

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

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.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food and Drug
5 Amendments of 2022”.

1 SEC. 2. TABLE OF CONTENTS.

2 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.

TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
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TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; finding.
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TITLE III—FEES RELATING TO GENERIC DRUGS

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- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
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TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Definitions.
- Sec. 403. Authority to assess and use biosimilar fees.
- Sec. 404. Reauthorization; reporting requirements.
- Sec. 405. Sunset dates.
- Sec. 406. Effective date.
- Sec. 407. Savings clause.

TITLE V—IMPROVING DIVERSITY IN CLINICAL STUDIES

- Sec. 501. Diversity action plans for clinical studies.
- Sec. 502. Evaluation of the need for FDA authority to mandate postapproval studies or postmarket surveillance due to insufficient demographic subgroup data.
- Sec. 503. Public workshops to enhance clinical study diversity.

- Sec. 504. Annual summary report on progress to increase diversity in clinical studies.
- Sec. 505. Public meeting on clinical study flexibilities initiated in response to COVID–19 pandemic.
- Sec. 506. Decentralized clinical studies.

TITLE VI—GENERIC DRUG COMPETITION

- Sec. 601. Increasing transparency in generic drug applications.
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- Sec. 701. Animal testing alternatives.
- Sec. 702. Emerging technology program.
- Sec. 703. Improving the treatment of rare diseases and conditions.
- Sec. 704. Antifungal research and development.
- Sec. 705. Advancing qualified infectious disease product innovation.
- Sec. 706. Advanced manufacturing technologies designation pilot program.
- Sec. 707. Public workshop on cell therapies.
- Sec. 708. Reauthorization of best pharmaceuticals for children.
- Sec. 709. Reauthorization for humanitarian device exemption and demonstration grants for improving pediatric availability.
- Sec. 710. Reauthorization of provision related to exclusivity of certain drugs containing single enantiomers.
- Sec. 711. Reauthorization of the critical path public-private partnership program.
- Sec. 712. Reauthorization of orphan drug grants.

Subtitle B—Inspections

- Sec. 721. Factory inspection.
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- Sec. 723. Improving FDA inspections.
- Sec. 724. GAO report on inspections of foreign establishments manufacturing drugs.
- Sec. 725. Unannounced foreign facility inspections pilot program.
- Sec. 726. Reauthorization of inspection program.
- Sec. 727. Enhancing intra-agency coordination and public health assessment with regard to compliance activities.
- Sec. 728. Reporting of mutual recognition agreements for inspections and review activities.
- Sec. 729. Enhancing transparency of drug facility inspection timelines.

TITLE VIII—TRANSPARENCY, PROGRAM INTEGRITY, AND REGULATORY IMPROVEMENTS

- Sec. 801. Prompt reports of marketing status by holders of approved applications for biological products.
- Sec. 802. Encouraging blood donation.
- Sec. 803. Regulation of certain products as drugs.
- Sec. 804. Postapproval studies and program integrity for accelerated approval drugs.
- Sec. 805. Facilitating the use of real world evidence.

- Sec. 806. Medical devices advisory committee meetings.
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Sec. 808. Public docket on proposed changes to third-party vendors.
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Sec. 810. Bans of devices for one or more intended uses.
Sec. 811. Clarifying application of exclusive approval, certification, or licensure for drugs designated for rare diseases or conditions.
Sec. 812. GAO report on third-party review.
Sec. 813. Reporting on pending generic drug applications and priority review applications.

1 **TITLE I—FEES RELATING TO**
2 **DRUGS**

3 **SEC. 101. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Prescription Drug User Fee Amendments of 2022”.

6 (b) **FINDING.**—The Congress finds that the fees au-
7 thorized by the amendments made by this title will be
8 dedicated toward expediting the drug development process
9 and the process for the review of human drug applications,
10 including postmarket drug safety activities, as set forth
11 in the goals identified for purposes of part 2 of subchapter
12 C of chapter VII of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 379g et seq.), in the letters from the Sec-
14 retary of Health and Human Services to the Chairman
15 of the Committee on Health, Education, Labor, and Pen-
16 sions of the Senate and the Chairman of the Committee
17 on Energy and Commerce of the House of Representa-
18 tives, as set forth in the Congressional Record.

1 **SEC. 102. DEFINITIONS.**

2 (a) HUMAN DRUG APPLICATION.—Section 735(1) of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379g(1)) is amended by striking “an allergenic extract
5 product, or” and inserting “does not include an applica-
6 tion with respect to an allergenic extract product licensed
7 before October 1, 2022, does not include an application
8 with respect to a standardized allergenic extract product
9 submitted pursuant to a notification to the applicant from
10 the Secretary regarding the existence of a potency test
11 that measures the allergenic activity of an allergenic ex-
12 tract product licensed by the applicant before October 1,
13 2022, does not include an application with respect to”.

14 (b) PRESCRIPTION DRUG PRODUCT.—Section 735(3)
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379g(3)) is amended—

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

19 (2) by striking “(3) The term” and inserting
20 “(3)(A) The term”;

21 (3) by striking “Such term does not include”
22 and inserting the following:

23 “(B) Such term does not include”;

24 (4) by striking “an allergenic extract product,”
25 and inserting “an allergenic extract product licensed
26 before October 1, 2022, a standardized allergenic ex-

1 tract product submitted pursuant to a notification to
2 the applicant from the Secretary regarding the exist-
3 ence of a potency test that measures the allergenic
4 activity of an allergenic extract product licensed by
5 the applicant before October 1, 2022,” ; and

6 (5) by adding at the end the following:

7 “(C)(i) If a written request to place a
8 product in the discontinued section of either of
9 the lists referenced in subparagraph (A)(iii) is
10 submitted to the Secretary on behalf of an ap-
11 plicant, and the request identifies the date the
12 product is withdrawn from sale, then for pur-
13 poses of assessing the prescription drug pro-
14 gram fee under section 736(a)(2), the Secretary
15 shall consider such product to have been in-
16 cluded in the discontinued section on the later
17 of—

18 “(I) the date such request was re-
19 ceived; or

20 “(II) if the product will be withdrawn
21 from sale on a future date, such future
22 date when the product is withdrawn from
23 sale.

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

1 sale once the applicant has ceased its own dis-
2 tribution of the product, whether or not the ap-
3 plicant has ordered recall of all previously dis-
4 tributed lots of the product, except that a rou-
5 tine, temporary interruption in supply shall not
6 render a product withdrawn from sale.”.

7 (c) SKIN-TEST DIAGNOSTIC PRODUCT.—Section 735
8 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379g) is amended by adding at the end the following:

10 “(12) The term ‘skin-test diagnostic product’—

11 “(A) means a product—

12 “(i) for prick, scratch, intradermal, or
13 subcutaneous administration;

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

17 “(iii) not intended to be a preventive
18 or therapeutic intervention; and

19 “(iv) intended to detect an immediate-
20 or delayed-type skin hypersensitivity reac-
21 tion to aid in the diagnosis of—

22 “(I) an allergy to an anti-
23 microbial agent;

24 “(II) an allergy that is not to an
25 antimicrobial agent, if the diagnostic

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

3 “(III) infection with fungal or
4 mycobacterial pathogens; and

5 “(B) includes positive and negative con-
6 trols required to interpret the results of a prod-
7 uct described in subparagraph (A).”.

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

9 (a) TYPES OF FEES.—

10 (1) HUMAN DRUG APPLICATION FEE.—Section
11 736(a) of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 379h(a)) is amended—

13 (A) in the matter preceding paragraph (1),
14 by striking “fiscal year 2018” and inserting
15 “fiscal year 2023”;

16 (B) in paragraph (1)(A), by striking
17 “(e)(5)” each place it appears and inserting
18 “(e)(6)”;

19 (C) in paragraph (1)(C), by inserting
20 “prior to approval” after “or was withdrawn”;
21 and

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

24 “(H) EXCEPTION FOR SKIN-TEST DIAG-
25 NOSTIC PRODUCTS.—A human drug application

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

3 (2) PRESCRIPTION DRUG PROGRAM FEE.—Sec-
4 tion 736(a)(2) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 379h(a)(2)) is amended—

6 (A) in subparagraph (A)—

7 (i) by striking “Except as provided in
8 subparagraphs (B) and (C)” and inserting
9 the following:

10 “(i) FEE.—Except as provided in sub-
11 paragraphs (B) and (C)”;

12 (ii) by striking “subsection (c)(5)”
13 and inserting “subsection (c)(6)”; and

14 (iii) by adding at the end the fol-
15 lowing:

16 “(ii) SPECIAL RULE.—If a drug prod-
17 uct that is identified in a human drug ap-
18 plication approved as of October 1 of a fis-
19 cal year is not a prescription drug product
20 as of that date because the drug product
21 is in the discontinued section of a list ref-
22 erenced in section 735(3)(A)(iii), and on
23 any subsequent day during such fiscal year
24 the drug product is a prescription drug
25 product, then except as provided in sub-

1 paragraphs (B) and (C), each person who
2 is named as the applicant in a human drug
3 application with respect to such product,
4 and who, after September 1, 1992, had
5 pending before the Secretary a human
6 drug application or supplement with re-
7 spect to such product, shall pay the annual
8 prescription drug program fee established
9 for a fiscal year under subsection (c)(6) for
10 such prescription drug product. Such fee
11 shall be due on the last business day of
12 such fiscal year and shall be paid only once
13 for each such product for a fiscal year in
14 which the fee is payable.”; and

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

17 “(B) EXCEPTION FOR CERTAIN PRESCRIP-
18 TION DRUG PRODUCTS.—A prescription drug
19 program fee shall not be assessed for a pre-
20 scription drug product under subparagraph (A)
21 if such product is—

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

1 including powders for reconstitution or phar-
2 macy bulk packages) identified on the list
3 compiled under section 505(j)(7);

4 “(ii) pharmaceutically equivalent (as
5 defined in section 314.3 of title 21, Code
6 of Federal Regulations (or any successor
7 regulation)) to another product on the list
8 of products compiled under section
9 505(j)(7) (not including the discontinued
10 section of such list); or

11 “(iii) a skin-test diagnostic product.”.

12 (b) FEE REVENUE AMOUNTS.—

13 (1) IN GENERAL.—Paragraph (1) of section
14 736(b) of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 379h(b)) is amended to read as follows:

16 “(1) IN GENERAL.—For each of the fiscal years
17 2023 through 2027, fees under subsection (a) shall,
18 except as provided in subsections (c), (d), (f), and
19 (g), be established to generate a total revenue
20 amount under such subsection that is equal to the
21 sum of—

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

1 “(B) the dollar amount equal to the infla-
2 tion adjustment for the fiscal year (as deter-
3 mined under subsection (c)(1));

4 “(C) the dollar amount equal to the stra-
5 tegic hiring and retention adjustment for the
6 fiscal year (as determined under subsection
7 (c)(2));

8 “(D) the dollar amount equal to the capac-
9 ity planning adjustment for the fiscal year (as
10 determined under subsection (c)(3));

11 “(E) the dollar amount equal to the oper-
12 ating reserve adjustment for the fiscal year, if
13 applicable (as determined under subsection
14 (c)(4));

15 “(F) the dollar amount equal to the addi-
16 tional direct cost adjustment for the fiscal year
17 (as determined under subsection (c)(5)); and

18 “(G) additional dollar amounts for each
19 fiscal year as follows:

20 “(i) \$65,773,693 for fiscal year 2023.

21 “(ii) \$25,097,671 for fiscal year 2024.

22 “(iii) \$14,154,169 for fiscal year
23 2025.

24 “(iv) \$4,864,860 for fiscal year 2026.

1 “(v) \$1,314,620 for fiscal year
2 2027.”.

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

7 “(3) ANNUAL BASE REVENUE.—For purposes
8 of paragraph (1), the dollar amount of the annual
9 base revenue for a fiscal year shall be—

10 “(A) for fiscal year 2023, \$1,151,522,958;
11 and

12 “(B) for fiscal years 2024 through 2027,
13 the dollar amount of the total revenue amount
14 established under paragraph (1) for the pre-
15 vious fiscal year, not including any adjustments
16 made under subsection (c)(4) or (c)(5).”.

17 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—

18 (1) INFLATION ADJUSTMENT.—Section
19 736(c)(1)(B)(ii) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is
21 amended by striking “Washington-Baltimore, DC-
22 MD-VA-WV” and inserting “Washington-Arlington-
23 Alexandria, DC-VA-MD-WV”.

24 (2) STRATEGIC HIRING AND RETENTION AD-
25 JUSTMENT.—Section 736(c) of the Federal Food,

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

3 (A) by redesignating paragraphs (2)
4 through (6) as paragraphs (3) through (7), re-
5 spectively; and

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

8 “(2) STRATEGIC HIRING AND RETENTION AD-
9 JUSTMENT.—For each fiscal year, after the annual
10 base revenue established in subsection (b)(1)(A) is
11 adjusted for inflation in accordance with paragraph
12 (1), the Secretary shall further increase the fee rev-
13 enue and fees by the following amounts:

14 “(A) For fiscal year 2023, \$9,000,000.

15 “(B) For each of fiscal years 2024 through
16 2027, \$4,000,000.”.

17 (3) CAPACITY PLANNING ADJUSTMENT.—Para-
18 graph (3), as redesignated, of section 736(e) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379h(e)) is amended to read as follows:

21 “(3) CAPACITY PLANNING ADJUSTMENT.—

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

1 be adjusted further for such fiscal year, in ac-
2 cordance with this paragraph, to reflect changes
3 in the resource capacity needs of the Secretary
4 for the process for the review of human drug
5 applications.

6 “(B) METHODOLOGY.—For purposes of
7 this paragraph, the Secretary shall employ the
8 capacity planning methodology utilized by the
9 Secretary in setting fees for fiscal year 2021, as
10 described in the notice titled ‘Prescription Drug
11 User Fee Rates for Fiscal Year 2021’ published
12 in the Federal Register on August 3, 2020 (85
13 Fed. Reg. 46651). The workload categories
14 used in applying such methodology in fore-
15 casting shall include only the activities de-
16 scribed in that notice and, as feasible, addi-
17 tional activities that are also directly related to
18 the direct review of applications and supple-
19 ments, including additional formal meeting
20 types, the direct review of postmarketing com-
21 mitments and requirements, the direct review of
22 risk evaluation and mitigation strategies, and
23 the direct review of annual reports for approved
24 prescription drug products. Subject to the ex-
25 ceptions in the preceding sentence, the Sec-

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

7 “(C) LIMITATION.—Under no cir-
8 cumstances shall an adjustment under this
9 paragraph result in fee revenue for a fiscal year
10 that is less than the sum of the amounts under
11 subsections (b)(1)(A) (the annual base revenue
12 for the fiscal year), (b)(1)(B) (the dollar
13 amount of the inflation adjustment for the fis-
14 cal year), and (b)(1)(C) (the dollar amount of
15 the strategic hiring and retention adjustment
16 for the fiscal year).

17 “(D) PUBLICATION IN FEDERAL REG-
18 ISTER.—The Secretary shall publish in the Fed-
19 eral Register notice under paragraph (6) of the
20 fee revenue and fees resulting from the adjust-
21 ment and the methodologies under this para-
22 graph.”.

23 (4) OPERATING RESERVE ADJUSTMENT.—Para-
24 graph (4), as redesignated, of section 736(c) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 379h(e)) is amended—

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

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

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

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

18 “(iii) For fiscal year 2025 and subse-
19 quent fiscal years, at least 10 weeks of op-
20 erating reserves.”; and

21 (B) in subparagraph (C), by striking
22 “paragraph (5)” and inserting “paragraph
23 (6)”.

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

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

3 “(5) ADDITIONAL DIRECT COST ADJUST-
4 MENT.—

5 “(A) INCREASE.—The Secretary shall, in
6 addition to adjustments under paragraphs (1),
7 (2), (3), and (4), further increase the fee rev-
8 enue and fees—

9 “(i) for fiscal year 2023, by
10 \$44,386,150; and

11 “(ii) for each of fiscal years 2024
12 through 2027, by the amount set forth in
13 clauses (i) through (iv) of subparagraph
14 (B), as applicable, multiplied by the Con-
15 sumer Price Index for urban consumers
16 (Washington-Arlington-Alexandria, DC-
17 VA-MD-WV; Not Seasonally Adjusted; All
18 Items; Annual Index) for the most recent
19 year of available data, divided by such
20 Index for 2021.

21 “(B) APPLICABLE AMOUNTS.—The
22 amounts referred to in subparagraph (A)(ii) are
23 the following:

24 “(i) For fiscal year 2024,
25 \$60,967,993.

1 “(ii) For fiscal year 2025,
2 \$35,799,314.

3 “(iii) For fiscal year 2026, \$35,799,
4 314.

5 “(iv) For fiscal year 2027,
6 \$35,799,314.”.

7 (6) ANNUAL FEE SETTING.—Paragraph (6), as
8 redesignated, of section 736(c) of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is
10 amended by striking “September 30, 2017” and in-
11 serting “September 30, 2022”.

12 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
13 tion 736(g)(3) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 379h(g)(3)) is amended by striking “fiscal
15 years 2018 through 2022” and inserting “fiscal years
16 2023 through 2027”.

17 (e) WRITTEN REQUESTS FOR WAIVERS, REDUC-
18 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
19 CERNING FEES.—Section 736(i) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is amended
21 to read as follows:

22 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
23 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
24 CERNING FEES.—To qualify for consideration for a waiver
25 or reduction under subsection (d), an exemption under

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

4 “(1) not later than 180 days after such fee is
5 due, submit to the Secretary a written request justi-
6 fying such waiver, reduction, exemption, or return;
7 and

8 “(2) include in the request any legal authorities
9 under which the request is made.”.

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

13 (1) in paragraph (1)(B), by striking “during
14 the previous year” and inserting “as determined
15 under paragraph (2)”; and

16 (2) by amending paragraph (2) to read as fol-
17 lows:

18 “(2) EVIDENCE OF QUALIFICATION.—An ex-
19 emption under paragraph (1) applies with respect to
20 a drug only if the applicant involved submits a cer-
21 tification that the applicant’s gross annual revenues
22 did not exceed \$50,000,000 for the last calendar
23 year ending prior to the fiscal year for which the ex-
24 emption is requested. Such certification shall be sup-
25 ported by—

1 “(A) tax returns submitted to the United
2 States Internal Revenue Service; or

3 “(B) as necessary, other appropriate finan-
4 cial information.”.

5 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

8 (1) in subsection (a)(1), by striking “Beginning
9 with fiscal year 2018, not” and inserting “Not”;

10 (2) by striking “Prescription Drug User Fee
11 Amendments of 2017” each place it appears and in-
12 serting “Prescription Drug User Fee Amendments
13 of 2022”;

14 (3) in subsection (a)(3)(A), by striking “Not
15 later than 30 calendar days after the end of the sec-
16 ond quarter of fiscal year 2018, and not later than
17 30 calendar days after the end of each quarter of
18 each fiscal year thereafter” and inserting “Not later
19 than 30 calendar days after the end of each quarter
20 of each fiscal year for which fees are collected under
21 this part”;

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

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

1 which the Secretary has determined that a
2 face-to-face meeting is appropriate, the
3 number of face-to-face meetings requested
4 by sponsors to be conducted in person (in
5 such manner as the Secretary shall pre-
6 scribe on the internet website of the Food
7 and Drug Administration), and the num-
8 ber of such in-person meetings granted by
9 the Secretary.”;

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

12 (6) in subsection (b), by striking “Beginning
13 with fiscal year 2018, not” and inserting “Not”;

14 (7) in subsection (c), by striking “Beginning
15 with fiscal year 2018, for” and inserting “For”; and

16 (8) in subsection (f)—

17 (A) in paragraph (1), in the matter pre-
18 ceding subparagraph (A), by striking “fiscal
19 year 2022” and inserting “fiscal year 2027”;
20 and

21 (B) in paragraph (5), by striking “January
22 15, 2022” and inserting “January 15, 2027”.

1 **SEC. 105. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 735 and 736 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
4 379h) shall cease to be effective October 1, 2027.

5 (b) REPORTING REQUIREMENTS.—Section 736B of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 379h–2) shall cease to be effective January 31, 2028.

8 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
9 ber 1, 2022, subsections (a) and (b) of section 104 of the
10 FDA Reauthorization Act of 2017 (Public Law 115–52)
11 are repealed.

12 **SEC. 106. EFFECTIVE DATE.**

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

21 **SEC. 107. SAVINGS CLAUSE.**

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

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

7 **TITLE II—FEES RELATING TO**
8 **DEVICES**

9 **SEC. 201. SHORT TITLE; FINDING.**

10 (a) **SHORT TITLE.**—This title may be cited as the
11 “Medical Device User Fee Amendments of 2022”.

12 (b) **FINDING.**—The Congress finds that the fees au-
13 thorized under the amendments made by this title will be
14 dedicated toward expediting the process for the review of
15 device applications and for assuring the safety and effec-
16 tiveness of devices, as set forth in the goals identified for
17 purposes of part 3 of subchapter C of chapter VII of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i
19 et seq.), in the letters from the Secretary of Health and
20 Human Services to the Chairman of the Committee on
21 Health, Education, Labor, and Pensions of the Senate and
22 the Chairman of the Committee on Energy and Commerce
23 of the House of Representatives, as set forth in the Con-
24 gressional Record.

1 **SEC. 202. DEFINITIONS.**

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

4 (1) in paragraph (9)—

5 (A) in the matter preceding subparagraph
6 (A), by striking “and premarket notification
7 submissions” and inserting “premarket notifica-
8 tion submissions, and de novo classification re-
9 quests”;

10 (B) in subparagraph (D), by striking “and
11 submissions” and inserting “submissions, and
12 requests”;

13 (C) in subparagraph (F), by striking “and
14 premarket notification submissions” and insert-
15 ing “premarket notification submissions, and de
16 novo classification requests”;

17 (D) in each of subparagraphs (G) and (H),
18 by striking “or submissions” and inserting
19 “submissions, or requests”; and

20 (E) in subparagraph (K), by striking “or
21 premarket notification submissions” and insert-
22 ing “premarket notification submissions, or de
23 novo classification requests”; and

24 (2) in paragraph (11), by striking “2016” and
25 inserting “2021”.

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

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

5 (1) in paragraph (1), by striking “fiscal year
6 2018” and inserting “fiscal year 2023”; and

7 (2) in paragraph (2)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i),
10 by striking “October 1, 2017” and insert-
11 ing “October 1, 2022”;

12 (ii) in clause (iii), by striking “75 per-
13 cent” and inserting “80 percent”; and

14 (iii) in clause (viii), by striking “3.4
15 percent” and inserting “4.5 percent”;

16 (B) in subparagraph (B)(iii), by striking
17 “or premarket notification submission” and in-
18 sserting “premarket notification submission, or
19 de novo classification request”; and

20 (C) in subparagraph (C), by striking “or
21 periodic reporting concerning a class III device”
22 and inserting “periodic reporting concerning a
23 class III device, or de novo classification re-
24 quest”.

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

4 (1) in paragraph (1), by striking “2018
 5 through 2022” and inserting “2023 through 2027”;

6 (2) by amending paragraph (2) to read as fol-
 7 lows:

8 “(2) BASE FEE AMOUNTS SPECIFIED.—For
 9 purposes of paragraph (1), the base fee amounts
 10 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

11 (3) by amending paragraph (3) to read as fol-
 12 lows:

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

16 “(A) \$312,606,000 for fiscal year 2023.

17 “(B) \$335,750,000 for fiscal year 2024.

18 “(C) \$350,746,400 for fiscal year 2025.

19 “(D) \$366,486,300 for fiscal year 2026.

20 “(E) \$418,343,000 for fiscal year 2027.”.

21 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
 22 738(c) of the Federal Food, Drug, and Cosmetic Act (21
 23 U.S.C. 379j(c)) is amended—

1 (1) in paragraph (1), by striking “2017” and
2 inserting “2022”;

3 (2) in paragraph (2)—

4 (A) in subparagraph (A), by striking
5 “2018” and inserting “2023”;

6 (B) in subparagraph (B)—

7 (i) in the matter preceding clause (i),
8 by striking “fiscal year 2018” and insert-
9 ing “fiscal year 2023”; and

10 (ii) in clause (ii), by striking “fiscal
11 year 2016” and inserting “fiscal year
12 2022”;

13 (C) in subparagraph (C), by striking
14 “Washington-Baltimore, DC–MD–VA–WV”
15 and inserting “Washington-Arlington-Alexan-
16 dria, DC–VA–MD–WV”; and

17 (D) in subparagraph (D), in the matter
18 preceding clause (i), by striking “fiscal years
19 2018 through 2022” and inserting “fiscal years
20 2023 through 2027”;

21 (3) in paragraph (3), by striking “2018
22 through 2022” and inserting “2023 through 2027”;

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

1 (5) by inserting after paragraph (3) the fol-
2 lowing:

3 “(4) PERFORMANCE IMPROVEMENT ADJUST-
4 MENT.—

5 “(A) IN GENERAL.—For each of fiscal
6 years 2025 through 2027, after the adjust-
7 ments under paragraphs (2) and (3), the base
8 establishment registration fee amounts for such
9 fiscal year shall be increased to reflect changes
10 in the resource needs of the Secretary due to
11 improved review performance goals for the proc-
12 ess for the review of device applications identi-
13 fied in the letters described in section 201(b) of
14 the Medical Device User Fee Amendments of
15 2022, as the Secretary determines necessary to
16 achieve an increase in total fee collections for
17 such fiscal year equal to the following amounts:

18 “(i) For fiscal year 2025, the product
19 of—

20 “(I) the amount determined
21 under subparagraph (B)(i)(I); and

22 “(II) the applicable inflation ad-
23 justment under paragraph (2)(B) for
24 such fiscal year.

1 “(ii) For fiscal year 2026, the product
2 of—

3 “(I) the sum of the amounts de-
4 termined under subparagraphs
5 (B)(i)(II), (B)(ii)(I), and (B)(iii)(I);
6 and

7 “(II) the applicable inflation ad-
8 justment under paragraph (2)(B) for
9 such fiscal year.

10 “(iii) For fiscal year 2027, the prod-
11 uct of—

12 “(I) the sum of the amounts de-
13 termined under subparagraphs
14 (B)(i)(III), (B)(ii)(II), and
15 (B)(iii)(II); and

16 “(II) the applicable inflation ad-
17 justment under paragraph (2)(B) for
18 such fiscal year.

19 “(B) AMOUNTS.—

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

1 “(I) For fiscal year 2025,
2 \$15,396,600 if such goal for fiscal
3 year 2023 is met.

4 “(II) For fiscal year 2026:

5 “(aa) \$15,396,600 if such
6 goal for fiscal year 2023 is met
7 and such goal for fiscal year
8 2024 is not met.

9 “(bb) \$36,792,200 if such
10 goal for fiscal year 2024 is met.

11 “(III) For fiscal year 2027:

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

16 “(bb) \$36,792,200 if such
17 goal for fiscal year 2024 is met
18 and such goal for fiscal year
19 2025 is not met.

20 “(cc) \$40,572,600 if such
21 goal for fiscal year 2025 is met.

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

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

3 “(I) For fiscal year 2026,
4 \$6,323,500 if such goal for fiscal year
5 2023 is met.

6 “(II) For fiscal year 2027:

7 “(aa) \$6,323,500 if such
8 goal for fiscal year 2023 is met
9 and such goal for fiscal year
10 2024 is not met.

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

13 “(iii) PREMARKET NOTIFICATION AND
14 PREMARKET APPROVAL AMOUNT.—For
15 purposes of subparagraph (A), with respect
16 to the 510(k) decision goal, 510(k) shared
17 outcome total time to decision goal, PMA
18 decision goal, and PMA shared outcome
19 total time to decision goal, the amounts de-
20 termined under this subparagraph are as
21 follows:

22 “(I) For fiscal year 2026,
23 \$1,020,000 if the four goals for fiscal
24 year 2023 are met.

25 “(II) For fiscal year 2027:

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

5 “(bb) \$3,906,000 if the four
6 goals for fiscal year 2024 are
7 met.

8 “(C) PERFORMANCE CALCULATION.—For
9 purposes of this paragraph, performance of the
10 goals listed in subparagraph (D) shall be deter-
11 mined as specified in the letters described in
12 section 201(b) of the Medical Device User Fee
13 Amendments of 2022 and based on data avail-
14 able as of the following dates:

15 “(i) The performance of the pre-sub-
16 mission written feedback goal shall be
17 based on data available as of—

18 “(I) for fiscal year 2023, March
19 31, 2024;

20 “(II) for fiscal year 2024, March
21 31, 2025; and

22 “(III) for fiscal year 2025,
23 March 31, 2026.

24 “(ii) The performance of the de novo
25 decision goal, 510(k) decision goal, 510(k)

1 shared outcome total time to decision goal,
2 PMA decision goal, and PMA shared out-
3 come total time to decision goal shall be
4 based on data available as of—

5 “(I) for fiscal year 2023, March
6 31, 2025; and

7 “(II) for fiscal year 2024, March
8 31, 2026.

9 “(D) GOALS DEFINED.—For purposes of
10 this paragraph, the terms ‘pre-submission writ-
11 ten feedback goal’, ‘de novo decision goal’,
12 ‘510(k) decision goal’, ‘510(k) shared outcome
13 total time to decision goal’, ‘PMA decision
14 goal’, and ‘PMA shared outcome total time to
15 decision goal’ refer to the goals identified by the
16 same names in the letters described in section
17 201(b) of the Medical Device User Fee Amend-
18 ments of 2022.

19 “(5) HIRING ADJUSTMENT.—

20 “(A) IN GENERAL.—For each of fiscal
21 years 2025 through 2027, after the adjust-
22 ments under paragraphs (2), (3), and (4), if ap-
23 plicable, if the number of hires to support the
24 process for the review of device applications
25 falls below the thresholds specified in subpara-

1 graph (B) for the applicable fiscal years, the
2 base establishment registration fee amounts
3 shall be decreased as the Secretary determines
4 necessary to achieve a reduction in total fee col-
5 lections equal to the hiring adjustment amount
6 under subparagraph (C).

7 “(B) THRESHOLDS.—The thresholds speci-
8 fied in this subparagraph are as follows:

9 “(i) For fiscal year 2025, the thresh-
10 old is 123 hires for fiscal year 2023.

11 “(ii) For fiscal year 2026, the thresh-
12 old is 38 hires for fiscal year 2024.

13 “(iii) For fiscal year 2027, the thresh-
14 old is—

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

20 “(II) 75 hires for fiscal year
21 2025 if such fees are so increased.

22 “(C) HIRING ADJUSTMENT AMOUNT.—The
23 hiring adjustment amount for fiscal year 2025
24 and each subsequent fiscal year is the product
25 of—

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

5 “(ii) \$72,877; and

6 “(iii) the applicable inflation adjust-
7 ment under paragraph (2)(B) for the fiscal
8 year for which the hiring goal was not met.

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

12 “(i) For fiscal year 2023, 144 hires.

13 “(ii) For fiscal year 2024, 42 hires.

14 “(iii) For fiscal year 2025:

15 “(I) 24 hires if the base estab-
16 lishment registration fees are not in-
17 creased by the amount determined
18 under paragraph (4)(A)(i).

19 “(II) 83 hires if the base estab-
20 lishment registration fees are in-
21 creased by the amount determined
22 under paragraph (4)(A)(i).

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

1 letters described in section 201(b) of the Med-
2 ical Device User Fee Amendments of 2022.

3 “(6) OPERATING RESERVE ADJUSTMENT.—

4 “(A) IN GENERAL.—For each of fiscal
5 years 2023 through 2027, after the adjust-
6 ments under paragraphs (2), (3), (4), and (5),
7 if applicable, if the Secretary has operating re-
8 serves of carryover user fees for the process for
9 the review of device applications in excess of the
10 designated amount in subparagraph (B), the
11 Secretary shall decrease the base establishment
12 registration fee amounts to provide for not
13 more than such designated amount of operating
14 reserves.

15 “(B) DESIGNATED AMOUNT.—Subject to
16 subparagraph (C), for each fiscal year, the des-
17 igned amount in this subparagraph is equal
18 to the sum of—

19 “(i) 13 weeks of operating reserves of
20 carryover user fees; and

21 “(ii) 1 month of operating reserves
22 maintained pursuant to paragraph (8).

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

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

4 (d) SMALL BUSINESSES.—Section 738 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
6 ed in each of subsections (d)(2)(B)(iii) and (e)(2)(B)(iii)
7 by inserting “, if extant,” after “national taxing author-
8 ity”.

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

12 (1) in paragraph (1)(A), by striking
13 “\$320,825,000” and inserting “\$398,566,000”; and

14 (2) in paragraph (2), by inserting “de novo
15 classification requests,” after “class III device,”.

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

19 “(3) AUTHORIZATION OF APPROPRIATIONS.—

20 “(A) IN GENERAL.—For each of fiscal
21 years 2023 through 2027, there is authorized to
22 be appropriated for fees under this section an
23 amount equal to the revenue amount deter-
24 mined under subparagraph (B), less the

1 amount of reductions determined under sub-
2 paragraph (C).

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

6 “(i) the total revenue amount under
7 subsection (b)(3) for the fiscal year, as ad-
8 justed under paragraphs (2) and (3) of
9 subsection (c); and

10 “(ii) the performance improvement
11 adjustment amount for the fiscal year
12 under subsection (c)(4), if applicable.

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

16 “(i) the hiring adjustment amount for
17 the fiscal year under subsection (c)(5), if
18 applicable; and

19 “(ii) the operating reserve adjustment
20 amount for the fiscal year under sub-
21 section (c)(6), if applicable.”.

22 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

23 (a) PERFORMANCE REPORTS.—Section 738A(a) of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379j-1(a)) is amended—

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

3 (2) by striking “Medical Device User Fee
4 Amendments of 2017” each place it appears and in-
5 serting “Medical Device User Fee Amendments of
6 2022”;

7 (3) in paragraph (1)—

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

11 (B) in subparagraph (A)(iv), by striking
12 “fiscal year 2020” and inserting “fiscal year
13 2023”; and

14 (4) in paragraph (4), by striking “2018
15 through 2022” and inserting “2023 through 2027”.

16 (b) REAUTHORIZATION.—Section 738A(b) of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
18 1(b)) is amended—

19 (1) in paragraph (1), by striking “2022” and
20 inserting “2027”; and

21 (2) in paragraph (5), by striking “2022” and
22 inserting “2027”.

1 **SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.**

2 Section 514(d) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360d(d)) is amended to read as fol-
4 lows:

5 “(d) ACCREDITATION SCHEME FOR CONFORMITY AS-
6 SESSMENT.—

7 “(1) IN GENERAL.—The Secretary shall estab-
8 lish a program under which—

9 “(A) testing laboratories meeting criteria
10 specified in guidance by the Secretary may be
11 accredited by accreditation bodies meeting cri-
12 teria specified in guidance by the Secretary, to
13 conduct testing to support the assessment of
14 the conformity of a device to certain standards
15 recognized under this section; and

16 “(B) subject to paragraph (2), results
17 from tests conducted to support the assessment
18 of conformity of devices as described in sub-
19 paragraph (A) conducted by testing laboratories
20 accredited pursuant to this subsection shall be
21 accepted by the Secretary for purposes of dem-
22 onstrating such conformity unless the Secretary
23 finds that certain results of such tests should
24 not be so accepted.

25 “(2) SECRETARIAL REVIEW OF ACCREDITED
26 LABORATORY RESULTS.—The Secretary may—

1 “(A) review the results of tests conducted
2 by testing laboratories accredited pursuant to
3 this subsection, including by conducting peri-
4 odic audits of such results or of the processes
5 of accredited bodies or testing laboratories;

6 “(B) following such review, take additional
7 measures under this Act, as the Secretary de-
8 termines appropriate, such as—

9 “(i) suspension or withdrawal of ac-
10 creditation of a testing laboratory or rec-
11 ognition of an accreditation body under
12 paragraph (1)(A); or

13 “(ii) requesting additional information
14 with respect to a device; and

15 “(C) if the Secretary becomes aware of in-
16 formation materially bearing on the safety or
17 effectiveness of a device for which an assess-
18 ment of conformity was supported by testing
19 conducted by a testing laboratory accredited
20 under this subsection, take such additional
21 measures under this Act, as the Secretary de-
22 termines appropriate, such as—

23 “(i) suspension or withdrawal of ac-
24 creditation of a testing laboratory or rec-

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

3 “(ii) requesting additional information
4 with regard to such device.

5 “(3) IMPLEMENTATION AND REPORTING.—

6 “(A) PILOT PROGRAM TRANSITION.—After
7 September 30, 2023, the pilot program pre-
8 viously initiated under this subsection, as in ef-
9 fect prior to the date of enactment of the Med-
10 ical Device User Fee Amendments of 2022,
11 shall be considered to be completed, and the
12 Secretary may continue operating a program
13 consistent with this subsection.

14 “(B) REPORT.—The Secretary shall make
15 available on the internet website of the Food
16 and Drug Administration an annual report on
17 the progress of the pilot program under this
18 subsection.”.

19 **SEC. 206. REAUTHORIZATION OF THIRD-PARTY REVIEW**
20 **PROGRAM.**

21 Section 523(c) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360m(c)) is amended by striking
23 “2022” and inserting “2027”.

1 **SEC. 207. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 737 and 738 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i;
4 379j) shall cease to be effective October 1, 2027.

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

9 (c) PREVIOUS SUNSET PROVISIONS.—Effective Octo-
10 ber 1, 2022, subsections (a) and (b) of section 210 of the
11 FDA Reauthorization Act of 2017 (Public Law 115–52)
12 are repealed.

13 **SEC. 208. EFFECTIVE DATE.**

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

22 **SEC. 209. SAVINGS CLAUSE.**

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

1 title, shall continue to be in effect with respect to the sub-
2 missions listed in section 738(a)(2)(A) of such Act (as de-
3 fined in such part as of such day) that on or after October
4 1, 2017, but before October 1, 2022, were received by the
5 Food and Drug Administration with respect to assessing
6 and collecting any fee required by such part for a fiscal
7 year prior to fiscal year 2023.

8 **TITLE III—FEES RELATING TO**
9 **GENERIC DRUGS**

10 **SEC. 301. SHORT TITLE; FINDING.**

11 (a) **SHORT TITLE.**—This title may be cited as the
12 “Generic Drug User Fee Amendments of 2022”.

13 (b) **FINDING.**—The Congress finds that the fees au-
14 thorized by the amendments made by this title will be
15 dedicated to human generic drug activities, as set forth
16 in the goals identified for purposes of part 7 of subchapter
17 C of chapter VII of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 379j–41 et seq.), in the letters from the
19 Secretary of Health and Human Services to the Chairman
20 of the Committee on Health, Education, Labor, and Pen-
21 sions of the Senate and the Chairman of the Committee
22 on Energy and Commerce of the House of Representa-
23 tives, as set forth in the Congressional Record.

1 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
2 **NERIC DRUG FEES.**

3 (a) TYPES OF FEES.—Section 744B(a) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
5 42(a)) is amended—

6 (1) in the matter preceding paragraph (1), by
7 striking “fiscal year 2018” and inserting “fiscal year
8 2023”;

9 (2) in paragraph (2)(C), by striking “2018
10 through 2022” and inserting “2023 through 2027”;

11 (3) in paragraph (3)(B), by striking “2018
12 through 2022” and inserting “2023 through 2027”;

13 (4) in paragraph (4)(D), by striking “2018
14 through 2022” and inserting “2023 through 2027”;
15 and

16 (5) in paragraph (5)(D), by striking “2018
17 through 2022” and inserting “2023 through 2027”.

18 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379j–42(b)) is amended—

21 (1) in paragraph (1)—

22 (A) in subparagraph (A)—

23 (i) in the heading, by striking “2018”
24 and inserting “2023”;

25 (ii) by striking “2018” and inserting
26 “2023”; and

1 (iii) by striking “\$493,600,000” and
2 inserting “\$582,500,000”; and

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

5 “(B) FISCAL YEARS 2024 THROUGH 2027.—

6 “(i) IN GENERAL.—For each of the
7 fiscal years 2024 through 2027, fees under
8 paragraphs (2) through (5) of subsection
9 (a) shall be established to generate a total
10 estimated revenue amount under such sub-
11 section that is equal to the base revenue
12 amount for the fiscal year under clause
13 (ii), as adjusted pursuant to subsection (c).

14 “(ii) BASE REVENUE AMOUNT.—The
15 base revenue amount for a fiscal year re-
16 ferred to in clause (i) is equal to the total
17 revenue amount established under this
18 paragraph for the previous fiscal year, not
19 including any adjustments made for such
20 previous fiscal year under subsection
21 (c)(3).”; and

22 (2) in paragraph (2)—

23 (A) in subparagraph (C), by striking “one-
24 third the amount” and inserting “twenty-four
25 percent”;

1 (B) in subparagraph (D), by striking
2 “Seven percent” and inserting “Six percent”;
3 and

4 (C) in subparagraph (E)(i), by striking
5 “Thirty-five percent” and inserting “Thirty-six
6 percent”.

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

10 (1) in paragraph (1)—

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

13 (i) by striking “2019” and inserting
14 “2024”; and

15 (ii) by striking “to equal the product
16 of the total revenues established in such
17 notice for the prior fiscal year multiplied”
18 and inserting “to equal the base revenue
19 amount for the fiscal year (as specified in
20 subsection (b)(1)(B)) multiplied”; and

21 (B) in subparagraph (C), by striking
22 “Washington-Baltimore, DC–MD–VA–WV”
23 and inserting “Washington-Arlington-Alexan-
24 dria, DC–VA–MD–WV”; and

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

3 “(2) CAPACITY PLANNING ADJUSTMENT.—

4 “(A) IN GENERAL.—Beginning with fiscal
5 year 2024, the Secretary shall, in addition to
6 the adjustment under paragraph (1), further in-
7 crease the fee revenue and fees under this sec-
8 tion for a fiscal year, in accordance with this
9 paragraph, to reflect changes in the resource
10 capacity needs of the Secretary for human ge-
11 neric drug activities.

12 “(B) CAPACITY PLANNING METHOD-
13 OLOGY.—The Secretary shall establish a capac-
14 ity planning methodology for purposes of this
15 paragraph, which shall—

16 “(i) be derived from the methodology
17 and recommendations made in the report
18 titled ‘Independent Evaluation of the
19 GDUFA Resource Capacity Planning Ad-
20 justment Methodology: Evaluation and
21 Recommendations’ announced in the Fed-
22 eral Register on August 3, 2020;

23 “(ii) incorporate approaches and at-
24 tributes determined appropriate by the
25 Secretary, including approaches and at-

1 tributes made in such report, except that
2 in incorporating such approaches and at-
3 tributes the workload categories used in
4 forecasting resources shall only be the
5 workload categories specified in section
6 VIII.B.2.e. of the letters described in sec-
7 tion 301(b) of the Generic Drug User Fee
8 Amendments of 2022; and

9 “(iii) be effective beginning with fiscal
10 year 2024.

11 “(C) LIMITATIONS.—

12 “(i) IN GENERAL.—Under no cir-
13 cumstances shall an adjustment under this
14 paragraph result in fee revenue for a fiscal
15 year that is less than the sum of the
16 amounts under subsection (b)(1)(B)(ii)
17 (the base revenue amount for the fiscal
18 year) and paragraph (1) (the dollar
19 amount of the inflation adjustment for the
20 fiscal year).

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

1 “(I) for purposes of a fiscal year
2 2024 adjustment, the Secretary deter-
3 mines that during the period from
4 April 1, 2021, through March 31,
5 2023—

6 “(aa) the total number of
7 abbreviated new drug applica-
8 tions submitted was greater than
9 or equal to 2,000; or

10 “(bb) thirty-five percent or
11 more of abbreviated new drug ap-
12 plications submitted related to
13 complex products (as that term is
14 defined in section XI of the let-
15 ters described in section 301(b)
16 of the Generic Drug User Fee
17 Amendments of 2022);

18 “(II) for purposes of a fiscal year
19 2025 adjustment, the Secretary deter-
20 mines that during the period from
21 April 1, 2022, through March 31,
22 2024—

23 “(aa) the total number of
24 abbreviated new drug applica-

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

3 “(bb) thirty-five percent or
4 more of abbreviated new drug ap-
5 plications submitted related to
6 complex products (as so defined);

7 “(III) for purposes of a fiscal
8 year 2026 adjustment, the Secretary
9 determines that during the period
10 from April 1, 2023, through March
11 31, 2025—

12 “(aa) the total number of
13 abbreviated new drug applica-
14 tions submitted was greater than
15 or equal to 2,300; or

16 “(bb) thirty-five percent or
17 more of abbreviated new drug ap-
18 plications submitted related to
19 complex products (as so defined);
20 and

21 “(IV) for purposes of a fiscal
22 year 2027 adjustment, the Secretary
23 determines that during the period
24 from April 1, 2024, through March
25 31, 2026—

1 “(aa) the total number of
2 abbreviated new drug applica-
3 tions submitted was greater than
4 or equal to 2,300; or

5 “(bb) thirty-five percent or
6 more of abbreviated new drug ap-
7 plications submitted related to
8 complex products (as so defined).

9 “(D) PUBLICATION IN FEDERAL REG-
10 ISTER.—The Secretary shall publish in the Fed-
11 eral Register notice referred to in subsection (a)
12 the fee revenue and fees resulting from the ad-
13 justment and the methodology under this para-
14 graph.

15 “(3) OPERATING RESERVE ADJUSTMENT.—

16 “(A) IN GENERAL.—For fiscal year 2024
17 and each subsequent fiscal year, the Secretary
18 may, in addition to adjustments under para-
19 graphs (1) and (2), further increase the fee rev-
20 enue and fees under this section for such fiscal
21 year if such an adjustment is necessary to pro-
22 vide operating reserves of carryover user fees
23 for human generic drug activities for not more
24 than the number of weeks specified in subpara-
25 graph (B) with respect to that fiscal year.

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

3 “(i) 8 weeks for fiscal year 2024;

4 “(ii) 9 weeks for fiscal year 2025; and

5 “(iii) 10 weeks for each of fiscal year
6 2026 and 2027.

7 “(C) DECREASE.—If the Secretary has
8 carryover balances for human generic drug ac-
9 tivities in excess of 12 weeks of the operating
10 reserves referred to in subparagraph (A), the
11 Secretary shall decrease the fee revenue and
12 fees referred to in such subparagraph to provide
13 for not more than 12 weeks of such operating
14 reserves.

15 “(D) RATIONALE FOR ADJUSTMENT.—If
16 an adjustment under this paragraph is made,
17 the rationale for the amount of the increase or
18 decrease (as applicable) in fee revenue and fees
19 shall be contained in the annual Federal Reg-
20 ister notice under subsection (a) publishing the
21 fee revenue and fees for the fiscal year in-
22 volved.”.

23 (d) ANNUAL FEE SETTING.—Section 744B(d)(1) of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379j-42(d)(1)) is amended—

1 (1) in the paragraph heading, by striking “2018
2 THROUGH 2022” and inserting “2023 THROUGH
3 2027”; and

4 (2) by striking “more than 60 days before the
5 first day of each of fiscal years 2018 through 2022”
6 and inserting “later than 60 days before the first
7 day of each of fiscal years 2023 through 2027”.

8 (e) CREDITING AND AVAILABILITY OF FEES.—Sec-
9 tion 744B(i)(3) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 379j–42(i)(3)) is amended by striking “fis-
11 cal years 2018 through 2022” and inserting “fiscal years
12 2023 through 2027”.

13 (f) EFFECT OF FAILURE TO PAY FEES.—The head-
14 ing of paragraph (3) of section 744B(g) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is
16 amended by striking “AND PRIOR APPROVAL SUPPLEMENT
17 FEE”.

18 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

21 (1) in subsection (a)(1), by striking “Beginning
22 with fiscal year 2018, not” and inserting “Not”;

23 (2) by striking “Generic Drug User Fee
24 Amendments of 2017” each place it appears and in-

1 serting “Generic Drug User Fee Amendments of
2 2022”;

3 (3) in subsection (a)(2), by striking “Not later
4 than 30 calendar days after the end of the second
5 quarter of fiscal year 2018, and not later than 30
6 calendar days after the end of each quarter of each
7 fiscal year thereafter” and inserting “Not later than
8 30 calendar days after the end of each quarter of
9 each fiscal year for which fees are collected under
10 this part”;

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

13 (5) in subsection (b), by striking “Beginning
14 with fiscal year 2018, not” and inserting “Not”;

15 (6) in subsection (c), by striking “Beginning
16 with fiscal year 2018, for” and inserting “For”; and

17 (7) in subsection (f)—

18 (A) in paragraph (1), in the matter pre-
19 ceding subparagraph (A), by striking “fiscal
20 year 2022” and inserting “fiscal year 2027”;
21 and

22 (B) in paragraph (5), by striking “January
23 15, 2022” and inserting “January 15, 2027”.

1 **SEC. 304. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 744A and 744B of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–41; 379j–42) shall cease to be effective October 1,
5 2027.

6 (b) REPORTING REQUIREMENTS.—Section 744C of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 379j–43) shall cease to be effective January 31, 2028.

9 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
10 ber 1, 2022, subsections (a) and (b) of section 305 of the
11 FDA Reauthorization Act of 2017 (Public Law 115–52)
12 are repealed.

13 **SEC. 305. EFFECTIVE DATE.**

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

22 **SEC. 306. SAVINGS CLAUSE.**

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

1 this title, shall continue to be in effect with respect to ab-
2 breviated new drug applications (as defined in such part
3 as of such day) that were received by the Food and Drug
4 Administration within the meaning of section 505(j)(5)(A)
5 of such Act (21 U.S.C. 355(j)(5)(A)), prior approval sup-
6 plements that were submitted, and drug master files for
7 Type II active pharmaceutical ingredients that were first
8 referenced on or after October 1, 2017, but before October
9 1, 2022, with respect to assessing and collecting any fee
10 required by such part for a fiscal year prior to fiscal year
11 2023.

12 **TITLE IV—FEES RELATING TO**
13 **BIOSIMILAR BIOLOGICAL**
14 **PRODUCTS**

15 **SEC. 401. SHORT TITLE; FINDING.**

16 (a) **SHORT TITLE.**—This title may be cited as the
17 “Biosimilar User Fee Amendments of 2022”.

18 (b) **FINDING.**—The Congress finds that the fees au-
19 thorized by the amendments made by this title will be
20 dedicated to expediting the process for the review of bio-
21 similar biological product applications, including
22 postmarket safety activities, as set forth in the goals iden-
23 tified for purposes of part 8 of subchapter C of chapter
24 VII of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 379j–51 et seq.), in the letters from the Secretary

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

6 **SEC. 402. DEFINITIONS.**

7 (a) ADJUSTMENT FACTOR.—Section 744G(1) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
9 51(1)) is amended to read as follows:

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

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

20 (1) by striking subclause (II) (relating to an al-
21 lergenic extract product); and

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

1 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
2 **FEEES.**

3 (a) TYPES OF FEES.—

4 (1) IN GENERAL.—The matter preceding para-
5 graph (1) in section 744H(a) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is
7 amended by striking “fiscal year 2018” and insert-
8 ing “fiscal year 2023”.

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

15 (3) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT
16 DEVELOPMENT FEE.—Section 744H(a)(1)(B) of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 379j–52(a)(1)(B)) is amended—

19 (A) in clause (i), by inserting before the
20 period at the end the following: “, except where
21 such product (including, where applicable, own-
22 ership of the relevant investigational new drug
23 application) is transferred to a licensee, as-
24 signee, or successor of such person, and written
25 notice of such transfer is provided to the Sec-
26 retary, in which case such licensee, assignee, or

1 successor shall pay the annual biosimilar bio-
2 logical product development fee”;

3 (B) in clause (iii)—

4 (i) in subclause (I), by striking “or”
5 at the end;

6 (ii) in subclause (II), by striking the
7 period at the end and inserting “; or”; and

8 (iii) by adding at the end the fol-
9 lowing:

10 “(III) been administratively re-
11 moved from the biosimilar biological
12 product development program for the
13 product under subparagraph (E)(v).”;
14 and

15 (C) in clause (iv), by striking “is accepted
16 for filing on or after October 1 of such fiscal
17 year” and inserting “is subsequently accepted
18 for filing”.

19 (4) REACTIVATION FEE.—Section
20 744H(a)(1)(D) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 379j–52(a)(1)(D)) is amended
22 to read as follows:

23 “(D) REACTIVATION FEE.—

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

1 biological product development program for
2 a product under subparagraph (C), or who
3 has been administratively removed from
4 the biosimilar biological product develop-
5 ment program for a product under sub-
6 paragraph (E)(v), shall, if the person seeks
7 to resume participation in such program,
8 pay all annual biosimilar biological product
9 development fees previously assessed for
10 such product and still owed and a fee (re-
11 ferred to in this section as ‘reactivation
12 fee’) by the earlier of the following:

13 “(I) Not later than 7 days after
14 the Secretary grants a request by
15 such person for a biosimilar biological
16 product development meeting for the
17 product (after the date on which such
18 participation was discontinued or the
19 date of administrative removal, as ap-
20 plicable).

21 “(II) Upon the date of submis-
22 sion (after the date on which such
23 participation was discontinued or the
24 date of administrative removal, as ap-
25 plicable) by such person of an inves-

1 tigation new drug application de-
2 scribing an investigation that the Sec-
3 retary determines is intended to sup-
4 port a biosimilar biological product
5 application for that product.

6 “(ii) APPLICATION OF ANNUAL
7 FEE.—A person that pays a reactivation
8 fee for a product shall pay for such prod-
9 uct, beginning in the next fiscal year, the
10 annual biosimilar biological product devel-
11 opment fee under subparagraph (B), ex-
12 cept where such product (including, where
13 applicable, ownership of the relevant inves-
14 tigational new drug application) is trans-
15 ferred to a licensee, assignee, or successor
16 of such person, and written notice of such
17 transfer is provided to the Secretary, in
18 which case such licensee, assignee, or suc-
19 cessor shall pay the annual biosimilar bio-
20 logical product development fee.”.

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

1 “(v) ADMINISTRATIVE REMOVAL FROM
2 THE BIOSIMILAR BIOLOGICAL PRODUCT
3 DEVELOPMENT PROGRAM.—If a person has
4 failed to pay an annual biosimilar biological
5 product development fee for a product
6 as required under subparagraph (B) for a
7 period of two consecutive fiscal years, the
8 Secretary may administratively remove
9 such person from the biosimilar biological
10 product development program for the prod-
11 uct. At least 30 days prior to administra-
12 tively removing a person from the bio-
13 similar biological product development pro-
14 gram for a product under this clause, the
15 Secretary shall provide written notice to
16 such person of the intended administrative
17 removal.”.

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

23 (7) BIOSIMILAR BIOLOGICAL PRODUCT PRO-
24 GRAM FEE.—Section 744H(a)(3) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
2 52(a)(3)) is amended—

3 (A) in subparagraph (A)—

4 (i) in clause (i), by striking “and” at
5 the end;

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

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

10 “(ii) may be dispensed only under pre-
11 scription pursuant to section 503(b); and”;
12 and

13 (B) by adding at the end the following:

14 “(E) MOVEMENT TO DISCONTINUED
15 LIST.—

16 “(i) DATE OF INCLUSION.—If a writ-
17 ten request to place a product on the list
18 referenced in subparagraph (A) of discon-
19 tinued biosimilar biological products is sub-
20 mitted to the Secretary on behalf of an ap-
21 plicant, and the request identifies the date
22 the product is withdrawn from sale, then
23 for purposes of assessing the biosimilar bi-
24 ological product program fee, the Secretary

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

3 “(I) the date such request was
4 received; or

5 “(II) if the product will be with-
6 drawn from sale on a future date,
7 such future date when the product is
8 withdrawn from sale.

9 “(ii) TREATMENT AS WITHDRAWN
10 FROM SALE.—For purposes of clause (i), a
11 product shall be considered withdrawn
12 from sale once the applicant has ceased its
13 own distribution of the product, whether or
14 not the applicant has ordered recall of all
15 previously distributed lots of the product,
16 except that a routine, temporary interrup-
17 tion in supply shall not render a product
18 withdrawn from sale.

19 “(iii) SPECIAL RULE.—If a biosimilar
20 biological product that is identified in a
21 biosimilar biological product application
22 approved as of October 1 of a fiscal year
23 appears, as of October 1 of such fiscal
24 year, on the list referenced in subpara-
25 graph (A) of discontinued biosimilar bio-

1 logical products, and on any subsequent
2 day during such fiscal year the biosimilar
3 biological product does not appear on such
4 list, then except as provided in subpara-
5 graph (D), each person who is named as
6 the applicant in a biosimilar biological
7 product application with respect to such
8 product shall pay the annual biosimilar bi-
9 ological product program fee established
10 for a fiscal year under subsection (c)(5) for
11 such biosimilar biological product. Not-
12 withstanding subparagraph (B), such fee
13 shall be due on the last business day of
14 such fiscal year and shall be paid only once
15 for each such product for each fiscal
16 year.”.

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

21 (c) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
22 tion 744H of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 379j–52) is amended—

24 (1) by striking paragraph (1);

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

3 (3) by amending paragraph (1) (as so redesign-
4 nated) to read as follows:

5 “(1) IN GENERAL.—For each of the fiscal years
6 2023 through 2027, fees under subsection (a) shall,
7 except as provided in subsection (c), be established
8 to generate a total revenue amount equal to the sum
9 of—

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

12 “(B) the dollar amount equal to the infla-
13 tion adjustment for the fiscal year (as deter-
14 mined under subsection (c)(1));

15 “(C) the dollar amount equal to the stra-
16 tegic hiring and retention adjustment (as deter-
17 mined under subsection (c)(2));

18 “(D) the dollar amount equal to the capac-
19 ity planning adjustment for the fiscal year (as
20 determined under subsection (c)(3));

21 “(E) the dollar amount equal to the oper-
22 ating reserve adjustment for the fiscal year, if
23 applicable (as determined under subsection
24 (c)(4));

1 “(F) for fiscal year 2023 an additional
2 amount of \$4,428,886; and

3 “(G) for fiscal year 2024 an additional
4 amount of \$320,569.”;

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

6 (A) in the paragraph heading, by striking
7 “; LIMITATIONS ON FEE AMOUNTS”;

8 (B) by striking subparagraph (B); and

9 (C) by redesignating subparagraphs (C)
10 and (D) as subparagraphs (B) and (C), respec-
11 tively; and

12 (5) by amending paragraph (3) (as so redesign-
13 ated) to read as follows:

14 “(3) ANNUAL BASE REVENUE.—For purposes
15 of paragraph (1), the dollar amount of the annual
16 base revenue for a fiscal year shall be—

17 “(A) for fiscal year 2023, \$43,376,922;
18 and

19 “(B) for fiscal years 2024 through 2027,
20 the dollar amount of the total revenue amount
21 established under paragraph (1) for the pre-
22 vious fiscal year, excluding any adjustments to
23 such revenue amount under subsection (c)(4).”.

1 (d) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
2 744H(e) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 379j–52(e)) is amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)—

6 (i) in the matter preceding clause (i),
7 by striking “subsection (b)(2)(B)” and in-
8 serting “subsection (b)(1)(B)”; and

9 (ii) in clause (i), by striking “sub-
10 section (b)” and inserting “subsection
11 (b)(1)(A)”; and

12 (B) in subparagraph (B)(ii), by striking
13 “Washington-Baltimore, DC–MD–VA–WV”
14 and inserting “Washington-Arlington-Alexan-
15 dria, DC–VA–MD–WV”;

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

18 “(2) STRATEGIC HIRING AND RETENTION AD-
19 JUSTMENT.—For each fiscal year, after the annual
20 base revenue under subsection (b)(1)(A) is adjusted
21 for inflation in accordance with paragraph (1), the
22 Secretary shall further increase the fee revenue and
23 fees by \$150,000.

24 “(3) CAPACITY PLANNING ADJUSTMENT.—

1 “(A) IN GENERAL.—For each fiscal year,
2 the Secretary shall, in addition to the adjust-
3 ments under paragraphs (1) and (2), further
4 adjust the fee revenue and fees under this sec-
5 tion for a fiscal year to reflect changes in the
6 resource capacity needs of the Secretary for the
7 process for the review of biosimilar biological
8 product applications.

9 “(B) METHODOLOGY.—For purposes of
10 this paragraph, the Secretary shall employ the
11 capacity planning methodology utilized by the
12 Secretary in setting fees for fiscal year 2021, as
13 described in the notice titled ‘Biosimilar User
14 Fee Rates for Fiscal Year 2021’ published in
15 the Federal Register on August 4, 2020 (85
16 Fed. Reg. 47220). The workload categories
17 used in applying such methodology in fore-
18 casting shall include only the activities de-
19 scribed in that notice and, as feasible, addi-
20 tional activities that are also directly related to
21 the direct review of biosimilar biological product
22 applications and supplements, including addi-
23 tional formal meeting types, the direct review of
24 postmarketing commitments and requirements,
25 the direct review of risk evaluation and mitiga-

1 tion strategies, and the direct review of annual
2 reports for approved biosimilar biological prod-
3 ucts. Subject to the exceptions in the preceding
4 sentence, the Secretary shall not include as
5 workload categories in applying such method-
6 ology in forecasting any non-core review activi-
7 ties, including those activities that the Sec-
8 retary referenced for potential future use in
9 such notice but did not utilize in setting fees for
10 fiscal year 2021.

11 “(C) LIMITATIONS.—Under no cir-
12 cumstances shall an adjustment under this
13 paragraph result in fee revenue for a fiscal year
14 that is less than the sum of the amounts under
15 subsections (b)(1)(A) (the annual base revenue
16 for the fiscal year), (b)(1)(B) (the dollar
17 amount of the inflation adjustment for the fis-
18 cal year), and (b)(1)(C) (the dollar amount of
19 the strategic hiring and retention adjustment).

20 “(D) PUBLICATION IN FEDERAL REG-
21 ISTER.—The Secretary shall publish in the Fed-
22 eral Register notice under paragraph (5) the fee
23 revenue and fees resulting from the adjustment
24 and the methodologies under this paragraph.

25 “(4) OPERATING RESERVE ADJUSTMENT.—

1 “(A) INCREASE.—For fiscal year 2023 and
2 subsequent fiscal years, the Secretary shall, in
3 addition to adjustments under paragraphs (1),
4 (2), and (3), further increase the fee revenue
5 and fees if such an adjustment is necessary to
6 provide for at least 10 weeks of operating re-
7 serves of carryover user fees for the process for
8 the review of biosimilar biological product appli-
9 cations.

10 “(B) DECREASE.—

11 “(i) FISCAL YEAR 2023.—For fiscal
12 year 2023, if the Secretary has carryover
13 balances for such process in excess of 33
14 weeks of such operating reserves, the Sec-
15 retary shall decrease such fee revenue and
16 fees to provide for not more than 33 weeks
17 of such operating reserves.

18 “(ii) FISCAL YEAR 2024.—For fiscal
19 year 2024, if the Secretary has carryover
20 balances for such process in excess of 27
21 weeks of such operating reserves, the Sec-
22 retary shall decrease such fee revenue and
23 fees to provide for not more than 27 weeks
24 of such operating reserves.

1 “(iii) FISCAL YEAR 2025 AND SUBSE-
2 QUENT FISCAL YEARS.—For fiscal year
3 2025 and subsequent fiscal years, if the
4 Secretary has carryover balances for such
5 process in excess of 21 weeks of such oper-
6 ating reserves, the Secretary shall decrease
7 such fee revenue and fees to provide for
8 not more than 21 weeks of such operating
9 reserves.

10 “(C) FEDERAL REGISTER NOTICE.—If an
11 adjustment under subparagraph (A) or (B) is
12 made, the rationale for the amount of the in-
13 crease or decrease in fee revenue and fees shall
14 be contained in the annual Federal Register no-
15 tice under paragraph (5)(B) establishing fee
16 revenue and fees for the fiscal year involved.”;
17 and

18 (3) in paragraph (5), in the matter preceding
19 subparagraph (A), by striking “2018” and inserting
20 “2023”.

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

1 (f) WRITTEN REQUESTS FOR WAIVERS AND RE-
2 TURNS; DISPUTES CONCERNING FEES.—Section 744H(h)
3 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–52(h)) is amended to read as follows:

5 “(h) WRITTEN REQUESTS FOR WAIVERS AND RE-
6 TURNS; DISPUTES CONCERNING FEES.—To qualify for
7 consideration for a waiver under subsection (d), or for the
8 return of any fee paid under this section, including if the
9 fee is claimed to have been paid in error, a person shall
10 submit to the Secretary a written request justifying such
11 waiver or return and, except as otherwise specified in this
12 section, such written request shall be submitted to the Sec-
13 retary not later than 180 days after such fee is due. A
14 request submitted under this paragraph shall include any
15 legal authorities under which the request is made.”.

16 **SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

19 (1) in subsection (a)(1), by striking “Beginning
20 with fiscal year 2018, not” and inserting “Not”;

21 (2) by striking “Biosimilar User Fee Amend-
22 ments of 2017” each place it appears and inserting
23 “Biosimilar User Fee Amendments of 2022”;

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

1 (4) in subsection (a)(3)(A), by striking “Not
2 later than 30 calendar days after the end of the sec-
3 ond quarter of fiscal year 2018, and not later than
4 30 calendar days after the end of each quarter of
5 each fiscal year thereafter” and inserting “Not later
6 than 30 calendar days after the end of each quarter
7 of each fiscal year for which fees are collected under
8 this part”;

9 (5) in subsection (b), by striking “Not later
10 than 120 days after the end of fiscal year 2018 and
11 each subsequent fiscal year for which fees are col-
12 lected under this part” and inserting “Not later
13 than 120 days after the end of each fiscal year for
14 which fees are collected under this part”;

15 (6) in subsection (c), by striking “Beginning
16 with fiscal year 2018, and for” and inserting “For”;
17 and

18 (7) in subsection (f)—

19 (A) in paragraph (1), in the matter pre-
20 ceeding subparagraph (A), by striking “fiscal
21 year 2022” and inserting “fiscal year 2027”;
22 and

23 (B) in paragraph (3), by striking “January
24 15, 2022” and inserting “January 15, 2027”.

1 **SEC. 405. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 744G and 744H of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–51, 379j–52) shall cease to be effective October 1,
5 2027.

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

9 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
10 ber 1, 2022, subsections (a) and (b) of section 405 of the
11 FDA Reauthorization Act of 2017 (Public Law 115–52)
12 are repealed.

13 **SEC. 406. EFFECTIVE DATE.**

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

22 **SEC. 407. SAVINGS CLAUSE.**

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

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

8 **TITLE V—IMPROVING DIVERSITY**
9 **IN CLINICAL STUDIES**

10 **SEC. 501. DIVERSITY ACTION PLANS FOR CLINICAL STUD-**
11 **IES.**

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

15 “(5)(A) In order for a new drug that is being studied
16 in a phase 3 study, as defined in section 312.21(c) of title
17 21, Code of Federal Regulations (or successor regula-
18 tions), or other pivotal study, to be exempt pursuant to
19 this subsection, the sponsor of a clinical investigation of
20 such new drug shall submit to the Secretary a diversity
21 action plan.

22 “(B) Such diversity action plan shall include—

23 “(i) the sponsor’s goals for enrollment in such
24 clinical investigation;

25 “(ii) the sponsor’s rationale for such goals; and

1 “(iii) an explanation of how the sponsor intends
2 to meet such goals.

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

8 “(D) The Secretary may waive the requirement in
9 subparagraph (A)—

10 “(i) if the Secretary determines that a waiver is
11 necessary based on what is known about the preva-
12 lence of the disease in terms of the patient popu-
13 lation that may use the new drug; or

14 “(ii) where the investigational drug is being
15 made available under section 561.”.

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

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

25 “(B) Such diversity action plan shall include—

1 “(i) the sponsor’s goals for enrollment in such
2 clinical investigation;

3 “(ii) the sponsor’s rationale for such goals; and

4 “(iii) an explanation of how the sponsor intends
5 to meet such goals.

6 “(C) Such diversity action plan shall be—

7 “(i) an application in the form and manner
8 specified in the guidance required by section 524B;
9 and

10 “(ii) if submission of an application for an in-
11 vestigational device exemption is not required, sub-
12 mitted in the form, manner, and timeframe specified
13 in the guidance required by section 524B as soon as
14 practicable during device development, but no later
15 than one month prior to commencing enrollment for
16 a study.

17 “(D) The Secretary may waive the requirement in
18 subparagraph (A)—

19 “(i) if the Secretary determines that a waiver is
20 necessary based on what is known about the preva-
21 lence of the disease in terms of the patient popu-
22 lation that may use the device; or

23 “(ii) where the investigational device is being
24 made available under section 561.”.

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

4 **“SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR**
5 **CLINICAL STUDIES.**

6 “(a) IN GENERAL.—The Secretary shall issue guid-
7 ance relating to—

8 “(1) the format and content of the diversity ac-
9 tion plans required by sections 505(i)(5) and
10 520(g)(9) of this Act, and section 351(a)(3) of the
11 Public Health Service Act, pertaining to the spon-
12 sor’s goals for clinical study enrollment,
13 disaggregated by age group, sex, race, geographic lo-
14 cation, socioeconomic status, and ethnicity, including
15 with respect to—

16 “(A) the rationale for the sponsor’s enroll-
17 ment goals, which may include—

18 “(i) the estimated prevalence or inci-
19 dence in the United States of the disease
20 or condition for which the drug or device
21 is being developed or investigated, if such
22 estimated prevalence or incidence is known
23 or can be determined based on available
24 data;

1 “(ii) what is known about the disease
2 or condition for which the drug or device
3 is being developed or investigated;

4 “(iii) any relevant pharmacokinetic or
5 pharmacogenomic data;

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

9 “(I) demographic information, in-
10 cluding age group, sex, race, geo-
11 graphic location, socioeconomic status,
12 and ethnicity;

13 “(II) non-demographic factors,
14 including co-morbidities frequently af-
15 fecting the patient population; and

16 “(III) potential barriers to enroll-
17 ing diverse participants, such as pa-
18 tient population size, geographic loca-
19 tion, and socioeconomic status; and

20 “(v) any other data or information
21 relevant to selecting appropriate enroll-
22 ment goals, disaggregated by demographic
23 subgroup, such as the inclusion of preg-
24 nant and lactating women;

1 “(B) an explanation for how the sponsor
2 intends to meet such goals, including demo-
3 graphic-specific outreach and enrollment strate-
4 gies, study-site selection, clinical study inclusion
5 and exclusion practices, and any diversity train-
6 ing for study personnel; and

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

11 “(2) how sponsors should include in regular re-
12 ports to the Secretary—

13 “(A) the sponsor’s progress in meeting the
14 goals referred to in paragraph (1)(A); and

15 “(B) if the sponsor does not expect to meet
16 such goals—

17 “(i) any updates needed to be made to
18 a diversity action plan referred to in para-
19 graph (1) to help meet such goals; and

20 “(ii) the sponsor’s reasons for why the
21 sponsor does not expect to meet such
22 goals.

23 “(b) ISSUANCE.—The Secretary shall—

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

1 or update existing draft guidance described in sub-
2 section (a); and

3 “(2) not later than 9 months after closing the
4 comment period on such draft guidance, finalize
5 such guidance.”.

6 (d) APPLICABILITY.—Sections 505(i)(5) and
7 520(g)(9) of the Federal Food, Drug, and Cosmetic Act,
8 and section 351(a)(3)(B) of the Public Health Service Act,
9 as added by subsections (a), (b), and (c) of this section,
10 apply only with respect to clinical investigations with re-
11 spect to which enrollment commences after the date that
12 is 180 days after the publication of final guidance under
13 section 524B(b)(2) of the Federal Food, Drug, and Cos-
14 metic Act, as added by subsection (d).

15 **SEC. 502. EVALUATION OF THE NEED FOR FDA AUTHORITY**
16 **TO MANDATE POSTAPPROVAL STUDIES OR**
17 **POSTMARKET SURVEILLANCE DUE TO INSUF-**
18 **FICIENT DEMOGRAPHIC SUBGROUP DATA.**

19 (a) IN GENERAL.—Not later than 2 years after the
20 date of publication of final guidance pursuant to section
21 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act,
22 as added by section 501(d) of this Act, the Secretary of
23 Health and Human Services shall commence an evaluation
24 to assess whether additions or changes to statutes or regu-

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

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

7 (2) the Secretary has requested additional stud-
8 ies be conducted.

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

15 **SEC. 503. PUBLIC WORKSHOPS TO ENHANCE CLINICAL**
16 **STUDY DIVERSITY.**

17 (a) IN GENERAL.—Not later than one year after the
18 date of enactment of this Act, the Secretary of Health and
19 Human Services, in consultation with drug sponsors, med-
20 ical device manufacturers, patients, and other stake-
21 holders, shall convene one or more public workshops to
22 solicit input from stakeholders on increasing the enroll-
23 ment of historically underrepresented populations in clin-
24 ical studies and encouraging clinical study participation
25 that reflects the prevalence of the disease or condition

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

3 (1) how and when to collect and present the
4 prevalence or incidence data on a disease or condi-
5 tion by demographic subgroup, including possible
6 sources for such data and methodologies for assess-
7 ing such data;

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

11 (3) the establishment of goals for enrollment in
12 clinical trials, including the relevance of the esti-
13 mated prevalence or incidence, as applicable, in the
14 United States of the disease or condition for which
15 the drug or device is being developed; and

16 (4) approaches to support inclusion of under-
17 represented populations and to encourage clinical
18 study participation that reflects the population ex-
19 pected to use the drug or device under study, includ-
20 ing with respect to—

21 (A) the establishment of inclusion and ex-
22 clusion criteria for certain demographic sub-
23 groups, such as pregnant and lactating women
24 and individuals with disabilities, including intel-

1 lectual or developmental disabilities or mental
2 illness;

3 (B) considerations regarding informed con-
4 sent with respect to individuals with intellectual
5 or developmental disabilities or mental illness,
6 including ethical and scientific considerations;

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

9 (D) clinical endpoints;

10 (E) biomarker selection; and

11 (F) studying analysis.

12 (b) PUBLIC DOCKET.—The Secretary of Health and
13 Human Services shall establish a public comment period
14 to receive written comments related to the topics ad-
15 dressed during each public workshop convened under this
16 section. The public comment period shall remain open for
17 60 days following the date on which each public workshop
18 is convened.

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

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

3 **SEC. 504. ANNUAL SUMMARY REPORT ON PROGRESS TO IN-**
4 **CREASE DIVERSITY IN CLINICAL STUDIES.**

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

11 (1) summarizes, in aggregate, the diversity ac-
12 tion plans received pursuant to section 505(i)(5) or
13 520(g)(9) of the Federal Food, Drug, and Cosmetic
14 Act, or section 351(a)(3)(B) of the Public Health
15 Service Act, as added by subsection (a), (b), or (c)
16 of section 501 of this Act; and

17 (2) contains information on—

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

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

3 (B) the reasons provided for why enroll-
4 ment goals from submitted diversity action
5 plans were not met; and

6 (C) any postmarket studies of a drug or
7 device in a demographic subgroup or subgroups
8 required or recommended by the Secretary
9 based on inadequate premarket clinical study
10 diversity or based on other reasons where a pre-
11 market study lacked adequate diversity, includ-
12 ing the status and completion date of any such
13 study.

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

20 **SEC. 505. PUBLIC MEETING ON CLINICAL STUDY FLEXIBILI-**
21 **TIES INITIATED IN RESPONSE TO COVID-19**
22 **PANDEMIC.**

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

1 public meeting to discuss the recommendations provided
2 by the Food and Drug Administration during the COVID–
3 19 emergency period to mitigate disruption of clinical
4 studies, including recommendations detailed in the guid-
5 ance entitled “Conduct of Clinical Trials of Medical Prod-
6 ucts During the COVID–19 Public Health Emergency,
7 Guidance for Industry, Investigators, and Institutional
8 Review Boards”, as updated on August 8, 2021, and by
9 any subsequent updates to such guidance. The Secretary
10 of Health and Human Services shall invite to such meet-
11 ing representatives from the pharmaceutical and medical
12 device industries who sponsored clinical studies during the
13 COVID–19 emergency period and organizations rep-
14 resenting patients.

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

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

1 (2) the characteristics of the sponsors, studies,
2 and patient populations impacted by such rec-
3 ommendations;

4 (3) a consideration of how recommendations in-
5 tended to mitigate disruption of clinical studies dur-
6 ing the COVID–19 emergency period, including any
7 recommendations to consider decentralized clinical
8 studies when appropriate, may have affected access
9 to clinical studies for certain patient populations, es-
10 pecially unrepresented racial and ethnic minorities;
11 and

12 (4) recommendations for incorporating certain
13 clinical study disruption mitigation recommendations
14 into current or additional guidance to improve clin-
15 ical study access and enrollment of diverse patient
16 populations.

17 (c) COVID–19 EMERGENCY PERIOD DEFINED.—In
18 this section, the term “COVID–19 emergency period” has
19 the meaning given the term “emergency period” in section
20 1135(g)(1)(B) of the Social Security Act (42 U.S.C.
21 1320b–5(g)(1)(B)).

22 **SEC. 506. DECENTRALIZED CLINICAL STUDIES.**

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

1 (1) not later than 12 months after the date of
2 enactment of this Act, issue draft guidance that ad-
3 dresses considerations for decentralized clinical stud-
4 ies, including considerations regarding the engage-
5 ment, enrollment, and retention of a meaningfully
6 diverse clinical population, with respect to race, eth-
7 nicity, age, sex, and geographic location, when ap-
8 propriate; and

9 (2) not later than 1 year after closing the com-
10 ment period on such draft guidance, finalize such
11 guidance.

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

14 (1) Recommendations for how digital health
15 technology or other remote assessment options, such
16 as telehealth, could support decentralized clinical
17 studies, including guidance on considerations for se-
18 lecting technological platforms and mediums, data
19 collection and use, data integrity and security, and
20 communication to study participants through digital
21 technology.

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

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

3 (3) Recommendations with respect to the eval-
4 uation of data collected within a decentralized clin-
5 ical study setting.

6 (c) DEFINITION.—In this section, the term “decen-
7 tralized clinical study” means a clinical study in which
8 some or all of the study-related activities occur at a loca-
9 tion separate from the investigator’s location.

10 **TITLE VI—GENERIC DRUG** 11 **COMPETITION**

12 **SEC. 601. INCREASING TRANSPARENCY IN GENERIC DRUG** 13 **APPLICATIONS.**

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

17 “(H)(i) Upon request (in controlled correspondence
18 or otherwise) by a person that has submitted or intends
19 to submit an abbreviated application for a new drug under
20 this subsection or on the Secretary’s own initiative during
21 the review of such abbreviated application, the Secretary
22 shall inform the person whether such new drug is quali-
23 tatively and quantitatively the same as the listed drug.

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

1 drug, the Secretary shall identify and disclose to the per-
2 son—

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

6 “(II) for any ingredient for which there is an
7 identified quantitative deviation, the amount of such
8 deviation.

9 “(iii) If the Secretary determines that such new drug
10 is qualitatively and quantitatively the same as the listed
11 drug, the Secretary shall not change or rescind such deter-
12 mination after the submission of an abbreviated applica-
13 tion for such new drug under this subsection unless—

14 “(I) the formulation of the listed drug has been
15 changed and the Secretary has determined that the
16 prior listed drug formulation was withdrawn for rea-
17 sons of safety or effectiveness; or

18 “(II) the Secretary makes a written determina-
19 tion that the prior determination must be changed
20 because an error has been identified.

21 “(iv) If the Secretary makes a written determination
22 described in clause (iii)(II), the Secretary shall provide no-
23 tice and a copy of the written determination to the person
24 making the request under clause (i).

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

4 (b) GUIDANCE.—

5 (1) IN GENERAL.—Not later than 1 year after
6 the date of enactment of this Act, the Secretary of
7 Health and Human Services shall issue draft guid-
8 ance, or update guidance, describing how the Sec-
9 retary will determine whether a new drug is quali-
10 tatively and quantitatively the same as the listed
11 drug (as such terms are used in section
12 505(j)(3)(H) of the Federal Food, Drug, and Cos-
13 metic Act, as added by subsection (a)), including
14 with respect to assessing pH adjusters.

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

18 (A) publish draft guidance;

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

21 (C) after considering any comments re-
22 ceived, and not later than one year after the
23 close of the comment period on the draft guid-
24 ance, publish final guidance.

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

6 **SEC. 602. ENHANCING ACCESS TO AFFORDABLE MEDI-**
7 **CINES.**

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

12 “(i) a revision to the labeling of the listed drug
13 has been approved by the Secretary within 90 days
14 of when the application is otherwise eligible for ap-
15 proval under this subsection;

16 “(ii) the sponsor of the application agrees to
17 submit revised labeling for the drug that is the sub-
18 ject of the application not later than 60 days after
19 approval under this subsection of the application;

20 “(iii) the labeling revision described under
21 clause (i) does not include a change to the ‘Warn-
22 ings’ section of the labeling; and”.

1 **TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN**
2 **IMPROVEMENTS**
3

4 **Subtitle A—In General**

5 **SEC. 701. ANIMAL TESTING ALTERNATIVES.**

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

8 (1) in subsection (b)(5)(B)(i)(II), by striking
9 “animal” and inserting “nonclinical tests”;

10 (2) in subsection (i)—

11 (A) in paragraph (1)(A), by striking “pre-
12 clinical tests (including tests on animals)” and
13 inserting “nonclinical tests”; and

14 (B) in paragraph (2)(B), by striking “ani-
15 mal” and inserting “nonclinical tests”; and

16 (3) after subsection (y), by inserting the fol-
17 lowing:

18 “(z) **NONCLINICAL TEST DEFINED.**—For purposes
19 of this section, the term ‘nonclinical test’ means a test con-
20 ducted in vitro, in silico, or in chemico, or a nonhuman
21 in vivo test, that occurs before or during the clinical trial
22 phase of the investigation of the safety and effectiveness
23 of a drug. Such test may include the following:

24 “(1) Cell-based assays.

1 “(2) Organ chips and microphysiological sys-
2 tems.

3 “(3) Computer modeling.

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

6 “(5) Animal tests.”.

7 **SEC. 702. EMERGING TECHNOLOGY PROGRAM.**

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

12 **“SEC. 566A. EMERGING TECHNOLOGY PROGRAM.**

13 “(a) PROGRAM ESTABLISHMENT.—

14 “(1) IN GENERAL.—The Secretary shall estab-
15 lish a program to support the adoption of, and im-
16 prove the development of, innovative approaches to
17 drug product design and manufacturing.

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

20 “(A) facilitate and increase communication
21 between public and private entities, consortia,
22 and individuals with respect to innovative drug
23 product design and manufacturing;

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

1 proaches to drug product design and manufac-
2 turing;

3 “(C) convene meetings with representatives
4 of industry, academia, other Federal agencies,
5 international agencies, and other interested per-
6 sons, as appropriate;

7 “(D) convene working groups to support
8 drug product design and manufacturing re-
9 search and development;

10 “(E) support education and training for
11 regulatory staff and scientists related to innova-
12 tive approaches to drug product design and
13 manufacturing;

14 “(F) advance regulatory science related to
15 the development and review of innovative ap-
16 proaches to drug product design and manufac-
17 turing;

18 “(G) convene or participate in working
19 groups to support the harmonization of inter-
20 national regulatory requirements related to in-
21 novative approaches to drug product design and
22 manufacturing; and

23 “(H) award grants or contracts to carry
24 out or support the program under paragraph
25 (1).

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

4 “(A) in such form and manner as the Sec-
5 retary may require; and

6 “(B) containing such information as the
7 Secretary may require, including a description
8 of—

9 “(i) how the entity will conduct the
10 activities to be supported through the
11 grant or contract; and

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

16 “(b) GUIDANCE.—The Secretary shall—

17 “(1) issue or update guidance to help facilitate
18 the adoption of, and advance the development of, in-
19 novative approaches to drug product design and
20 manufacturing; and

21 “(2) include in such guidance descriptions of—

22 “(A) any regulatory requirements related
23 to the development or review of technologies re-
24 lated to innovative approaches to drug product
25 design and manufacturing, including updates

1 and improvements to such technologies after
2 product approval; and

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

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

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

14 “(2) a description of how Food and Drug Ad-
15 ministration staff were utilized to carry out this sec-
16 tion and, as applicable, any challenges or limitations
17 related to staffing;

18 “(3) the number of meetings held or partici-
19 pated in by the Food and Drug Administration, in-
20 cluding meetings convened as part of a working
21 group described in subparagraph (D) or (G) of sub-
22 section (a)(2), and the topics of each such meeting;
23 and

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

1 using an innovative approach to drug product design
2 and manufacturing.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
4 carry out this section, there is authorized to be appro-
5 priated \$20,000,000 for each fiscal year 2023 through
6 2027.”.

7 **SEC. 703. IMPROVING THE TREATMENT OF RARE DISEASES**
8 **AND CONDITIONS.**

9 (a) REPORT ON ORPHAN DRUG PROGRAM.—

10 (1) IN GENERAL.—Not later than September
11 30, 2026, the Secretary shall submit to the Com-
12 mittee on Energy and Commerce of the House of
13 Representatives and the Committee on Health, Edu-
14 cation, Labor, and Pensions of the Senate a report
15 summarizing the activities of the Food and Drug
16 Administration related to designating drugs under
17 section 526 of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 360bb) for a rare disease or
19 condition and approving such drugs under section
20 505 of such Act (21 U.S.C. 355) or licensing such
21 drugs under section 351 of the Public Health Serv-
22 ice Act (42 U.S.C. 262), including—

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

1 section 351 of the Public Health Service Act
2 (42 U.S.C. 262) received by the Food and Drug
3 Administration, the number of such applica-
4 tions accepted and rejected for filing, and the
5 number of such applications pending, approved,
6 and disapproved by the Food and Drug Admin-
7 istration;

8 (B) a description of trends in drug approv-
9 als for rare diseases and conditions across re-
10 view divisions at the Food and Drug Adminis-
11 tration;

12 (C) the extent to which the Food and Drug
13 Administration is consulting with external ex-
14 perts pursuant to section 569(a)(2) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
16 360bbb–8(a)(2)) on topics pertaining to drugs
17 for a rare disease or condition, including how
18 and when any such consultation is occurring;
19 and

20 (D) the Food and Drug Administration’s
21 efforts to promote best practices in the develop-
22 ment of novel treatments for rare diseases, in-
23 cluding—

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

1 (ii) new regulatory science and coordi-
2 nated support for patient and stakeholder
3 engagement.

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

8 (3) INFORMATION DISCLOSURE.—Nothing in
9 this subsection shall be construed to authorize the
10 disclosure of information that is prohibited from dis-
11 closure under section 1905 of title 18, United States
12 Code, or subject to withholding under paragraph (4)
13 of section 552(b), United States Code (commonly re-
14 ferred to as the “Freedom of Information Act”).

15 (b) STUDY ON EUROPEAN UNION SAFETY AND EFFI-
16 CACY REVIEWS OF DRUGS FOR RARE DISEASES AND CON-
17 DITIONS.—

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

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

1 the European Union specific to rare diseases or
2 conditions;

3 (B) the consideration and use of supple-
4 mental data submitted during review processes
5 in the United States and the European Union,
6 including data associated with open label exten-
7 sion studies and expanded access programs spe-
8 cific to rare diseases or conditions;

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

12 (i) product development programs
13 under review;

14 (ii) policies under development re-
15 cently issued; and

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

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

21 (2) CONSULTATION.—The contract under para-
22 graph (1) shall provide for consultation with relevant
23 stakeholders, including—

1 (A) representatives from the Food and
2 Drug Administration and the European Medi-
3 cines Agency;

4 (B) rare disease or condition patients; and

5 (C) patient groups that—

6 (i) represent rare disease or condition
7 patients; and

8 (ii) have international patient out-
9 reach.

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

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

15 (B) the submission of a report on the re-
16 sults of such study to the Committee on Energy
17 and Commerce of the House of Representatives
18 and the Committee on Health, Education,
19 Labor, and Pensions of the Senate.

20 (4) PUBLIC AVAILABILITY.—The contract under
21 paragraph (1) shall provide for the appropriate enti-
22 ty referred to in paragraph (1) to make the report
23 under paragraph (3) available to the public, includ-
24 ing by posting the report on the website of the ap-
25 propriate entity.

1 (c) PUBLIC MEETING.—

2 (1) IN GENERAL.—Not later than December 31,
3 2023, the Secretary of Health and Human Services,
4 acting through the Commissioner of Food and
5 Drugs, shall convene one or more public meetings to
6 solicit input from stakeholders regarding the ap-
7 proaches described in paragraph (2).

8 (2) APPROACHES.—The public meeting or
9 meetings under paragraph (1) shall address ap-
10 proaches to increasing and improving engagement
11 with rare disease or condition patients, groups rep-
12 resenting such patients, rare disease or condition ex-
13 perts, and experts on small population studies, in
14 order to improve the understanding with respect to
15 rare diseases or conditions of—

16 (A) patient burden;

17 (B) treatment options; and

18 (C) side effects of treatments, including—

19 (i) comparing the side effects of treat-
20 ments; and

21 (ii) understanding the risks of side ef-
22 fects relative to the health status of the pa-
23 tient and the progression of the disease or
24 condition.

1 (3) PUBLIC DOCKET.—The Secretary of Health
2 and Human Services shall establish a public docket
3 to receive written comments related to the ap-
4 proaches addressed during each public meeting
5 under paragraph (1). Such public docket shall re-
6 main open for 60 days following the date of each
7 such public meeting.

8 (4) REPORTS.—Not later than 180 days after
9 each public meeting under paragraph (1), the Com-
10 missioner of Food and Drugs shall develop and pub-
11 lish on the website of the Food and Drug Adminis-
12 tration a report on—

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

15 (B) any related recommendations.

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

20 “(C) SMALL POPULATION STUDIES.—The
21 external experts on the list maintained pursuant
22 to subparagraph (A) may include experts on the
23 science of small population studies.”.

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

1 CLINICIAN PERSPECTIVE IN FDA PROCESSES RELATED
2 TO APPLICATIONS CONCERNING DRUGS FOR RARE DIS-
3 EASES OR CONDITIONS.—

4 (1) IN GENERAL.—The Comptroller General of
5 the United States shall conduct a study on the use
6 of Food and Drug Administration mechanisms and
7 tools to ensure that patient and physician perspec-
8 tives are considered and incorporated throughout the
9 processes of the Food and Drug Administration—

10 (A) for approving or licensing under sec-
11 tion 505 of the Federal Food, Drug, or Cos-
12 metic Act (21 U.S.C. 355) or section 351 of the
13 Public Health Service Act (42 U.S.C. 262) a
14 drug designated as a drug for a rare disease or
15 condition under section 526 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C.
17 360bb); and

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

- 21 (i) safety or effectiveness; or
22 (ii) postapproval safety monitoring.

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

1 (A) identify and compare the processes
2 that the Food and Drug Administration has
3 formally put in place and utilized to gather ex-
4 ternal expertise (including patients, patient
5 groups, and physicians) on specific applications
6 for rare diseases or conditions;

7 (B) examine tools or mechanisms to im-
8 prove efforts and initiatives of the Food and
9 Drug Administration to collect and consider
10 such external expertise with respect to applica-
11 tions for rare diseases or conditions throughout
12 the application review and approval or licensure
13 processes, including within internal benefit-risk
14 assessments, advisory committee processes, and
15 postapproval safety monitoring; and

16 (C) examine processes or alternatives to
17 address or resolve conflicts of interest that im-
18 pede the Food and Drug Administration in
19 gaining external expert input on rare diseases
20 or conditions with a limited set of clinical and
21 research experts.

22 (3) REPORT.—Not later than 2 years after the
23 date of enactment of this Act, the Comptroller Gen-
24 eral of the United States shall—

1 (A) complete the study under paragraph
2 (1);

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

5 (C) include in such report recommenda-
6 tions, if appropriate, for changes to the proc-
7 esses and authorities of the Food and Drug Ad-
8 ministration to improve the collection and con-
9 sideration of external expert opinions of pa-
10 tients, patient groups, and physicians with ex-
11 pertise in rare diseases or conditions.

12 (f) DEFINITION.—In this section, the term “rare dis-
13 ease or condition” has the meaning given such term in
14 section 526(a)(2) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 360bb(a)(2)).

16 **SEC. 704. ANTIFUNGAL RESEARCH AND DEVELOPMENT.**

17 (a) DRAFT GUIDANCE.—Not later than 3 years after
18 the date of the enactment of this Act, the Secretary of
19 Health and Human Services, acting through the Commis-
20 sioner of Food and Drugs, shall issue draft guidance for
21 industry for the purposes of assisting entities seeking ap-
22 proval under section 505 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355) or licensure under section
24 351 of the Public Health Service Act (42 U.S.C. 262) of

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

3 (b) FINAL GUIDANCE.—Not later than 18 months
4 after the close of the public comment period on the draft
5 guidance issued pursuant to subsection (a), the Secretary
6 of Health and Human Services, acting through the Com-
7 missioner of Food and Drugs, shall finalize the draft guid-
8 ance.

9 (c) WORKSHOP.—To assist entities developing pre-
10 ventive vaccines for fungal infections and coccidioidomy-
11 cosis, the Secretary of Health and Human Services shall
12 hold a public workshop.

13 **SEC. 705. ADVANCING QUALIFIED INFECTIOUS DISEASE**
14 **PRODUCT INNOVATION.**

15 (a) IN GENERAL.—Section 505E of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amend-
17 ed—

18 (1) in subsection (c)—

19 (A) in paragraph (2), by striking “or” at
20 the end;

21 (B) in paragraph (3), by striking the pe-
22 riod at the end and inserting “; or”; and

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

24 “(4) an application pursuant to section 351(a)
25 of the Public Health Service Act.”;

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

4 (3) by amending subsection (g) to read as fol-
5 lows:

6 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
7 The term ‘qualified infectious disease product’ means a
8 drug, including an antibacterial or antifungal drug or a
9 biological product, for human use that—

10 “(1) acts directly on bacteria or fungi or on
11 substances produced by such bacteria or fungi; and

12 “(2) is intended to treat a serious or life-threat-
13 ening infection, including such an infection caused
14 by—

15 “(A) an antibacterial or antifungal resist-
16 ant pathogen, including novel or emerging in-
17 fectious pathogens; or

18 “(B) qualifying pathogens listed by the
19 Secretary under subsection (f).”.

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

1 **SEC. 706. ADVANCED MANUFACTURING TECHNOLOGIES**
2 **DESIGNATION PILOT PROGRAM.**

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

7 **“SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES**
8 **DESIGNATION PILOT PROGRAM.**

9 “(a) IN GENERAL.—Not later than 1 year after the
10 date of enactment of this section, the Secretary shall ini-
11 tiate a pilot program under which persons may request
12 designation of an advanced manufacturing technology as
13 described in subsection (b).

14 “(b) DESIGNATION PROCESS.—The Secretary shall
15 establish a process for the designation under this section
16 of methods of manufacturing drugs, including biological
17 products, and active pharmaceutical ingredients of such
18 drugs, as advanced manufacturing technologies. A method
19 of manufacturing, or a combination of manufacturing
20 methods, is eligible for designation as an advanced manu-
21 facturing technology if such method or combination of
22 methods incorporates a novel technology, or uses an estab-
23 lished technique or technology in a novel way, that will
24 substantially improve the manufacturing process for a
25 drug and maintain equivalent or provide superior drug
26 quality, including by—

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

3 “(2) increasing or maintaining the supply of—

4 “(A) a drug that is described in section
5 506C(a) and is intended to treat a serious or
6 life-threatening condition; or

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

9 “(c) EVALUATION AND DESIGNATION OF AN AD-
10 VANCED MANUFACTURING TECHNOLOGY.—

11 “(1) SUBMISSION.—A person who requests des-
12 ignation of a method of manufacturing as an ad-
13 vanced manufacturing technology under this section
14 shall submit to the Secretary data or information
15 demonstrating that the method of manufacturing
16 meets the criteria described in subsection (b) in a
17 particular context of use. The Secretary may facili-
18 tate the development and review of such data or in-
19 formation by—

20 “(A) providing timely advice to, and inter-
21 active communication with, such person regard-
22 ing the development of the method of manufac-
23 turing; and

24 “(B) involving senior managers and experi-
25 enced staff of the Food and Drug Administra-

1 tion, as appropriate, in a collaborative, cross-
2 disciplinary review of the method of manufac-
3 turing, as applicable.

4 “(2) EVALUATION AND DESIGNATION.—Not
5 later than 180 calendar days after the receipt of a
6 request under paragraph (1), the Secretary shall de-
7 termine whether to designate such method of manu-
8 facturing as an advanced manufacturing technology,
9 in a particular context of use, based on the data and
10 information submitted under paragraph (1) and the
11 criteria described in subsection (b).

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

16 “(1) expedite the development and review of an
17 application submitted under section 505 of this Act
18 or section 351 of the Public Health Service Act, in-
19 cluding supplemental applications, for drugs that are
20 manufactured using a designated advanced manufac-
21 turing technology and could help mitigate or prevent
22 a shortage or substantially improve manufacturing
23 processes for a drug and maintain equivalent or pro-
24 vide superior drug quality, as described in subsection
25 (b); and

1 “(2) allow the holder of an advanced technology
2 designation, or a person authorized by the advanced
3 manufacturing technology designation holder, to ref-
4 erence or rely upon, in an application submitted
5 under section 505 of this Act or section 351 of the
6 Public Health Service Act, including a supplemental
7 application, data and information about the des-
8 ignated advanced manufacturing technology for use
9 in manufacturing drugs in the same context of use
10 for which the designation was granted.

11 “(e) IMPLEMENTATION AND EVALUATION OF AD-
12 VANCED MANUFACTURING TECHNOLOGIES PILOT.—

13 “(1) PUBLIC MEETING.—The Secretary shall
14 publish in the Federal Register a notice of a public
15 meeting, to be held not later than 180 days after the
16 date of enactment of this section, to discuss, and ob-
17 tain input and recommendations from relevant
18 stakeholders regarding—

19 “(A) the goals and scope of the pilot pro-
20 gram, and a suitable framework, procedures,
21 and requirements for such program; and

22 “(B) ways in which the Food and Drug
23 Administration will support the use of advanced
24 manufacturing technologies and other innova-
25 tive manufacturing approaches for drugs.

1 “(2) PILOT PROGRAM GUIDANCE.—

2 “(A) IN GENERAL.—The Secretary shall—

3 “(i) not later than 180 days after the
4 public meeting under paragraph (1), issue
5 draft guidance regarding the goals and im-
6 plementation of the pilot program under
7 this section; and

8 “(ii) not later than 2 years after the
9 date of enactment of this section, issue
10 final guidance regarding the implementa-
11 tion of such program.

12 “(B) CONTENT.—The guidance described
13 in subparagraph (A) shall address—

14 “(i) the process by which a person
15 may request a designation under sub-
16 section (b);

17 “(ii) the data and information that a
18 person requesting such a designation is re-
19 quired to submit under subsection (c), and
20 how the Secretary intends to evaluate such
21 submissions;

22 “(iii) the process to expedite the de-
23 velopment and review of applications under
24 subsection (d); and

1 “(iv) the criteria described in sub-
2 section (b) for eligibility for such a des-
3 ignation.

4 “(3) REPORT.—Not later than 3 years after the
5 date of enactment of this section and annually there-
6 after, the Secretary shall publish on the website of
7 the Food and Drug Administration and submit to
8 the Committee on Health, Education, Labor, and
9 Pensions of the Senate and the Committee on En-
10 ergy and Commerce of the House of Representatives
11 a report containing a description and evaluation of
12 the pilot program being conducted under this sec-
13 tion, including the types of innovative manufacturing
14 approaches supported under the program. Such re-
15 port shall include the following:

16 “(A) The number of persons that have re-
17 quested designations and that have been grant-
18 ed designations.

19 “(B) The number of methods of manufac-
20 turing that have been the subject of designation
21 requests and that have been granted designa-
22 tions.

23 “(C) The average number of calendar days
24 for completion of evaluations under subsection
25 (c)(2).

1 “(D) An analysis of the factors in data
2 submissions that are relevant to determinations
3 to designate and not to designate after evalua-
4 tion under subsection (c)(2).

5 “(E) The number of applications received
6 under section 505 of this Act or section 351 of
7 the Public Health Service Act, including supple-
8 mental applications, that have included an ad-
9 vanced manufacturing technology designated
10 under this section, and the number of such ap-
11 plications approved.

12 “(f) SUNSET.—The Secretary—

13 “(1) may not consider any requests for designa-
14 tion submitted under subsection (c) after October 1,
15 2029; and

16 “(2) may continue all activities under this sec-
17 tion with respect to advanced manufacturing tech-
18 nologies that were designated pursuant to subsection
19 (d) prior to such date, if the Secretary determines
20 such activities are in the interest of the public
21 health.”.

22 **SEC. 707. PUBLIC WORKSHOP ON CELL THERAPIES.**

23 Not later than 3 years after the date of the enact-
24 ment of this Act, the Secretary of Health and Human
25 Services, acting through the Commissioner of Food and

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

11 **SEC. 708. REAUTHORIZATION OF BEST PHARMACEUTICALS**
12 **FOR CHILDREN.**

13 Section 409I(d)(1) of the Public Health Service Act
14 (42 U.S.C. 284m(d)(1)) is amended by striking “2018
15 through 2022” and inserting “2023 through 2027”.

16 **SEC. 709. REAUTHORIZATION FOR HUMANITARIAN DEVICE**
17 **EXEMPTION AND DEMONSTRATION GRANTS**
18 **FOR IMPROVING PEDIATRIC AVAILABILITY.**

19 (a) HUMANITARIAN DEVICE EXEMPTION.—Section
20 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by
22 striking “2022” and inserting “2027”.

23 (b) PEDIATRIC MEDICAL DEVICE SAFETY AND IM-
24 PROVEMENT ACT.—Section 305(e) of the Pediatric Med-
25 ical Device Safety and Improvement Act (Public Law

1 110–85) is amended by striking “2018 through 2022” and
2 inserting “2023 through 2027”.

3 **SEC. 710. REAUTHORIZATION OF PROVISION RELATED TO**
4 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
5 **TAINING SINGLE ENANTIOMERS.**

6 Section 505(u)(4) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by strik-
8 ing “2022” and inserting “2027”.

9 **SEC. 711. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
10 **LIC-PRIVATE PARTNERSHIP PROGRAM.**

11 Section 566(f) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
13 “\$6,000,000 for each of fiscal years 2018 through 2022”
14 and inserting “\$10,000,000 for each of fiscal years 2023
15 through 2027”.

16 **SEC. 712. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

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

19 (1) in subsection (a)—

20 (A) by striking “and (3)” and inserting
21 “(3)”; and

22 (B) by inserting before the period at the
23 end the following: “, and (4) developing regu-
24 latory science pertaining to the chemistry, man-
25 ufacturing, and controls of individualized med-

1 ical products to treat individuals with rare dis-
2 eases or conditions”; and

3 (2) in subsection (c), by striking “2018 through
4 2022” and inserting “2023 through 2027”.

5 **Subtitle B—Inspections**

6 **SEC. 721. FACTORY INSPECTION.**

7 (a) IN GENERAL.—Section 704(a)(1) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is
9 amended by striking “restricted devices” each place it ap-
10 pears and inserting “devices”.

11 (b) RECORDS OR OTHER INFORMATION.—

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

15 (A) by striking “an establishment that is
16 engaged in the manufacture, preparation, prop-
17 agation, compounding, or processing of a drug”
18 and inserting “an establishment that is engaged
19 in the manufacture, preparation, propagation,
20 compounding, or processing of a drug or device,
21 or that is subject to inspection under paragraph
22 (5)(C),”; and

23 (B) by inserting after “a sufficient descrip-
24 tion of the records requested” the following:
25 “and a rationale for requesting such records or

1 other information in advance of, or in lieu of,
2 an inspection”.

3 (2) GUIDANCE.—

4 (A) IN GENERAL.—The Secretary of
5 Health and Human Services shall issue or up-
6 date guidance describing—

7 (i) circumstances in which the Sec-
8 retary intends to issue requests for records
9 or other information in advance of, or in
10 lieu of, an inspection under section
11 704(a)(4) of the Federal Food, Drug, and
12 Cosmetic Act, as amended by paragraph
13 (1);

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

17 (iii) factors the Secretary intends to
18 consider in evaluating whether such
19 records and other information are provided
20 within a reasonable timeframe, within rea-
21 sonable limits, and in a reasonable man-
22 ner, accounting for resource and other lim-
23 itations that may exist, including for small
24 businesses.

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

3 (i) not later than 1 year after the date
4 of enactment of this Act, issue draft guid-
5 ance under subparagraph (A); and

6 (ii) not later than 1 year after the
7 close of the comment period for such draft
8 guidance, issue final guidance under sub-
9 paragraph (A).

10 (c) BIORESEARCH MONITORING INSPECTIONS.—

11 (1) IN GENERAL.—Section 704(a) of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C.
13 374(a)) is amended by adding at the end the fol-
14 lowing:

15 “(5) BIORESEARCH MONITORING INSPECTIONS.—

16 “(A) IN GENERAL.—The Secretary may, to en-
17 sure the accuracy and reliability of studies and
18 records or other information described in subpara-
19 graph (B) and to assess compliance with applicable
20 requirements under this Act or the Public Health
21 Service Act, enter sites and facilities specified in
22 subparagraph (C) in order to inspect such records or
23 other information.

24 “(B) INFORMATION SUBJECT TO INSPEC-
25 TION.—An inspection under this paragraph shall ex-

1 tend to all records and other information related to
2 the studies and submissions described in subpara-
3 graph (E), including records and information related
4 to the conduct, results, and analyses of, and the pro-
5 tection of human and animal trial participants par-
6 ticipating in, such studies.

7 “(C) SITES AND FACILITIES SUBJECT TO IN-
8 SPECTION.—

9 “(i) SITES AND FACILITIES DESCRIBED.—

10 The sites and facilities subject to inspection by
11 the Secretary under this paragraph are those
12 owned or operated by a person described in
13 clause (ii) and which are (or were) utilized by
14 such person in connection with—

15 “(I) developing an application or other
16 submission to the Secretary under this Act
17 or the Public Health Service Act related to
18 marketing authorization for a product de-
19 scribed in paragraph (1);

20 “(II) preparing, conducting, or ana-
21 lyzing the results of a study described in
22 subparagraph (E); or

23 “(III) holding any records or other in-
24 formation described in subparagraph (B).

1 “(ii) PERSONS DESCRIBED.—A person de-
2 scribed in this clause is—

3 “(I) the sponsor of an application or
4 submission specified in subparagraph (E);

5 “(II) a person engaged in any activity
6 described in clause (i) on behalf of such a
7 sponsor, through a contract, grant, or
8 other business arrangement with such
9 sponsor;

10 “(III) an institutional review board,
11 or other individual or entity, engaged by
12 contract, grant, or other business arrange-
13 ment with a nonsponsor in preparing, col-
14 lecting, or analyzing records or other infor-
15 mation described in subparagraph (B); or

16 “(IV) any person not otherwise de-
17 scribed in this clause that conducts, or has
18 conducted, a study described in subpara-
19 graph (E) yielding records or other infor-
20 mation described in subparagraph (B).

21 “(D) CONDITIONS OF INSPECTION.—

22 “(i) ACCESS TO INFORMATION SUBJECT TO
23 INSPECTION.—Subject to clause (ii), an entity
24 that owns or operates any site or facility sub-
25 ject to inspection under this paragraph shall

1 provide the Secretary with access to records
2 and other information described in subpara-
3 graph (B) that is held by or under the control
4 of such entity, including—

5 “(I) permitting the Secretary to
6 record or copy such information for pur-
7 poses of this paragraph;

8 “(II) providing the Secretary with ac-
9 cess to any electronic information system
10 utilized by such entity to hold, process,
11 analyze, or transfer any records or other
12 information described in subparagraph
13 (B); and

14 “(III) permitting the Secretary to in-
15 spect the facilities, equipment, written pro-
16 cedures, processes, and conditions through
17 which records or other information de-
18 scribed in subparagraph (B) is or was gen-
19 erated, held, processed, analyzed, or trans-
20 ferred.

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

1 or any other Act, preventing or limiting the dis-
2 closure of confidential commercial information
3 or other information considered proprietary or
4 trade secret.

5 “(iii) REASONABLENESS OF INSPEC-
6 TIONS.—An inspection under this paragraph
7 shall be conducted at reasonable times and
8 within reasonable limits and in a reasonable
9 manner.

10 “(E) STUDIES AND SUBMISSIONS DE-
11 SCRIBED.—The studies and submissions described in
12 this subparagraph are each of the following:

13 “(i) Clinical and nonclinical studies sub-
14 mitted to the Secretary in support of, or other-
15 wise related to, applications and other submis-
16 sions to the Secretary under this Act or the
17 Public Health Service Act for marketing au-
18 thorization of a product described in paragraph
19 (1).

20 “(ii) Postmarket safety activities conducted
21 under this Act or the Public Health Service
22 Act.

23 “(iii) Any other clinical investigation of—

1 “(I) a drug subject to section 505 or
2 512 of this Act or section 351 of the Pub-
3 lic Health Service Act; or

4 “(II) a device subject to section
5 520(g).

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

11 “(F) CLARIFICATION.—This paragraph clarifies
12 the authority of the Secretary to conduct inspections
13 of the type described in this paragraph and shall not
14 be construed as a basis for inferring that, prior to
15 the date of enactment of this paragraph, the Sec-
16 retary lacked the authority to conduct such inspec-
17 tions, including under this Act or the Public Health
18 Service Act.”.

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

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

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

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

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

8 (B) GUIDANCE.—

9 (i) IN GENERAL.—The Secretary of
10 Health and Human Services shall issue
11 guidance describing the processes and
12 practices applicable to inspections of sites
13 and facilities described in subparagraph
14 (C)(i) of section 704(a)(5) of the Federal
15 Food, Drug, and Cosmetic Act, as added
16 by paragraph (1), including with respect to
17 the types of records and information re-
18 quired to be provided, best practices for
19 communication between the Food and
20 Drug Administration and industry in ad-
21 vance of or during an inspection or request
22 for records or other information, and other
23 inspections-related conduct, to the extent
24 not specified in existing publicly available

1 Food and Drug Administration guides and
2 manuals for such inspections.

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

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

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

13 **SEC. 722. USES OF CERTAIN EVIDENCE.**

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

17 “(c) APPLICABILITY.—The limitations on the Sec-
18 retary’s use of evidence obtained under this section, or any
19 evidence which is directly or indirectly derived from such
20 evidence, in a criminal prosecution of the person from
21 whom such evidence was obtained shall not apply to evi-
22 dence, including records or other information, obtained
23 under authorities other than this section, unless such limi-
24 tations are specifically incorporated by reference in such
25 other authorities.”.

1 **SEC. 723. IMPROVING FDA INSPECTIONS.**

2 (a) RISK FACTORS FOR ESTABLISHMENTS.—Section
3 510(h)(4) of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 360(h)(4)) is amended—

5 (1) by redesignating subparagraph (F) as sub-
6 paragraph (G); and

7 (2) by inserting after subparagraph (E) the fol-
8 lowing:

9 “(F) The compliance history of establish-
10 ments in the country or region in which the es-
11 tablishment is located that are subject to regu-
12 lation under this Act, including the history of
13 violations related to products exported from
14 such country or region that are subject to such
15 regulation.”.

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

19 (1) by redesignating subparagraph (C) as sub-
20 paragraph (D); and

21 (2) by inserting after subparagraph (B) the fol-
22 lowing:

23 “(C) The Secretary may rely on any records or other
24 information that the Secretary may inspect under this sec-
25 tion to satisfy requirements that may pertain to a
26 preapproval or risk-based surveillance inspection, or to re-

1 solve deficiencies identified during such inspections, if ap-
2 plicable and appropriate.”.

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

6 (1) in subsection (a)(1), by inserting
7 “preapproval or” before “risk-based inspections”;
8 and

9 (2) by adding at the end the following:

10 “(c) PERIODIC REVIEW.—

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

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

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

3 **SEC. 724. GAO REPORT ON INSPECTIONS OF FOREIGN ES-**
4 **TABLISHMENTS MANUFACTURING DRUGS.**

5 (a) IN GENERAL.—Not later than 18 months after
6 the date of the enactment of this Act, the Comptroller
7 General of the United States shall submit to the Com-
8 mittee on Energy and Commerce of the House of Rep-
9 resentatives and the Committee on Health, Education,
10 Labor, and Pensions of the Senate a report on inspections
11 conducted by—

12 (1) the Secretary of Health and Human Serv-
13 ices (in this section referred to as the “Secretary”)
14 of foreign establishments pursuant to subsections (h)
15 and (i) of section 510 and 704 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360, 374); or

17 (2) a foreign government or an agency of a for-
18 eign government pursuant to section 809 of such
19 Act (21 U.S.C. 384e).

20 (b) CONTENTS.—The report conducted under sub-
21 section (a) shall include—

22 (1) what alternative tools, including remote in-
23 spections or remote evaluations, other countries are
24 utilizing to facilitate inspections of foreign establish-
25 ments;

1 (2) how frequently trusted foreign regulators
2 conduct inspections of foreign facilities that could be
3 useful to the Food and Drug Administration to re-
4 view in lieu of its own inspections;

5 (3) how frequently and under what cir-
6 cumstances, including for what types of inspections,
7 the Secretary utilizes existing agreements or ar-
8 rangements under section 809 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 384e) and
10 whether the use of such agreements could be appro-
11 priately expanded;

12 (4) whether the Secretary has accepted reports
13 of inspections of facilities in China and India con-
14 ducted by entities with which they have entered into
15 such an agreement or arrangement;

16 (5) what additional foreign governments or
17 agencies of foreign governments the Secretary has
18 considered entering into a mutual recognition agree-
19 ment with and, if applicable, reasons why the Sec-
20 retary declined to enter into a mutual recognition
21 agreement with such foreign governments or agen-
22 cies;

23 (6) what tools, if any, the Secretary used to fa-
24 cilitate inspections of domestic facilities that could

1 also be effectively utilized to appropriately inspect
2 foreign facilities;

3 (7) what steps the Secretary has taken to iden-
4 tify and evaluate tools and strategies the Secretary
5 may use to continue oversight with respect to inspec-
6 tions when in-person inspections are disrupted;

7 (8) how the Secretary is considering incor-
8 porating alternative tools into the inspection activi-
9 ties conducted pursuant to the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 321 et seq.); and

11 (9) what steps the Secretary has taken to iden-
12 tify and evaluate how the Secretary may use alter-
13 native tools to address workforce shortages to carry
14 out such inspection activities.

15 **SEC. 725. UNANNOUNCED FOREIGN FACILITY INSPECTIONS**

16 **PILOT PROGRAM.**

17 (a) IN GENERAL.—The Secretary of Health and
18 Human Services (referred to in this section as the “Sec-
19 retary”) shall conduct a pilot program under which the
20 Secretary increases the conduct of unannounced surveil-
21 lance inspections of foreign human drug establishments
22 and evaluates the differences between such inspections of
23 domestic and foreign human drug establishments, includ-
24 ing the impact of announcing inspections to persons who
25 own or operate foreign human drug establishments in ad-

1 vance of an inspection. Such pilot program shall evalu-
2 ate—

3 (1) differences in the number and type of viola-
4 tions of section 501(a)(2)(B) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))
6 resulting from unannounced and announced inspec-
7 tions of foreign human drug establishments and any
8 other significant differences between each type of in-
9 spection;

10 (2) costs and benefits associated with con-
11 ducting announced and unannounced inspections of
12 foreign human drug establishments;

13 (3) barriers to conducting unannounced inspec-
14 tions of foreign human drug establishments and any
15 challenges to achieving parity between domestic and
16 foreign human drug establishment inspections; and

17 (4) approaches for mitigating any negative ef-
18 fects of conducting announced inspections of foreign
19 human drug establishments.

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

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

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

6 (d) REPORT.—The Secretary shall, not later than
7 180 days following the completion of the pilot program
8 under this section, make available on the website of the
9 Food and Drug Administration a final report on the pilot
10 program under this section, including—

11 (1) findings and any associated recommenda-
12 tions with respect to the evaluation under subsection
13 (a), including any recommendations to address iden-
14 tified barriers to conducting unannounced inspec-
15 tions of foreign human drug establishments;

16 (2) findings and any associated recommenda-
17 tions regarding how the Secretary may achieve par-
18 ity between domestic and foreign human drug in-
19 spections; and

20 (3) the number of unannounced inspections
21 during the pilot program that would not be unan-
22 nounced under existing practices.

1 **SEC. 726. REAUTHORIZATION OF INSPECTION PROGRAM.**

2 Section 704(g)(11) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
4 ing “2022” and inserting “2027”.

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

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

11 “(g) COORDINATION.—The Secretary shall ensure
12 timely and effective internal coordination and alignment
13 among the field investigators of the Food and Drug Ad-
14 ministration and the staff of the Center for Drug Evalua-
15 tion and Research’s Office of Compliance and Drug Short-
16 age Program regarding—

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

19 “(2) any feedback or corrective or preventive
20 actions in response to such reports.”.

21 (b) REPORTING.—

22 (1) IN GENERAL.—Section 506C–1(a)(2) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 356c–1(a)(2)) is amended to read as follows:

25 “(2)(A) describes the communication between
26 the field investigators of the Food and Drug Admin-

1 istration and the staff of the Center for Drug Eval-
2 uation and Research’s Office of Compliance and
3 Drug Shortage Program, including the Food and
4 Drug Administration’s procedures for enabling and
5 ensuring such communication;

6 “(B) provides the number of reports described
7 in section 704(b)(2) that were required to be sent to
8 the appropriate offices of the Food and Drug Ad-
9 ministration and the number of such reports that
10 were sent; and

11 “(C) describes the coordination and alignment
12 activities undertaken pursuant to section 506D(g);”.

13 (2) APPLICABILITY.—The amendment made by
14 paragraph (1) shall apply with respect to reports
15 submitted on or after March 31, 2023.

16 **SEC. 728. REPORTING OF MUTUAL RECOGNITION AGREE-**
17 **MENTS FOR INSPECTIONS AND REVIEW AC-**
18 **TIVITIES.**

19 (a) IN GENERAL.—Not later than December 31,
20 2022, and annually thereafter, the Secretary of Health
21 and Human Services (referred to in this section as the
22 “Secretary”) shall publish a report on the public website
23 of the Food and Drug Administration on the utilization
24 of agreements entered into pursuant to section 809 of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e)

1 or otherwise entered into by the Secretary in the previous
2 fiscal year to recognize inspections between drug regu-
3 latory authorities across countries and international re-
4 gions with analogous review criteria to the Food and Drug
5 Administration, such as the Pharmaceutical Inspection
6 Co-Operation Scheme, the Mutual Recognition Agreement
7 with the European Union, and the Australia-Canada-
8 Singapore-Switzerland-United Kingdom Consortium.

9 (b) CONTENT.—The report under subsection (a) shall
10 include each of the following:

11 (1) The total number of establishments that are
12 registered under section 510(i) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the
14 number of such establishments in each region of in-
15 terest.

16 (2) The total number of inspections conducted
17 at establishments described in paragraph (1),
18 disaggregated by inspections conducted—

19 (A) pursuant to an agreement or other rec-
20 ognition described in subsection (a); and

21 (B) by employees or contractors of the
22 Food and Drug Administration.

23 (3) Of the inspections described in paragraph
24 (2), the total number of inspections in each region
25 of interest.

1 (4) Of the inspections in each region of interest
2 reported pursuant to paragraph (3), the number of
3 inspections in each FDA inspection category.

4 (5) Of the number of inspections reported
5 under each of paragraphs (3) and (4)—

6 (A) the number of inspections which have
7 been conducted pursuant to an agreement or
8 other recognition described in subsection (a);
9 and

10 (B) the number of inspections which have
11 been conducted by employees or contractors of
12 the Food and Drug Administration.

13 (c) DEFINITIONS.—In this subsection:

14 (1) FDA INSPECTION CATEGORY.—The term
15 “FDA inspection category” means the following in-
16 spection categories:

17 (A) Inspections to support approvals of
18 changes to the manufacturing process of drugs
19 approved under section 505 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 355)
21 or section 351 of the Public Health Service Act
22 (42 U.S.C. 262).

23 (B) Surveillance inspections.

24 (C) For-cause inspections.

1 (2) REGION OF INTEREST.—The term “region
2 of interest” means China, India, the European
3 Union, and any other geographic region as the Sec-
4 retary determines appropriate.

5 **SEC. 729. ENHANCING TRANSPARENCY OF DRUG FACILITY**
6 **INSPECTION TIMELINES.**

7 Section 902 of the FDA Reauthorization Act of 2017
8 (21 U.S.C. 355 note) is amended to read as follows:

9 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

10 “Not later than 120 days after the end of each fiscal
11 year, the Secretary of Health and Human Services shall
12 post on the public website of the Food and Drug Adminis-
13 tration information related to inspections of facilities nec-
14 essary for approval of a drug under subsection (c) or (j)
15 of section 505 of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 355), approval of a device under section
17 515 of such Act (21 U.S.C. 360e), or clearance of a device
18 under section 510(k) of such Act (21 U.S.C. 360(k)) that
19 were conducted during the previous fiscal year. Such infor-
20 mation shall include the following:

21 “(1) The median time following a request from
22 staff of the Food and Drug Administration review-
23 ing an application or report to the beginning of the
24 inspection, including—

1 “(A) the median time for drugs described
2 in section 505(j)(11)(A)(i) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(11)(A)(i));

5 “(B) the median time for drugs described
6 in section 506C(a) of such Act (21 U.S.C.
7 356c(a)) only; and

8 “(C) the median time for drugs on the
9 drug shortage list in effect under section 506E
10 of such Act (21 U.S.C. 356f).

11 “(2) The median time from the issuance of a
12 report pursuant to section 704(b) of such Act (21
13 U.S.C. 374(b)) to the sending of a warning letter,
14 issuance of an import alert, or holding of a regu-
15 latory meeting for inspections for which the Sec-
16 retary concluded that regulatory or enforcement ac-
17 tion was indicated, including the median time for
18 each category of drugs listed in subparagraphs (A)
19 through (C) of paragraph (1).

20 “(3) The median time from the sending of a
21 warning letter, issuance of an import alert, or hold-
22 ing of a regulatory meeting to resolution of the ac-
23 tions indicated to address the conditions or practices
24 observed during an inspection.

1 “(4) The number of facilities that failed to im-
2 plement requested corrective or preventive actions as
3 requested following a report pursuant to such sec-
4 tion 704(b), resulting in a withhold recommendation,
5 including the number of such times for each cat-
6 egory of drugs listed in subparagraphs (A) through
7 (C) of paragraph (1).”.

8 **TITLE VIII—TRANSPARENCY,**
9 **PROGRAM INTEGRITY, AND**
10 **REGULATORY IMPROVE-**
11 **MENTS**

12 **SEC. 801. PROMPT REPORTS OF MARKETING STATUS BY**
13 **HOLDERS OF APPROVED APPLICATIONS FOR**
14 **BIOLOGICAL PRODUCTS.**

15 (a) IN GENERAL.—Section 506I of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

17 (1) in subsection (a)—

18 (A) in the matter preceding paragraph (1),
19 by striking “The holder of an application ap-
20 proved under subsection (c) or (j) of section
21 505” and inserting “The holder of an applica-
22 tion approved under subsection (c) or (j) of sec-
23 tion 505 of this Act or subsection (a) or (k) of
24 section 351 of the Public Health Service Act”;

1 (B) in paragraph (2), by striking “estab-
2 lished name” and inserting “established name
3 (for biological products, by proper name)”; and

4 (C) in paragraph (3), by striking “or ab-
5 breviated application number” and inserting “,
6 abbreviated application number, or biologics li-
7 cense application number”; and

8 (2) in subsection (b)—

9 (A) in the matter preceding paragraph (1),
10 by striking “The holder of an application ap-
11 proved under subsection (c) or (j)” and insert-
12 ing “The holder of an application approved
13 under subsection (c) or (j) of section 505 of
14 this Act or subsection (a) or (k) of section 351
15 of the Public Health Service Act”;

16 (B) in paragraph (1), by striking “estab-
17 lished name” and inserting “established name
18 (for biological products, by proper name)”; and

19 (C) in paragraph (2), by striking “or ab-
20 breviated application number” and inserting “,
21 abbreviated application number, or biologics li-
22 cense application number”.

23 (b) **ADDITIONAL ONE-TIME REPORT.**—Subsection
24 (c) of section 506I of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 356i) is amended to read as follows:

1 “(c) ADDITIONAL ONE-TIME REPORT.—Within 180
2 days of the date of enactment of the Food and Drug
3 Amendments of 2022, all holders of applications approved
4 under subsection (a) or (k) of section 351 of the Public
5 Health Service Act shall review the information in the list
6 published under section 351(k)(9)(A) and shall submit a
7 written notice to the Secretary—

8 “(1) stating that all of the application holder’s
9 biological products in the list published under sec-
10 tion 351(k)(9)(A) that are not listed as discontinued
11 are available for sale; or

12 “(2) including the information required pursu-
13 ant to subsection (a) or (b), as applicable, for each
14 of the application holder’s biological products that
15 are in the list published under section 351(k)(9)(A)
16 and not listed as discontinued, but have been discon-
17 tinued from sale or never have been available for
18 sale.”.

19 (c) PURPLE BOOK.—Section 506I of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-
21 ed—

22 (1) by striking subsection (d) and inserting the
23 following:

24 “(d) FAILURE TO MEET REQUIREMENTS.—If a hold-
25 er of an approved application fails to submit the informa-

1 tion required under subsection (a), (b), or (c), the Sec-
2 retary may—

3 “(1) move the application holder’s drugs from
4 the active section of the list published under section
5 505(j)(7)(A) to the discontinued section of the list,
6 except that the Secretary shall remove from the list
7 in accordance with section 505(j)(7)(C) drugs the
8 Secretary determines have been withdrawn from sale
9 for reasons of safety or effectiveness; and

10 “(2) identify the application holder’s biological
11 products as discontinued in the list published under
12 section 351(k)(9)(A) of the Public Health Service
13 Act, except that the Secretary shall remove from the
14 list in accordance with section 351(k)(9)(B) of such
15 Act biological products for which the license has
16 been revoked or suspended for reasons of safety, pu-
17 rity, or potency.”; and

18 (2) in subsection (e)—

19 (A) by inserting after the first sentence the
20 following: “The Secretary shall update the list
21 published under section 351(k)(9)(A) of the
22 Public Health Service Act based on information
23 provided under subsections (a), (b), and (c) by
24 identifying as discontinued biological products
25 that are not available for sale, except that bio-

1 logical products for which the license has been
2 revoked or suspended for safety, purity, or po-
3 tency reasons shall be removed from the list in
4 accordance with section 351(k)(9)(B) of the
5 Public Health Service Act.”;

6 (B) by striking “monthly updates to the
7 list” and inserting “monthly updates to the lists
8 referred to in the preceding sentences”; and

9 (C) by striking “and shall update the list
10 based on” and inserting “and shall update such
11 lists based on”.

12 (d) **TECHNICAL CORRECTIONS.**—Section 506I(e) of
13 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 356i(e)) is amended—

15 (1) by striking “subsection 505(j)(7)(A)” and
16 inserting “section 505(j)(7)(A)”; and

17 (2) by striking “subsection 505(j)(7)(C)” and
18 inserting “section 505(j)(7)(C)”.

19 **SEC. 802. ENCOURAGING BLOOD DONATION.**

20 Section 3003 of the 21st Century Cures Act (21
21 U.S.C. 360bbb–8c note) is amended to read as follows:

1 **“SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR**
2 **INPUT.**

3 “Chapter 35 of title 44, United States Code, shall
4 not apply to the collection of information to which a re-
5 sponse is voluntary, to solicit—

6 “(1) the views and perspectives of patients
7 under section 569C of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended
9 by section 3001) or section 3002; or

10 “(2) information from blood donors or potential
11 blood donors to support the development of rec-
12 ommendations by the Secretary of Health and
13 Human Services acting through the Commissioner of
14 Food and Drugs concerning blood donation.”.

15 **SEC. 803. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

16 Section 503 of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 353) is amended by adding at the end the
18 following:

19 “(h)(1) Any contrast agent, radioactive drug, or OTC
20 monograph drug shall be deemed to be a drug under sec-
21 tion 201(g) and not a device under section 201(h).

22 “(2) For purposes of this subsection:

23 “(A) The term ‘contrast agent’ means an arti-
24 cle that is intended for use in conjunction with a
25 medical imaging device, and—

1 “(i) is a diagnostic radiopharmaceutical, as
2 defined in sections 315.2 and 601.31 of title
3 21, Code of Federal Regulations (or any suc-
4 cessor regulations); or

5 “(ii) is a diagnostic agent that improves
6 the visualization of structure or function within
7 the body by increasing the relative difference in
8 signal intensity within the target tissue, struc-
9 ture, or fluid.

10 “(B) The term ‘radioactive drug’ has the mean-
11 ing given such term in section 310.3(n) of title 21,
12 Code of Federal Regulations (or any successor regu-
13 lations), except that such term does not include—

14 “(i) an implant or article similar to an im-
15 plant;

16 “(ii) an article that applies radiation from
17 outside of the body; or

18 “(iii) the radiation source of an article de-
19 scribed in clause (i) or (ii).

20 “(C) The term ‘OTC monograph drug’ has the
21 meaning given such term in section 744L.

22 “(3) Nothing in this subsection shall be construed as
23 allowing for the classification of a product as a drug (as
24 defined in section 201(g)) if such product—

25 “(A) is not described in paragraph (1); and

1 “(B) meets the definition of a device under sec-
2 tion 201(h),
3 unless another provision of this Act otherwise indicates a
4 different classification.”.

5 **SEC. 804. POSTAPPROVAL STUDIES AND PROGRAM INTEG-**
6 **RITY FOR ACCELERATED APPROVAL DRUGS.**

7 (a) IN GENERAL.—Section 506(c) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is
9 amended—

10 (1) by striking paragraph (2) and inserting the
11 following:

12 “(2) LIMITATION.—

13 “(A) IN GENERAL.—Approval of a product
14 under this subsection may be subject to 1 or
15 both of the following requirements:

16 “(i) That the sponsor conduct an ap-
17 propriate postapproval study or studies
18 (which may be augmented or supported by
19 real world evidence) to verify and describe
20 the predicted effect on irreversible mor-
21 bidity or mortality or other clinical benefit.

22 “(ii) That the sponsor submit copies
23 of all promotional materials related to the
24 product during the preapproval review pe-
25 riod and, following approval and for such

1 period thereafter as the Secretary deter-
2 mines to be appropriate, at least 30 days
3 prior to dissemination of the materials.

4 “(B) STUDIES NOT REQUIRED.—If the
5 Secretary does not require that the sponsor of
6 a product approved under accelerated approval
7 conduct a postapproval study under this para-
8 graph, the Secretary shall publish on the
9 website of the Food and Drug Administration
10 the rationale for why such study is not appro-
11 priate or necessary.

12 “(C) POSTAPPROVAL STUDY CONDI-
13 TIONS.—Not later than the time of approval of
14 a product under accelerated approval, the Sec-
15 retary shall specify the conditions for a post-
16 approval study or studies required to be con-
17 ducted under this paragraph with respect to
18 such product, which may include enrollment
19 targets, the study protocol, and milestones, in-
20 cluding the target date of study completion.

21 “(D) STUDIES BEGUN BEFORE AP-
22 PROVAL.—The Secretary may require such
23 study or studies to be underway prior to ap-
24 proval.”; and

1 (2) by striking paragraph (3) and inserting the
2 following:

3 “(3) EXPEDITED WITHDRAWAL OF AP-
4 PROVAL.—

5 “(A) IN GENERAL.—The Secretary may
6 withdraw approval of a product approved under
7 accelerated approval using expedited procedures
8 described in subparagraph (B), if—

9 “(i) the sponsor fails to conduct any
10 required postapproval study of the product
11 with due diligence, including with respect
12 to conditions specified by the Secretary
13 under paragraph (2)(C);

14 “(ii) a study required to verify and
15 describe the predicted effect on irreversible
16 morbidity or mortality or other clinical
17 benefit of the product fails to verify and
18 describe such effect or benefit;

19 “(iii) other evidence demonstrates
20 that the product is not shown to be safe or
21 effective under the conditions of use; or

22 “(iv) the sponsor disseminates false or
23 misleading promotional materials with re-
24 spect to the product.

1 “(B) EXPEDITED PROCEDURES DE-
2 SCRIBED.—Expedited procedures described in
3 this subparagraph shall consist of, prior to the
4 withdrawal of accelerated approval—

5 “(i) providing the sponsor with—

6 “(I) due notice;

7 “(II) an explanation for the pro-
8 posed withdrawal;

9 “(III) an opportunity for a meet-
10 ing with the Commissioner of Food
11 and Drugs or the Commissioner’s des-
12 ignee; and

13 “(IV) an opportunity for written
14 appeal to—

15 “(aa) the Commissioner of
16 Food and Drugs; or

17 “(bb) a designee of the
18 Commissioner who has not par-
19 ticipated in the proposed with-
20 drawal of approval (other than a
21 meeting pursuant to subclause
22 (III)) and is not a subordinate of
23 an individual (other than the
24 Commissioner) who participated
25 in such proposed withdrawal;

1 “(ii) providing an opportunity for
2 public comment on the notice proposing to
3 withdraw approval;

4 “(iii) the publication of a summary of
5 the public comments received, and the Sec-
6 retary’s response to such comments, on the
7 website of the Food and Drug Administra-
8 tion; and

9 “(iv) convening and consulting an ad-
10 visory committee on issues related to the
11 proposed withdrawal, if requested by the
12 sponsor and if no such advisory committee
13 has previously advised the Secretary on
14 such issues with respect to the withdrawal
15 of the product prior to the sponsor’s re-
16 quest.

17 “(4) LABELING.—

18 “(A) IN GENERAL.—Subject to subpara-
19 graph (B), the labeling for a product approved
20 under accelerated approval shall include—

21 “(i) a statement indicating that the
22 product was approved under accelerated
23 approval;

24 “(ii) a statement indicating that con-
25 tinued approval of the product is subject to

1 postmarketing studies to verify clinical
2 benefit;

3 “(iii) identification of the surrogate or
4 intermediate endpoint or endpoints that
5 supported approval and any known limita-
6 tions of such surrogate or intermediate
7 endpoint or endpoints in determining clin-
8 ical benefit; and

9 “(iv) a succinct description of the
10 product and any uncertainty about antici-
11 pated clinical benefit and a discussion of
12 available evidence with respect to such clin-
13 ical benefit.

14 “(B) APPLICABILITY.—The labeling re-
15 quirements of subparagraph (A) shall apply
16 only to products approved under accelerated ap-
17 proval for which the predicted effect on irre-
18 versible morbidity or mortality or other clinical
19 benefit has not been verified.

20 “(5) REPORTING.—Not later than September
21 30, 2025, the Secretary shall submit to the Com-
22 mittee on Energy and Commerce of the House of
23 Representatives and the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Senate a report
25 describing circumstances in which the Secretary con-

1 sidered real world evidence submitted to support
2 postapproval studies required under this subsection
3 that were completed after the date of enactment of
4 the Food and Drug Amendments of 2022.”.

5 (b) REPORTS OF POSTMARKETING STUDIES.—Sec-
6 tion 506B(a) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 356b(a)) is amended—

8 (1) by redesignating paragraph (2) as para-
9 graph (3); and

10 (2) by inserting after paragraph (1) the fol-
11 lowing:

12 “(2) ACCELERATED APPROVAL.—Notwith-
13 standing paragraph (1), a sponsor of a drug ap-
14 proved under accelerated approval shall submit to
15 the Secretary a report of the progress of any study
16 required under section 506(c), including progress to-
17 ward any agreed upon enrollment targets, mile-
18 stones, and other information as required by the
19 Secretary, not later than 180 days after the ap-
20 proval of such drug and not less frequently than
21 every 180 days thereafter, until the study is com-
22 pleted or terminated.”.

23 (c) GUIDANCE.—

24 (1) IN GENERAL.—The Secretary of Health and
25 Human Services shall issue guidance describing—

1 (A) how sponsor questions related to the
2 identification of novel surrogate or intermediate
3 clinical endpoints may be addressed in early-
4 stage development meetings with the Food and
5 Drug Administration;

6 (B) the use of novel clinical trial designs
7 that may be used to conduct appropriate post-
8 approval studies as may be required under sec-
9 tion 506(c)(2)(A) of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 356(c)(2)(A)), as
11 amended by subsection (a); and

12 (C) the expedited procedures described in
13 section 506(c)(3)(B) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C.
15 356(c)(3)(B)).

16 (2) FINAL GUIDANCE.—The Secretary shall
17 issue—

18 (A) draft guidance under paragraph (1)
19 not later than 18 months after the date of en-
20 actment of this Act; and

21 (B) final guidance not later than 1 year
22 after the close of the public comment period on
23 such draft guidance.

24 (d) RARE DISEASE ENDPOINT ADVANCEMENT
25 PILOT.—

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services shall establish a pilot program
3 under which the Secretary will establish procedures
4 to provide increased interaction with sponsors of
5 rare disease drug development programs for pur-
6 poses of advancing the development of efficacy
7 endpoints, including surrogate and intermediate
8 endpoints, for drugs intended to treat rare diseases,
9 including through—

10 (A) determining eligibility of participants
11 for such a program; and

12 (B) developing and implementing a process
13 for applying to, and participating in, such a
14 program.

15 (2) PUBLIC WORKSHOPS.—The Secretary shall
16 conduct up to 3 public workshops, which shall be
17 completed not later than September 30, 2026, to
18 discuss topics relevant to the development of
19 endpoints for rare diseases, which may include dis-
20 cussions about—

21 (A) novel endpoints developed through the
22 pilot program established under this subsection;
23 and

24 (B) as appropriate, the use of real world
25 evidence and real world data to support the val-

1 idation of efficacy endpoints, including surro-
2 gate and intermediate endpoints, for rare dis-
3 eases.

4 (3) REPORT.—Not later than September 30,
5 2027, the Secretary shall submit to the Committee
6 on Energy and Commerce of the House of Rep-
7 resentatives and the Committee on Health, Edu-
8 cation, Labor, and Pensions of the Senate a report
9 describing the outcomes of the pilot program estab-
10 lished under this subsection.

11 (4) GUIDANCE.—Not later than September 30,
12 2027, the Secretary shall issue guidance describing
13 best practices and strategies for development of effi-
14 cacy endpoints, including surrogate and intermediate
15 endpoints, for rare diseases.

16 (5) SUNSET.—The Secretary may not accept
17 any new application or request to participate in the
18 program established by this subsection on or after
19 October 1, 2027.

20 **SEC. 805. FACILITATING THE USE OF REAL WORLD EVI-**
21 **DENCE.**

22 (a) GUIDANCE.—Not later than 1 year after the date
23 of the enactment of this Act, the Secretary of Health and
24 Human Services shall issue, or revise existing, guidance
25 on considerations for the use of real world data and real

1 world evidence to support regulatory decisionmaking, as
2 follows:

3 (1) With respect to drugs, such guidance shall
4 address—

5 (A) the use of such data and evidence to
6 support the approval of a drug application
7 under section 505 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 355) or a biologi-
9 cal product application under section 351 of the
10 Public Health Service Act (42 U.S.C. 262), or
11 to support an investigational use exemption
12 under section 505(i) of the Federal Food, Drug,
13 and Cosmetic Act or section 351(a)(3) of the
14 Public Health Service Act; and

15 (B) the use of such data and evidence ob-
16 tained as a result of the use of drugs author-
17 ized for emergency use under section 564 of the
18 Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 360bbb-3) in such applications, submis-
20 sions, or requests; and

21 (C) standards and methodologies which
22 may be used for collection and analysis of real
23 world evidence included in such applications,
24 submissions, or requests, as appropriate.

1 (2) With respect to devices, such guidance shall
2 address—

3 (A) the use of such data and evidence to
4 support the approval, clearance, or classification
5 of a device pursuant to an application or sub-
6 mission submitted under section 510(k),
7 513(f)(2), or 515 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 360(k),
9 360c(f)(2), 360e), or to support an investiga-
10 tional use exemption under section 520(g) of
11 such Act (21 U.S.C. 360j(g));

12 (B) the use of such data and evidence ob-
13 tained as a result of the use of devices author-
14 ized for emergency use under section 564 of the
15 Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 360bbb-3), in such applications, submis-
17 sions, or requests; and

18 (C) standards and methodologies which
19 may be used for collection and analysis of real
20 world evidence included in such applications,
21 submissions, or requests, as appropriate.

22 (b) REPORT TO CONGRESS.—Not later than 2 years
23 after the termination of the public health emergency deter-
24 mination by the Secretary of Health and Human Services
25 under section 564 of the Federal Food, Drug, and Cos-

1 metric Act (21 U.S.C. 360bbb-3) on February 4, 2020,
2 with respect to the Coronavirus Disease 2019 (COVID-
3 19), the Secretary shall submit a report to the Committee
4 on Energy and Commerce of the House of Representatives
5 and the Committee on Health, Education, Labor, and
6 Pensions of the Senate on—

7 (1) the number of applications, submissions, or
8 requests submitted for clearance or approval under
9 section 505, 510(k), or 515 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355, 360(k),
11 360e(f)(2), 360e) or section 351 of the Public
12 Health Service Act, for which an authorization
13 under section 564 of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 360bbb-3) was previously
15 granted;

16 (2) of the number of applications so submitted,
17 the number of such applications—

18 (A) for which real world evidence was sub-
19 mitted and used to support a regulatory deci-
20 sion; and

21 (B) for which real world evidence was sub-
22 mitted and determined to be insufficient to sup-
23 port a regulatory decision; and

24 (3) a summary explanation of why, in the case
25 of applications described in paragraph (2)(B), real

1 world evidence could not be used to support regu-
2 latory decisions.

3 (c) INFORMATION DISCLOSURE.—Nothing in this
4 section shall be construed to authorize the disclosure of
5 information that is prohibited from disclosure under sec-
6 tion 1905 of title 18, United States Code, or subject to
7 withholding under subsection (b)(4) of section 552 of title
8 5, United States Code (commonly referred to as the
9 “Freedom of Information Act”).

10 **SEC. 806. MEDICAL DEVICES ADVISORY COMMITTEE MEET-**
11 **INGS.**

12 (a) IN GENERAL.—The Secretary shall convene one
13 or more panels of the Medical Devices Advisory Committee
14 not less than once per year for the purpose of providing
15 advice to the Secretary on topics related to medical devices
16 used in pandemic preparedness and response, including
17 topics related to in vitro diagnostics.

18 (b) REQUIRED PANEL MEMBER.—A panel convened
19 under subsection (a) shall include at least 1 population
20 health-specific representative.

21 (c) SUNSET.—This section shall cease to be effective
22 on October 1, 2027.

1 **SEC. 807. ENSURING CYBERSECURITY OF MEDICAL DE-**
2 **VICES.**

3 (a) IN GENERAL.—Subchapter A of chapter V of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
5 et seq.), as amended by section 501, is further amended
6 by adding at the end the following:

7 **“SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.**

8 “(a) IN GENERAL.—For purposes of ensuring cyber-
9 security throughout the lifecycle of a cyber device, any per-
10 son who submits a premarket submission for the cyber de-
11 vice shall include such information as the Secretary may
12 require to ensure that the cyber device meets such cyberse-
13 curity requirements as the Secretary determines to be ap-
14 propriate to demonstrate a reasonable assurance of safety
15 and effectiveness, including at a minimum the cybersecuri-
16 ty requirements under subsection (b).

17 “(b) CYBERSECURITY REQUIREMENTS.—At a min-
18 imum, the manufacturer of a cyber device shall meet the
19 following cybersecurity requirements:

20 “(1) The manufacturer shall have a plan to ap-
21 propriately monitor, identify, and address in a rea-
22 sonable time postmarket cybersecurity vulnerabilities
23 and exploits, including coordinated vulnerability dis-
24 closure and procedures.

25 “(2) The manufacturer shall design, develop,
26 and maintain processes and procedures to ensure the

1 device and related systems are cybersecure, and shall
2 make available updates and patches to the cyber de-
3 vice and related systems throughout the lifecycle of
4 the cyber device to address—

5 “(A) on a reasonably justified regular
6 cycle, known unacceptable vulnerabilities; and

7 “(B) as soon as possible out of cycle, crit-
8 ical vulnerabilities that could cause uncontrolled
9 risks.

10 “(3) The manufacturer shall provide in the la-
11 beling of the cyber device a software bill of mate-
12 rials, including commercial, open-source, and off-the-
13 shelf software components.

14 “(4) The manufacturer shall comply with such
15 other requirements as the Secretary may require to
16 demonstrate reasonable assurance of the safety and
17 effectiveness of the device for purposes of cybersecu-
18 rity, which the Secretary may require by an order
19 published in the Federal Register.

20 “(c) SUBSTANTIAL EQUIVALENCE.—In making a de-
21 termination of substantial equivalence under section
22 513(i) for a cyber device, the Secretary may—

23 “(1) find that cybersecurity information for the
24 cyber device described in the relevant premarket

1 submission in the cyber device’s use environment is
2 inadequate; and

3 “(2) issue a nonsubstantial equivalence deter-
4 mination based on this finding.

5 “(d) DEFINITION.—In this section:

6 “(1) CYBER DEVICE.—The term ‘cyber device’
7 means a device that—

8 “(A) includes software, including software
9 as or in a device;

10 “(B) has the ability to connect to the
11 internet; or

12 “(C) contains any such technological char-
13 acteristics that could be vulnerable to cyberse-
14 curity threats.

15 “(2) LIFECYCLE OF THE CYBER DEVICE.—The
16 term ‘lifecycle of the cyber device’ includes the
17 postmarket lifecycle of the cyber device.

18 “(3) PREMARKET SUBMISSION.—The term ‘pre-
19 market submission’ means any submission under
20 section 510(k), 513, 515(e), 515(f), or 520(m).

21 “(e) EXEMPTION.—The Secretary may identify de-
22 vices or types of devices that are exempt from meeting
23 the cybersecurity requirements established by this section
24 and regulations promulgated pursuant to this section. The
25 Secretary shall publish in the Federal Register, and up-

1 date, as appropriate, a list of the devices and types of de-
2 vices so identified by the Secretary.”.

3 (b) PROHIBITED ACT.—Section 301(q) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(q))
5 is amended by adding at the end the following:

6 “(3) The failure to comply with any requirement
7 under section 524C (relating to ensuring device cybersecu-
8 rity).”.

9 (c) ADULTERATION.—Section 501 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-
11 ed by inserting after paragraph (j) the following:

12 “(k) If it is a device subject to the requirements set
13 forth in section 524C (relating to ensuring device cyberse-
14 curity) and fails to comply with any requirement under
15 that section.”.

16 (d) MISBRANDING.—Section 502(t) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is
18 amended—

19 (1) by striking “or (3)” and inserting “(3)”;
20 and

21 (2) by inserting before the period at the end the
22 following: “, or (4) to furnish a software bill of ma-
23 terials as required under section 524C (relating to
24 ensuring device cybersecurity)”.

1 **SEC. 808. PUBLIC DOCKET ON PROPOSED CHANGES TO**
2 **THIRD-PARTY VENDORS.**

3 (a) IN GENERAL.—

4 (1) OPENING PUBLIC DOCKET.—Not later than
5 90 days after the date of enactment of this Act, the
6 Secretary of Health and Human Services shall open
7 a single public docket to solicit comments on factors
8 that generally should be considered by the Secretary
9 when reviewing requests from sponsors of drugs sub-
10 ject to risk evaluation and mitigation strategies to
11 change third-party vendors engaged by sponsors to
12 aid in implementation and management of the strat-
13 egies.

14 (2) FACTORS.—Such factors include the poten-
15 tial effects of changes in third-party vendors on—

16 (A) patient access; and

17 (B) prescribing and administration of the
18 drugs by health care providers.

19 (3) CLOSING PUBLIC DOCKET.—The Secretary
20 of Health and Human Services may close such pub-
21 lic docket not earlier than 90 days after such docket
22 is opened.

23 (4) NO DELAY.—Nothing in this section shall
24 delay agency action on any modification to a risk
25 evaluation and mitigation strategy.

1 (b) GAO REPORT.—Not later than December 31,
2 2026, the Comptroller General of the United States shall
3 submit to the Committee on Energy and Commerce of the
4 House of Representatives and the Committee on Health,
5 Education, Labor, and Pensions of the Senate a report
6 on—

7 (1) the number of changes in third-party ven-
8 dors (engaged by sponsors to aid implementation
9 and management of risk evaluation and mitigation
10 strategies) for an approved risk evaluation and miti-
11 gation strategy the Secretary of Health and Human
12 Services has approved under section 505–1(h) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 355–1(h));

15 (2) any issues affecting patient access to the
16 drug that is subject to the strategy or considerations
17 with respect to the administration or prescribing of
18 such drug by health care providers that arose as a
19 result of such modifications; and

20 (3) how such issues were resolved, as applica-
21 ble.

22 **SEC. 809. FACILITATING EXCHANGE OF PRODUCT INFOR-**
23 **MATION PRIOR TO APPROVAL.**

24 (a) IN GENERAL.—Section 502 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 352) is amended—

1 (1) in paragraph (a)—

2 (A) by striking “drugs for coverage” and
3 inserting “drugs or devices for coverage”; and

4 (B) by striking “drug” each place it ap-
5 pears and inserting “drug or device”, respec-
6 tively;

7 (2) in paragraph (a)(2)(B), by striking “under
8 section 505 or under section 351 of the Public
9 Health Service Act for such drug” and inserting
10 “under section 505, 510(k), 513(f)(2), or 515 of this
11 Act or section 351 of the Public Health Service
12 Act”; and

13 (3) by adding at the end the following:

14 “(gg)(1) Unless its labeling bears adequate directions
15 for use in accordance with paragraph (f), except that (in
16 addition to drugs or devices that conform with exemptions
17 pursuant to such paragraph) no drug or device shall be
18 deemed to be misbranded under such paragraph through
19 the provision of product information to a payor, formulary
20 committee, or other similar entity with knowledge and ex-
21 pertise in the area of health care economic analysis car-
22 rying out its responsibilities for the selection of drugs or
23 devices for coverage or reimbursement if the product infor-
24 mation relates to an investigational drug or device or in-
25 vestigational use of a drug or device that is approved,

1 cleared, granted marketing authorization, or licensed
2 under section 505, 510(k), 513(f)(2), or 515 of this Act
3 or section 351 of the Public Health Service Act (as appli-
4 cable), provided—

5 “(A) the product information includes—

6 “(i) a clear statement that the investiga-
7 tional drug or device or investigational use of a
8 drug or device has not been approved, cleared,
9 granted marketing authorization, or licensed
10 under section 505, 510(k), 513(f)(2), or 515 of
11 this Act or section 351 of the Public Health
12 Service Act (as applicable) and that the safety
13 and effectiveness of the drug or device or use
14 has not been established;

15 “(ii) information related to the stage of de-
16 velopment of the drug or device involved, such
17 as—

18 “(I) the status of any study or studies
19 in which the investigational drug or device
20 or investigational use is being investigated;

21 “(II) how the study or studies relate
22 to the overall plan for the development of
23 the drug or device; and

24 “(III) whether an application, pre-
25 market notification, or request for classi-

1 fication for the investigational drug or de-
2 vice or investigational use has been sub-
3 mitted to the Secretary and when such a
4 submission is planned;

5 “(iii) in the case of information that in-
6 cludes factual presentations of results from
7 studies, which shall not be selectively presented,
8 a description of—

9 “(I) all material aspects of study de-
10 sign, methodology, and results; and

11 “(II) all material limitations related
12 to the study design, methodology, and re-
13 sults;

14 “(iv) where applicable, a prominent state-
15 ment disclosing the indication or indications for
16 which the Secretary has approved, granted mar-
17 keting authorization, cleared, or licensed the
18 product pursuant to section 505, 510(k),
19 513(f)(2), or 515 of this Act or section 351 of
20 the Public Health Service Act, and a copy of
21 the most current required labeling; and

22 “(v) updated information, if previously
23 communicated information becomes materially
24 outdated as a result of significant changes or as

1 a result of new information regarding the prod-
2 uct or its review status; and

3 “(B) the product information does not in-
4 clude—

5 “(i) information that represents that an
6 unapproved product—

7 “(I) has been approved, cleared,
8 granted marketing authorization, or li-
9 censed under section 505, 510(k),
10 513(f)(2), or 515 of this Act or section
11 351 of the Public Health Service Act (as
12 applicable); or

13 “(II) has otherwise been determined
14 to be safe or effective for the purpose or
15 purposes for which the drug or device is
16 being studied; or

17 “(ii) information that represents that an
18 unapproved use of a drug or device that has
19 been so approved, granted marketing authoriza-
20 tion, cleared, or licensed—

21 “(I) is so approved, granted mar-
22 keting authorization, cleared, or licensed;
23 or

1 “(II) that the product is safe or effec-
2 tive for the use or uses for which the drug
3 or device is being studied.

4 “(2) For purposes of this paragraph, the term ‘prod-
5 uct information’ includes—

6 “(A) information describing the drug or device
7 (such as drug class, device description, and fea-
8 tures);

9 “(B) information about the indication or indica-
10 tions being investigated;

11 “(C) the anticipated timeline for a possible ap-
12 proval, clearance, marketing authorization, or licen-
13 sure pursuant to section 505, 510(k), 513, or 515
14 of this Act or section 351 of the Public Health Serv-
15 ice Act;

16 “(D) drug or device pricing information;

17 “(E) patient utilization projections;

18 “(F) product-related programs or services; and

19 “(G) factual presentations of results from stud-
20 ies that do not characterize or make conclusions re-
21 garding safety or efficacy.”.

22 (b) GAO STUDY AND REPORT.—Beginning on the
23 date that is 5 years and 6 months after the date of enact-
24 ment of this Act, the Comptroller General of the United
25 States shall conduct a study on the provision and use of

1 information pursuant to section 502(gg) of the Federal
2 Food, Drug, and Cosmetic Act, as added by this sub-
3 section (a), between manufacturers of drugs and devices
4 (as defined in section 201 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 321)) and entities described in
6 such section 502(gg). Such study shall include an analysis
7 of the following:

8 (1) The types of information communicated be-
9 tween such manufacturers and payors.

10 (2) The manner of communication between
11 such manufacturers and payors.

12 (3)(A) Whether such manufacturers file an ap-
13 plication for approval, marketing authorization,
14 clearance, or licensing of a new drug or device or the
15 new use of a drug or device that is the subject of
16 communication between such manufacturers and
17 payors under section 502(gg) of the Federal Food,
18 Drug, and Cosmetic Act, as added by subsection (a).

19 (B) How frequently the Food and Drug Admin-
20 istration approves, grants marketing authorization,
21 clears, or licenses the new drug or device or new use.

22 (C) The timeframe between the initial commu-
23 nications permitted under section 502(gg) of the
24 Federal Food, Drug, and Cosmetic Act, as added by
25 subsection (a), regarding an investigational drug or

1 device or investigational use, and the initial mar-
2 keting of such drug or device.

3 **SEC. 810. BANS OF DEVICES FOR ONE OR MORE INTENDED**
4 **USES.**

5 (a) IN GENERAL.—Section 516(a) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360f(a)) is
7 amended—

8 (1) in paragraph (1), by inserting “for one or
9 more intended use” before the semicolon at the end;
10 and

11 (2) in the matter following paragraph (2), by
12 inserting “for any such intended use or uses. A de-
13 vice that is banned for one or more intended uses is
14 not a legally marketed device under section 1006
15 when intended for such use or uses” after “banned
16 device”.

17 (b) SPECIFIC DEVICES DEEMED BANNED.—Section
18 516 of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 360f) is further amended by adding at the end the
20 following:

21 “(c) SPECIFIC DEVICE BANNED.—Electrical stimula-
22 tion devices that apply a noxious electrical stimulus to a
23 person’s skin intended to reduce or cease self-injurious be-
24 havior or aggressive behavior are deemed to be banned de-
25 vices, as described in subsection (a).

1 “(d) REVERSAL BY REGULATION.—Devices banned
2 under this section are banned devices unless or until the
3 Secretary promulgates a regulation to make such devices
4 or use of such devices no longer banned based on a finding
5 that such devices or use of such devices does not present
6 substantial deception or an unreasonable and substantial
7 risk of illness or injury, or that such risk can be corrected
8 or eliminated by labeling.”.

9 **SEC. 811. CLARIFYING APPLICATION OF EXCLUSIVE AP-**
10 **PROVAL, CERTIFICATION, OR LICENSURE**
11 **FOR DRUGS DESIGNATED FOR RARE DIS-**
12 **EASES OR CONDITIONS.**

13 (a) APPLICATION OF EXCLUSIVE APPROVAL, CER-
14 TIFICATION, OR LICENSURE FOR DRUGS DESIGNATED
15 FOR RARE DISEASES OR CONDITIONS.—Section 527 of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360cc) is amended—

18 (1) in subsection (a), in the matter following
19 paragraph (2), by striking “same disease or condi-
20 tion” and inserting “same approved indication or
21 use within such rare disease or condition”;

22 (2) in subsection (b)—

23 (A) in the matter preceding paragraph (1),
24 by striking “same rare disease or condition”
25 and inserting “same indication or use for which

1 the Secretary has approved or licensed such
2 drug”; and

3 (B) in paragraph (1), by striking “with the
4 disease or condition for which the drug was des-
5 ignated” and inserting “for whom the drug is
6 indicated”; and

7 (3) in subsection (c), by striking “same rare
8 disease or condition” and inserting “same indication
9 or use”.

10 (b) APPLICATION OF AMENDMENTS.—The amend-
11 ments made by subsection (a) shall apply with respect to
12 any drug designated under section 526 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
14 less of the date on which the drug was so designated, and
15 regardless of the date on which the drug was approved
16 under section 505 of such Act (21 U.S.C. 355) or licensed
17 under section 351 of the Public Health Service Act (42
18 U.S.C. 262).

19 **SEC. 812. GAO REPORT ON THIRD-PARTY REVIEW.**

20 Not later than September 30, 2026, the Comptroller
21 General of the United States shall submit to the Com-
22 mittee on Energy and Commerce of the House of Rep-
23 resentatives and the Committee on Health, Education,
24 Labor, and Pensions of the Senate a report on the third-
25 party review program described in section 523 of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360m).

2 Such report shall include—

3 (1) a description of the financial and staffing
4 resources used to carry out such program;

5 (2) a description of actions taken by the Sec-
6 retary pursuant section 523(b)(2)(C) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C.
8 360m(b)(2)(C)); and

9 (3) the results of an audit of the performance
10 of select persons accredited under such program.

11 **SEC. 813. REPORTING ON PENDING GENERIC DRUG APPLI-**
12 **CATIONS AND PRIORITY REVIEW APPLICA-**
13 **TIONS.**

14 Section 807 of the FDA Reauthorization Act of 2017
15 (Public Law 115–52) is amended, in the matter preceding
16 paragraph (1), by striking “2022” and inserting “2027”.