage under subparagraph (C).."; and

(C) in subparagraph (C)—

(i) in the matter preceding clause (i), by inserting "the sum of" after "is equal to";

(ii) by striking clause (i);

(iii) by redesignating subclauses (I) and (II) of clause (ii) as clauses (i) and (ii), respectively, and adjusting the margins accordingly;

(iv) by striking "(ii) for each of fiscal years 2024 and 2025, the sum of—"; and

(v) in clause (ii), as so redesignated, by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington–Arlington–Alexandria–DC–VA–MD–WV";

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) by striking "fiscal year 2021 and subsequent fiscal years" and inserting "each fiscal year";

(ii) by striking "subsections (b)(1)(B) and (b)(2)(C)" and inserting "subsection (b)(1)(C)"; and

(iii) by striking "the number of weeks specified in subparagraph (B)" and inserting "10 weeks";

(B) by striking subparagraph (B);

(C) by redesignating subparagraphs (C) and (D) as subparagraphs (B) and (C), respectively; and

(D) in subparagraph (C), as so redesignated, by striking "paragraph (4) establishing" and inserting "paragraph (5) publishing";

(3) in paragraph (3)—

(A) in the matter preceding subparagraph (A), by striking "subsection (b)(2)(D)" and inserting "subsection (b)(1)(D)"; and

(B) by striking subparagraphs (A) through (E) and inserting the following:

"(A) $135,000 for fiscal year 2026;

"(B) $300,000 for fiscal year 2027;

"(C) $55,000 for fiscal year 2028;

"(D) $30,000 for fiscal year 2029; and

"(E) $0 for fiscal year 2030."; and

(4) by striking paragraph (4) and inserting the following:

"(4) ONE-TIME FACILITY FEE WORKLOAD ADJUSTMENT.—

"(A) IN GENERAL.—In addition to the adjustments under paragraphs (1), (2), and (3), the Secretary may further increase the fee revenues and fees through a one-time adjustment made for fiscal year 2028, 2029, or 2030, in accordance with this paragraph.

"(B) ADJUSTMENT DESCRIBED.—

"(i) CONDITIONS FOR ADJUSTMENT.—An adjustment under this paragraph may be made for a fiscal year only if—

"(I) an adjustment under this paragraph had not been made for any prior fiscal year;

"(II) the average number of OTC monograph drug facilities subject to a facility fee under subsection (a)(1) over the period of the preceding 3 fiscal years exceeds 1,625; and

"(III) with respect to facilities described in subclause (II), the average number of such facilities (expressed as a percentage) that appeared on the arrears lists pursuant to subsection (e)(1)(A)(i) over the period of the preceding 3 fiscal years is less than 30 percent.

"(ii) AMOUNT OF ADJUSTMENT.—An adjustment under this paragraph for a fiscal year shall equal the product of—

"(I) the total facility revenue amount determined under subsection (b) for the fiscal year, exclusive of the

adjustment under this paragraph for such fiscal year; and

"(II) the excess facility percentage described in clause (iii).

"(iii) EXCESS FACILITY PERCENTAGE.—The excess facility percentage described in this clause is—

"(I) the amount by which the average number of OTC monograph drug facilities subject to a facility fee under subsection (a)(1) over the preceding 3 fiscal years exceeds 1,625; divided by

"(II) 1,625.

"(5) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the first day of each fiscal year—

"(A) establish for such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

"(i) OTC monograph drug facility fees under subsection (a)(1); and

"(ii) OTC monograph order request fees under subsection (a)(2); and

"(B) publish such fee revenue amounts, facility fees, and OTC monograph order request fees in the Federal Register.".

(d) CREDITING AND AVAILABILITY OF FEES.—Section 744M(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(f)) is amended—

(1) in paragraph (2)(D)—

(A) in the subparagraph heading, by striking "IN SUBSEQUENT YEARS"; and

(B) by striking "(after fiscal year 2021)"; and

(2) in paragraph (3), by striking "2021 through 2025" and inserting "2026 through 2030".

SEC. 5. REAUTHORIZATION; REPORTING REQUIREMENTS.

(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 fiscal year 2021, and not later than 120 calendar days after the end of each fiscal year thereafter" and inserting the following:

"(1) IN GENERAL.—Not later than 120 calendar days after the end of each fiscal year";

(B) by striking "section 3861(b) of the CARES Act" and inserting "section 2 of the Over-the-Counter Monograph Drug User Fee Amendments"; 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;

"(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;

"(C) the status of implementation of evidence and testing standards for nonprescription drugs intended for topical administration, including—

"(i) the application of evidence or testing standards; and

"(ii) the number of active ingredient requests for nonprescription drugs intended

for topical administration reviewed using the standards under section 505G(b); and

"(D) the progress of the Food and Drug Administration in allowing nonclinical testing alternatives to animal testing for the consideration of sunscreen active ingredients.

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

(2) in subsection (b), by striking "fiscal year 2021 and each subsequent fiscal year" and inserting "each fiscal year"; and

(3) in subsection (d)—

(A) by striking "2025" each place it appears and inserting "2030"; and

(B) by adding at the end 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 meet-

ings 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 September 30, 2027, 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) 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 the Food and Drug Administration may need to ensure the stability of the supply chain of over-the-counter monograph drugs.

SEC. 6. TREATMENT OF ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRATION.

(a) IN GENERAL.—Section 505G of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h) is amended by adding at the end the following:

"(r) EVIDENCE AND TESTING STANDARDS FOR ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRATION.—

"(1) EVIDENCE AND TESTING STANDARDS FOR ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRATION.—The Secretary shall—

"(A) in evaluating the generally recognized as safe and effective status of active ingredients used in nonprescription drugs intended for topical administration for purposes of subsection (a), utilize standards that allow for the use of real world evidence (as defined in section 505F(b)), as appropriate, as part of a comprehensive evaluation of scientific evidence to demonstrate the safety and effectiveness of such active ingredients, to supplement evidence from traditional clinical trials, provided that such standards allow the Secretary to evaluate whether the benefits of such active ingredients outweigh the risks; and

"(B) apply subsection (b)(6)(C) to the regulation of active ingredients used in drugs intended for topical administration.

"(2) NON-ANIMAL TESTING METHODS FOR TOPICAL ACTIVE INGREDIENTS.—

"(A) IN GENERAL.—The Secretary shall consider the types of nonclinical tests described in paragraphs (1) through (4) of the first sub-

section (z) of section 505 (as inserted by section 3209(a)(2) of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022 (division FF of Public Law 117–328)), or any other alternative to animal testing that the Secretary determines appropriate, in the consideration of drugs intended for topical administration under this section.

"(B) GUIDANCE.—Not later than 1 year after the date of enactment of this subsection, the Secretary shall issue new draft guidance on how sponsors can use nonclinical testing alternatives to animal testing, as appropriate, to meet safety and efficacy standards under this section for drugs intended for topical administration.

"(3) CLARIFICATION.—Nothing in this subsection shall be construed to alter, supersede, or limit the standards for making determinations of whether a drug is generally recognized as safe and effective under section 201(p) or the standards set forth under section 505 for determining the safety and effectiveness of drugs.".

(b) SUNSCREEN FINAL ADMINISTRATIVE ORDER.—A final administrative order on nonprescription sunscreen ac-

tive ingredients issued under section 3854 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136; 21 U.S.C. 360fff–3 note) shall—

(1) account for historical data regarding the safety of sunscreen active ingredients that have previously been accepted for marketing in the United States;

(2) account for the role of broad spectrum sunscreens with a Sun Protection Factor of 15 or higher in effective skin cancer prevention; and

(3) incorporate the evidence and testing standards for sunscreen active ingredients detailed in section 505G(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h) (as added by subsection (a)).

SEC. 7. INCREASING THE CLARITY AND PREDICTABILITY OF THE PROCESS FOR DEVELOPING APPLICATIONS FOR RX-TO-NONPRESCRIPTION SWITCHES.

(a) IN GENERAL.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

"(7) RX-TO-NONPRESCRIPTION SWITCHES.—

"(A) MEETINGS.—Any person planning to submit an application for an Rx-to-nonprescription switch may submit to the Secretary a writ-

ten request for a meeting, for purposes of developing a plan for such application that addresses the potential risks to public health of such switch and the evidence necessary to support such application, including the design of any necessary studies, and the format and content of the planned application. The Secretary may grant such a meeting, as appropriate, consistent with established procedures for granting meetings with, and providing written responses to, sponsors of applications under this section. Each such meeting shall be documented in meeting minutes.

"(B) GUIDANCE.—

"(i) IN GENERAL.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall issue guidance to increase the clarity and predictability of the process and standards for approval of applications for nonprescription drugs under this section, including in the case of applications for an Rx-to-nonprescription switch, especially with respect to prescription drugs with well-established

safety profiles for which an applicant may seek approval for nonprescription use.

"(ii) CONTENTS.—The guidance under clause (i) shall—

"(I) describe how published reports in medical literature, any previous finding of safety or effectiveness for the drug under this section, the results of significant human experience with the drug, unpublished studies and other data, and other sources of information may be used to support an application for a nonprescription drug, including in the context of an application for an Rx-to-nonprescription switch;

"(II) set forth procedures for sponsors to request meetings described in subparagraph (A) and document the recommendations made in such meetings;

"(III) describe evidentiary expectations to support approval of an application for a nonprescription drug, including in the context of an applica-

tion for an Rx-to-nonprescription switch, including how sponsors can demonstrate that consumers can appropriately self-select and use the drug and comprehend the nonprescription drug label; and

"(IV) provide recommendations for how mechanisms, in addition to the required Drug Facts Label, such as mobile applications and decision aids, can be incorporated into the information submitted in support of an application for an Rx-to-nonprescription switch.

"(C) PLAN TO ENGAGE WITH STAKEHOLDERS.—Not later than 1 year after the date of enactment of this paragraph, the Secretary shall develop and make publicly available on the website of the Food and Drug Administration a plan to engage stakeholders on steps and factors for application holders and other stakeholders to consider in identifying approved prescription drugs that may be promising candidates for applications for an Rx-to-nonprescription switch.

"(D) DEFINITION.—The term 'Rx-to-nonprescription switch' means the approval of an application, or supplemental application, as applicable, submitted under this section by the holder of an approved application for a prescription drug seeking approval to market such drug as a nonprescription drug, including for—

"(i) a full Rx-to-nonprescription switch, under which a drug previously approved for prescription use only is—

"(I) approved for nonprescription use under the same conditions of use as applied to the drug when approved for prescription use; or

"(II) approved for nonprescription use subject to one or more additional conditions for nonprescription use; and

"(ii) a partial Rx-to-nonprescription switch, under which the drug is approved for nonprescription use only under certain conditions of use described in the approved labeling, while the drug otherwise remains approved for prescription use only.

"(E) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to—

"(i) supersede or modify the authority of the Secretary under section 505G with respect to the regulation of OTC monograph drugs; or

"(ii) authorize the disclosure by the Secretary of confidential commercial information or trade secrets.".

(b) GAO REPORT.—

(1) IN GENERAL.—Not later than 1 year 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 that evaluates—

(A) the number of applications for an Rx-to-nonprescription switch approved during the period beginning on October 1, 2022, and ending on the date of the report;

(B) the number of drugs for which an application for an Rx-to-nonprescription switch was approved during such period subject to an additional condition for nonprescription use;

(C) among the drugs for which an application for a full or partial Rx-to-nonprescription switch was approved during such period, the average length of time from receipt by the Food and Drug Administration of the application to the approval of such application;

(D) the number of partial Rx-to-nonprescription switch applications approved during such period, and the number of applications for such a partial switch was not approved;

(E) any barriers to timely and predictable review of applications for an Rx-to-nonprescription switch;

(F) engagement by the Food and Drug Administration with public stakeholders, including public meetings or additional activities, to support review of applications for an Rx-to-nonprescription switch; and

(G) opportunities for collaboration between the Center for Drug Evaluation and Research and the Centers for Medicare & Medicaid Services for the purpose of analyzing health insurance claims data for commonly prescribed drugs that appear to be suitable for an Rx-to-nonprescription switch.

(2) DEFINITION.—In this subsection, the term "Rx-to-nonprescription switch" has the meaning given such term in paragraph (7) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 244(b)), as added by subsection (a).

SEC. 8. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744L and 744M of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71; 379j–72) shall cease to be effective October 1, 2030.

(b) REPORTING REQUIREMENTS.—Section 744N of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–73) shall cease to be effective January 31, 2031.

SEC. 9. EFFECTIVE DATE.

The amendments made by this Act shall take effect on October 1, 2025, or the date of the enactment of this Act, whichever is later, except that fees under part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71 et seq.) shall be assessed beginning October 1, 2025, regardless of the date of the enactment of this Act.

SEC. 10. SAVINGS CLAUSE.

Notwithstanding the amendments made by this Act, part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71 et seq.), as in effect on the day before the date of enactment of this Act,

shall continue to be in effect with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2026.

Calendar No. 152

119TH CONGRESS
1ST SESSION

S. 2292

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-the-counter monograph drugs, and for other purposes.

SEPTEMBER 8, 2025

Reported with an amendment