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117TH CONGRESS
2^D SESSION

H. R. 7667

[Report No. 117-348]

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

IN THE HOUSE OF REPRESENTATIVES

MAY 6, 2022

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

JUNE 7, 2022

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on May 6, 2022]

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Food and Drug Amend-*
 5 *ments of 2022”.*

6 **SEC. 2. TABLE OF CONTENTS.**

7 *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. Sunset dates.

Sec. 208. Effective date.

Sec. 209. Savings clause.

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

TITLE VI—GENERIC DRUG COMPETITION

- Sec. 601. Increasing transparency in generic drug applications.*
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.
Sec. 713. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs.

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. Dual Submission for Certain Devices.

Sec. 807. Medical Devices Advisory Committee meetings.

Sec. 808. Ensuring cybersecurity of medical devices.

Sec. 809. Public docket on proposed changes to third-party vendors.

Sec. 810. Facilitating exchange of product information prior to approval.

Sec. 811. Bans of devices for one or more intended uses.

Sec. 812. Clarifying application of exclusive approval, certification, or licensure for drugs designated for rare diseases or conditions.

Sec. 813. GAO report on third-party review.

Sec. 814. Reporting on pending generic drug applications and priority review applications.

Sec. 815. FDA Workforce Improvements.

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 author-*
7 ized by the amendments made by this title will be dedicated
8 toward expediting the drug development process and the
9 process for the review of human drug applications, includ-
10 ing postmarket drug safety activities, as set forth in the
11 goals identified for purposes of part 2 of subchapter C of
12 chapter VII of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 379g et seq.), in the letters from the Secretary
14 of Health and Human Services to the Chairman of the

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

5 **SEC. 102. DEFINITIONS.**

6 (a) *HUMAN DRUG APPLICATION.*—Section 735(1) of
7 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
8 *379g(1)) is amended by striking “an allergenic extract*
9 *product, or” and inserting “does not include an application*
10 *with respect to an allergenic extract product licensed before*
11 *October 1, 2022, does not include an application with re-*
12 *spect to a standardized allergenic extract product submitted*
13 *pursuant to a notification to the applicant from the Sec-*
14 *retary regarding the existence of a potency test that meas-*
15 *ures the allergenic activity of an allergenic extract product*
16 *licensed by the applicant before October 1, 2022, does not*
17 *include an application with respect to”.*

18 (b) *PRESCRIPTION DRUG PRODUCT.*—Section 735(3)
19 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
20 *379g(3)) is amended—*

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

23 (2) *by striking “(3) The term” and inserting*
24 *“(3)(A) The term”;*

1 (3) by striking “Such term does not include
2 whole blood” and inserting the following:

3 “(B) Such term does not include whole blood”;

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

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

13 “(C)(i) If a written request to place a prod-
14 uct in the discontinued section of either of the
15 lists referenced in subparagraph (A)(iii) is sub-
16 mitted to the Secretary on behalf of an appli-
17 cant, and the request identifies the date the prod-
18 uct is withdrawn from sale, then for purposes of
19 assessing the prescription drug program fee
20 under section 736(a)(2), the Secretary shall con-
21 sider such product to have been included in the
22 discontinued section on the later of—

23 “(I) the date such request was received;

24 or

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

4 “(ii) For purposes of this subparagraph, a
5 product shall be considered withdrawn from sale
6 once the applicant has ceased its own distribu-
7 tion of the product, whether or not the applicant
8 has ordered recall of all previously distributed
9 lots of the product, except that a routine, tem-
10 porary interruption in supply shall not render a
11 product withdrawn from sale.”.

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

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

16 “(A) means a product—

17 “(i) for prick, scratch, intradermal, or
18 subcutaneous administration;

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

22 “(iii) not intended to be a preventive
23 or therapeutic intervention; and

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

4 “(I) an allergy to an anti-
5 microbial agent;

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

10 “(III) infection with fungal or
11 mycobacterial pathogens; and

12 “(B) includes positive and negative controls
13 required to interpret the results of a product de-
14 scribed in subparagraph (A).”.

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

16 (a) *TYPES OF FEES.*—

17 (1) *HUMAN DRUG APPLICATION FEE.*—Section
18 736(a) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 379h(a)) is amended—

20 (A) in the matter preceding paragraph (1),
21 by striking “fiscal year 2018” and inserting “fis-
22 cal year 2023”;

23 (B) in paragraph (1)(A), by striking
24 “(c)(5)” each place it appears and inserting
25 “(c)(6)”;

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

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

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

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

13 (A) in subparagraph (A)—

14 (i) by striking “Except as provided in
15 subparagraphs (B) and (C)” and inserting
16 the following:

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

19 (ii) by striking “subsection (c)(5)” and
20 inserting “subsection (c)(6)”; and

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

23 “(ii) SPECIAL RULE.—If a drug prod-
24 uct that is identified in a human drug ap-
25 plication approved as of October 1 of a fis-

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

22 *(B) by amending subparagraph (B) to read*
23 *as follows:*

24 *“(B) EXCEPTION FOR CERTAIN PRESCRIP-*
25 *TION DRUG PRODUCTS.—A prescription drug*

1 *program fee shall not be assessed for a prescrip-*
2 *tion drug product under subparagraph (A) if*
3 *such product is—*

4 *“(i) a large volume parenteral product*
5 *(a sterile aqueous drug product packaged in*
6 *a single-dose container with a volume great-*
7 *er than or equal to 100 mL, not including*
8 *powders for reconstitution or pharmacy*
9 *bulk packages) identified on the list com-*
10 *plied under section 505(j)(7);*

11 *“(ii) pharmaceutically equivalent (as*
12 *defined in section 314.3 of title 21, Code of*
13 *Federal Regulations (or any successor regu-*
14 *lation)) to another product on the list of*
15 *products compiled under section 505(j)(7)*
16 *(not including the discontinued section of*
17 *such list); or*

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

19 ***(b) FEE REVENUE AMOUNTS.—***

20 ***(1) IN GENERAL.—****Paragraph (1) of section*
21 ***736(b) of the Federal Food, Drug, and Cosmetic Act***
22 ***(21 U.S.C. 379h(b)) is amended to read as follows:***

23 ***“(1) IN GENERAL.—****For each of the fiscal years*
24 ***2023 through 2027, fees under subsection (a) shall, ex-***
25 ***cept as provided in subsections (c), (d), (f), and (g),***

1 *be established to generate a total revenue amount*
2 *under such subsection that is equal to the sum of—*

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

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

8 *“(C) the dollar amount equal to the stra-*
9 *tegic hiring and retention adjustment for the fis-*
10 *cal year (as determined under subsection (c)(2));*

11 *“(D) the dollar amount equal to the capac-*
12 *ity planning adjustment for the fiscal year (as*
13 *determined under subsection (c)(3));*

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

18 *“(F) the dollar amount equal to the addi-*
19 *tional direct cost adjustment for the fiscal year*
20 *(as determined under subsection (c)(5)); and*

21 *“(G) additional dollar amounts for each fis-*
22 *cal year as follows:*

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

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

25 *“(iii) \$14,154,169 for fiscal year 2025.*

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

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

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

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

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

11 and

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

17 (c) *ADJUSTMENTS; ANNUAL FEE SETTING.*—

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

1 (2) *STRATEGIC HIRING AND RETENTION ADJUST-*
2 *MENT.—Section 736(c) of the Federal Food, Drug,*
3 *and Cosmetic Act (21 U.S.C. 379h(c)) is amended—*

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

7 (B) *by inserting after paragraph (1) the fol-*
8 *lowing:*

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

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

16 “(B) *For each of fiscal years 2024 through*
17 *2027, \$4,000,000.”.*

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

22 “(3) *CAPACITY PLANNING ADJUSTMENT.—*

23 “(A) *IN GENERAL.—For each fiscal year,*
24 *after the annual base revenue established in sub-*
25 *section (b)(1)(A) is adjusted in accordance with*

1 paragraphs (1) and (2), such revenue shall be
2 adjusted further for such fiscal year, in accord-
3 ance with this paragraph, to reflect changes in
4 the resource capacity needs of the Secretary for
5 the process for the review of human drug appli-
6 cations.

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

1 *tence, the Secretary shall not include as work-*
2 *load categories in applying such methodology in*
3 *forecasting any non-core review activities, in-*
4 *cluding those activities that the Secretary ref-*
5 *erenced for potential future use in such notice*
6 *but did not utilize in setting fees for fiscal year*
7 *2021.*

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

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

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

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

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

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

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

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

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

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

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

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

3 “(5) *ADDITIONAL DIRECT COST ADJUSTMENT.*—

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

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

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

20 “(B) *APPLICABLE AMOUNTS.*—*The amounts*
21 *referred to in subparagraph (A)(ii) are the fol-*
22 *lowing:*

23 “(i) *For fiscal year 2024, \$60,967,993.*

24 “(ii) *For fiscal year 2025, \$35,799,314.*

1 “(iii) For fiscal year 2026, \$35,799,
2 314.

3 “(iv) For fiscal year 2027,
4 \$35,799,314.”.

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

10 (d) CREDITING AND AVAILABILITY OF FEES.—Section
11 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 379h(g)(3)) is amended by striking “fiscal years
13 2018 through 2022” and inserting “fiscal years 2023
14 through 2027”.

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

19 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,
20 EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING
21 FEES.—To qualify for consideration for a waiver or reduc-
22 tion under subsection (d), an exemption under subsection
23 (k), or the return of any fee paid under this section, includ-
24 ing if the fee is claimed to have been paid in error, a person
25 shall—

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

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

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

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

13 (2) by amending paragraph (2) to read as fol-
14 lows:

15 “(2) *EVIDENCE OF QUALIFICATION.*—An exemp-
16 tion under paragraph (1) applies with respect to a
17 drug only if the applicant involved submits a certifi-
18 cation that the applicant’s gross annual revenues did
19 not exceed \$50,000,000 for the last calendar year end-
20 ing prior to the fiscal year for which the exemption
21 is requested. Such certification shall be supported
22 by—

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

1 “(B) as necessary, other appropriate finan-
2 cial information.”.

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

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

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

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

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

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

22 “(v) For fiscal years 2023 and 2024, of
23 the meeting requests from sponsors for
24 which the Secretary has determined that a
25 face-to-face meeting is appropriate, the

1 *number of face-to-face meetings requested by*
2 *sponsors to be conducted in person (in such*
3 *manner as the Secretary shall prescribe on*
4 *the internet website of the Food and Drug*
5 *Administration), and the number of such*
6 *in-person meetings granted by the Sec-*
7 *retary.”;*

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

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

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

14 (8) *in subsection (f)—*

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

19 (B) *in paragraph (5), by striking “January*
20 *15, 2022” and inserting “January 15, 2027”.*

21 **SEC. 105. SUNSET DATES.**

22 (a) *AUTHORIZATION.—Sections 735 and 736 of the*
23 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;*
24 *379h) shall cease to be effective October 1, 2027.*

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

4 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
5 1, 2022, subsections (a) and (b) of section 104 of the *FDA*
6 *Reauthorization Act of 2017* (Public Law 115–52) are re-
7 pealed.

8 **SEC. 106. EFFECTIVE DATE.**

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

16 **SEC. 107. SAVINGS CLAUSE.**

17 *Notwithstanding the amendments made by this title,*
18 *part 2 of subchapter C of chapter VII of the Federal Food,*
19 *Drug, and Cosmetic Act* (21 U.S.C. 379g *et seq.*), as in effect
20 *on the day before the date of the enactment of this title,*
21 *shall continue to be in effect with respect to human drug*
22 *applications and supplements (as defined in such part as*
23 *of such day) that on or after October 1, 2017, but before*
24 *October 1, 2022, were accepted by the Food and Drug Ad-*
25 *ministration for filing with respect to assessing and col-*

1 lecting any fee required by such part for a fiscal year prior
2 to fiscal year 2023.

3 **TITLE II—FEES RELATING TO**
4 **DEVICES**

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

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

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

20 **SEC. 202. DEFINITIONS.**

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

23 (1) in paragraph (9)—

24 (A) in the matter preceding subparagraph

25 (A), by striking “and premarket notification

1 *submissions” and inserting “premarket notifica-*
2 *tion submissions, and de novo classification re-*
3 *quests”;*

4 *(B) in subparagraph (D), by striking “and*
5 *submissions” and inserting “submissions, and*
6 *requests”;*

7 *(C) in subparagraph (F), by striking “and*
8 *premarket notification submissions” and insert-*
9 *ing “premarket notification submissions, and de*
10 *novo classification requests”;*

11 *(D) in each of subparagraphs (G) and (H),*
12 *by striking “or submissions” and inserting “sub-*
13 *missions, or requests”;* and

14 *(E) in subparagraph (K), by striking “or*
15 *premarket notification submissions” and insert-*
16 *ing “premarket notification submissions, or de*
17 *novo classification requests”;* and

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

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

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

24 *(1) in paragraph (1), by striking “fiscal year*
25 *2018” and inserting “fiscal year 2023”;* and

1 (2) *in paragraph (2)—*

2 (A) *in subparagraph (A)—*

3 (i) *in the matter preceding clause (i),*
4 *by striking “October 1, 2017” and inserting*
5 *“October 1, 2022”;*

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

8 (iii) *in clause (viii), by striking “3.4*
9 *percent” and inserting “4.5 percent”;*

10 (B) *in subparagraph (B)(iii), by striking*
11 *“or premarket notification submission” and in-*
12 *serting “premarket notification submission, or de*
13 *novo classification request”; and*

14 (C) *in subparagraph (C), by striking “or*
15 *periodic reporting concerning a class III device”*
16 *and inserting “periodic reporting concerning a*
17 *class III device, or de novo classification re-*
18 *quest”.*

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

22 (1) *in paragraph (1), by striking “2018 through*
23 *2022” and inserting “2023 through 2027”;*

24 (2) *by amending paragraph (2) to read as fol-*
25 *lows:*

1 “(2) *BASE FEE AMOUNTS SPECIFIED.*—For pur-
 2 poses of paragraph (1), the base fee amounts specified
 3 in this paragraph are as follows:

| <i>“Fee Type</i> | <i>Fiscal Year 2023</i> | <i>Fiscal Year 2024</i> | <i>Fiscal Year 2025</i> | <i>Fiscal Year 2026</i> | <i>Fiscal Year 2027</i> |
|---|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| <i>Premarket Application</i> | <i>\$425,000</i> | <i>\$435,000</i> | <i>\$445,000</i> | <i>\$455,000</i> | <i>\$470,000</i> |
| <i>Establishment Registration</i> | <i>\$6,250</i> | <i>\$6,875</i> | <i>\$7,100</i> | <i>\$7,575</i> | <i>\$8,465”;</i> <i>and</i> |

4 (3) *by amending paragraph (3) to read as fol-*
 5 *lows:*

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

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

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

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

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

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

14 (c) *ANNUAL FEE SETTING; ADJUSTMENTS.*—Section
 15 738(c) of the Federal Food, Drug, and Cosmetic Act (21
 16 U.S.C. 379j(c)) is amended—

17 (1) *in paragraph (1), by striking “2017” and in-*
 18 *serting “2022”;*

19 (2) *in paragraph (2)—*

20 (A) *in subparagraph (A), by striking*
 21 *“2018” and inserting “2023”;*

22 (B) *in subparagraph (B)—*

1 (i) in the matter preceding clause (i),
2 by striking “fiscal year 2018” and inserting
3 “fiscal year 2023”; and

4 (ii) in clause (ii), by striking “fiscal
5 year 2016” and inserting “fiscal year
6 2022”;

7 (C) in subparagraph (C), by striking
8 “Washington-Baltimore, DC–MD–VA–WV” and
9 inserting “Washington-Arlington-Alexandria,
10 DC–VA–MD–WV”; and

11 (D) in subparagraph (D), in the matter
12 preceding clause (i), by striking “fiscal years
13 2018 through 2022” and inserting “fiscal years
14 2023 through 2027”;

15 (3) in paragraph (3), by striking “2018 through
16 2022” and inserting “2023 through 2027”;

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

19 (5) by inserting after paragraph (3) the fol-
20 lowing:

21 “(4) *PERFORMANCE IMPROVEMENT ADJUST-*
22 *MENT.—*

23 “(A) *IN GENERAL.—*For each of fiscal years
24 2025 through 2027, after the adjustments under
25 paragraphs (2) and (3), the base establishment

1 registration fee amounts for such fiscal year shall
2 be increased to reflect changes in the resource
3 needs of the Secretary due to improved review
4 performance goals for the process for the review
5 of device applications identified in the letters de-
6 scribed in section 201(b) of the Medical Device
7 User Fee Amendments of 2022, as the Secretary
8 determines necessary to achieve an increase in
9 total fee collections for such fiscal year equal to
10 the following amounts:

11 “(i) For fiscal year 2025, the product
12 of—

13 “(I) the amount determined under
14 subparagraph (B)(i)(I); and

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

18 “(ii) For fiscal year 2026, the product
19 of—

20 “(I) the sum of the amounts deter-
21 mined under subparagraphs (B)(i)(II),
22 (B)(ii)(I), and (B)(iii)(I); and

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

1 “(iii) For fiscal year 2027, the product
2 of—

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

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

10 “(B) AMOUNTS.—

11 “(i) PRE-SUBMISSION AMOUNT.—For
12 purposes of subparagraph (A), with respect
13 to the pre-submission written feedback goal,
14 the amounts determined under this sub-
15 paragraph are as follows:

16 “(I) For fiscal year 2025,
17 \$15,396,600 if such goal for fiscal year
18 2023 is met.

19 “(II) For fiscal year 2026:

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

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

1 “(III) For fiscal year 2027:

2 “*(aa)* \$15,396,600 if such
3 goal for fiscal year 2023 is met
4 and such goal for each of fiscal
5 years 2024 and 2025 is not met.

6 “*(bb)* \$36,792,200 if such
7 goal for fiscal year 2024 is met
8 and such goal for fiscal year 2025
9 is not met.

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

12 “(ii) *DE NOVO CLASSIFICATION*
13 *AMOUNT.—For purposes of subparagraph*
14 *(A), with respect to the de novo decision*
15 *goal, the amounts determined under this*
16 *subparagraph are as follows:*

17 “(I) For fiscal year 2026,
18 \$6,323,500 if such goal for fiscal year
19 2023 is met.

20 “(II) For fiscal year 2027:

21 “*(aa)* \$6,323,500 if such goal
22 for fiscal year 2023 is met and
23 such goal for fiscal year 2024 is
24 not met.

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

3 “(iii) *PREMARKET NOTIFICATION AND*
4 *PREMARKET APPROVAL AMOUNT.—For pur-*
5 *poses of subparagraph (A), with respect to*
6 *the 510(k) decision goal, 510(k) shared out-*
7 *come total time to decision goal, PMA deci-*
8 *sion goal, and PMA shared outcome total*
9 *time to decision goal, the amounts deter-*
10 *mined under this subparagraph are as fol-*
11 *lows:*

12 “(I) *For fiscal year 2026,*
13 *\$1,020,000 if the four goals for fiscal*
14 *year 2023 are met.*

15 “(II) *For fiscal year 2027:*

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

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

22 “(C) *PERFORMANCE CALCULATION.—For*
23 *purposes of this paragraph, performance of the*
24 *goals listed in subparagraph (D) shall be deter-*
25 *mined as specified in the letters described in sec-*

1 *tion 201(b) of the Medical Device User Fee*
2 *Amendments of 2022 and based on data avail-*
3 *able as of the following dates:*

4 *“(i) The performance of the pre-sub-*
5 *mission written feedback goal shall be based*
6 *on data available as of—*

7 *“(I) for fiscal year 2023, March*
8 *31, 2024;*

9 *“(II) for fiscal year 2024, March*
10 *31, 2025; and*

11 *“(III) for fiscal year 2025, March*
12 *31, 2026.*

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

19 *“(I) for fiscal year 2023, March*
20 *31, 2025; and*

21 *“(II) for fiscal year 2024, March*
22 *31, 2026.*

23 *“(D) GOALS DEFINED.—For purposes of*
24 *this paragraph, the terms ‘pre-submission writ-*
25 *ten feedback goal’, ‘de novo decision goal’, ‘510(k)*

1 *decision goal*, ‘510(k) shared outcome total time
2 *to decision goal*, ‘PMA decision goal’, and ‘PMA
3 *shared outcome total time to decision goal*’ refer
4 *to the goals identified by the same names in the*
5 *letters described in section 201(b) of the Medical*
6 *Device User Fee Amendments of 2022.*

7 “(5) *HIRING ADJUSTMENT.*—

8 “(A) *IN GENERAL.*—*For each of fiscal years*
9 *2025 through 2027, after the adjustments under*
10 *paragraphs (2), (3), and (4), if applicable, if the*
11 *number of hires to support the process for the re-*
12 *view of device applications falls below the thresh-*
13 *olds specified in subparagraph (B) for the appli-*
14 *cable fiscal years, the base establishment registra-*
15 *tion fee amounts shall be decreased as the Sec-*
16 *retary determines necessary to achieve a reduc-*
17 *tion in total fee collections equal to the hiring*
18 *adjustment amount under subparagraph (C).*

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

21 “(i) *For fiscal year 2025, the threshold*
22 *is 123 hires for fiscal year 2023.*

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

1 “(iii) For fiscal year 2027, the thresh-
2 old is—

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

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

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

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

18 “(ii) \$72,877; and

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

22 “(D) *HIRING GOALS.*—The hiring goals for
23 each of fiscal years 2023 through 2025 are as fol-
24 lows:

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

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

2 “(iii) For fiscal year 2025:

3 “*(I)* 24 hires if the base establish-
4 ment registration fees are not increased
5 by the amount determined under para-
6 graph (4)(A)(i).

7 “*(II)* 83 hires if the base establish-
8 ment registration fees are increased by
9 the amount determined under para-
10 graph (4)(A)(i).

11 “(E) NUMBER OF HIRES.—For purposes of
12 this paragraph, the number of hires shall be de-
13 termined by the Secretary as set forth in the let-
14 ters described in section 201(b) of the Medical
15 Device User Fee Amendments of 2022.

16 “(6) OPERATING RESERVE ADJUSTMENT.—

17 “(A) IN GENERAL.—For each of fiscal years
18 2023 through 2027, after the adjustments under
19 paragraphs (2), (3), (4), and (5), if applicable,
20 if the Secretary has operating reserves of carry-
21 over user fees for the process for the review of de-
22 vice applications in excess of the designated
23 amount in subparagraph (B), the Secretary shall
24 decrease the base establishment registration fee

1 *amounts to provide for not more than such des-*
2 *ignated amount of operating reserves.*

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

7 “(i) *13 weeks of operating reserves of*
8 *carryover user fees; and*

9 “(ii) *1 month of operating reserves*
10 *maintained pursuant to paragraph (8).*

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

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

21 (e) *CONDITIONS.*—*Section 738(g) of the Federal Food,*
22 *Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is 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 clas-*
2 *sification requests,*” after “*class III device,*”.

3 (f) *CREDITING AND AVAILABILITY OF FEES.*—Section
4 738(h)(3) of the *Federal Food, Drug, and Cosmetic Act* (21
5 *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 years
8 2023 through 2027, there is authorized to be ap-
9 propriated for fees under this section an amount
10 equal to the revenue amount determined under
11 subparagraph (B), less the amount of reductions
12 determined under subparagraph (C).

13 “(B) *REVENUE AMOUNT.*—For purposes of
14 this paragraph, the revenue amount for each fis-
15 cal year is the sum of—

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

20 “(ii) the performance improvement ad-
21 justment amount for the fiscal year under
22 subsection (c)(4), if applicable.

23 “(C) *REDUCTIONS.*—For purposes of this
24 paragraph, the amount of reductions for each fis-
25 cal year is the sum of—

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

4 “(ii) the operating reserve adjustment
5 amount for the fiscal year under subsection
6 (c)(6), if applicable.”.

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

8 (a) *PERFORMANCE REPORTS.*—Section 738A(a) of the
9 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
10 *1(a)) is amended—*

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

13 (2) *by striking “Medical Device User Fee*
14 *Amendments of 2017” each place it appears and in-*
15 *serting “Medical Device User Fee Amendments of*
16 *2022”;*

17 (3) *in paragraph (1)—*

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

21 (B) *in subparagraph (A)(iv), by striking*
22 *“fiscal year 2020” and inserting “fiscal year*
23 *2023”;* and

24 (4) *in paragraph (4), by striking “2018 through*
25 *2022” and inserting “2023 through 2027”.*

1 (b) *REAUTHORIZATION.*—Section 738A(b) of the Fed-
2 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b))*
3 *is amended—*

4 (1) *in paragraph (1), by striking “2022” and in-*
5 *serting “2027”; and*

6 (2) *in paragraph (5), by striking “2022” and in-*
7 *serting “2027”.*

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

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

12 “(d) *ACCREDITATION SCHEME FOR CONFORMITY AS-*
13 *SESSMENT.*—

14 “(1) *IN GENERAL.*—*The Secretary shall establish*
15 *a program under which—*

16 “(A) *testing laboratories meeting criteria*
17 *specified in guidance by the Secretary may be*
18 *accredited by accreditation bodies meeting cri-*
19 *teria specified in guidance by the Secretary, to*
20 *conduct testing to support the assessment of the*
21 *conformity of a device to certain standards rec-*
22 *ognized under this section; and*

23 “(B) *subject to paragraph (2), results from*
24 *tests conducted to support the assessment of con-*
25 *formity of devices as described in subparagraph*

1 (A) conducted by testing laboratories accredited
2 pursuant to this subsection shall be accepted by
3 the Secretary for purposes of demonstrating such
4 conformity unless the Secretary finds that cer-
5 tain results of such tests should not be so accept-
6 ed.

7 “(2) SECRETARIAL REVIEW OF ACCREDITED LAB-
8 ORATORY RESULTS.—The Secretary may—

9 “(A) review the results of tests conducted by
10 testing laboratories accredited pursuant to this
11 subsection, including by conducting periodic au-
12 dits of such results or of the processes of accred-
13 ited bodies or testing laboratories;

14 “(B) following such review, take additional
15 measures under this Act, as the Secretary deter-
16 mines appropriate, such as—

17 “(i) suspension or withdrawal of ac-
18 creditation of a testing laboratory or rec-
19 ognition of an accreditation body under
20 paragraph (1)(A); or

21 “(ii) requesting additional information
22 with respect to a device; and

23 “(C) if the Secretary becomes aware of in-
24 formation materially bearing on the safety or ef-
25 fectiveness of a device for which an assessment of

1 *conformity was supported by testing conducted*
2 *by a testing laboratory accredited under this*
3 *subsection, take such additional measures under*
4 *this Act, as the Secretary determines appro-*
5 *priate, such as—*

6 “(i) *suspension or withdrawal of ac-*
7 *creditation of a testing laboratory or rec-*
8 *ognition of an accreditation body under*
9 *paragraph (1)(A); or*

10 “(ii) *requesting additional information*
11 *with regard to such device.*

12 “(3) *IMPLEMENTATION AND REPORTING.—*

13 “(A) *PILOT PROGRAM TRANSITION.—After*
14 *September 30, 2023, the pilot program pre-*
15 *viously initiated under this subsection, as in ef-*
16 *fect prior to the date of enactment of the Medical*
17 *Device User Fee Amendments of 2022, shall be*
18 *considered to be completed, and the Secretary*
19 *may continue operating a program consistent*
20 *with this subsection.*

21 “(B) *REPORT.—The Secretary shall make*
22 *available on the internet website of the Food and*
23 *Drug Administration an annual report on the*
24 *progress of the pilot program under this sub-*
25 *section.”.*

1 **SEC. 206. REAUTHORIZATION OF THIRD-PARTY REVIEW**
2 **PROGRAM.**

3 *Section 523(c) of the Federal Food, Drug, and Cos-*
4 *metic Act (21 U.S.C. 360m(c)) is amended by striking*
5 *“2022” and inserting “2027”.*

6 **SEC. 207. SUNSET DATES.**

7 (a) *AUTHORIZATION.*—*Sections 737 and 738 of the*
8 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i;*
9 *379j) shall cease to be effective October 1, 2027.*

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

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

18 **SEC. 208. EFFECTIVE DATE.**

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

1 **SEC. 209. SAVINGS CLAUSE.**

2 *Notwithstanding the amendments made by this title,*
3 *part 3 of subchapter C of chapter VII of the Federal Food,*
4 *Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect*
5 *on the day before the date of the enactment of this title,*
6 *shall continue to be in effect with respect to the submissions*
7 *listed in section 738(a)(2)(A) of such Act (as defined in such*
8 *part as of such day) that on or after October 1, 2017, but*
9 *before October 1, 2022, were received by the Food and Drug*
10 *Administration with respect to assessing and collecting any*
11 *fee required by such part for a fiscal year prior to fiscal*
12 *year 2023.*

13 **TITLE III—FEES RELATING TO**
14 **GENERIC DRUGS**

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

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

18 (b) *FINDING.*—*The Congress finds that the fees author-*
19 *ized by the amendments made by this title will be dedicated*
20 *to human generic drug activities, as set forth in the goals*
21 *identified for purposes of part 7 of subchapter C of chapter*
22 *VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
23 *379j–41 et seq.), in the letters from the Secretary of Health*
24 *and Human Services to the Chairman of the Committee on*
25 *Health, Education, Labor, and Pensions of the Senate and*
26 *the Chairman of the Committee on Energy and Commerce*

1 *of the House of Representatives, as set forth in the Congres-*
2 *sional Record.*

3 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
4 **NERIC DRUG FEES.**

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

8 *(1) in the matter preceding paragraph (1), by*
9 *striking “fiscal year 2018” and inserting “fiscal year*
10 *2023”;*

11 *(2) in paragraph (2)(C), by striking “2018*
12 *through 2022” and inserting “2023 through 2027”;*

13 *(3) in paragraph (3)(B), by striking “2018*
14 *through 2022” and inserting “2023 through 2027”;*

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

18 *(5) in paragraph (5)(D), by striking “2018*
19 *through 2022” and inserting “2023 through 2027”.*

20 *(b) FEE REVENUE AMOUNTS.—Section 744B(b) of the*
21 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
22 *42(b)) is amended—*

23 *(1) in paragraph (1)—*

24 *(A) in subparagraph (A)—*

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

3 (ii) by striking “2018” and inserting
4 “2023”; and

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

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

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

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

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

1 (2) *in paragraph (2)—*

2 (A) *in subparagraph (C), by striking “one-*
3 *third the amount” and inserting “twenty-four*
4 *percent”;*

5 (B) *in subparagraph (D), by striking*
6 *“Seven percent” and inserting “Six percent”;*
7 *and*

8 (C) *in subparagraph (E)(i), by striking*
9 *“Thirty-five percent” and inserting “Thirty-six*
10 *percent”.*

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

14 (1) *in paragraph (1)—*

15 (A) *in the matter preceding subparagraph*

16 (A)—

17 (i) *by striking “2019” and inserting*
18 *“2024”; and*

19 (ii) *by striking “to equal the product of*
20 *the total revenues established in such notice*
21 *for the prior fiscal year multiplied” and in-*
22 *serting “to equal the base revenue amount*
23 *for the fiscal year (as specified in subsection*
24 *(b)(1)(B)) multiplied”; and*

1 (B) in subparagraph (C), by striking
2 “Washington-Baltimore, DC-MD-VA-WV” and
3 inserting “Washington-Arlington-Alexandria,
4 DC-VA-MD-WV”; and
5 (2) by striking paragraph (2) and inserting the
6 following:

7 “(2) *CAPACITY PLANNING ADJUSTMENT.*—

8 “(A) *IN GENERAL.*—Beginning with fiscal
9 year 2024, the Secretary shall, in addition to the
10 adjustment under paragraph (1), further in-
11 crease the fee revenue and fees under this section
12 for a fiscal year, in accordance with this para-
13 graph, to reflect changes in the resource capacity
14 needs of the Secretary for human generic drug
15 activities.

16 “(B) *CAPACITY PLANNING METHODOLOGY.*—
17 The Secretary shall establish a capacity plan-
18 ning methodology for purposes of this paragraph,
19 which shall—

20 “(i) be derived from the methodology
21 and recommendations made in the report ti-
22 tled ‘Independent Evaluation of the
23 GDUFA Resource Capacity Planning Ad-
24 justment Methodology: Evaluation and Rec-

1 *ommendations’ announced in the Federal*
2 *Register on August 3, 2020;*

3 *“(ii) incorporate approaches and at-*
4 *tributes determined appropriate by the Sec-*
5 *retary, including approaches and attributes*
6 *made in such report, except that in incor-*
7 *porating such approaches and attributes the*
8 *workload categories used in forecasting re-*
9 *sources shall only be the workload categories*
10 *specified in section VIII.B.2.e. of the letters*
11 *described in section 301(b) of the Generic*
12 *Drug User Fee Amendments of 2022; and*

13 *“(iii) be effective beginning with fiscal*
14 *year 2024.*

15 *“(C) LIMITATIONS.—*

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

24 *“(ii) PERCENTAGE LIMITATION.—An*
25 *adjustment under this paragraph shall not*

1 *exceed three percent of the sum described in*
2 *clause (i) for the fiscal year, except that*
3 *such limitation shall be four percent if—*

4 *“(I) for purposes of a fiscal year*
5 *2024 adjustment, the Secretary deter-*
6 *mines that during the period from*
7 *April 1, 2021, through March 31,*
8 *2023—*

9 *“(aa) the total number of ab-*
10 *breivated new drug applications*
11 *submitted was greater than or*
12 *equal to 2,000; or*

13 *“(bb) thirty-five percent or*
14 *more of abbreviated new drug ap-*
15 *plications submitted related to*
16 *complex products (as that term is*
17 *defined in section XI of the letters*
18 *described in section 301(b) of the*
19 *Generic Drug User Fee Amend-*
20 *ments of 2022);*

21 *“(II) for purposes of a fiscal year*
22 *2025 adjustment, the Secretary deter-*
23 *mines that during the period from*
24 *April 1, 2022, through March 31,*
25 *2024—*

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

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

9 “(III) for purposes of a fiscal year
10 2026 adjustment, the Secretary deter-
11 mines that during the period from
12 April 1, 2023, through March 31,
13 2025—

14 “(aa) the total number of ab-
15 breviated new drug applications
16 submitted was greater than or
17 equal to 2,300; or

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

23 “(IV) for purposes of a fiscal year
24 2027 adjustment, the Secretary deter-
25 mines that during the period from

1 April 1, 2024, through March 31,
2 2026—

3 “(aa) the total number of ab-
4 breviated new drug applications
5 submitted was greater than or
6 equal to 2,300; or

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

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

17 “(3) OPERATING RESERVE ADJUSTMENT.—

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

1 *the number of weeks specified in subparagraph*
2 *(B) with respect to that fiscal year.*

3 “(B) *NUMBER OF WEEKS.*—*The number of*
4 *weeks specified in this subparagraph is—*

5 “(i) *8 weeks for fiscal year 2024;*

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

7 “(iii) *10 weeks for each of fiscal year*
8 *2026 and 2027.*

9 “(C) *DECREASE.*—*If the Secretary has car-*
10 *ryover balances for human generic drug activi-*
11 *ties in excess of 12 weeks of the operating re-*
12 *serves referred to in subparagraph (A), the Sec-*
13 *retary shall decrease the fee revenue and fees re-*
14 *ferred to in such subparagraph to provide for not*
15 *more than 12 weeks of such operating reserves.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (7) in subsection (f)—

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

19 (B) in paragraph (5), by striking “January
20 15, 2022” and inserting “January 15, 2027”.

21 **SEC. 304. SUNSET DATES.**

22 (a) *AUTHORIZATION.*—Sections 744A and 744B of the
23 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
24 41; 379j–42) shall cease to be effective October 1, 2027.

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

4 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
5 1, 2022, subsections (a) and (b) of section 305 of the *FDA*
6 *Reauthorization Act of 2017* (Public Law 115–52) are re-
7 pealed.

8 **SEC. 305. EFFECTIVE DATE.**

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

17 **SEC. 306. SAVINGS CLAUSE.**

18 *Notwithstanding the amendments made by this title,*
19 *part 7 of subchapter C of chapter VII of the Federal Food,*
20 *Drug, and Cosmetic Act* (21 U.S.C. 379j–41 *et seq.*), as in
21 *effect on the day before the date of the enactment of this*
22 *title, shall continue to be in effect with respect to abbrevi-*
23 *ated new drug applications (as defined in such part as*
24 *of such day) that were received by the Food and Drug Ad-*
25 *ministration within the meaning of section 505(j)(5)(A) of*

1 *such Act (21 U.S.C. 355(j)(5)(A)), prior approval supple-*
2 *ments that were submitted, and drug master files for Type*
3 *II active pharmaceutical ingredients that were first ref-*
4 *erenced on or after October 1, 2017, but before October 1,*
5 *2022, with respect to assessing and collecting any fee re-*
6 *quired by such part for a fiscal year prior to fiscal year*
7 *2023.*

8 **TITLE IV—FEES RELATING TO**
9 **BIOSIMILAR BIOLOGICAL**
10 **PRODUCTS**

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

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

14 (b) *FINDING.*—*The Congress finds that the fees author-*
15 *ized by the amendments made by this title will be dedicated*
16 *to expediting the process for the review of biosimilar biologi-*
17 *cal product applications, including postmarket safety ac-*
18 *tivities, as set forth in the goals identified for purposes of*
19 *part 8 of subchapter C of chapter VII of the Federal Food,*
20 *Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), in the*
21 *letters from the Secretary of Health and Human Services*
22 *to the Chairman of the Committee on Health, Education,*
23 *Labor, and Pensions of the Senate and the Chairman of*
24 *the Committee on Energy and Commerce of the House of*
25 *Representatives, as set forth in the Congressional Record.*

1 **SEC. 402. DEFINITIONS.**

2 (a) *ADJUSTMENT FACTOR.*—Section 744G(1) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
4 51(1)) is amended to read as follows:

5 “(1) The term ‘adjustment factor’ applicable to a
6 fiscal year is the Consumer Price Index for urban
7 consumers (Washington-Arlington-Alexandria, DC–
8 VA–MD–WV; Not Seasonally Adjusted; All items; An-
9 nual Index) for September of the preceding fiscal year
10 divided by such Index for September 2011.”.

11 (b) *BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-*
12 *TION.*—Section 744G(4)(B)(iii) of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 379j–51(4)(B)(iii)) is amend-
14 ed—

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

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

19 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
20 **FEES.**

21 (a) *TYPES OF FEES.*—

22 (1) *IN GENERAL.*—The matter preceding para-
23 graph (1) in section 744H(a) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is
25 amended by striking “fiscal year 2018” and inserting
26 “fiscal year 2023”.

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

7 (3) *ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT*
8 *DEVELOPMENT FEE.*—*Section 744H(a)(1)(B) of the*
9 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
10 *379j–52(a)(1)(B)) is amended—*

11 *(A) in clause (i), by inserting before the pe-*
12 *riod at the end the following: “, except where*
13 *such product (including, where applicable, own-*
14 *ership of the relevant investigational new drug*
15 *application) is transferred to a licensee, assignee,*
16 *or successor of such person, and written notice of*
17 *such transfer is provided to the Secretary, in*
18 *which case such licensee, assignee, or successor*
19 *shall pay the annual biosimilar biological prod-*
20 *uct development fee”;*

21 *(B) in clause (iii)—*

22 *(i) in subclause (I), by striking “or” at*
23 *the end;*

24 *(ii) in subclause (II), by striking the*
25 *period at the end and inserting “; or”; and*

1 (iii) by adding at the end the fol-
2 lowing:

3 “(III) been administratively re-
4 moved from the biosimilar biological
5 product development program for the
6 product under subparagraph (E)(v).”;
7 and

8 (C) in clause (iv), by striking “is accepted
9 for filing on or after October 1 of such fiscal
10 year” and inserting “is subsequently accepted for
11 filing”.

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

16 “(D) REACTIVATION FEE.—

17 “(i) IN GENERAL.—A person that has
18 discontinued participation in the biosimilar
19 biological product development program for
20 a product under subparagraph (C), or who
21 has been administratively removed from the
22 biosimilar biological product development
23 program for a product under subparagraph
24 (E)(v), shall, if the person seeks to resume
25 participation in such program, pay all an-

1 *nual biosimilar biological product develop-*
2 *ment fees previously assessed for such prod-*
3 *uct and still owed and a fee (referred to in*
4 *this section as ‘reactivation fee’) by the ear-*
5 *lier of the following:*

6 *“(I) Not later than 7 days after*
7 *the Secretary grants a request by such*
8 *person for a biosimilar biological prod-*
9 *uct development meeting for the prod-*
10 *uct (after the date on which such parti-*
11 *cipation was discontinued or the date*
12 *of administrative removal, as applica-*
13 *ble).*

14 *“(II) Upon the date of submission*
15 *(after the date on which such partici-*
16 *pation was discontinued or the date of*
17 *administrative removal, as applicable)*
18 *by such person of an investigational*
19 *new drug application describing an in-*
20 *vestigation that the Secretary deter-*
21 *mines is intended to support a bio-*
22 *similar biological product application*
23 *for that product.*

24 *“(ii) APPLICATION OF ANNUAL FEE.—*
25 *A person that pays a reactivation fee for a*

1 *product shall pay for such product, begin-*
2 *ning in the next fiscal year, the annual bio-*
3 *similar biological product development fee*
4 *under subparagraph (B), except where such*
5 *product (including, where applicable, own-*
6 *ership of the relevant investigational new*
7 *drug application) is transferred to a li-*
8 *censee, assignee, or successor of such person,*
9 *and written notice of such transfer is pro-*
10 *vided to the Secretary, in which case such*
11 *licensee, assignee, or successor shall pay the*
12 *annual biosimilar biological product devel-*
13 *opment fee.”.*

14 (5) *EFFECT OF FAILURE TO PAY FEES.—Section*
15 *744H(a)(1)(E) of the Federal Food, Drug, and Cos-*
16 *metic Act (21 U.S.C. 379j–52(a)(1)(E)) is amended*
17 *by adding at the end the following:*

18 “(v) *ADMINISTRATIVE REMOVAL FROM*
19 *THE BIOSIMILAR BIOLOGICAL PRODUCT DE-*
20 *VELOPMENT PROGRAM.—If a person has*
21 *failed to pay an annual biosimilar biologi-*
22 *cal product development fee for a product as*
23 *required under subparagraph (B) for a pe-*
24 *riod of two consecutive fiscal years, the Sec-*
25 *retary may administratively remove such*

1 *person from the biosimilar biological prod-*
2 *uct development program for the product.*
3 *At least 30 days prior to administratively*
4 *removing a person from the biosimilar bio-*
5 *logical product development program for a*
6 *product under this clause, the Secretary*
7 *shall provide written notice to such person*
8 *of the intended administrative removal.”.*

9 (6) *BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-*
10 *TION FEE.—Section 744H(a)(2)(D) of the Federal*
11 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
12 *52(a)(2)(D)) is amended by inserting after “or was*
13 *withdrawn” the following: “prior to approval”.*

14 (7) *BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM*
15 *FEE.—Section 744H(a)(3) of the Federal Food, Drug,*
16 *and Cosmetic Act (21 U.S.C. 379j–52(a)(3)) is*
17 *amended—*

18 (A) *in subparagraph (A)—*

19 (i) *in clause (i), by striking “and” at*
20 *the end;*

21 (ii) *by redesignating clause (ii) as*
22 *clause (iii); and*

23 (iii) *by inserting after clause (i) the*
24 *following:*

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

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

5 “(E) MOVEMENT TO DISCONTINUED LIST.—

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

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

19 “(II) if the product will be with-
20 drawn from sale on a future date, such
21 future date when the product is with-
22 drawn from sale.

23 “(ii) TREATMENT AS WITHDRAWN
24 FROM SALE.—For purposes of clause (i), a
25 product shall be considered withdrawn from

1 *sale once the applicant has ceased its own*
2 *distribution of the product, whether or not*
3 *the applicant has ordered recall of all pre-*
4 *viously distributed lots of the product, ex-*
5 *cept that a routine, temporary interruption*
6 *in supply shall not render a product with-*
7 *drawn from sale.*

8 “(iii) *SPECIAL RULE.—If a biosimilar*
9 *biological product that is identified in a*
10 *biosimilar biological product application*
11 *approved as of October 1 of a fiscal year*
12 *appears, as of October 1 of such fiscal year,*
13 *on the list referenced in subparagraph (A)*
14 *of discontinued biosimilar biological prod-*
15 *ucts, and on any subsequent day during*
16 *such fiscal year the biosimilar biological*
17 *product does not appear on such list, then*
18 *except as provided in subparagraph (D),*
19 *each person who is named as the applicant*
20 *in a biosimilar biological product applica-*
21 *tion with respect to such product shall pay*
22 *the annual biosimilar biological product*
23 *program fee established for a fiscal year*
24 *under subsection (c)(5) for such biosimilar*
25 *biological product. Notwithstanding sub-*

1 *paragraph (B), such fee shall be due on the*
2 *last business day of such fiscal year and*
3 *shall be paid only once for each such prod-*
4 *uct for each fiscal year.”.*

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

9 (c) *FEE REVENUE AMOUNTS.—Subsection (b) of sec-*
10 *tion 744H of the Federal Food, Drug, and Cosmetic Act*
11 *(21 U.S.C. 379j–52) is amended—*

12 (1) *by striking paragraph (1);*

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

15 (3) *by amending paragraph (1) (as so redesign-*
16 *ated) to read as follows:*

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

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

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

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

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

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

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

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

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

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

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

22 (C) by redesignating subparagraphs (C)
23 and (D) as subparagraphs (B) and (C), respec-
24 tively; and

1 (5) *by amending paragraph (3) (as so redesign-*
2 *ated) to read as follows:*

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

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

7 “(B) *for fiscal years 2024 through 2027, the*
8 *dollar amount of the total revenue amount estab-*
9 *lished under paragraph (1) for the previous fis-*
10 *cal year, excluding any adjustments to such rev-*
11 *enue amount under subsection (c)(4).”.*

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

15 (1) *in paragraph (1)—*

16 (A) *in subparagraph (A)—*

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

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

23 (B) *in subparagraph (B)(ii), by striking*
24 *“Washington-Baltimore, DC–MD–VA–WV” and*

1 inserting “Washington-Arlington-Alexandria,
2 DC-VA-MD-WV”;

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

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

11 “(3) *CAPACITY PLANNING ADJUSTMENT.—*

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

20 “(B) *METHODOLOGY.—For purposes of this*
21 *paragraph, the Secretary shall employ the capac-*
22 *ity planning methodology utilized by the Sec-*
23 *retary in setting fees for fiscal year 2021, as de-*
24 *scribed in the notice titled ‘Biosimilar User Fee*
25 *Rates for Fiscal Year 2021’ published in the Fed-*

1 *eral Register on August 4, 2020 (85 Fed. Reg.*
2 *47220). The workload categories used in apply-*
3 *ing such methodology in forecasting shall include*
4 *only the activities described in that notice and,*
5 *as feasible, additional activities that are also di-*
6 *rectly related to the direct review of biosimilar*
7 *biological product applications and supplements,*
8 *including additional formal meeting types, the*
9 *direct review of postmarketing commitments and*
10 *requirements, the direct review of risk evaluation*
11 *and mitigation strategies, and the direct review*
12 *of annual reports for approved biosimilar bio-*
13 *logical products. Subject to the exceptions in the*
14 *preceding sentence, the Secretary shall not in-*
15 *clude as workload categories in applying such*
16 *methodology in forecasting any non-core review*
17 *activities, including those activities that the Sec-*
18 *retary referenced for potential future use in such*
19 *notice but did not utilize in setting fees for fiscal*
20 *year 2021.*

21 “(C) *LIMITATIONS.—Under no cir-*
22 *cumstances shall an adjustment under this para-*
23 *graph result in fee revenue for a fiscal year that*
24 *is less than the sum of the amounts under sub-*
25 *sections (b)(1)(A) (the annual base revenue for*

1 the fiscal year), (b)(1)(B) (the dollar amount of
2 the inflation adjustment for the fiscal year), and
3 (b)(1)(C) (the dollar amount of the strategic hir-
4 ing and retention adjustment).

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

10 “(4) OPERATING RESERVE ADJUSTMENT.—

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

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 Sec-*
13 *retary has carryover balances for such proc-*
14 *ess in excess of 21 weeks of such operating*
15 *reserves, the Secretary shall decrease such*
16 *fee revenue and fees to provide for not more*
17 *than 21 weeks of such operating reserves.*

18 “(C) *FEDERAL REGISTER NOTICE.—If an*
19 *adjustment under subparagraph (A) or (B) is*
20 *made, the rationale for the amount of the in-*
21 *crease or decrease in fee revenue and fees shall be*
22 *contained in the annual Federal Register notice*
23 *under paragraph (5)(B) establishing fee revenue*
24 *and fees for the fiscal year involved.”; and*

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

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

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

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

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

2 *Section 744I of the Federal Food, Drug, and Cosmetic*
3 *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 each*
15 *fiscal year thereafter” and inserting “Not later than*
16 *30 calendar days after the end of each quarter of each*
17 *fiscal year for which fees are collected under this*
18 *part”;*

19 *(5) in subsection (b), by striking “Not later than*
20 *120 days after the end of fiscal year 2018 and each*
21 *subsequent fiscal year for which fees are collected*
22 *under this part” and inserting “Not later than 120*
23 *days after the end of each fiscal year for which fees*
24 *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 the
13 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
14 51, 379j–52) shall cease to be effective October 1, 2027.

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

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

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 sub-*

1 *chapter C of chapter VII of the Federal Food, Drug, and*
2 *Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be assessed*
3 *for all biosimilar biological product applications received*
4 *on or after October 1, 2022, regardless of the date of the*
5 *enactment of this 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 (21 U.S.C. 379j–51 et seq.), as in*
10 *effect on the day before the date of the enactment of this*
11 *title, shall continue to be in effect with respect to biosimilar*
12 *biological product applications and supplements (as defined*
13 *in such part as of such day) that were accepted by the Food*
14 *and Drug Administration for filing on or after October 1,*
15 *2017, but before October 1, 2022, with respect to assessing*
16 *and collecting any fee required by such part for a fiscal*
17 *year prior 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, Drug,*
23 *and Cosmetic Act (21 U.S.C. 355(i)) is amended by adding*
24 *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 regulations),*
4 *or other pivotal study (other than bioavailability or bio-*
5 *equivalence studies), to be exempt pursuant to this sub-*
6 *section, the sponsor of a clinical investigation of such new*
7 *drug shall submit to the Secretary a diversity action plan.*

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

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

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 re-*
16 *quired by section 524B as soon as practicable but no later*
17 *than when the sponsor seeks feedback regarding such a*
18 *phase 3 study or other pivotal study of the drug.*

19 “(D) *The Secretary may waive the requirement in sub-*
20 *paragraph (A) if the Secretary determines that a waiver*
21 *is necessary based on what is known about the prevalence*
22 *of the disease in terms of the patient population that may*
23 *use the new drug.*

24 “(E) *No diversity action plan shall be required for a*
25 *submission described in section 561.”.*

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

4 “(9)(A)(i) *In order for a device in a clinical study for*
5 *which submission of an application for an investigational*
6 *device exemption is required to be exempt under this sub-*
7 *section, the sponsor of such study shall submit to the Sec-*
8 *retary in such application a diversity action plan in the*
9 *form and manner specified in the guidance required by sec-*
10 *tion 524B.*

11 “(ii) *In order for a device in a clinical study for which*
12 *submission of an application for an investigational device*
13 *exemption is not required, except for a device being studied*
14 *as described in section 812.2(c) of title 21, Code of Federal*
15 *Regulations (or successor regulations), to be exempt under*
16 *this subsection, the sponsor of such study shall develop and*
17 *implement a diversity action plan. Such diversity action*
18 *plan shall be submitted to the Secretary in any premarket*
19 *notification under section 510(k), request for classification*
20 *under section 513(f)(2), or application for premarket ap-*
21 *proval under section 515 for such device.*

22 “(B) *A diversity action plan under clause (i) or (ii)*
23 *of subparagraph (A) shall include—*

24 “(i) *the sponsor’s goals for enrollment in the*
25 *clinical study;*

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

2 “(iii) an explanation of how the sponsor intends

3 to meet such goals.

4 “(C) The Secretary may waive the requirement in sub-

5 paragraph (A) or (B) if the Secretary determines that a

6 waiver is necessary based on what is known about the prev-

7 alence of the disease in terms of the patient population that

8 may use the device.

9 “(D) No diversity action plan shall be required for a

10 submission described in section 561.”

11 (c) *GUIDANCE*.—Subchapter A of chapter V of the Fed-

12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 351 *et seq.*)

13 is amended by adding at the end the following:

14 **“SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR**

15 **CLINICAL STUDIES.**

16 “(a) *IN GENERAL*.—The Secretary shall issue guidance

17 relating to—

18 “(1) the format and content of the diversity ac-

19 tion plans required by sections 505(i)(5) and

20 520(g)(9) pertaining to the sponsor’s goals for clinical

21 study enrollment, disaggregated by age group, sex,

22 race, geographic location, socioeconomic status, and

23 ethnicity, including with respect to—

24 “(A) the rationale for the sponsor’s enroll-

25 ment goals, which may include—

1 “(i) *the estimated prevalence or inci-*
2 *dence in the United States of the disease or*
3 *condition for which the drug or device is*
4 *being developed or investigated, if such esti-*
5 *mated prevalence or incidence is known or*
6 *can be determined based on available data;*

7 “(ii) *what is known about the disease*
8 *or condition for which the drug or device is*
9 *being developed or investigated;*

10 “(iii) *any relevant pharmacokinetic or*
11 *pharmacogenomic data;*

12 “(iv) *what is known about the patient*
13 *population for such disease or condition, in-*
14 *cluding, to the extent data is available—*

15 “(I) *demographic information, in-*
16 *cluding age group, sex, race, geo-*
17 *graphic location, socioeconomic status,*
18 *and ethnicity;*

19 “(II) *non-demographic factors, in-*
20 *cluding co-morbidities affecting the pa-*
21 *tient population; and*

22 “(III) *potential barriers to enroll-*
23 *ing diverse participants, such as pa-*
24 *tient population size, geographic loca-*
25 *tion, and socioeconomic status; and*

1 “(v) any other data or information rel-
2 evant to selecting appropriate enrollment
3 goals, disaggregated by demographic sub-
4 group, such as the inclusion of pregnant
5 and lactating women;

6 “(B) an explanation for how the sponsor in-
7 tends to meet such goals, including demographic-
8 specific outreach and enrollment strategies,
9 study-site selection, clinical study inclusion and
10 exclusion practices, and any diversity training
11 for study personnel; and

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

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

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

20 “(B) if the sponsor does not expect to meet
21 such goals—

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

1 “(i) *the sponsor’s reasons for why the*
2 *sponsor does not expect to meet such goals.*

3 “(b) *ISSUANCE.—The Secretary shall—*

4 “(1) *not later than 12 months after the date of*
5 *enactment of this section, issue new draft guidance or*
6 *update existing draft guidance described in subsection*
7 *(a); and*

8 “(2) *not later than 9 months after closing the*
9 *comment period on such draft guidance, finalize such*
10 *guidance.”.*

11 “(d) *APPLICABILITY.—Sections 505(i)(5) and 520(g)(9)*
12 *of the Federal Food, Drug, and Cosmetic Act, as added by*
13 *subsections (a) and (b) of this section, apply only with re-*
14 *spect to clinical investigations with respect to which enroll-*
15 *ment commences after the date that is 180 days after the*
16 *publication of final guidance under section 524B(b)(2) of*
17 *the Federal Food, Drug, and Cosmetic Act, as added by sub-*
18 *section (c).*

19 **SEC. 502. EVALUATION OF THE NEED FOR FDA AUTHORITY**
20 **TO MANDATE POSTAPPROVAL STUDIES OR**
21 **POSTMARKET SURVEILLANCE DUE TO INSUF-**
22 **FICIENT DEMOGRAPHIC SUBGROUP DATA.**

23 “(a) *IN GENERAL.—Not later than 2 years after the*
24 *date of publication of final guidance pursuant to section*
25 *524B(b)(2) of the Federal Food, Drug, and Cosmetic Act,*

1 *as added by section 501(c) of this Act, the Secretary of*
2 *Health and Human Services shall commence an evaluation*
3 *to assess whether additions or changes to statutes or regula-*
4 *tions are warranted to ensure that sponsors conduct post-*
5 *approval studies or postmarket surveillance where—*

6 (1) *premarket studies collected insufficient data*
7 *for underrepresented subgroups according to the goals*
8 *specified in the diversity action plans of such spon-*
9 *sors; and*

10 (2) *the Secretary has requested additional stud-*
11 *ies be conducted.*

12 (b) *DETERMINATION AND REPORTING.—Not later than*
13 *180 days after the commencement of the evaluation under*
14 *subsection (a), the Secretary of Health and Human Services*
15 *shall submit a report to the Congress on the outcome of such*
16 *evaluation, including any recommendations related to addi-*
17 *tional needed authorities.*

18 **SEC. 503. PUBLIC WORKSHOPS TO ENHANCE CLINICAL**
19 **STUDY DIVERSITY.**

20 (a) *IN GENERAL.—Not later than one year after the*
21 *date of enactment of this Act, the Secretary of Health and*
22 *Human Services, in consultation with drug sponsors, med-*
23 *ical device manufacturers, patients, and other stakeholders,*
24 *shall convene one or more public workshops to solicit input*
25 *from stakeholders on increasing the enrollment of histori-*

1 cally underrepresented populations in clinical studies and
2 encouraging clinical study participation that reflects the
3 prevalence of the disease or condition among demographic
4 subgroups, where appropriate, and other topics, includ-
5 ing—

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

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

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

19 (4) approaches to support inclusion of underrep-
20 resented populations and to encourage clinical study
21 participation that reflects the population expected to
22 use the drug or device under study, including with re-
23 spect to—

24 (A) the establishment of inclusion and ex-
25 clusion criteria for certain subgroups, such as

1 *pregnant and lactating women and individuals*
2 *with disabilities, including intellectual or devel-*
3 *opmental disabilities or mental illness;*

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

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

10 *(D) clinical endpoints;*

11 *(E) biomarker selection; and*

12 *(F) studying analysis.*

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

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

1 *mary of, and response to, recommendations raised in such*
2 *workshop.*

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

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

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

15 *(2) contains information on—*

16 *(A) for drugs, biological products, and de-*
17 *VICES approved, licensed, cleared, or classified*
18 *under section 505, 515, 510(k), or 513(f)(2) of*
19 *the Federal Food, Drug, and Cosmetic Act (21*
20 *U.S.C. 355; 360e; 360(k); and 360(f)(2)), or sec-*
21 *tion 351(a) of the Public Health Service Act (42*
22 *U.S.C. 262(a)), whether the clinical studies con-*
23 *ducted with respect to such applications met the*
24 *demographic subgroup enrollment goals from the*

1 *diversity action plan submitted for such applica-*
2 *tions;*

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

6 *(C) any postmarket studies of a drug or de-*
7 *vice in a demographic subgroup or subgroups re-*
8 *quired or recommended by the Secretary based*
9 *on inadequate premarket clinical study diversity*
10 *or based on other reasons where a premarket*
11 *study lacked adequate diversity, including the*
12 *status and completion date of any such study.*

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

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

22 *(a) IN GENERAL.—Not later than 180 days after the*
23 *date on which the COVID-19 emergency period ends, the*
24 *Secretary of Health and Human Services shall convene a*
25 *public meeting to discuss the recommendations provided by*

1 *the Food and Drug Administration during the COVID–19*
2 *emergency period to mitigate disruption of clinical studies,*
3 *including recommendations detailed in the guidance enti-*
4 *tled “Conduct of Clinical Trials of Medical Products Dur-*
5 *ing the COVID–19 Public Health Emergency, Guidance for*
6 *Industry, Investigators, and Institutional Review Boards”,*
7 *as updated on August 8, 2021, and by any subsequent up-*
8 *dates to such guidance. The Secretary of Health and*
9 *Human Services shall invite to such meeting representatives*
10 *from the pharmaceutical and medical device industries who*
11 *sponsored clinical studies during the COVID–19 emergency*
12 *period and organizations representing patients.*

13 **(b) TOPICS.**—*Not later than 90 days after the date on*
14 *which the public meeting under subsection (a) is convened,*
15 *the Secretary of Health and Human Services shall make*
16 *available on the public website of the Food and Drug Ad-*
17 *ministration a report on the topics discussed at such meet-*
18 *ing. Such topics shall include discussion of—*

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

22 **(2)** *the characteristics of the sponsors, studies,*
23 *and patient populations impacted by such rec-*
24 *ommendations;*

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

8 (4) recommendations for incorporating certain
9 clinical study disruption mitigation recommendations
10 into current or additional guidance to improve clin-
11 ical study access and enrollment of diverse patient
12 populations.

13 (c) *COVID–19 EMERGENCY PERIOD DEFINED.*—In
14 this section, the term “COVID–19 emergency period” has
15 the meaning given the term “emergency period” in section
16 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–
17 5(g)(1)(B)).

18 **SEC. 506. DECENTRALIZED CLINICAL STUDIES.**

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

21 (1) not later than 12 months after the date of en-
22 actment of this Act, issue draft guidance that address-
23 es considerations for decentralized clinical studies, in-
24 cluding considerations regarding the engagement, en-
25 rollment, and retention of a meaningfully diverse

1 *clinical population, with respect to race, ethnicity,*
2 *age, sex, and geographic location, when appropriate;*
3 *and*

4 *(2) not later than 1 year after closing the com-*
5 *ment period on such draft guidance, finalize such*
6 *guidance.*

7 *(b) CONTENT OF GUIDANCE.—The guidance under sub-*
8 *section (a) shall address the following:*

9 *(1) Recommendations for how digital health*
10 *technology or other remote assessment options, such as*
11 *telehealth, could support decentralized clinical studies,*
12 *including guidance on considerations for selecting*
13 *technological platforms and mediums, data collection*
14 *and use, data integrity and security, and commu-*
15 *nication to study participants through digital tech-*
16 *nology.*

17 *(2) Recommendations for subject recruitment*
18 *and retention, including considerations for sponsors*
19 *to minimize or reduce burdens for clinical study par-*
20 *ticipants through the use of digital health technology,*
21 *telehealth, local health care providers and labora-*
22 *tories, or other means.*

23 *(3) Recommendations with respect to the evalua-*
24 *tion of data collected within a decentralized clinical*
25 *study setting.*

1 (c) *DEFINITION.*—*In this section, the term “decentral-*
2 *ized clinical study” means a clinical study in which some*
3 *or all of the study-related activities occur at a location sepa-*
4 *rate from the investigator’s location.*

5 **TITLE VI—GENERIC DRUG**
6 **COMPETITION**

7 **SEC. 601. INCREASING TRANSPARENCY IN GENERIC DRUG**
8 **APPLICATIONS.**

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

12 “(H)(i) *Upon request (in controlled correspondence or*
13 *otherwise) by a person that has submitted or intends to sub-*
14 *mit an abbreviated application for a new drug under this*
15 *subsection for which the Secretary has specified in regula-*
16 *tion, including under section 314.94(a)(9), title 21, Code*
17 *of Federal Regulations (or a successor regulation), or rec-*
18 *ommended in applicable guidance, certain qualitative or*
19 *quantitative criteria with respect to an inactive ingredient,*
20 *or on the Secretary’s own initiative during the review of*
21 *such abbreviated application, the Secretary shall inform the*
22 *person whether such new drug is qualitatively and quan-*
23 *titatively the same as the listed drug.*

24 “(ii) *Notwithstanding section 301(j), if the Secretary*
25 *determines that such new drug is not qualitatively or quan-*

1 *titatively the same as the listed drug, the Secretary shall*
2 *identify and disclose to the person—*

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

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

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

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

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

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

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

4 **(b) GUIDANCE.—**

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

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

18 **(A)** *publish draft guidance;*

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

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

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

6 **SEC. 602. ENHANCING ACCESS TO AFFORDABLE MEDICINES.**

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

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

14 “(ii) the sponsor of the application agrees to sub-
15 mit revised labeling for the drug that is the subject of
16 the application not later than 60 days after approval
17 under this subsection of the application;

18 “(iii) the labeling revision described under clause
19 (i) does not include a change to the ‘Warnings’ sec-
20 tion of the labeling; and”.

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

3 **Subtitle A—In General**

4 **SEC. 701. ANIMAL TESTING ALTERNATIVES.**

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

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

9 *(2) in subsection (i)—*

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

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

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

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

23 *(1) Cell-based assays.*

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

3 “(3) *Computer modeling.*

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

6 “(5) *Animal tests.*”.

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

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

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

12 “(a) *PROGRAM ESTABLISHMENT.*—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 *provements to such technologies after product ap-*
2 *proval; and*

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

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

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

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

18 “(3) *the number of public meetings held or par-*
19 *ticipated in by the Food and Drug Administration*
20 *pursuant to this section, including meetings convened*
21 *as part of a working group described in subparagraph*
22 *(D) or (G) of subsection (a)(2), and the topics of each*
23 *such meeting; and*

24 “(4) *the number of drug products approved or li-*
25 *censed, after the date of enactment of this section,*

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

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

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

8 (a) *REPORT ON ORPHAN DRUG PROGRAM.—*

9 (1) *IN GENERAL.—Not later than September 30,*
10 *2026, the Secretary shall submit to the Committee on*
11 *Energy and Commerce of the House of Representa-*
12 *tives and the Committee on Health, Education,*
13 *Labor, and Pensions of the Senate a report summa-*
14 *rizing the activities of the Food and Drug Adminis-*
15 *tration related to designating drugs under section 526*
16 *of the Federal Food, Drug, and Cosmetic Act (21*
17 *U.S.C. 360bb) for a rare disease or condition and ap-*
18 *proving such drugs under section 505 of such Act (21*
19 *U.S.C. 355) or licensing such drugs under section 351*
20 *of the Public Health Service Act (42 U.S.C. 262), in-*
21 *cluding—*

22 (A) *the number of applications for such*
23 *drugs under section 505 of the Federal Food,*
24 *Drug, and Cosmetic Act (21 U.S.C. 355) or sec-*
25 *tion 351 of the Public Health Service Act (42*

1 *U.S.C. 262) received by the Food and Drug Ad-*
2 *ministration, the number of such applications*
3 *accepted and rejected for filing, and the number*
4 *of such applications pending, approved, and dis-*
5 *approved by the Food and Drug Administration;*

6 *(B) a description of trends in drug approv-*
7 *als for rare diseases and conditions across review*
8 *divisions at the Food and Drug Administration;*

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

17 *(D) the Food and Drug Administration’s ef-*
18 *forts to promote best practices in the development*
19 *of novel treatments for rare diseases, including—*

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

22 *(ii) new regulatory science and coordi-*
23 *nated support for patient and stakeholder*
24 *engagement.*

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

5 (3) *INFORMATION DISCLOSURE.*—*Nothing in this*
6 *subsection shall be construed to authorize the disclo-*
7 *sure of information that is prohibited from disclosure*
8 *under section 1905 of title 18, United States Code, or*
9 *subject to withholding under paragraph (4) of section*
10 *552(b) of title 5, United States Code (commonly re-*
11 *ferred to as the “Freedom of Information Act”).*

12 (b) *STUDY ON EUROPEAN UNION SAFETY AND EFFI-*
13 *CACY REVIEWS OF DRUGS FOR RARE DISEASES AND CON-*
14 *DITIONS.*—

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

21 (A) *flexibilities, authorities, or mechanisms*
22 *available to regulators in the United States and*
23 *the European Union specific to rare diseases or*
24 *conditions;*

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

7 (C) *an assessment of collaborative efforts be-*
8 *tween United States and European Union regu-*
9 *lators related to—*

10 (i) *product development programs*
11 *under review;*

12 (ii) *policies under development recently*
13 *issued; and*

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

16 (D) *recommendations for how Congress can*
17 *support collaborative efforts described in sub-*
18 *paragraph (C).*

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

22 (A) *representatives from the Food and Drug*
23 *Administration and the European Medicines*
24 *Agency;*

25 (B) *rare disease or condition patients; and*

1 (C) *patient groups that—*

2 (i) *represent rare disease or condition*
3 *patients; and*

4 (ii) *have international patient out-*
5 *reach.*

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

9 (A) *the completion of the study under para-*
10 *graph (1); and*

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

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

22 (c) *PUBLIC MEETING.—*

23 (1) *IN GENERAL.—Not later than December 31,*
24 *2023, the Secretary of Health and Human Services,*
25 *acting through the Commissioner of Food and Drugs,*

1 *shall convene one or more public meetings to solicit*
2 *input from stakeholders regarding the approaches de-*
3 *scribed in paragraph (2).*

4 (2) *APPROACHES.—The public meeting or meet-*
5 *ings under paragraph (1) shall address approaches to*
6 *increasing and improving engagement with rare dis-*
7 *ease or condition patients, groups representing such*
8 *patients, rare disease or condition experts, and ex-*
9 *erts on small population studies, in order to improve*
10 *the understanding with respect to rare diseases or*
11 *conditions of—*

12 (A) *patient burden;*

13 (B) *treatment options; and*

14 (C) *side effects of treatments, including—*

15 (i) *comparing the side effects of treat-*
16 *ments; and*

17 (ii) *understanding the risks of side ef-*
18 *fects relative to the health status of the pa-*
19 *tient and the progression of the disease or*
20 *condition.*

21 (3) *PUBLIC DOCKET.—The Secretary of Health*
22 *and Human Services shall establish a public docket to*
23 *receive written comments related to the approaches*
24 *addressed during each public meeting under para-*
25 *graph (1). Such public docket shall remain open for*

1 60 days following the date of each such public meet-
2 ing.

3 (4) *REPORTS.*—Not later than 180 days after
4 each public meeting under paragraph (1), the Com-
5 missioner of Food and Drugs shall develop and pub-
6 lish on the website of the Food and Drug Administra-
7 tion a report on—

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

10 (B) any related recommendations.

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

15 “(C) *SMALL POPULATION STUDIES.*—The
16 external experts on the list maintained pursuant
17 to subparagraph (A) may include experts on the
18 science of small population studies.”.

19 (e) *STUDY ON SUFFICIENCY AND USE OF FDA MECHA-*
20 *NISMS FOR INCORPORATING THE PATIENT AND CLINICIAN*
21 *PERSPECTIVE IN FDA PROCESSES RELATED TO APPLICA-*
22 *TIONS CONCERNING DRUGS FOR RARE DISEASES OR CON-*
23 *DITIONS.*—

24 (1) *IN GENERAL.*—The Comptroller General of
25 the United States shall conduct a study on the use of

1 *Food and Drug Administration mechanisms and tools*
2 *to ensure that patient and physician perspectives are*
3 *considered and incorporated throughout the processes*
4 *of the Food and Drug Administration—*

5 *(A) for approving or licensing under section*
6 *505 of the Federal Food, Drug, or Cosmetic Act*
7 *(21 U.S.C. 355) or section 351 of the Public*
8 *Health Service Act (42 U.S.C. 262) a drug des-*
9 *ignated as a drug for a rare disease or condition*
10 *under section 526 of the Federal Food, Drug,*
11 *and Cosmetic Act (21 U.S.C. 360bb); and*

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

15 *(i) safety or effectiveness; or*

16 *(ii) postapproval safety monitoring.*

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

19 *(A) identify and compare the processes that*
20 *the Food and Drug Administration has formally*
21 *put in place and utilized to gather external ex-*
22 *pertise (including patients, patient groups, and*
23 *physicians) related to applications for rare dis-*
24 *eases or conditions;*

1 (B) examine tools or mechanisms to im-
2 prove efforts and initiatives of the Food and
3 Drug Administration to collect and consider such
4 external expertise with respect to applications for
5 rare diseases or conditions throughout the appli-
6 cation review and approval or licensure proc-
7 esses, including within internal benefit-risk as-
8 sessments, advisory committee processes, and
9 postapproval safety monitoring; and

10 (C) examine processes or alternatives to ad-
11 dress or resolve conflicts of interest that impede
12 the Food and Drug Administration in gaining
13 external expert input on rare diseases or condi-
14 tions with a limited set of clinical and research
15 experts.

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

19 (A) complete the study under paragraph
20 (1);

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

23 (C) include in such report recommenda-
24 tions, if appropriate, for changes to the processes
25 and authorities of the Food and Drug Adminis-

1 *tration to improve the collection and consider-*
2 *ation of external expert opinions of patients, pa-*
3 *tient groups, and physicians with expertise in*
4 *rare diseases or conditions.*

5 *(f) DEFINITION.—In this section, the term “rare dis-*
6 *ease or condition” has the meaning given such term in sec-*
7 *tion 526(a)(2) of the Federal Food, Drug, and Cosmetic Act*
8 *(21 U.S.C. 360bb(a)(2)).*

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

10 *(a) DRAFT GUIDANCE.—Not later than 3 years after*
11 *the date of the enactment of this Act, the Secretary of Health*
12 *and Human Services, acting through the Commissioner of*
13 *Food and Drugs, shall issue draft guidance for industry for*
14 *the purposes of assisting entities seeking approval under*
15 *section 505 of the Federal Food, Drug, and Cosmetic Act*
16 *(21 U.S.C. 355) or licensure under section 351 of the Public*
17 *Health Service Act (42 U.S.C. 262) of antifungal therapies*
18 *designed to treat coccidioidomycosis (commonly known as*
19 *Valley Fever).*

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

1 (c) *WORKSHOP.*—*To assist entities developing preven-*
2 *tive vaccines for fungal infections and coccidioidomycosis,*
3 *the Secretary of Health and Human Services shall hold a*
4 *public workshop.*

5 **SEC. 705. ADVANCING QUALIFIED INFECTIOUS DISEASE**
6 **PRODUCT INNOVATION.**

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

9 (1) *in subsection (c)—*

10 (A) *in paragraph (2), by striking “or” at*
11 *the end;*

12 (B) *in paragraph (3), by striking the period*
13 *at the end and inserting “; or”; and*

14 (C) *by adding at the end the following:*

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

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

20 (3) *by amending subsection (g) to read as fol-*
21 *lows:*

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

1 “(1) acts directly on bacteria or fungi or on sub-
2 stances produced by such bacteria or fungi; and

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

6 “(A) an antibacterial or antifungal resist-
7 ant pathogen, including novel or emerging infec-
8 tious pathogens; or

9 “(B) qualifying pathogens listed by the Sec-
10 retary under subsection (f).”.

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

17 **SEC. 706. ADVANCED MANUFACTURING TECHNOLOGIES**
18 **DESIGNATION PILOT PROGRAM.**

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

22 **“SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES**
23 **DESIGNATION PILOT PROGRAM.**

24 “(a) *IN GENERAL*.—Not later than 1 year after the
25 date of enactment of this section, the Secretary shall initiate

1 a pilot program under which persons may request designa-
2 tion of an advanced manufacturing technology as described
3 in subsection (b).

4 “(b) *DESIGNATION PROCESS.*—The Secretary shall es-
5 tablish a process for the designation under this section of
6 methods of manufacturing drugs, including biological prod-
7 ucts, and active pharmaceutical ingredients of such drugs,
8 as advanced manufacturing technologies. A method of man-
9 ufacturing, or a combination of manufacturing methods, is
10 eligible for designation as an advanced manufacturing tech-
11 nology if such method or combination of methods incor-
12 porates a novel technology, or uses an established technique
13 or technology in a novel way, that will substantially im-
14 prove the manufacturing process for a drug and maintain
15 equivalent or provide superior drug quality, including by—

16 “(1) reducing development time for a drug using
17 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 list
23 under section 506E.

24 “(c) *EVALUATION AND DESIGNATION OF AN ADVANCED*
25 *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 infor-*
9 *mation 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 later
20 *than 180 calendar days after the receipt of a request*
21 *under paragraph (1), the Secretary shall determine*
22 *whether to designate such method of manufacturing as*
23 *an advanced manufacturing technology, in a par-*
24 *ticular context of use, based on the data and informa-*

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

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

7 *“(1) expedite the development and review of an*
8 *application submitted under section 505 of this Act or*
9 *section 351 of the Public Health Service Act, includ-*
10 *ing 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 *ignated advanced manufacturing technology for use*

1 *in manufacturing drugs in the same context of use for*
2 *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 stake-*
10 *holders regarding—*

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

14 “(B) *ways in which the Food and Drug Ad-*
15 *ministration will support the use of advanced*
16 *manufacturing technologies and other innovative*
17 *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 final
3 guidance regarding the implementation of
4 such program.

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

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

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

14 “(iii) the process to expedite the devel-
15 opment and review of applications under
16 subsection (d); and

17 “(iv) the criteria described in sub-
18 section (b) for eligibility for such a designa-
19 tion.

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

1 *Commerce of the House of Representatives a report*
2 *containing a description and evaluation of the pilot*
3 *program being conducted under this section, includ-*
4 *ing the types of innovative manufacturing approaches*
5 *supported under the program. Such report shall in-*
6 *clude the following:*

7 “(A) *The number of persons that have re-*
8 *quested designations and that have been granted*
9 *designations.*

10 “(B) *The number of methods of manufac-*
11 *turing that have been the subject of designation*
12 *requests and that have been granted designations.*

13 “(C) *The average number of calendar days*
14 *for completion of evaluations under subsection*
15 *(c)(2).*

16 “(D) *An analysis of the factors in data sub-*
17 *missions that are relevant to determinations to*
18 *designate and not to designate after evaluation*
19 *under subsection (c)(2).*

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

1 *under this section, and the number of such appli-*
2 *cations approved.*

3 “(f) *SUNSET.*—*The Secretary—*

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

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

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

14 *Not later than 3 years after the date of the enactment*
15 *of this Act, the Secretary of Health and Human Services,*
16 *acting through the Commissioner of Food and Drugs, shall*
17 *convene a public workshop with relevant stakeholders to dis-*
18 *cuss best practices on generating scientific data necessary*
19 *to further facilitate the development of certain human cell-*
20 *, tissue-, and cellular-based medical products (and the latest*
21 *scientific information about such products) that are regu-*
22 *lated as drugs under the Federal Food, Drug, and Cosmetic*
23 *Act (21 U.S.C. 301 et seq.) and biological products under*
24 *section 351 of the Public Health Service Act (42 U.S.C.*
25 *262), namely, stem-cell and other cellular therapies.*

1 **SEC. 708. REAUTHORIZATION OF BEST PHARMACEUTICALS**
2 **FOR CHILDREN.**

3 *Section 409I(d)(1) of the Public Health Service Act*
4 *(42 U.S.C. 284m(d)(1)) is amended by striking “2018*
5 *through 2022” and inserting “2023 through 2027”.*

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

9 *(a) HUMANITARIAN DEVICE EXEMPTION.—Section*
10 *520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic*
11 *Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking*
12 *“2022” and inserting “2027”.*

13 *(b) PEDIATRIC MEDICAL DEVICE SAFETY AND IM-*
14 *PROVEMENT ACT.—Section 305(e) of the Pediatric Medical*
15 *Device Safety and Improvement Act of 2007 (Public Law*
16 *110–85) is amended by striking “2018 through 2022” and*
17 *inserting “2023 through 2027”.*

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

21 *Section 505(u)(4) of the Federal Food, Drug, and Cos-*
22 *metic Act (21 U.S.C. 355(u)(4)) is amended by striking*
23 *“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” and*
6 *inserting “\$10,000,000 for each of fiscal years 2023 through*
7 *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 end*
15 *the following: “, and (4) developing regulatory*
16 *science pertaining to the chemistry, manufac-*
17 *turing, and controls of individualized medical*
18 *products to treat individuals with rare diseases*
19 *or conditions”; and*

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

22 **SEC. 713. RESEARCH INTO PEDIATRIC USES OF DRUGS; AD-**
23 **DITIONAL AUTHORITIES OF FOOD AND DRUG**
24 **ADMINISTRATION REGARDING MOLECU-**
25 **LARLY TARGETED CANCER DRUGS.**

26 *(a) IN GENERAL.—*

1 (1) *ADDITIONAL ACTIVE INGREDIENT FOR APPLI-*
2 *CATION DRUG; LIMITATION REGARDING NOVEL-COM-*
3 *BINATION APPLICATION DRUG.*—Section 505B(a)(3) of
4 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
5 *355c(a)(3)) is amended—*

6 (A) *by redesignating subparagraphs (B)*
7 *and (C) as subparagraphs (C) and (D), respec-*
8 *tively; and*

9 (B) *by striking subparagraph (A) and in-*
10 *serting the following:*

11 “(A) *IN GENERAL.*—*For purposes of para-*
12 *graph (1)(B), the investigation described in this*
13 *paragraph is (as determined by the Secretary) a*
14 *molecularly targeted pediatric cancer investiga-*
15 *tion of—*

16 “(i) *the drug or biological product for*
17 *which the application referred to in such*
18 *paragraph is submitted; or*

19 “(ii) *such drug or biological product in*
20 *combination with—*

21 “(I) *an active ingredient of a*
22 *drug or biological product—*

23 “(aa) *for which an approved*
24 *application under section 505(j)*
25 *under this Act or under section*

1 351(k) of the Public Health Serv-
2 vice Act is in effect; and

3 “(bb) that is determined by
4 the Secretary to be the standard of
5 care for treating a pediatric can-
6 cer; or

7 “(II) an active ingredient of a
8 drug or biological product—

9 “(aa) for which an approved
10 application under section 505(b)
11 of this Act or section 351(a) of the
12 Public Health Service Act to treat
13 an adult cancer is in effect and is
14 held by the same person submit-
15 ting the application under para-
16 graph (1)(B); and

17 “(bb) that is directed at a
18 molecular target that the Sec-
19 retary determines to be substan-
20 tially relevant to the growth or
21 progression of a pediatric cancer.

22 “(B) ADDITIONAL REQUIREMENTS.—

23 “(i) DESIGN OF INVESTIGATION.—A
24 molecularly targeted pediatric cancer inves-
25 tigation referred to in subparagraph (A)

1 shall be designed to yield clinically mean-
2 ingful pediatric study data that is gathered
3 using appropriate formulations for each age
4 group for which the study is required, re-
5 garding dosing, safety, and preliminary ef-
6 ficacy to inform potential pediatric label-
7 ing.

8 “(ii) *LIMITATION.*—An investigation
9 described in subparagraph (A)(ii) may be
10 required only if the drug or biological prod-
11 uct for which the application referred to in
12 paragraph (1)(B) contains either—

13 “(I) a single new active ingre-
14 dient; or

15 “(II) more than one active ingre-
16 dient, if an application for the com-
17 bination of active ingredients has not
18 previously been approved but each ac-
19 tive ingredient has been previously ap-
20 proved to treat an adult cancer.

21 “(iii) *RESULTS OF ALREADY-COM-*
22 *PLETED PRECLINICAL STUDIES OF APPLICA-*
23 *TION DRUG.*—The Secretary may require
24 that reports on an investigation required
25 pursuant to paragraph (1)(B) include the

1 *results of all preclinical studies on which*
2 *the decision to conduct such investigation*
3 *was based.*

4 “(iv) *RULE OF CONSTRUCTION RE-*
5 *GARDING INACTIVE INGREDIENTS.—With re-*
6 *spect to a combination of active ingredients*
7 *referred to in subparagraph (A)(ii), such*
8 *subparagraph shall not be construed as ad-*
9 *ressing the use of inactive ingredients with*
10 *such combination.”.*

11 (2) *DETERMINATION OF APPLICABLE REQUIRE-*
12 *MENTS.—Section 505B(e)(1) of the Federal Food,*
13 *Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is*
14 *amended by adding at the end the following: “The*
15 *Secretary shall determine whether subparagraph (A)*
16 *or (B) of subsection (a)(1) shall apply with respect to*
17 *an application before the date on which the applicant*
18 *is required to submit the initial pediatric study plan*
19 *under paragraph (2)(A).”.*

20 (3) *CLARIFYING APPLICABILITY.—Section*
21 *505B(a)(1) of the Federal Food, Drug, and Cosmetic*
22 *Act (21 U.S.C. 355c(a)(1)) is amended by adding at*
23 *the end the following:*

24 “(C) *RULE OF CONSTRUCTION.—No appli-*
25 *cation that is subject to the requirements of sub-*

1 *paragraph (B) shall be subject to the require-*
2 *ments of subparagraph (A), and no application*
3 *(or supplement to an application) that is subject*
4 *to the requirements of subparagraph (A) shall be*
5 *subject to the requirements of subparagraph*
6 *(B).”.*

7 (4) CONFORMING AMENDMENTS.—*Section*
8 *505B(a) of the Federal Food, Drug, and Cosmetic Act*
9 *(21 U.S.C. 355c(a)) is amended—*

10 (A) *in paragraph (3)(C), as redesignated by*
11 *paragraph (1)(A) of this subsection, by striking*
12 *“investigations described in this paragraph” and*
13 *inserting “investigations referred to in subpara-*
14 *graph (A)”*; and

15 (B) *in paragraph (3)(D), as redesignated*
16 *by paragraph (1)(A) of this subsection, by strik-*
17 *ing “the assessments under paragraph (2)(B)”*
18 *and inserting “the assessments required under*
19 *paragraph (1)(A)”.*

20 (b) *GUIDANCE.—The Secretary shall—*

21 (1) *not later than 6 months after the date of en-*
22 *actment of this Act, issue draft guidance on the im-*
23 *plementation of the requirements in subsection (a);*
24 *and*

1 (2) *not later than 12 months after closing the*
2 *comment period on such draft guidance, finalize such*
3 *guidance.*

4 (c) *APPLICABILITY.—The amendments made by this*
5 *section apply with respect to any application under section*
6 *505(i) of the Federal Food, Drug, and Cosmetic Act (21*
7 *U.S.C. 355(i)) and any application under section 351(a)*
8 *of the Public Health Service Act (42 U.S.C. 262), that is*
9 *submitted on or after the date that is 3 years after the date*
10 *of enactment of this Act.*

11 (d) *REPORTS TO CONGRESS.—*

12 (1) *SECRETARY OF HEALTH AND HUMAN SERV-*
13 *ICES.—Not later than 2 years after the date of enact-*
14 *ment of this Act, the Secretary of Health and Human*
15 *Services shall submit to the Committee on Energy*
16 *and Commerce of the House of Representatives and*
17 *the Committee on Health, Education, Labor, and*
18 *Pensions of the Senate a report on the Secretary's ef-*
19 *forts, in coordination with industry, to ensure imple-*
20 *mentation of the amendments made by subsection (a).*

21 (2) *GAO STUDY AND REPORT.—*

22 (A) *STUDY.—Not later than 2 years after*
23 *the date of enactment of this Act, the Comptroller*
24 *General of the United States shall conduct a*
25 *study of the effectiveness of requiring assessments*

1 *and investigations described in section 505B of*
2 *the Federal Food, Drug, and Cosmetic Act (21*
3 *U.S.C.355c), as amended by subsection (a), in*
4 *the development of drugs and biological products*
5 *for pediatric cancer indications.*

6 *(B) FINDINGS.—Not later than 4 years*
7 *after the date of enactment of this Act, the*
8 *Comptroller General shall submit to the Com-*
9 *mittee on Energy and Commerce of the House of*
10 *Representatives and the Committee on Health,*
11 *Education, Labor, and Pensions of the Senate a*
12 *report containing the findings of the study con-*
13 *ducted under subparagraph (A).*

14 ***Subtitle B—Inspections***

15 ***SEC. 721. FACTORY INSPECTION.***

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

20 *(b) RECORDS OR OTHER INFORMATION.—*

21 *(1) ESTABLISHMENTS.—Section 704(a)(4)(A) of*
22 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
23 *374(a)(4)(A)) is amended—*

24 *(A) by striking “an establishment that is*
25 *engaged in the manufacture, preparation, propa-*

1 *gation, compounding, or processing of a drug”*
2 *and inserting “an establishment that is engaged*
3 *in the manufacture, preparation, propagation,*
4 *compounding, or processing of a drug or device,*
5 *or that is subject to inspection under paragraph*
6 *(5)(C),”;* and

7 *(B) by inserting after “a sufficient descrip-*
8 *tion of the records requested” the following: “and*
9 *a rationale for requesting such records or other*
10 *information in advance of, or in lieu of, an in-*
11 *spection”.*

12 *(2) GUIDANCE.—*

13 *(A) IN GENERAL.—The Secretary of Health*
14 *and Human Services shall issue or update guid-*
15 *ance describing—*

16 *(i) circumstances in which the Sec-*
17 *retary intends to issue requests for records*
18 *or other information in advance of, or in*
19 *lieu of, an inspection under section*
20 *704(a)(4) of the Federal Food, Drug, and*
21 *Cosmetic Act, as amended by paragraph*
22 *(1);*

23 *(ii) processes for responding to such re-*
24 *quests electronically or in physical form;*
25 *and*

1 (iii) factors the Secretary intends to
2 consider in evaluating whether such records
3 and other information are provided within
4 a reasonable timeframe, within reasonable
5 limits, and in a reasonable manner, ac-
6 counting for resource and other limitations
7 that may exist, including for small busi-
8 nesses.

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

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

14 (ii) not later than 1 year after the close
15 of the comment period for such draft guid-
16 ance, issue final guidance under subpara-
17 graph (A).

18 (c) *BIORESEARCH MONITORING INSPECTIONS.*—

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

22 “(5) *BIORESEARCH MONITORING INSPECTIONS.*—

23 “(A) *IN GENERAL.*—The Secretary may, to
24 ensure the accuracy and reliability of studies
25 and records or other information described in

1 *subparagraph (B) and to assess compliance with*
2 *applicable requirements under this Act or the*
3 *Public Health Service Act, enter sites and facili-*
4 *ties specified in subparagraph (C) in order to in-*
5 *spect such records or other information.*

6 “(B) *INFORMATION SUBJECT TO INSPEC-*
7 *TION.—An inspection under this paragraph shall*
8 *extend to all records and other information re-*
9 *lated to the studies and submissions described in*
10 *subparagraph (E), including records and infor-*
11 *mation related to the conduct, results, and anal-*
12 *yses of, and the protection of human and animal*
13 *trial participants participating in, such studies.*

14 “(C) *SITES AND FACILITIES SUBJECT TO IN-*
15 *SPECTION.—*

16 “(i) *SITES AND FACILITIES DE-*
17 *SCRIBED.—The sites and facilities subject to*
18 *inspection by the Secretary under this*
19 *paragraph are those owned or operated by*
20 *a person described in clause (ii) and which*
21 *are (or were) utilized by such person in*
22 *connection with—*

23 “(I) *developing an application or*
24 *other submission to the Secretary*
25 *under this Act or the Public Health*

1 *Service Act related to marketing au-*
2 *thorization for a product described in*
3 *paragraph (1);*

4 “*(II) preparing, conducting, or*
5 *analyzing the results of a study de-*
6 *scribed in subparagraph (E); or*

7 “*(III) holding any records or*
8 *other information described in sub-*
9 *paragraph (B).*

10 “*(i) PERSONS DESCRIBED.—A person*
11 *described in this clause is—*

12 “*(I) the sponsor of an application*
13 *or submission specified in subpara-*
14 *graph (E);*

15 “*(II) a person engaged in any ac-*
16 *tivity described in clause (i) on behalf*
17 *of such a sponsor, through a contract,*
18 *grant, or other business arrangement*
19 *with such sponsor;*

20 “*(III) an institutional review*
21 *board, or other individual or entity,*
22 *engaged by contract, grant, or other*
23 *business arrangement with a non-*
24 *sponsor in preparing, collecting, or*

1 *analyzing records or other information*
2 *described in subparagraph (B); or*

3 *“(IV) any person not otherwise*
4 *described in this clause that conducts,*
5 *or has conducted, a study described in*
6 *subparagraph (E) yielding records or*
7 *other information described in sub-*
8 *paragraph (B).*

9 *“(D) CONDITIONS OF INSPECTION.—*

10 *“(i) ACCESS TO INFORMATION SUBJECT*
11 *TO INSPECTION.—Subject to clause (ii), an*
12 *entity that owns or operates any site or fa-*
13 *cility subject to inspection under this para-*
14 *graph shall provide the Secretary with ac-*
15 *cess to records and other information de-*
16 *scribed in subparagraph (B) that is held by*
17 *or under the control of such entity, includ-*
18 *ing—*

19 *“(I) permitting the Secretary to*
20 *record or copy such information for*
21 *purposes of this paragraph;*

22 *“(II) providing the Secretary with*
23 *access to any electronic information*
24 *system utilized by such entity to hold,*
25 *process, analyze, or transfer any*

1 records or other information described
2 in subparagraph (B); and

3 “(III) permitting the Secretary to
4 inspect the facilities, equipment, writ-
5 ten procedures, processes, and condi-
6 tions through which records or other
7 information described in subparagraph
8 (B) is or was generated, held, proc-
9 essed, analyzed, or transferred.

10 “(ii) NO EFFECT ON APPLICABILITY OF
11 PROVISIONS FOR PROTECTION OF PROPRI-
12 ETARY INFORMATION OR TRADE SECRETS.—
13 Nothing in clause (i) shall negate, super-
14 sede, or otherwise affect the applicability of
15 provisions, under this or any other Act, pre-
16 venting or limiting the disclosure of con-
17 fidential commercial information or other
18 information considered proprietary or trade
19 secret.

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

1 “(E) *STUDIES AND SUBMISSIONS DE-*
2 *SCRIBED.—The studies and submissions de-*
3 *scribed in this subparagraph are each of the fol-*
4 *lowing:*

5 “(i) *Clinical and nonclinical studies*
6 *submitted to the Secretary in support of, or*
7 *otherwise related to, applications and other*
8 *submissions to the Secretary under this Act*
9 *or the Public Health Service Act for mar-*
10 *keting authorization of a product described*
11 *in paragraph (1).*

12 “(ii) *Postmarket safety activities con-*
13 *ducted under this Act or the Public Health*
14 *Service Act.*

15 “(iii) *Any other clinical investigation*
16 *of—*

17 “(I) *a drug subject to section 505*
18 *or 512 of this Act or section 351 of the*
19 *Public Health Service Act; or*

20 “(II) *a device subject to section*
21 *520(g).*

22 “(iv) *Any other submissions made*
23 *under this Act or the Public Health Service*
24 *Act with respect to which the Secretary de-*
25 *termines an inspection under this para-*

1 *graph is warranted in the interest of public*
2 *health.*

3 “(F) *CLARIFICATION.*—*This paragraph*
4 *clarifies the authority of the Secretary to conduct*
5 *inspections of the type described in this para-*
6 *graph and shall not be construed as a basis for*
7 *inferring that, prior to the date of enactment of*
8 *this paragraph, the Secretary lacked the author-*
9 *ity to conduct such inspections, including under*
10 *this Act or the Public Health Service Act.”.*

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

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

15 (i) *review processes and practices in ef-*
16 *fect as of the date of enactment of this Act*
17 *applicable to inspections of foreign and do-*
18 *mestic sites and facilities described in sub-*
19 *paragraph (C)(i) of section 704(a)(5) of the*
20 *Federal Food, Drug, and Cosmetic Act, as*
21 *added by paragraph (1); and*

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

25 (B) *GUIDANCE.*—

1 (i) *IN GENERAL.*—*The Secretary of*
2 *Health and Human Services shall issue*
3 *guidance describing the processes and prac-*
4 *tices applicable to inspections of sites and*
5 *facilities described in subparagraph (C)(i)*
6 *of section 704(a)(5) of the Federal Food,*
7 *Drug, and Cosmetic Act, as added by para-*
8 *graph (1), including with respect to the*
9 *types of records and information required to*
10 *be provided, best practices for communica-*
11 *tion between the Food and Drug Adminis-*
12 *tration and industry in advance of or dur-*
13 *ing an inspection or request for records or*
14 *other information, and other inspections-re-*
15 *lated conduct, to the extent not specified in*
16 *existing publicly available Food and Drug*
17 *Administration guides and manuals for*
18 *such inspections.*

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

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

24 (II) *not later than 1 year after*
25 *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 Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 373) is amended by adding at the end the
6 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 (21
19 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 *tablissement is located that are subject to regula-*
2 *tion under this Act, including the history of vio-*
3 *lations related to products exported from such*
4 *country or region that are subject to such regula-*
5 *tion.”.*

6 **(b) USE OF RECORDS.**—*Section 704(a)(4) of the Fed-*
7 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4))*
8 *is amended—*

9 *(1) by redesignating subparagraph (C) as sub-*
10 *paragraph (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 INSPEC-**
20 *TIONS.*—*Section 809 of the Federal Food, Drug, and Cos-*
21 *metic Act (21 U.S.C. 384e) is amended—*

22 *(1) in subsection (a)(1), by inserting*
23 *“preapproval or” before “risk-based inspections”; and*

24 *(2) by adding at the end the following:*

25 *“(c) PERIODIC REVIEW.—*

1 “(1) *IN GENERAL.*—Beginning not later than 1
2 year after the date of the enactment of the Food and
3 Drug Amendments of 2022, the Secretary shall peri-
4 odically assess whether additional arrangements and
5 agreements with a foreign government or an agency
6 of a foreign government, as allowed under this sec-
7 tion, are appropriate.

8 “(2) *REPORTS TO CONGRESS.*—Beginning not
9 later than 4 years after the date of the enactment of
10 the Food and Drug Amendments of 2022, and every
11 4 years thereafter, the Secretary shall submit to the
12 Committee 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 de-
15 scribing the findings and conclusions of each review
16 conducted under paragraph (1).”.

17 **SEC. 724. GAO REPORT ON INSPECTIONS OF FOREIGN ES-**
18 **TABLISHMENTS MANUFACTURING DRUGS.**

19 (a) *IN GENERAL.*—Not later than 18 months after the
20 date of the enactment of this Act, the Comptroller General
21 of the United States shall submit to the Committee on En-
22 ergy and Commerce of the House of Representatives and
23 the Committee on Health, Education, Labor, and Pensions
24 of the Senate a report on inspections conducted by—

1 (1) *the Secretary of Health and Human Services*
2 *(in this section referred to as the “Secretary”) of for-*
3 *foreign establishments pursuant to subsections (h) and*
4 *(i) of section 510 and section 704 of the Federal Food,*
5 *Drug, and Cosmetic Act (21 U.S.C. 360; 374); or*

6 (2) *a foreign government or an agency of a for-*
7 *foreign government pursuant to section 809 of such Act*
8 *(21 U.S.C. 384e).*

9 (b) *CONTENTS.—The report conducted under sub-*
10 *section (a) shall include—*

11 (1) *what alternative tools, including remote in-*
12 *spections or remote evaluations, other countries are*
13 *utilizing to facilitate inspections of foreign establish-*
14 *ments;*

15 (2) *how frequently trusted foreign regulators con-*
16 *duct inspections of foreign facilities that could be use-*
17 *ful to the Food and Drug Administration to review*
18 *in lieu of its own inspections;*

19 (3) *how frequently and under what cir-*
20 *cumstances, including for what types of inspections,*
21 *the Secretary utilizes existing agreements or arrange-*
22 *ments under section 809 of the Federal Food, Drug,*
23 *and Cosmetic Act (21 U.S.C. 384e) and whether the*
24 *use of such agreements could be appropriately ex-*
25 *panded;*

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

5 (5) *what additional foreign governments or agen-*
6 *cies of foreign governments the Secretary has consid-*
7 *ered entering into a mutual recognition agreement*
8 *with and, if applicable, reasons why the Secretary de-*
9 *clined to enter into a mutual recognition agreement*
10 *with such foreign governments or agencies;*

11 (6) *what tools, if any, the Secretary used to fa-*
12 *cilitate inspections of domestic facilities that could*
13 *also be effectively utilized to appropriately inspect*
14 *foreign facilities;*

15 (7) *what steps the Secretary has taken to iden-*
16 *tify and evaluate tools and strategies the Secretary*
17 *may use to continue oversight with respect to inspec-*
18 *tions when in-person inspections are disrupted;*

19 (8) *how the Secretary is considering incor-*
20 *porating alternative tools into the inspection activi-*
21 *ties conducted pursuant to the Federal Food, Drug,*
22 *and Cosmetic Act (21 U.S.C. 301 et seq.); and*

23 (9) *what steps the Secretary has taken to iden-*
24 *tify and evaluate how the Secretary may use alter-*

1 *native tools to address workforce shortages to carry*
2 *out such inspection activities.*

3 **SEC. 725. UNANNOUNCED FOREIGN FACILITY INSPECTIONS**

4 **PILOT PROGRAM.**

5 *(a) IN GENERAL.—The Secretary of Health and*
6 *Human Services (referred to in this section as the “Sec-*
7 *retary”)* shall conduct a pilot program under which the Sec-
8 *retary increases the conduct of unannounced surveillance*
9 *inspections of foreign human drug establishments and eval-*
10 *uates the differences between such inspections of domestic*
11 *and foreign human drug establishments, including the im-*
12 *pect of announcing inspections to persons who own or oper-*
13 *ate foreign human drug establishments in advance of an*
14 *inspection. Such pilot program shall evaluate—*

15 (1) *differences in the number and type of viola-*
16 *tions of section 501(a)(2)(B) of the Federal Food,*
17 *Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))*
18 *identified as a result of unannounced and announced*
19 *inspections of foreign human drug establishments and*
20 *any other significant differences between each type of*
21 *inspection;*

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

1 (3) *barriers to conducting unannounced inspec-*
2 *tions of foreign human drug establishments and any*
3 *challenges to achieving parity between domestic and*
4 *foreign human drug establishment inspections; and*

5 (4) *approaches for mitigating any negative ef-*
6 *fects of conducting announced inspections of foreign*
7 *human drug establishments.*

8 (b) *PILOT PROGRAM SCOPE.*—*The inspections evalu-*
9 *ated under the pilot program under this section shall be*
10 *routine surveillance inspections and shall not include in-*
11 *spections conducted as part of the Secretary’s evaluation*
12 *of a request for approval to market a drug submitted under*
13 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301*
14 *et seq.) or the Public Health Service Act (42 U.S.C. 201*
15 *et seq.).*

16 (c) *PILOT PROGRAM INITIATION.*—*The Secretary shall*
17 *initiate the pilot program under this section not later than*
18 *180 days after the date of enactment of this Act.*

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

24 (1) *findings and any associated recommenda-*
25 *tions with respect to the evaluation under subsection*

1 (a), including any recommendations to address iden-
2 tified barriers to conducting unannounced inspections
3 of foreign human drug establishments;

4 (2) findings and any associated recommenda-
5 tions regarding how the Secretary may achieve parity
6 between domestic and foreign human drug inspec-
7 tions; and

8 (3) the number of unannounced inspections dur-
9 ing the pilot program that would not be unannounced
10 under existing practices.

11 **SEC. 726. REAUTHORIZATION OF INSPECTION PROGRAM.**

12 Section 704(g)(11) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 374(g)(11)) is amended by striking
14 “2022” and inserting “2027”.

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

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

21 “(g) *COORDINATION.*—The Secretary shall ensure
22 timely and effective internal coordination and alignment
23 among the field investigators of the Food and Drug Admin-
24 istration and the staff of the Center for Drug Evaluation

1 *and Research's Office of Compliance and Drug Shortage*
2 *Program regarding—*

3 “(1) *the reviews of reports shared pursuant to*
4 *section 704(b)(2); and*

5 “(2) *any feedback or corrective or preventive ac-*
6 *tions in response to such reports.”.*

7 *(b) REPORTING.—*

8 (1) *IN GENERAL.—Section 506C–1(a)(2) of the*
9 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
10 *356c–1(a)(2)) is amended to read as follows:*

11 “(2)(A) *describes the communication between the*
12 *field investigators of the Food and Drug Administra-*
13 *tion and the staff of the Center for Drug Evaluation*
14 *and Research's Office of Compliance and Drug Short-*
15 *age Program, including the Food and Drug Adminis-*
16 *tration's procedures for enabling and ensuring such*
17 *communication;*

18 “(B) *provides the number of reports described in*
19 *section 704(b)(2) that were required to be sent to the*
20 *appropriate offices of the Food and Drug Administra-*
21 *tion and the number of such reports that were sent;*
22 *and*

23 “(C) *describes the coordination and alignment*
24 *activities undertaken pursuant to section 506D(g);”.*

1 (2) *APPLICABILITY.*—*The amendment made by*
2 *paragraph (1) shall apply with respect to reports sub-*
3 *mitted on or after March 31, 2023.*

4 **SEC. 728. REPORTING OF MUTUAL RECOGNITION AGREE-**
5 **MENTS FOR INSPECTIONS AND REVIEW AC-**
6 **TIVITIES.**

7 (a) *IN GENERAL.*—*Not later than December 31, 2022,*
8 *and annually thereafter, the Secretary of Health and*
9 *Human Services (referred to in this section as the “Sec-*
10 *retary”)* shall publish a report on the public website of the
11 *Food and Drug Administration on the utilization of agree-*
12 *ments entered into pursuant to section 809 of the Federal*
13 *Food, Drug, and Cosmetic Act (21 U.S.C. 384e) or other-*
14 *wise entered into by the Secretary in the previous fiscal*
15 *year to recognize inspections between drug regulatory au-*
16 *thorities across countries and international regions with*
17 *analogous review criteria to the Food and Drug Adminis-*
18 *tration, such as the Pharmaceutical Inspection Co-Oper-*
19 *ation Scheme, the Mutual Recognition Agreement with the*
20 *European Union, and the Australia-Canada-Singapore-*
21 *Switzerland-United Kingdom Consortium.*

22 (b) *CONTENT.*—*The report under subsection (a) shall*
23 *include each of the following:*

24 (1) *The total number of establishments that are*
25 *registered under section 510(i) of the Federal Food,*

1 *Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the*
2 *number of such establishments in each region of inter-*
3 *est.*

4 (2) *The total number of inspections conducted at*
5 *establishments described in paragraph (1),*
6 *disaggregated by inspections conducted—*

7 (A) *pursuant to an agreement or other rec-*
8 *ognition described in subsection (a); and*

9 (B) *by employees or contractors of the Food*
10 *and Drug Administration.*

11 (3) *Of the inspections described in paragraph*
12 *(2), the total number of inspections in each region of*
13 *interest.*

14 (4) *Of the inspections in each region of interest*
15 *reported pursuant to paragraph (3), the number of*
16 *inspections in each FDA inspection category.*

17 (5) *Of the number of inspections reported under*
18 *each of paragraphs (3) and (4)—*

19 (A) *the number of inspections which have*
20 *been conducted pursuant to an agreement or*
21 *other recognition described in subsection (a); and*

22 (B) *the number of inspections which have*
23 *been conducted by employees or contractors of the*
24 *Food and Drug Administration.*

25 (c) *DEFINITIONS.—In this section:*

1 (1) *FDA INSPECTION CATEGORY.*—*The term*
2 *“FDA inspection category” means the following in-*
3 *spection categories:*

4 (A) *Inspections to support approvals of*
5 *changes to the manufacturing process of drugs*
6 *approved under section 505 of the Federal Food,*
7 *Drug, and Cosmetic Act (21 U.S.C. 355) or sec-*
8 *tion 351 of the Public Health Service Act (42*
9 *U.S.C. 262).*

10 (B) *Surveillance inspections.*

11 (C) *For-cause inspections.*

12 (2) *REGION OF INTEREST.*—*The term “region of*
13 *interest” means China, India, the European Union,*
14 *and any other geographic region as the Secretary de-*
15 *termines appropriate.*

16 **SEC. 729. ENHANCING TRANSPARENCY OF DRUG FACILITY**
17 **INSPECTION TIMELINES.**

18 *Section 902 of the FDA Reauthorization Act of 2017*
19 *(21 U.S.C. 355 note) is amended to read as follows:*

20 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

21 *“Not later than 120 days after the end of each fiscal*
22 *year, the Secretary of Health and Human Services shall*
23 *post on the public website of the Food and Drug Adminis-*
24 *tration information related to inspections of facilities nec-*
25 *essary for approval of a drug under subsection (c) or (j)*

1 *of section 505 of the Federal Food, Drug, and Cosmetic Act*
2 *(21 U.S.C. 355), approval of a device under section 515*
3 *of such Act (21 U.S.C. 360e), or clearance of a device under*
4 *section 510(k) of such Act (21 U.S.C. 360(k)) that were con-*
5 *ducted during the previous fiscal year. Such information*
6 *shall include the following:*

7 “(1) *The median time following a request from*
8 *staff of the Food and Drug Administration reviewing*
9 *an application or report to the beginning of the in-*
10 *spection, including—*

11 “(A) *the median time for drugs described in*
12 *section 505(j)(11)(A)(i) of the Federal Food,*
13 *Drug, and Cosmetic Act (21 U.S.C.*
14 *355(j)(11)(A)(i));*

15 “(B) *the median time for drugs described in*
16 *section 506C(a) of such Act (21 U.S.C. 356c(a))*
17 *only; and*

18 “(C) *the median time for drugs on the drug*
19 *shortage list in effect under section 506E of such*
20 *Act (21 U.S.C. 356e).*

21 “(2) *The median time from the issuance of a re-*
22 *port pursuant to section 704(b) of such Act (21*
23 *U.S.C. 374(b)) to the sending of a warning letter,*
24 *issuance of an import alert, or holding of a regulatory*
25 *meeting for inspections for which the Secretary con-*

1 *cluded that regulatory or enforcement action was in-*
2 *cluded, including the median time for each category*
3 *of drugs listed in subparagraphs (A) through (C) of*
4 *paragraph (1).*

5 *“(3) The median time from the sending of a*
6 *warning letter, issuance of an import alert, or hold-*
7 *ing of a regulatory meeting to resolution of the ac-*
8 *tions indicated to address the conditions or practices*
9 *observed during an inspection.*

10 *“(4) The number of facilities that failed to im-*
11 *plement adequate corrective or preventive actions fol-*
12 *lowing a report pursuant to such section 704(b), re-*
13 *sulting in a withhold recommendation, including the*
14 *number of such times for each category of drugs listed*
15 *in subparagraphs (A) through (C) of paragraph (1).”.*

16 **TITLE VIII—TRANSPARENCY,**
17 **PROGRAM INTEGRITY, AND**
18 **REGULATORY IMPROVE-**
19 **MENTS**

20 **SEC. 801. PROMPT REPORTS OF MARKETING STATUS BY**
21 **HOLDERS OF APPROVED APPLICATIONS FOR**
22 **BIOLOGICAL PRODUCTS.**

23 *(a) IN GENERAL.—Section 506I of the Federal Food,*
24 *Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—*

25 *(1) in subsection (a)—*

1 (A) in the matter preceding paragraph (1),
2 by striking “The holder of an application ap-
3 proved under subsection (c) or (j) of section 505”
4 and inserting “The holder of an application ap-
5 proved under subsection (c) or (j) of section 505
6 of this Act or subsection (a) or (k) of section 351
7 of the Public Health Service Act”;

8 (B) in paragraph (2), by striking “estab-
9 lished name” and inserting “established name
10 (for biological products, by proper name)”; and

11 (C) in paragraph (3), by striking “or abbre-
12 viated application number” and inserting “, ab-
13 breviated application number, or biologics license
14 application number”; and

15 (2) in subsection (b)—

16 (A) in the matter preceding paragraph (1),
17 by striking “The holder of an application ap-
18 proved under subsection (c) or (j)” and inserting
19 “*The holder of an application approved under*
20 *subsection (c) or (j) of section 505 of this Act or*
21 *subsection (a) or (k) of section 351 of the Public*
22 *Health Service Act”;*

23 (B) in paragraph (1), by striking “estab-
24 lished name” and inserting “established name
25 (for biological products, by proper name)”; and

1 (C) in paragraph (2), by striking “or abbrevi-
2 viated application number” and inserting “, ab-
3 breviated application number, or biologics license
4 application number”.

5 (b) *ADDITIONAL ONE-TIME REPORT*.—Subsection (c)
6 of section 506I of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 356i) is amended to read as follows:

8 “(c) *ADDITIONAL ONE-TIME REPORT*.—Within 180
9 days of the date of enactment of the Food and Drug Amend-
10 ments of 2022, all holders of applications approved under
11 subsection (a) or (k) of section 351 of the Public Health
12 Service Act shall review the information in the list pub-
13 lished under section 351(k)(9)(A) and shall submit a writ-
14 ten notice to the Secretary—

15 “(1) stating that all of the application holder’s
16 biological products in the list published under section
17 351(k)(9)(A) that are not listed as discontinued are
18 available for sale; or

19 “(2) including the information required pursu-
20 ant to subsection (a) or (b), as applicable, for each of
21 the application holder’s biological products that are
22 in the list published under section 351(k)(9)(A) and
23 not listed as discontinued, but have been discontinued
24 from sale or never have been available for sale.”.

1 (c) *PURPLE BOOK*.—Section 506I of the Federal Food,
2 *Drug, and Cosmetic Act* (21 U.S.C. 356i) is amended—

3 (1) by striking subsection (d) and inserting the
4 following:

5 “(d) *FAILURE TO MEET REQUIREMENTS*.—If a holder
6 of an approved application fails to submit the information
7 required under subsection (a), (b), or (c), the Secretary
8 may—

9 “(1) move the application holder’s drugs from
10 the active section of the list published under section
11 505(j)(7)(A) to the discontinued section of the list, ex-
12 cept that the Secretary shall remove from the list in
13 accordance with section 505(j)(7)(C) drugs the Sec-
14 retary determines have been withdrawn from sale for
15 reasons of safety or effectiveness; and

16 “(2) identify the application holder’s biological
17 products as discontinued in the list published under
18 section 351(k)(9)(A) of the *Public Health Service Act*,
19 except that the Secretary shall remove from the list in
20 accordance with section 351(k)(9)(B) of such Act bio-
21 logical products for which the license has been revoked
22 or suspended for reasons of safety, purity, or po-
23 tency.”; and

24 (2) in subsection (e)—

1 (A) by inserting after the first sentence the
2 following: “The Secretary shall update the list
3 published under section 351(k)(9)(A) of the Pub-
4 lic Health Service Act based on information pro-
5 vided under subsections (a), (b), and (c) by iden-
6 tifying as discontinued biological products that
7 are not available for sale, except that biological
8 products for which the license has been revoked
9 or suspended for safety, purity, or potency rea-
10 sons shall be removed from the list in accordance
11 with section 351(k)(9)(B) of the Public Health
12 Service Act.”;

13 (B) by striking “monthly updates to the
14 list” and inserting “monthly updates to the lists
15 referred to in the preceding sentences”; and

16 (C) by striking “and shall update the list
17 based on” and inserting “and shall update such
18 lists based on”.

19 (d) *TECHNICAL CORRECTIONS.*—Section 506I(e) of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i(e))
21 is amended—

22 (1) by striking “subsection 505(j)(7)(A)” and in-
23 serting “section 505(j)(7)(A)”; and

24 (2) by striking “subsection 505(j)(7)(C)” and in-
25 serting “section 505(j)(7)(C)”.

1 **SEC. 802. ENCOURAGING BLOOD DONATION.**

2 (a) *STREAMLINING PATIENT AND BLOOD DONOR*
3 *INPUT.*—Section 3003 of the 21st Century Cures Act (21
4 U.S.C. 360bbb–8c note) is amended to read as follows:

5 **“SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR**
6 **INPUT.**

7 “Chapter 35 of title 44, United States Code, shall not
8 apply to the collection of information to which a response
9 is voluntary, to solicit—

10 “(1) the views and perspectives of patients under
11 section 569C of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 360bbb–8c) (as amended by section
13 3001) or section 3002; or

14 “(2) information from blood donors or potential
15 blood donors to support the development of rec-
16 ommendations by the Secretary of Health and
17 Human Services acting through the Commissioner of
18 Food and Drugs concerning blood donation.”.

19 (b) *CLERICAL AMENDMENT.*—The table of contents in
20 section 1(b) of the 21st Century Cures Act is amended by
21 striking the item relating to section 3003 and inserting the
22 following:

“Sec. 3003. Streamlining patient and blood donor input.”.

1 **SEC. 803. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

2 *Section 503 of the Federal Food, Drug, and Cosmetic*
3 *Act (21 U.S.C. 353) is amended by adding at the end the*
4 *following:*

5 “(h)(1) *Any contrast agent, radioactive drug, or OTC*
6 *monograph drug shall be deemed to be a drug under section*
7 *201(g) and not a device under section 201(h).*

8 “(2) *For purposes of this subsection:*

9 “(A) *The term ‘contrast agent’ means an article*
10 *that is intended for use in conjunction with a medical*
11 *imaging device, and—*

12 “(i) *is a diagnostic radiopharmaceutical, as*
13 *defined in sections 315.2 and 601.31 of title 21,*
14 *Code of Federal Regulations (or any successor*
15 *regulations); or*

16 “(ii) *is a diagnostic agent that improves the*
17 *visualization of structure or function within the*
18 *body by increasing the relative difference in sig-*
19 *nal intensity within the target tissue, structure,*
20 *or fluid.*

21 “(B) *The term ‘radioactive drug’ has the mean-*
22 *ing given such term in section 310.3(n) of title 21,*
23 *Code of Federal Regulations (or any successor regula-*
24 *tions), except that such term does not include—*

25 “(i) *an implant or article similar to an im-*
26 *plant;*

1 “(ii) an article that applies radiation from
2 outside of the body; or

3 “(iii) the radiation source of an article de-
4 scribed in clause (i) or (ii).

5 “(C) The term ‘OTC monograph drug’ has the
6 meaning given such term in section 744L.

7 “(3) Nothing in this subsection shall be construed as
8 allowing for the classification of a product as a drug (as
9 defined in section 201(g)) if such product—

10 “(A) is not described in paragraph (1); and

11 “(B) meets the definition of a device under sec-
12 tion 201(h),

13 unless another provision of this Act otherwise indicates a
14 different classification.”.

15 **SEC. 804. POSTAPPROVAL STUDIES AND PROGRAM INTEG-**
16 **RITY FOR ACCELERATED APPROVAL DRUGS.**

17 (a) *IN GENERAL.*—Section 506(c) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 356(c)) is amended—

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

21 “(2) *LIMITATION.*—

22 “(A) *IN GENERAL.*—Approval of a product
23 under this subsection may be subject to 1 or both
24 of the following requirements:

1 “(i) That the sponsor conduct an ap-
2 propriate postapproval study or studies
3 (which may be augmented or supported by
4 real world evidence) to verify and describe
5 the predicted effect on irreversible morbidity
6 or mortality or other clinical benefit.

7 “(ii) That the sponsor submit copies of
8 all promotional materials related to the
9 product during the preapproval review pe-
10 riod and, following approval and for such
11 period thereafter as the Secretary deter-
12 mines to be appropriate, at least 30 days
13 prior to dissemination of the materials.

14 “(B) *STUDIES NOT REQUIRED.*—If the Sec-
15 retary does not require that the sponsor of a
16 product approved under accelerated approval
17 conduct a postapproval study under this para-
18 graph, the Secretary shall publish on the website
19 of the Food and Drug Administration the ration-
20 ale for why such study is not appropriate or nec-
21 essary.

22 “(C) *POSTAPPROVAL STUDY CONDITIONS.*—
23 Not later than the time of approval of a product
24 under accelerated approval, the Secretary shall
25 specify the conditions for a postapproval study

1 *or studies required to be conducted under this*
2 *paragraph with respect to such product, which*
3 *may include enrollment targets, the study pro-*
4 *tol, and milestones, including the target date of*
5 *study completion.*

6 “(D) *STUDIES BEGUN BEFORE APPROVAL.—*

7 *The Secretary may require such study or studies*
8 *to be underway prior to approval.”; and*

9 *(2) by striking paragraph (3) and inserting the*
10 *following:*

11 “(3) *EXPEDITED WITHDRAWAL OF APPROVAL.—*

12 “(A) *IN GENERAL.—The Secretary may*
13 *withdraw approval of a product approved under*
14 *accelerated approval using expedited procedures*
15 *described in subparagraph (B), if—*

16 “(i) *the sponsor fails to conduct any*
17 *required postapproval study of the product*
18 *with due diligence, including with respect to*
19 *conditions specified by the Secretary under*
20 *paragraph (2)(C);*

21 “(ii) *a study required to verify and de-*
22 *scribe the predicted effect on irreversible*
23 *morbidity or mortality or other clinical*
24 *benefit of the product fails to verify and de-*
25 *scribe such effect or benefit;*

1 “(iii) other evidence demonstrates that
2 the product is not shown to be safe or effec-
3 tive under the conditions of use; or

4 “(iv) the sponsor disseminates false or
5 misleading promotional materials with re-
6 spect to the product.

7 “(B) EXPEDITED PROCEDURES DE-
8 SCRIBED.—Expedited procedures described in
9 this subparagraph shall consist of, prior to the
10 withdrawal of accelerated approval—

11 “(i) providing the sponsor with—

12 “(I) due notice;

13 “(II) an explanation for the pro-
14 posed withdrawal;

15 “(III) an opportunity for a meet-
16 ing with the Commissioner of Food
17 and Drugs or the Commissioner’s des-
18 ignee; and

19 “(IV) an opportunity for written
20 appeal to—

21 “(aa) the Commissioner of
22 Food and Drugs; or

23 “(bb) a designee of the Com-
24 missioner who has not partici-
25 pated in the proposed withdrawal

1 *of approval (other than a meeting*
2 *pursuant to subclause (III)) and*
3 *is not a subordinate of an indi-*
4 *vidual (other than the Commis-*
5 *sioner) who participated in such*
6 *proposed withdrawal;*

7 “(ii) *providing an opportunity for*
8 *public comment on the notice proposing to*
9 *withdraw approval;*

10 “(iii) *the publication of a summary of*
11 *the public comments received, and the Sec-*
12 *retary’s response to such comments, on the*
13 *website of the Food and Drug Administra-*
14 *tion; and*

15 “(iv) *convening and consulting an ad-*
16 *visory committee on issues related to the*
17 *proposed withdrawal, if requested by the*
18 *sponsor and if no such advisory committee*
19 *has previously advised the Secretary on*
20 *such issues with respect to the withdrawal*
21 *of the product prior to the sponsor’s request.*

22 “(4) *LABELING.—*

23 “(A) *IN GENERAL.—Subject to subpara-*
24 *graph (B), the labeling for a product approved*
25 *under accelerated approval shall include—*

1 “(i) a statement indicating that the
2 product was approved under accelerated ap-
3 proval;

4 “(ii) a statement indicating that con-
5 tinued approval of the product is subject to
6 postmarketing studies to verify clinical ben-
7 efit;

8 “(iii) identification of the surrogate or
9 intermediate endpoint or endpoints that
10 supported approval and any known limita-
11 tions of such surrogate or intermediate end-
12 point or endpoints in determining clinical
13 benefit; and

14 “(iv) a succinct description of the
15 product and any uncertainty about antici-
16 pated clinical benefit and a discussion of
17 available evidence with respect to such clin-
18 ical benefit.

19 “(B) *APPLICABILITY.*—The labeling require-
20 ments of subparagraph (A) shall apply only to
21 products approved under accelerated approval
22 for which the predicted effect on irreversible mor-
23 bidity or mortality or other clinical benefit has
24 not been verified.

1 “(C) *RULE OF CONSTRUCTION.*—*With re-*
2 *spect to any application pending before the Sec-*
3 *retary on the date of enactment of the Food and*
4 *Drug Amendments of 2022, the Secretary shall*
5 *allow any applicable changes to the product la-*
6 *beling required to comply with subparagraph (A)*
7 *to be made by supplement after the approval of*
8 *such application.*

9 “(5) *REPORTING.*—*Not later than September 30,*
10 *2025, the Secretary shall submit to the Committee on*
11 *Energy and Commerce of the House of Representa-*
12 *tives and the Committee on Health, Education,*
13 *Labor, and Pensions of the Senate a report describing*
14 *circumstances in which the Secretary considered real*
15 *world evidence submitted to support postapproval*
16 *studies required under this subsection that were com-*
17 *pleted after the date of enactment of the Food and*
18 *Drug Amendments of 2022.”.*

19 “(b) *REPORTS OF POSTMARKETING STUDIES.*—*Section*
20 *506B(a) of the Federal Food, Drug, and Cosmetic Act (21*
21 *U.S.C. 356b(a)) is amended—*

22 (1) *by redesignating paragraph (2) as para-*
23 *graph (3); and*

24 (2) *by inserting after paragraph (1) the fol-*
25 *lowing:*

1 “(2) *ACCELERATED APPROVAL.*—*Notwith-*
2 *standing paragraph (1), a sponsor of a drug ap-*
3 *proved under accelerated approval shall submit to the*
4 *Secretary a report of the progress of any study re-*
5 *quired under section 506(c), including progress to-*
6 *ward enrollment targets, milestones, and other infor-*
7 *mation as required by the Secretary, not later than*
8 *180 days after the approval of such drug and not less*
9 *frequently than every 180 days thereafter, until the*
10 *study is completed or terminated.”.*

11 *(c) GUIDANCE.—*

12 *(1) IN GENERAL.—The Secretary of Health and*
13 *Human Services shall issue guidance describing—*

14 *(A) how sponsor questions related to the*
15 *identification of novel surrogate or intermediate*
16 *clinical endpoints may be addressed in early-*
17 *stage development meetings with the Food and*
18 *Drug Administration;*

19 *(B) the use of novel clinical trial designs*
20 *that may be used to conduct appropriate post-*
21 *approval studies as may be required under sec-*
22 *tion 506(c)(2)(A) of the Federal Food, Drug, and*
23 *Cosmetic Act (21 U.S.C. 356(c)(2)(A)), as*
24 *amended by subsection (a); and*

1 (C) *the expedited procedures described in*
2 *section 506(c)(3)(B) of the Federal Food, Drug,*
3 *and Cosmetic Act (21 U.S.C. 356(c)(3)(B)).*

4 (2) *FINAL GUIDANCE.—The Secretary shall*
5 *issue—*

6 (A) *draft guidance under paragraph (1) not*
7 *later than 18 months after the date of enactment*
8 *of this Act; and*

9 (B) *final guidance not later than 1 year*
10 *after the close of the public comment period on*
11 *such draft guidance.*

12 (d) *RARE DISEASE ENDPOINT ADVANCEMENT*
13 *PILOT.—*

14 (1) *IN GENERAL.—The Secretary of Health and*
15 *Human Services shall establish a pilot program*
16 *under which the Secretary will establish procedures to*
17 *provide increased interaction with sponsors of rare*
18 *disease drug development programs for purposes of*
19 *advancing the development of efficacy endpoints, in-*
20 *cluding surrogate and intermediate endpoints, for*
21 *drugs intended to treat rare diseases, including*
22 *through—*

23 (A) *determining eligibility of participants*
24 *for such a program; and*

1 (B) developing and implementing a process
2 for applying to, and participating in, such a
3 program.

4 (2) *PUBLIC WORKSHOPS.*—The Secretary shall
5 conduct up to 3 public workshops, which shall be com-
6 pleted not later than September 30, 2026, to discuss
7 topics relevant to the development of endpoints for
8 rare diseases, which may include discussions about—

9 (A) novel endpoints developed through the
10 pilot program established under this subsection;
11 and

12 (B) as appropriate, the use of real world
13 evidence and real world data to support the vali-
14 dation of efficacy endpoints, including surrogate
15 and intermediate endpoints, for rare diseases.

16 (3) *REPORT.*—Not later than September 30,
17 2027, the Secretary shall submit to the Committee on
18 Energy and Commerce of the House of Representa-
19 tives and the Committee on Health, Education,
20 Labor, and Pensions of the Senate a report describing
21 the outcomes of the pilot program established under
22 this subsection.

23 (4) *GUIDANCE.*—Not later than September 30,
24 2027, the Secretary shall issue guidance describing
25 best practices and strategies for development of effi-

1 *cacy endpoints, including surrogate and intermediate*
2 *endpoints, for rare diseases.*

3 (5) *SUNSET.*—*The Secretary may not accept any*
4 *new application or request to participate in the pro-*
5 *gram established by this subsection on or after Octo-*
6 *ber 1, 2027.*

7 **SEC. 805. FACILITATING THE USE OF REAL WORLD EVI-**
8 **DENCE.**

9 (a) *GUIDANCE.*—*Not later than 1 year after the date*
10 *of the enactment of this Act, the Secretary of Health and*
11 *Human Services shall issue, or revise existing, guidance on*
12 *considerations for the use of real world data and real world*
13 *evidence to support regulatory decisionmaking, as follows:*

14 (1) *With respect to drugs, such guidance shall*
15 *address—*

16 (A) *the use of such data and evidence to*
17 *support the approval of a drug application*
18 *under section 505 of the Federal Food, Drug,*
19 *and Cosmetic Act (21 U.S.C. 355) or a biological*
20 *product application under section 351 of the*
21 *Public Health Service Act (42 U.S.C. 262), or to*
22 *support an investigational use exemption under*
23 *section 505(i) of the Federal Food, Drug, and*
24 *Cosmetic Act or section 351(a)(3) of the Public*
25 *Health Service Act; and*

1 (B) the use of such data and evidence ob-
2 tained as a result of the use of drugs authorized
3 for emergency use under section 564 of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.
5 360bbb-3) in such applications, submissions, or
6 requests; and

7 (C) standards and methodologies which may
8 be used for collection and analysis of real world
9 evidence included in such applications, submis-
10 sions, or requests, as appropriate.

11 (2) With respect to devices, such guidance shall
12 address—

13 (A) the use of such data and evidence to
14 support the approval, clearance, or classification
15 of a device pursuant to an application or sub-
16 mission submitted under section 510(k),
17 513(f)(2), or 515 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 360(k), 360c(f)(2),
19 360e), or to support an investigational use ex-
20 emption under section 520(g) of such Act (21
21 U.S.C. 360j(g));

22 (B) the use of such data and evidence ob-
23 tained as a result of the use of devices authorized
24 for emergency use under section 564 of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 360bbb–3), in such applications, submissions, or
2 requests; and

3 (C) standards and methodologies which may
4 be used for collection and analysis of real world
5 evidence included in such applications, submis-
6 sions, or requests, as appropriate.

7 (b) *REPORT TO CONGRESS*.—Not later than 2 years
8 after the termination of the public health emergency deter-
9 mination by the Secretary of Health and Human Services
10 under section 564 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 360bbb–3) on February 4, 2020, with respect
12 to the Coronavirus Disease 2019 (COVID–19), the Secretary
13 shall submit a report to the Committee on Energy and Com-
14 merce of the House of Representatives and the Committee
15 on Health, Education, Labor, and Pensions of the Senate
16 on—

17 (1) the number of applications, submissions, or
18 requests submitted for clearance or approval under
19 section 505, 510(k), 513(f)(2), or 515 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 355,
21 360(k), 360c(f)(2), 360e) or section 351 of the Public
22 Health Service Act, for which an authorization under
23 section 564 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 360bbb–3) was previously granted;

1 (2) of the number of applications so submitted,
2 the number of such applications—

3 (A) for which real world evidence was sub-
4 mitted and used to support a regulatory deci-
5 sion; and

6 (B) for which real world evidence was sub-
7 mitted and determined to be insufficient to sup-
8 port a regulatory decision; and

9 (3) a summary explanation of why, in the case
10 of applications described in paragraph (2)(B), real
11 world evidence could not be used to support regu-
12 latory decisions.

13 (c) *INFORMATION DISCLOSURE.*—Nothing in this sec-
14 tion shall be construed to authorize the disclosure of infor-
15 mation that is prohibited from disclosure under section
16 1905 of title 18, United States Code, or subject to with-
17 holding under subsection (b)(4) of section 552 of title 5,
18 United States Code (commonly referred to as the “Freedom
19 of Information Act”).

20 **SEC. 806. DUAL SUBMISSION FOR CERTAIN DEVICES.**

21 Section 513 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 360c) is amended by adding at the end the
23 following:

24 “(k) For a device authorized for emergency use under
25 section 564 for which, in accordance with section 564(m),

1 *the Secretary has deemed a laboratory examination or pro-*
2 *cedure associated with such device to be in the category of*
3 *examinations and procedures described in section 353(d)(3)*
4 *of the Public Health Service Act, the sponsor of such device*
5 *may, when submitting a request for classification under sec-*
6 *tion 513(f)(2), submit a single submission containing—*

7 “(1) *the information needed for such a request;*
8 *and*

9 “(2) *sufficient information to enable the Sec-*
10 *retary to determine whether such laboratory examina-*
11 *tion or procedure satisfies the criteria to be cat-*
12 *egorized under section 353(d)(3) of the Public Health*
13 *Service Act.”.*

14 **SEC. 807. MEDICAL DEVICES ADVISORY COMMITTEE MEET-**
15 **INGS.**

16 (a) *IN GENERAL.*—*The Secretary shall convene one or*
17 *more panels of the Medical Devices Advisory Committee not*
18 *less than once per year for the purpose of providing advice*
19 *to the Secretary on topics related to medical devices used*
20 *in pandemic preparedness and response, including topics*
21 *related to in vitro diagnostics.*

22 (b) *REQUIRED PANEL MEMBER.*—*A panel convened*
23 *under subsection (a) shall include at least 1 population*
24 *health-specific representative.*

1 (c) *SUNSET.*—*This section shall cease to be effective on*
2 *October 1, 2027.*

3 **SEC. 808. ENSURING CYBERSECURITY OF MEDICAL DE-**
4 **VICES.**

5 (a) *IN GENERAL.*—*Subchapter A of chapter V of the*
6 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et*
7 *seq.), as amended by section 501, is further amended by*
8 *adding at the end the following:*

9 **“SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.**

10 “(a) *IN GENERAL.*—*For purposes of ensuring cyberse-*
11 *curity throughout the lifecycle of a cyber device, any person*
12 *who submits a premarket submission for the cyber device*
13 *shall include such information as the Secretary may require*
14 *to ensure that the cyber device meets such cybersecurity re-*
15 *quirements as the Secretary determines to be appropriate*
16 *to demonstrate a reasonable assurance of safety and effec-*
17 *tiveness, including at a minimum the cybersecurity require-*
18 *ments under subsection (b).*

19 “(b) *CYBERSECURITY REQUIREMENTS.*—*At a min-*
20 *imum, the manufacturer of a cyber device shall meet the*
21 *following cybersecurity requirements:*

22 “(1) *The manufacturer shall have a plan to ap-*
23 *propriately monitor, identify, and address in a rea-*
24 *sonable time postmarket cybersecurity vulnerabilities*

1 *and exploits, including coordinated vulnerability dis-*
2 *closure and procedures.*

3 “(2) *The manufacturer shall design, develop, and*
4 *maintain processes and procedures to ensure the de-*
5 *vice and related systems are cybersecure, and shall*
6 *make available updates and patches to the cyber de-*
7 *vice and related systems throughout the lifecycle of the*
8 *cyber device to address—*

9 “(A) *on a reasonably justified regular cycle,*
10 *known unacceptable vulnerabilities; and*

11 “(B) *as soon as possible out of cycle, critical*
12 *vulnerabilities that could cause uncontrolled*
13 *risks.*

14 “(3) *The manufacturer shall provide in the label-*
15 *ing of the cyber device a software bill of materials, in-*
16 *cluding commercial, open-source, and off-the-shelf*
17 *software components.*

18 “(4) *The manufacturer shall comply with such*
19 *other requirements as the Secretary may require to*
20 *demonstrate reasonable assurance of the safety and ef-*
21 *fectiveness of the device for purposes of cybersecurity,*
22 *which the Secretary may require by an order pub-*
23 *lished in the Federal Register.*

1 “(c) *SUBSTANTIAL EQUIVALENCE.*—*In making a de-*
2 *termination of substantial equivalence under section 513(i)*
3 *for a cyber device, the Secretary may—*

4 “(1) *find that cybersecurity information for the*
5 *cyber device described in the relevant premarket sub-*
6 *mission in the cyber device’s use environment is inad-*
7 *equate; and*

8 “(2) *issue a nonsubstantial equivalence deter-*
9 *mination based on this finding.*

10 “(d) *DEFINITION.*—*In this section:*

11 “(1) *CYBER DEVICE.*—*The term ‘cyber device’*
12 *means a device that—*

13 “(A) *includes software, including software*
14 *as or in a device;*

15 “(B) *has the ability to connect to the inter-*
16 *net; or*

17 “(C) *contains any such technological char-*
18 *acteristics that could be vulnerable to cybersecu-*
19 *rity threats.*

20 “(2) *LIFECYCLE OF THE CYBER DEVICE.*—*The*
21 *term ‘lifecycle of the cyber device’ includes the*
22 *postmarket lifecycle of the cyber device.*

23 “(3) *PREMARKET SUBMISSION.*—*The term ‘pre-*
24 *market submission’ means any submission under sec-*
25 *tion 510(k), 513, 515(c), 515(f), or 520(m).*

1 “(e) *EXEMPTION.*—*The Secretary may identify devices*
2 *or types of devices that are exempt from meeting the cyberse-*
3 *curity requirements established by this section and regula-*
4 *tions promulgated pursuant to this section. The Secretary*
5 *shall publish in the Federal Register, and update, as appro-*
6 *priate, a list of the devices and types of devices so identified*
7 *by the Secretary.*”.

8 (b) *PROHIBITED ACT.*—*Section 301(q) of the Federal*
9 *Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)) is amend-*
10 *ed by adding at the end the following:*

11 “(3) *The failure to comply with any requirement*
12 *under section 524C (relating to ensuring device cybersecur-*
13 *ity).*”.

14 (c) *ADULTERATION.*—*Section 501 of the Federal Food,*
15 *Drug, and Cosmetic Act (21 U.S.C. 351) is amended by*
16 *inserting after paragraph (j) the following:*

17 “(k) *If it is a device subject to the requirements set*
18 *forth in section 524C (relating to ensuring device cybersecur-*
19 *ity) and fails to comply with any requirement under that*
20 *section.*”.

21 (d) *MISBRANDING.*—*Section 502(t) of the Federal*
22 *Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is amend-*
23 *ed—*

24 (1) *by striking “or (3)” and inserting “(3)”;* and

1 (2) *by inserting before the period at the end the*
2 *following: “, or (4) to furnish a software bill of mate-*
3 *rials as required under section 524C (relating to en-*
4 *sureing device cybersecurity)”.*

5 **SEC. 809. PUBLIC DOCKET ON PROPOSED CHANGES TO**
6 **THIRD-PARTY VENDORS.**

7 (a) *IN GENERAL.*—

8 (1) *OPENING PUBLIC DOCKET.*—*Not later than*
9 *90 days after the date of enactment of this Act, the*
10 *Secretary of Health and Human Services shall open*
11 *a single public docket to solicit comments on factors*
12 *that generally should be considered by the Secretary*
13 *when reviewing requests from sponsors of drugs sub-*
14 *ject to risk evaluation and mitigation strategies to*
15 *change third-party vendors engaged by sponsors to*
16 *aid in implementation and management of the strate-*
17 *gies.*

18 (2) *FACTORS.*—*Such factors include the potential*
19 *effects of changes in third-party vendors on—*

20 (A) *patient access; and*

21 (B) *prescribing and administration of the*
22 *drugs by health care providers.*

23 (3) *CLOSING PUBLIC DOCKET.*—*The Secretary of*
24 *Health and Human Services may close such public*

1 *docket not earlier than 90 days after such docket is*
2 *opened.*

3 (4) *NO DELAY.*—*Nothing in this section shall*
4 *delay agency action on any modification to a risk*
5 *evaluation and mitigation strategy.*

6 (b) *GAO REPORT.*—*Not later than December 31, 2026,*
7 *the Comptroller General of the United States shall submit*
8 *to the Committee on Energy and Commerce of the House*
9 *of Representatives and the Committee on Health, Edu-*
10 *cation, Labor, and Pensions of the Senate a report on—*

11 (1) *the number of changes in third-party vendors*
12 *(engaged by sponsors to aid implementation and*
13 *management of risk evaluation and mitigation strate-*
14 *gies) for an approved risk evaluation and mitigation*
15 *strategy the Secretary of Health and Human Services*
16 *has approved under section 505–1(h) of the Federal*
17 *Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(h));*

18 (2) *any issues affecting patient access to the*
19 *drug that is subject to the strategy or considerations*
20 *with respect to the administration or prescribing of*
21 *such drug by health care providers that arose as a re-*
22 *sult of such modifications; and*

23 (3) *how such issues were resolved, as applicable.*

1 **SEC. 810. FACILITATING EXCHANGE OF PRODUCT INFORMA-**
2 **TION PRIOR TO APPROVAL.**

3 (a) *IN GENERAL.*—Section 502 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 352) is amended—

5 (1) in paragraph (a)—

6 (A) by striking “drugs for coverage” and in-
7 serting “drugs or devices for coverage”; and

8 (B) by striking “drug” each place it ap-
9 pears and inserting “drug or device”, respec-
10 tively;

11 (2) in paragraphs (a)(1) and (a)(2)(B), by strik-
12 ing “under section 505 or under section 351 of the
13 Public Health Service Act” and inserting “under sec-
14 tion 505, 510(k), 513(f)(2), or 515 of this Act or sec-
15 tion 351 of the Public Health Service Act”;

16 (3) in paragraph (a)(1)—

17 (A) by striking “under section 505 or under
18 section 351(a) of the Public Health Service Act”
19 and inserting “under section 505, 510(k),
20 513(f)(2), or 515 of this Act or section 351 of the
21 Public Health Service Act”; and

22 (B) by striking “in section 505(a) or in
23 subsections (a) and (k) of section 351 of the Pub-
24 lic Health Service Act” and inserting “in section
25 505, 510(k), 513(f)(2), or 515 of this Act or sec-
26 tion 351 of the Public Health Service Act”; and

1 (4) *by adding at the end the following:*

2 “(gg)(1) *Unless its labeling bears adequate directions*
3 *for use in accordance with paragraph (f), except that (in*
4 *addition to drugs or devices that conform with exemptions*
5 *pursuant to such paragraph) no drug or device shall be*
6 *deemed to be misbranded under such paragraph through the*
7 *provision of product information to a payor, formulary*
8 *committee, or other similar entity with knowledge and ex-*
9 *pertise in the area of health care economic analysis car-*
10 *rying out its responsibilities for the selection of drugs or*
11 *devices for coverage or reimbursement if the product infor-*
12 *mation relates to an investigational drug or device or inves-*
13 *tigational use of a drug or device that is approved, cleared,*
14 *granted marketing authorization, or licensed under section*
15 *505, 510(k), 513(f)(2), or 515 of this Act or section 351*
16 *of the Public Health Service Act (as applicable), provided—*

17 “(A) *the product information includes—*

18 “(i) *a clear statement that the investiga-*
19 *tional drug or device or investigational use of a*
20 *drug or device has not been approved, cleared,*
21 *granted marketing authorization, or licensed*
22 *under section 505, 510(k), 513(f)(2), or 515 of*
23 *this Act or section 351 of the Public Health*
24 *Service Act (as applicable) and that the safety*

1 *and effectiveness of the drug or device or use has*
2 *not been established;*

3 “(i) *information related to the stage of de-*
4 *velopment of the drug or device involved, such*
5 *as—*

6 “(I) *the status of any study or studies*
7 *in which the investigational drug or device*
8 *or investigational use is being investigated;*

9 “(II) *how the study or studies relate to*
10 *the overall plan for the development of the*
11 *drug or device; and*

12 “(III) *whether an application, pre-*
13 *market notification, or request for classi-*
14 *fication for the investigational drug or de-*
15 *vice or investigational use has been sub-*
16 *mitted to the Secretary and when such a*
17 *submission is planned;*

18 “(iii) *in the case of information that in-*
19 *cludes factual presentations of results from stud-*
20 *ies, which shall not be selectively presented, a de-*
21 *scription of—*

22 “(I) *all material aspects of study de-*
23 *sign, methodology, and results; and*

24 “(II) *all material limitations related to*
25 *the study design, methodology, and results;*

1 “(iv) where applicable, a prominent state-
2 ment disclosing the indication or indications for
3 which the Secretary has approved, granted mar-
4 keting authorization, cleared, or licensed the
5 product pursuant to section 505, 510(k),
6 513(f)(2), or 515 of this Act or section 351 of the
7 Public Health Service Act, and a copy of the
8 most current required labeling; and

9 “(v) updated information, if previously
10 communicated information becomes materially
11 outdated as a result of significant changes or as
12 a result of new information regarding the prod-
13 uct or its review status; and

14 “(B) the product information does not include—

15 “(i) information that represents that an un-
16 approved product—

17 “(I) has been approved, cleared, grant-
18 ed marketing authorization, or licensed
19 under section 505, 510(k), 513(f)(2), or 515
20 of this Act or section 351 of the Public
21 Health Service Act (as applicable); or

22 “(II) has otherwise been determined to
23 be safe or effective for the purpose or pur-
24 poses for which the drug or device is being
25 studied; or

1 “(ii) information that represents that an
2 unapproved use of a drug or device that has been
3 so approved, granted marketing authorization,
4 cleared, or licensed—

5 “(I) is so approved, granted marketing
6 authorization, cleared, or licensed; or

7 “(II) that the product is safe or effec-
8 tive for the use or uses for which the drug
9 or device is being studied.

10 “(2) For purposes of this paragraph, the term ‘product
11 information’ includes—

12 “(A) information describing the drug or device
13 (such as drug class, device description, and features);

14 “(B) information about the indication or indica-
15 tions being investigated;

16 “(C) the anticipated timeline for a possible ap-
17 proval, clearance, marketing authorization, or licen-
18 sure pursuant to section 505, 510(k), 513, or 515 of
19 this Act or section 351 of the Public Health Service
20 Act;

21 “(D) drug or device pricing information;

22 “(E) patient utilization projections;

23 “(F) product-related programs or services; and

1 “(G) *factual presentations of results from studies*
2 *that do not characterize or make conclusions regard-*
3 *ing safety or efficacy.*”.

4 **(b) GAO STUDY AND REPORT.**—*Beginning on the date*
5 *that is 5 years and 6 months after the date of enactment*
6 *of this Act, the Comptroller General of the United States*
7 *shall conduct a study on the provision and use of informa-*
8 *tion pursuant to section 502(gg) of the Federal Food, Drug,*
9 *and Cosmetic Act, as added by this subsection (a), between*
10 *manufacturers of drugs and devices (as defined in section*
11 *201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
12 *321)) and entities described in such section 502(gg). Such*
13 *study shall include an analysis of the following:*

14 (1) *The types of information communicated be-*
15 *tween such manufacturers and payors.*

16 (2) *The manner of communication between such*
17 *manufacturers and payors.*

18 (3)(A) *Whether such manufacturers file an ap-*
19 *plication for approval, marketing authorization,*
20 *clearance, or licensing of a new drug or device or the*
21 *new use of a drug or device that is the subject of com-*
22 *munication between such manufacturers and payors*
23 *under section 502(gg) of the Federal Food, Drug, and*
24 *Cosmetic Act, as added by subsection (a).*

1 (B) *How frequently the Food and Drug Admin-*
2 *istration approves, grants marketing authorization,*
3 *clears, or licenses the new drug or device or new use.*

4 (C) *The timeframe between the initial commu-*
5 *nications permitted under section 502(gg) of the Fed-*
6 *eral Food, Drug, and Cosmetic Act, as added by sub-*
7 *section (a), regarding an investigational drug or de-*
8 *vice or investigational use, and the initial marketing*
9 *of such drug or device.*

10 **SEC. 811. BANS OF DEVICES FOR ONE OR MORE INTENDED**
11 **USES.**

12 (a) *IN GENERAL.*—Section 516(a) of the Federal Food,
13 *Drug, and Cosmetic Act (21 U.S.C. 360f(a)) is amended—*

14 (1) *in paragraph (1), by inserting “for one or*
15 *more intended use” before the semicolon at the end;*
16 *and*

17 (2) *in the matter following paragraph (2), by in-*
18 *serting “for any such intended use or uses. A device*
19 *that is banned for one or more intended uses is not*
20 *a legally marketed device under section 1006 when in-*
21 *tended for such use or uses” after “banned device”.*

22 (b) *SPECIFIC DEVICES DEEMED BANNED.*—Section
23 *516 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
24 *360f) is further amended by adding at the end the following:*

1 “(c) *SPECIFIC DEVICE BANNED.*—*Electrical stimula-*
2 *tion devices that apply a noxious electrical stimulus to a*
3 *person’s skin intended to reduce or cease self-injurious be-*
4 *havior or aggressive behavior are deemed to be banned de-*
5 *vices, as described in subsection (a).*

6 “(d) *REVERSAL BY REGULATION.*—*Devices banned*
7 *under this section are banned devices unless or until the*
8 *Secretary promulgates a regulation to make such devices*
9 *or use of such devices no longer banned based on a finding*
10 *that such devices or use of such devices does not present*
11 *substantial deception or an unreasonable and substantial*
12 *risk of illness or injury, or that such risk can be corrected*
13 *or eliminated by labeling.”.*

14 **SEC. 812. CLARIFYING APPLICATION OF EXCLUSIVE AP-**
15 **PROVAL, CERTIFICATION, OR LICENSURE FOR**
16 **DRUGS DESIGNATED FOR RARE DISEASES OR**
17 **CONDITIONS.**

18 (a) *APPLICATION OF EXCLUSIVE APPROVAL, CERTIFI-*
19 *CATION, OR LICENSURE FOR DRUGS DESIGNATED FOR*
20 *RARE DISEASES OR CONDITIONS.*—*Section 527 of the Fed-*
21 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is*
22 *amended—*

23 (1) *in subsection (a), in the matter following*
24 *paragraph (2), by striking “same disease or condi-*

1 *tion” and inserting “same approved indication or use*
2 *within such rare disease or condition”;*

3 *(2) in subsection (b)—*

4 *(A) in the matter preceding paragraph (1),*
5 *by striking “same rare disease or condition” and*
6 *inserting “same indication or use for which the*
7 *Secretary has approved or licensed such drug”;*
8 *and*

9 *(B) in paragraph (1), by striking “with the*
10 *disease or condition for which the drug was des-*
11 *ignated” and inserting “for whom the drug is*
12 *indicated”;* *and*

13 *(3) in subsection (c), by striking “same rare dis-*
14 *ease or condition” and inserting “same indication or*
15 *use”.*

16 *(b) APPLICATION OF AMENDMENTS.—The amendments*
17 *made by subsection (a) shall apply with respect to any drug*
18 *designated under section 526 of the Federal Food, Drug,*
19 *and Cosmetic Act (21 U.S.C. 360bb), regardless of the date*
20 *on which the drug was so designated, and regardless of the*
21 *date on which the drug was approved under section 505*
22 *of such Act (21 U.S.C. 355) or licensed under section 351*
23 *of the Public Health Service Act (42 U.S.C. 262).*

1 **SEC. 813. GAO REPORT ON THIRD-PARTY REVIEW.**

2 *Not later than September 30, 2026, the Comptroller*
3 *General of the United States shall submit to the Committee*
4 *on Energy and Commerce of the House of Representatives*
5 *and the Committee on Health, Education, Labor, and Pen-*
6 *sions of the Senate a report on the third-party review pro-*
7 *gram described in section 523 of the Federal Food, Drug,*
8 *and Cosmetic Act (21 U.S.C. 360m). Such report shall in-*
9 *clude—*

10 *(1) a description of the financial and staffing re-*
11 *sources used to carry out such program;*

12 *(2) a description of actions taken by the Sec-*
13 *retary pursuant section 523(b)(2)(C) of the Federal*
14 *Food, Drug, and Cosmetic Act (21 U.S.C.*
15 *360m(b)(2)(C)); and*

16 *(3) the results of an audit of the performance of*
17 *select persons accredited under such program.*

18 **SEC. 814. REPORTING ON PENDING GENERIC DRUG APPLI-**
19 **CATIONS AND PRIORITY REVIEW APPLICA-**
20 **TIONS.**

21 *Section 807 of the FDA Reauthorization Act of 2017*
22 *(Public Law 115–52) is amended, in the matter preceding*
23 *paragraph (1), by striking “2022” and inserting “2027”.*

24 **SEC. 815. FDA WORKFORCE IMPROVEMENTS.**

25 *Section 714A of the Federal Food, Drug, and Cosmetic*
26 *Act (21 U.S.C. 379d–3a) is amended—*

1 (1) *in subsection (a), by striking “medical prod-*
2 *ucts” and inserting “products regulated by the Food*
3 *and Drug Administration”;* and

4 (2) *by striking subsection (d) and inserting the*
5 *following:*

6 “(d) *AGENCY-WIDE STRATEGIC WORKFORCE PLAN.—*

7 “(1) *IN GENERAL.—Not later than 1 year after*
8 *the date of enactment of the Food and Drug Amend-*
9 *ments of 2022, the Commissioner of Food and Drugs*
10 *shall develop and begin implementation of an agency-*
11 *wide strategic workforce plan at the Food and Drug*
12 *Administration, which shall include—*

13 “(A) *agency-wide human capital goals and*
14 *strategies;*

15 “(B) *performance measures, benchmarks, or*
16 *other elements to facilitate the monitoring and*
17 *evaluation of the progress made toward such*
18 *goals and the effectiveness of such strategies; and*

19 “(C) *a process for updating such plan based*
20 *on timely and relevant information on an ongo-*
21 *ing basis.*

22 “(2) *REPORT TO CONGRESS.—Not later than 18*
23 *months after the date of enactment of the Food and*
24 *Drug Amendments of 2022, the Secretary shall submit*
25 *to the Committee on Energy and Commerce of the*

1 *House of Representatives and the Committee on*
2 *Health, Education, Labor, and Pensions of the Senate*
3 *a report describing the plan under paragraph (1) and*
4 *the status of its implementation.”.*

Union Calendar No. 262

117TH CONGRESS
2^D SESSION

H. R. 7667

[Report No. 117-348]

A BILL

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

JUNE 7, 2022

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed