

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 7667
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

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

4 SEC. 2. TABLE OF CONTENTS.

5 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.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Reauthorization; reporting requirements.
- Sec. 105. Sunset dates.
- Sec. 106. Effective date.
- Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; finding.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirements.
- Sec. 205. Conformity assessment pilot program.
- Sec. 206. Reauthorization of third-party review program.
- Sec. 207. Savings clause.
- Sec. 208. Effective date.
- Sec. 209. Sunset dates.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Authority to assess and use human generic drug fees.

- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Savings clause.

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 trial diversity.
- Sec. 504. Annual report on progress to increase diversity in clinical studies.
- Sec. 505. Public meeting on clinical trial 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.
- Sec. 602. Enhancing access to affordable medicines.

TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN
IMPROVEMENTS

Subtitle A—In General

- 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.
- Sec. 722. Uses of certain evidence.

- 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.
 Sec. 807. Ensuring cybersecurity of medical devices.
 Sec. 808. Public docket on proposed modifications to approved strategies.
 Sec. 809. Facilitating exchange of product information prior to approval.
 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 in this title will be dedi-
 8 cated toward expediting the drug development process and
 9 the process for the review of human drug applications, in-
 10 cluding postmarket drug safety activities, as set forth in
 11 the goals identified for purposes of part 2 of subchapter

1 C of chapter VII of the Federal Food, Drug, and Cosmetic
2 Act, in the letters from the Secretary of Health and
3 Human Services to the Chairman of the Committee on
4 Health, Education, Labor, and Pensions of the Senate and
5 the Chairman of the Committee on Energy and Commerce
6 of the House of Representatives, as set forth in the Con-
7 gressional Record.

8 **SEC. 102. DEFINITIONS.**

9 (a) HUMAN DRUG APPLICATION.—Section 735(1) of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379g(1)) is amended by striking “an allergenic extract
12 product, or” and inserting “does not include an applica-
13 tion with respect to an allergenic extract product licensed
14 before October 1, 2022, does not include an application
15 with respect to a standardized allergenic extract product
16 submitted pursuant to a notification to the applicant from
17 the Secretary regarding the existence of a potency test
18 that measures the allergenic activity of an allergenic ex-
19 tract product licensed by the applicant before October 1,
20 2022, does not include an application with respect to”.

21 (b) PRESCRIPTION DRUG PRODUCT.—Section 735(3)
22 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 379g(3)) is amended—

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

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

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

5 “(B) Such term does not include”;

6 (4) by striking “an allergenic extract product,”
7 and inserting “an allergenic extract product licensed
8 before October 1, 2022, a standardized allergenic ex-
9 tract product submitted pursuant to a notification to
10 the applicant from the Secretary regarding the exist-
11 ence of a potency test that measures the allergenic
12 activity of an allergenic extract product licensed by
13 the applicant before October 1, 2022,” ; and

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

15 “(C)(i) If a written request to place a
16 product in the discontinued section of either of
17 the lists referenced in subparagraph (A)(iii) is
18 submitted to the Secretary on behalf of an ap-
19 plicant, and the request identifies the date the
20 product is withdrawn from sale, then for pur-
21 poses of assessing the prescription drug pro-
22 gram fee under section 736(a)(2), the Secretary
23 shall consider such product to have been in-
24 cluded in the discontinued section on the later
25 of—

1 “(I) the date such request was re-
2 ceived; or

3 “(II) if the product will be withdrawn
4 from sale on a future date, such future
5 date when the product is withdrawn from
6 sale.

7 “(ii) For purposes of this subparagraph, a
8 product shall be considered withdrawn from
9 sale once the applicant has ceased its own dis-
10 tribution of the product, whether or not the ap-
11 plicant has ordered recall of all previously dis-
12 tributed lots of the product, except that a rou-
13 tine, temporary interruption in supply shall not
14 render a product withdrawn from sale.”.

15 (c) SKIN-TEST DIAGNOSTIC PRODUCT.—Section 735
16 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 379g) is amended by adding at the end the following:

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

19 “(A) means a product—

20 “(i) for prick, scratch, intradermal, or
21 subcutaneous administration;

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

1 “(iii) not intended to be a preventive
2 or therapeutic intervention; and

3 “(iv) intended to detect an immediate-
4 or delayed-type skin hypersensitivity reac-
5 tion to aid in the diagnosis of—

6 “(I) an allergy to an anti-
7 microbial agent;

8 “(II) an allergy that is not to an
9 antimicrobial agent, if the diagnostic
10 product was authorized for marketing
11 prior to October 1, 2022; or

12 “(III) infection with fungal or
13 mycobacterial pathogens; and

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

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

18 (a) TYPES OF FEES.—

19 (1) HUMAN DRUG APPLICATION FEE.—Section
20 736(a) of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 379h(a)) is amended—

22 (A) in the matter preceding paragraph (1),
23 by striking “fiscal year 2018” and inserting
24 “fiscal year 2023”.

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

4 (C) in paragraph (1)(C), by inserting
5 “prior to approval” after “or was withdrawn”;
6 and

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

9 “(H) EXCEPTION FOR SKIN-TEST DIAG-
10 NOSTIC PRODUCTS.—A human drug application
11 for a skin-test diagnostic product shall not be
12 subject to a fee under subparagraph (A).”.

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

16 (A) in subparagraph (A)—

17 (i) by striking “Except as provided in
18 subparagraphs (B) and (C)” and inserting
19 the following:

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

22 (ii) by striking “subsection (c)(5)”
23 and inserting “subsection (c)(6)”;

24 (iii) by adding at the end the fol-
25 lowing:

1 “(ii) SPECIAL RULE.—If a drug prod-
2 uct that is identified in a human drug ap-
3 plication approved as of October 1 of a fis-
4 cal year is not a prescription drug product
5 as of that date because the drug product
6 is in the discontinued section of a list ref-
7 erenced in section 735(3)(A)(iii), and on
8 any subsequent day during such fiscal year
9 the drug product is a prescription drug
10 product, then except as provided in sub-
11 paragraphs (B) and (C), each person who
12 is named as the applicant in a human drug
13 application with respect to such product,
14 and who, after September 1, 1992, had
15 pending before the Secretary a human
16 drug application or supplement with re-
17 spect to such product, shall pay the annual
18 prescription drug program fee established
19 for a fiscal year under subsection (c)(6) for
20 such prescription drug product. Such fee
21 shall be due on the last business day of
22 such fiscal year and shall be paid only once
23 for each such product for a fiscal year in
24 which the fee is payable.”; and

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

3 “(B) EXCEPTION FOR CERTAIN PRESCRIP-
4 TION DRUG PRODUCTS.—A prescription drug
5 program fee shall not be assessed for a pre-
6 scription drug product under subparagraph (A)
7 if such product is—

8 “(i) a large volume parenteral product
9 (a sterile aqueous drug product packaged
10 in a single-dose container with a volume
11 greater than or equal to 100 mL, not in-
12 cluding powders for reconstitution or phar-
13 macy bulk packages) identified on the list
14 compiled under section 505(j)(7);

15 “(ii) pharmaceutically equivalent (as
16 defined in section 314.3 of title 21, Code
17 of Federal Regulations (or any successor
18 regulation)) to another product on the list
19 of products compiled under section
20 505(j)(7) (not including the discontinued
21 section of such list); or

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

23 (b) FEE REVENUE AMOUNTS.—

1 (1) IN GENERAL.—Paragraph (1) of section
2 736(b) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 379h(b)) is amended to read as follows:

4 “(1) IN GENERAL.—For each of the fiscal years
5 2023 through 2027, fees under subsection (a) shall,
6 except as provided in subsections (c), (d), (f), and
7 (g), be established to generate a total revenue
8 amount under such subsection that is equal to the
9 sum 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 reserve adjustment for the fis-
17 cal year (as determined under subsection
18 (c)(2));

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

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

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

4 “(G) additional dollar amounts for each
5 fiscal year as follows:

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

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

8 “(iii) \$14,154,169 for fiscal year
9 2025.

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

11 “(v) \$1,314,620 for fiscal year
12 2027.”.

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

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

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

22 “(B) for fiscal years 2024 through 2027,
23 the dollar amount of the total revenue amount
24 established under paragraph (1) for the pre-

1 vious fiscal year, not including any adjustments
2 made under subsection (c)(4) or (c)(5).”.

3 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—

4 (1) INFLATION ADJUSTMENT.—Section
5 736(c)(1)(B)(ii) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is
7 amended by striking “Washington-Baltimore, DC–
8 MD–VA–WV” and inserting “Washington-Arlington-
9 Alexandria, DC–VA–MD–WV”.

10 (2) STRATEGIC HIRING AND RETENTION AD-
11 JUSTMENT.—Section 736(c) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is
13 amended—

14 (A) by redesignating paragraphs (2)
15 through (6) as paragraphs (3) through (7), re-
16 spectively; and

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

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

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

1 “(B) For each of fiscal years 2024 through
2 2027, \$4,000,000.”.

3 (3) CAPACITY PLANNING ADJUSTMENT.—Para-
4 graph (3), as redesignated, of section 736(e) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379h(e)) is amended to read as follows:

7 “(3) CAPACITY PLANNING ADJUSTMENT.—

8 “(A) IN GENERAL.—For each fiscal year,
9 after the annual base revenue established in
10 subsection (b)(1)(A) is adjusted in accordance
11 with paragraphs (1) and (2), such revenue shall
12 be adjusted further for such fiscal year, in ac-
13 cordance with this paragraph, to reflect changes
14 in the resource capacity needs of the Secretary
15 for the process for the review of human drug
16 applications.

17 “(B) METHODOLOGY.—For purposes of
18 this paragraph, the Secretary shall employ the
19 capacity planning methodology utilized by the
20 Secretary in setting fees for fiscal year 2021, as
21 described in the notice titled ‘Prescription Drug
22 User Fee Rates for Fiscal Year 2021’ published
23 in the Federal Register on August 3, 2020 (85
24 Fed. Reg. 46651). The workload categories
25 used in applying such methodology in fore-

1 casting shall include only the activities de-
2 scribed in that notice and, as feasible, addi-
3 tional activities that are also directly related to
4 the direct review of applications and supple-
5 ments, including additional formal meeting
6 types, the direct review of postmarketing com-
7 mitments and requirements, the direct review of
8 risk evaluation and mitigation strategies, and
9 the direct review of annual reports for approved
10 prescription drug products. Subject to the ex-
11 ceptions in the preceding sentence, the Sec-
12 retary shall not include as workload categories
13 in applying such methodology in forecasting any
14 non-core review activities, including those activi-
15 ties that the Secretary referenced for potential
16 future use in such notice but did not utilize in
17 setting fees for fiscal year 2021.

18 “(C) LIMITATION.—Under no cir-
19 cumstances shall an adjustment under this
20 paragraph result in fee revenue for a fiscal year
21 that is less than the sum of the amounts under
22 subsections (b)(1)(A) (the annual base revenue
23 for the fiscal year), (b)(1)(B) (the dollar
24 amount of the inflation adjustment for the fis-
25 cal year), and (b)(1)(C) (the dollar amount of

1 the strategic hiring and retention adjustment
2 for the fiscal year).

3 “(D) PUBLICATION IN FEDERAL REG-
4 ISTER.—The Secretary shall publish in the Fed-
5 eral Register notice under paragraph (6) of the
6 fee revenue and fees resulting from the adjust-
7 ment and the methodologies under this para-
8 graph.”.

9 (4) OPERATING RESERVE ADJUSTMENT.—Para-
10 graph (4), as redesignated, of section 736(e) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 379h(e)) is amended—

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

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

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

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

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

6 (B) in subparagraph (C), by striking
7 “paragraph (5)” and inserting “paragraph
8 (6)”.

9 (5) ADDITIONAL DIRECT COST ADJUSTMENT.—
10 Paragraph (5), as redesignated, of section 736(c) of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 379h(e)) is amended to read as follows:

13 “(5) ADDITIONAL DIRECT COST ADJUST-
14 MENT.—

15 “(A) INCREASE.—The Secretary shall, in
16 addition to adjustments under paragraphs (1),
17 (2), (3), and (4), further increase the fee rev-
18 enue and fees—

19 “(i) for fiscal year 2023, by
20 \$44,386,150; and

21 “(ii) for each of fiscal years 2024
22 through 2027, by the amount set forth in
23 clauses (i) through (iv) of subparagraph
24 (B), as applicable, multiplied by the Con-
25 sumer Price Index for urban consumers

1 (Washington-Arlington-Alexandria, DC–
2 VA–MD–WV; Not Seasonally Adjusted; All
3 Items; Annual Index) for the most recent
4 year of available data, divided by such
5 Index for 2021.

6 “(B) APPLICABLE AMOUNTS.—The
7 amounts referred to in subparagraph (A)(ii) are
8 the following:

9 “(i) For fiscal year 2024,
10 \$60,967,993.

11 “(ii) For fiscal year 2025,
12 \$35,799,314.

13 “(iii) For fiscal year 2026, \$35,799,
14 314.

15 “(iv) For fiscal year 2027,
16 \$35,799,314.”.

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

22 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
23 tion 736(g)(3) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 379h(g)(3)) is amended by striking “fiscal

1 years 2018 through 2022” and inserting “fiscal years
2 2023 through 2027”.

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

8 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
9 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
10 CERNING FEES.—To qualify for consideration for a waiver
11 or reduction under subsection (d), an exemption under
12 subsection (k), or the return of any fee paid under this
13 section, including if the fee is claimed to have been paid
14 in error, a person shall—

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

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

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

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

4 (2) by amending paragraph (2) to read as fol-
5 lows:

6 “(2) EVIDENCE OF QUALIFICATION.—An ex-
7 emption under paragraph (1) applies with respect to
8 a drug only if the applicant involved submits a cer-
9 tification that the applicant’s gross annual revenues
10 did not exceed \$50,000,000 for the last calendar
11 year ending prior to the fiscal year for which the ex-
12 emption is requested. Such certification shall be sup-
13 ported by—

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

16 “(B) as necessary, other appropriate finan-
17 cial information.”.

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

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

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

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

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

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

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

13 “(v) For fiscal years 2023 and 2024,
14 of the meeting requests from sponsors for
15 which the Secretary has determined that a
16 face-to-face meeting is appropriate, the
17 number of face-to-face meetings requested
18 by sponsors to be conducted in person (in
19 such manner as the Secretary shall pre-
20 scribe on the internet website of the Food
21 and Drug Administration), and the num-
22 ber of such in-person meetings granted by
23 the Secretary.”;

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

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

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

5 (8) in subsection (f)—

6 (A) in paragraph (1), in the matter pre-
7 ceding subparagraph (A), by striking “fiscal
8 year 2022” and inserting “fiscal year 2027”;
9 and

10 (B) in paragraph (5), by striking “January
11 15, 2022” and inserting “January 15, 2027”.

12 **SEC. 105. SUNSET DATES.**

13 (a) AUTHORIZATION.—Sections 735 and 736 of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
15 379h) shall cease to be effective October 1, 2027.

16 (b) REPORTING REQUIREMENTS.—Section 736B of
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 379h–2) shall cease to be effective January 31, 2028.

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

23 **SEC. 106. EFFECTIVE DATE.**

24 The amendments made by this title shall take effect
25 on October 1, 2022, or the date of the enactment of this

1 Act, whichever is later, except that fees under part 2 of
2 subchapter C of chapter VII of the Federal Food, Drug,
3 and Cosmetic Act shall be assessed for all human drug
4 applications received on or after October 1, 2022, regard-
5 less of the date of the enactment of this Act.

6 **SEC. 107. SAVINGS CLAUSE.**

7 Notwithstanding the amendments made by this title,
8 part 2 of subchapter C of chapter VII of the Federal Food,
9 Drug, and Cosmetic Act, as in effect on the day before
10 the date of the enactment of this title, shall continue to
11 be in effect with respect to human drug applications and
12 supplements (as defined in such part as of such day) that
13 on or after October 1, 2017, but before October 1, 2022,
14 were accepted by the Food and Drug Administration for
15 filing with respect to assessing and collecting any fee re-
16 quired by such part for a fiscal year prior to fiscal year
17 2023.

18 **TITLE II—FEES RELATING TO**
19 **DEVICES**

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

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

23 (b) **FINDING.**—The Congress finds that the fees au-
24 thorized under the amendments made by this title will be
25 dedicated toward expediting the process for the review of

1 device applications and for assuring the safety and effec-
2 tiveness of devices, as set forth in the goals identified for
3 purposes of part 3 of subchapter C of chapter VII of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i
5 et seq.) in the letters from the Secretary of Health and
6 Human Services to the Chairman of the Committee on
7 Health, Education, Labor, and Pensions of the Senate and
8 the Chairman of the Committee on Energy and Commerce
9 of the House of Representatives, as set forth in the Con-
10 gressional Record.

11 **SEC. 202. DEFINITIONS.**

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

14 (1) in paragraph (9)—

15 (A) in the matter preceding subparagraph
16 (A), by striking “and premarket notification
17 submissions” and inserting “premarket notifica-
18 tion submissions, and de novo classification re-
19 quests”;

20 (B) in subparagraph (D), by striking “and
21 submissions” and inserting “submissions, and
22 requests”;

23 (C) in subparagraph (F), by striking “and
24 premarket notification submissions” and insert-

1 ing “premarket notification submissions, and de
2 novo classification requests”;

3 (D) in each of subparagraphs (G) and (H),
4 by striking “or submissions” and inserting
5 “submissions, or requests”; and

6 (E) in subparagraph (K), by striking “or
7 premarket notification submissions” and insert-
8 ing “premarket notification submissions, or de
9 novo classification requests”; and

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

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

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

16 (1) in paragraph (1), by striking “fiscal year
17 2018” and inserting “fiscal year 2023”; and

18 (2) in paragraph (2)—

19 (A) in subparagraph (A)—

20 (i) in the matter preceding clause (i),
21 by striking “October 1, 2017” and insert-
22 ing “October 1, 2022”;

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

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

3 (B) in subparagraph (B)(iii), by striking
4 “or premarket notification submission” and in-
5 serting “premarket notification submission, or
6 de novo classification request”; and

7 (C) in subparagraph (C), by striking “or
8 periodic reporting concerning a class III device”
9 and inserting “periodic reporting concerning a
10 class III device, or de novo classification re-
11 quest”.

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

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

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

19 “(2) BASE FEE AMOUNTS SPECIFIED.—For
20 purposes of paragraph (1), the base fee amounts
21 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

22 (3) by amending paragraph (3) to read as fol-
23 lows:

1 “(3) TOTAL REVENUE AMOUNTS SPECIFIED.—

2 For purposes of paragraph (1), the total revenue
3 amounts specified in this paragraph are as follows:

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

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

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

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

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

9 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
10 738(c) of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 379j(c)) is amended—

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

14 (2) in paragraph (2)—

15 (A) in subparagraph (A), by striking
16 “2018” and inserting “2023”;

17 (B) in subparagraph (B)—

18 (i) in the matter preceding clause (i),
19 by striking “fiscal year 2018” and insert-
20 ing “fiscal year 2023”; and

21 (ii) in clause (ii), by striking “fiscal
22 year 2016” and inserting “fiscal year
23 2022”;

24 (C) in subparagraph (C), by striking
25 “Washington-Baltimore, DC–MD–VA–WV”

1 and inserting “Washington-Arlington-Alexan-
2 dria, DC–VA–MD–WV”.

3 (D) in subparagraph (D), in the matter
4 preceding clause (i), by striking “fiscal years
5 2018 through 2022” and inserting “fiscal years
6 2023 through 2027”;

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

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

11 (5) by inserting after paragraph (3) the fol-
12 lowing:

13 “(4) PERFORMANCE IMPROVEMENT ADJUST-
14 MENT.—

15 “(A) IN GENERAL.—For each of fiscal
16 years 2025 through 2027, after the adjust-
17 ments under paragraphs (2) and (3), the base
18 establishment registration fee amounts for such
19 fiscal year shall be increased to reflect changes
20 in the resource needs of the Secretary due to
21 improved review performance goals for the proc-
22 ess for the review of device applications identi-
23 fied in the letters described in section 201(b) of
24 the Medical Device User Fee Amendments of
25 2022, as the Secretary determines necessary to

1 achieve an increase in total fee collections for
2 such fiscal year equal to the following amounts:

3 “(i) For fiscal year 2025, the product
4 of—

5 “(I) the amount determined
6 under subparagraph (B)(i)(I); and

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

10 “(ii) For fiscal year 2026, the product
11 of—

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

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

19 “(iii) For fiscal year 2027, the prod-
20 uct of—

21 “(I) the sum of the amounts de-
22 termined under subparagraphs
23 (B)(i)(III), (B)(ii)(II), and
24 (B)(iii)(II); and

1 “(II) the applicable inflation ad-
2 justment under paragraph (2)(B) for
3 such fiscal year.

4 “(B) AMOUNTS.—

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

10 “(I) For fiscal year 2025,
11 \$15,396,600 if such goal for fiscal
12 year 2023 is met.

13 “(II) For fiscal year 2026:

14 “(aa) \$15,396,600 if such
15 goal for fiscal year 2023 is met
16 and such goal for fiscal year
17 2024 is not met.

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

20 “(III) For fiscal year 2027:

21 “(aa) \$15,396,600 if such
22 goal for fiscal year 2023 is met
23 and such goal for each of fiscal
24 years 2024 and 2025 is not met.

1 “(bb) \$36,792,200 if such
2 goal for fiscal year 2024 is met
3 and such goal for fiscal year
4 2025 is not met.

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

7 “(ii) DE NOVO CLASSIFICATION
8 AMOUNT.—For purposes of subparagraph
9 (A), with respect to the de novo decision
10 goal, the amounts determined under this
11 subparagraph are as follows:

12 “(I) For fiscal year 2026,
13 \$6,323,500 if such goal for fiscal year
14 2023 is met.

15 “(II) For fiscal year 2027—

16 “(aa) \$6,323,500 if such
17 goal for fiscal year 2023 is met
18 and such goal for fiscal year
19 2024 is not met.

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

22 “(iii) PREMARKET NOTIFICATION AND
23 PREMARKET APPROVAL AMOUNT.—For
24 purposes of subparagraph (A), with respect
25 to the 510(k) decision goal, 510(k) shared

1 outcome total time to decision goal, PMA
2 decision goal, and PMA shared outcome
3 total time to decision goal, the amounts de-
4 termined under this subparagraph are as
5 follows:

6 “(I) For fiscal year 2026,
7 \$1,020,000 if the four goals for fiscal
8 year 2023 are met.

9 “(II) For fiscal year 2027:

10 “(aa) \$1,020,000 if the four
11 goals for fiscal year 2023 are met
12 and one or more of the four goals
13 for fiscal year 2024 is not met.

14 “(bb) \$3,906,000 if the four
15 goals for fiscal year 2024 are
16 met.

17 “(C) PERFORMANCE CALCULATION.—For
18 purposes of this paragraph, performance of the
19 goals listed in subparagraph (D) shall be deter-
20 mined as specified in the letters described in
21 section 201(b) of the Medical Device User Fee
22 Amendments of 2022 and based on data avail-
23 able as of the following dates:

1 “(i) The performance of the pre-sub-
2 mission written feedback goal shall be
3 based on data available as of—

4 “(I) for fiscal year 2023, March
5 31, 2024;

6 “(II) for fiscal year 2024, March
7 31, 2025; and

8 “(III) for fiscal year 2025,
9 March 31, 2026.

10 “(ii) The performance of the de novo
11 decision goal, 510(k) decision goal, 510(k)
12 shared outcome total time to decision goal,
13 PMA decision goal, and PMA shared out-
14 come total time to decision goal shall be
15 based on data available as of—

16 “(I) for fiscal year 2023, March
17 31, 2025; and

18 “(II) for fiscal year 2024, March
19 31, 2026.

20 “(D) GOALS DEFINED.—For purposes of
21 this paragraph, the terms ‘pre-submission writ-
22 ten feedback goal’, ‘de novo decision goal’,
23 ‘510(k) decision goal’, ‘510(k) shared outcome
24 total time to decision goal’, ‘PMA decision
25 goal’, and ‘PMA shared outcome total time to

1 decision goal’ refer to the goals identified by the
2 same names in the letters described in section
3 201(b) of the Medical Device User Fee Amend-
4 ments of 2022.

5 “(5) HIRING ADJUSTMENT.—

6 “(A) IN GENERAL.—For each of fiscal
7 years 2025 through 2027, after the adjust-
8 ments under paragraphs (2), (3), and (4), if ap-
9 plicable, if the number of hires to support the
10 process for the review of device applications
11 falls below the thresholds specified in subpara-
12 graph (B) for the applicable fiscal years, the
13 base establishment registration fee amounts
14 shall be decreased as the Secretary determines
15 necessary to achieve a reduction in total fee col-
16 lections equal to the hiring adjustment amount
17 under subparagraph (C).

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

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

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

24 “(iii) For fiscal year 2027, the thresh-
25 old is—

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

6 “(II) 75 hires for fiscal year
7 2025 if such fees are so increased.

8 “(C) HIRING ADJUSTMENT AMOUNT.—The
9 hiring adjustment amount for fiscal year 2025
10 and each subsequent fiscal year is the product
11 of—

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

16 “(ii) \$72,877; and

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

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

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

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

25 “(iii) For fiscal year 2025:

1 “(I) 24 hires if the base estab-
2 lishment registration fees are not in-
3 creased by the amount determined
4 under paragraph (4)(A)(i).

5 “(II) 83 hires if the base estab-
6 lishment registration fees are in-
7 creased by the amount determined
8 under paragraph (4)(A)(i).

9 “(E) NUMBER OF HIRES.—For purposes
10 of this paragraph, the number of hires shall be
11 determined by the Secretary as set forth in the
12 letters described in section 201(b) of the Med-
13 ical Device User Fee Amendments of 2022.

14 “(6) OPERATING RESERVE ADJUSTMENT.—

15 “(A) IN GENERAL.—For each of fiscal
16 years 2023 through 2027, after the adjust-
17 ments under paragraphs (2), (3), (4), and (5),
18 if applicable, if the Secretary has operating re-
19 serves of carryover user fees for the process for
20 the review of device applications in excess of the
21 designated amount in subparagraph (B), the
22 Secretary shall decrease the base establishment
23 registration fee amounts to provide for not
24 more than such designated amount of operating
25 reserves.

1 “(B) DESIGNATED AMOUNT.—Subject to
2 subparagraph (C), for each fiscal year, the des-
3 ignated amount in this subparagraph is equal
4 to the sum of—

5 “(i) 13 weeks of operating reserves of
6 carryover user fees; and

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

9 “(C) EXCLUDED AMOUNT.—For the period
10 of fiscal years 2023 through 2026, a total
11 amount equal to \$118,000,000 shall not be con-
12 sidered part of the designated amount under
13 subparagraph (B) and shall not be subject to
14 the decrease under subparagraph (A).”.

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

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

23 (1) in paragraph (1)(A), by striking
24 “\$320,825,000” and inserting “\$398,566,000”; and

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

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

6 “(3) AUTHORIZATION OF APPROPRIATIONS.—

7 “(A) IN GENERAL.—For each of fiscal
8 years 2023 through 2027, there is authorized to
9 be appropriated for fees under this section an
10 amount equal to the revenue amount deter-
11 mined under subparagraph (B), less the
12 amount of reductions determined under sub-
13 paragraph (C).

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

17 “(i) the total revenue amount under
18 subsection (b)(3) for the fiscal year, as ad-
19 justed under paragraphs (2) and (3) of
20 subsection (c); and

21 “(ii) the performance improvement
22 adjustment amount for the fiscal year
23 under subsection (c)(4), if applicable.

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

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

7 “(ii) the operating reserve adjustment
8 amount for the fiscal year under sub-
9 section (c)(6), if applicable.”.

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

11 (a) PERFORMANCE REPORTS.—Section 738A(a) of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 379j–1(a)) is amended—

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

16 (2) by striking “Medical Device User Fee
17 Amendments of 2017” each place it appears and in-
18 serting “Medical Device User Fee Amendments of
19 2022”;

20 (3) in paragraph (1)—

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

1 (B) in subparagraph (A)(iv), by striking
2 “fiscal year 2020” and inserting “fiscal year
3 2023”; and

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

6 (b) REAUTHORIZATION.—Section 738A(b) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
8 1(b)) is amended—

9 (1) in paragraph (1), by striking “2022” and
10 inserting “2027”; and

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

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

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

17 “(d) ACCREDITATION SCHEME FOR CONFORMITY AS-
18 SESSMENT.—

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

21 “(A) testing laboratories meeting criteria
22 specified in guidance by the Secretary may be
23 accredited by accreditation bodies meeting cri-
24 teria specified in guidance by the Secretary, to
25 conduct testing to support the assessment of

1 the conformity of a device to certain standards
2 recognized under this section; and

3 “(B) subject to paragraph (2), results
4 from tests conducted to support the assessment
5 of conformity of devices as described in sub-
6 paragraph (A) conducted by testing laboratories
7 accredited pursuant to this subsection shall be
8 accepted by the Secretary for purposes of dem-
9 onstrating such conformity unless the Secretary
10 finds that certain results of such tests should
11 not be so accepted.

12 “(2) SECRETARIAL REVIEW OF ACCREDITED
13 LABORATORY RESULTS.—The Secretary may—

14 “(A) review the results of tests conducted
15 by testing laboratories accredited pursuant to
16 this subsection, including by conducting peri-
17 odic audits of such results or of the processes
18 of accredited bodies or testing laboratories;

19 “(B) following such review, take additional
20 measures under this Act, as the Secretary de-
21 termines appropriate, such as—

22 “(i) suspension or withdrawal of ac-
23 creditation of a testing laboratory or rec-
24 ognition of an accreditation body under
25 paragraph (1)(A); or

1 “(ii) requesting additional information
2 with respect to a device; and

3 “(C) if the Secretary becomes aware of in-
4 formation materially bearing on the safety or
5 effectiveness of a device for which an assess-
6 ment of conformity was supported by testing
7 conducted by a testing laboratory accredited
8 under this subsection, take such additional
9 measures under this Act, as the Secretary de-
10 termines appropriate, such as—

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

15 “(ii) requesting additional information
16 with regard to such device.

17 “(3) IMPLEMENTATION AND REPORTING.—

18 “(A) PILOT PROGRAM TRANSITION.—After
19 September 30, 2023, the pilot program pre-
20 viously initiated under this subsection, as in ef-
21 fect prior to the date of enactment of the Med-
22 ical Device User Fee Amendments of 2022,
23 shall be considered to be completed, and the
24 Secretary may continue operating a program
25 consistent with this subsection.

1 “(B) REPORT.—The Secretary shall make
2 available on the internet website of the Food
3 and Drug Administration an annual report on
4 the progress of the pilot program under this
5 subsection.”.

6 **SEC. 206. REAUTHORIZATION OF THIRD-PARTY REVIEW**
7 **PROGRAM.**

8 Section 523(c) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 360m(c)) is amended by striking
10 “2022” and inserting “2027”.

11 **SEC. 207. SAVINGS CLAUSE.**

12 Notwithstanding the amendments made by this title,
13 part 3 of subchapter C of chapter VII of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
15 effect on the day before the date of the enactment of this
16 title, shall continue to be in effect with respect to the sub-
17 missions listed in section 738(a)(2)(A) of such Act (as de-
18 fined in such part as of such day) that on or after October
19 1, 2017, but before October 1, 2022, were received by the
20 Food and Drug Administration with respect to assessing
21 and collecting any fee required by such part for a fiscal
22 year prior to fiscal year 2023.

23 **SEC. 208. EFFECTIVE DATE.**

24 The amendments made by this title shall take effect
25 on October 1, 2022, or the date of the enactment of this

1 Act, whichever is later, except that fees under part 3 of
2 subchapter C of chapter VII of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 379i et seq.) shall be as-
4 sessed for all submissions listed in section 738(a)(2)(A)
5 of such Act received on or after October 1, 2022, regard-
6 less of the date of the enactment of this Act.

7 **SEC. 209. SUNSET DATES.**

8 (a) **AUTHORIZATION.**—Sections 737 and 738 of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;
10 739j) shall cease to be effective October 1, 2027.

11 (b) **REPORTING REQUIREMENTS.**—Section 738A (21
12 U.S.C. 739j– 1) of the Federal Food, Drug, and Cosmetic
13 Act (regarding reauthorization and reporting require-
14 ments) shall cease to be effective January 31, 2028.

15 (c) **PREVIOUS SUNSET PROVISIONS.**—Effective Octo-
16 ber 1, 2022, subsections (a) and (b) of section 210 of the
17 FDA Reauthorization Act of 2017 (Public Law 115–52)
18 are repealed.

19 **TITLE III—FEES RELATING TO**
20 **GENERIC DRUGS**

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

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

24 (b) **FINDING.**—The Congress finds that the fees au-
25 thorized by the amendments made in this title will be dedi-

1 cated to human generic drug activities, as set forth in the
2 goals identified for purposes of part 7 of subchapter C
3 of chapter VII of the Federal Food, Drug, and Cosmetic
4 Act, in the letters from the Secretary of Health and
5 Human Services to the Chairman of the Committee on
6 Health, Education, Labor, and Pensions of the Senate and
7 the Chairman of the Committee on Energy and Commerce
8 of the House of Representatives, as set forth in the Con-
9 gressional Record.

10 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
11 **NERIC DRUG FEES.**

12 (a) TYPES OF FEES.—Section 744B(a) of the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
14 42(a)) is amended—

15 (1) in the matter preceding paragraph (1), by
16 striking “fiscal year 2018” and inserting “fiscal year
17 2023”;

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

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

22 (4) in paragraph (4)(D), by striking “2018
23 through 2022” and inserting “2023 through 2027”;

24 and

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

3 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 379j–42(b)) is amended—

6 (1) in paragraph (1)—

7 (A) in subparagraph (A)—

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

10 (ii) by striking “2018” and inserting
11 “2023”; and

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

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

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

17 “(i) IN GENERAL.—For each of the
18 fiscal years 2024 through 2027, fees under
19 paragraphs (2) through (5) of subsection
20 (a) shall be established to generate a total
21 estimated revenue amount under such sub-
22 section that is equal to the base revenue
23 amount for the fiscal year under clause
24 (ii), as adjusted pursuant to subsection (c).

1 “(ii) BASE REVENUE AMOUNT.—The
2 base revenue amount for a fiscal year re-
3 ferred to in clause (i) is equal to the total
4 revenue amount established under this
5 paragraph for the previous fiscal year, not
6 including any adjustments made for such
7 previous fiscal year under subsection
8 (c)(3).”; and

9 (2) in paragraph (2)—

10 (A) in subparagraph (C), by striking “one-
11 third the amount” and inserting “twenty-four
12 percent”;

13 (B) in subparagraph (D), by striking
14 “Seven percent” and inserting “Six percent”;
15 and

16 (C) in subparagraph (E)(i), by striking
17 “Thirty-five percent” and inserting “Thirty-six
18 percent”.

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

22 (1) in paragraph (1)—

23 (A) in the matter preceding subparagraph

24 (A)—

1 (i) by striking “2019” and inserting
2 “2024”; and

3 (ii) by striking “to equal the product
4 of the total revenues established in such
5 notice for the prior fiscal year multiplied”
6 and inserting “to equal the base revenue
7 amount for the fiscal year (as specified in
8 subsection (b)(1)(B)) multiplied”; and

9 (B) in subparagraph (C), by striking
10 “Washington-Baltimore, DC–MD–VA–WV”
11 and inserting “Washington-Arlington-Alexan-
12 dria, DC–VA–MD–WV”; and

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

15 “(2) CAPACITY PLANNING ADJUSTMENT.—

16 “(A) IN GENERAL.—Beginning with fiscal
17 year 2024, the Secretary shall, in addition to
18 the adjustment under paragraph (1), further in-
19 crease the fee revenue and fees under this sec-
20 tion for a fiscal year, in accordance with this
21 paragraph, to reflect changes in the resource
22 capacity needs of the Secretary for human ge-
23 neric drug activities.

24 “(B) CAPACITY PLANNING METHOD-
25 OLOGY.—The Secretary shall establish a capaci-

1 ity planning methodology for purposes of this
2 paragraph, which shall—

3 “(i) be derived from the methodology
4 and recommendations made in the report
5 titled ‘Independent Evaluation of the
6 GDUFA Resource Capacity Planning Ad-
7 justment Methodology: Evaluation and
8 Recommendations’ announced in the Fed-
9 eral Register on August 3, 2020;

10 “(ii) incorporate approaches and at-
11 tributes determined appropriate by the
12 Secretary, including approaches and at-
13 tributes made in such report, except that
14 in incorporating such approaches and at-
15 tributes the workload categories used in
16 forecasting resources shall only be the
17 workload categories specified in section
18 VIII.B.2.e. of the letters described in sec-
19 tion 301(b) of the Generic Drug User Fee
20 Amendments of 2022; and

21 “(iii) be effective beginning with fiscal
22 year 2024.

23 “(C) LIMITATIONS.—

24 “(i) IN GENERAL.—Under no cir-
25 cumstances shall an adjustment under this

1 paragraph result in fee revenue for a fiscal
2 year that is less than the sum of the
3 amounts under subsection (b)(1)(B)(ii)
4 (the base revenue amount for the fiscal
5 year) and paragraph (1) (the dollar
6 amount of the inflation adjustment for the
7 fiscal year).

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

13 “(I) for purposes of a fiscal year
14 2024 adjustment, the Secretary deter-
15 mines that during the period from
16 April 1, 2021, through March 31,
17 2023—

18 “(aa) the total number of
19 abbreviated new drug applica-
20 tions submitted was greater than
21 or equal to 2,000; or

22 “(bb) thirty-five percent or
23 more of abbreviated new drug ap-
24 plications submitted related to
25 complex products (as that term is

1 defined in section XI of the let-
2 ters described in section 301(b)
3 of the Generic Drug User Fee
4 Amendments of 2022);

5 “(II) for purposes of a fiscal year
6 2025 adjustment, the Secretary deter-
7 mines that during the period from
8 April 1, 2022, through March 31,
9 2024—

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

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

18 “(III) for purposes of a fiscal
19 year 2026 adjustment, the Secretary
20 determines that during the period
21 from April 1, 2023, through March
22 31, 2025—

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 and

8 “(IV) for purposes of a fiscal
9 year 2027 adjustment, the Secretary
10 determines that during the period
11 from April 1, 2024, through March
12 31, 2026—

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

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

21 “(D) PUBLICATION IN FEDERAL REG-
22 ISTER.—The Secretary shall publish in the Fed-
23 eral Register notice referred to in subsection (a)
24 the fee revenue and fees resulting from the ad-

1 justment and the methodology under this para-
2 graph.

3 “(3) OPERATING RESERVE ADJUSTMENT.—

4 “(A) IN GENERAL.—For fiscal year 2024
5 and each subsequent fiscal year, the Secretary
6 may, in addition to adjustments under para-
7 graphs (1) and (2), further increase the fee rev-
8 enue and fees under this section for such fiscal
9 year if such an adjustment is necessary to pro-
10 vide operating reserves of carryover user fees
11 for human generic drug activities for not more
12 than the number of weeks specified in subpara-
13 graph (B) with respect to that fiscal year.

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

16 “(i) 8 weeks for fiscal year 2024;

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

18 “(iii) 10 weeks for each of fiscal year
19 2026 and 2027.

20 “(C) DECREASE.—If the Secretary has
21 carryover balances for human generic drug ac-
22 tivities in excess of 12 weeks of the operating
23 reserves referred to in subparagraph (A), the
24 Secretary shall decrease the fee revenue and
25 fees referred to in such subparagraph to provide

1 for not more than 12 weeks of such operating
2 reserves.

3 “(D) RATIONALE FOR ADJUSTMENT.—If
4 an adjustment under this paragraph is made,
5 the rationale for the amount of the increase or
6 decrease (as applicable) in fee revenue and fees
7 shall be contained in the annual Federal Reg-
8 ister notice under subsection (a) publishing the
9 fee revenue and fees for the fiscal year in-
10 volved.”.

11 (d) ANNUAL FEE SETTING.—Section 744B(d)(1) of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 379j–42(d)(1)) is amended—

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

17 (2) by striking “more than 60 days before the
18 first day of each of fiscal years 2018 through 2022”
19 and inserting “later than 60 days before the first
20 day of each of fiscal years 2023 through 2027”.

21 (e) CREDITING AND AVAILABILITY OF FEES.—Sec-
22 tion 744B(i)(3) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 379j–42(i)(3)) is amended by striking “fis-
24 cal years 2018 through 2022” and inserting “fiscal years
25 2023 through 2027”.

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

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

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

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

11 (2) by striking “Generic Drug User Fee
12 Amendments of 2017” each place it appears and in-
13 serting “Generic Drug User Fee Amendments of
14 2022”;

15 (3) in subsection (a)(2), by striking “Not later
16 than 30 calendar days after the end of the second
17 quarter of fiscal year 2018, and not later than 30
18 calendar days after the end of each quarter of each
19 fiscal year thereafter” and inserting “Not later than
20 30 calendar days after the end of each quarter of
21 each fiscal year for which fees are collected under
22 this part”;

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

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

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

5 (7) in subsection (f)—

6 (A) in paragraph (1), in the matter pre-
7 ceding subparagraph (A), by striking “fiscal
8 year 2022” and inserting “fiscal year 2027”;
9 and

10 (B) in paragraph (5), by striking “January
11 15, 2022” and inserting “January 15, 2027”.

12 **SEC. 304. SUNSET DATES.**

13 (a) AUTHORIZATION.—Sections 744A and 744B of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 379j–41; 379j–42) shall cease to be effective October 1,
16 2027.

17 (b) REPORTING REQUIREMENTS.—Section 744C of
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 379j–43) shall cease to be effective January 31, 2028.

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

1 **SEC. 305. EFFECTIVE DATE.**

2 The amendments made by this title shall take effect
3 on October 1, 2022, or the date of the enactment of this
4 Act, whichever is later, except that fees under part 7 of
5 subchapter C of chapter VII of the Federal Food, Drug,
6 and Cosmetic Act shall be assessed for all abbreviated new
7 drug applications received on or after October 1, 2022,
8 regardless of the date of the enactment of this Act.

9 **SEC. 306. SAVINGS CLAUSE.**

10 Notwithstanding the amendments made by this title,
11 part 7 of subchapter C of chapter VII of the Federal Food,
12 Drug, and Cosmetic Act, as in effect on the day before
13 the date of the enactment of this title, shall continue to
14 be in effect with respect to abbreviated new drug applica-
15 tions (as defined in such part as of such day) that were
16 received by the Food and Drug Administration within the
17 meaning of section 505(j)(5)(A) of such Act (21 U.S.C.
18 355(j)(5)(A)), prior approval supplements that were sub-
19 mitted, and drug master files for Type II active pharma-
20 ceutical ingredients that were first referenced on or after
21 October 1, 2017, but before October 1, 2022, with respect
22 to assessing and collecting any fee required by such part
23 for a fiscal year prior to fiscal year 2023.

1 **TITLE IV—FEES RELATING TO**
2 **BIOSIMILAR BIOLOGICAL**
3 **PRODUCTS**

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

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

7 (b) **FINDING.**—The Congress finds that the fees au-
8 thorized by the amendments made in this title will be dedi-
9 cated to expediting the process for the review of biosimilar
10 biological product applications, including postmarket safe-
11 ty activities, as set forth in the goals identified for pur-
12 poses of part 8 of subchapter C of chapter VII of the Fed-
13 eral Food, Drug, and Cosmetic Act, in the letters from
14 the Secretary of Health and Human Services to the Chair-
15 man of the Committee on Health, Education, Labor, and
16 Pensions of the Senate and the Chairman of the Com-
17 mittee on Energy and Commerce of the House of Rep-
18 resentatives, as set forth in the Congressional Record.

19 **SEC. 402. DEFINITIONS.**

20 (a) **ADJUSTMENT FACTOR.**—Section 744G(1) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
22 51(1)) is amended to read as follows:

23 “(1) The term ‘adjustment factor’ applicable to
24 a fiscal year is the Consumer Price Index for urban
25 consumers (Washington-Arlington-Alexandria, DC–

1 VA–MD–WV; Not Seasonally Adjusted; All items;
2 Annual Index) for September of the preceding fiscal
3 year divided by such Index for September 2011.”.

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

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

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

12 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
13 **FEEES.**

14 (a) TYPES OF FEES.—

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

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

1 (3) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT
2 DEVELOPMENT FEE.—Section 744H(a)(1)(B) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–52(a)(1)(B)) is amended—

5 (A) in clause (i), by inserting before the
6 period at the end the following: “, except where
7 such product (including, where applicable, own-
8 ership of the relevant investigational new drug
9 application) is transferred to a licensee, as-
10 signee, or successor of such person, and written
11 notice of such transfer is provided to the Sec-
12 retary, in which case such licensee, assignee, or
13 successor shall pay the annual biosimilar bio-
14 logical product development fee”;

15 (B) in clause (iii)—

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

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

20 (iii) by adding at the end the fol-
21 lowing:

22 “(III) been administratively re-
23 moved from the biosimilar biological
24 product development program for the

1 product under subparagraph (E)(v).”;

2 and

3 (C) in clause (iv), by striking “is accepted
4 for filing on or after October 1 of such fiscal
5 year” and inserting “is subsequently accepted
6 for filing”.

7 (4) REACTIVATION FEE.—Section
8 744H(a)(1)(D) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 379j–52(a)(1)(D)) is amended
10 to read as follows:

11 “(D) REACTIVATION FEE.—

12 “(i) IN GENERAL.—A person that has
13 discontinued participation in the biosimilar
14 biological product development program for
15 a product under subparagraph (C), or who
16 has been administratively removed from
17 the biosimilar biological product develop-
18 ment program for a product under sub-
19 paragraph (E)(v), shall, if the person seeks
20 to resume participation in such program,
21 pay all annual biosimilar biological product
22 development fees previously assessed for
23 such product and still owed and a fee (re-
24 ferred to in this section as ‘reactivation
25 fee’) by the earlier of the following:

1 “(I) Not later than 7 days after
2 the Secretary grants a request by
3 such person for a biosimilar biological
4 product development meeting for the
5 product (after the date on which such
6 participation was discontinued or the
7 date of administrative removal, as ap-
8 plicable).

9 “(II) Upon the date of submis-
10 sion (after the date on which such
11 participation was discontinued or the
12 date of administrative removal, as ap-
13 plicable) by such person of an inves-
14 tigational new drug application de-
15 scribing an investigation that the Sec-
16 retary determines is intended to sup-
17 port a biosimilar biological product
18 application for that product.

19 “(ii) APPLICATION OF ANNUAL
20 FEE.—A person that pays a reactivation
21 fee for a product shall pay for such prod-
22 uct, beginning in the next fiscal year, the
23 annual biosimilar biological product devel-
24 opment fee under subparagraph (B), ex-
25 cept where such product (including, where

1 applicable, ownership of the relevant inves-
2 tigational new drug application) is trans-
3 ferred to a licensee, assignee, or successor
4 of such person, and written notice of such
5 transfer is provided to the Secretary, in
6 which case such licensee, assignee, or suc-
7 cessor shall pay the annual biosimilar bio-
8 logical product development fee.”.

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

13 “(v) ADMINISTRATIVE REMOVAL FROM
14 THE BIOSIMILAR BIOLOGICAL PRODUCT
15 DEVELOPMENT PROGRAM.—If a person has
16 failed to pay an annual biosimilar biologi-
17 cal product development fee for a product
18 as required under subparagraph (B) for a
19 period of two consecutive fiscal years, the
20 Secretary may administratively remove
21 such person from the biosimilar biological
22 product development program for the prod-
23 uct. At least 30 days prior to administra-
24 tively removing a person from the bio-
25 similar biological product development pro-

1 gram for a product under this clause, the
2 Secretary shall provide written notice to
3 such person of the intended administrative
4 removal.”.

5 (6) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
6 TION FEE.—Section 744H(a)(2)(D) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
8 52(a)(2)(D)) is amended by inserting after “or was
9 withdrawn” the following: “prior to approval”.

10 (7) BIOSIMILAR BIOLOGICAL PRODUCT PRO-
11 GRAM FEE.—Section 744H(a)(3) of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
13 52(a)(3)) is amended—

14 (A) in subparagraph (A)—

15 (i) in clause (i), by striking “and” at
16 the end;

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

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

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

23 and

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

1 “(E) MOVEMENT TO DISCONTINUED
2 LIST.—

3 “(i) DATE OF INCLUSION.—If a writ-
4 ten request to place a product on the list
5 referenced in subparagraph (A) of discon-
6 tinued biosimilar biological products is sub-
7 mitted to the Secretary on behalf of an ap-
8 plicant, and the request identifies the date
9 the product is withdrawn from sale, then
10 for purposes of assessing the biosimilar bi-
11 ological product program fee, the Secretary
12 shall consider such product to have been
13 included on such list on the later of—

14 “(I) the date such request was
15 received; or

16 “(II) if the product will be with-
17 drawn from sale on a future date,
18 such future date when the product is
19 withdrawn from sale.

20 “(ii) TREATMENT AS WITHDRAWN
21 FROM SALE.—For purposes of clause (i), a
22 product shall be considered withdrawn
23 from sale once the applicant has ceased its
24 own distribution of the product, whether or
25 not the applicant has ordered recall of all

1 previously distributed lots of the product,
2 except that a routine, temporary interrup-
3 tion in supply shall not render a product
4 withdrawn from sale.

5 “(iii) SPECIAL RULE.—If a biosimilar
6 biological product that is identified in a
7 biosimilar biological product application
8 approved as of October 1 of a fiscal year
9 appears, as of October 1 of such fiscal
10 year, on the list referenced in subpara-
11 graph (A) of discontinued biosimilar bio-
12 logical products, and on any subsequent
13 day during such fiscal year the biosimilar
14 biological product does not appear on such
15 list, then except as provided in subpara-
16 graph (D), each person who is named as
17 the applicant in a biosimilar biological
18 product application with respect to such
19 product shall pay the annual biosimilar bi-
20 ological product program fee established
21 for a fiscal year under subsection (c)(5) for
22 such biosimilar biological product. Not-
23 withstanding subparagraph (B), such fee
24 shall be due on the last business day of
25 such fiscal year and shall be paid only once

1 for each such product for each fiscal
2 year.”.

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

7 (c) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
8 tion 744H of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 379j–52) is amended—

10 (1) by striking paragraph (1);

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

13 (3) by amending paragraph (1) (as so redesign-
14 ated) to read as follows:

15 “(1) IN GENERAL.—For each of the fiscal years
16 2023 through 2027, fees under subsection (a) shall,
17 except as provided in subsection (c), be established
18 to generate a total revenue amount equal to the sum
19 of—

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

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

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

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

7 “(E) the dollar amount equal to the oper-
8 ating reserve adjustment for the fiscal year, if
9 applicable (as determined under subsection
10 (c)(4));

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

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

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

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

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

19 (C) by redesignating subparagraphs (C)
20 and (D) as subparagraphs (B) and (C), respec-
21 tively; and

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

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

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

6 “(B) for fiscal years 2024 through 2027,
7 the dollar amount of the total revenue amount
8 established under paragraph (1) for the pre-
9 vious fiscal year, excluding any adjustments to
10 such revenue amount under subsection (c)(4).”.

11 (d) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
12 744H(c) of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 379j–52(c)) is amended—

14 (1) in paragraph (1)—

15 (A) in subparagraph (A)—

16 (i) in the matter preceding clause (i),
17 by striking “subsection (b)(2)(B)” and in-
18 serting “subsection (b)(1)(B)”; and

19 (ii) in clause (i), by striking “sub-
20 section (b)” and inserting “subsection
21 (b)(1)(A)”; and

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

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

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

9 “(3) CAPACITY PLANNING ADJUSTMENT.—

10 “(A) IN GENERAL.—For each fiscal year,
11 the Secretary shall, in addition to the adjust-
12 ments under paragraphs (1) and (2), further
13 adjust the fee revenue and fees under this sec-
14 tion for a fiscal year to reflect changes in the
15 resource capacity needs of the Secretary for the
16 process for the review of biosimilar biological
17 product applications.

18 “(B) METHODOLOGY.— For purposes of
19 this paragraph, the Secretary shall employ the
20 capacity planning methodology utilized by the
21 Secretary in setting fees for fiscal year 2021, as
22 described in the notice titled ‘Biosimilar User
23 Fee Rates for Fiscal Year 2021’ published in
24 the Federal Register on August 4, 2020 (85
25 Fed. Reg. 47220). The workload categories

1 used in applying such methodology in fore-
2 casting shall include only the activities de-
3 scribed in that notice and, as feasible, addi-
4 tional activities that are also directly related to
5 the direct review of biosimilar biological product
6 applications and supplements, including addi-
7 tional formal meeting types, the direct review of
8 postmarketing commitments and requirements,
9 the direct review of risk evaluation and mitiga-
10 tion strategies, and the direct review of annual
11 reports for approved biosimilar biological prod-
12 ucts. Subject to the exceptions in the preceding
13 sentence, the Secretary shall not include as
14 workload categories in applying such method-
15 ology in forecasting any non-core review activi-
16 ties, including those activities that the Sec-
17 retary referenced for potential future use in
18 such notice but did not utilize in setting fees for
19 fiscal year 2021.

20 “(C) LIMITATIONS.—Under no cir-
21 cumstances shall an adjustment under this
22 paragraph result in fee revenue for a fiscal year
23 that is less than the sum of the amounts under
24 subsections (b)(1)(A)(the annual base revenue
25 for the fiscal year), (b)(1)(B) (the dollar

1 amount of the inflation adjustment for the fis-
2 cal year), and (b)(1)(C) (the dollar amount of
3 the strategic hiring and retention adjustment).

4 “(D) PUBLICATION IN FEDERAL REG-
5 ISTER.—The Secretary shall publish in the Fed-
6 eral Register notice under paragraph (5) the fee
7 revenue and fees resulting from the adjustment
8 and the methodologies under this paragraph.

9 “(4) OPERATING RESERVE ADJUSTMENT.—

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

19 “(B) DECREASE.—

20 “(i) FISCAL YEAR 2023.—For fiscal
21 year 2023, if the Secretary has carryover
22 balances for such process in excess of 33
23 weeks of such operating reserves, the Sec-
24 retary shall decrease such fee revenue and

1 fees to provide for not more than 33 weeks
2 of such operating reserves.

3 “(ii) FISCAL YEAR 2024.—For fiscal
4 year 2024, if the Secretary has carryover
5 balances for such process in excess of 27
6 weeks of such operating reserves, the Sec-
7 retary shall decrease such fee revenue and
8 fees to provide for not more than 27 weeks
9 of such operating reserves.

10 “(iii) FISCAL YEAR 2025 AND SUBSE-
11 QUENT FISCAL YEARS.—For fiscal year
12 2025 and subsequent fiscal years, if the
13 Secretary has carryover balances for such
14 process in excess of 21 weeks of such oper-
15 ating reserves, the Secretary shall decrease
16 such fee revenue and fees to provide for
17 not more than 21 weeks of such operating
18 reserves.

19 “(C) FEDERAL REGISTER NOTICE.—If an
20 adjustment under subparagraph (A) or (B) is
21 made, the rationale for the amount of the in-
22 crease or decrease in fee revenue and fees shall
23 be contained in the annual Federal Register no-
24 tice under paragraph (5)(B) establishing fee

1 revenue and fees for the fiscal year involved.”;

2 and

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

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

11 (f) WRITTEN REQUESTS FOR WAIVERS AND RE-
12 TURNS; DISPUTES CONCERNING FEES.—Section 744H(h)
13 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 379j–52(h)) is amended to read as follows:

15 “(h) WRITTEN REQUESTS FOR WAIVERS AND RE-
16 TURNS; DISPUTES CONCERNING FEES.—To qualify for
17 consideration for a waiver under subsection (d), or for the
18 return of any fee paid under this section, including if the
19 fee is claimed to have been paid in error, a person shall
20 submit to the Secretary a written request justifying such
21 waiver or return and, except as otherwise specified in this
22 section, such written request shall be submitted to the Sec-
23 retary not later than 180 days after such fee is due. A
24 request submitted under this paragraph shall include any
25 legal authorities under which the request is made.”.

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

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

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

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

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

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

19 (5) in subsection (b), by striking “Not later
20 than 120 days after the end of fiscal year 2018 and
21 each subsequent fiscal year for which fees are col-
22 lected under this part” and inserting “Not later
23 than 120 days after the end of each fiscal year for
24 which fees are collected under this part”;

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

4 (7) in subsection (f)—

5 (A) in paragraph (1), in the matter pre-
6 ceding subparagraph (A), by striking “fiscal
7 year 2022” and inserting “fiscal year 2027”;
8 and

9 (B) in paragraph (3), by striking “January
10 15, 2022” and inserting “January 15, 2027”.

11 **SEC. 405. SUNSET DATES.**

12 (a) AUTHORIZATION.—Sections 744G and 744H of
13 the Federal Food, Drug, and Cosmetic Act shall cease to
14 be effective October 1, 2027.

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

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

22 **SEC. 406. EFFECTIVE DATE.**

23 The amendments made by this title shall take effect
24 on October 1, 2022, or the date of the enactment of this
25 Act, whichever is later, except that fees under part 8 of

1 subchapter C of chapter VII of the Federal Food, Drug,
2 and Cosmetic Act shall be assessed for all biosimilar bio-
3 logical product applications received on or after October
4 1, 2022, regardless of the date of the enactment of this
5 Act.

6 **SEC. 407. SAVINGS CLAUSE.**

7 Notwithstanding the amendments made by this title,
8 part 8 of subchapter C of chapter VII of the Federal Food,
9 Drug, and Cosmetic Act, as in effect on the day before
10 the date of the enactment of this title, shall continue to
11 be in effect with respect to biosimilar biological product
12 applications and supplements (as defined in such part as
13 of such day) that were accepted by the Food and Drug
14 Administration for filing on or after October 1, 2017, but
15 before October 1, 2022, with respect to assessing and col-
16 lecting any fee required by such part for a fiscal year prior
17 to fiscal year 2023.

18 **TITLE V—IMPROVING DIVERSITY**
19 **IN CLINICAL STUDIES**

20 **SEC. 501. DIVERSITY ACTION PLANS FOR CLINICAL STUD-**
21 **IES.**

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

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

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

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

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

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

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

19 “(D) The Secretary may waive the requirement in
20 subparagraph (A)—

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

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

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

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

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

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

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

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

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

19 “(i) an application in the form and manner
20 specified in the guidance required by section 524B;
21 and

22 “(ii) if submission of an application for an in-
23 vestigational device exemption is not required, sub-
24 mitted in the form, manner, and timeframe specified
25 in the guidance required by section 524B as soon as

1 practicable during device development, but no later
2 than one month prior to commencing enrollment for
3 a study.

4 “(D) The Secretary may waive the requirement in
5 subparagraph (A)—

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

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

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

15 **“SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR**
16 **CLINICAL STUDIES.**

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

19 “(1) the format and content of the diversity ac-
20 tion plans required by sections 505(i)(5) and
21 520(g)(9) of this Act, and section 351(a)(3) of the
22 Public Health Service Act, pertaining to the spon-
23 sor’s goals for clinical study enrollment,
24 disaggregated by age group, sex, race, geographic lo-

1 cation, socioeconomic status, and ethnicity, including
2 with respect to—

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

5 “(i) the estimated prevalence or inci-
6 dence in the United States of the disease
7 or condition for which the drug or device
8 is being developed or investigated, if such
9 estimated prevalence or incidence is known
10 or can be determined based on available
11 data;

12 “(ii) what is known about the disease
13 or condition for which the drug or device
14 is being developed or investigated;

15 “(iii) any relevant pharmacokinetic or
16 pharmacogenomic data;

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

20 “(I) demographic information, in-
21 cluding age group, sex, race, geo-
22 graphic location, socioeconomic status,
23 and ethnicity;

1 “(II) non-demographic factors,
2 including co-morbidities frequently af-
3 fecting the patient population; and

4 “(III) potential barriers to enroll-
5 ing diverse participants, such as pa-
6 tient population size, geographic loca-
7 tion, and socioeconomic status; and

8 “(v) any other data or information
9 relevant to selecting appropriate enroll-
10 ment goals, disaggregated by demographic
11 subgroup, such as the inclusion of preg-
12 nant and lactating women;

13 “(B) an explanation for how the sponsor
14 intends to meet such goals, including demo-
15 graphic-specific outreach and enrollment strate-
16 gies, study-site selection, clinical study inclusion
17 and exclusion practices, and any diversity train-
18 ing for study personnel; and

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

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

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

3 “(B) if the sponsor does not expect to meet
4 such goals—

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

8 “(ii) the sponsor’s reasons for why the
9 sponsor does not expect to meet such
10 goals.

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

12 “(1) not later than 12 months after the date of
13 enactment of this section, issue new draft guidance
14 or update existing draft guidance described in sub-
15 section (a); and

16 “(2) not later than 9 months after closing the
17 comment period on such draft guidance, finalize
18 such guidance.”.

19 (d) APPLICABILITY.—Sections 505(i)(5) and
20 520(g)(9) of the Federal Food, Drug, and Cosmetic Act,
21 and section 351(a)(3)(B) of the Public Health Service Act,
22 as added by subsections (a), (b), and (c) of this section,
23 apply only with respect to clinical investigations with re-
24 spect to which enrollment commences after the date that
25 is 180 days after the publication of final guidance under

1 section 524B(b)(2) of the Federal Food, Drug, and Cos-
2 metic Act, as added by subsection (d).

3 **SEC. 502. EVALUATION OF THE NEED FOR FDA AUTHORITY**
4 **TO MANDATE POSTAPPROVAL STUDIES OR**
5 **POSTMARKET SURVEILLANCE DUE TO INSUF-**
6 **FICIENT DEMOGRAPHIC SUBGROUP DATA.**

7 (a) IN GENERAL.—Not later than 2 years after the
8 date of publication of final guidance pursuant to section
9 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act,
10 as added by section 501(d) of this Act, the Secretary of
11 Health and Human Services shall commence an evaluation
12 to assess whether additions or changes to statutes or regu-
13 lations are warranted to ensure that sponsors conduct
14 post-approval studies or postmarket surveillance where—

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

19 (2) the Secretary has requested additional stud-
20 ies be conducted.

21 (b) DETERMINATION AND REPORTING.—Not later
22 than 180 days after the commencement of the evaluation
23 under subsection (a), the Secretary of Health and Human
24 Services shall submit a report to the Congress on the out-

1 come of the such evaluation, including any recommenda-
2 tions related to additional needed authorities.

3 **SEC. 503. PUBLIC WORKSHOPS TO ENHANCE CLINICAL**
4 **STUDY DIVERSITY.**

5 (a) IN GENERAL.—Not later than one year after the
6 date of enactment of this Act, the Secretary of Health and
7 Human Services, in consultation with drug sponsors, med-
8 ical device manufacturers, patients, and other stake-
9 holders, shall convene one or more public workshops to
10 solicit input from stakeholders on increasing the enroll-
11 ment of historically underrepresented populations in clin-
12 ical studies and encouraging clinical study participation
13 that reflects the prevalence of the disease or condition
14 among demographic subgroups, where appropriate, and
15 other topics, including—

16 (1) how and when to collect and present the
17 prevalence or incidence data on a disease or condi-
18 tion by demographic subgroup, including possible
19 sources for such data and methodologies for assess-
20 ing such data;

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

24 (3) the establishment of goals for enrollment in
25 clinical trials, including the relevance of the esti-

1 mated prevalence or incidence, as applicable, in the
2 United States of the disease or condition for which
3 the drug or device is being developed; and

4 (4) approaches to support inclusion of under-
5 represented populations and to encourage clinical
6 study participation that reflects the population ex-
7 pected to use the drug or device under study, includ-
8 ing with respect to—

9 (A) the establishment of inclusion and ex-
10 clusion criteria for certain demographic sub-
11 groups, such as pregnant and lactating women
12 and individuals with disabilities, including intel-
13 lectual or developmental disabilities or mental
14 illness;

15 (B) considerations regarding informed con-
16 sent with respect to individuals with intellectual
17 or developmental disabilities or mental illness,
18 including ethical and scientific considerations;

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

21 (D) clinical endpoints;

22 (E) biomarker selection; and

23 (F) studying analysis.

24 (b) PUBLIC DOCKET.—The Secretary of Health and
25 Human Services shall establish a public comment period

1 to receive written comments related to the topics ad-
2 dressed during each public workshop convened under this
3 section. The public comment period shall remain open for
4 60 days following the date on which each public workshop
5 is convened.

6 (c) REPORT.—Not later than 180 days after the close
7 of the public comment period for each public workshop
8 convened under this section, the Secretary of Health and
9 Human Services shall make available on the public website
10 of the Food and Drug Administration a report on the top-
11 ics discussed at such workshop. The report shall include
12 a summary of, and response to, recommendations raised
13 in such workshop.

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

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

22 (1) summarizes, in aggregate, the diversity ac-
23 tion plans received pursuant to section 505(i)(5) or
24 520(g)(9) of the Federal Food, Drug, and Cosmetic
25 Act, or section 351(a)(3)(B) of the Public Health

1 Service Act, as added by subsection (a), (b), or (c)
2 of section 501 of this Act; and

3 (2) contains information on—

4 (A) for drugs that have been approved by
5 the Food and Drug Administration and devices
6 that have been approved, cleared, or classified
7 under section 513(f)(2) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2))
9 by the Food and Drug Administration, whether
10 the clinical studies conducted with respect to
11 such applications met the demographic sub-
12 group enrollment goals from the diversity action
13 plan submitted for such applications;

14 (B) the reasons provided for why enroll-
15 ment goals from submitted diversity action
16 plans were not met; and

17 (C) any postmarket studies of a drug or
18 device in a demographic subgroup or subgroups
19 required or recommended by the Secretary
20 based on inadequate premarket clinical study
21 diversity or based on other reasons where a pre-
22 market study lacked adequate diversity, includ-
23 ing the status and completion date of any such
24 study.

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

7 **SEC. 505. PUBLIC MEETING ON CLINICAL STUDY FLEXIBILI-**
8 **TIES INITIATED IN RESPONSE TO COVID-19**
9 **PANDEMIC.**

10 (a) IN GENERAL.—Not later than 180 days after the
11 date on which the COVID-19 emergency period ends, the
12 Secretary of Health and Human Services shall convene a
13 public meeting to discuss the recommendations provided
14 by the Food and Drug Administration during the COVID-
15 19 emergency period to mitigate disruption of clinical
16 studies, including recommendations detailed in the guid-
17 ance entitled “Conduct of Clinical Trials of Medical Prod-
18 ucts During the COVID-19 Public Health Emergency,
19 Guidance for Industry, Investigators, and Institutional
20 Review Boards”, as updated on August 8, 2021, and by
21 any subsequent updates to such guidance. The Secretary
22 of Health and Human Services shall invite to such meet-
23 ing representatives from the pharmaceutical and medical
24 device industries who sponsored clinical studies during the

1 COVID–19 emergency period and organizations rep-
2 resenting patients.

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

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

12 (2) the characteristics of the sponsors, studies,
13 and patient populations impacted by such rec-
14 ommendations;

15 (3) a consideration of how recommendations in-
16 tended to mitigate disruption of clinical studies dur-
17 ing the COVID–19 emergency period, including any
18 recommendations to consider decentralized clinical
19 studies when appropriate, may have affected access
20 to clinical studies for certain patient populations, es-
21 pecially unrepresented racial and ethnic minorities;
22 and

23 (4) recommendations for incorporating certain
24 clinical study disruption mitigation recommendations
25 into current or additional guidance to improve clin-

1 ical study access and enrollment of diverse patient
2 populations.

3 (c) COVID–19 EMERGENCY PERIOD DEFINED.—In
4 this section, the term “COVID–19 emergency period” has
5 the meaning given the term “emergency period” in section
6 1135(g)(1)(B) of the Social Security Act (42 U.S.C.
7 1320b–5(g)(1)(B)).

8 **SEC. 506. DECENTRALIZED CLINICAL STUDIES.**

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

11 (1) not later than 12 months after the date of
12 enactment of this Act, issue draft guidance that ad-
13 dresses considerations for decentralized clinical stud-
14 ies, including considerations regarding the engage-
15 ment, enrollment, and retention of a meaningfully
16 diverse clinical population, with respect to race, eth-
17 nicity, age, sex, and geographic location, when ap-
18 propriate; and

19 (2) not later than 1 year after closing the com-
20 ment period on such draft guidance, finalize such
21 guidance.

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

24 (1) Recommendations for how digital health
25 technology or other remote assessment options, such

1 as telehealth, could support decentralized clinical
2 studies, including guidance on considerations for se-
3 lecting technological platforms and mediums, data
4 collection and use, data integrity and security, and
5 communication to study participants through digital
6 technology.

7 (2) Recommendations for subject recruitment
8 and retention, including considerations for sponsors
9 to minimize or reduce burdens for clinical study par-
10 ticipants through the use of digital health technology,
11 telehealth, local health care providers and labora-
12 tories, or other means.

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

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

1 **TITLE VI—GENERIC DRUG**
2 **COMPETITION**

3 **SEC. 601. INCREASING TRANSPARENCY IN GENERIC DRUG**
4 **APPLICATIONS.**

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

8 “(H)(i) Upon request (in controlled correspondence
9 or otherwise) by a person that has submitted or intends
10 to submit an abbreviated application for a new drug under
11 this subsection or on the Secretary’s own initiative during
12 the review of such abbreviated application, the Secretary
13 shall inform the person whether such new drug is quali-
14 tatively and quantitatively the same as the listed drug.

15 “(ii) If the Secretary determines that such new drug
16 is not qualitatively or quantitatively the same as the listed
17 drug, the Secretary shall identify and disclose to the per-
18 son—

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

22 “(II) for any ingredient for which there is an
23 identified quantitative deviation, the amount of such
24 deviation.

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

6 “(I) the formulation of the listed drug has been
7 changed and the Secretary has determined that the
8 prior listed drug formulation was withdrawn for rea-
9 sons of safety or effectiveness; or

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

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

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

20 (b) GUIDANCE.—

21 (1) IN GENERAL.—Not later than one year
22 after the date of enactment of this Act, the Sec-
23 retary of Health and Human Services shall issue
24 draft guidance, or update guidance, describing how
25 the Secretary will determine whether a new drug is

1 qualitatively and quantitatively the same as the list-
2 ed drug (as such terms are used in section
3 505(j)(3)(H) of the Federal Food, Drug, and Cos-
4 metic Act, as added by subsection (a)), including
5 with respect to assessing pH adjusters.

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

9 (A) publish draft guidance;

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

12 (C) after considering any comments re-
13 ceived, and not later than one year after the
14 close of the comment period on the draft guid-
15 ance, publish final guidance.

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

21 **SEC. 602. ENHANCING ACCESS TO AFFORDABLE MEDI-**
22 **CINES.**

23 Section 505(j)(10)(A) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended

1 by striking clauses (i) through (iii) and inserting the fol-
2 lowing:

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

7 “(ii) the sponsor of the application agrees to
8 submit revised labeling for the drug that is the sub-
9 ject of the application not later than 60 days after
10 approval under this subsection of the application;

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

14 **TITLE VII—RESEARCH, DEVEL-**
15 **OPMENT, AND SUPPLY CHAIN**
16 **IMPROVEMENTS**

17 **Subtitle A—In General**

18 **SEC. 701. ANIMAL TESTING ALTERNATIVES.**

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

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

23 (2) in subsection (i)—

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

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

6 (3) after subsection (y), by inserting the fol-
7 lowing:

8 “(z) NONCLINICAL TEST DEFINED.—For purposes
9 of this section, the term ‘nonclinical test’ means a test con-
10 ducted in vitro, in silico, or in chemico, or a nonhuman
11 in vivo test, that occurs before or during the clinical trial
12 phase of the investigation of the safety and effectiveness
13 of a drug. Such test may include the following:

14 “(1) Cell-based assays.

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

17 “(3) Computer modeling.

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

20 “(5) Animal tests.”.

21 **SEC. 702. EMERGING TECHNOLOGY PROGRAM.**

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

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

2 “(a) PROGRAM ESTABLISHMENT.—

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

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

9 “(A) facilitate and increase communication
10 between public and private entities, consortia,
11 and individuals with respect to innovative drug
12 product design and manufacturing;

13 “(B) solicit information regarding, and
14 conduct or support research on, innovative ap-
15 proaches to drug product design and manufac-
16 turing;

17 “(C) convene meetings with representatives
18 of industry, academia, other Federal agencies,
19 international agencies, and other interested per-
20 sons, as appropriate;

21 “(D) convene working groups to support
22 drug product design and manufacturing re-
23 search and development;

24 “(E) support education and training for
25 regulatory staff and scientists related to innova-

1 tive approaches to drug product design and
2 manufacturing;

3 “(F) advance regulatory science related to
4 the development and review of innovative ap-
5 proaches to drug product design and manufac-
6 turing;

7 “(G) convene or participate in working
8 groups to support the harmonization of inter-
9 national regulatory requirements related to in-
10 novative approaches to drug product design and
11 manufacturing; and

12 “(H) award grants or contracts to carry
13 out or support the program under paragraph
14 (1).

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

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

20 “(B) containing such information as the
21 Secretary may require, including a description
22 of—

23 “(i) how the entity will conduct the
24 activities to be supported through the
25 grant or contract; and

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

5 “(b) GUIDANCE.—The Secretary shall—

6 “(1) issue or update guidance to help facilitate
7 the adoption of, and advance the development of, in-
8 novative approaches to drug product design and
9 manufacturing; and

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

11 “(A) any regulatory requirements related
12 to the development or review of technologies re-
13 lated to innovative approaches to drug product
14 design and manufacturing, including updates
15 and improvements to such technologies after
16 product approval; and

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

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

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

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

7 “(3) the number of meetings held or partici-
8 pated in by the Food and Drug Administration, in-
9 cluding meetings convened as part of a working
10 group described in subparagraph (D) or (G) of sub-
11 section (a)(2), and the topics of each such meeting;
12 and

13 “(4) the number of drug products approved or
14 licensed, after the date of enactment of this section,
15 using an innovative approach to drug product design
16 and manufacturing.

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

21 **SEC. 703. IMPROVING THE TREATMENT OF RARE DISEASES**
22 **AND CONDITIONS.**

23 (a) REPORT ON ORPHAN DRUG PROGRAM.—

24 (1) IN GENERAL.—Not later than September
25 30, 2026, the Secretary shall submit to the Com-

1 mittee on Energy and Commerce of the House of
2 Representatives and the Committee on Health, Edu-
3 cation, Labor, and Pensions of the Senate a report
4 summarizing the activities of the Food and Drug
5 Administration related to designating drugs under
6 section 526 of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 360bb) for a rare disease or
8 condition and approving such drugs under section
9 505 of such Act (21 U.S.C. 355) or licensing such
10 drugs under section 351 of the Public Health Serv-
11 ice Act (42 U.S.C. 262), including—

12 (A) the number of applications for such
13 drugs under section 505 of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 355) or
15 section 351 of the Public Health Service Act
16 (42 U.S.C. 262) received by the Food and Drug
17 Administration, the number of such applica-
18 tions accepted and rejected for filing, and the
19 number of such applications pending, approved,
20 and disapproved by the Food and Drug Admin-
21 istration;

22 (B) a description of trends in drug approv-
23 als for rare diseases and conditions across re-
24 view divisions at the Food and Drug Adminis-
25 tration;

1 (C) the extent to which the Food and Drug
2 Administration is consulting with external ex-
3 perts pursuant to section 569(a)(2) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.
5 360bbb–8(a)(2)) on topics pertaining to drugs
6 for a rare disease or condition, including how
7 and when any such consultation is occurring;
8 and

9 (D) the Food and Drug Administration’s
10 efforts to promote best practices in the develop-
11 ment of novel treatments for rare diseases, in-
12 cluding—

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

15 (ii) new regulatory science and coordi-
16 nated support for patient and stakeholder
17 engagement.

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

22 (3) INFORMATION DISCLOSURE.—Nothing in
23 this subsection shall be construed to authorize the
24 disclosure of information that is prohibited from dis-
25 closure under section 1905 of title 18, United States

1 Code, or subject to withholding under paragraph (4)
2 of section 552(b), United States Code (commonly re-
3 ferred to as the “Freedom of Information Act”).

4 (b) STUDY ON EUROPEAN UNION SAFETY AND EFFI-
5 CACY REVIEWS OF DRUGS FOR RARE DISEASES AND CON-
6 DITIONS.—

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

13 (A) flexibilities, authorities, or mechanisms
14 available to regulators in the United States and
15 the European Union specific to rare diseases or
16 conditions;

17 (B) the consideration and use of supple-
18 mental data submitted during review processes
19 in the United States and the European Union,
20 including data associated with open label exten-
21 sion studies and expanded access programs spe-
22 cific to rare diseases or conditions;

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

1 (i) product development programs
2 under review;

3 (ii) policies under development re-
4 cently issued; and

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

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

10 (2) CONSULTATION.—The contract under para-
11 graph (1) shall provide for consultation with relevant
12 stakeholders, including—

13 (A) representatives from the Food and
14 Drug Administration and the European Medi-
15 cines Agency;

16 (B) rare disease or condition patients; and

17 (C) patient groups that—

18 (i) represent rare disease or condition
19 patients; and

20 (ii) have international patient out-
21 reach.

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

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

3 (B) the submission of a report on the re-
4 sults of such study to the Committee on Energy
5 and Commerce of the House of Representatives
6 and the Committee on Health, Education,
7 Labor, and Pensions of the Senate.

8 (4) PUBLIC AVAILABILITY.—The contract under
9 paragraph (1) shall provide for the appropriate enti-
10 ty referred to in paragraph (1) to make the report
11 under paragraph (3) available to the public, includ-
12 ing by posting the report on the website of the ap-
13 propriate entity.

14 (c) PUBLIC MEETING.—

15 (1) IN GENERAL.—Not later than December 31,
16 2023, the Secretary of Health and Human Services,
17 acting through the Commissioner of Food and
18 Drugs, shall convene one or more public meetings to
19 solicit input from stakeholders regarding the ap-
20 proaches described in paragraph (2).

21 (2) APPROACHES.—The public meeting or
22 meetings under paragraph (1) shall address ap-
23 proaches to increasing and improving engagement
24 with rare disease or condition patients, groups rep-
25 resenting such patients, rare disease or condition ex-

1 perts, and experts on small population studies, in
2 order to improve the understanding with respect to
3 rare diseases or conditions of—

4 (A) patient burden;

5 (B) treatment options; and

6 (C) side effects of treatments, including—

7 (i) comparing the side effects of treat-
8 ments; and

9 (ii) understanding the risks of side ef-
10 fects relative to the health status of the pa-
11 tient and the progression of the disease or
12 condition.

13 (3) PUBLIC DOCKET.—The Secretary of Health
14 and Human Services shall establish a public docket
15 to receive written comments related to the ap-
16 proaches addressed during each public meeting
17 under paragraph (1). Such public docket shall re-
18 main open for 60 days following the date of each
19 such public meeting.

20 (4) REPORTS.—Not later than 180 days after
21 each public meeting under paragraph (1), the Com-
22 missioner of Food and Drugs shall develop and pub-
23 lish on the website of the Food and Drug Adminis-
24 tration a report on—

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

3 (B) any related recommendations.

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

8 “(C) SMALL POPULATION STUDIES.—The
9 external experts on the list maintained pursuant
10 to subparagraph (A) may include experts on the
11 science of small population studies.”.

12 (e) STUDY ON SUFFICIENCY AND USE OF FDA
13 MECHANISMS FOR INCORPORATING THE PATIENT AND
14 CLINICIAN PERSPECTIVE IN FDA PROCESSES RELATED
15 TO APPLICATIONS CONCERNING DRUGS FOR RARE DIS-
16 EASES OR CONDITIONS.—

17 (1) IN GENERAL.—The Comptroller General of
18 the United States shall conduct a study on the use
19 of Food and Drug Administration mechanisms and
20 tools to ensure that patient and physician perspec-
21 tives are considered and incorporated throughout the
22 processes of the Food and Drug Administration—

23 (A) for approving or licensing under sec-
24 tion 505 of the Federal Food, Drug, or Cos-
25 metic Act (21 U.S.C. 355) or section 351 of the

1 Public Health Service Act (42 U.S.C. 262) a
2 drug designated as a drug for a rare disease or
3 condition under section 526 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C.
5 360bb); and

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

9 (i) safety or effectiveness; or

10 (ii) postapproval safety monitoring.

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

13 (A) identify and compare the processes
14 that the Food and Drug Administration has
15 formally put in place and utilized to gather ex-
16 ternal expertise (including patients, patient
17 groups, and physicians) on specific applications
18 for rare diseases or conditions;

19 (B) examine tools or mechanisms to im-
20 prove efforts and initiatives of the Food and
21 Drug Administration to collect and consider
22 such external expertise with respect to applica-
23 tions for rare diseases or conditions throughout
24 the application review and approval or licensure
25 processes, including within internal benefit-risk

1 assessments, advisory committee processes, and
2 postapproval safety monitoring; and

3 (C) examine processes or alternatives to
4 address or resolve conflicts of interest that im-
5 pede the Food and Drug Administration in
6 gaining external expert input on rare diseases
7 or conditions with a limited set of clinical and
8 research experts.

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

12 (A) complete the study under paragraph
13 (1);

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

16 (C) include in such report recommenda-
17 tions, if appropriate, for changes to the proc-
18 esses and authorities of the Food and Drug Ad-
19 ministration to improve the collection and con-
20 sideration of external expert opinions of pa-
21 tients, patient groups, and physicians with ex-
22 pertise in rare diseases or conditions.

23 (f) DEFINITION.—In this section, the term “rare dis-
24 ease or condition” has the meaning given such term in

1 section 526(a)(2) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 360bb(a)(2)).

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

4 (a) DRAFT GUIDANCE.—Not later than 3 years after
5 the date of the enactment of this Act, the Secretary of
6 Health and Human Services, acting through the Commis-
7 sioner of Food and Drugs, shall issue draft guidance for
8 industry for the purposes of assisting entities seeking ap-
9 proval under section 505 of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 355) or licensure under section
11 351 of the Public Health Service Act (42 U.S.C. 262) of
12 antifungal therapies designed to treat coccidioidomycosis
13 (commonly known as Valley Fever).

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

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

1 **SEC. 705. ADVANCING QUALIFIED INFECTIOUS DISEASE**
2 **PRODUCT INNOVATION.**

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

6 (1) in subsection (c)—

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

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

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

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

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

17 (3) by amending subsection (g) to read as fol-
18 lows:

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

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

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

4 “(A) an antibacterial or antifungal resist-
5 ant pathogen, including novel or emerging in-
6 fectious pathogens; or

7 “(B) qualifying pathogens listed by the
8 Secretary under subsection (f).”.

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

15 **SEC. 706. ADVANCED MANUFACTURING TECHNOLOGIES**

16 **DESIGNATION PILOT PROGRAM.**

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

21 **“SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES**

22 **DESIGNATION PILOT PROGRAM.**

23 “(a) IN GENERAL.—Not later than 1 year after the
24 date of enactment of this section, the Secretary shall ini-
25 tiate a pilot program under which persons may request

1 designation of an advanced manufacturing technology as
2 described in subsection (b).

3 “(b) DESIGNATION PROCESS.—The Secretary shall
4 establish a process for the designation under this section
5 of methods of manufacturing drugs, including biological
6 products, and active pharmaceutical ingredients of such
7 drugs, as advanced manufacturing technologies. A method
8 of manufacturing, or a combination of manufacturing
9 methods, is eligible for designation as an advanced manu-
10 facturing technology if such method or combination of
11 methods incorporates a novel technology, or uses an estab-
12 lished technique or technology in a novel way, that will
13 substantially improve the manufacturing process for a
14 drug and maintain equivalent or provide superior drug
15 quality, including by—

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

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

19 “(A) a drug that is described in section
20 506C(a) and is intended to treat a serious or
21 life-threatening condition; or

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

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

1 “(1) SUBMISSION.—A person who requests des-
2 ignation of a method of manufacturing as an ad-
3 vanced manufacturing technology under this section
4 shall submit to the Secretary data or information
5 demonstrating that the method of manufacturing
6 meets the criteria described in subsection (b) in a
7 particular context of use. The Secretary may facili-
8 tate the development and review of such data or in-
9 formation by—

10 “(A) providing timely advice to, and inter-
11 active communication with, such person regard-
12 ing the development of the method of manufac-
13 turing; and

14 “(B) involving senior managers and experi-
15 enced staff of the Food and Drug Administra-
16 tion, as appropriate, in a collaborative, cross-
17 disciplinary review of the method of manufac-
18 turing, as applicable.

19 “(2) EVALUATION AND DESIGNATION.—Not
20 later than 180 calendar days after the receipt of a
21 request under paragraph (1), the Secretary shall de-
22 termine whether to designate such method of manu-
23 facturing as an advanced manufacturing technology,
24 in a particular context of use, based on the data and

1 information submitted under paragraph (1) and the
2 criteria described in subsection (b).

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

7 “(1) expedite the development and review of an
8 application submitted under section 505 of this Act
9 or section 351 of the Public Health Service Act, in-
10 cluding supplemental applications, for drugs that are
11 manufactured using a designated advanced manufac-
12 turing technology and could help mitigate or prevent
13 a shortage or substantially improve manufacturing
14 processes for a drug and maintain equivalent or pro-
15 vide superior drug quality, as described in subsection
16 (b); and

17 “(2) allow the holder of an advanced technology
18 designation, or a person authorized by the advanced
19 manufacturing technology designation holder, to ref-
20 erence or rely upon, in an application submitted
21 under section 505 of this Act or section 351 of the
22 Public Health Service Act, including a supplemental
23 application, data and information about the des-
24 igned advanced manufacturing technology for use

1 in manufacturing drugs in the same context of use
2 for which the designation was granted.

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

5 “(1) PUBLIC MEETING.—The Secretary shall
6 publish in the Federal Register a notice of a public
7 meeting, to be held not later than 180 days after the
8 date of enactment of this section, to discuss, and ob-
9 tain input and recommendations from relevant
10 stakeholders regarding—

11 “(A) the goals and scope of the pilot pro-
12 gram, and a suitable framework, procedures,
13 and requirements for such program; and

14 “(B) ways in which the Food and Drug
15 Administration will support the use of advanced
16 manufacturing technologies and other innova-
17 tive manufacturing approaches for drugs.

18 “(2) PILOT PROGRAM GUIDANCE.—

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

20 “(i) not later than 180 days after the
21 public meeting under paragraph (1), issue
22 draft guidance regarding the goals and im-
23 plementation of the pilot program under
24 this section; and

1 “(ii) not later than 2 years after the
2 date of enactment of this section, issue
3 final guidance regarding the implementa-
4 tion of such program.

5 “(B) CONTENT.—The guidance described
6 in subparagraph (A) shall address—

7 “(i) the process by which a person
8 may request a designation under sub-
9 section (b);

10 “(ii) the data and information that a
11 person requesting such a designation is re-
12 quired to submit under subsection (c), and
13 how the Secretary intends to evaluate such
14 submissions;

15 “(iii) the process to expedite the de-
16 velopment and review of applications under
17 subsection (d); and

18 “(iv) the criteria described in sub-
19 section (b) for eligibility for such a des-
20 ignation.

21 “(3) REPORT.—Not later than 3 years after the
22 date of enactment of this section and annually there-
23 after, the Secretary shall publish on the website of
24 the Food and Drug Administration and submit to
25 the Committee on Health, Education, Labor, and

1 Pensions of the Senate and the Committee on En-
2 ergy and Commerce of the House of Representatives
3 a report containing a description and evaluation of
4 the pilot program being conducted under this sec-
5 tion, including the types of innovative manufacturing
6 approaches supported under the program. Such re-
7 port shall include the following:

8 “(A) The number of persons that have re-
9 quested designations and that have been grant-
10 ed designations.

11 “(B) The number of methods of manufac-
12 turing that have been the subject of designation
13 requests and that have been granted designa-
14 tions.

15 “(C) The average number of calendar days
16 for completion of evaluations under subsection
17 (c)(2).

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

22 “(E) The number of applications received
23 under section 505 of this Act or section 351 of
24 the Public Health Service Act, including supple-
25 mental applications, that have included an ad-

1 vanded manufacturing technology designated
2 under this section, and the number of such ap-
3 plications approved.

4 “(f) SUNSET.—The Secretary—

5 “(1) may not consider any requests for designa-
6 tion submitted under subsection (c) after October 1,
7 2029; and

8 “(2) may continue all activities under this sec-
9 tion with respect to advanced manufacturing tech-
10 nologies that were designated pursuant to subsection
11 (d) prior to such date, if the Secretary determines
12 such activities are in the interest of the public
13 health.”.

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

15 Not later than 3 years after the date of the enact-
16 ment of this Act, the Secretary of Health and Human
17 Services, acting through the Commissioner of Food and
18 Drugs, shall convene a public workshop with relevant
19 stakeholders to discuss best practices on generating sci-
20 entific data necessary to further facilitate the development
21 of certain human cell-, tissue-, and cellular-based medical
22 products (and the latest scientific information about such
23 products) that are regulated as drugs under the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
25 or biological products under section 351 of the Public

1 Health Service Act (42 U.S.C. 262), namely, stem-cell and
2 other cellular therapies.

3 **SEC. 708. REAUTHORIZATION OF BEST PHARMACEUTICALS**
4 **FOR CHILDREN.**

5 Section 409I(d)(1) of the Public Health Service Act
6 (42 U.S.C. 284m(d)(1)) is amended by striking “2018
7 through 2022” and inserting “2023 through 2027”.

8 **SEC. 709. REAUTHORIZATION FOR HUMANITARIAN DEVICE**
9 **EXEMPTION AND DEMONSTRATION GRANTS**
10 **FOR IMPROVING PEDIATRIC AVAILABILITY.**

11 (a) HUMANITARIAN DEVICE EXEMPTION.—Section
12 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by
14 striking “2022” and inserting “2027”.

15 (b) PEDIATRIC MEDICAL DEVICE SAFETY AND IM-
16 PROVEMENT ACT.—Section 305(e) of the Pediatric Med-
17 ical Device Safety and Improvement Act (Public Law
18 110–85) is amended by striking “2018 through 2022” and
19 inserting “2023 through 2027”.

20 **SEC. 710. REAUTHORIZATION OF PROVISION RELATED TO**
21 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
22 **TAINING SINGLE ENANTIOMERS.**

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

1 **SEC. 711. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
2 **LIC-PRIVATE PARTNERSHIP PROGRAM.**

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

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

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

11 (1) in subsection (a)—

12 (A) by striking “and (3)” and inserting
13 “(3)”; and

14 (B) by inserting before the period at the
15 end the following: “, and (4) developing regu-
16 latory science pertaining to the chemistry, man-
17 ufacturing, and controls of individualized med-
18 ical products to treat individuals with rare dis-
19 eases or conditions”; and

20 (2) in subsection (c), by striking “2018 through
21 2022” and inserting “2023 through 2027”.

22 **Subtitle B—Inspections**

23 **SEC. 721. FACTORY INSPECTION.**

24 (a) IN GENERAL.—Section 704(a)(1) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is

1 amended by striking “restricted devices” each place it ap-
2 pears and inserting “devices”.

3 (b) RECORDS OR OTHER INFORMATION.—

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

7 (A) by striking “an establishment that is
8 engaged in the manufacture, preparation, prop-
9 agation, compounding, or processing of a drug”
10 and inserting “an establishment that is engaged
11 in the manufacture, preparation, propagation,
12 compounding, or processing of a drug or device,
13 or that is subject to inspection under paragraph
14 (5)(C),”; and

15 (B) by inserting after “a sufficient descrip-
16 tion of the records requested” the following:
17 “and a rationale for requesting such records or
18 other information in advance of, or in lieu of,
19 an inspection”.

20 (2) GUIDANCE.—

21 (A) IN GENERAL.—The Secretary of
22 Health and Human Services shall issue or up-
23 date guidance describing—

24 (i) circumstances in which the Sec-
25 retary intends to issue requests for records

1 or other information in advance of, or in
2 lieu of, an inspection under section
3 704(a)(4) of the Federal Food, Drug, and
4 Cosmetic Act, as amended by paragraph
5 (1);

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

9 (iii) factors the Secretary intends to
10 consider in evaluating whether such
11 records and other information are provided
12 within a reasonable timeframe, within rea-
13 sonable limits, and in a reasonable man-
14 ner, accounting for resource and other lim-
15 itations that may exist, including for small
16 businesses.

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

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

22 (ii) not later than 1 year after the
23 close of the comment period for such draft
24 guidance, issue final guidance under sub-
25 paragraph (A).

1 (c) BIORESEARCH MONITORING INSPECTIONS.—

2 (1) IN GENERAL.—Section 704(a) of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 374(a)) is amended by adding at the end the fol-
5 lowing:

6 “(5) BIORESEARCH MONITORING INSPECTIONS.—

7 “(A) IN GENERAL.—The Secretary may, to en-
8 sure the accuracy and reliability of studies and
9 records or other information described in subpara-
10 graph (B) and to assess compliance with applicable
11 requirements under this Act or the Public Health
12 Service Act, enter sites and facilities specified in
13 subparagraph (C) in order to inspect such records or
14 other information.

15 “(B) INFORMATION SUBJECT TO INSPEC-
16 TION.—An inspection under this paragraph shall ex-
17 tend to all records and other information related to
18 the studies and submissions described in subpara-
19 graph (E), including records and information related
20 to the conduct, results, and analyses of, and the pro-
21 tection of human and animal trial participants par-
22 ticipating in, such studies.

23 “(C) SITES AND FACILITIES SUBJECT TO IN-
24 SPECTION.—

1 “(i) SITES AND FACILITIES DESCRIBED.—

2 The sites and facilities subject to inspection by
3 the Secretary under this paragraph are those
4 owned or operated by a person described in
5 clause (ii) and which are (or were) utilized by
6 such person in connection with—

7 “(I) developing an application or other
8 submission to the Secretary under this Act
9 or the Public Health Service Act related to
10 marketing authorization for a product de-
11 scribed in paragraph (1);

12 “(II) preparing, conducting, or ana-
13 lyzing the results of a study described in
14 subparagraph (E); or

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

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

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

21 “(II) a person engaged in any activity
22 described in clause (i) on behalf of such a
23 sponsor, through a contract, grant, or
24 other business arrangement with such
25 sponsor;

1 “(III) an institutional review board,
2 or other individual or entity, engaged by
3 contract, grant, or other business arrange-
4 ment with a nonsponsor in preparing, col-
5 lecting, or analyzing records or other infor-
6 mation described in subparagraph (B); or

7 “(IV) any person not otherwise de-
8 scribed in this clause that conducts, or has
9 conducted, a study described in subpara-
10 graph (E) yielding records or other infor-
11 mation described in subparagraph (B).

12 “(D) CONDITIONS OF INSPECTION.—

13 “(i) ACCESS TO INFORMATION SUBJECT TO
14 INSPECTION.—Subject to clause (ii), an entity
15 that owns or operates any site or facility sub-
16 ject to inspection under this paragraph shall
17 provide the Secretary with access to records
18 and other information described in subpara-
19 graph (B) that is held by or under the control
20 of such entity, including—

21 “(I) permitting the Secretary to
22 record or copy such information for pur-
23 poses of this paragraph;

24 “(II) providing the Secretary with ac-
25 cess to any electronic information system

1 utilized by such entity to hold, process,
2 analyze, or transfer any records or other
3 information described in subparagraph
4 (B); and

5 “(III) permitting the Secretary to in-
6 spect the facilities, equipment, written pro-
7 cedures, processes, and conditions through
8 which records or other information de-
9 scribed in subparagraph (B) is or was gen-
10 erated, held, processed, analyzed, or trans-
11 ferred.

12 “(ii) NO EFFECT ON APPLICABILITY OF
13 PROVISIONS FOR PROTECTION OF PROPRIETARY
14 INFORMATION OR TRADE SECRETS.—Nothing in
15 clause (i) shall negate, supersede, or otherwise
16 affect the applicability of provisions, under this
17 or any other Act, preventing or limiting the dis-
18 closure of confidential commercial information
19 or other information considered proprietary or
20 trade secret.

21 “(iii) REASONABLENESS OF INSPEC-
22 TIONS.—An inspection under this paragraph
23 shall be conducted at reasonable times and
24 within reasonable limits and in a reasonable
25 manner.

1 “(E) STUDIES AND SUBMISSIONS DE-
2 SCRIBED.—The studies and submissions described in
3 this subparagraph are each of the following:

4 “(i) Clinical and nonclinical studies sub-
5 mitted to the Secretary in support of, or other-
6 wise related to, applications and other submis-
7 sions to the Secretary under this Act or the
8 Public Health Service Act for marketing au-
9 thorization of a product described in paragraph
10 (1).

11 “(ii) Postmarket safety activities conducted
12 under this Act or the Public Health Service
13 Act.

14 “(iii) Any other clinical investigation of—

15 “(I) a drug subject to section 505 or
16 512 of this Act or section 351 of the Pub-
17 lic Health Service Act; or

18 “(II) a device subject to section
19 520(g).

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

1 “(F) CLARIFICATION.—This paragraph clarifies
2 the authority of the Secretary to conduct inspections
3 of the type described in this paragraph and shall not
4 be construed as a basis for inferring that, prior to
5 the date of enactment of this paragraph, the Sec-
6 retary lacked the authority to conduct such inspec-
7 tions, including under this Act or the Public Health
8 Service Act.”.

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

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

13 (i) review processes and practices in
14 effect as of the date of enactment of this
15 Act applicable to inspections of foreign and
16 domestic sites and facilities described in
17 subparagraph (C)(i) of section 704(a)(5) of
18 the Federal Food, Drug, and Cosmetic
19 Act, as added by paragraph (1); and

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

23 (B) GUIDANCE.—

24 (i) IN GENERAL.—The Secretary of
25 Health and Human Services shall issue

1 guidance describing the processes and
2 practices applicable to inspections of sites
3 and facilities described in subparagraph
4 (C)(i) of section 704(a)(5) of the Federal
5 Food, Drug, and Cosmetic Act, as added
6 by paragraph (1), including with respect to
7 the types of records and information re-
8 quired to be provided, best practices for
9 communication between the Food and
10 Drug Administration and industry in ad-
11 vance of or during an inspection or request
12 for records or other information, and other
13 inspections-related conduct, to the extent
14 not specified in existing publicly available
15 Food and Drug Administration guides and
16 manuals for such inspections.

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

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

23 (II) not later than 1 year after
24 the close of the public comment period

1 for such draft guidance, issue final
2 guidance under clause (i).

3 **SEC. 722. USES OF CERTAIN EVIDENCE.**

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

7 “(c) **APPLICABILITY.**—The limitations on the Sec-
8 retary’s use of evidence obtained under this section, or any
9 evidence which is directly or indirectly derived from such
10 evidence, in a criminal prosecution of the person from
11 whom such evidence was obtained shall not apply to evi-
12 dence, including records or other information, obtained
13 under authorities other than this section, unless such limi-
14 tations are specifically incorporated by reference in such
15 other authorities.”.

16 **SEC. 723. IMPROVING FDA INSPECTIONS.**

17 (a) **RISK FACTORS FOR ESTABLISHMENTS.**—Section
18 510(h)(4) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 360(h)(4)) is amended—

20 (1) by redesignating subparagraph (F) as sub-
21 paragraph (G); and

22 (2) by inserting after subparagraph (E) the fol-
23 lowing:

24 “(F) The compliance history of establish-
25 ments in the country or region in which the es-

1 establishment is located that are subject to regu-
2 lation under this Act, including the history of
3 violations related to products exported from
4 such country or region that are subject to such
5 regulation.”.

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

9 (1) by redesignating subparagraph (C) as sub-
10 paraphrase (D); and

11 (2) by inserting after subparagraph (B) the fol-
12 lowing:

13 “(C) The Secretary may rely on any records or other
14 information that the Secretary may inspect under this sec-
15 tion to satisfy requirements that may pertain to a
16 preapproval or risk-based surveillance inspection, or to re-
17 solve deficiencies identified during such inspections, if ap-
18 plicable and appropriate.”.

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

22 (1) in subsection (a)(1), by inserting
23 “preapproval or” before “risk-based inspections”;
24 and

25 (2) by adding at the end the following:

1 “(c) PERIODIC REVIEW.—

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

9 “(2) REPORTS TO CONGRESS.—Beginning not
10 later than 4 years after the date of the enactment
11 of the Food and Drug Amendments of 2022, and
12 every 4 years thereafter, the Secretary shall submit
13 to the Committee on Energy and Commerce of the
14 House of Representatives and the Committee on
15 Health, Education, Labor, and Pensions a report de-
16 scribing the findings and conclusions of each review
17 conducted under paragraph (1).”.

18 **SEC. 724. GAO REPORT ON INSPECTIONS OF FOREIGN ES-**
19 **TABLISHMENTS MANUFACTURING DRUGS.**

20 (a) IN GENERAL.—Not later than 18 months after
21 the date of the enactment of this Act, the Comptroller
22 General of the United States shall submit to the Com-
23 mittee on Energy and Commerce of the House of Rep-
24 resentatives and the Committee on Health, Education,

1 Labor and Pensions of the Senate a report on inspections
2 conducted by—

3 (1) the Secretary of Health and Human Serv-
4 ices (in this section referred to as the “Secretary”)
5 of foreign establishments pursuant to subsections (h)
6 and (i) of section 510 and 704 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360, 374); or

8 (2) a foreign government or an agency of a for-
9 eign government pursuant to section 809 of such
10 Act (21 U.S.C. 384e).

11 (b) CONTENTS.—The report conducted under sub-
12 section (a) shall include—

13 (1) what alternative tools, including remote in-
14 spections or remote evaluations, other countries are
15 utilizing to facilitate inspections of foreign establish-
16 ments;

17 (2) how frequently trusted foreign regulators
18 conduct inspections of foreign facilities that could be
19 useful to the Food and Drug Administration to re-
20 view in lieu of its own inspections;

21 (3) how frequently and under what cir-
22 cumstances, including for what types of inspections,
23 the Secretary utilizes existing agreements or ar-
24 rangements under section 809 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 384e) and

1 whether the use of such agreements could be appro-
2 priately expanded;

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

7 (5) what additional foreign governments or
8 agencies of foreign governments the Secretary has
9 considered entering into a mutual recognition agree-
10 ment with and, if applicable, reasons why the Sec-
11 retary declined to enter into a mutual recognition
12 agreement with such foreign governments or agen-
13 cies;

14 (6) what tools, if any, the Secretary used to fa-
15 cilitate inspections of domestic facilities that could
16 also be effectively utilized to appropriately inspect
17 foreign facilities;

18 (7) what steps the Secretary has taken to iden-
19 tify and evaluate tools and strategies the Secretary
20 may use to continue oversight with respect to inspec-
21 tions when in-person inspections are disrupted;

22 (8) how the Secretary is considering incor-
23 porating alternative tools into the inspection activi-
24 ties conducted pursuant to the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 321 et seq.); and

1 (9) what steps the Secretary has taken to iden-
2 tify and evaluate how the Secretary may use alter-
3 native tools to address workforce shortages to carry
4 out such inspection activities.

5 **SEC. 725. UNANNOUNCED FOREIGN FACILITY INSPECTIONS**
6 **PILOT PROGRAM.**

7 (a) IN GENERAL.—The Secretary of Health and
8 Human Services (referred to in this section as the “Sec-
9 retary”) shall conduct a pilot program under which the
10 Secretary increases the conduct of unannounced surveil-
11 lance inspections of foreign human drug establishments
12 and evaluates the differences between such inspections of
13 domestic and foreign human drug establishments, includ-
14 ing the impact of announcing inspections to persons who
15 own or operate foreign human drug establishments in ad-
16 vance of an inspection. Such pilot program shall evalu-
17 ate—

18 (1) differences in the number and type of viola-
19 tions of section 501(a)(2)(B) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))
21 resulting from unannounced and announced inspec-
22 tions of foreign human drug establishments and any
23 other significant differences between each type of in-
24 spection;

1 (2) costs and benefits associated with con-
2 ducting announced and unannounced inspections of
3 foreign human drug establishments;

4 (3) barriers to conducting unannounced inspec-
5 tions of foreign human drug establishments and any
6 challenges to achieving parity between domestic and
7 foreign human drug establishment inspections; and

8 (4) approaches for mitigating any negative ef-
9 fects of conducting announced inspections of foreign
10 human drug establishments.

11 (b) PILOT PROGRAM SCOPE.—The inspections evalu-
12 ated under the pilot program under this section shall be
13 routine surveillance inspections and shall not include in-
14 spections conducted as part of the Secretary’s evaluation
15 of a request for approval to market a drug submitted
16 under the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 301 et seq.) or the Public Health Service Act (42
18 U.S.C. 201 et seq.).

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

22 (d) REPORT.—The Secretary shall, not later than
23 180 days following the completion of the pilot program
24 under this section, make available on the website of the

1 Food and Drug Administration a final report on the pilot
2 program under this section, including—

3 (1) findings and any associated recommenda-
4 tions with respect to the evaluation under subsection
5 (a), including any recommendations to address iden-
6 tified barriers to conducting unannounced inspec-
7 tions of foreign human drug establishments;

8 (2) findings and any associated recommenda-
9 tions regarding how the Secretary may achieve par-
10 ity between domestic and foreign human drug in-
11 spections; and

12 (3) the number of unannounced inspections
13 during the pilot program that would not be unan-
14 nounced under existing practices.

15 **SEC. 726. REAUTHORIZATION OF INSPECTION PROGRAM.**

16 Section 704(g)(11) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
18 ing “2022” and inserting “2027”.

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

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

1 “(g) COORDINATION.—The Secretary shall ensure
2 timely and effective internal coordination and alignment
3 among the field investigators of the Food and Drug Ad-
4 ministration and the staff of the Center for Drug Evalua-
5 tion and Research’s Office of Compliance and Drug Short-
6 age Program regarding—

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

9 “(2) any feedback or corrective or preventive
10 actions in response to such reports.”.

11 (b) REPORTING.—

12 (1) IN GENERAL.—Section 506C–1(a)(2) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 356e–1(a)(2)) is amended to read as follows:

15 “(2)(A) describes the communication between
16 the field investigators of the Food and Drug Admin-
17 istration and the staff of the Center for Drug Eval-
18 uation and Research’s Office of Compliance and
19 Drug Shortage Program, including the Food and
20 Drug Administration’s procedures for enabling and
21 ensuring such communication;

22 “(B) provides the number of reports described
23 in section 704(b)(2) that were required to be sent to
24 the appropriate offices of the Food and Drug Ad-

1 ministration and the number of such reports that
2 were sent; and

3 “(C) describes the coordination and alignment
4 activities undertaken pursuant to section 506D(g);”.

5 (2) APPLICABILITY.—The amendment made by
6 paragraph (1) shall apply with respect to reports
7 submitted on or after March 31, 2023.

8 **SEC. 728. REPORTING OF MUTUAL RECOGNITION AGREE-**
9 **MENTS FOR INSPECTIONS AND REVIEW AC-**
10 **TIVITIES.**

11 (a) IN GENERAL.—Not later than December 31,
12 2022, and annually thereafter, the Secretary of Health
13 and Human Services (referred to in this section as the
14 “Secretary”) shall publish a report on the public website
15 of the Food and Drug Administration on the utilization
16 of agreements entered into pursuant to section 809 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e)
18 or otherwise entered into by the Secretary in the previous
19 fiscal year to recognize inspections between drug regu-
20 latory authorities across countries and international re-
21 gions with analogous review criteria to the Food and Drug
22 Administration, such as the Pharmaceutical Inspection
23 Co-Operation Scheme, the Mutual Recognition Agreement
24 with the European Union, and the Australia-Canada-
25 Singapore-Switzerland-United Kingdom Consortium.

1 (b) CONTENT.—The report under subsection (a) shall
2 include each of the following:

3 (1) The total number of establishments that are
4 registered under section 510(i) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the
6 number of such establishments in each region of in-
7 terest.

8 (2) The total number of inspections conducted
9 at establishments described in paragraph (1),
10 disaggregated by inspections conducted—

11 (A) pursuant to an agreement or other rec-
12 ognition described in subsection (a); and

13 (B) by employees or contractors of the
14 Food and Drug Administration.

15 (3) Of the inspections described in paragraph
16 (2), the total number of inspections in each region
17 of interest.

18 (4) Of the inspections in each region of interest
19 reported pursuant to paragraph (3), the number of
20 inspections in each FDA inspection category.

21 (5) Of the number of inspections reported
22 under each of paragraphs (3) and (4)—

23 (A) the number of inspections which have
24 been conducted pursuant to an agreement or

1 other recognition described in subsection (a);
2 and

3 (B) the number of inspections which have
4 been conducted by employees or contractors of
5 the Food and Drug Administration.

6 (c) DEFINITIONS.—In this subsection:

7 (1) FDA INSPECTION CATEGORY.—The term
8 “FDA inspection category” means the following in-
9 spection categories:

10 (A) Inspections to support approvals of
11 changes to the manufacturing process of drugs
12 approved under section 505 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 355)
14 or section 351 of the Public Health Service Act
15 (42 U.S.C. 262).

16 (B) Surveillance inspections.

17 (C) For-cause inspections.

18 (2) REGION OF INTEREST.—The term “region
19 of interest” means China, India, the European
20 Union, and any other geographic region as the Sec-
21 retary determines appropriate.

22 **SEC. 729. ENHANCING TRANSPARENCY OF DRUG FACILITY**
23 **INSPECTION TIMELINES.**

24 Section 902 of the FDA Reauthorization Act of 2017
25 (21 U.S.C. 355 note) is amended to read as follows:

1 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

2 “Not later than 120 days after the end of each fiscal
3 year, the Secretary of Health and Human Services shall
4 post on the public website of the Food and Drug Adminis-
5 tration information related to inspections of facilities nec-
6 essary for approval of a drug under subsection (c) or (j)
7 of section 505 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 355), approval of a device under section
9 515 of such Act (21 U.S.C. 360e), or clearance of a device
10 under section 510(k) of such Act (21 U.S.C. 360(k)) that
11 were conducted during the previous fiscal year. Such infor-
12 mation shall include the following:

13 “(1) The median time following a request from
14 staff of the Food and Drug Administration review-
15 ing an application or report to the beginning of the
16 inspection, including—

17 “(A) the median time for drugs described
18 in section 505(j)(11)(A)(i) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C.
20 355(j)(11)(A)(i));

21 “(B) the median time for drugs described
22 in section 506C(a) of such Act (21 U.S.C.
23 356c(a)) only; and

24 “(C) the median time for drugs on the
25 drug shortage list in effect under section 506E
26 of such Act (21 U.S.C. 356f).

1 “(2) The median time from the issuance of a
2 report pursuant to section 704(b) of such Act (21
3 U.S.C. 374(b)) to the sending of a warning letter,
4 issuance of an import alert, or holding of a regu-
5 latory meeting for inspections for which the Sec-
6 retary concluded that regulatory or enforcement ac-
7 tion was indicated, including the median time for
8 each category of drugs listed in subparagraphs (A)
9 through (C) of paragraph (1).

10 “(3) The median time from the sending of a
11 warning letter, issuance of an import alert, or hold-
12 ing of a regulatory meeting to resolution of the ac-
13 tions indicated to address the conditions or practices
14 observed during an inspection.

15 “(4) The number of facilities that failed to im-
16 plement requested corrective or preventive actions as
17 requested following a report pursuant to such sec-
18 tion 704(b), resulting in a withhold recommendation,
19 including the number of such times for each cat-
20 egory of drugs listed in subparagraphs (A) through
21 (C) of paragraph (1).”.

1 **TITLE VIII—TRANSPARENCY,**
2 **PROGRAM INTEGRITY, AND**
3 **REGULATORY IMPROVE-**
4 **MENTS**

5 **SEC. 801. PROMPT REPORTS OF MARKETING STATUS BY**
6 **HOLDERS OF APPROVED APPLICATIONS FOR**
7 **BIOLOGICAL PRODUCTS.**

8 (a) IN GENERAL.—Section 506I of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

10 (1) in subsection (a)—

11 (A) in the matter preceding paragraph (1),
12 by striking “The holder of an application ap-
13 proved under subsection (c) or (j) of section
14 505” and inserting “The holder of an applica-
15 tion approved under subsection (c) or (j) of sec-
16 tion 505 of this Act or subsection (a) or (k) of
17 section 351 of the Public Health Service Act”;

18 (B) in paragraph (2), by striking “estab-
19 lished name” and inserting “established name
20 (for biological products, by proper name)”; and

21 (C) in paragraph (3), by striking “or ab-
22 breviated application number” and inserting “,
23 abbreviated application number, or biologics li-
24 cense application number”; and

25 (2) in subsection (b)—

1 (A) in the matter preceding paragraph (1),
2 by striking “The holder of an application ap-
3 proved under subsection (c) or (j)” and insert-
4 ing “The holder of an application approved
5 under subsection (c) or (j) of section 505 of
6 this Act or subsection (a) or (k) of section 351
7 of the Public Health Service Act”;

8 (B) in paragraph (1), by striking “estab-
9 lished name” and inserting “established name
10 (for biological products, by proper name)”; and

11 (C) in paragraph (2), by striking “or ab-
12 breviated application number” and inserting “,
13 abbreviated application number, or biologics li-
14 cense application number”.

15 (b) **ADDITIONAL ONE-TIME REPORT.**—Subsection
16 (c) of section 506I of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 356i) is amended to read as follows:

18 “(c) **ADDITIONAL ONE-TIME REPORT.**—Within 180
19 days of the date of enactment of the Food and Drug
20 Amendments of 2022, all holders of applications approved
21 under subsection (a) or (k) of section 351 of the Public
22 Health Service Act shall review the information in the list
23 published under section 351(k)(9)(A) and shall submit a
24 written notice to the Secretary—

1 “(1) stating that all of the application holder’s
2 biological products in the list published under sec-
3 tion 351(k)(9)(A) that are not listed as discontinued
4 are available for sale; or

5 “(2) including the information required pursu-
6 ant to subsection (a) or (b), as applicable, for each
7 of the application holder’s biological products that
8 are in the list published under section 351(k)(9)(A)
9 and not listed as discontinued, but have been discon-
10 tinued from sale or never have been available for
11 sale.”.

12 (c) PURPLE BOOK.—Section 506I of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-
14 ed—

15 (1) by striking subsection (d) and inserting the
16 following:

17 “(d) FAILURE TO MEET REQUIREMENTS.—If a hold-
18 er of an approved application fails to submit the informa-
19 tion required under subsection (a), (b), or (c), the Sec-
20 retary may—

21 “(1) move the application holder’s drugs from
22 the active section of the list published under section
23 505(j)(7)(A) to the discontinued section of the list,
24 except that the Secretary shall remove from the list
25 in accordance with section 505(j)(7)(C) drugs the

1 Secretary determines have been withdrawn from sale
2 for reasons of safety or effectiveness; and

3 “(2) identify the application holder’s biological
4 products as discontinued in the list published under
5 section 351(k)(9)(A) of the Public Health Service
6 Act, except that the Secretary shall remove from the
7 list in accordance with section 351(k)(9)(B) of such
8 Act biological products for which the license has
9 been revoked or suspended for reasons of safety, pu-
10 rity, or potency.”; and

11 (2) in subsection (e)—

12 (A) by inserting after the first sentence the
13 following: “The Secretary shall update the list
14 published under section 351(k)(9)(A) of the
15 Public Health Service Act based on information
16 provided under subsections (a), (b), and (c) by
17 identifying as discontinued biological products
18 that are not available for sale, except that bio-
19 logical products for which the license has been
20 revoked or suspended for safety, purity, or po-
21 tency reasons shall be removed from the list in
22 accordance with section 351(k)(9)(B) of the
23 Public Health Service Act.”;

1 (B) by striking “monthly updates to the
2 list” and inserting “monthly updates to the lists
3 referred to in the preceding sentences”; and

4 (C) by striking “and shall update the list
5 based on” and inserting “and shall update such
6 lists based on”.

7 (d) **TECHNICAL CORRECTIONS.**—Section 506I(e) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 356i(e)) is amended—

10 (1) by striking “subsection 505(j)(7)(A)” and
11 inserting “section 505(j)(7)(A)”; and

12 (2) by striking “subsection 505(j)(7)(C)” and
13 inserting “section 505(j)(7)(C)”.

14 **SEC. 802. ENCOURAGING BLOOD DONATION.**

15 Section 3003 of the 21st Century Cures Act (21
16 U.S.C. 360bbb–8c note) is amended to read as follows:

17 **“SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR
18 INPUT.**

19 “Chapter 35 of title 44, United States Code, shall
20 not apply to the collection of information to which a re-
21 sponse is voluntary, to solicit—

22 “(1) the views and perspectives of patients
23 under section 569C of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended
25 by section 3001) or section 3002; or

1 “(2) information from blood donors or potential
2 blood donors to support the development of rec-
3 ommendations by the Secretary of Health and
4 Human Services acting through the Commissioner of
5 Food and Drugs concerning blood donation.”.

6 **SEC. 803. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

7 Section 503 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 353) is amended by adding at the end the
9 following:

10 “(h)(1) Any contrast agent, radioactive drug, or OTC
11 monograph drug shall be deemed to be a drug under sec-
12 tion 201(g) and not a device under section 201(h).

13 “(2) For purposes of this subsection:

14 “(A) The term ‘contrast agent’ means an arti-
15 cle that is intended for use in conjunction with a
16 medical imaging device, and—

17 “(i) is a diagnostic radiopharmaceutical, as
18 defined in sections 315.2 and 601.31 of title
19 21, Code of Federal Regulations (or any suc-
20 cessor regulations); or

21 “(ii) is a diagnostic agent that improves
22 the visualization of structure or function within
23 the body by increasing the relative difference in
24 signal intensity within the target tissue, struc-
25 ture, or fluid.

1 “(B) The term ‘radioactive drug’ has the mean-
2 ing given such term in section 310.3(n) of title 21,
3 Code of Federal Regulations (or any successor regu-
4 lations), except that such term does not include—

5 “(i) an implant or article similar to an im-
6 plant;

7 “(ii) an article that applies radiation from
8 outside of the body; or

9 “(iii) the radiation source of an article de-
10 scribed in (i) or (ii).

11 “(C) The term ‘OTC monograph drug’ has the
12 meaning given such term in section 744L.

13 “(3) Nothing in this subsection shall be construed as
14 allowing for the classification of a product as a drug (as
15 defined in section 201(g)) if such product—

16 “(A) is not described in paragraph (1); and

17 “(B) meets the definition of a device under sec-
18 tion 201(h),

19 unless another provision of this Act otherwise indicates a
20 different classification.”.

21 **SEC. 804. POSTAPPROVAL STUDIES AND PROGRAM INTEG-**
22 **RITY FOR ACCELERATED APPROVAL DRUGS.**

23 (a) **IN GENERAL.**—Section 506(c) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is
25 amended—

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

3 “(2) LIMITATION.—

4 “(A) IN GENERAL.—Approval of a product
5 under this subsection may be subject to 1 or
6 both of the following requirements:

7 “(i) That the sponsor conduct an ap-
8 propriate postapproval study or studies
9 (which may be augmented or supported by
10 real world evidence) to verify and describe
11 the predicted effect on irreversible mor-
12 bidity or mortality or other clinical benefit.

13 “(ii) That the sponsor submit copies
14 of all promotional materials related to the
15 product during the preapproval review pe-
16 riod and, following approval and for such
17 period thereafter as the Secretary deter-
18 mines to be appropriate, at least 30 days
19 prior to dissemination of the materials.

20 “(B) STUDIES NOT REQUIRED.—If the
21 Secretary does not require that the sponsor of
22 a product approved under accelerated approval
23 conduct a postapproval study under this para-
24 graph, the Secretary shall publish on the
25 website of the Food and Drug Administration

1 the rationale for why such study is not appro-
2 priate or necessary.

3 “(C) POSTAPPROVAL STUDY CONDI-
4 TIONS.—Not later than the time of approval of
5 a product under accelerated approval, the Sec-
6 retary shall specify the conditions for a post-
7 approval study or studies required to be con-
8 ducted under this paragraph with respect to
9 such product, which may include enrollment
10 targets, the study protocol, and milestones, in-
11 cluding the target date of study completion.

12 “(D) STUDIES BEGUN BEFORE AP-
13 PROVAL.—The Secretary may require such
14 study or studies to be underway prior to ap-
15 proval.”; and

16 (2) by striking paragraph (3) and inserting the
17 following:

18 “(3) EXPEDITED WITHDRAWAL OF AP-
19 PROVAL.—

20 “(A) IN GENERAL.—The Secretary may
21 withdraw approval of a product approved under
22 accelerated approval using expedited procedures
23 described in subparagraph (B), if—

24 “(i) the sponsor fails to conduct any
25 required postapproval study of the product

1 with due diligence, including with respect
2 to conditions specified by the Secretary
3 under paragraph (2)(C);

4 “(ii) a study required to verify and
5 describe the predicted effect on irreversible
6 morbidity or mortality or other clinical
7 benefit of the product fails to verify and
8 describe such effect or benefit;

9 “(iii) other evidence demonstrates
10 that the product is not shown to be safe or
11 effective under the conditions of use; or

12 “(iv) the sponsor disseminates false or
13 misleading promotional materials with re-
14 spect to the product.

15 “(B) EXPEDITED PROCEDURES DE-
16 SCRIBED.—Expedited procedures described in
17 this subparagraph shall consist of, prior to the
18 withdrawal of accelerated approval—

19 “(i) providing the sponsor with—

20 “(I) due notice;

21 “(II) an explanation for the pro-
22 posed withdrawal;

23 “(III) an opportunity for a meet-
24 ing with the Commissioner of Food

1 and Drugs or the Commissioner’s des-
2 ignee; and

3 “(IV) an opportunity for written
4 appeal to—

5 “(aa) the Commissioner of
6 Food and Drugs; or

7 “(bb) a designee of the
8 Commissioner who has not par-
9 ticipated in the proposed with-
10 drawal of approval (other than a
11 meeting pursuant to subclause
12 (III)) and is not a subordinate of
13 an individual (other than the
14 Commissioner) who participated
15 in such proposed withdrawal;

16 “(ii) providing an opportunity for
17 public comment on the notice proposing to
18 withdraw approval;

19 “(iii) the publication of a summary of
20 the public comments received, and the Sec-
21 retary’s response to such comments, on the
22 website of the Food and Drug Administra-
23 tion; and

24 “(iv) convening and consulting an ad-
25 visory committee on issues related to the

1 proposed withdrawal, if requested by the
2 sponsor and if no such advisory committee
3 has previously advised the Secretary on
4 such issues with respect to the withdrawal
5 of the product prior to the sponsor's re-
6 quest.

7 “(4) LABELING.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), the labeling for a product approved
10 under accelerated approval shall include—

11 “(i) a statement indicating that the
12 product was approved under accelerated
13 approval;

14 “(ii) a statement indicating that con-
15 tinued approval of the product is subject to
16 postmarketing studies to verify clinical
17 benefit;

18 “(iii) identification of the surrogate or
19 intermediate endpoint or endpoints that
20 supported approval and any known limita-
21 tions of such surrogate or intermediate
22 endpoint or endpoints in determining clin-
23 ical benefit; and

24 “(iv) a succinct description of the
25 product and any uncertainty about antici-

1 pated clinical benefit and a discussion of
2 available evidence with respect to such clin-
3 ical benefit.

4 “(B) APPLICABILITY.—The labeling re-
5 quirements of subparagraph (A) shall apply
6 only to products approved under accelerated ap-
7 proval for which the predicted effect on irre-
8 versible morbidity or mortality or other clinical
9 benefit has not been verified.

10 “(5) REPORTING.—Not later than September
11 30, 2025, 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 describing circumstances in which the Secretary con-
16 sidered real world evidence submitted to support
17 postapproval studies required under this subsection
18 that were completed after the date of enactment of
19 the Food and Drug Amendments of 2022.”.

20 (b) REPORTS OF POSTMARKETING STUDIES.—Sec-
21 tion 506B(a) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 356b(a)) is amended—

23 (1) by redesignating paragraph (2) as para-
24 graph (3); and

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

3 “(2) ACCELERATED APPROVAL.—Notwith-
4 standing paragraph (1), a sponsor of a drug ap-
5 proved under accelerated approval shall submit to
6 the Secretary a report of the progress of any study
7 required under section 506(c), including progress to-
8 ward any agreed upon enrollment targets, mile-
9 stones, and other information as required by the
10 Secretary, not later than 180 days after the ap-
11 proval of such drug and not less frequently than
12 every 180 days thereafter, until the study is com-
13 pleted or terminated.”.

14 (c) GUIDANCE.—

15 (1) IN GENERAL.—The Secretary of Health and
16 Human Services shall issue guidance describing—

17 (A) how sponsor questions related to the
18 identification of novel surrogate or intermediate
19 clinical endpoints may be addressed in early-
20 stage development meetings with the Food and
21 Drug Administration;

22 (B) the use of novel clinical trial designs
23 that may be used to conduct appropriate post-
24 approval studies as may be required under sec-
25 tion 506(c)(2)(A) of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 356(c)(2)(A)), as
2 amended by subsection (a); and

3 (C) the expedited procedures described in
4 section 506(c)(3)(B) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C.
6 356(c)(3)(B)).

7 (2) FINAL GUIDANCE.—The Secretary shall
8 issue—

9 (A) draft guidance under paragraph (1)
10 not later than 18 months after the date of en-
11 actment of this Act; and

12 (B) final guidance not later than 1 year
13 after the close of the public comment period on
14 such draft guidance.

15 (d) RARE DISEASE ENDPOINT ADVANCEMENT
16 PILOT.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services shall establish a pilot program
19 under which the Secretary will establish procedures
20 to provide increased interaction with sponsors of
21 rare disease drug development programs for pur-
22 poses of advancing the development of efficacy
23 endpoints, including surrogate and intermediate
24 endpoints, for drugs intended to treat rare diseases,
25 including through—

1 (A) determining eligibility of participants
2 for such a program; and

3 (B) developing and implementing a process
4 for applying to, and participating in, such a
5 program.

6 (2) PUBLIC WORKSHOPS.—The Secretary shall
7 conduct up to 3 public workshops, which shall be
8 completed not later than September 30, 2026, to
9 discuss topics relevant to the development of
10 endpoints for rare diseases, which may include dis-
11 cussions about—

12 (A) novel endpoints developed through the
13 pilot program established under this subsection;
14 and

15 (B) as appropriate, the use of real world
16 evidence and real world data to support the val-
17 idation of efficacy endpoints, including surro-
18 gate and intermediate endpoints, for rare dis-
19 eases.

20 (3) REPORT.—Not later than September 30,
21 2027, the Secretary shall submit to the Committee
22 on Energy and Commerce of the House of Rep-
23 resentatives and the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Senate a report

1 describing the outcomes of the pilot program estab-
2 lished under this subsection.

3 (4) GUIDANCE.—Not later than September 30,
4 2027, the Secretary shall issue guidance describing
5 best practices and strategies for development of effi-
6 cacy endpoints, including surrogate and intermediate
7 endpoints, for rare diseases.

8 (5) SUNSET.—The Secretary may not accept
9 any new application or request to participate in the
10 program established by this subsection on or after
11 October 1, 2027.

12 **SEC. 805. FACILITATING THE USE OF REAL WORLD EVI-**
13 **DENCE.**

14 (a) GUIDANCE.—Not later than 1 year after the date
15 of the enactment of this Act, the Secretary of Health and
16 Human Services shall issue, or revise existing, guidance
17 on considerations for the use of real world data and real
18 world evidence to support regulatory decisionmaking, as
19 follows:

20 (1) With respect to drugs, such guidance shall
21 address—

22 (A) the use of such data and evidence to
23 support the approval of a drug application
24 under section 505 of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 355) or a biologi-

1 cal product application under section 351 of the
2 Public Health Service Act (42 U.S.C. 262), or
3 to support an investigational use exemption
4 under section 505(i) of the Federal Food, Drug,
5 and Cosmetic Act or section 351(a)(3) of the
6 Public Health Service Act; and

7 (B) the use of such data and evidence ob-
8 tained as a result of the use of drugs author-
9 ized for emergency use under section 564 of the
10 Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 360bbb-3) in such applications, submis-
12 sions, or requests; and

13 (C) standards and methodologies which
14 may be used for collection and analysis of real
15 world evidence included in such applications,
16 submissions, or requests, as appropriate.

17 (2) With respect to devices, such guidance shall
18 address—

19 (A) the use of such data and evidence to
20 support the approval, clearance, or classification
21 of a device pursuant to an application or sub-
22 mission submitted under section 510(k),
23 513(f)(2), or 515 of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 360(k),
25 360c(f)(2), 360e), or to support an investiga-

1 tional use exemption under section 520(g) of
2 such Act (21 U.S.C. 360j(g)); and

3 (B) the use of such data and evidence ob-
4 tained as a result of the use of devices author-
5 ized for emergency use under section 564 of the
6 Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 360bbb-3), in such applications, submis-
8 sions, or requests; and

9 (C) standards and methodologies which
10 may be used for collection and analysis of real
11 world evidence included in such applications,
12 submissions, or requests, as appropriate.

13 (b) REPORT TO CONGRESS.—Not later than 2 years
14 after the termination of the public health emergency deter-
15 mination by the Secretary of Health and Human Services
16 under section 564 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 360bbb-3) on February 4, 2020,
18 with respect to the Coronavirus Disease 2019 (COVID-
19 19), the Secretary shall submit a report to the Committee
20 on Energy and Commerce of the House of Representatives
21 and the Committee on Health, Education, Labor, and
22 Pensions of the Senate on—

23 (1) the number of applications, submissions, or
24 requests submitted for clearance or approval under
25 sections 505, 510(k), or 515 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355, 360(k),
2 360e(f)(2), 360e) or section 351 of the Public
3 Health Service Act, for which an authorization
4 under section 564 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 360bbb-3) was previously
6 granted;

7 (2) of the number of applications so submitted,
8 the number of such applications—

9 (A) for which real world evidence was sub-
10 mitted and used to support a regulatory deci-
11 sion; and

12 (B) for which real world evidence was sub-
13 mitted and determined to be insufficient to sup-
14 port a regulatory decision; and

15 (3) a summary explanation of why, in the case
16 of applications described in paragraph (2)(B), real
17 world evidence could not be used to support regu-
18 latory decisions.

19 (c) INFORMATION DISCLOSURE.—Nothing in this
20 section shall be construed to authorize the disclosure of
21 information that is prohibited from disclosure under sec-
22 tion 1905 of title 18, United States Code, or subject to
23 withholding under subsection (b)(4) of section 552 of title
24 5, United States Code (commonly referred to as the
25 “Freedom of Information Act”).

1 **SEC. 806. MEDICAL DEVICES ADVISORY COMMITTEE MEET-**
2 **INGS.**

3 (a) IN GENERAL.—The Secretary shall convene one
4 or more panels of the Medical Devices Advisory Committee
5 not less than once per year for the purpose of providing
6 advice to the Secretary on topics related to medical devices
7 used in pandemic preparedness and response, including
8 topics related to in vitro diagnostics.

9 (b) REQUIRED PANEL MEMBER.—A panel convened
10 under subsection (a) shall include at least 1 population
11 health-specific representative.

12 (c) SUNSET.—This section shall cease to be effective
13 on October 1, 2027.

14 **SEC. 807. ENSURING CYBERSECURITY OF MEDICAL DE-**
15 **VICES.**

16 (a) IN GENERAL.—Subchapter A of chapter V of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
18 et seq.), as amended by section 501, is further amended
19 by adding at the end the following:

20 **“SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.**

21 “(a) IN GENERAL.—For purposes of ensuring cyber-
22 security throughout the lifecycle of a cyber device, any per-
23 son who submits a premarket submission for the cyber de-
24 vice shall include such information as the Secretary may
25 require to ensure that the cyber device meets such cyberse-
26 curity requirements as the Secretary determines to be ap-

1 appropriate to demonstrate a reasonable assurance of safety
2 and effectiveness, including at a minimum the cybersecu-
3 rity requirements under subsection (b).

4 “(b) CYBERSECURITY REQUIREMENTS.—At a min-
5 imum, the manufacturer of a cyber device shall meet the
6 following cybersecurity requirements:

7 “(1) The manufacturer shall have a plan to ap-
8 propriately monitor, identify, and address in a rea-
9 sonable time postmarket cybersecurity vulnerabilities
10 and exploits, including coordinated vulnerability dis-
11 closure and procedures.

12 “(2) The manufacturer shall design, develop,
13 and maintain processes and procedures to ensure the
14 device and related systems are cybersecure, and shall
15 make available updates and patches to the cyber de-
16 vice and related systems throughout the lifecycle of
17 the cyber device to address—

18 “(A) on a reasonably justified regular
19 cycle, known unacceptable vulnerabilities; and

20 “(B) as soon as possible out of cycle, crit-
21 ical vulnerabilities that could cause uncontrolled
22 risks.

23 “(3) The manufacturer shall provide in the la-
24 beling of the cyber device a software bill of mate-

1 rials, including commercial, open-source, and off-the-
2 shelf software components.

3 “(4) The manufacturer shall comply with such
4 other requirements as the Secretary may require to
5 demonstrate reasonable assurance of the safety and
6 effectiveness of the device for purposes of cybersecu-
7 rity, which the Secretary may require by an order
8 published in the Federal Register.

9 “(c) SUBSTANTIAL EQUIVALENCE.—In making a de-
10 termination of substantial equivalence under section
11 513(i) for a cyber device, the Secretary may—

12 “(1) find that cybersecurity information for the
13 cyber device described in the relevant premarket
14 submission in the cyber device’s use environment is
15 inadequate; and

16 “(2) issue a nonsubstantial equivalence deter-
17 mination based on this finding.

18 “(d) DEFINITION.—In this section:

19 “(1) CYBER DEVICE.—The term ‘cyber device’
20 means a device that—

21 “(A) includes software, including software
22 as or in a device;

23 “(B) has the ability to connect to the
24 internet; or

1 “(C) contains any such technological char-
2 acteristics that could be vulnerable to cyberse-
3 curity threats.

4 “(2) LIFECYCLE OF THE CYBER DEVICE.—The
5 term ‘lifecycle of the cyber device’ includes the
6 postmarket lifecycle of the cyber device.

7 “(3) PREMARKET SUBMISSION.—The term ‘pre-
8 market submission’ means any submission under
9 section 510(k), 513, 515(e), 515(f), or 520(m).

10 “(e) EXEMPTION.—The Secretary may identify de-
11 vices or types of devices that are exempt from meeting
12 the cybersecurity requirements established by this section
13 and regulations promulgated pursuant to this section. The
14 Secretary shall publish in the Federal Register, and up-
15 date, as appropriate, a list of the devices and types of de-
16 vices so identified by the Secretary.”.

17 (b) PROHIBITED ACT.—Section 301(q) of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(q))
19 is amended by adding at the end the following:

20 “(3) The failure to comply with any requirement
21 under section 524C (relating to ensuring device cybersecu-
22 rity).”.

23 (c) ADULTERATION.—Section 501 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-
25 ed by inserting after paragraph (j) the following:

1 “(k) If it is a device subject to the requirements set
2 forth in section 524C (relating to ensuring device cyberse-
3 curity) and fails to comply with any requirement under
4 that section.”.

5 (d) MISBRANDING.—Section 502(t) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is
7 amended—

8 (1) by striking “or (3)” and inserting “(3)”;
9 and

10 (2) by inserting before the period at the end the
11 following: “, or (4) to furnish a software bill of ma-
12 terials as required under section 524C (relating to
13 ensuring device cybersecurity)”.

14 **SEC. 808. PUBLIC DOCKET ON PROPOSED CHANGES TO**
15 **THIRD-PARTY VENDORS.**

16 (a) IN GENERAL.—

17 (1) OPENING PUBLIC DOCKET.—Not later than
18 90 days after the date of enactment of this Act, the
19 Secretary of Health and Human Services shall open
20 a single public docket to solicit comments on factors
21 that generally should be considered by the Secretary
22 when reviewing requests from sponsors of drugs sub-
23 ject to risk evaluation and mitigation strategies to
24 change third-party vendors engaged by sponsors to

1 aid in implementation and management of the strat-
2 egies.

3 (2) FACTORS.—Such factors include the poten-
4 tial effects of changes in third-party vendors on—

5 (A) patient access; and

6 (B) prescribing and administration of the
7 drugs by health care providers.

8 (3) CLOSING PUBLIC DOCKET.—The Secretary
9 of Health and Human Services may close such pub-
10 lic docket not earlier than 90 days after such docket
11 is opened.

12 (4) NO DELAY.—Nothing in this section shall
13 delay agency action on any modification to a risk
14 evaluation and mitigation strategy.

15 (b) GAO REPORT.—Not later than December 31,
16 2026, the Comptroller General of the United States shall
17 submit to the Committee on Energy and Commerce of the
18 House of Representatives and the Committee on Health,
19 Education, Labor, and Pensions of the Senate a report
20 on—

21 (1) the number of changes in third-party ven-
22 dors (engaged by sponsors to aid implementation
23 and management of risk evaluation and mitigation
24 strategies) for an approved risk evaluation and miti-
25 gation strategy the Secretary of Health and Human

1 Services has approved under section 505–1(h) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355–1(h));

4 (2) any issues affecting patient access to the
5 drug that is subject to the strategy or considerations
6 with respect to the administration or prescribing of
7 such drug by health care providers that arose as a
8 result of such modifications; and

9 (3) how such issues were resolved, as applica-
10 ble.

11 **SEC. 809. FACILITATING EXCHANGE OF PRODUCT INFOR-**
12 **MATION PRIOR TO APPROVAL.**

13 (a) IN GENERAL.—Section 502 of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 352) is amended

15 (1) in paragraph (a)—

16 (A) by striking “drugs for coverage” and
17 inserting “drugs or devices for coverage”; and

18 (B) by striking “drug” each place it ap-
19 pears and inserting “drug or device”, respec-
20 tively;

21 (2) in paragraph (a)(2)(B), by striking “under
22 section 505 or under section 351 of the Public
23 Health Service Act for such drug” and inserting
24 “under section 505, 510(k), 513(f)(2), or 515 of this

1 Act or section 351 of the Public Health Service
2 Act”; and

3 (3) by adding at the end the following:

4 “(gg)(1) Unless its labeling bears adequate directions
5 for use in accordance with paragraph (f), except that (in
6 addition to drugs or devices that conform with exemptions
7 pursuant to such paragraph) no drug or device shall be
8 deemed to be misbranded under such paragraph through
9 the provision of product information to a payor, formulary
10 committee, or other similar entity with knowledge and ex-
11 pertise in the area of health care economic analysis car-
12 rying out its responsibilities for the selection of drugs or
13 devices for coverage or reimbursement if the product infor-
14 mation relates to an investigational drug or device or in-
15 vestigational use of a drug or device that is approved,
16 cleared, granted marketing authorization, or licensed
17 under section 505, 510(k), 513(f)(2), or 515 of this Act
18 or section 351 of the Public Health Service Act (as appli-
19 cable), provided—

20 “(A) the product information includes—

21 “(i) a clear statement that the investiga-
22 tional drug or device or investigational use of a
23 drug or device has not been approved, cleared,
24 granted marketing authorization, or licensed
25 under section 505, 510(k), 513(f)(2), or 515 of

1 this Act or section 351 of the Public Health
2 Service Act (as applicable) and that the safety
3 and effectiveness of the drug or device or use
4 has not been established;

5 “(ii) information related to the stage of de-
6 velopment of the drug or device involved, such
7 as—

8 “(I) the status of any study or studies
9 in which the investigational drug or device
10 or investigational use is being investigated;

11 “(II) how the study or studies relate
12 to the overall plan for the development of
13 the drug or device; and

14 “(III) whether an application, pre-
15 market notification, or request for classi-
16 fication for the investigational drug or de-
17 vice or investigational use has been sub-
18 mitted to the Secretary and when such a
19 submission is planned;

20 “(iii) in the case of information that in-
21 cludes factual presentations of results from
22 studies, which shall not be selectively presented,
23 a description of—

24 “(I) all material aspects of study de-
25 sign, methodology, and results; and

1 “(II) all material limitations related
2 to the study design, methodology, and re-
3 sults;

4 “(iv) where applicable, a prominent state-
5 ment disclosing the indication or indications for
6 which the Secretary has approved, granted mar-
7 keting authorization, cleared, or licensed the
8 product pursuant to section 505, 510(k),
9 513(f)(2), or 515 of this Act or section 351 of
10 the Public Health Service Act, and a copy of
11 the most current required labeling; and

12 “(v) updated information, if previously
13 communicated information becomes materially
14 outdated as a result of significant changes or as
15 a result of new information regarding the prod-
16 uct or its review status; and

17 “(B) the product information does not in-
18 clude—

19 “(i) information that represents that an
20 unapproved product—

21 “(I) has been approved, cleared,
22 granted marketing authorization, or li-
23 censed under section 505, 510(k),
24 513(f)(2), or 515 of this Act or section

1 351 of the Public Health Service Act (as
2 applicable); or

3 “(II) has otherwise been determined
4 to be safe or effective for the purpose or
5 purposes for which the drug or device is
6 being studied; or

7 “(ii) information that represents that an
8 unapproved use of a drug or device that has
9 been so approved, granted marketing authoriza-
10 tion, cleared, or licensed—

11 “(I) is so approved, granted mar-
12 keting authorization, cleared, or licensed;
13 or

14 “(II) that the product is safe or effec-
15 tive for the use or uses for which the drug
16 or device is being studied.

17 “(2) For purposes of this paragraph, the term ‘prod-
18 uct information’ includes—

19 “(A) information describing the drug or device
20 (such as drug class, device description, and fea-
21 tures);

22 “(B) information about the indication or indica-
23 tions being investigated;

24 “(C) the anticipated timeline for a possible ap-
25 proval, clearance, marketing authorization, or licen-

1 sure pursuant to section 505, 510(k), 513, or 515
2 of this Act or section 351 of the Public Health Serv-
3 ice Act;

4 “(D) drug or device pricing information;

5 “(E) patient utilization projections;

6 “(F) product-related programs or services; and

7 “(G) factual presentations of results from stud-
8 ies that do not characterize or make conclusions re-
9 garding safety or efficacy.”.

10 (b) GAO STUDY AND REPORT.—Beginning on the
11 date that is 5 years and 6 months after the date of enact-
12 ment of this Act, the Comptroller General of the United
13 States shall conduct a study on the provision and use of
14 information pursuant to section 502(gg) of the Federal
15 Food, Drug, and Cosmetic Act, as added by this sub-
16 section (a), between manufacturers of drugs and devices
17 (as defined in section 201 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 321)) and entities described in
19 such section 502(gg). Such study shall include an analysis
20 of the following:

21 (1) The types of information communicated be-
22 tween such manufacturers and payors.

23 (2) The manner of communication between
24 such manufacturers and payors.

1 (3)(A) Whether such manufacturers file an ap-
2 plication for approval, marketing authorization,
3 clearance, or licensing of a new drug or device or the
4 new use of a drug or device that is the subject of
5 communication between such manufacturers and
6 payors under section 502(gg) of the Federal Food,
7 Drug, and Cosmetic Act, as added by subsection (a).

8 (B) How frequently the Food and Drug Admin-
9 istration approves, grants marketing authorization,
10 clears, or licenses the new drug or device or new use.

11 (C) The timeframe between the initial commu-
12 nications permitted under section 502(gg) of the
13 Federal Food, Drug, and Cosmetic Act, as added by
14 subsection (a), regarding an investigational drug or
15 device or investigational use, and the initial mar-
16 keting of such drug or device.

17 **SEC. 810. BANS OF DEVICES FOR ONE OR MORE INTENDED**
18 **USES.**

19 (a) IN GENERAL.—Section 516(a) of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 360f(a)) is
21 amended—

22 (1) in paragraph (1), by inserting “for one or
23 more intended use” before the semicolon at the end;
24 and

1 (2) in the matter following paragraph (2), by
2 inserting “for any such intended use or uses. A de-
3 vice that is banned for one or more intended uses is
4 not a legally marketed device under section 1006
5 when intended for such use or uses” after “banned
6 device”.

7 (b) SPECIFIC DEVICES DEEMED BANNED.—Section
8 516 of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 360f) is further amended by adding at the end the
10 following:

11 “(c) SPECIFIC DEVICE BANNED.—Electrical stimula-
12 tion devices that apply a noxious electrical stimulus to a
13 person’s skin intended to reduce or cease self-injurious be-
14 havior or aggressive behavior are deemed to be banned de-
15 vices, as described in subsection (a).

16 “(d) REVERSAL BY REGULATION.—Devices banned
17 under this section are banned devices unless or until the
18 Secretary promulgates a regulation to make such devices
19 or use of such devices no longer banned based on a finding
20 that such devices or use of such devices does not present
21 substantial deception or an unreasonable and substantial
22 risk of illness or injury, or that such risk can be corrected
23 or eliminated by labeling.”.

1 **SEC. 811. CLARIFYING APPLICATION OF EXCLUSIVE AP-**
2 **PROVAL, CERTIFICATION, OR LICENSURE**
3 **FOR DRUGS DESIGNATED FOR RARE DIS-**
4 **EASES OR CONDITIONS.**

5 (a) APPLICATION OF EXCLUSIVE APPROVAL, CER-
6 TIFICATION, OR LICENSURE FOR DRUGS DESIGNATED
7 FOR RARE DISEASES OR CONDITIONS.—Section 527 of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 360cc) is amended—

10 (1) in subsection (a), in the matter following
11 paragraph (2), by striking “same disease or condi-
12 tion” and inserting “same approved indication or
13 use within such rare disease or condition”;

14 (2) in subsection (b)—

15 (A) in the matter preceding paragraph (1),
16 by striking “same rare disease or condition”
17 and inserting “same indication or use for which
18 the Secretary has approved or licensed such
19 drug”; and

20 (B) in paragraph (1), by striking “with the
21 disease or condition for which the drug was des-
22 ignated” and inserting “for whom the drug is
23 indicated”; and

24 (3) in subsection (c), by striking “same rare
25 disease or condition” and inserting “same indication
26 or use”.

1 (b) APPLICATION OF AMENDMENTS.—The amend-
2 ments made by subsection (a) shall apply with respect to
3 any drug designated under section 526 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
5 less of the date on which the drug was so designated, and
6 regardless of the date on which the drug was approved
7 under section 505 of such Act (21 U.S.C. 355) or licensed
8 under section 351 of the Public Health Service Act (42
9 U.S.C. 262).

10 **SEC. 812. GAO REPORT ON THIRD-PARTY REVIEW.**

11 Not later than September 30, 2026, the Comptroller
12 General of the United States shall submit to the Com-
13 mittee on Energy and Commerce of the House of Rep-
14 resentatives and the Committee on Health, Education,
15 Labor, and Pensions of the Senate a report on the third-
16 party review program described in section 523 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360m).
18 Such report shall include—

19 (1) a description of the financial and staffing
20 resources used to carry out such program;

21 (2) a description of actions taken by the Sec-
22 retary pursuant section 523(b)(2)(C) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 360m(b)(2)(C)); and

1 (3) the results of an audit of the performance
2 of select persons accredited under such program.

3 **SEC. 813. REPORTING ON PENDING GENERIC DRUG APPLI-**
4 **CATIONS AND PRIORITY REVIEW APPLICA-**
5 **TIONS.**

6 Section 807 of the FDA Reauthorization Act of 2017
7 (Public Law 115–52) is amended, in the matter preceding
8 paragraph (1), by striking “2022” and inserting “2027”.

