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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. 7667

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

IN THE HOUSE OF REPRESENTATIVES

Ms. ESHOO introduced the following bill; which was referred to the Committee
on _____

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

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

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

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

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- Sec. 2. Table of contents.

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

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

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

6 (b) **FINDING.**—The Congress finds that the fees au-
7 thorized by the amendments made in this title will be dedi-
8 cated toward expediting the drug development process and
9 the process for the review of human drug applications, in-
10 cluding postmarket drug safety activities, as set forth in
11 the goals identified for purposes of part 2 of subchapter
12 C of chapter VII of the Federal Food, Drug, and Cosmetic
13 Act, in the letters from the Secretary of Health and
14 Human Services to the Chairman of the Committee on
15 Health, Education, Labor, and Pensions of the Senate and
16 the Chairman of the Committee on Energy and Commerce
17 of the House of Representatives, as set forth in the Con-
18 gressional Record.

19 **SEC. 102. DEFINITIONS.**

20 (a) **HUMAN DRUG APPLICATION.**—Section 735(1) of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 379g(1)) is amended by striking “an allergenic extract

1 product, or” and inserting “does not include an applica-
2 tion with respect to an allergenic extract product licensed
3 before October 1, 2022, does not include an application
4 with respect to a standardized allergenic extract product
5 submitted pursuant to a notification to the applicant from
6 the Secretary regarding the existence of a potency test
7 that measures the allergenic activity of an allergenic ex-
8 tract product licensed by the applicant before October 1,
9 2022, does not include an application with respect to”.

10 (b) PRESCRIPTION DRUG PRODUCT.—Section 735(3)
11 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 379g(3)) is amended—

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

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

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

19 “(B) Such term does not include”;

20 (4) by striking “an allergenic extract product,”
21 and inserting “an allergenic extract product licensed
22 before October 1, 2022, a standardized allergenic ex-
23 tract product submitted pursuant to a notification to
24 the applicant from the Secretary regarding the exist-
25 ence of a potency test that measures the allergenic

1 activity of an allergenic extract product licensed by
2 the applicant before October 1, 2022,” ; and

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

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

15 “(I) the date such request was re-
16 ceived; or

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

21 “(ii) For purposes of this subparagraph, a
22 product shall be considered withdrawn from
23 sale once the applicant has ceased its own dis-
24 tribution of the product, whether or not the ap-
25 plicant has ordered recall of all previously dis-

1 tributed lots of the product, except that a rou-
2 tine, temporary interruption in supply shall not
3 render a product withdrawn from sale.”.

4 (c) SKIN-TEST DIAGNOSTIC PRODUCT.—Section 735
5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379g) is amended by adding at the end the following:

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

8 “(A) means a product—

9 “(i) for prick, scratch, intradermal, or
10 subcutaneous administration;

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

14 “(iii) not intended to be a preventive
15 or therapeutic intervention; and

16 “(iv) intended to detect an immediate-
17 or delayed-type skin hypersensitivity reac-
18 tion to aid in the diagnosis of—

19 “(I) an allergy to an anti-
20 microbial agent;

21 “(II) an allergy that is not to an
22 antimicrobial agent, if the diagnostic
23 product was authorized for marketing
24 prior to October 1, 2022; or

1 “(III) infection with fungal or
2 mycobacterial pathogens; and

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

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

7 (a) TYPES OF FEES.—

8 (1) HUMAN DRUG APPLICATION FEE.—Section
9 736(a) of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 379h(a)) is amended—

11 (A) in the matter preceding paragraph (1),
12 by striking “fiscal year 2018” and inserting
13 “fiscal year 2023”.

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

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

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

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

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

4 (A) in subparagraph (A)—

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

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

10 (ii) by striking “subsection (c)(5)”
11 and inserting “subsection (c)(6)”;

12 (iii) by adding at the end the fol-
13 lowing:

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

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

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

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

20 “(i) a large volume parenteral product
21 (a sterile aqueous drug product packaged
22 in a single-dose container with a volume
23 greater than or equal to 100 mL, not in-
24 cluding powders for reconstitution or phar-

1 macy bulk packages) identified on the list
2 compiled under section 505(j)(7);

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

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

11 (b) FEE REVENUE AMOUNTS.—

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

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

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

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

1 “(C) the dollar amount equal to the stra-
2 tegic hiring and reserve adjustment for the fis-
3 cal year (as determined under subsection
4 (c)(2));

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

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

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

15 “(G) additional dollar amounts for each
16 fiscal year as follows:

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

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

19 “(iii) \$14,154,169 for fiscal year
20 2025.

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

22 “(v) \$1,314,620 for fiscal year
23 2027.”.

24 (2) ANNUAL BASE REVENUE.—Paragraph (3)
25 of section 736(b) of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 379h(b)) is amended to
2 read as follows:

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

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

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

13 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—

14 (1) INFLATION ADJUSTMENT.—Section
15 736(c)(1)(B)(ii) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is
17 amended by striking “Washington-Baltimore, DC-
18 MD-VA-WV” and inserting “Washington-Arlington-
19 Alexandria, DC-VA-MD-WV”.

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

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

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

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

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

13 “(B) For each of fiscal years 2024 through
14 2027, \$4,000,000.”.

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

19 “(3) CAPACITY PLANNING ADJUSTMENT.—

20 “(A) IN GENERAL.—For each fiscal year,
21 after the annual base revenue established in
22 subsection (b)(1)(A) is adjusted in accordance
23 with paragraphs (1) and (2), such revenue shall
24 be adjusted further for such fiscal year, in ac-
25 cordance with this paragraph, to reflect changes

1 in the resource capacity needs of the Secretary
2 for the process for the review of human drug
3 applications.

4 “(B) METHODOLOGY.—For purposes of
5 this paragraph, the Secretary shall employ the
6 capacity planning methodology utilized by the
7 Secretary in setting fees for fiscal year 2021, as
8 described in the notice titled ‘Prescription Drug
9 User Fee Rates for Fiscal Year 2021’ published
10 in the Federal Register on August 3, 2020 (85
11 Fed. Reg. 46651). The workload categories
12 used in applying such methodology in fore-
13 casting shall include only the activities de-
14 scribed in that notice and, as feasible, addi-
15 tional activities that are also directly related to
16 the direct review of applications and supple-
17 ments, including additional formal meeting
18 types, the direct review of postmarketing com-
19 mitments and requirements, the direct review of
20 risk evaluation and mitigation strategies, and
21 the direct review of annual reports for approved
22 prescription drug products. Subject to the ex-
23 ceptions in the preceding sentence, the Sec-
24 retary shall not include as workload categories
25 in applying such methodology in forecasting any

1 non-core review activities, including those activi-
2 ties that the Secretary referenced for potential
3 future use in such notice but did not utilize in
4 setting fees for fiscal year 2021.

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

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

21 (4) OPERATING RESERVE ADJUSTMENT.—Para-
22 graph (4), as redesignated, of section 736(e) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379h(e)) is amended—

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

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

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

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

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

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

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

1 “(5) ADDITIONAL DIRECT COST ADJUST-
2 MENT.—

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

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

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

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

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

24 “(ii) For fiscal year 2025,
25 \$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.—Sec-
11 tion 736(g)(3) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 379h(g)(3)) is amended by striking “fiscal
13 years 2018 through 2022” and inserting “fiscal years
14 2023 through 2027”.

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

20 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
21 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
22 CERNING FEES.—To qualify for consideration for a waiver
23 or reduction under subsection (d), an exemption under
24 subsection (k), or the return of any fee paid under this

1 section, including if the fee is claimed to have been paid
2 in error, a person shall—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (8) in subsection (f)—

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

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

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

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

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

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

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

13 The amendments made by this title shall take effect
14 on October 1, 2022, or the date of the enactment of this
15 Act, whichever is later, except that fees under part 2 of
16 subchapter C of chapter VII of the Federal Food, Drug,
17 and Cosmetic Act shall be assessed for all human drug
18 applications received on or after October 1, 2022, regard-
19 less of the date of the enactment of this Act.

20 **SEC. 107. SAVINGS CLAUSE.**

21 Notwithstanding the amendments made by this title,
22 part 2 of subchapter C of chapter VII of the Federal Food,
23 Drug, and Cosmetic Act, as in effect on the day before
24 the date of the enactment of this title, shall continue to
25 be in effect with respect to human drug applications and
26 supplements (as defined in such part as of such day) that

1 on or after October 1, 2017, but before October 1, 2022,
2 were accepted by the Food and Drug Administration for
3 filing with respect to assessing and collecting any fee re-
4 quired by such part for a fiscal year prior to fiscal year
5 2023.

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

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

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

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

1 **SEC. 202. DEFINITIONS.**

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

4 (1) in paragraph (9)—

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

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

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

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

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

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

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

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

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

7 (2) in paragraph (2)—

8 (A) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (2) in paragraph (2)—

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

6 (B) in subparagraph (B)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 “(B) AMOUNTS.—

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

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

4 “(II) For fiscal year 2026:

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

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

11 “(III) For fiscal year 2027:

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

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

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

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

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

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

6 “(II) For fiscal year 2027—

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

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

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

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

25 “(II) For fiscal year 2027:

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

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

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

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

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

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

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

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

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

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

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

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

19 “(5) HIRING ADJUSTMENT.—

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

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

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

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

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

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

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

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

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

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

5 “(ii) \$72,877; and

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

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

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

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

14 “(iii) For fiscal year 2025:

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

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

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

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

3 “(6) OPERATING RESERVE ADJUSTMENT.—

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

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

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

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

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

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

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

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

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

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

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

19 “(3) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

7 (3) in paragraph (1)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(3) IMPLEMENTATION AND REPORTING.—

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

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

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

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

1 **SEC. 207. 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
5 effect on the day before the date of the enactment of this
6 title, shall continue to be in effect with respect to the sub-
7 missions listed in section 738(a)(2)(A) of such Act (as de-
8 fined in such part as of such day) that on or after October
9 1, 2017, but before October 1, 2022, were accepted by
10 the Food and Drug Administration for filing with respect
11 to assessing and collecting any fee required by such part
12 for a fiscal year prior to fiscal year 2023.

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

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

22 **SEC. 209. SUNSET DATES.**

23 (a) AUTHORIZATION.—Sections 737 and 738 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;
25 739j) shall cease to be effective October 1, 2027.

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

5 (c) PREVIOUS SUNSET PROVISIONS.—Effective Octo-
6 ber 1, 2022, subsections (a) and (b) of section 210 of the
7 Medical Device User Fee Amendments of 2017 (Public
8 Law 115–52) are repealed.

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

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

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

14 (b) FINDING.—The Congress finds that the fees au-
15 thorized by the amendments made in this title will be dedi-
16 cated to human generic drug activities, as set forth in the
17 goals identified for purposes of part 7 of subchapter C
18 of chapter VII of the Federal Food, Drug, and Cosmetic
19 Act, in the letters from the Secretary of Health and
20 Human Services to the Chairman of the Committee on
21 Health, Education, Labor, and Pensions of the Senate and
22 the Chairman of the Committee on Energy and Commerce
23 of the House of Representatives, as set forth in the Con-
24 gressional Record.

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

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

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

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

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

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

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

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

21 (1) in paragraph (1)—

22 (A) in subparagraph (A)—

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

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

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

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

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

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

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

22 (2) in paragraph (2)—

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

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

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

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

10 (1) in paragraph (1)—

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

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

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

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

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

3 “(2) CAPACITY PLANNING ADJUSTMENT.—

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

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

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

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

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

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

11 “(C) LIMITATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(3) OPERATING RESERVE ADJUSTMENT.—

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

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

3 “(i) 8 weeks for fiscal year 2024;

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

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

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

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

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

1 (1) in the paragraph heading, by striking “2018
2 THROUGH 2022” and inserting “2023 THROUGH 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
7 day of each of fiscal years 2023 through 2027”.

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

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

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

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

18 (2) by striking “Generic Drug User Fee
19 Amendments of 2017” each place it appears and in-
20 serting “Generic Drug User Fee Amendments of
21 2022”;

22 (3) in subsection (a)(2), by striking “Not later
23 than 30 calendar days after the end of the second
24 quarter of fiscal year 2018, and not later than 30
25 calendar days after the end of each quarter of each

1 fiscal year thereafter” and inserting “Not later than
2 30 calendar days after the end of each quarter of
3 each fiscal year for which fees are collected under
4 this part”;

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

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

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

11 (7) in subsection (f)—

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

16 (B) in paragraph (5), by striking “January
17 15, 2022” and inserting “January 15, 2027”.

18 **SEC. 304. SUNSET DATES.**

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

23 (b) **REPORTING REQUIREMENTS.**—Section 744C of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379j–43) shall cease to be effective January 31, 2028.

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

5 **SEC. 305. EFFECTIVE DATE.**

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

13 **SEC. 306. SAVINGS CLAUSE.**

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

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

3 **TITLE IV—FEES RELATING TO**
4 **BIOSIMILAR BIOLOGICAL**
5 **PRODUCTS**

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

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

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

21 **SEC. 402. DEFINITIONS.**

22 (a) **ADJUSTMENT FACTOR.**—Section 744G(1) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
24 51(1)) is amended to read as follows:

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

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

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

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

15 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
16 **FEEES.**

17 (a) TYPES OF FEEES.—

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

23 (2) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT
24 DEVELOPMENT FEE.—Clauses (iv)(I) and (v)(II) of
25 section 744H(a)(1)(A) of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(A)) are
2 each amended by striking “5 days” and inserting “7
3 days”.

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

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

18 (B) in clause (iii)—

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

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

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

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

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

10 (4) REACTIVATION FEE.—Section
11 744H(a)(1)(D) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 379j-52(a)(1)(D)) is amended
13 to read as follows:

14 “(D) REACTIVATION FEE.—

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

1 such product and still owed and a fee (re-
2 ferred to in this section as ‘reactivation
3 fee’) by the earlier of the following:

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

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

22 “(ii) APPLICATION OF ANNUAL
23 FEE.—A person that pays a reactivation
24 fee for a product shall pay for such prod-
25 uct, beginning in the next fiscal year, the

1 annual biosimilar biological product devel-
2 opment fee under subparagraph (B), ex-
3 cept where such product (including, where
4 applicable, ownership of the relevant inves-
5 tigational new drug application) is trans-
6 ferred to a licensee, assignee, or successor
7 of such person, and written notice of such
8 transfer is provided to the Secretary, in
9 which case such licensee, assignee, or suc-
10 cessor shall pay the annual biosimilar bio-
11 logical product development fee.”.

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

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

1 uct. At least 30 days prior to administra-
2 tively removing a person from the bio-
3 similar biological product development pro-
4 gram for a product under this clause, the
5 Secretary shall provide written notice to
6 such person of the intended administrative
7 removal.”.

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

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

17 (A) in subparagraph (A)—

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

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

22 (iii) by inserting after clause (i) the
23 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
6 LIST.—

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

18 “(I) the date such request was
19 received; or

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

24 “(ii) TREATMENT AS WITHDRAWN
25 FROM SALE.—For purposes of clause (i), a

1 product shall be considered withdrawn
2 from sale once the applicant has ceased its
3 own distribution of the product, whether or
4 not the applicant has ordered recall of all
5 previously distributed lots of the product,
6 except that a routine, temporary interrup-
7 tion in supply shall not render a product
8 withdrawn from sale.

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

1 such biosimilar biological product. Not-
2 withstanding subparagraph (B), such fee
3 shall be due on the last business day of
4 such fiscal year and shall be paid only once
5 for each such product for each fiscal
6 year.”.

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

11 (c) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
12 tion 744H of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 379j–52) is amended—

14 (1) by striking paragraph (1);

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

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

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

24 “(A) the annual base revenue for the fiscal
25 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 redesignated) to read as follows:

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

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

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

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

6 (1) in paragraph (1)—

7 (A) in subparagraph (A)—

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

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

10 (B) in subparagraph (B)(ii), by striking “Washington-Baltimore, DC–MD–VA–WV”

1 and inserting “Washington-Arlington-Alexan-
2 dria, 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
15 adjust the fee revenue and fees under this sec-
16 tion for a fiscal year to reflect changes in the
17 resource capacity needs of the Secretary for the
18 process for the review of biosimilar biological
19 product applications.

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

1 the Federal Register on August 4, 2020 (85
2 Fed. Reg. 47220). The workload categories
3 used in applying such methodology in fore-
4 casting shall include only the activities de-
5 scribed in that notice and, as feasible, addi-
6 tional activities that are also directly related to
7 the direct review of biosimilar biological product
8 applications and supplements, including addi-
9 tional formal meeting types, the direct review of
10 postmarketing commitments and requirements,
11 the direct review of risk evaluation and mitiga-
12 tion strategies, and the direct review of annual
13 reports for approved biosimilar biological prod-
14 ucts. Subject to the exceptions in the preceding
15 sentence, the Secretary shall not include as
16 workload categories in applying such method-
17 ology in forecasting any non-core review activi-
18 ties, including those activities that the Sec-
19 retary referenced for potential future use in
20 such notice but did not utilize in setting fees for
21 fiscal year 2021.

22 “(C) LIMITATIONS.—Under no cir-
23 cumstances shall an adjustment under this
24 paragraph result in fee revenue for a fiscal year
25 that is less than the sum of the amounts under

1 subsections (b)(1)(A)(the annual base revenue
2 for the fiscal year), (b)(1)(B) (the dollar
3 amount of the inflation adjustment for the fis-
4 cal year), and (b)(1)(C) (the dollar amount of
5 the strategic hiring and retention adjustment).

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

11 “(4) OPERATING RESERVE ADJUSTMENT.—

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

21 “(B) DECREASE.—

22 “(i) FISCAL YEAR 2023.—For fiscal
23 year 2023, if the Secretary has carryover
24 balances for such process in excess of 33
25 weeks of such operating reserves, the Sec-

1 retary shall decrease such fee revenue and
2 fees to provide for not more than 33 weeks
3 of such operating reserves.

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

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

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

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

2 and

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

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

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

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

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

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

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

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

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

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

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

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

4 (7) in subsection (f)—

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

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

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

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

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

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

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

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

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

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

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

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

20 **SEC. 501. PREMARKET REPORTING OF DIVERSITY ACTION**
21 **PLANS FOR CLINICAL TRIALS AND STUDIES.**

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

1 “(5)(A) In order for a new drug to be exempt pursu-
2 ant to this subsection, the sponsor of a clinical investiga-
3 tion of such new drug shall submit to the Secretary a di-
4 versity action plan.

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

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

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

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

11 “(C) The sponsor shall, in such form and manner as
12 specified in the guidance required by section 524B, submit
13 such diversity action plan as soon as practicable during
14 drug development, but not later than—

15 “(i) one month prior to an End-of-Phase 2
16 meeting, as described in section 312.47(b) of title
17 21, Code of Federal Regulations (or successor regu-
18 lations); or

19 “(ii) if there is no End-of-Phase 2 meeting, one
20 month prior to commencing enrollment for a Phase
21 3 study.

22 “(D) The Secretary may waive the requirement in
23 subparagraph (A) if the Secretary determines that a waiv-
24 er is necessary based on what is known about the preva-

1 lence of the disease in terms of the patient population that
2 may use the new drug.”.

3 (b) BIOLOGICAL PRODUCTS.—Section 351(a)(3) of
4 the Public Health Service Act (42 U.S.C. 262(a)(3)) is
5 amended—

6 (1) by striking “(3) The Secretary” and insert-
7 ing “(3)(A) The Secretary”; and

8 (2) by adding at the end the following:

9 “(B)(i) In order for a biological product to be exempt
10 pursuant to this paragraph, the sponsor of a clinical inves-
11 tigation of such biological product shall submit to the Sec-
12 retary a diversity action plan.

13 “(ii) Such diversity action plan shall include—

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

16 “(II) the sponsor’s rationale for such goals; and

17 “(III) an explanation of how the sponsor in-
18 tends to meet such goals.

19 “(iii) The sponsor shall, in such form and manner
20 as specified in the guidance required by section 524B, sub-
21 mit such diversity action plan as soon as practicable dur-
22 ing biological product development, but not later than—

23 “(I) one month prior to an End-of-Phase 2
24 meeting, as described in section 312.47(b) of title

1 21, Code of Federal Regulations (or successor regu-
2 lations); or

3 “(II) if there is no End-of-Phase 2 meeting, one
4 month prior to commencing enrollment for a Phase
5 3 study.

6 “(iv) The Secretary may waive the requirement in
7 subparagraph (A) if the Secretary determines that a waiv-
8 er is necessary based on what is known about the preva-
9 lence of the disease in terms of the patient population that
10 may use the biological product.”.

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

14 “(9)(A) In order for a device to be exempt under this
15 subsection, the sponsor of a clinical investigation of such
16 device shall submit to the Secretary a diversity action plan
17 the sponsor of a clinical investigation of such device shall
18 submit to the Secretary a diversity action plan.

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

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

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

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

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

1 “(i) if submission of an application for an inves-
2 tigational device exemption is required, submitted in
3 such application; and

4 “(ii) if submission of an application for inves-
5 tigational device exemption is not required, sub-
6 mitted as soon as practicable during device develop-
7 ment, but no later than one month prior to com-
8 mencing enrollment for a study.

9 “(D) The Secretary may waive the requirement in
10 subparagraph (A) if the Secretary determines that a waiv-
11 er is necessary based on what is known about the preva-
12 lence of the disease in terms of the patient population that
13 may use the device.”.

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

17 **“SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR**
18 **CLINICAL TRIALS AND STUDIES.**

19 “(a) IN GENERAL.—The Secretary shall by guidance
20 provide recommendations relating to—

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

1 by age group, sex, race, geographic location, and
2 ethnicity, including with respect to—

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

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

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

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

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

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

22 “(II) co-morbidities frequently
23 affecting the patient population; and

24 “(III) potential barriers to enroll-
25 ing diverse participants, such as pa-

1 tient population size and geographic
2 location; and

3 “(v) any other data or information the
4 sponsor deems relevant to selecting appro-
5 priate enrollment goals, disaggregated by
6 demographic subgroup, such as the inclu-
7 sion of pregnant and lactating women;

8 “(B) an explanation for how the sponsor
9 intends to meet such goals, including demo-
10 graphic-specific outreach and enrollment strate-
11 gies, study-site selection, clinical trial inclusion
12 and exclusion practices, and any diversity train-
13 ing for trial personnel; and

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

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

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

22 “(B) if the sponsor does not expect to meet
23 such goals—

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

4 “(ii) the sponsor’s reasons for why the
5 sponsor does not expect to meet such
6 goals.

7 “(b) ISSUANCE.—The Secretary shall—

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

12 “(2) not later than 6 months after closing the
13 comment period on such draft guidance, finalize
14 such guidance.”.

15 (e) APPLICABILITY.—Sections 505(i)(5) and
16 520(g)(9) of the Federal Food, Drug, and Cosmetic Act,
17 and section 351(a)(3)(B) of the Public Health Service Act,
18 as added by subsections (a), (b), and (c) of this section,
19 apply only with respect to clinical investigations with re-
20 spect to which enrollment commences after the date that
21 is 180 days after the publication of final guidance under
22 section 524B(b)(2) of the Federal Food, Drug, and Cos-
23 metic Act, as added by subsection (d).

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

5 (a) IN GENERAL.—Not later than 2 years after the
6 date of publication of final guidance pursuant to section
7 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act,
8 as added by section 501(d) of this Act, the Secretary of
9 Health and Human Services shall commence an evaluation
10 to assess whether additions or changes to statutes or regu-
11 lations are needed to assure that sponsors conduct post-
12 approval studies or postmarket surveillance when they do
13 not meet the enrollment goals submitted in their diversity
14 action plan under section 505(i)(5) or 520(g)(9) of the
15 Federal Food, Drug, and Cosmetic Act, or section
16 351(a)(3)(B) of the Public Health Service Act, as added
17 by subsection (a), (b), or (c) of section 501 of this Act.

18 (b) DETERMINATION AND REPORTING.—Not later
19 than 180 days after the commencement of the evaluation
20 under subsection (a), the Secretary of Health and Human
21 Services shall submit a report to the Congress on the out-
22 come of the such evaluation, including any recommenda-
23 tions related to additional needed authorities.

1 **SEC. 503. PUBLIC WORKSHOPS TO ENHANCE CLINICAL**
2 **TRIAL DIVERSITY.**

3 (a) IN GENERAL.—Not later than September 30,
4 2023, the Secretary of Health and Human Services, in
5 consultation with drug sponsors, medical device manufac-
6 turers, patients, and other stakeholders, shall convene one
7 or more public workshops to solicit input from stake-
8 holders on increasing the enrollment of historically under-
9 represented populations in clinical trials and encouraging
10 clinical trial participation that reflects the prevalence of
11 the disease or condition among demographic subgroups,
12 and other topics, including—

13 (1) how and when to collect and present demo-
14 graphic subgroup and disease or condition preva-
15 lence data from clinical trials, including with respect
16 to—

17 (A) such data intended to support post-
18 approval study requirements; and

19 (B) the utilization of real world evidence
20 (as defined in section 505F(b) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C.
22 355g(b)));

23 (2) methodologies for assessing the diversity of
24 a patient population;

1 (3) methodologies for the dissemination of in-
2 formation to the public on clinical trial enrollment
3 demographic data;

4 (4) the establishment of goals for enrollment in
5 clinical trials with respect to the estimated preva-
6 lence in the United States of the disease or condition
7 for which the drug is being developed or inves-
8 tigated, disaggregated by demographic subgroup (in-
9 cluding by age group, race, ethnicity, and sex); and

10 (5) approaches to support inclusion of under-
11 represented populations and to encourage clinical
12 trial participation that reflects the prevalence of the
13 disease or condition in certain demographic sub-
14 groups, including with respect to—

15 (A) the establishment of inclusion and ex-
16 clusion criteria for certain demographic sub-
17 groups, such as pregnant and lactating women
18 and individuals with disabilities, including intel-
19 lectual or developmental disabilities;

20 (B) considerations regarding informed con-
21 sent with respect to individuals with intellectual
22 or developmental disabilities;

23 (C) clinical trial designs, including utiliza-
24 tion of decentralized trials or digital health
25 tools;

- 1 (D) clinical endpoints;
2 (E) biomarker selection; and
3 (F) studying analysis.

4 (b) PUBLIC DOCKET.—The Secretary of Health and
5 Human Services shall establish a public comment period
6 to receive written comments related to the topics ad-
7 dressed during each public workshop convened under this
8 section. The public comment period shall remain open for
9 60 days following the date on which each public workshop
10 is convened.

11 (c) REPORT.—Not later than 180 days after the date
12 of each public workshop convened under this section, the
13 Secretary of Health and Human Services shall make avail-
14 able on the public website of the Food and Drug Adminis-
15 tration a report on the topics discussed at such workshop.
16 The report shall include a summary of, and response to,
17 recommendations raised in such workshop.

18 **SEC. 504. ANNUAL REPORT ON PROGRESS TO INCREASE DI-**
19 **VERSITY IN CLINICAL TRIALS AND STUDIES.**

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

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

7 (2) contains information on—

8 (A) whether the clinical trials conducted
9 with respect to such applications met the demo-
10 graphic subgroup enrollment goals from the di-
11 versity action plan submitted for such applica-
12 tions;

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

16 (C) any postmarket studies of a drug or
17 device in a demographic subgroup or subgroups
18 required or recommended by the Secretary
19 based on inadequate premarket clinical trial di-
20 versity, including the status and completion
21 date of any such study; and

22 (D) additional authorities, if any, the Sec-
23 retary plans to use or considers necessary to en-
24 sure compliance with the requirements of the
25 amendments made by section 501.

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

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

10 (a) IN GENERAL.—Not later than 180 days after the
11 date on which the COVID–19 emergency period ends, the
12 Secretary of Health and Human Services shall convene a
13 public meeting to discuss the recommendations provided
14 by the Food and Drug Administration during the COVID–
15 19 emergency period to mitigate disruption of clinical
16 trials, including recommendations detailed in the March
17 2020 guidance entitled “Conduct of Clinical Trials of
18 Medical Products During the COVID–19 Public Health
19 Emergency, Guidance for Industry, Investigators, and In-
20 stitutional Review Boards”, and any subsequent updates
21 to such guidance. The Secretary of Health and Human
22 Services shall invite to such meeting representatives from
23 the pharmaceutical and medical device industries who
24 sponsored clinical trials during the COVID–19 emergency
25 period and organizations representing patients.

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

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

10 (2) the characteristics of the sponsors, trials,
11 and patient populations impacted by such rec-
12 ommendations;

13 (3) a consideration of how recommendations in-
14 tended to mitigate disruption of clinical trials during
15 the COVID–19 emergency period, including any rec-
16 ommendations to consider decentralized clinical
17 trials when appropriate, may have affected access to
18 clinical trials for certain patient populations, espe-
19 cially unrepresented racial and ethnic minorities;
20 and

21 (4) recommendations for incorporating certain
22 clinical trial disruption mitigation recommendations
23 into current or additional guidance to improve clin-
24 ical trial access and enrollment of diverse patient
25 populations.

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

6 **SEC. 506. DECENTRALIZED CLINICAL TRIALS.**

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

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

17 (2) not later than 6 months after closing the
18 comment period on such draft guidance, finalize
19 such guidance.

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

22 (1) Recommendations for how digital health
23 technology or other remote assessment options, such
24 as telehealth, could support decentralized clinical
25 trials, including guidance on considerations for se-

1 lecting technological platforms and mediums, data
2 collection and use, data integrity and security, and
3 communication to study participants through digital
4 technology.

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

11 (3) Recommendations with respect to the eval-
12 uation of data collected within a decentralized clin-
13 ical trial setting.

14 (c) DEFINITION.—In this section, the term “decen-
15 tralized clinical trial” means a clinical trial in which some
16 or all of the trial-related activities occur at a location sepa-
17 rate from the investigator’s location.

18 **TITLE VI—GENERIC DRUG** 19 **COMPETITION**

20 **SEC. 601. INCREASING TRANSPARENCY IN GENERIC DRUG** 21 **APPLICATIONS.**

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

1 “(H)(i) Upon request (in controlled correspondence
2 or otherwise) by a person that has submitted or intends
3 to submit an abbreviated application for a new drug under
4 this subsection or on the Secretary’s own initiative during
5 the review of such abbreviated application, the Secretary
6 shall inform the person whether such new drug is quali-
7 tatively and quantitatively the same as the listed drug.

8 “(ii) If the Secretary determines that such new drug
9 is not qualitatively or quantitatively the same as the listed
10 drug, the Secretary shall identify and disclose to the per-
11 son—

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

15 “(II) for any ingredient for which there is an
16 identified quantitative deviation, the amount of such
17 deviation.

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

23 “(I) the formulation of the listed drug has been
24 changed and the Secretary has determined that the

1 prior listed drug formulation was withdrawn for rea-
2 sons of safety or effectiveness; or

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

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

10 “(v) The disclosures required by this subparagraph
11 are disclosures authorized by law under section 1905 of
12 title 18, United States Code.”.

13 (b) GUIDANCE.—

14 (1) IN GENERAL.—Not later than one year
15 after the date of enactment of this Act, the Sec-
16 retary of Health and Human Services shall issue
17 guidance describing how the Secretary will deter-
18 mine whether a new drug is qualitatively and quan-
19 titatively the same as the listed drug (as such terms
20 are used in section 505(j)(3)(H) of the Federal
21 Food, Drug, and Cosmetic Act, as added by sub-
22 section (a)), including with respect to assessing pH
23 adjusters.

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

4 (A) publish draft guidance;

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

7 (C) after considering any comments re-
8 ceived, publish final guidance.

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

14 **SEC. 602. ENHANCING ACCESS TO AFFORDABLE MEDI-**
15 **CINES.**

16 Section 505(j)(10)(A) of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended
18 by striking clauses (i) through (iv) and inserting the fol-
19 lowing:

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

24 “(ii) the sponsor of the application agrees to
25 submit revised labeling for the drug that is the sub-

1 ject of the application not later than 60 days after
2 approval under this subsection of the application;
3 and

4 “(iii) the labeling revision described under
5 clause (i) does not include a change to the ‘Warn-
6 ings’ section of the labeling.”.

7 **TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN**
8 **IMPROVEMENTS**

9 **Subtitle A—In General**

10 **SEC. 701. ANIMAL TESTING ALTERNATIVES.**

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

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

15 (2) in subsection (i)—

16 (A) in paragraph (1)(A), by striking “pre-
17 clinical tests (including tests on animals)” and
18 inserting “nonclinical tests”; and
19 inserting “nonclinical tests”; and

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

22 (3) after subsection (y), by inserting the fol-
23 lowing:

24 “(z) **NONCLINICAL TEST DEFINED.**—For purposes
25 of this section, the term ‘nonclinical test’ means a test con-

1 ducted in vitro, in silico, or in chemico, or a nonhuman
2 in vivo test, that occurs before or during the clinical trial
3 phase of the investigation of the safety and effectiveness
4 of a drug. Such test may include the following:

5 “(1) Cell-based assays.

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

8 “(3) Sophisticated computer modeling.

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

11 “(5) Animal tests.”.

12 **SEC. 702. EMERGING TECHNOLOGY PROGRAM.**

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

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

18 “(a) PROGRAM ESTABLISHMENT.—

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

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

1 “(A) facilitate and increase communication
2 between public and private entities, consortia,
3 and individuals with respect to innovative drug
4 product design and manufacturing;

5 “(B) solicit information regarding, and
6 conduct or support research on, innovative ap-
7 proaches to drug product design and manufac-
8 turing;

9 “(C) convene meetings with representatives
10 of industry, academia, other Federal agencies,
11 international agencies, and other interested per-
12 sons, as appropriate;

13 “(D) convene working groups to support
14 drug product design and manufacturing re-
15 search and development;

16 “(E) support education and training for
17 regulatory staff and scientists related to innova-
18 tive approaches to drug product design and
19 manufacturing;

20 “(F) advance regulatory science related to
21 the development and review of innovative ap-
22 proaches to drug product design and manufac-
23 turing;

24 “(G) convene or participate in working
25 groups to support the harmonization of inter-

1 national regulatory requirements related to in-
2 novative approaches to drug product design and
3 manufacturing; and

4 “(H) award grants or contracts to carry
5 out or support the program under paragraph
6 (1).

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

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

12 “(B) containing such information as the
13 Secretary may require, including a description
14 of—

15 “(i) how the entity will conduct the
16 activities to be supported through the
17 grant or contract; and

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

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

23 “(1) issue or update guidance to help facilitate
24 the adoption of, and advance the development of, in-

1 novative approaches to drug product design and
2 manufacturing; and

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

4 “(A) any regulatory requirements related
5 to the development or review of technologies re-
6 lated to innovative approaches to drug product
7 design and manufacturing, including updates
8 and improvements to such technologies after
9 product approval; and

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

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

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

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

1 “(3) the number of meetings held or partici-
2 pated in by the Food and Drug Administration, in-
3 cluding meetings convened as part of a working
4 group described in subparagraph (D) or (G) of sub-
5 section (a)(2), and the topics of each such meeting;
6 and

7 “(4) the number of drug products approved or
8 licensed, after the date of enactment of this section,
9 using an innovative approach to drug product design
10 and manufacturing.

11 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
12 carry out this section, there is authorized to be appro-
13 priated \$20,000,000 for each fiscal year 2023 through
14 2027.”

15 **SEC. 703. IMPROVING THE TREATMENT OF RARE DISEASES**
16 **AND CONDITIONS.**

17 (a) REPORT ON ORPHAN DRUG PROGRAM.—

18 (1) IN GENERAL.—Not later than September
19 30, 2026, the Secretary shall submit to the Com-
20 mittee on Energy and Commerce of the House of
21 Representatives and the Committee on Health, Edu-
22 cation, Labor, and Pensions of the Senate a report
23 summarizing the activities of the Food and Drug
24 Administration related to designating drugs under
25 section 526 of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 360bb) for a rare disease or
2 condition and approving such drugs under section
3 505 of such Act (21 U.S.C. 355) or licensing such
4 drugs under section 351 of the Public Health Serv-
5 ice Act (42 U.S.C. 262), including—

6 (A) the number of applications for such
7 drugs under section 505 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355) or li-
9 censing such drugs under section 351 of the
10 Public Health Service Act (42 U.S.C. 262) re-
11 ceived by the Food and Drug Administration,
12 the number of such applications accepted and
13 rejected for filing, and the number of such ap-
14 plications pending, approved, and disapproved
15 by the Food and Drug Administration;

16 (B) a description of trends in drug approv-
17 als for rare diseases and conditions across re-
18 view divisions at the Food and Drug Adminis-
19 tration;

20 (C) the extent to which the Food and Drug
21 Administration is consulting with external ex-
22 perts pursuant to section 569(a)(2) of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C.
24 360bbb–8(a)(2)) on topics pertaining to drugs
25 for a rare disease or condition, including how

1 and when any such consultation is occurring;
2 and

3 (D) the Food and Drug Administration's
4 efforts to promote best practices in the develop-
5 ment of novel treatments for rare diseases, in-
6 cluding—

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

9 (ii) new regulatory science and coordi-
10 nated support for patient and stakeholder
11 engagement.

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

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

23 (b) STUDY ON EUROPEAN UNION SAFETY AND EFFI-
24 CACY REVIEWS OF DRUGS FOR RARE DISEASES AND CON-
25 DITIONS.—

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

7 (A) flexibilities, authorities, or mechanisms
8 available to regulators in the United States and
9 the European Union specific to rare diseases or
10 conditions;

11 (B) the consideration and use of supple-
12 mental data submitted during review processes
13 in the United States and the European Union,
14 including data associated with open label exten-
15 sion studies and expanded access programs spe-
16 cific to rare diseases or conditions;

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

20 (i) product development programs
21 under review;

22 (ii) policies under development re-
23 cently issued; and

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

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

4 (2) CONSULTATION.—The contract under para-
5 graph (1) shall provide for consultation with relevant
6 stakeholders, including—

7 (A) representatives from the Food and
8 Drug Administration and the European Medi-
9 cines Agency;

10 (B) rare disease or condition patients; and

11 (C) patient groups that—

12 (i) represent rare disease or condition
13 patients; and

14 (ii) have international patient out-
15 reach.

16 (3) REPORT.—The contract under paragraph
17 (1) shall provide for, not later than 2 years after the
18 date of enactment of this Act—

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

21 (B) the submission of a report on the re-
22 sults of such study to the Committee on Energy
23 and Commerce of the House of Representatives
24 and the Committee on Health, Education,
25 Labor, and Pensions of the Senate.

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

7 (c) PUBLIC MEETING.—

8 (1) IN GENERAL.—Not later than December 31,
9 2023, the Secretary of Health and Human Services,
10 acting through the Commissioner of Food and
11 Drugs, shall convene one or more public meetings to
12 solicit input from stakeholders regarding the ap-
13 proaches described in paragraph (2).

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

22 (A) patient burden;

23 (B) treatment options; and

24 (C) side effects of treatments, including—

1 (i) comparing the side effects of treat-
2 ments; and

3 (ii) understanding the risks of side ef-
4 fects relative to the health status of the pa-
5 tient and the progression of the disease or
6 condition.

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

14 (4) REPORTS.—Not later than 180 days after
15 each public meeting under paragraph (1), the Com-
16 missioner of Food and Drugs shall develop and pub-
17 lish on the website of the Food and Drug Adminis-
18 tration a report on—

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

21 (B) any related recommendations.

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

1 “(C) SMALL POPULATION STUDIES.—The
2 external experts on the list maintained pursuant
3 to subparagraph (A) may include experts on the
4 science of small population studies.”.

5 (e) STUDY ON SUFFICIENCY AND USE OF FDA
6 MECHANISMS FOR INCORPORATING THE PATIENT AND
7 CLINICIAN PERSPECTIVE IN FDA PROCESSES RELATED
8 TO APPLICATIONS CONCERNING DRUGS FOR RARE DIS-
9 EASES OR CONDITIONS.—

10 (1) IN GENERAL.—The Comptroller General of
11 the United States shall conduct a study on the use
12 of Food and Drug Administration mechanisms and
13 tools to ensure that patient and physician perspec-
14 tives are considered and incorporated throughout the
15 processes of the Food and Drug Administration—

16 (A) for approving or licensing under sec-
17 tion 505 of the Federal Food, Drug, or Cos-
18 metic Act (21 U.S.C. 355) or section 351 of the
19 Public Health Service Act (42 U.S.C. 262) a
20 drug designated as a drug for a rare disease or
21 condition under section 526 of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C.
23 360bb); and

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

4 (i) safety or effectiveness; or

5 (ii) postapproval safety monitoring.

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

8 (A) identify and compare the processes
9 that the Food and Drug Administration has
10 formally put in place and utilized to gather ex-
11 ternal expertise (including patients, patient
12 groups, and physicians) on specific applications
13 for diseases or conditions affecting 20,000 or
14 fewer patients in the United States and specific
15 applications for diseases or conditions affecting
16 200,000 or fewer patients in the United States;

17 (B) examine tools or mechanisms to im-
18 prove efforts and initiatives of the Food and
19 Drug Administration to collect and consider
20 such external expertise with respect to applica-
21 tions for diseases or conditions affecting 20,000
22 or fewer patients in the United States com-
23 pared to applications for diseases or conditions
24 affecting 200,000 or fewer patients in the
25 United States throughout the application review

1 and approval or licensure processes, including
2 within internal benefit-risk assessments, advisory
3 committee processes, and postapproval
4 safety monitoring; and

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

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

14 (A) complete the study under paragraph
15 (1);

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

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

1 conditions affecting 20,000 or fewer patients in
2 the United States.

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

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

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

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

24 (c) WORKSHOP.—To assist entities developing pre-
25 ventive vaccines for fungal infections and coccidioidomy-

1 cosis, the Secretary of Health and Human Services shall
2 hold a public workshop.

3 **SEC. 705. ADVANCING QUALIFIED INFECTIOUS DISEASE**
4 **PRODUCT INNOVATION.**

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

8 (1) in subsection (c)—

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

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

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

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

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

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

21 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—

22 The term ‘qualified infectious disease product’ means a
23 drug, including an antibacterial or antifungal drug or a
24 biological product, for human use that—

1 “(1) acts directly on bacteria or fungi or on
2 substances 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 in-
8 fectious pathogens; or

9 “(B) qualifying pathogens listed by the
10 Secretary 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
16 or 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,
20 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
21 ed by inserting after section 506J (21 U.S.C. 356j) the
22 following:

1 **“SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES**
2 **DESIGNATION PILOT PROGRAM.**

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

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

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

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

24 “(A) a drug that is described in section
25 506C(a) and is intended to treat a serious or
26 life-threatening condition; or

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

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

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

14 “(A) providing timely advice to, and inter-
15 active communication with, such person regard-
16 ing the development of the method of manufac-
17 turing; and

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

23 “(2) EVALUATION AND DESIGNATION.—Not
24 later than 180 calendar days after the receipt of a
25 request under paragraph (1), the Secretary shall de-

1 termine whether to designate such method of manu-
2 facturing as an advanced manufacturing technology,
3 in a particular context of use, based on the data and
4 information submitted under paragraph (1) and the
5 criteria described in subsection (b).

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

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

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

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

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

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

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

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

19 “(2) PILOT PROGRAM GUIDANCE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 “(f) SUNSET.—The Secretary—

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

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

14 **SEC. 707. PUBLIC WORKSHOP ON CELL AND GENE THERA-**
15 **PIES.**

16 Not later than 3 years after the date of the enact-
17 ment of this Act, the Secretary of Health and Human
18 Services, acting through the Commissioner of Food and
19 Drugs, shall convene a public workshop with relevant
20 stakeholders to discuss best practices on generating sci-
21 entific data necessary to further facilitate the development
22 of human cell-, tissue-, and cellular-based medical prod-
23 ucts, and the latest scientific information about such prod-
24 ucts.

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) is amended by striking “2018 through
5 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 Cos-
11 metic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by
12 striking “2022” and inserting “2027”.

13 (b) PEDIATRIC MEDICAL DEVICE SAFETY AND IM-
14 PROVEMENT ACT.—Section 305(e) of the Pediatric Med-
15 ical Device Safety and Improvement Act (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
22 Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by strik-
23 ing “2022” and inserting “2027”.

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

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

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

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

11 (1) in subsection (a)—

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

14 (B) by inserting before the period at the
15 end the following: “, and (4) developing regu-
16 latory science pertaining to the chemistry, man-
17 ufacturing, regulatory approval of, and controls
18 of individualized medical products to treat indi-
19 viduals with rare diseases or conditions”; and

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

22 **Subtitle B—Inspections**

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

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

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

3 (b) RECORDS OR OTHER INFORMATION.—

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

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

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

20 (2) GUIDANCE.—

21 (A) IN GENERAL.—The Secretary of
22 Health and Human Services shall issue guid-
23 ance describing—

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

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

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

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

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

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

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

1 (c) BIORESEARCH MONITORING INSPECTIONS.—

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

6 “(5) BIORESEARCH MONITORING INSPECTIONS.—

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

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

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

1 “(i) SITES AND FACILITIES DESCRIBED.—

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

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

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

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

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

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

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

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

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

12 “(D) CONDITIONS OF INSPECTION.—

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

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

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

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

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

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

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

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

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

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

14 “(iii) Any other clinical investigation of—

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

18 “(II) a device subject to section
19 520(g).

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

1 “(F) CLARIFICATION.—This paragraph clarifies
2 the authority of the Secretary to conduct inspections
3 of the type described in this paragraph and shall not
4 be construed as a basis for inferring that, prior to
5 the date of enactment of this paragraph, the Sec-
6 retary lacked the authority to conduct such inspec-
7 tions, including under this Act or the Public Health
8 Service Act.”.

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

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

13 (i) review processes and practices in
14 effect as of the date of enactment of this
15 Act applicable to inspections of foreign and
16 domestic sites and facilities described in
17 subparagraph (C)(i) of section 704(a)(5) of
18 the Federal Food, Drug, and Cosmetic
19 Act, as added by paragraph (1); and

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

23 (B) GUIDANCE.—

24 (i) IN GENERAL.—The Secretary of
25 Health and Human Services shall issue

1 guidance describing the processes and
2 practices applicable to inspections of sites
3 and facilities described in subparagraph
4 (C)(i) of section 704(a)(5) of the Federal
5 Food, Drug, and Cosmetic Act, as added
6 by paragraph (1), including with respect to
7 the types of records and information re-
8 quired to be provided, best practices for
9 communication between the Food and
10 Drug Administration and industry in ad-
11 vance of or during an inspection or request
12 for records or other information, and other
13 inspections-related conduct, to the extent
14 not specified in existing publicly available
15 Food and Drug Administration guides and
16 manuals for such inspections.

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

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

23 (II) not later than 1 year after
24 the close of the public comment period

1 for such draft guidance, issue final
2 guidance under clause (i).

3 **SEC. 722. USES OF CERTAIN EVIDENCE.**

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

7 “(c) **APPLICABILITY.**—The limitations on the Sec-
8 retary’s use of evidence obtained under this section, or any
9 evidence which is directly or indirectly derived from such
10 evidence, in a criminal prosecution of the person from
11 whom such evidence was obtained shall not apply to evi-
12 dence obtained under authorities other than this section,
13 unless such limitations are specifically incorporated by ref-
14 erence in such other authorities.”.

15 **SEC. 723. IMPROVING FDA INSPECTIONS.**

16 (a) **RISK FACTORS FOR ESTABLISHMENTS.**—Section
17 510(h)(4) of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360(h)(4)) is amended—

19 (1) by redesignating subparagraph (F) as sub-
20 paragraph (G); and

21 (2) by inserting after subparagraph (E) the fol-
22 lowing:

23 “(F) The compliance history of establish-
24 ments in the country or region in which the es-
25 tablishment is located that are subject to regu-

1 lation under this Act, including the history of
2 violations related to products exported from
3 such country or region that are subject to such
4 regulation.”.

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

8 (1) by redesignating subparagraph (C) as sub-
9 paragraph (D); and

10 (2) by inserting after subparagraph (B) the fol-
11 lowing:

12 “(C) The Secretary may rely on any records or other
13 information that the Secretary may inspect under this sec-
14 tion to satisfy requirements that may pertain to a
15 preapproval or risk-based surveillance inspection, or to re-
16 solve deficiencies found in such inspections, if applicable
17 and appropriate.”.

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

21 (1) in subsection (a)(1), by inserting
22 “preapproval or” before “risk-based inspections”;
23 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
3 and Drug Amendments of 2022 the Secretary shall
4 periodically assess whether additional arrangements
5 and agreements with a foreign government or an
6 agency of a foreign government, as allowed under
7 this section, are appropriate.

8 “(2) REPORTS TO CONGRESS.—Beginning not
9 later than 4 years after the date of the enactment
10 of the Food and Drug Amendments of 2022, and
11 every 4 years thereafter, the Secretary shall submit
12 to the Committee on Energy and Commerce of the
13 House of Representatives and the Committee on
14 Health, Education, Labor, and Pensions 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
20 the date of the enactment of this Act, the Comptroller
21 General of the United States shall submit to the Com-
22 mittee on Energy and Commerce of the House of Rep-
23 resentatives and the Committee on Health, Education,
24 Labor and Pensions of the Senate a report on inspections
25 conducted by—

1 (1) the Secretary of Health and Human Serv-
2 ices (in this section referred to as the “Secretary”)
3 of foreign establishments pursuant to subsections (h)
4 and (i) of section 510 and 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 eign government pursuant to section 809 of such
8 Act (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
16 conduct inspections of foreign facilities that could be
17 useful to the Food and Drug Administration to re-
18 view 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 ar-
22 rangements under section 809 of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 384e) and
24 whether the use of such agreements could be appro-
25 priately expanded;

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

5 (5) what additional foreign governments or
6 agencies of foreign governments the Secretary has
7 considered entering into a mutual recognition agree-
8 ment with and, if applicable, reasons why the Sec-
9 retary declined to enter into a mutual recognition
10 agreement with such foreign governments or agen-
11 cies;

12 (6) what tools, if any, the Secretary used to fa-
13 cilitate inspections of domestic facilities that could
14 also be effectively utilized to appropriately inspect
15 foreign facilities;

16 (7) what steps the Secretary has taken to iden-
17 tify and evaluate tools and strategies the Secretary
18 may use to continue oversight with respect to inspec-
19 tions when in-person inspections are disrupted;

20 (8) how the Secretary is considering incor-
21 porating alternative tools into the inspection activi-
22 ties conducted pursuant to the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 321 et seq.); and

24 (9) what steps the Secretary has taken to iden-
25 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
8 Secretary increases the conduct of unannounced surveil-
9 lance inspections of foreign human drug establishments
10 and evaluates the differences between such inspections of
11 domestic and foreign human drug establishments, includ-
12 ing the impact of announcing inspections to persons who
13 own or operate foreign human drug establishments in ad-
14 vance of an inspection. Such pilot program shall evalu-
15 ate—

16 (1) differences in the number and type of viola-
17 tions of section 501(a)(2)(B) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))
19 identified during unannounced and announced in-
20 spections of foreign human drug establishments and
21 any other significant differences between each type
22 of inspection;

23 (2) costs and benefits associated with con-
24 ducting announced and unannounced inspections of
25 foreign 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
13 under the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 301 et seq.) or the Public Health Service Act (42
15 U.S.C. 201 et seq.).

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

19 (d) REPORT.—The Secretary shall, not later than
20 180 days following the completion of the pilot program
21 under this section, make available on the website of the
22 Food and Drug Administration a final report on the pilot
23 program 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 inspec-
3 tions of foreign human drug establishments;

4 (2) findings and any associated recommenda-
5 tions regarding how the Secretary may achieve par-
6 ity between domestic and foreign human drug in-
7 spections; and

8 (3) the number of unannounced inspections
9 during the pilot program that would not be unan-
10 nounced under existing practices.

11 **SEC. 726. REAUTHORIZATION OF INSPECTION PROGRAM.**

12 Section 704(g)(11) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
14 ing “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
20 amended 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 Ad-
24 ministration and the staff of the Center for Drug Evalua-

1 tion and Research’s Office of Compliance and Drug Short-
2 age 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
6 actions 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
12 the field investigators of the Food and Drug Admin-
13 istration and the staff of the Center for Drug Eval-
14 uation and Research’s Office of Compliance and
15 Drug Shortage Program, including the Food and
16 Drug Administration’s procedures for enabling and
17 ensuring such communication;

18 “(B) provides the number of reports described
19 in section 704(b)(2) that were required to be sent to
20 the appropriate offices of the Food and Drug Ad-
21 ministration and the number of such reports that
22 were sent; 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
3 submitted 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,
8 2022, and annually thereafter, the Secretary of Health
9 and Human Services (referred to in this section as the
10 “Secretary”) shall publish a report on the public website
11 of the Food and Drug Administration on the utilization
12 of agreements entered into pursuant to section 809 of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e)
14 or otherwise entered into by the Secretary in the previous
15 fiscal year to recognize inspections between drug regu-
16 latory authorities across countries and international re-
17 gions with analogous review criteria to the Food and Drug
18 Administration, such as the Pharmaceutical Inspection
19 Co-Operation Scheme, the Mutual Recognition Agreement
20 with the European Union, and the Australia-Canada-
21 Singapore-Switzerland 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 in-
3 terest.

4 (2) The total number of inspections conducted
5 at 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
10 Food and Drug Administration.

11 (3) Of the inspections described in paragraph
12 (2), the total number of inspections in each region
13 of 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
18 under 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);
22 and

23 (B) the number of inspections which have
24 been conducted by employees or contractors of
25 the Food and Drug Administration.

1 (c) DEFINITIONS.—In this subsection:

2 (1) FDA INSPECTION CATEGORY.—The term
3 “FDA inspection category” means the following in-
4 spection categories:

5 (A) Inspections to support approvals of
6 changes to the manufacturing process of drugs
7 approved under section 505 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 355)
9 or section 351 of the Public Health Service Act
10 (42 U.S.C. 262).

11 (B) Surveillance inspections.

12 (C) For-cause inspections.

13 (2) REGION OF INTEREST.—The term “region
14 of interest” means China, India, the European
15 Union, and any other geographic region as the Sec-
16 retary determines appropriate.

17 **SEC. 729. ENHANCING TRANSPARENCY OF DRUG FACILITY**
18 **INSPECTION TIMELINES.**

19 Section 902 of the FDA Reauthorization Act of 2017
20 (21 U.S.C. 355 note) is amended to read as follows:

21 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

22 “Not later than 120 days after the end of each fiscal
23 year, the Secretary of Health and Human Services shall
24 post on the public website of the Food and Drug Adminis-
25 tration information related to inspections of facilities, in-

1 cluding inspections that are necessary for approval of a
2 drug under subsection (c) or (j) of section 505 of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355), ap-
4 proval of a device under section 515 of such Act (21
5 U.S.C. 360e), or clearance of a device under section
6 510(k) of such Act (21 U.S.C. 360(k)) that were con-
7 ducted during the previous fiscal year. Such information
8 shall include the following:

9 “(1) The median time following a request from
10 staff of the Food and Drug Administration review-
11 ing an application or report to the beginning of the
12 inspection, including—

13 “(A) the median time for drugs described
14 in section 505(j)(11)(A)(i) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C.
16 355(j)(11)(A)(i));

17 “(B) the median time for drugs described
18 in section 506C(a) of such Act (21 U.S.C.
19 356c(a)) only; and

20 “(C) the median time for drugs on the
21 drug shortage list in effect under section 506E
22 of such Act (21 U.S.C. 356f).

23 “(2) The median time from the issuance of a
24 report pursuant to section 704(b) of such Act (21
25 U.S.C. 374(b)) to the sending of a warning letter,

1 issuance of an import alert, or holding of a regu-
2 latory meeting for inspections for which the Sec-
3 retary concluded that regulatory or enforcement ac-
4 tion was indicated, including the median time for
5 each category of drugs listed in subparagraphs (A)
6 through (C) of paragraph (1).

7 “(3) The median time from the sending of a
8 warning letter, issuance of an import alert, or hold-
9 ing of a regulatory meeting to resolution of the ac-
10 tions indicated to address the conditions or practices
11 observed during an inspection.

12 “(4) The number of facilities that were unable
13 to implement requested corrective or preventive ac-
14 tions following a report pursuant to such section
15 704(b), resulting in a withhold recommendation, in-
16 cluding the number of such times for each category
17 of drugs listed in subparagraphs (A) through (C) of
18 paragraph (1).”.

1 **TITLE VIII—TRANSPARENCY,**
2 **PROGRAM INTEGRITY, AND**
3 **REGULATORY IMPROVE-**
4 **MENTS**

5 **SEC. 801. PROMPT REPORTS OF MARKETING STATUS BY**
6 **HOLDERS OF APPROVED APPLICATIONS FOR**
7 **BIOLOGICAL PRODUCTS.**

8 (a) IN GENERAL.—Section 506I of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

10 (1) in subsection (a)—

11 (A) in the matter preceding paragraph (1),
12 by striking “The holder of an application ap-
13 proved under subsection (c) or (j) of section
14 505” and inserting “The holder of an applica-
15 tion approved under subsection (c) or (j) of sec-
16 tion 505 of this Act or subsection (a) or (k) of
17 section 351 of the Public Health Service Act”;

18 (B) in paragraph (2), by striking “estab-
19 lished name” and inserting “established name
20 (for biological products, by proper name)”; and

21 (C) in paragraph (3), by striking “or ab-
22 breviated application number” and inserting “,
23 abbreviated application number, or biologics li-
24 cense application number”; and

25 (2) in subsection (b)—

1 (A) in the matter preceding paragraph (1),
2 by striking “The holder of an application ap-
3 proved under subsection (c) or (j)” and insert-
4 ing “The holder of an application approved
5 under subsection (c) or (j) of section 505 of
6 this Act or subsection (a) or (k) of section 351
7 of the Public Health Service Act”;

8 (B) in paragraph (1), by striking “estab-
9 lished name” and inserting “established name
10 (for biological products, by proper name)”; and

11 (C) in paragraph (2), by striking “or ab-
12 breviated application number” and inserting “,
13 abbreviated application number, or biologics li-
14 cense application number”.

15 (b) **ADDITIONAL ONE-TIME REPORT.**—Subsection
16 (c) of section 506I of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 356i) is amended to read as follows:

18 “(c) **ADDITIONAL ONE-TIME REPORT.**—Within 180
19 days of the date of enactment of the Food and Drug
20 Amendments of 2022, all holders of applications approved
21 under subsection (a) or (k) of section 351 of the Public
22 Health Service Act shall review the information in the list
23 published under section 351(k)(9)(A) and shall submit a
24 written notice to the Secretary—

1 “(1) stating that all of the application holder’s
2 biological products in the list published under sec-
3 tion 351(k)(9)(a) that are not listed as discontinued
4 are available for sale; or

5 “(2) including the information required pursu-
6 ant to subsection (a) or (b), as applicable, for each
7 of the application holder’s biological products that
8 are in the list published under section 351(k)(9)(a)
9 and not listed as discontinued, but have been discon-
10 tinued from sale or never have been available for
11 sale.”.

12 (c) PURPLE BOOK.—Section 506I of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-
14 ed—

15 (1) by striking subsection (d) and inserting the
16 following:

17 “(d) FAILURE TO MEET REQUIREMENTS.—If a hold-
18 er of an approved application fails to submit the informa-
19 tion required under subsection (a), (b), or (c), the Sec-
20 retary may—

21 “(1) move the application holder’s drugs from
22 the active section of the list published under section
23 505(j)(7)(A) to the discontinued section of the list,
24 except that the Secretary shall remove from the list
25 in accordance with section 505(j)(7)(C) drugs the

1 Secretary determines have been withdrawn from sale
2 for reasons of safety of effectiveness; and

3 “(2) identify the application holder’s biological
4 products as discontinued in the list published under
5 section 351(k)(9)(A) of the Public Health Service
6 Act, except that the Secretary shall remove from the
7 list in accordance with section 351(k)(9)(B) of such
8 Act biological products for which the license has
9 been revoked or suspended for reasons of safety, pu-
10 rity, or potency.”; and

11 (2) in subsection (e)—

12 (A) by inserting after the first sentence the
13 following: “The Secretary shall update the list
14 published under section 351(k)(9)(A) of the
15 Public Health Service Act based on information
16 provided under subsections (a), (b), and (c) by
17 identifying as discontinued biological products
18 that are not available for sale, except that bio-
19 logical products for which the license has been
20 revoked or suspended for safety, purity, or po-
21 tency reasons shall be removed from the list in
22 accordance with section 351(k)(9)(B) of the
23 Public Health Service Act.”;

1 (B) by striking “monthly updates to the
2 list” and inserting “monthly updates to the lists
3 referred to in the preceding sentences”; and

4 (C) by striking “and shall update the list
5 based on” and inserting “and shall update such
6 lists based on”.

7 (d) **TECHNICAL CORRECTIONS.**—Section 506I(e) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 356i(e)) is amended—

10 (1) by striking “subsection 505(j)(7)(A)” and
11 inserting “section 505(j)(7)(A)”; and

12 (2) by striking “subsection 505(j)(7)(C)” and
13 inserting “section 505(j)(7)(C)”.

14 **SEC. 802. ENCOURAGING BLOOD DONATION.**

15 Section 3003 of the 21st Century Cures Act (21
16 U.S.C. 360bbb–8c note) is amended to read as follows:

17 **“SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR**
18 **INPUT.**

19 “Chapter 35 of title 44, United States Code, shall
20 not apply to the collection of information to which a re-
21 sponse is voluntary, to solicit—

22 “(1) the views and perspectives of patients
23 under section 569C of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended
25 by section 3001) or section 3002; or

1 “(2) information from blood donors or potential
2 blood donors to support the development of rec-
3 ommendations by the Secretary of Health and
4 Human Services concerning blood donation.”.

5 **SEC. 803. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

6 Section 503 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 353) is amended by adding at the end the
8 following:

9 “(h)(1) Any contrast agent, radioactive drug, or OTC
10 monograph drug shall be deemed to be a drug under sec-
11 tion 201(g) and not a device under section 201(h).

12 “(2) For purposes of this subsection:

13 “(A) The term ‘contrast agent’ means a drug
14 that is intended for use in conjunction with an appli-
15 cable medical imaging device, and—

16 “(i) is a diagnostic radiopharmaceutical, as
17 defined in sections 315.2 and 601.31 of title
18 21, Code of Federal Regulations (or any suc-
19 cessor regulations); or

20 “(ii) is a diagnostic agent that improves
21 the visualization of structure or function within
22 the body by increasing the relative difference in
23 signal intensity within the target tissue, struc-
24 ture, or fluid.

1 “(B) The term ‘radioactive drug’ has the mean-
2 ing given such term in section 310.3(n) of title 21,
3 Code of Federal Regulations (or any successor regu-
4 lations), except that such term does not include—

5 “(i) an implant or article similar to an im-
6 plant;

7 “(ii) an article that applies radiation from
8 outside of the body; or

9 “(iii) the radiation source of an article de-
10 scribed in (i) or (ii).

11 “(C) The term ‘OTC monograph drug’ has the
12 meaning given such term in section 744L.

13 “(3) Nothing in this subsection shall be construed as
14 allowing for the classification a product as a drug (as de-
15 fined in section 201(g)) if such product—

16 “(A) is not described in paragraph (1); and

17 “(B) meets the definition of a device under sec-
18 tion 201(h).”.

19 **SEC. 804. POSTAPPROVAL STUDIES AND PROGRAM INTEG-**
20 **RITY FOR ACCELERATED APPROVAL DRUGS.**

21 (a) IN GENERAL.—Section 506(c) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is
23 amended—

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

1 “(2) LIMITATION.—

2 “(A) IN GENERAL.—Approval of a product
3 under this subsection may be subject to 1 or
4 both of the following requirements:

5 “(i) That the sponsor conduct an ap-
6 propriate postapproval study or studies
7 (which may be augmented or supported by
8 real world evidence) to verify and describe
9 the predicted effect on irreversible mor-
10 bidity or mortality or other clinical benefit.

11 “(ii) That the sponsor submit copies
12 of all promotional materials related to the
13 product during the preapproval review pe-
14 riod and, following approval and for such
15 period thereafter as the Secretary deter-
16 mines to be appropriate, at least 30 days
17 prior to dissemination of the materials.

18 “(B) STUDIES NOT REQUIRED.—If the
19 Secretary does not require that the sponsor of
20 a product approved under accelerated approval
21 conduct a postapproval study under this para-
22 graph, the Secretary shall publish on the
23 website of the Food and Drug Administration
24 the rationale for why such study is not appro-
25 priate or necessary.

1 “(C) POSTAPPROVAL STUDY CONDI-
2 TIONS.—Not later than the time of approval of
3 a product under accelerated approval, the Sec-
4 retary shall specify the conditions for a post-
5 approval study or studies required to be con-
6 ducted under this paragraph with respect to
7 such product, which may include enrollment
8 targets, the study protocol, and milestones, in-
9 cluding the target date of study completion.

10 “(D) STUDIES BEGUN BEFORE AP-
11 PROVAL.—The Secretary may require such
12 study or studies to be underway prior to ap-
13 proval.”; and

14 (2) by striking paragraph (3) and inserting the
15 following:

16 “(3) EXPEDITED WITHDRAWAL OF AP-
17 PROVAL.—

18 “(A) IN GENERAL.—The Secretary may
19 withdraw approval of a product approved under
20 accelerated approval using expedited procedures
21 described in subparagraph (B), if—

22 “(i) the sponsor fails to conduct any
23 required postapproval study of the product
24 with due diligence, including with respect

1 to conditions specified by the Secretary
2 under paragraph (2)(C);

3 “(ii) a study required to verify and
4 describe the predicted effect on irreversible
5 morbidity or mortality or other clinical
6 benefit of the product fails to verify and
7 describe such effect or benefit;

8 “(iii) other evidence demonstrates
9 that the product is not shown to be safe or
10 effective under the conditions of use; or

11 “(iv) the sponsor disseminates false or
12 misleading promotional materials with re-
13 spect to the product.

14 “(B) EXPEDITED PROCEDURES DE-
15 SCRIBED.—Expedited procedures described in
16 this subparagraph shall consist of, prior to the
17 withdrawal of accelerated approval—

18 “(i) providing the sponsor with—

19 “(I) due notice;

20 “(II) an explanation for the pro-
21 posed withdrawal;

22 “(III) an opportunity for a meet-
23 ing with the Commissioner of Food
24 and Drugs or the Commissioner’s des-
25 ignee; and

1 “(IV) an opportunity for written
2 appeal to—
3 “(aa) the Commissioner of
4 Food and Drugs; or
5 “(bb) a designee of the
6 Commissioner who has not par-
7 ticipated in the proposed with-
8 drawal of approval (other than a
9 meeting pursuant to subclause
10 (III)) and is not a subordinate of
11 an individual (other than the
12 Commissioner) who participated
13 in such proposed withdrawal;
14 “(ii) providing an opportunity for
15 public comment on the notice proposing to
16 withdraw approval;
17 “(iii) the publication of a summary of
18 the public comments received, and the Sec-
19 retary’s response to such comments, on the
20 website of the Food and Drug Administra-
21 tion; and
22 “(iv) convening and consulting an ad-
23 visory committee on issues related to the
24 proposed withdrawal, if requested by the
25 sponsor and if no such advisory committee

1 has previously advised the Secretary on
2 such issues with respect to the withdrawal
3 of the product prior to the sponsor's re-
4 quest.

5 “(4) LABELING.—

6 “(A) IN GENERAL.—Subject to subpara-
7 graph (B), the label for a product approved
8 under accelerated approval shall include—

9 “(i) a statement indicating that the
10 product was approved under accelerated
11 approval;

12 “(ii) a statement indicating that con-
13 tinued approval of the product is subject to
14 postmarketing studies to verify clinical
15 benefit;

16 “(iii) identification of the surrogate or
17 intermediate endpoint or endpoints that
18 supported approval and any known limita-
19 tions of such surrogate or intermediate
20 endpoint or endpoints in determining clin-
21 ical benefit; and

22 “(iv) a succinct description of the
23 product and any uncertainty about antici-
24 pated clinical benefit and a discussion of

1 available evidence with respect to such clin-
2 ical benefit.

3 “(B) APPLICABILITY.—The labeling re-
4 quirements of subparagraph (A) shall apply
5 only to products approved under accelerated ap-
6 proval for which the predicted effect on irre-
7 versible morbidity or mortality or other clinical
8 benefit has not been verified.

9 “(5) REPORTING.—Not later than September
10 30, 2025, the Secretary shall submit to the Com-
11 mittee on Energy and Commerce of the House of
12 Representatives and the Committee on Health, Edu-
13 cation, Labor, and Pensions of the Senate a report
14 describing circumstances in which the Secretary con-
15 sidered real world evidence submitted to support
16 postapproval studies required under this subsection
17 that were completed after the date of enactment of
18 the Food and Drug Amendments of 2022.”.

19 (b) REPORTS OF POSTMARKETING STUDIES.—Sec-
20 tion 506B(a) of the Federal Food, Drug, and Cosmetic
21 Act (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
4 the Secretary a report of the progress of any study
5 required under section 506(c), including progress to-
6 ward any agreed upon enrollment targets, mile-
7 stones, and other information as required by the
8 Secretary, not later than 180 days after the ap-
9 proval of such drug and not less frequently than
10 every 180 days thereafter, until the study is com-
11 pleted or terminated.”.

12 (c) GUIDANCE.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services shall issue guidance describing—

15 (A) how sponsor questions related to the
16 identification of novel surrogate or intermediate
17 clinical endpoints may be addressed in early-
18 stage development meetings with the Food and
19 Drug Administration;

20 (B) the use of novel clinical trial designs
21 that may be used to conduct appropriate post-
22 approval studies as may be required under sec-
23 tion 506(c)(2)(A) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 356(c)(2)(A)), as
25 amended by subsection (a); and

1 (C) the expedited procedures described in
2 section 506(c)(3)(B) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C.
4 356(c)(3)(B)).

5 (2) FINAL GUIDANCE.—The Secretary shall
6 issue—

7 (A) draft guidance under paragraph (1)
8 not later than 18 months after the date of en-
9 actment of this Act; and

10 (B) final guidance not later than 1 year
11 after the close of the public comment period on
12 each draft guidance.

13 (d) RARE DISEASE ENDPOINT ADVANCEMENT
14 PILOT.—

15 (1) IN GENERAL.—The Secretary of Health and
16 Human Services shall establish a pilot program
17 under which the Secretary will establish procedures
18 to provide increased interaction with sponsors of
19 rare disease drug development programs for pur-
20 poses of advancing the development of efficacy
21 endpoints, including surrogate and intermediate
22 endpoints, for drugs intended to treat rare diseases,
23 including through—

24 (A) determining eligibility of participants
25 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
6 completed not later than September 30, 2026, to
7 discuss topics relevant to the development of
8 endpoints for rare diseases, which may include dis-
9 cussions about—

10 (A) novel endpoints developed through the
11 pilot program established under this subsection;
12 and

13 (B) as appropriate, the use of real world
14 evidence and real world data to support the val-
15 idation of efficacy endpoints, including surro-
16 gate and intermediate endpoints, for rare dis-
17 eases.

18 (3) REPORT.—Not later than September 30,
19 2027, the Secretary shall submit to the Committee
20 on Energy and Commerce of the House of Rep-
21 resentatives and the Committee on Health, Edu-
22 cation, Labor, and Pensions of the Senate a report
23 describing the outcomes of the pilot program estab-
24 lished under this subsection.

1 (4) GUIDANCE.—Not later than September 30,
2 2027, the Secretary shall issue guidance describing
3 best practices and strategies for development of effi-
4 cacy endpoints, including surrogate and intermediate
5 endpoints, for rare diseases.

6 (5) SUNSET.—The Secretary may not accept
7 any new application or request to participate in the
8 program established by this subsection on or after
9 October 1, 2027.

10 **SEC. 805. FACILITATING THE USE OF REAL WORLD EVI-**
11 **DENCE.**

12 (a) GUIDANCE.—Not later than 1 year after the date
13 of the enactment of this Act, the Secretary of Health and
14 Human Services shall issue, or revise existing, guidance
15 on considerations for the use of real world data and real
16 world evidence to support regulatory decisionmaking, as
17 follows:

18 (1) With respect to drugs, such guidance shall
19 address—

20 (A) the use of such data and evidence to
21 support the approval of a drug application
22 under section 505 of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 355) or a biologi-
24 cal product application under section 351 of the
25 Public Health Service Act (42 U.S.C. 262), or

1 to support an investigational use exemption
2 under section 505(i) of the Federal Food, Drug,
3 and Cosmetic Act or section 351(a)(3) of the
4 Public Health Service Act; and

5 (B) the use of such data and evidence ob-
6 tained as a result of the use of drugs author-
7 ized for emergency use under section 564 of the
8 Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 360bbb-3) in such applications, submis-
10 sions, or requests; and

11 (C) standards and methodologies which
12 may be used for collection and analysis of real
13 world evidence included in such applications,
14 submissions, or requests, as appropriate.

15 (2) With respect to devices, such guidance shall
16 address—

17 (A) the use of such data and evidence to
18 support the approval, clearance, or classification
19 of a device pursuant to an application or sub-
20 mission submitted under section 510(k),
21 513(f)(2), or 515 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 360(k),
23 360c(f)(2), 360e), or to support an investiga-
24 tional use exemption under section 520(g) of
25 such Act (21 U.S.C. 360j(g)); and

1 (B) the use of such data and evidence ob-
2 tained as a result of the use of devices author-
3 ized for emergency use under section 564 of the
4 Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 360bbb-3), in such applications, submis-
6 sions, or requests; and

7 (C) standards and methodologies which
8 may be used for collection and analysis of real
9 world evidence included in such applications,
10 submissions, or requests, as appropriate.

11 (b) REPORT TO CONGRESS.—Not later than 2 years
12 after the termination of the public health emergency deter-
13 mination by the Secretary of Health and Human Services
14 under section 564 of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 360bbb-3) on February 4, 2020,
16 with respect to the Coronavirus Disease 2019 (COVID-
17 19), the Secretary shall submit a report to the Committee
18 on Energy and Commerce of the House of Representatives
19 and the Committee on Health, Education, Labor, and
20 Pensions of the Senate on—

21 (1) the number of applications submitted for
22 clearance or approval under sections 505, 510(k), or
23 515 of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 355, 360(k), 360e(f)(2), 360e) or section
25 351 of the Public Health Service Act, for which an

1 authorization under section 564 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–
3 3) was previously granted;

4 (2) of the number of applications so submitted,
5 the number of such applications—

6 (A) for which real world evidence was sub-
7 mitted and used to support a regulatory deci-
8 sion; and

9 (B) for which real world evidence was sub-
10 mitted and determined to be insufficient to sup-
11 port a regulatory decision; and

12 (3) a summary explanation of why, in the case
13 of applications described in paragraph (2)(B), real
14 world evidence could not be used to support regu-
15 latory decisions.

16 **SEC. 806. MEDICAL DEVICES ADVISORY COMMITTEE MEET-**
17 **INGS.**

18 (a) IN GENERAL.—The Secretary shall convene one
19 or more panels of the Medical Devices Advisory Committee
20 not less than once per year for the purpose of providing
21 advice to the Secretary on topics related to medical devices
22 in pandemic preparedness and response, including the
23 issues related to in vitro diagnostics.

1 (b) REQUIRED PANEL MEMBER.—A panel convened
2 under subsection (a) shall include at least 1 population
3 health-specific representative.

4 (c) SUNSET.—This section shall cease to be effective
5 on October 1, 2027.

6 **SEC. 807. ENSURING CYBERSECURITY OF MEDICAL DE-**
7 **VICES.**

8 (a) IN GENERAL.—Subchapter A of chapter V of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
10 et seq.), as amended by section 501, is further amended
11 by adding at the end the following:

12 **“SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.**

13 “(a) IN GENERAL.—For purposes of ensuring cyber-
14 security throughout the lifecycle of a cyber device, any per-
15 son who submits a premarket submission for the cyber de-
16 vice shall include such information as the Secretary may
17 require to ensure that the cyber device meets such cyberse-
18 curity requirements as the Secretary determines to be ap-
19 propriate to demonstrate a reasonable assurance of safety
20 and effectiveness, including at a minimum the cybersecu-
21 rity requirements under subsection (b).

22 “(b) CYBERSECURITY REQUIREMENTS.—At a min-
23 imum, the manufacturer of a cyber device shall meet the
24 following cybersecurity requirements:

1 “(1) The manufacturer shall have a plan to ap-
2 propriately monitor, identify, and address in a rea-
3 sonable time postmarket cybersecurity vulnerabilities
4 and exploits, including coordinated vulnerability dis-
5 closure and procedures.

6 “(2) The manufacturer shall design, develop,
7 and maintain processes and procedures to ensure the
8 device and related systems are cybersecure, and shall
9 make available updates and patches to the cyber de-
10 vice and related systems throughout the lifecycle of
11 the cyber device to address—

12 “(A) on a reasonably justified regular
13 cycle, known unacceptable vulnerabilities; and

14 “(B) as soon as possible out of cycle, crit-
15 ical vulnerabilities that could cause uncontrolled
16 risks.

17 “(3) The manufacturer shall provide in the la-
18 beling of the cyber device a software bill of mate-
19 rials, including commercial, open-source, and off-the-
20 shelf software components.

21 “(4) The manufacturer shall comply with such
22 other requirements as the Secretary may require to
23 demonstrate reasonable assurance of the safety and
24 effectiveness of the device for purposes of cybersecu-

1 rity, which the Secretary may require by an order
2 published in the Federal Register.

3 “(c) SUBSTANTIAL EQUIVALENCE.—In making a de-
4 termination of substantial equivalence under section
5 513(i) for a cyber device, the Secretary may—

6 “(1) find that cybersecurity information for the
7 cyber device described in the relevant premarket
8 submission in the cyber device’s use environment is
9 inadequate; and

10 “(2) issue a nonsubstantial equivalence deter-
11 mination based on this finding.

12 “(d) DEFINITION.—In this section:

13 “(1) CYBER DEVICE.—The term ‘cyber device’
14 means a device that—

15 “(A) includes software, including software
16 as or in a device;

17 “(B) is intended to connect to the internet;
18 or

19 “(C) contains any such technological char-
20 acteristics that could be vulnerable to cyberse-
21 curity threats.

22 “(2) LIFECYCLE OF THE CYBER DEVICE.—The
23 term ‘lifecycle of the cyber device’ includes the
24 postmarket lifecycle of the cyber device.

1 “(3) **PREMARKET SUBMISSION.**—The term ‘pre-
2 market submission’ means any submission under
3 section 510(k), 513, 515(e), 515(f), or 520(m).

4 “(e) **EXEMPTION.**—The Secretary may identify de-
5 vices or types of devices that are exempt from meeting
6 the cybersecurity requirements established by this section
7 and regulations promulgated pursuant to this section. The
8 Secretary shall publish in the Federal Register, and up-
9 date, as appropriate, a list of the devices and types of de-
10 vices so identified by the Secretary.”.

11 (b) **PROHIBITED ACT.**—Section 301(q) of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(q))
13 is amended by adding at the end the following:

14 “(3) The failure to comply with any requirement
15 under section 524C (relating to ensuring device cyberse-
16 curity).”.

17 (c) **ADULTERATION.**—Section 501 of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-
19 ed by inserting after paragraph (j) the following:

20 “(k) If it is a device subject to the requirements set
21 forth in section 524C (relating to ensuring device cyberse-
22 curity) and fails to comply with any requirement under
23 that section.”.

1 (d) MISBRANDING.—Section 502(t) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is
3 amended—

4 (1) by striking “or (3)” and inserting “(3)”;
5 and

6 (2) by inserting before the period at the end the
7 following: “, or (4) to furnish a software bill of ma-
8 terials as required under section 524C (relating to
9 ensuring device cybersecurity)”.

10 **SEC. 808. PUBLIC DOCKET ON PROPOSED MODIFICATIONS**
11 **TO APPROVED STRATEGIES.**

12 (a) IN GENERAL.—Not later than 90 days after the
13 date of the enactment of this Act, the Secretary of Health
14 and Human Services shall open a public docket for the
15 submission of public comments regarding factors related
16 to patient access to a drug that is subject to a risk evalua-
17 tion and mitigation strategy and the administration or
18 prescribing of such drug by health care providers that
19 should be taken into consideration when a proposed modi-
20 fication to such strategy is reviewed under section 505–
21 1(h) of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 255–1(h)). The Secretary may close such public
23 docket not earlier than 90 days after such docket is
24 opened.

1 (b) GAO REPORT.—Not later than December 31,
2 2026, the Comptroller General of the United States shall
3 submit to the Committee on Energy and Commerce of the
4 House of Representatives and the Committee on Health,
5 Education, Labor, and Pensions of the Senate a report
6 on—

7 (1) the number of proposed modifications to an
8 approved risk evaluation and mitigation strategy the
9 Secretary has granted under section 505–1(h) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 255–1(h));

12 (2) any issues affecting patient access to the
13 drug that is subject to the strategy or considerations
14 with respect to the administration or prescribing of
15 such drug by health care providers that arose as a
16 result of such modifications; and

17 (3) how such issues were resolved, as applica-
18 ble.

19 **SEC. 809. FACILITATING EXCHANGE OF PRODUCT INFOR-**
20 **MATION PRIOR TO APPROVAL.**

21 (a) IN GENERAL.—Section 502 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 352) is amended

23 (1) in paragraph (a), by striking “drug” each
24 place it appears and inserting “drug or device”;

1 (2) in paragraph (a)(2)(B), by striking “under
2 section 505 or under section 351 of the Public
3 Health Service Act for such drug” and inserting
4 “under section 505, 510(k), 513, or 515 of this Act
5 or section 351 of the Public Health Service Act”;
6 and

7 (3) by adding at the end the following:

8 “(gg)(1) Unless its labeling bears adequate directions
9 for use in accordance with paragraph (f), except that (in
10 addition to drugs or devices that conform with exemptions
11 pursuant to such paragraph) no drug or device shall be
12 considered misbranded under such paragraph through the
13 provision of product information to a payor, formulary
14 committee, or other similar entity with knowledge and ex-
15 pertise in the area of health care economic analysis car-
16 rying out its responsibilities for the selection of drugs or
17 devices for coverage or reimbursement if the product infor-
18 mation relates to an investigational drug or device or in-
19 vestigational use of a drug or device that is approved,
20 cleared, granted marketing authorization, or licensed
21 under section 505, 510(k), 513(f)(2), or 515 of this Act
22 or section 351 of the Public Health Service Act (as appli-
23 cable), provided—

24 “(A) the product information includes—

1 “(i) a clear statement that the investiga-
2 tional drug or device or investigational use of a
3 drug or device has not been approved, cleared,
4 granted marketing authorization, or licensed
5 under section 505, 510(k), 513(f)(2), or 515 of
6 this Act or section 351 of the Public Health
7 Service Act (as applicable) and that the safety
8 and effectiveness of the drug or device or use
9 has not been established;

10 “(ii) information related to the stage of de-
11 velopment of the drug or device involved, such
12 as—

13 “(I) the status of any study or studies
14 in which the investigational drug or device
15 or investigational use is being investigated;

16 “(II) how the study or studies relate
17 to the overall plan for the development of
18 the drug or device; and

19 “(III) whether a premarket applica-
20 tion, premarket notification, or request for
21 classification for the investigational drug
22 or device or investigational use has been
23 submitted to the Secretary and when such
24 a submission is planned;

1 “(iii) in the case of information that in-
2 cludes factual presentations of results from
3 studies, which shall not be selectively presented,
4 a description of—

5 “(I) all material aspects of study de-
6 sign, methodology, and results; and

7 “(II) all material limitations related
8 to the study design, methodology, and re-
9 sults;

10 “(iv) where applicable, a prominent state-
11 ment disclosing the indication or indications for
12 which the Food and Drug Administration has
13 approved, granted marketing authorization,
14 cleared, or licensed the product pursuant to sec-
15 tion 505, 510(k), 513(f)(2), or 515 of this Act
16 or section 351 of the Public Health Service Act,
17 and a copy of the most current approved label-
18 ing; and

19 “(v) updated information, if previously
20 communicated information becomes materially
21 outdated as a result of significant changes or as
22 a result of new information regarding the prod-
23 uct or its review status; and

24 “(B) the product information does not in-
25 clude—

1 “(i) information that represents that an
2 unapproved product—

3 “(I) has been approved, cleared,
4 granted marketing authorization, or li-
5 censed under section 505, 510(k),
6 513(f)(2), or 515 of this Act or section
7 351 of the Public Health Service Act (as
8 applicable); or

9 “(II) has otherwise been determined
10 to be safe or effective for the purpose or
11 purposes for which the drug or device is
12 being studied; or

13 “(ii) information that represents that an
14 unapproved use of a drug or device that has
15 been so approved, granted marketing authoriza-
16 tion, cleared, or licensed—

17 “(I) is so approved, granted mar-
18 keting authorization, cleared, or licensed;
19 or

20 “(II) that the product is safe or effec-
21 tive for the use or uses for which the drug
22 or device is being studied.

23 “(2) For purposes of this subsection, the term ‘prod-
24 uct information’ includes—

1 “(A) information describing the drug or device
2 (such as drug class, device description, and fea-
3 tures);

4 “(B) information about the indication or indica-
5 tions being investigated;

6 “(C) the anticipated timeline for a possible ap-
7 proval, clearance, marketing authorization, or licen-
8 sure pursuant to section 505, 510(k), 513, or 515
9 of this Act or section 351 of the Public Health Serv-
10 ice Act;

11 “(D) drug or device pricing information;

12 “(E) patient utilization projections;

13 “(F) product-related programs or services; and

14 “(G) factual presentations of results from stud-
15 ies that do not characterize or make conclusions re-
16 garding safety or efficacy.”.

17 (b) GAO STUDY AND REPORT.—Beginning on the
18 date that is 5 years and 6 months after the date of enact-
19 ment of this Act, the Comptroller General of the United
20 States shall conduct a study on the provision and use of
21 information pursuant to section 502(gg) of the Federal
22 Food, Drug, and Cosmetic Act, as added by this sub-
23 section (a), between manufacturers of drugs and devices
24 (as defined in section 201 of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 321)) and entities described in

1 such section 520(gg). Such study shall include an analysis
2 of the following:

3 (1) The types of information communicated be-
4 tween such manufacturers and payors.

5 (2) The manner of communication between
6 such manufacturers and payors.

7 (3)(A) Whether such manufacturers file a sub-
8 mission for approval, marketing authorization, clear-
9 ance, or licensing of a new drug or device or the new
10 use of a drug or device that is the subject of commu-
11 nication between such manufacturers and payors
12 under section 502(gg) of the Federal Food, Drug,
13 and Cosmetic Act, as added by subsection (a).

14 (B) How frequently the Food and Drug Admin-
15 istration approves, grants marketing authorization,
16 clears, or licenses the new drug or device or new use.

17 (C) The timeframe between the initial commu-
18 nications permitted under section 502(gg) of the
19 Federal Food, Drug, and Cosmetic Act, as added by
20 subsection (a), regarding an investigational drug or
21 device or investigational use, and the initial mar-
22 keting of such drug or device.

1 **SEC. 810. BANS OF DEVICES FOR ONE OR MORE INTENDED**
2 **USES.**

3 (a) IN GENERAL.—Section 516(a) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360f(a)) is
5 amended—

6 (1) in paragraph (1), by inserting “for one or
7 more intended use” before the semicolon at the end;
8 and

9 (2) in the matter following paragraph (2), by
10 inserting “for any such intended use or uses. A de-
11 vice that is banned for one or more intended uses is
12 not a legally marketed device under section 1006
13 when intended for such use or uses” after “banned
14 device”.

15 (b) SPECIFIC DEVICES DEEMED BANNED.—Section
16 516 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 360f) is further amended by adding at the end the
18 following:

19 “(c) SPECIFIC DEVICE BANNED.—Electrical stimula-
20 tion devices that apply a noxious electrical stimulus to a
21 person’s skin intended to reduce or cease self-injurious be-
22 havior or aggressive behavior are deemed to be banned de-
23 vices, as described in subsection (a). Such devices are
24 banned unless or until the Secretary promulgates a regula-
25 tion to make such devices no longer banned based on a
26 finding that such devices do not present an unreasonable

1 and substantial risk of illness or injury, or that such risk
2 can be corrected or eliminated by labeling.”.

3 **SEC. 811. CLARIFYING APPLICATION OF EXCLUSIVE AP-**
4 **PROVAL, CERTIFICATION, OR LICENSURE**
5 **FOR DRUGS DESIGNATED FOR RARE DIS-**
6 **EASES OR CONDITIONS.**

7 Section 527 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 360cc) is amended—

9 (1) in subsection (a), in the matter following
10 paragraph (2), by striking “same disease or condi-
11 tion” and inserting “same indication or use for
12 which the Secretary has approved or licensed such
13 drug”;

14 (2) in subsection (b)—

15 (A) in the matter preceding paragraph (1),
16 by striking “same rare disease or condition”
17 and inserting “same indication or use for which
18 the Secretary has approved or licensed such
19 drug”; and

20 (B) in paragraph (1), by striking “with the
21 disease or condition for which the drug was des-
22 ignated” and inserting “for whom the drug is
23 indicated”; and

1 (3) in subsection (c), by striking “same rare
2 disease or condition” and inserting “same indication
3 or use”.

4 **SEC. 812. GAO REPORT ON THIRD-PARTY REVIEW.**

5 Not later than September 30, 2026, the Comptroller
6 General of the United States shall submit to the Com-
7 mittee on Energy and Commerce of the House of Rep-
8 resentatives and the Committee on Health, Education,
9 Labor, and Pensions of the Senate a report on the third-
10 party review program described in section 523 of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360m).
12 Such report shall include—

13 (1) a description of the financial and staffing
14 resources used to carry out such program;

15 (2) a description of actions taken by the Sec-
16 retary pursuant section 523(b)(2)(C) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C.
18 360m(b)(2)(C)); and

19 (3) the results of an audit of the performance
20 of select persons accredited under such program.

21 **SEC. 813. REAUTHORIZATION OF DEVICE PILOT PROJECTS.**

22 Section 519(i)(10) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360i(i)(10)) is amended by strik-
24 ing “2022” and inserting “2027”.

1 **SEC. 814. REPORTING ON PENDING GENERIC DRUG APPLI-**
2 **CATIONS AND PRIORITY REVIEW APPLICA-**
3 **TIONS.**

4 Section 807 of the FDA Reauthorization Act of 2017
5 (Public Law 115–52) is amended, in the matter preceding
6 paragraph (1), by striking “2022” and inserting “2027”.