Committee Print

(SHOWING THE TEXT OF H.R. 7667, AS FAVORABLY FORWARDED BY THE SUBCOMMITTEE ON HEALTH ON MAY 11, 2022)

117TH CONGRESS
2D SESSION

H. R. 7667

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 6, 2022

Ms. ESHOO (for herself, Mr. GUTHRIE, Mr. PALLONE, and Mrs. RODGERS of Washington) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, 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 ''Food and Drug Amendments of 2022''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2022''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made by this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

(a) HUMAN DRUG APPLICATION.—Section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is amended by striking ''an allergenic extract product, or'' and inserting ''does not include an application with respect to an allergenic extract product licensed before October 1, 2022, does not include an application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, does not include an application with respect to''.

(b) PRESCRIPTION DRUG PRODUCT.—Section 735(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(3)) is amended—

(1) by redesignating subparagraphs (A), (B), and (C) as clauses (i), (ii), and (iii), respectively;

(2) by striking ''(3) The term'' and inserting ''(3)(A) The term'';

(3) by striking ''Such term does not include'' and inserting the following:

''(B) Such term does not include'';

(4) by striking ''an allergenic extract product,'' and inserting ''an allergenic extract product licensed before October 1, 2022, a standardized allergenic ex-

tract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022,'' ; and

(5) by adding at the end the following:

''(C)(i) If a written request to place a product in the discontinued section of either of the lists referenced in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is withdrawn from sale, then for purposes of assessing the prescription drug program fee under section 736(a)(2), the Secretary shall consider such product to have been included in the discontinued section on the later of—

''(I) the date such request was received; or

''(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

''(ii) For purposes of this subparagraph, a product shall be considered withdrawn from

sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.''.

(c) SKIN-TEST DIAGNOSTIC PRODUCT.—Section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) is amended by adding at the end the following:

''(12) The term 'skin-test diagnostic product'—

''(A) means a product—

''(i) for prick, scratch, intradermal, or subcutaneous administration;

''(ii) expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;

''(iii) not intended to be a preventive or therapeutic intervention; and

''(iv) intended to detect an immediate- or delayed-type skin hypersensitivity reaction to aid in the diagnosis of—

''(I) an allergy to an antimicrobial agent;

''(II) an allergy that is not to an antimicrobial agent, if the diagnostic

product was authorized for marketing prior to October 1, 2022; or

''(III) infection with fungal or mycobacterial pathogens; and

''(B) includes positive and negative controls required to interpret the results of a product described in subparagraph (A).''.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—

(1) HUMAN DRUG APPLICATION FEE.—Section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is amended—

(A) in the matter preceding paragraph (1), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023'';

(B) in paragraph (1)(A), by striking ''(c)(5)'' each place it appears and inserting ''(c)(6)'';

(C) in paragraph (1)(C), by inserting ''prior to approval'' after ''or was withdrawn''; and

(D) in paragraph (1), by adding at the end the following:

''(H) EXCEPTION FOR SKIN-TEST DIAGNOSTIC PRODUCTS.—A human drug application

for a skin-test diagnostic product shall not be subject to a fee under subparagraph (A).''.

(2) PRESCRIPTION DRUG PROGRAM FEE.—Section 736(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(2)) is amended—

(A) in subparagraph (A)—

(i) by striking ''Except as provided in subparagraphs (B) and (C)'' and inserting the following:

''(i) FEE.—Except as provided in subparagraphs (B) and (C)'';

(ii) by striking ''subsection (c)(5)'' and inserting ''subsection (c)(6)''; and

(iii) by adding at the end the following:

''(ii) SPECIAL RULE.—If a drug product that is identified in a human drug application approved as of October 1 of a fiscal year is not a prescription drug product as of that date because the drug product is in the discontinued section of a list referenced in section 735(3)(A)(iii), and on any subsequent day during such fiscal year the drug product is a prescription drug product, then except as provided in sub-

paragraphs (B) and (C), each person who is named as the applicant in a human drug application with respect to such product, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement with respect to such product, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for such prescription drug product. Such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for a fiscal year in which the fee is payable.''; and

(B) by amending subparagraph (B) to read as follows:

''(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

''(i) a large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not in-

cluding powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 505(j)(7);

''(ii) pharmaceutically equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulation)) to another product on the list of products compiled under section 505(j)(7) (not including the discontinued section of such list); or

''(iii) a skin-test diagnostic product.''.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Paragraph (1) of section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

''(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

''(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

"(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 strategic hiring and retention adjustment for the fiscal year (as determined under subsection (c)(2));

"(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

"(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

"(F) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(5)); and

"(G) additional dollar amounts for each fiscal year as follows:

"(i) $65,773,693 for fiscal year 2023.

"(ii) $25,097,671 for fiscal year 2024.

"(iii) $14,154,169 for fiscal year 2025.

"(iv) $4,864,860 for fiscal year 2026.

"(v) $1,314,620 for fiscal year 2027.".

(2) ANNUAL BASE REVENUE.—Paragraph (3) of section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

"(3) 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 2023, $1,151,522,958; and

"(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, not including any adjustments made under subsection (c)(4) or (c)(5).".

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is amended by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington-Arlington-Alexandria, DC–VA–MD–WV".

(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—Section 736(c) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (2) through (6) as paragraphs (3) through (7), respectively; and

(B) by inserting after paragraph (1) the following:

''(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by the following amounts:

''(A) For fiscal year 2023, $9,000,000.

''(B) For each of fiscal years 2024 through 2027, $4,000,000.''.

(3) CAPACITY PLANNING ADJUSTMENT.—Paragraph (3), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended to read as follows:

''(3) CAPACITY PLANNING ADJUSTMENT.—

''(A) IN GENERAL.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted in accordance with paragraphs (1) and (2), such revenue shall

be adjusted further for such fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for the process for the review of human drug applications.

''(B) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled 'Prescription Drug User Fee Rates for Fiscal Year 2021' published in the Federal Register on August 3, 2020 (85 Fed. Reg. 46651). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are also directly related to the direct review of applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products. Subject to the exceptions in the preceding sentence, the Sec-

retary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

''(C) LIMITATION.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment for the fiscal year).

''(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (6) of the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.''.

(4) OPERATING RESERVE ADJUSTMENT.—Paragraph (4), as redesignated, of section 736(c) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(A) by amending subparagraph (A) to read as follows:

''(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for operating reserves of carryover user fees for the process for the review of human drug applications for each fiscal year in at least the following amounts:

''(i) For fiscal year 2023, at least 8 weeks of operating reserves.

''(ii) For fiscal year 2024, at least 9 weeks of operating reserves.

''(iii) For fiscal year 2025 and subsequent fiscal years, at least 10 weeks of operating reserves.''; and

(B) in subparagraph (C), by striking ''paragraph (5)'' and inserting ''paragraph (6)''.

(5) ADDITIONAL DIRECT COST ADJUSTMENT.—Paragraph (5), as redesignated, of section 736(c) of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended to read as follows:

"(5) ADDITIONAL DIRECT COST ADJUSTMENT.—

"(A) INCREASE.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), (3), and (4), further increase the fee revenue and fees—

"(i) for fiscal year 2023, by $44,386,150; and

"(ii) for each of fiscal years 2024 through 2027, by the amount set forth in clauses (i) through (iv) of subparagraph (B), as applicable, multiplied by the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2021.

"(B) APPLICABLE AMOUNTS.—The amounts referred to in subparagraph (A)(ii) are the following:

"(i) For fiscal year 2024, $60,967,993.

''(ii) For fiscal year 2025, $35,799,314.

''(iii) For fiscal year 2026, $35,799,314.

''(iv) For fiscal year 2027, $35,799,314.''.

(6) ANNUAL FEE SETTING.—Paragraph (6), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended by striking ''September 30, 2017'' and inserting ''September 30, 2022''.

(d) CREDITING AND AVAILABILITY OF FEES.—Section 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(3)) is amended by striking ''fiscal years 2018 through 2022'' and inserting ''fiscal years 2023 through 2027''.

(e) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—Section 736(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is amended to read as follows:

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver or reduction under subsection (d), an exemption under

subsection (k), or the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall—

''(1) not later than 180 days after such fee is due, submit to the Secretary a written request justifying such waiver, reduction, exemption, or return; and

''(2) include in the request any legal authorities under which the request is made.''.

(f) ORPHAN DRUGS.—Section 736(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is amended—

(1) in paragraph (1)(B), by striking ''during the previous year'' and inserting ''as determined under paragraph (2)''; and

(2) by amending paragraph (2) to read as follows:

''(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that the applicant's gross annual revenues did not exceed $50,000,000 for the last calendar year ending prior to the fiscal year for which the exemption is requested. Such certification shall be supported by—

''(A) tax returns submitted to the United States Internal Revenue Service; or

''(B) as necessary, other appropriate financial information.''.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) is amended—

(1) in subsection (a)(1), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(2) by striking ''Prescription Drug User Fee Amendments of 2017'' each place it appears and inserting ''Prescription Drug User Fee Amendments of 2022'';

(3) in subsection (a)(3)(A), by striking ''Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter'' and inserting ''Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part'';

(4) in subsection (a)(3)(B), by adding at the end the following:

''(v) For fiscal years 2023 and 2024, of the meeting requests from sponsors for

which the Secretary has determined that a face-to-face meeting is appropriate, the number of face-to-face meetings requested by sponsors to be conducted in person (in such manner as the Secretary shall prescribe on the internet website of the Food and Drug Administration), and the number of such in-person meetings granted by the Secretary.'';

(5) in subsection (a)(4), by striking ''Beginning with fiscal year 2020, the'' and inserting ''The'';

(6) in subsection (b), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(7) in subsection (c), by striking ''Beginning with fiscal year 2018, for'' and inserting ''For''; and

(8) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''fiscal year 2022'' and inserting ''fiscal year 2027''; and

(B) in paragraph (5), by striking ''January 15, 2022'' and inserting ''January 15, 2027''.

SEC. 105. SUNSET DATES.

(a) AUTHORIZATION.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 104 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall be assessed for all human drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 107. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human

drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2017, but before October 1, 2022, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Medical Device User Fee Amendments of 2022''.

(b) FINDING.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

Section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i) is amended—

(1) in paragraph (9)—

(A) in the matter preceding subparagraph (A), by striking ''and premarket notification submissions'' and inserting ''premarket notification submissions, and de novo classification requests'';

(B) in subparagraph (D), by striking ''and submissions'' and inserting ''submissions, and requests'';

(C) in subparagraph (F), by striking ''and premarket notification submissions'' and inserting ''premarket notification submissions, and de novo classification requests'';

(D) in each of subparagraphs (G) and (H), by striking ''or submissions'' and inserting ''submissions, or requests''; and

(E) in subparagraph (K), by striking ''or premarket notification submissions'' and inserting ''premarket notification submissions, or de novo classification requests''; and

(2) in paragraph (11), by striking ''2016'' and inserting ''2021''.

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''October 1, 2017'' and inserting ''October 1, 2022'';

(ii) in clause (iii), by striking ''75 percent'' and inserting ''80 percent''; and

(iii) in clause (viii), by striking ''3.4 percent'' and inserting ''4.5 percent'';

(B) in subparagraph (B)(iii), by striking ''or premarket notification submission'' and inserting ''premarket notification submission, or de novo classification request''; and

(C) in subparagraph (C), by striking ''or periodic reporting concerning a class III device'' and inserting ''periodic reporting concerning a class III device, or de novo classification request''.

(b) FEE AMOUNTS.—Section 738(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is amended—

(1) in paragraph (1), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(2) by amending paragraph (2) to read as follows:

''(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

''Fee Type	Fiscal Year 2023	Fiscal Year 2024	Fiscal Year 2025	Fiscal Year 2026	Fiscal Year 2027
Premarket Application	$425,000	$435,000	$445,000	$455,000	$470,000
Establishment Registration	$6,250	$6,875	$7,100	$7,575	$8,465''; and

(3) by amending paragraph (3) to read as follows:

''(3) TOTAL REVENUE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

''(A) $312,606,000 for fiscal year 2023.

''(B) $335,750,000 for fiscal year 2024.

''(C) $350,746,400 for fiscal year 2025.

''(D) $366,486,300 for fiscal year 2026.

''(E) $418,343,000 for fiscal year 2027.''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(c)) is amended—

(1) in paragraph (1), by striking ''2017'' and inserting ''2022'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''2018'' and inserting ''2023'';

(B) in subparagraph (B)—

(i) in the matter preceding clause (i), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''; and

(ii) in clause (ii), by striking ''fiscal year 2016'' and inserting ''fiscal year 2022'';

(C) in subparagraph (C), by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington-Arlington-Alexandria, DC–VA–MD–WV''; and

(D) in subparagraph (D), in the matter preceding clause (i), by striking ''fiscal years 2018 through 2022'' and inserting ''fiscal years 2023 through 2027'';

(3) in paragraph (3), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(4) by redesignating paragraphs (4) and (5) as paragraphs (7) and (8), respectively; and

(5) by inserting after paragraph (3) the following:

''(4) PERFORMANCE IMPROVEMENT ADJUSTMENT.—

''(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2) and (3), the base establishment registration fee amounts for such fiscal year shall be increased to reflect changes in the resource needs of the Secretary due to improved review performance goals for the process for the review of device applications identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022, as the Secretary determines necessary to achieve an increase in total fee collections for such fiscal year equal to the following amounts:

''(i) For fiscal year 2025, the product of—

''(I) the amount determined under subparagraph (B)(i)(I); and

''(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

''(ii) For fiscal year 2026, the product of—

''(I) the sum of the amounts determined under subparagraphs (B)(i)(II), (B)(ii)(I), and (B)(iii)(I); and

''(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

''(iii) For fiscal year 2027, the product of—

''(I) the sum of the amounts determined under subparagraphs (B)(i)(III), (B)(ii)(II), and (B)(iii)(II); and

''(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

''(B) AMOUNTS.—

''(i) PRE-SUBMISSION AMOUNT.—For purposes of subparagraph (A), with respect to the pre-submission written feedback goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2025, $15,396,600 if such goal for fiscal year 2023 is met.

"(II) For fiscal year 2026:

"(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

"(bb) $36,792,200 if such goal for fiscal year 2024 is met.

"(III) For fiscal year 2027:

"(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for each of fiscal years 2024 and 2025 is not met.

"(bb) $36,792,200 if such goal for fiscal year 2024 is met and such goal for fiscal year 2025 is not met.

"(cc) $40,572,600 if such goal for fiscal year 2025 is met.

"(ii) DE NOVO CLASSIFICATION AMOUNT.—For purposes of subparagraph (A), with respect to the de novo decision

goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2026, $6,323,500 if such goal for fiscal year 2023 is met.

"(II) For fiscal year 2027:

"(aa) $6,323,500 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

"(bb) $11,765,400 if such goal for fiscal year 2024 is met.

"(iii) PREMARKET NOTIFICATION AND PREMARKET APPROVAL AMOUNT.—For purposes of subparagraph (A), with respect to the 510(k) decision goal, 510(k) shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2026, $1,020,000 if the four goals for fiscal year 2023 are met.

"(II) For fiscal year 2027:

''(aa) $1,020,000 if the four goals for fiscal year 2023 are met and one or more of the four goals for fiscal year 2024 are not met.

''(bb) $3,906,000 if the four goals for fiscal year 2024 are met.

''(C) PERFORMANCE CALCULATION.—For purposes of this paragraph, performance of the goals listed in subparagraph (D) shall be determined as specified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022 and based on data available as of the following dates:

''(i) The performance of the pre-submission written feedback goal shall be based on data available as of—

''(I) for fiscal year 2023, March 31, 2024;

''(II) for fiscal year 2024, March 31, 2025; and

''(III) for fiscal year 2025, March 31, 2026.

''(ii) The performance of the de novo decision goal, 510(k) decision goal, 510(k)

shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal shall be based on data available as of—

''(I) for fiscal year 2023, March 31, 2025; and

''(II) for fiscal year 2024, March 31, 2026.

''(D) GOALS DEFINED.—For purposes of this paragraph, the terms 'pre-submission written feedback goal', 'de novo decision goal', '510(k) decision goal', '510(k) shared outcome total time to decision goal', 'PMA decision goal', and 'PMA shared outcome total time to decision goal' refer to the goals identified by the same names in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

''(5) HIRING ADJUSTMENT.—

''(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2), (3), and (4), if applicable, if the number of hires to support the process for the review of device applications falls below the thresholds specified in subpara-

graph (B) for the applicable fiscal years, the base establishment registration fee amounts shall be decreased as the Secretary determines necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount under subparagraph (C).

''(B) THRESHOLDS.—The thresholds specified in this subparagraph are as follows:

''(i) For fiscal year 2025, the threshold is 123 hires for fiscal year 2023.

''(ii) For fiscal year 2026, the threshold is 38 hires for fiscal year 2024.

''(iii) For fiscal year 2027, the threshold is—

''(I) 22 hires for fiscal year 2025 if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i); or

''(II) 75 hires for fiscal year 2025 if such fees are so increased.

''(C) HIRING ADJUSTMENT AMOUNT.—The hiring adjustment amount for fiscal year 2025 and each subsequent fiscal year is the product of—

"(i) the number of hires by which the hiring goal specified in subparagraph (D) for the fiscal year before the prior fiscal year was not met;

"(ii) $72,877; and

"(iii) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year for which the hiring goal was not met.

"(D) HIRING GOALS.—The hiring goals for each of fiscal years 2023 through 2025 are as follows:

"(i) For fiscal year 2023, 144 hires.

"(ii) For fiscal year 2024, 42 hires.

"(iii) For fiscal year 2025:

"(I) 24 hires if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i).

"(II) 83 hires if the base establishment registration fees are increased by the amount determined under paragraph (4)(A)(i).

"(E) NUMBER OF HIRES.—For purposes of this paragraph, the number of hires shall be determined by the Secretary as set forth in the

letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

''(6) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For each of fiscal years 2023 through 2027, after the adjustments under paragraphs (2), (3), (4), and (5), if applicable, if the Secretary has operating reserves of carryover user fees for the process for the review of device applications in excess of the designated amount in subparagraph (B), the Secretary shall decrease the base establishment registration fee amounts to provide for not more than such designated amount of operating reserves.

''(B) DESIGNATED AMOUNT.—Subject to subparagraph (C), for each fiscal year, the designated amount in this subparagraph is equal to the sum of—

''(i) 13 weeks of operating reserves of carryover user fees; and

''(ii) 1 month of operating reserves maintained pursuant to paragraph (8).

''(C) EXCLUDED AMOUNT.—For the period of fiscal years 2023 through 2026, a total amount equal to $118,000,000 shall not be con-

sidered part of the designated amount under subparagraph (B) and shall not be subject to the decrease under subparagraph (A).''.

(d) SMALL BUSINESSES.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended in each of subsections (d)(2)(B)(iii) and (e)(2)(B)(iii) by inserting '', if extant,'' after ''national taxing authority''.

(e) CONDITIONS.—Section 738(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is amended—

(1) in paragraph (1)(A), by striking ''$320,825,000'' and inserting ''$398,566,000''; and

(2) in paragraph (2), by inserting ''de novo classification requests,'' after ''class III device,''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 738(h)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)(3)) is amended to read as follows:

''(3) AUTHORIZATION OF APPROPRIATIONS.—

''(A) IN GENERAL.—For each of fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the revenue amount determined under subparagraph (B), less the

amount of reductions determined under subparagraph (C).

''(B) REVENUE AMOUNT.—For purposes of this paragraph, the revenue amount for each fiscal year is the sum of—

''(i) the total revenue amount under subsection (b)(3) for the fiscal year, as adjusted under paragraphs (2) and (3) of subsection (c); and

''(ii) the performance improvement adjustment amount for the fiscal year under subsection (c)(4), if applicable.

''(C) REDUCTIONS.—For purposes of this paragraph, the amount of reductions for each fiscal year is the sum of—

''(i) the hiring adjustment amount for the fiscal year under subsection (c)(5), if applicable; and

''(ii) the operating reserve adjustment amount for the fiscal year under subsection (c)(6), if applicable.''.

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORTS.—Section 738A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is amended—

(1) by striking ''fiscal year 2018'' each place it appears and inserting ''fiscal year 2023'';

(2) by striking ''Medical Device User Fee Amendments of 2017'' each place it appears and inserting ''Medical Device User Fee Amendments of 2022'';

(3) in paragraph (1)—

(A) in subparagraph (A), by redesignating the second clause (iv) (relating to analysis) as clause (v); and

(B) in subparagraph (A)(iv), by striking ''fiscal year 2020'' and inserting ''fiscal year 2023''; and

(4) in paragraph (4), by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

(b) REAUTHORIZATION.—Section 738A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking ''2022'' and inserting ''2027''; and

(2) in paragraph (5), by striking ''2022'' and inserting ''2027''.

SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.

Section 514(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(d)) is amended to read as follows:

''(d) ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—

''(1) IN GENERAL.—The Secretary shall establish a program under which—

''(A) testing laboratories meeting criteria specified in guidance by the Secretary may be accredited by accreditation bodies meeting criteria specified in guidance by the Secretary, to conduct testing to support the assessment of the conformity of a device to certain standards recognized under this section; and

''(B) subject to paragraph (2), results from tests conducted to support the assessment of conformity of devices as described in subparagraph (A) conducted by testing laboratories accredited pursuant to this subsection shall be accepted by the Secretary for purposes of demonstrating such conformity unless the Secretary finds that certain results of such tests should not be so accepted.

''(2) SECRETARIAL REVIEW OF ACCREDITED LABORATORY RESULTS.—The Secretary may—

''(A) review the results of tests conducted by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such results or of the processes of accredited bodies or testing laboratories;

''(B) following such review, take additional measures under this Act, as the Secretary determines appropriate, such as—

''(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

''(ii) requesting additional information with respect to a device; and

''(C) if the Secretary becomes aware of information materially bearing on the safety or effectiveness of a device for which an assessment of conformity was supported by testing conducted by a testing laboratory accredited under this subsection, take such additional measures under this Act, as the Secretary determines appropriate, such as—

''(i) suspension or withdrawal of accreditation of a testing laboratory or rec-

ognition of an accreditation body under paragraph (1)(A); or

"(ii) requesting additional information with regard to such device.

"(3) IMPLEMENTATION AND REPORTING.—

"(A) PILOT PROGRAM TRANSITION.—After September 30, 2023, the pilot program previously initiated under this subsection, as in effect prior to the date of enactment of the Medical Device User Fee Amendments of 2022, shall be considered to be completed, and the Secretary may continue operating a program consistent with this subsection.

"(B) REPORT.—The Secretary shall make available on the internet website of the Food and Drug Administration an annual report on the progress of the pilot program under this subsection.".

SEC. 206. REAUTHORIZATION OF THIRD-PARTY REVIEW PROGRAM.

Section 523(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(c)) is amended by striking "2022" and inserting "2027".

SEC. 207. SUNSET DATES.

(a) AUTHORIZATION.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i; 379j) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 738A (21 U.S.C. 379j– 1) of the Federal Food, Drug, and Cosmetic Act (regarding reauthorization and reporting requirements) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISIONS.—Effective October 1, 2022, subsections (a) and (b) of section 210 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 208. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.) shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 209. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this

title, shall continue to be in effect with respect to the submissions listed in section 738(a)(2)(A) of such Act (as defined in such part as of such day) that on or after October 1, 2017, but before October 1, 2022, were received by the Food and Drug Administration with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Generic Drug User Fee Amendments of 2022''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made by this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41 et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

(a) TYPES OF FEES.—Section 744B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)) is amended—

(1) in the matter preceding paragraph (1), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023'';

(2) in paragraph (2)(C), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(3) in paragraph (3)(B), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(4) in paragraph (4)(D), by striking ''2018 through 2022'' and inserting ''2023 through 2027''; and

(5) in paragraph (5)(D), by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

(b) FEE REVENUE AMOUNTS.—Section 744B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the heading, by striking ''2018'' and inserting ''2023'';

(ii) by striking ''2018'' and inserting ''2023''; and

(iii) by striking ''$493,600,000'' and inserting ''$582,500,000''; and

(B) by amending subparagraph (B) to read as follows:

''(B) FISCAL YEARS 2024 THROUGH 2027.—

''(i) IN GENERAL.—For each of the fiscal years 2024 through 2027, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to the base revenue amount for the fiscal year under clause (ii), as adjusted pursuant to subsection (c).

''(ii) BASE REVENUE AMOUNT.—The base revenue amount for a fiscal year referred to in clause (i) is equal to the total revenue amount established under this paragraph for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(3).''; and

(2) in paragraph (2)—

(A) in subparagraph (C), by striking ''one-third the amount'' and inserting ''twenty-four percent'';

(B) in subparagraph (D), by striking ''Seven percent'' and inserting ''Six percent''; and

(C) in subparagraph (E)(i), by striking ''Thirty-five percent'' and inserting ''Thirty-six percent''.

(c) ADJUSTMENTS.—Section 744B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A)—

(i) by striking ''2019'' and inserting ''2024''; and

(ii) by striking ''to equal the product of the total revenues established in such notice for the prior fiscal year multiplied'' and inserting ''to equal the base revenue amount for the fiscal year (as specified in subsection (b)(1)(B)) multiplied''; and

(B) in subparagraph (C), by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington-Arlington-Alexandria, DC–VA–MD–WV''; and

(2) by striking paragraph (2) and inserting the following:

''(2) CAPACITY PLANNING ADJUSTMENT.—

''(A) IN GENERAL.—Beginning with fiscal year 2024, the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

''(B) CAPACITY PLANNING METHODOLOGY.—The Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

''(i) be derived from the methodology and recommendations made in the report titled 'Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations' announced in the Federal Register on August 3, 2020;

''(ii) incorporate approaches and attributes determined appropriate by the Secretary, including approaches and at-

tributes made in such report, except that in incorporating such approaches and attributes the workload categories used in forecasting resources shall only be the workload categories specified in section VIII.B.2.e. of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022; and

''(iii) be effective beginning with fiscal year 2024.

''(C) LIMITATIONS.—

''(i) IN GENERAL.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

''(ii) PERCENTAGE LIMITATION.—An adjustment under this paragraph shall not exceed three percent of the sum described in clause (i) for the fiscal year, except that such limitation shall be four percent if—

''(I) for purposes of a fiscal year 2024 adjustment, the Secretary determines that during the period from April 1, 2021, through March 31, 2023—

''(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,000; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022);

''(II) for purposes of a fiscal year 2025 adjustment, the Secretary determines that during the period from April 1, 2022, through March 31, 2024—

''(aa) the total number of abbreviated new drug applica-

tions submitted was greater than or equal to 2,300; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined);

''(III) for purposes of a fiscal year 2026 adjustment, the Secretary determines that during the period from April 1, 2023, through March 31, 2025—

''(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined); and

''(IV) for purposes of a fiscal year 2027 adjustment, the Secretary determines that during the period from April 1, 2024, through March 31, 2026—

''(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined).

''(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice referred to in subsection (a) the fee revenue and fees resulting from the adjustment and the methodology under this paragraph.

''(3) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2024 and each subsequent fiscal year, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section for such fiscal year if such an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B) with respect to that fiscal year.

''(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

''(i) 8 weeks for fiscal year 2024;

''(ii) 9 weeks for fiscal year 2025; and

''(iii) 10 weeks for each of fiscal year 2026 and 2027.

''(C) DECREASE.—If the Secretary has carryover balances for human generic drug activities in excess of 12 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 12 weeks of such operating reserves.

''(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under subsection (a) publishing the fee revenue and fees for the fiscal year involved.''.

(d) ANNUAL FEE SETTING.—Section 744B(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(d)(1)) is amended—

(1) in the paragraph heading, by striking ''2018 THROUGH 2022'' and inserting ''2023 THROUGH 2027''; and

(2) by striking ''more than 60 days before the first day of each of fiscal years 2018 through 2022'' and inserting ''later than 60 days before the first day of each of fiscal years 2023 through 2027''.

(e) CREDITING AND AVAILABILITY OF FEES.—Section 744B(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(i)(3)) is amended by striking ''fiscal years 2018 through 2022'' and inserting ''fiscal years 2023 through 2027''.

(f) EFFECT OF FAILURE TO PAY FEES.—The heading of paragraph (3) of section 744B(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is amended by striking ''AND PRIOR APPROVAL SUPPLEMENT FEE''.

SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) is amended—

(1) in subsection (a)(1), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(2) by striking ''Generic Drug User Fee Amendments of 2017'' each place it appears and in-

serting ''Generic Drug User Fee Amendments of 2022'';

(3) in subsection (a)(2), by striking ''Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter'' and inserting ''Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part'';

(4) in subsection (a)(3), by striking ''Beginning with fiscal year 2020, the'' and inserting ''The'';

(5) in subsection (b), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(6) in subsection (c), by striking ''Beginning with fiscal year 2018, for'' and inserting ''For''; and

(7) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''fiscal year 2022'' and inserting ''fiscal year 2027''; and

(B) in paragraph (5), by striking ''January 15, 2022'' and inserting ''January 15, 2027''.

SEC. 304. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41; 379j–42) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 305 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41 et seq.) shall be assessed for all abbreviated new drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 306. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41 et seq.), as in effect on the day before the date of the enactment of

this title, shall continue to be in effect with respect to abbreviated new drug applications (as defined in such part as of such day) that were received by the Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Biosimilar User Fee Amendments of 2022''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made by this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), in the letters from the Secretary

of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 402. DEFINITIONS.

(a) ADJUSTMENT FACTOR.—Section 744G(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(1)) is amended to read as follows:

''(1) The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for September of the preceding fiscal year divided by such Index for September 2011.''.

(b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—Section 744G(4)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(4)(B)(iii)) is amended—

(1) by striking subclause (II) (relating to an allergenic extract product); and

(2) by redesignating subclauses (III) and (IV) as subclauses (II) and (III), respectively.

SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—The matter preceding paragraph (1) in section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''.

(2) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—Clauses (iv)(I) and (v)(II) of section 744H(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(A)) are each amended by striking ''5 days'' and inserting ''7 days''.

(3) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—Section 744H(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(B)) is amended—

(A) in clause (i), by inserting before the period at the end the following: '', except where such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, in which case such licensee, assignee, or

successor shall pay the annual biosimilar biological product development fee'';

(B) in clause (iii)—

(i) in subclause (I), by striking ''or'' at the end;

(ii) in subclause (II), by striking the period at the end and inserting ''; or''; and

(iii) by adding at the end the following:

''(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).''; and

(C) in clause (iv), by striking ''is accepted for filing on or after October 1 of such fiscal year'' and inserting ''is subsequently accepted for filing''.

(4) REACTIVATION FEE.—Section 744H(a)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(D)) is amended to read as follows:

''(D) REACTIVATION FEE.—

''(i) IN GENERAL.—A person that has discontinued participation in the biosimilar

biological product development program for a product under subparagraph (C), or who has been administratively removed from the biosimilar biological product development program for a product under subparagraph (E)(v), shall, if the person seeks to resume participation in such program, pay all annual biosimilar biological product development fees previously assessed for such product and still owed and a fee (referred to in this section as 'reactivation fee') by the earlier of the following:

''(I) Not later than 7 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued or the date of administrative removal, as applicable).

''(II) Upon the date of submission (after the date on which such participation was discontinued or the date of administrative removal, as applicable) by such person of an inves-

tigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

''(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B), except where such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, in which case such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.''.

(5) EFFECT OF FAILURE TO PAY FEES.—Section 744H(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(E)) is amended by adding at the end the following:

''(v) ADMINISTRATIVE REMOVAL FROM THE BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM.—If a person has failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of two consecutive fiscal years, the Secretary may administratively remove such person from the biosimilar biological product development program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to such person of the intended administrative removal.''.

(6) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—Section 744H(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(2)(D)) is amended by inserting after ''or was withdrawn'' the following: ''prior to approval''.

(7) BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.—Section 744H(a)(3) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(3)) is amended—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''and'' at the end;

(ii) by redesignating clause (ii) as clause (iii); and

(iii) by inserting after clause (i) the following:

''(ii) may be dispensed only under prescription pursuant to section 503(b); and''; and

(B) by adding at the end the following:

''(E) MOVEMENT TO DISCONTINUED LIST.—

''(i) DATE OF INCLUSION.—If a written request to place a product on the list referenced in subparagraph (A) of discontinued biosimilar biological products is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is withdrawn from sale, then for purposes of assessing the biosimilar biological product program fee, the Secretary

shall consider such product to have been included on such list on the later of—

''(I) the date such request was received; or

''(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

''(ii) TREATMENT AS WITHDRAWN FROM SALE.—For purposes of clause (i), a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

''(iii) SPECIAL RULE.—If a biosimilar biological product that is identified in a biosimilar biological product application approved as of October 1 of a fiscal year appears, as of October 1 of such fiscal year, on the list referenced in subparagraph (A) of discontinued biosimilar bio-

logical products, and on any subsequent day during such fiscal year the biosimilar biological product does not appear on such list, then except as provided in subparagraph (D), each person who is named as the applicant in a biosimilar biological product application with respect to such product shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for such biosimilar biological product. Notwithstanding subparagraph (B), such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for each fiscal year.''.

(8) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—Section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended by striking paragraph (4).

(c) FEE REVENUE AMOUNTS.—Subsection (b) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is amended—

(1) by striking paragraph (1);

(2) by redesignating paragraphs (2) through (4) as paragraphs (1) through (3), respectively;

(3) by amending paragraph (1) (as so redesignated) to read as follows:

''(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, fees under subsection (a) shall, except as provided in subsection (c), be established to generate a total revenue amount equal to the sum of—

''(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

''(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 strategic hiring and retention adjustment (as determined under subsection (c)(2));

''(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

''(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

''(F) for fiscal year 2023 an additional amount of $4,428,886; and

''(G) for fiscal year 2024 an additional amount of $320,569.'';

(4) in paragraph (2) (as so redesignated)—

(A) in the paragraph heading, by striking ''; LIMITATIONS ON FEE AMOUNTS'';

(B) by striking subparagraph (B); and

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

(5) by amending paragraph (3) (as so redesignated) to read as follows:

''(3) 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 2023, $43,376,922; and

''(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(4).''.

(d) ADJUSTMENTS; ANNUAL FEE SETTING.—Section 744H(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(c)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''subsection (b)(2)(B)'' and inserting ''subsection (b)(1)(B)''; and

(ii) in clause (i), by striking ''subsection (b)'' and inserting ''subsection (b)(1)(A)''; and

(B) in subparagraph (B)(ii), by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington-Arlington-Alexandria, DC–VA–MD–WV'';

(2) by striking paragraphs (2) through (4) and inserting the following:

''(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by $150,000.

''(3) CAPACITY PLANNING ADJUSTMENT.—

"(A) IN GENERAL.—For each fiscal year, the Secretary shall, in addition to the adjustments under paragraphs (1) and (2), further adjust the fee revenue and fees under this section for a fiscal year to reflect changes in the resource capacity needs of the Secretary for the process for the review of biosimilar biological product applications.

"(B) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled 'Biosimilar User Fee Rates for Fiscal Year 2021' published in the Federal Register on August 4, 2020 (85 Fed. Reg. 47220). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitiga-

tion strategies, and the direct review of annual reports for approved biosimilar biological products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

''(C) LIMITATIONS.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment).

''(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

''(4) OPERATING RESERVE ADJUSTMENT.—

''(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

''(B) DECREASE.—

''(i) FISCAL YEAR 2023.—For fiscal year 2023, if the Secretary has carryover balances for such process in excess of 33 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves.

''(ii) FISCAL YEAR 2024.—For fiscal year 2024, if the Secretary has carryover balances for such process in excess of 27 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 27 weeks of such operating reserves.

''(iii) FISCAL YEAR 2025 AND SUBSEQUENT FISCAL YEARS.—For fiscal year 2025 and subsequent fiscal years, if the Secretary has carryover balances for such process in excess of 21 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves.

''(C) FEDERAL REGISTER NOTICE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5)(B) establishing fee revenue and fees for the fiscal year involved.''; and

(3) in paragraph (5), in the matter preceding subparagraph (A), by striking ''2018'' and inserting ''2023''.

(e) CREDITING AND AVAILABILITY OF FEES.—Subsection (f)(3) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(f)(3)) is amended by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

(f) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—Section 744H(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(h)) is amended to read as follows:

''(h) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver under subsection (d), or for the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such waiver or return and, except as otherwise specified in this section, such written request shall be submitted to the Secretary not later than 180 days after such fee is due. A request submitted under this paragraph shall include any legal authorities under which the request is made.''.

SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) is amended—

(1) in subsection (a)(1), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(2) by striking ''Biosimilar User Fee Amendments of 2017'' each place it appears and inserting ''Biosimilar User Fee Amendments of 2022'';

(3) in subsection (a)(2), by striking ''Beginning with fiscal year 2018, the'' and inserting ''The'';

(4) in subsection (a)(3)(A), by striking ''Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter'' and inserting ''Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part'';

(5) in subsection (b), by striking ''Not later than 120 days after the end of fiscal year 2018 and each subsequent fiscal year for which fees are collected under this part'' and inserting ''Not later than 120 days after the end of each fiscal year for which fees are collected under this part'';

(6) in subsection (c), by striking ''Beginning with fiscal year 2018, and for'' and inserting ''For''; and

(7) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''fiscal year 2022'' and inserting ''fiscal year 2027''; and

(B) in paragraph (3), by striking ''January 15, 2022'' and inserting ''January 15, 2027''.

SEC. 405. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51, 379j–52) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 405 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 406. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be assessed for all biosimilar biological product applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 407. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as in effect on the day before the date of the enactment of

this title, shall continue to be in effect with respect to biosimilar biological product applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE V—IMPROVING DIVERSITY IN CLINICAL STUDIES

SEC. 501. DIVERSITY ACTION PLANS FOR CLINICAL STUDIES.

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

''(5)(A) In order for a new drug that is being studied in a phase 3 study, as defined in section 312.21(c) of title 21, Code of Federal Regulations (or successor regulations), or other pivotal study, to be exempt pursuant to this subsection, the sponsor of a clinical investigation of such new drug shall submit to the Secretary a diversity action plan.

''(B) Such diversity action plan shall include—

''(i) the sponsor's goals for enrollment in such clinical investigation;

''(ii) the sponsor's rationale for such goals; and

''(iii) an explanation of how the sponsor intends to meet such goals.

''(C) The sponsor shall submit such diversity action plan in the form and manner specified in the guidance required by section 524B as soon as practicable but no later than when the sponsor seeks feedback regarding such a phase 3 study or other pivotal study of the drug.

''(D) The Secretary may waive the requirement in subparagraph (A)—

''(i) if the Secretary determines that a waiver is necessary based on what is known about the prevalence of the disease in terms of the patient population that may use the new drug; or

''(ii) where the investigational drug is being made available under section 561.''.

(b) DEVICES.—Section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(9)(A) In order for a device to be exempt under this subsection, except for a device being studied as described in section 812.2(c) of title 21, Code of Federal Regulations (or successor regulations), the sponsor of a clinical investigation of such device shall submit to the Secretary a diversity action plan.

''(B) Such diversity action plan shall include—

''(i) the sponsor's goals for enrollment in such clinical investigation;

''(ii) the sponsor's rationale for such goals; and

''(iii) an explanation of how the sponsor intends to meet such goals.

''(C) Such diversity action plan shall be—

''(i) an application in the form and manner specified in the guidance required by section 524B; and

''(ii) if submission of an application for an investigational device exemption is not required, submitted in the form, manner, and timeframe specified in the guidance required by section 524B as soon as practicable during device development, but no later than one month prior to commencing enrollment for a study.

''(D) The Secretary may waive the requirement in subparagraph (A)—

''(i) if the Secretary determines that a waiver is necessary based on what is known about the prevalence of the disease in terms of the patient population that may use the device; or

''(ii) where the investigational device is being made available under section 561.''.

(c) GUIDANCE.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR CLINICAL STUDIES.

''(a) IN GENERAL.—The Secretary shall issue guidance relating to—

''(1) the format and content of the diversity action plans required by sections 505(i)(5) and 520(g)(9) of this Act, and section 351(a)(3) of the Public Health Service Act, pertaining to the sponsor's goals for clinical study enrollment, disaggregated by age group, sex, race, geographic location, socioeconomic status, and ethnicity, including with respect to—

''(A) the rationale for the sponsor's enrollment goals, which may include—

''(i) the estimated prevalence or incidence in the United States of the disease or condition for which the drug or device is being developed or investigated, if such estimated prevalence or incidence is known or can be determined based on available data;

''(ii) what is known about the disease or condition for which the drug or device is being developed or investigated;

''(iii) any relevant pharmacokinetic or pharmacogenomic data;

''(iv) what is known about the patient population for such disease or condition, including, to the extent data is available—

''(I) demographic information, including age group, sex, race, geographic location, socioeconomic status, and ethnicity;

''(II) non-demographic factors, including co-morbidities frequently affecting the patient population; and

''(III) potential barriers to enrolling diverse participants, such as patient population size, geographic location, and socioeconomic status; and

''(v) any other data or information relevant to selecting appropriate enrollment goals, disaggregated by demographic subgroup, such as the inclusion of pregnant and lactating women;

''(B) an explanation for how the sponsor intends to meet such goals, including demographic-specific outreach and enrollment strategies, study-site selection, clinical study inclusion and exclusion practices, and any diversity training for study personnel; and

''(C) procedures for the public posting of key information from the diversity action plan that would be useful to patients and providers on the sponsor's website, as appropriate; and

''(2) how sponsors should include in regular reports to the Secretary—

''(A) the sponsor's progress in meeting the goals referred to in paragraph (1)(A); and

''(B) if the sponsor does not expect to meet such goals—

''(i) any updates needed to be made to a diversity action plan referred to in paragraph (1) to help meet such goals; and

''(ii) the sponsor's reasons for why the sponsor does not expect to meet such goals.

''(b) ISSUANCE.—The Secretary shall—

''(1) not later than 12 months after the date of enactment of this section, issue new draft guidance

or update existing draft guidance described in subsection (a); and

''(2) not later than 9 months after closing the comment period on such draft guidance, finalize such guidance.''.

(d) APPLICABILITY.—Sections 505(i)(5) and 520(g)(9) of the Federal Food, Drug, and Cosmetic Act, and section 351(a)(3)(B) of the Public Health Service Act, as added by subsections (a), (b), and (c) of this section, apply only with respect to clinical investigations with respect to which enrollment commences after the date that is 180 days after the publication of final guidance under section 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (d).

SEC. 502. EVALUATION OF THE NEED FOR FDA AUTHORITY TO MANDATE POSTAPPROVAL STUDIES OR POSTMARKET SURVEILLANCE DUE TO INSUFFICIENT DEMOGRAPHIC SUBGROUP DATA.

(a) IN GENERAL.—Not later than 2 years after the date of publication of final guidance pursuant to section 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 501(d) of this Act, the Secretary of Health and Human Services shall commence an evaluation to assess whether additions or changes to statutes or regu-

lations are warranted to ensure that sponsors conduct post-approval studies or postmarket surveillance where—

(1) premarket studies collected insufficient data for underrepresented subgroups according to the goals specified in the diversity action plans of such sponsors; and

(2) the Secretary has requested additional studies be conducted.

(b) DETERMINATION AND REPORTING.—Not later than 180 days after the commencement of the evaluation under subsection (a), the Secretary of Health and Human Services shall submit a report to the Congress on the outcome of such evaluation, including any recommendations related to additional needed authorities.

SEC. 503. PUBLIC WORKSHOPS TO ENHANCE CLINICAL STUDY DIVERSITY.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with drug sponsors, medical device manufacturers, patients, and other stakeholders, shall convene one or more public workshops to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence of the disease or condition

among demographic subgroups, where appropriate, and other topics, including—

(1) how and when to collect and present the prevalence or incidence data on a disease or condition by demographic subgroup, including possible sources for such data and methodologies for assessing such data;

(2) considerations for the dissemination, after approval, of information to the public on clinical study enrollment demographic data;

(3) the establishment of goals for enrollment in clinical trials, including the relevance of the estimated prevalence or incidence, as applicable, in the United States of the disease or condition for which the drug or device is being developed; and

(4) approaches to support inclusion of underrepresented populations and to encourage clinical study participation that reflects the population expected to use the drug or device under study, including with respect to—

(A) the establishment of inclusion and exclusion criteria for certain demographic subgroups, such as pregnant and lactating women and individuals with disabilities, including intel-

lectual or developmental disabilities or mental illness;

(B) considerations regarding informed consent with respect to individuals with intellectual or developmental disabilities or mental illness, including ethical and scientific considerations;

(C) the appropriate use of decentralized trials or digital health tools;

(D) clinical endpoints;

(E) biomarker selection; and

(F) studying analysis.

(b) PUBLIC DOCKET.—The Secretary of Health and Human Services shall establish a public comment period to receive written comments related to the topics addressed during each public workshop convened under this section. The public comment period shall remain open for 60 days following the date on which each public workshop is convened.

(c) REPORT.—Not later than 180 days after the close of the public comment period for each public workshop convened under this section, the Secretary of Health and Human Services shall make available on the public website of the Food and Drug Administration a report on the topics discussed at such workshop. The report shall include

a summary of, and response to, recommendations raised in such workshop.

SEC. 504. ANNUAL SUMMARY REPORT ON PROGRESS TO INCREASE DIVERSITY IN CLINICAL STUDIES.

(a) IN GENERAL.—Beginning not later than 2 years after the date of enactment of this Act, and each year thereafter, the Secretary of Health and Human Services shall submit to the Congress, and publish on the public website of the Food and Drug Administration, a report that—

(1) summarizes, in aggregate, the diversity action plans received pursuant to section 505(i)(5) or 520(g)(9) of the Federal Food, Drug, and Cosmetic Act, or section 351(a)(3)(B) of the Public Health Service Act, as added by subsection (a), (b), or (c) of section 501 of this Act; and

(2) contains information on—

(A) for drugs that have been approved by the Food and Drug Administration and devices that have been approved, cleared, or classified under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)) by the Food and Drug Administration, whether the clinical studies conducted with respect to such applications met the demographic sub-

group enrollment goals from the diversity action plan submitted for such applications;

(B) the reasons provided for why enrollment goals from submitted diversity action plans were not met; and

(C) any postmarket studies of a drug or device in a demographic subgroup or subgroups required or recommended by the Secretary based on inadequate premarket clinical study diversity or based on other reasons where a premarket study lacked adequate diversity, including the status and completion date of any such study.

(b) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary of Health and Human Services to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 505. PUBLIC MEETING ON CLINICAL STUDY FLEXIBILITIES INITIATED IN RESPONSE TO COVID–19 PANDEMIC.

(a) IN GENERAL.—Not later than 180 days after the date on which the COVID–19 emergency period ends, the Secretary of Health and Human Services shall convene a

public meeting to discuss the recommendations provided by the Food and Drug Administration during the COVID–19 emergency period to mitigate disruption of clinical studies, including recommendations detailed in the guidance entitled ''Conduct of Clinical Trials of Medical Products During the COVID–19 Public Health Emergency, Guidance for Industry, Investigators, and Institutional Review Boards'', as updated on August 8, 2021, and by any subsequent updates to such guidance. The Secretary of Health and Human Services shall invite to such meeting representatives from the pharmaceutical and medical device industries who sponsored clinical studies during the COVID–19 emergency period and organizations representing patients.

(b) TOPICS.—Not later than 90 days after the date on which the public meeting under subsection (a) is convened, the Secretary of Health and Human Services shall make available on the public website of the Food and Drug Administration a report on the topics discussed at such meeting. Such topics shall include discussion of—

(1) the actions drug sponsors took to utilize such recommendations and the frequency at which such recommendations were employed;

(2) the characteristics of the sponsors, studies, and patient populations impacted by such recommendations;

(3) a consideration of how recommendations intended to mitigate disruption of clinical studies during the COVID–19 emergency period, including any recommendations to consider decentralized clinical studies when appropriate, may have affected access to clinical studies for certain patient populations, especially unrepresented racial and ethnic minorities; and

(4) recommendations for incorporating certain clinical study disruption mitigation recommendations into current or additional guidance to improve clinical study access and enrollment of diverse patient populations.

(c) COVID–19 EMERGENCY PERIOD DEFINED.—In this section, the term ''COVID–19 emergency period'' has the meaning given the term ''emergency period'' in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)).

SEC. 506. DECENTRALIZED CLINICAL STUDIES.

(a) GUIDANCE.—The Secretary of Health and Human Services shall—

(1) not later than 12 months after the date of enactment of this Act, issue draft guidance that addresses considerations for decentralized clinical studies, including considerations regarding the engagement, enrollment, and retention of a meaningfully diverse clinical population, with respect to race, ethnicity, age, sex, and geographic location, when appropriate; and

(2) not later than 1 year after closing the comment period on such draft guidance, finalize such guidance.

(b) CONTENT OF GUIDANCE.—The guidance under subsection (a) shall address the following:

(1) Recommendations for how digital health technology or other remote assessment options, such as telehealth, could support decentralized clinical studies, including guidance on considerations for selecting technological platforms and mediums, data collection and use, data integrity and security, and communication to study participants through digital technology.

(2) Recommendations for subject recruitment and retention, including considerations for sponsors to minimize or reduce burdens for clinical study participants through the use of digital health tech-

nology, telehealth, local health care providers and laboratories, or other means.

(3) Recommendations with respect to the evaluation of data collected within a decentralized clinical study setting.

(c) DEFINITION.—In this section, the term ''decentralized clinical study'' means a clinical study in which some or all of the study-related activities occur at a location separate from the investigator's location.

TITLE VI—GENERIC DRUG COMPETITION

SEC. 601. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) IN GENERAL.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is amended by adding at the end the following:

''(H)(i) Upon request (in controlled correspondence or otherwise) by a person that has submitted or intends to submit an abbreviated application for a new drug under this subsection or on the Secretary's own initiative during the review of such abbreviated application, the Secretary shall inform the person whether such new drug is qualitatively and quantitatively the same as the listed drug.

''(ii) If the Secretary determines that such new drug is not qualitatively or quantitatively the same as the listed

drug, the Secretary shall identify and disclose to the person—

''(I) the ingredient or ingredients that cause the new drug not to be qualitatively or quantitatively the same as the listed drug; and

''(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

''(iii) If the Secretary determines that such new drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such new drug under this subsection unless—

''(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

''(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

''(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

''(v) The disclosures required by this subparagraph are disclosures authorized by law including for purposes of section 1905 of title 18, United States Code.''.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a new drug is qualitatively and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance as required by paragraph (1), the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received, and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.

SEC. 602. ENHANCING ACCESS TO AFFORDABLE MEDICINES.

Section 505(j)(10)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended by striking clauses (i) through (iii) and inserting the following:

''(i) a revision to the labeling of the listed drug has been approved by the Secretary within 90 days of when the application is otherwise eligible for approval under this subsection;

''(ii) the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application not later than 60 days after approval under this subsection of the application;

''(iii) the labeling revision described under clause (i) does not include a change to the 'Warnings' section of the labeling; and''.

TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN IMPROVEMENTS

Subtitle A—In General

SEC. 701. ANIMAL TESTING ALTERNATIVES.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(5)(B)(i)(II), by striking ''animal'' and inserting ''nonclinical tests'';

(2) in subsection (i)—

(A) in paragraph (1)(A), by striking ''preclinical tests (including tests on animals)'' and inserting ''nonclinical tests''; and

(B) in paragraph (2)(B), by striking ''animal'' and inserting ''nonclinical tests''; and

(3) after subsection (y), by inserting the following:

''(z) NONCLINICAL TEST DEFINED.—For purposes of this section, the term 'nonclinical test' means a test conducted in vitro, in silico, or in chemico, or a nonhuman in vivo test, that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. Such test may include the following:

''(1) Cell-based assays.

''(2) Organ chips and microphysiological systems.

''(3) Computer modeling.

''(4) Other nonhuman or human biology-based test methods.

''(5) Animal tests.''.

SEC. 702. EMERGING TECHNOLOGY PROGRAM.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.) is amended by inserting after section 566 of such Act (21 U.S.C. 360bbb–5) the following:

''SEC. 566A. EMERGING TECHNOLOGY PROGRAM.

''(a) PROGRAM ESTABLISHMENT.—

''(1) IN GENERAL.—The Secretary shall establish a program to support the adoption of, and improve the development of, innovative approaches to drug product design and manufacturing.

''(2) ACTIONS.—In carrying out the program under paragraph (1), the Secretary may—

''(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative drug product design and manufacturing;

''(B) solicit information regarding, and conduct or support research on, innovative ap-

proaches to drug product design and manufacturing;

''(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

''(D) convene working groups to support drug product design and manufacturing research and development;

''(E) support education and training for regulatory staff and scientists related to innovative approaches to drug product design and manufacturing;

''(F) advance regulatory science related to the development and review of innovative approaches to drug product design and manufacturing;

''(G) convene or participate in working groups to support the harmonization of international regulatory requirements related to innovative approaches to drug product design and manufacturing; and

''(H) award grants or contracts to carry out or support the program under paragraph (1).

''(3) GRANTS AND CONTRACTS.—To seek a grant or contract under this section, an entity shall submit an application—

''(A) in such form and manner as the Secretary may require; and

''(B) containing such information as the Secretary may require, including a description of—

''(i) how the entity will conduct the activities to be supported through the grant or contract; and

''(ii) how such activities will further research and development related to, or adoption of, innovative approaches to drug product design and manufacturing.

''(b) GUIDANCE.—The Secretary shall—

''(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to drug product design and manufacturing; and

''(2) include in such guidance descriptions of—

''(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to drug product design and manufacturing, including updates

and improvements to such technologies after product approval; and

''(B) data that can be used to demonstrate the identity, safety, purity, and potency of drugs manufactured using such technologies.

''(c) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

''(1) an annual accounting of the allocation of funds made available to carry out this section;

''(2) a description of how Food and Drug Administration staff were utilized to carry out this section and, as applicable, any challenges or limitations related to staffing;

''(3) the number of meetings held or participated in by the Food and Drug Administration, including meetings convened as part of a working group described in subparagraph (D) or (G) of subsection (a)(2), and the topics of each such meeting; and

''(4) the number of drug products approved or licensed, after the date of enactment of this section,

using an innovative approach to drug product design and manufacturing.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $20,000,000 for each fiscal year 2023 through 2027.''.

SEC. 703. IMPROVING THE TREATMENT OF RARE DISEASES AND CONDITIONS.

(a) REPORT ON ORPHAN DRUG PROGRAM.—

(1) IN GENERAL.—Not later than September 30, 2026, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report summarizing the activities of the Food and Drug Administration related to designating drugs under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition and approving such drugs under section 505 of such Act (21 U.S.C. 355) or licensing such drugs under section 351 of the Public Health Service Act (42 U.S.C. 262), including—

(A) the number of applications for such drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or

section 351 of the Public Health Service Act (42 U.S.C. 262) received by the Food and Drug Administration, the number of such applications accepted and rejected for filing, and the number of such applications pending, approved, and disapproved by the Food and Drug Administration;

(B) a description of trends in drug approvals for rare diseases and conditions across review divisions at the Food and Drug Administration;

(C) the extent to which the Food and Drug Administration is consulting with external experts pursuant to section 569(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8(a)(2)) on topics pertaining to drugs for a rare disease or condition, including how and when any such consultation is occurring; and

(D) the Food and Drug Administration's efforts to promote best practices in the development of novel treatments for rare diseases, including—

(i) reviewer training on rare disease-related policies, methods, and tools; and

(ii) new regulatory science and coordinated support for patient and stakeholder engagement.

(2) PUBLIC AVAILABILITY.—The Secretary shall make the report under paragraph (1) available to the public, including by posting the report on the website of the Food and Drug Administration.

(3) INFORMATION DISCLOSURE.—Nothing in this subsection shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 1905 of title 18, United States Code, or subject to withholding under paragraph (4) of section 552(b), United States Code (commonly referred to as the ''Freedom of Information Act'').

(b) STUDY ON EUROPEAN UNION SAFETY AND EFFICACY REVIEWS OF DRUGS FOR RARE DISEASES AND CONDITIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with an appropriate entity to conduct a study on processes for evaluating the safety and efficacy of drugs for rare diseases or conditions in the United States and the European Union, including—

(A) flexibilities, authorities, or mechanisms available to regulators in the United States and

the European Union specific to rare diseases or conditions;

(B) the consideration and use of supplemental data submitted during review processes in the United States and the European Union, including data associated with open label extension studies and expanded access programs specific to rare diseases or conditions;

(C) an assessment of collaborative efforts between United States and European Union regulators related to—

(i) product development programs under review;

(ii) policies under development recently issued; and

(iii) scientific information related to product development or regulation; and

(D) recommendations for how Congress can support collaborative efforts described in subparagraph (C).

(2) CONSULTATION.—The contract under paragraph (1) shall provide for consultation with relevant stakeholders, including—

(A) representatives from the Food and Drug Administration and the European Medicines Agency;

(B) rare disease or condition patients; and

(C) patient groups that—

(i) represent rare disease or condition patients; and

(ii) have international patient outreach.

(3) REPORT.—The contract under paragraph (1) shall provide for, not later than 2 years after the date of entering into such contract—

(A) the completion of the study under paragraph (1); and

(B) the submission of a report on the results of such study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(4) PUBLIC AVAILABILITY.—The contract under paragraph (1) shall provide for the appropriate entity referred to in paragraph (1) to make the report under paragraph (3) available to the public, including by posting the report on the website of the appropriate entity.

(c) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than December 31, 2023, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall convene one or more public meetings to solicit input from stakeholders regarding the approaches described in paragraph (2).

(2) APPROACHES.—The public meeting or meetings under paragraph (1) shall address approaches to increasing and improving engagement with rare disease or condition patients, groups representing such patients, rare disease or condition experts, and experts on small population studies, in order to improve the understanding with respect to rare diseases or conditions of—

(A) patient burden;

(B) treatment options; and

(C) side effects of treatments, including—

(i) comparing the side effects of treatments; and

(ii) understanding the risks of side effects relative to the health status of the patient and the progression of the disease or condition.

(3) PUBLIC DOCKET.—The Secretary of Health and Human Services shall establish a public docket to receive written comments related to the approaches addressed during each public meeting under paragraph (1). Such public docket shall remain open for 60 days following the date of each such public meeting.

(4) REPORTS.—Not later than 180 days after each public meeting under paragraph (1), the Commissioner of Food and Drugs shall develop and publish on the website of the Food and Drug Administration a report on—

(A) the approaches discussed at the public meeting; and

(B) any related recommendations.

(d) CONSULTATION ON THE SCIENCE OF SMALL POPULATION STUDIES.—Section 569(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8(b)) is amended by adding at the end the following:

''(C) SMALL POPULATION STUDIES.—The external experts on the list maintained pursuant to subparagraph (A) may include experts on the science of small population studies.''.

(e) STUDY ON SUFFICIENCY AND USE OF FDA MECHANISMS FOR INCORPORATING THE PATIENT AND

CLINICIAN PERSPECTIVE IN FDA PROCESSES RELATED TO APPLICATIONS CONCERNING DRUGS FOR RARE DISEASES OR CONDITIONS.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the use of Food and Drug Administration mechanisms and tools to ensure that patient and physician perspectives are considered and incorporated throughout the processes of the Food and Drug Administration—

(A) for approving or licensing under section 505 of the Federal Food, Drug, or Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) a drug designated as a drug for a rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb); and

(B) in making any determination related to such a drug's approval, including assessment of the drug's—

(i) safety or effectiveness; or

(ii) postapproval safety monitoring.

(2) TOPICS.—The study under paragraph (1) shall—

(A) identify and compare the processes that the Food and Drug Administration has formally put in place and utilized to gather external expertise (including patients, patient groups, and physicians) on specific applications for rare diseases or conditions;

(B) examine tools or mechanisms to improve efforts and initiatives of the Food and Drug Administration to collect and consider such external expertise with respect to applications for rare diseases or conditions throughout the application review and approval or licensure processes, including within internal benefit-risk assessments, advisory committee processes, and postapproval safety monitoring; and

(C) examine processes or alternatives to address or resolve conflicts of interest that impede the Food and Drug Administration in gaining external expert input on rare diseases or conditions with a limited set of clinical and research experts.

(3) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall—

(A) complete the study under paragraph (1);

(B) submit a report on the results of such study to the Congress; and

(C) include in such report recommendations, if appropriate, for changes to the processes and authorities of the Food and Drug Administration to improve the collection and consideration of external expert opinions of patients, patient groups, and physicians with expertise in rare diseases or conditions.

(f) DEFINITION.—In this section, the term ''rare disease or condition'' has the meaning given such term in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)).

SEC. 704. ANTIFUNGAL RESEARCH AND DEVELOPMENT.

(a) DRAFT GUIDANCE.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance for industry for the purposes of assisting entities seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of

antifungal therapies designed to treat coccidioidomycosis (commonly known as Valley Fever).

(b) FINAL GUIDANCE.—Not later than 18 months after the close of the public comment period on the draft guidance issued pursuant to subsection (a), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance.

(c) WORKSHOP.—To assist entities developing preventive vaccines for fungal infections and coccidioidomycosis, the Secretary of Health and Human Services shall hold a public workshop.

SEC. 705. ADVANCING QUALIFIED INFECTIOUS DISEASE PRODUCT INNOVATION.

(a) IN GENERAL.—Section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(1) in subsection (c)—

(A) in paragraph (2), by striking ''or'' at the end;

(B) in paragraph (3), by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(4) an application pursuant to section 351(a) of the Public Health Service Act.'';

(2) in subsection (d)(1), by inserting ''of this Act or section 351(a) of the Public Health Service Act'' after ''section 505(b)''; and

(3) by amending subsection (g) to read as follows:

''(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means a drug, including an antibacterial or antifungal drug or a biological product, for human use that—

''(1) acts directly on bacteria or fungi or on substances produced by such bacteria or fungi; and

''(2) is intended to treat a serious or life-threatening infection, including such an infection caused by—

''(A) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(B) qualifying pathogens listed by the Secretary under subsection (f).''.

(b) PRIORITY REVIEW.—Section 524A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a)) is amended by inserting ''of this Act or section 351(a) of the Public Health Service Act that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness'' before the period at the end.

SEC. 706. ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PILOT PROGRAM.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506J (21 U.S.C. 356j) the following:

"SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PILOT PROGRAM.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall initiate a pilot program under which persons may request designation of an advanced manufacturing technology as described in subsection (b).

''(b) DESIGNATION PROCESS.—The Secretary shall establish a process for the designation under this section of methods of manufacturing drugs, including biological products, and active pharmaceutical ingredients of such drugs, as advanced manufacturing technologies. A method of manufacturing, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology if such method or combination of methods incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process for a drug and maintain equivalent or provide superior drug quality, including by—

''(1) reducing development time for a drug using the designated manufacturing method; or

''(2) increasing or maintaining the supply of—

''(A) a drug that is described in section 506C(a) and is intended to treat a serious or life-threatening condition; or

''(B) a drug that is on the drug shortage list under section 506E.

''(c) EVALUATION AND DESIGNATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

''(1) SUBMISSION.—A person who requests designation of a method of manufacturing as an advanced manufacturing technology under this section shall submit to the Secretary data or information demonstrating that the method of manufacturing meets the criteria described in subsection (b) in a particular context of use. The Secretary may facilitate the development and review of such data or information by—

''(A) providing timely advice to, and interactive communication with, such person regarding the development of the method of manufacturing; and

''(B) involving senior managers and experienced staff of the Food and Drug Administra-

tion, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing, as applicable.

''(2) EVALUATION AND DESIGNATION.—Not later than 180 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether to designate such method of manufacturing as an advanced manufacturing technology, in a particular context of use, based on the data and information submitted under paragraph (1) and the criteria described in subsection (b).

''(d) REVIEW OF ADVANCED MANUFACTURING TECHNOLOGIES.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology, the Secretary shall—

''(1) expedite the development and review of an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, for drugs that are manufactured using a designated advanced manufacturing technology and could help mitigate or prevent a shortage or substantially improve manufacturing processes for a drug and maintain equivalent or provide superior drug quality, as described in subsection (b); and

''(2) allow the holder of an advanced technology designation, or a person authorized by the advanced manufacturing technology designation holder, to reference or rely upon, in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including a supplemental application, data and information about the designated advanced manufacturing technology for use in manufacturing drugs in the same context of use for which the designation was granted.

''(e) IMPLEMENTATION AND EVALUATION OF ADVANCED MANUFACTURING TECHNOLOGIES PILOT.—

''(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting, to be held not later than 180 days after the date of enactment of this section, to discuss, and obtain input and recommendations from relevant stakeholders regarding—

''(A) the goals and scope of the pilot program, and a suitable framework, procedures, and requirements for such program; and

''(B) ways in which the Food and Drug Administration will support the use of advanced manufacturing technologies and other innovative manufacturing approaches for drugs.

''(2) PILOT PROGRAM GUIDANCE.—

''(A) IN GENERAL.—The Secretary shall—

''(i) not later than 180 days after the public meeting under paragraph (1), issue draft guidance regarding the goals and implementation of the pilot program under this section; and

''(ii) not later than 2 years after the date of enactment of this section, issue final guidance regarding the implementation of such program.

''(B) CONTENT.—The guidance described in subparagraph (A) shall address—

''(i) the process by which a person may request a designation under subsection (b);

''(ii) the data and information that a person requesting such a designation is required to submit under subsection (c), and how the Secretary intends to evaluate such submissions;

''(iii) the process to expedite the development and review of applications under subsection (d); and

''(iv) the criteria described in subsection (b) for eligibility for such a designation.

''(3) REPORT.—Not later than 3 years after the date of enactment of this section and annually thereafter, the Secretary shall publish on the website of the Food and Drug Administration and 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 containing a description and evaluation of the pilot program being conducted under this section, including the types of innovative manufacturing approaches supported under the program. Such report shall include the following:

''(A) The number of persons that have requested designations and that have been granted designations.

''(B) The number of methods of manufacturing that have been the subject of designation requests and that have been granted designations.

''(C) The average number of calendar days for completion of evaluations under subsection (c)(2).

''(D) An analysis of the factors in data submissions that are relevant to determinations to designate and not to designate after evaluation under subsection (c)(2).

''(E) The number of applications received under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, that have included an advanced manufacturing technology designated under this section, and the number of such applications approved.

''(f) SUNSET.—The Secretary—

''(1) may not consider any requests for designation submitted under subsection (c) after October 1, 2029; and

''(2) may continue all activities under this section with respect to advanced manufacturing technologies that were designated pursuant to subsection (d) prior to such date, if the Secretary determines such activities are in the interest of the public health.''.

SEC. 707. PUBLIC WORKSHOP ON CELL THERAPIES.

Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and

Drugs, shall convene a public workshop with relevant stakeholders to discuss best practices on generating scientific data necessary to further facilitate the development of certain human cell-, tissue-, and cellular-based medical products (and the latest scientific information about such products) that are regulated as drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), namely, stem-cell and other cellular therapies.

SEC. 708. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

SEC. 709. REAUTHORIZATION FOR HUMANITARIAN DEVICE EXEMPTION AND DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC AVAILABILITY.

(a) HUMANITARIAN DEVICE EXEMPTION.—Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking ''2022'' and inserting ''2027''.

(b) PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT.—Section 305(e) of the Pediatric Medical Device Safety and Improvement Act (Public Law

110–85) is amended by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

SEC. 710. REAUTHORIZATION OF PROVISION RELATED TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by striking ''2022'' and inserting ''2027''.

SEC. 711. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIP PROGRAM.

Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5(f)) is amended by striking ''$6,000,000 for each of fiscal years 2018 through 2022'' and inserting ''$10,000,000 for each of fiscal years 2023 through 2027''.

SEC. 712. REAUTHORIZATION OF ORPHAN DRUG GRANTS.

Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a)—

(A) by striking ''and (3)'' and inserting ''(3)''; and

(B) by inserting before the period at the end the following: '', and (4) developing regulatory science pertaining to the chemistry, manufacturing, and controls of individualized med-

ical products to treat individuals with rare diseases or conditions''; and

(2) in subsection (c), by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

Subtitle B—Inspections

SEC. 721. FACTORY INSPECTION.

(a) IN GENERAL.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by striking ''restricted devices'' each place it appears and inserting ''devices''.

(b) RECORDS OR OTHER INFORMATION.—

(1) ESTABLISHMENTS.—Section 704(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)(A)) is amended—

(A) by striking ''an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug'' and inserting ''an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device, or that is subject to inspection under paragraph (5)(C),''; and

(B) by inserting after ''a sufficient description of the records requested'' the following: ''and a rationale for requesting such records or

other information in advance of, or in lieu of, an inspection''.

(2) GUIDANCE.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall issue or update guidance describing—

(i) circumstances in which the Secretary intends to issue requests for records or other information in advance of, or in lieu of, an inspection under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by paragraph (1);

(ii) processes for responding to such requests electronically or in physical form; and

(iii) factors the Secretary intends to consider in evaluating whether such records and other information are provided within a reasonable timeframe, within reasonable limits, and in a reasonable manner, accounting for resource and other limitations that may exist, including for small businesses.

(B) TIMING.—The Secretary of Health and Human Services shall—

(i) not later than 1 year after the date of enactment of this Act, issue draft guidance under subparagraph (A); and

(ii) not later than 1 year after the close of the comment period for such draft guidance, issue final guidance under subparagraph (A).

(c) BIORESEARCH MONITORING INSPECTIONS.—

(1) IN GENERAL.—Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended by adding at the end the following:

''(5) BIORESEARCH MONITORING INSPECTIONS.—

''(A) IN GENERAL.—The Secretary may, to ensure the accuracy and reliability of studies and records or other information described in subparagraph (B) and to assess compliance with applicable requirements under this Act or the Public Health Service Act, enter sites and facilities specified in subparagraph (C) in order to inspect such records or other information.

''(B) INFORMATION SUBJECT TO INSPECTION.—An inspection under this paragraph shall ex-

tend to all records and other information related to the studies and submissions described in subparagraph (E), including records and information related to the conduct, results, and analyses of, and the protection of human and animal trial participants participating in, such studies.

''(C) SITES AND FACILITIES SUBJECT TO INSPECTION.—

''(i) SITES AND FACILITIES DESCRIBED.—The sites and facilities subject to inspection by the Secretary under this paragraph are those owned or operated by a person described in clause (ii) and which are (or were) utilized by such person in connection with—

''(I) developing an application or other submission to the Secretary under this Act or the Public Health Service Act related to marketing authorization for a product described in paragraph (1);

''(II) preparing, conducting, or analyzing the results of a study described in subparagraph (E); or

''(III) holding any records or other information described in subparagraph (B).

''(ii) PERSONS DESCRIBED.—A person described in this clause is—

''(I) the sponsor of an application or submission specified in subparagraph (E);

''(II) a person engaged in any activity described in clause (i) on behalf of such a sponsor, through a contract, grant, or other business arrangement with such sponsor;

''(III) an institutional review board, or other individual or entity, engaged by contract, grant, or other business arrangement with a nonsponsor in preparing, collecting, or analyzing records or other information described in subparagraph (B); or

''(IV) any person not otherwise described in this clause that conducts, or has conducted, a study described in subparagraph (E) yielding records or other information described in subparagraph (B).

''(D) CONDITIONS OF INSPECTION.—

''(i) ACCESS TO INFORMATION SUBJECT TO INSPECTION.—Subject to clause (ii), an entity that owns or operates any site or facility subject to inspection under this paragraph shall

provide the Secretary with access to records and other information described in subparagraph (B) that is held by or under the control of such entity, including—

''(I) permitting the Secretary to record or copy such information for purposes of this paragraph;

''(II) providing the Secretary with access to any electronic information system utilized by such entity to hold, process, analyze, or transfer any records or other information described in subparagraph (B); and

''(III) permitting the Secretary to inspect the facilities, equipment, written procedures, processes, and conditions through which records or other information described in subparagraph (B) is or was generated, held, processed, analyzed, or transferred.

''(ii) NO EFFECT ON APPLICABILITY OF PROVISIONS FOR PROTECTION OF PROPRIETARY INFORMATION OR TRADE SECRETS.—Nothing in clause (i) shall negate, supersede, or otherwise affect the applicability of provisions, under this

or any other Act, preventing or limiting the disclosure of confidential commercial information or other information considered proprietary or trade secret.

''(iii) REASONABLENESS OF INSPECTIONS.—An inspection under this paragraph shall be conducted at reasonable times and within reasonable limits and in a reasonable manner.

''(E) STUDIES AND SUBMISSIONS DESCRIBED.—The studies and submissions described in this subparagraph are each of the following:

''(i) Clinical and nonclinical studies submitted to the Secretary in support of, or otherwise related to, applications and other submissions to the Secretary under this Act or the Public Health Service Act for marketing authorization of a product described in paragraph (1).

''(ii) Postmarket safety activities conducted under this Act or the Public Health Service Act.

''(iii) Any other clinical investigation of—

''(I) a drug subject to section 505 or 512 of this Act or section 351 of the Public Health Service Act; or

''(II) a device subject to section 520(g).

''(iv) Any other submissions made under this Act or the Public Health Service Act with respect to which the Secretary determines an inspection under this paragraph is warranted in the interest of public health.

''(F) CLARIFICATION.—This paragraph clarifies the authority of the Secretary to conduct inspections of the type described in this paragraph and shall not be construed as a basis for inferring that, prior to the date of enactment of this paragraph, the Secretary lacked the authority to conduct such inspections, including under this Act or the Public Health Service Act.''.

(2) REVIEW OF PROCESSES AND PRACTICES; GUIDANCE FOR INDUSTRY.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall—

(i) review processes and practices in effect as of the date of enactment of this Act applicable to inspections of foreign and

domestic sites and facilities described in subparagraph (C)(i) of section 704(a)(5) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1); and

(ii) evaluate whether any updates are needed to facilitate the consistency of such processes and practices.

(B) GUIDANCE.—

(i) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance describing the processes and practices applicable to inspections of sites and facilities described in subparagraph (C)(i) of section 704(a)(5) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), including with respect to the types of records and information required to be provided, best practices for communication between the Food and Drug Administration and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct, to the extent not specified in existing publicly available

Food and Drug Administration guides and manuals for such inspections.

(ii) TIMING.—The Secretary of Health and Human Services shall—

(I) not later than 18 months after the date of enactment of this Act, issue draft guidance under clause (i); and

(II) not later than 1 year after the close of the public comment period for such draft guidance, issue final guidance under clause (i).

SEC. 722. USES OF CERTAIN EVIDENCE.

Section 703 of the of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended by adding at the end the following:

''(c) APPLICABILITY.—The limitations on the Secretary's use of evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, in a criminal prosecution of the person from whom such evidence was obtained shall not apply to evidence, including records or other information, obtained under authorities other than this section, unless such limitations are specifically incorporated by reference in such other authorities.''.

SEC. 723. IMPROVING FDA INSPECTIONS.

(a) RISK FACTORS FOR ESTABLISHMENTS.—Section 510(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)(4)) is amended—

(1) by redesignating subparagraph (F) as subparagraph (G); and

(2) by inserting after subparagraph (E) the following:

''(F) The compliance history of establishments in the country or region in which the establishment is located that are subject to regulation under this Act, including the history of violations related to products exported from such country or region that are subject to such regulation.''.

(b) USE OF RECORDS.—Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended—

(1) by redesignating subparagraph (C) as subparagraph (D); and

(2) by inserting after subparagraph (B) the following:

''(C) The Secretary may rely on any records or other information that the Secretary may inspect under this section to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to re-

solve deficiencies identified during such inspections, if applicable and appropriate.''.

(c) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) is amended—

(1) in subsection (a)(1), by inserting ''preapproval or'' before ''risk-based inspections''; and

(2) by adding at the end the following:

''(c) PERIODIC REVIEW.—

''(1) IN GENERAL.—Beginning not later than 1 year after the date of the enactment of the Food and Drug Amendments of 2022 the Secretary shall periodically assess whether additional arrangements and agreements with a foreign government or an agency of a foreign government, as allowed under this section, are appropriate.

''(2) REPORTS TO CONGRESS.—Beginning not later than 4 years after the date of the enactment of the Food and Drug Amendments of 2022, and every 4 years thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions a report de-

scribing the findings and conclusions of each review conducted under paragraph (1).''.

SEC. 724. GAO REPORT ON INSPECTIONS OF FOREIGN ESTABLISHMENTS MANUFACTURING DRUGS.

(a) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on inspections conducted by—

(1) the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') of foreign establishments pursuant to subsections (h) and (i) of section 510 and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 374); or

(2) a foreign government or an agency of a foreign government pursuant to section 809 of such Act (21 U.S.C. 384e).

(b) CONTENTS.—The report conducted under subsection (a) shall include—

(1) what alternative tools, including remote inspections or remote evaluations, other countries are utilizing to facilitate inspections of foreign establishments;

(2) how frequently trusted foreign regulators conduct inspections of foreign facilities that could be useful to the Food and Drug Administration to review in lieu of its own inspections;

(3) how frequently and under what circumstances, including for what types of inspections, the Secretary utilizes existing agreements or arrangements under section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) and whether the use of such agreements could be appropriately expanded;

(4) whether the Secretary has accepted reports of inspections of facilities in China and India conducted by entities with which they have entered into such an agreement or arrangement;

(5) what additional foreign governments or agencies of foreign governments the Secretary has considered entering into a mutual recognition agreement with and, if applicable, reasons why the Secretary declined to enter into a mutual recognition agreement with such foreign governments or agencies;

(6) what tools, if any, the Secretary used to facilitate inspections of domestic facilities that could

also be effectively utilized to appropriately inspect foreign facilities;

(7) what steps the Secretary has taken to identify and evaluate tools and strategies the Secretary may use to continue oversight with respect to inspections when in-person inspections are disrupted;

(8) how the Secretary is considering incorporating alternative tools into the inspection activities conducted pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.); and

(9) what steps the Secretary has taken to identify and evaluate how the Secretary may use alternative tools to address workforce shortages to carry out such inspection activities.

SEC. 725. UNANNOUNCED FOREIGN FACILITY INSPECTIONS PILOT PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall conduct a pilot program under which the Secretary increases the conduct of unannounced surveillance inspections of foreign human drug establishments and evaluates the differences between such inspections of domestic and foreign human drug establishments, including the impact of announcing inspections to persons who own or operate foreign human drug establishments in ad-

vance of an inspection. Such pilot program shall evaluate—

(1) differences in the number and type of violations of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) resulting from unannounced and announced inspections of foreign human drug establishments and any other significant differences between each type of inspection;

(2) costs and benefits associated with conducting announced and unannounced inspections of foreign human drug establishments;

(3) barriers to conducting unannounced inspections of foreign human drug establishments and any challenges to achieving parity between domestic and foreign human drug establishment inspections; and

(4) approaches for mitigating any negative effects of conducting announced inspections of foreign human drug establishments.

(b) PILOT PROGRAM SCOPE.—The inspections evaluated under the pilot program under this section shall be routine surveillance inspections and shall not include inspections conducted as part of the Secretary's evaluation of a request for approval to market a drug submitted under the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.).

(c) PILOT PROGRAM INITIATION.—The Secretary shall initiate the pilot program under this section not later than 180 days after the date of enactment of this Act.

(d) REPORT.—The Secretary shall, not later than 180 days following the completion of the pilot program under this section, make available on the website of the Food and Drug Administration a final report on the pilot program under this section, including—

(1) findings and any associated recommendations with respect to the evaluation under subsection (a), including any recommendations to address identified barriers to conducting unannounced inspections of foreign human drug establishments;

(2) findings and any associated recommendations regarding how the Secretary may achieve parity between domestic and foreign human drug inspections; and

(3) the number of unannounced inspections during the pilot program that would not be unannounced under existing practices.

SEC. 726. REAUTHORIZATION OF INSPECTION PROGRAM.

Section 704(g)(11) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by striking ''2022'' and inserting ''2027''.

SEC. 727. ENHANCING INTRA-AGENCY COORDINATION AND PUBLIC HEALTH ASSESSMENT WITH REGARD TO COMPLIANCE ACTIVITIES.

(a) COORDINATION.—Section 506D of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356d) is amended by adding at the end the following:

''(g) COORDINATION.—The Secretary shall ensure timely and effective internal coordination and alignment among the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding—

''(1) the reviews of reports shared pursuant to section 704(b)(2); and

''(2) any feedback or corrective or preventive actions in response to such reports.''.

(b) REPORTING.—

(1) IN GENERAL.—Section 506C–1(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c–1(a)(2)) is amended to read as follows:

''(2)(A) describes the communication between the field investigators of the Food and Drug Admin-

istration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

''(B) provides the number of reports described in section 704(b)(2) that were required to be sent to the appropriate offices of the Food and Drug Administration and the number of such reports that were sent; and

''(C) describes the coordination and alignment activities undertaken pursuant to section 506D(g);''.

(2) APPLICABILITY.—The amendment made by paragraph (1) shall apply with respect to reports submitted on or after March 31, 2023.

SEC. 728. REPORTING OF MUTUAL RECOGNITION AGREEMENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.

(a) IN GENERAL.—Not later than December 31, 2022, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall publish a report on the public website of the Food and Drug Administration on the utilization of agreements entered into pursuant to section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e)

or otherwise entered into by the Secretary in the previous fiscal year to recognize inspections between drug regulatory authorities across countries and international regions with analogous review criteria to the Food and Drug Administration, such as the Pharmaceutical Inspection Co-Operation Scheme, the Mutual Recognition Agreement with the European Union, and the Australia-Canada-Singapore-Switzerland-United Kingdom Consortium.

(b) CONTENT.—The report under subsection (a) shall include each of the following:

(1) The total number of establishments that are registered under section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the number of such establishments in each region of interest.

(2) The total number of inspections conducted at establishments described in paragraph (1), disaggregated by inspections conducted—

(A) pursuant to an agreement or other recognition described in subsection (a); and

(B) by employees or contractors of the Food and Drug Administration.

(3) Of the inspections described in paragraph (2), the total number of inspections in each region of interest.

(4) Of the inspections in each region of interest reported pursuant to paragraph (3), the number of inspections in each FDA inspection category.

(5) Of the number of inspections reported under each of paragraphs (3) and (4)—

(A) the number of inspections which have been conducted pursuant to an agreement or other recognition described in subsection (a); and

(B) the number of inspections which have been conducted by employees or contractors of the Food and Drug Administration.

(c) DEFINITIONS.—In this subsection:

(1) FDA INSPECTION CATEGORY.—The term ''FDA inspection category'' means the following inspection categories:

(A) Inspections to support approvals of changes to the manufacturing process of drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(B) Surveillance inspections.

(C) For-cause inspections.

(2) REGION OF INTEREST.—The term ''region of interest'' means China, India, the European Union, and any other geographic region as the Secretary determines appropriate.

SEC. 729. ENHANCING TRANSPARENCY OF DRUG FACILITY INSPECTION TIMELINES.

Section 902 of the FDA Reauthorization Act of 2017 (21 U.S.C. 355 note) is amended to read as follows:

''SEC. 902. ANNUAL REPORT ON INSPECTIONS.

''Not later than 120 days after the end of each fiscal year, the Secretary of Health and Human Services shall post on the public website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval of a device under section 515 of such Act (21 U.S.C. 360e), or clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)) that were conducted during the previous fiscal year. Such information shall include the following:

''(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, including—

''(A) the median time for drugs described in section 505(j)(11)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

''(B) the median time for drugs described in section 506C(a) of such Act (21 U.S.C. 356c(a)) only; and

''(C) the median time for drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C. 356f).

''(2) The median time from the issuance of a report pursuant to section 704(b) of such Act (21 U.S.C. 374(b)) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated, including the median time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

''(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting to resolution of the actions indicated to address the conditions or practices observed during an inspection.

''(4) The number of facilities that failed to implement requested corrective or preventive actions as requested following a report pursuant to such section 704(b), resulting in a withhold recommendation, including the number of such times for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).''.

TITLE VIII—TRANSPARENCY, PROGRAM INTEGRITY, AND REGULATORY IMPROVEMENTS

SEC. 801. PROMPT REPORTS OF MARKETING STATUS BY HOLDERS OF APPROVED APPLICATIONS FOR BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''The holder of an application approved under subsection (c) or (j) of section 505'' and inserting ''The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act'';

(B) in paragraph (2), by striking ''established name'' and inserting ''established name (for biological products, by proper name)''; and

(C) in paragraph (3), by striking ''or abbreviated application number'' and inserting '', abbreviated application number, or biologics license application number''; and

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''The holder of an application approved under subsection (c) or (j)'' and inserting ''The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act'';

(B) in paragraph (1), by striking ''established name'' and inserting ''established name (for biological products, by proper name)''; and

(C) in paragraph (2), by striking ''or abbreviated application number'' and inserting '', abbreviated application number, or biologics license application number''.

(b) ADDITIONAL ONE-TIME REPORT.—Subsection (c) of section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended to read as follows:

''(c) ADDITIONAL ONE-TIME REPORT.—Within 180 days of the date of enactment of the Food and Drug Amendments of 2022, all holders of applications approved under subsection (a) or (k) of section 351 of the Public Health Service Act shall review the information in the list published under section 351(k)(9)(A) and shall submit a written notice to the Secretary—

''(1) stating that all of the application holder's biological products in the list published under section 351(k)(9)(A) that are not listed as discontinued are available for sale; or

''(2) including the information required pursuant to subsection (a) or (b), as applicable, for each of the application holder's biological products that are in the list published under section 351(k)(9)(A) and not listed as discontinued, but have been discontinued from sale or never have been available for sale.''.

(c) PURPLE BOOK.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) by striking subsection (d) and inserting the following:

''(d) FAILURE TO MEET REQUIREMENTS.—If a holder of an approved application fails to submit the informa-

tion required under subsection (a), (b), or (c), the Secretary may—

''(1) move the application holder's drugs from the active section of the list published under section 505(j)(7)(A) to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with section 505(j)(7)(C) drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness; and

''(2) identify the application holder's biological products as discontinued in the list published under section 351(k)(9)(A) of the Public Health Service Act, except that the Secretary shall remove from the list in accordance with section 351(k)(9)(B) of such Act biological products for which the license has been revoked or suspended for reasons of safety, purity, or potency.''; and

(2) in subsection (e)—

(A) by inserting after the first sentence the following: ''The Secretary shall update the list published under section 351(k)(9)(A) of the Public Health Service Act based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that bio-

logical products for which the license has been revoked or suspended for safety, purity, or potency reasons shall be removed from the list in accordance with section 351(k)(9)(B) of the Public Health Service Act.'';

(B) by striking ''monthly updates to the list'' and inserting ''monthly updates to the lists referred to in the preceding sentences''; and

(C) by striking ''and shall update the list based on'' and inserting ''and shall update such lists based on''.

(d) TECHNICAL CORRECTIONS.—Section 506I(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i(e)) is amended—

(1) by striking ''subsection 505(j)(7)(A)'' and inserting ''section 505(j)(7)(A)''; and

(2) by striking ''subsection 505(j)(7)(C)'' and inserting ''section 505(j)(7)(C)''.

SEC. 802. ENCOURAGING BLOOD DONATION.

Section 3003 of the 21st Century Cures Act (21 U.S.C. 360bbb–8c note) is amended to read as follows:

"SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR INPUT.

''Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, to solicit—

''(1) the views and perspectives of patients under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002; or

''(2) information from blood donors or potential blood donors to support the development of recommendations by the Secretary of Health and Human Services acting through the Commissioner of Food and Drugs concerning blood donation.''.

SEC. 803. REGULATION OF CERTAIN PRODUCTS AS DRUGS.

Section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Any contrast agent, radioactive drug, or OTC monograph drug shall be deemed to be a drug under section 201(g) and not a device under section 201(h).

''(2) For purposes of this subsection:

''(A) The term 'contrast agent' means an article that is intended for use in conjunction with a medical imaging device, and—

''(i) is a diagnostic radiopharmaceutical, as defined in sections 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

''(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.

''(B) The term 'radioactive drug' has the meaning given such term in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations), except that such term does not include—

''(i) an implant or article similar to an implant;

''(ii) an article that applies radiation from outside of the body; or

''(iii) the radiation source of an article described in clause (i) or (ii).

''(C) The term 'OTC monograph drug' has the meaning given such term in section 744L.

''(3) Nothing in this subsection shall be construed as allowing for the classification of a product as a drug (as defined in section 201(g)) if such product—

''(A) is not described in paragraph (1); and

''(B) meets the definition of a device under section 201(h),

unless another provision of this Act otherwise indicates a different classification.''.

SEC. 804. POSTAPPROVAL STUDIES AND PROGRAM INTEGRITY FOR ACCELERATED APPROVAL DRUGS.

(a) IN GENERAL.—Section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is amended—

(1) by striking paragraph (2) and inserting the following:

''(2) LIMITATION.—

''(A) IN GENERAL.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

''(i) That the sponsor conduct an appropriate postapproval study or studies (which may be augmented or supported by real world evidence) to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

''(ii) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such

period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

''(B) STUDIES NOT REQUIRED.—If the Secretary does not require that the sponsor of a product approved under accelerated approval conduct a postapproval study under this paragraph, the Secretary shall publish on the website of the Food and Drug Administration the rationale for why such study is not appropriate or necessary.

''(C) POSTAPPROVAL STUDY CONDITIONS.—Not later than the time of approval of a product under accelerated approval, the Secretary shall specify the conditions for a postapproval study or studies required to be conducted under this paragraph with respect to such product, which may include enrollment targets, the study protocol, and milestones, including the target date of study completion.

''(D) STUDIES BEGUN BEFORE APPROVAL.—The Secretary may require such study or studies to be underway prior to approval.''; and

(2) by striking paragraph (3) and inserting the following:

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—

"(A) IN GENERAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures described in subparagraph (B), if—

"(i) the sponsor fails to conduct any required postapproval study of the product with due diligence, including with respect to conditions specified by the Secretary under paragraph (2)(C);

"(ii) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

"(iii) other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; or

"(iv) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(B) EXPEDITED PROCEDURES DESCRIBED.—Expedited procedures described in this subparagraph shall consist of, prior to the withdrawal of accelerated approval—

"(i) providing the sponsor with—

"(I) due notice;

"(II) an explanation for the proposed withdrawal;

"(III) an opportunity for a meeting with the Commissioner of Food and Drugs or the Commissioner's designee; and

"(IV) an opportunity for written appeal to—

"(aa) the Commissioner of Food and Drugs; or

"(bb) a designee of the Commissioner who has not participated in the proposed withdrawal of approval (other than a meeting pursuant to subclause (III)) and is not a subordinate of an individual (other than the Commissioner) who participated in such proposed withdrawal;

''(ii) providing an opportunity for public comment on the notice proposing to withdraw approval;

''(iii) the publication of a summary of the public comments received, and the Secretary's response to such comments, on the website of the Food and Drug Administration; and

''(iv) convening and consulting an advisory committee on issues related to the proposed withdrawal, if requested by the sponsor and if no such advisory committee has previously advised the Secretary on such issues with respect to the withdrawal of the product prior to the sponsor's request.

''(4) LABELING.—

''(A) IN GENERAL.—Subject to subparagraph (B), the labeling for a product approved under accelerated approval shall include—

''(i) a statement indicating that the product was approved under accelerated approval;

''(ii) a statement indicating that continued approval of the product is subject to

postmarketing studies to verify clinical benefit;

''(iii) identification of the surrogate or intermediate endpoint or endpoints that supported approval and any known limitations of such surrogate or intermediate endpoint or endpoints in determining clinical benefit; and

''(iv) a succinct description of the product and any uncertainty about anticipated clinical benefit and a discussion of available evidence with respect to such clinical benefit.

''(B) APPLICABILITY.—The labeling requirements of subparagraph (A) shall apply only to products approved under accelerated approval for which the predicted effect on irreversible morbidity or mortality or other clinical benefit has not been verified.

''(5) REPORTING.—Not later than September 30, 2025, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing circumstances in which the Secretary con-

sidered real world evidence submitted to support postapproval studies required under this subsection that were completed after the date of enactment of the Food and Drug Amendments of 2022.''.

(b) REPORTS OF POSTMARKETING STUDIES.—Section 506B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356b(a)) is amended—

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by inserting after paragraph (1) the following:

''(2) ACCELERATED APPROVAL.—Notwithstanding paragraph (1), a sponsor of a drug approved under accelerated approval shall submit to the Secretary a report of the progress of any study required under section 506(c), including progress toward any agreed upon enrollment targets, milestones, and other information as required by the Secretary, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or terminated.''.

(c) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance describing—

(A) how sponsor questions related to the identification of novel surrogate or intermediate clinical endpoints may be addressed in early-stage development meetings with the Food and Drug Administration;

(B) the use of novel clinical trial designs that may be used to conduct appropriate post-approval studies as may be required under section 506(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)(2)(A)), as amended by subsection (a); and

(C) the expedited procedures described in section 506(c)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)(3)(B)).

(2) FINAL GUIDANCE.—The Secretary shall issue—

(A) draft guidance under paragraph (1) not later than 18 months after the date of enactment of this Act; and

(B) final guidance not later than 1 year after the close of the public comment period on such draft guidance.

(d) RARE DISEASE ENDPOINT ADVANCEMENT PILOT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall establish a pilot program under which the Secretary will establish procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints, including surrogate and intermediate endpoints, for drugs intended to treat rare diseases, including through—

(A) determining eligibility of participants for such a program; and

(B) developing and implementing a process for applying to, and participating in, such a program.

(2) PUBLIC WORKSHOPS.—The Secretary shall conduct up to 3 public workshops, which shall be completed not later than September 30, 2026, to discuss topics relevant to the development of endpoints for rare diseases, which may include discussions about—

(A) novel endpoints developed through the pilot program established under this subsection; and

(B) as appropriate, the use of real world evidence and real world data to support the val-

idation of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.

(3) REPORT.—Not later than September 30, 2027, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the outcomes of the pilot program established under this subsection.

(4) GUIDANCE.—Not later than September 30, 2027, the Secretary shall issue guidance describing best practices and strategies for development of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.

(5) SUNSET.—The Secretary may not accept any new application or request to participate in the program established by this subsection on or after October 1, 2027.

SEC. 805. FACILITATING THE USE OF REAL WORLD EVIDENCE.

(a) GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue, or revise existing, guidance on considerations for the use of real world data and real

world evidence to support regulatory decisionmaking, as follows:

(1) With respect to drugs, such guidance shall address—

(A) the use of such data and evidence to support the approval of a drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product application under section 351 of the Public Health Service Act (42 U.S.C. 262), or to support an investigational use exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of the Public Health Service Act; and

(B) the use of such data and evidence obtained as a result of the use of drugs authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) in such applications, submissions, or requests; and

(C) standards and methodologies which may be used for collection and analysis of real world evidence included in such applications, submissions, or requests, as appropriate.

(2) With respect to devices, such guidance shall address—

(A) the use of such data and evidence to support the approval, clearance, or classification of a device pursuant to an application or submission submitted under section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f)(2), 360e), or to support an investigational use exemption under section 520(g) of such Act (21 U.S.C. 360j(g));

(B) the use of such data and evidence obtained as a result of the use of devices authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), in such applications, submissions, or requests; and

(C) standards and methodologies which may be used for collection and analysis of real world evidence included in such applications, submissions, or requests, as appropriate.

(b) REPORT TO CONGRESS.—Not later than 2 years after the termination of the public health emergency determination by the Secretary of Health and Human Services under section 564 of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 360bbb–3) on February 4, 2020, with respect to the Coronavirus Disease 2019 (COVID–19), the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on—

(1) the number of applications, submissions, or requests submitted for clearance or approval under section 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360c(f)(2), 360e) or section 351 of the Public Health Service Act, for which an authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) was previously granted;

(2) of the number of applications so submitted, the number of such applications—

(A) for which real world evidence was submitted and used to support a regulatory decision; and

(B) for which real world evidence was submitted and determined to be insufficient to support a regulatory decision; and

(3) a summary explanation of why, in the case of applications described in paragraph (2)(B), real

world evidence could not be used to support regulatory decisions.

(c) INFORMATION DISCLOSURE.—Nothing in this section shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 1905 of title 18, United States Code, or subject to withholding under subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the ''Freedom of Information Act'').

SEC. 806. MEDICAL DEVICES ADVISORY COMMITTEE MEETINGS.

(a) IN GENERAL.—The Secretary shall convene one or more panels of the Medical Devices Advisory Committee not less than once per year for the purpose of providing advice to the Secretary on topics related to medical devices used in pandemic preparedness and response, including topics related to in vitro diagnostics.

(b) REQUIRED PANEL MEMBER.—A panel convened under subsection (a) shall include at least 1 population health-specific representative.

(c) SUNSET.—This section shall cease to be effective on October 1, 2027.

SEC. 807. ENSURING CYBERSECURITY OF MEDICAL DEVICES.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by section 501, is further amended by adding at the end the following:

"SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.

''(a) IN GENERAL.—For purposes of ensuring cybersecurity throughout the lifecycle of a cyber device, any person who submits a premarket submission for the cyber device shall include such information as the Secretary may require to ensure that the cyber device meets such cybersecurity requirements as the Secretary determines to be appropriate to demonstrate a reasonable assurance of safety and effectiveness, including at a minimum the cybersecurity requirements under subsection (b).

''(b) CYBERSECURITY REQUIREMENTS.—At a minimum, the manufacturer of a cyber device shall meet the following cybersecurity requirements:

''(1) The manufacturer shall have a plan to appropriately monitor, identify, and address in a reasonable time postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and procedures.

''(2) The manufacturer shall design, develop, and maintain processes and procedures to ensure the

device and related systems are cybersecure, and shall make available updates and patches to the cyber device and related systems throughout the lifecycle of the cyber device to address—

''(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and

''(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks.

''(3) The manufacturer shall provide in the labeling of the cyber device a software bill of materials, including commercial, open-source, and off-the-shelf software components.

''(4) The manufacturer shall comply with such other requirements as the Secretary may require to demonstrate reasonable assurance of the safety and effectiveness of the device for purposes of cybersecurity, which the Secretary may require by an order published in the Federal Register.

''(c) SUBSTANTIAL EQUIVALENCE.—In making a determination of substantial equivalence under section 513(i) for a cyber device, the Secretary may—

''(1) find that cybersecurity information for the cyber device described in the relevant premarket

submission in the cyber device's use environment is inadequate; and

"(2) issue a nonsubstantial equivalence determination based on this finding.

"(d) DEFINITION.—In this section:

"(1) CYBER DEVICE.—The term 'cyber device' means a device that—

"(A) includes software, including software as or in a device;

"(B) has the ability to connect to the internet; or

"(C) contains any such technological characteristics that could be vulnerable to cybersecurity threats.

"(2) LIFECYCLE OF THE CYBER DEVICE.—The term 'lifecycle of the cyber device' includes the postmarket lifecycle of the cyber device.

"(3) PREMARKET SUBMISSION.—The term 'premarket submission' means any submission under section 510(k), 513, 515(c), 515(f), or 520(m).

"(e) EXEMPTION.—The Secretary may identify devices or types of devices that are exempt from meeting the cybersecurity requirements established by this section and regulations promulgated pursuant to this section. The Secretary shall publish in the Federal Register, and up-

date, as appropriate, a list of the devices and types of devices so identified by the Secretary.''.

(b) PROHIBITED ACT.—Section 301(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)) is amended by adding at the end the following:

''(3) The failure to comply with any requirement under section 524C (relating to ensuring device cybersecurity).''.

(c) ADULTERATION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after paragraph (j) the following:

''(k) If it is a device subject to the requirements set forth in section 524C (relating to ensuring device cybersecurity) and fails to comply with any requirement under that section.''.

(d) MISBRANDING.—Section 502(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is amended—

(1) by striking ''or (3)'' and inserting ''(3)''; and

(2) by inserting before the period at the end the following: '', or (4) to furnish a software bill of materials as required under section 524C (relating to ensuring device cybersecurity)''.

SEC. 808. PUBLIC DOCKET ON PROPOSED CHANGES TO THIRD-PARTY VENDORS.

(a) IN GENERAL.—

(1) OPENING PUBLIC DOCKET.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall open a single public docket to solicit comments on factors that generally should be considered by the Secretary when reviewing requests from sponsors of drugs subject to risk evaluation and mitigation strategies to change third-party vendors engaged by sponsors to aid in implementation and management of the strategies.

(2) FACTORS.—Such factors include the potential effects of changes in third-party vendors on—

(A) patient access; and

(B) prescribing and administration of the drugs by health care providers.

(3) CLOSING PUBLIC DOCKET.—The Secretary of Health and Human Services may close such public docket not earlier than 90 days after such docket is opened.

(4) NO DELAY.—Nothing in this section shall delay agency action on any modification to a risk evaluation and mitigation strategy.

(b) GAO REPORT.—Not later than December 31, 2026, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on—

(1) the number of changes in third-party vendors (engaged by sponsors to aid implementation and management of risk evaluation and mitigation strategies) for an approved risk evaluation and mitigation strategy the Secretary of Health and Human Services has approved under section 505–1(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(h));

(2) any issues affecting patient access to the drug that is subject to the strategy or considerations with respect to the administration or prescribing of such drug by health care providers that arose as a result of such modifications; and

(3) how such issues were resolved, as applicable.

SEC. 809. FACILITATING EXCHANGE OF PRODUCT INFORMATION PRIOR TO APPROVAL.

(a) IN GENERAL.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended—

(1) in paragraph (a)—

(A) by striking ''drugs for coverage'' and inserting ''drugs or devices for coverage''; and

(B) by striking ''drug'' each place it appears and inserting ''drug or device'', respectively;

(2) in paragraph (a)(2)(B), by striking ''under section 505 or under section 351 of the Public Health Service Act for such drug'' and inserting ''under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act''; and

(3) by adding at the end the following:

''(gg)(1) Unless its labeling bears adequate directions for use in accordance with paragraph (f), except that (in addition to drugs or devices that conform with exemptions pursuant to such paragraph) no drug or device shall be deemed to be misbranded under such paragraph through the provision of product information to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement if the product information relates to an investigational drug or device or investigational use of a drug or device that is approved,

cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable), provided—

''(A) the product information includes—

''(i) a clear statement that the investigational drug or device or investigational use of a drug or device has not been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable) and that the safety and effectiveness of the drug or device or use has not been established;

''(ii) information related to the stage of development of the drug or device involved, such as—

''(I) the status of any study or studies in which the investigational drug or device or investigational use is being investigated;

''(II) how the study or studies relate to the overall plan for the development of the drug or device; and

''(III) whether an application, premarket notification, or request for classi-

fication for the investigational drug or device or investigational use has been submitted to the Secretary and when such a submission is planned;

''(iii) in the case of information that includes factual presentations of results from studies, which shall not be selectively presented, a description of—

''(I) all material aspects of study design, methodology, and results; and

''(II) all material limitations related to the study design, methodology, and results;

''(iv) where applicable, a prominent statement disclosing the indication or indications for which the Secretary has approved, granted marketing authorization, cleared, or licensed the product pursuant to section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act, and a copy of the most current required labeling; and

''(v) updated information, if previously communicated information becomes materially outdated as a result of significant changes or as

a result of new information regarding the product or its review status; and

''(B) the product information does not include—

''(i) information that represents that an unapproved product—

''(I) has been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable); or

''(II) has otherwise been determined to be safe or effective for the purpose or purposes for which the drug or device is being studied; or

''(ii) information that represents that an unapproved use of a drug or device that has been so approved, granted marketing authorization, cleared, or licensed—

''(I) is so approved, granted marketing authorization, cleared, or licensed; or

''(II) that the product is safe or effective for the use or uses for which the drug or device is being studied.

''(2) For purposes of this paragraph, the term 'product information' includes—

''(A) information describing the drug or device (such as drug class, device description, and features);

''(B) information about the indication or indications being investigated;

''(C) the anticipated timeline for a possible approval, clearance, marketing authorization, or licensure pursuant to section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act;

''(D) drug or device pricing information;

''(E) patient utilization projections;

''(F) product-related programs or services; and

''(G) factual presentations of results from studies that do not characterize or make conclusions regarding safety or efficacy.''.

(b) GAO STUDY AND REPORT.—Beginning on the date that is 5 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study on the provision and use of

information pursuant to section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by this subsection (a), between manufacturers of drugs and devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) and entities described in such section 502(gg). Such study shall include an analysis of the following:

(1) The types of information communicated between such manufacturers and payors.

(2) The manner of communication between such manufacturers and payors.

(3)(A) Whether such manufacturers file an application for approval, marketing authorization, clearance, or licensing of a new drug or device or the new use of a drug or device that is the subject of communication between such manufacturers and payors under section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(B) How frequently the Food and Drug Administration approves, grants marketing authorization, clears, or licenses the new drug or device or new use.

(C) The timeframe between the initial communications permitted under section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), regarding an investigational drug or

device or investigational use, and the initial marketing of such drug or device.

SEC. 810. BANS OF DEVICES FOR ONE OR MORE INTENDED USES.

(a) IN GENERAL.—Section 516(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360f(a)) is amended—

(1) in paragraph (1), by inserting ''for one or more intended use'' before the semicolon at the end; and

(2) in the matter following paragraph (2), by inserting ''for any such intended use or uses. A device that is banned for one or more intended uses is not a legally marketed device under section 1006 when intended for such use or uses'' after ''banned device''.

(b) SPECIFIC DEVICES DEEMED BANNED.—Section 516 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360f) is further amended by adding at the end the following:

''(c) SPECIFIC DEVICE BANNED.—Electrical stimulation devices that apply a noxious electrical stimulus to a person's skin intended to reduce or cease self-injurious behavior or aggressive behavior are deemed to be banned devices, as described in subsection (a).

''(d) REVERSAL BY REGULATION.—Devices banned under this section are banned devices unless or until the Secretary promulgates a regulation to make such devices or use of such devices no longer banned based on a finding that such devices or use of such devices does not present substantial deception or an unreasonable and substantial risk of illness or injury, or that such risk can be corrected or eliminated by labeling.''.

SEC. 811. CLARIFYING APPLICATION OF EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSURE FOR DRUGS DESIGNATED FOR RARE DISEASES OR CONDITIONS.

(a) APPLICATION OF EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSURE FOR DRUGS DESIGNATED FOR RARE DISEASES OR CONDITIONS.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), in the matter following paragraph (2), by striking ''same disease or condition'' and inserting ''same approved indication or use within such rare disease or condition'';

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''same rare disease or condition'' and inserting ''same indication or use for which

the Secretary has approved or licensed such drug''; and

(B) in paragraph (1), by striking ''with the disease or condition for which the drug was designated'' and inserting ''for whom the drug is indicated''; and

(3) in subsection (c), by striking ''same rare disease or condition'' and inserting ''same indication or use''.

(b) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply with respect to any drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regardless of the date on which the drug was so designated, and regardless of the date on which the drug was approved under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 812. GAO REPORT ON THIRD-PARTY REVIEW.

Not later than September 30, 2026, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the third-party review program described in section 523 of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 360m). Such report shall include—

(1) a description of the financial and staffing resources used to carry out such program;

(2) a description of actions taken by the Secretary pursuant section 523(b)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(b)(2)(C)); and

(3) the results of an audit of the performance of select persons accredited under such program.

SEC. 813. REPORTING ON PENDING GENERIC DRUG APPLICATIONS AND PRIORITY REVIEW APPLICATIONS.

Section 807 of the FDA Reauthorization Act of 2017 (Public Law 115–52) is amended, in the matter preceding paragraph (1), by striking ''2022'' and inserting ''2027''.