

117<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 7667

---

## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

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

4 **SEC. 2. TABLE OF CONTENTS.**

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

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

TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Reauthorization; reporting requirements.
- Sec. 105. Sunset dates.
- Sec. 106. Effective date.
- Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

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

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Savings clause.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL  
PRODUCTS

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

TITLE V—IMPROVING DIVERSITY IN CLINICAL STUDIES

- Sec. 501. Diversity action plans for clinical studies.
- Sec. 502. Evaluation of the need for FDA authority to mandate postapproval studies or postmarket surveillance due to insufficient demographic subgroup data.
- Sec. 503. Public workshops to enhance clinical study diversity.
- Sec. 504. Annual summary report on progress to increase diversity in clinical studies.
- Sec. 505. Public meeting on clinical study flexibilities initiated in response to COVID–19 pandemic.
- Sec. 506. Decentralized clinical studies.

#### TITLE VI—GENERIC DRUG COMPETITION

- Sec. 601. Increasing transparency in generic drug applications.
- Sec. 602. Enhancing access to affordable medicines.

#### TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN IMPROVEMENTS

##### Subtitle A—In General

- Sec. 701. Animal testing alternatives.
- Sec. 702. Emerging technology program.
- Sec. 703. Improving the treatment of rare diseases and conditions.
- Sec. 704. Antifungal research and development.
- Sec. 705. Advancing qualified infectious disease product innovation.
- Sec. 706. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing.
- Sec. 707. Advanced manufacturing technologies designation pilot program.
- Sec. 708. Public workshop on cell therapies.
- Sec. 709. Reauthorization of best pharmaceuticals for children.
- Sec. 710. Reauthorization for humanitarian device exemption and demonstration grants for improving pediatric availability.
- Sec. 711. Reauthorization of provision related to exclusivity of certain drugs containing single enantiomers.
- Sec. 712. Reauthorization of the critical path public-private partnership program.
- Sec. 713. Reauthorization of orphan drug grants.
- Sec. 714. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs.

##### Subtitle B—Inspections

- Sec. 721. Factory inspection.
- Sec. 722. Uses of certain evidence.
- Sec. 723. Improving FDA inspections.
- Sec. 724. GAO report on inspections of foreign establishments manufacturing drugs.
- Sec. 725. Unannounced foreign facility inspections pilot program.
- Sec. 726. Reauthorization of inspection program.
- Sec. 727. Enhancing intra-agency coordination and public health assessment with regard to compliance activities.
- Sec. 728. Reporting of mutual recognition agreements for inspections and review activities.
- Sec. 729. Enhancing transparency of drug facility inspection timelines.



1 retary of Health and Human Services to the Chairman  
2 of the Committee on Health, Education, Labor, and Pen-  
3 sions of the Senate and the Chairman of the Committee  
4 on Energy and Commerce of the House of Representa-  
5 tives, as set forth in the Congressional Record.

6 **SEC. 102. DEFINITIONS.**

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

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

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

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

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

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

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

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

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

24           “(I) the date such request was re-  
25 ceived; or

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

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

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

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

17                         “(A) means a product—

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

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

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

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

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

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

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

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

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

16 (a) TYPES OF FEES.—

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

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

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



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

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

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

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

13 (A) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

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

19 (b) FEE REVENUE AMOUNTS.—

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

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

1 (g), be established to generate a total revenue  
2 amount under such subsection that is equal to the  
3 sum of—

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

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

9 “(C) the dollar amount equal to the stra-  
10 tegic hiring and retention adjustment for the  
11 fiscal year (as determined under subsection  
12 (c)(2));

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

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

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

23 “(G) additional dollar amounts for each  
24 fiscal year as follows:

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

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

2 “(iii) \$14,154,169 for fiscal year  
3 2025.

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

5 “(v) \$1,314,620 for fiscal year  
6 2027.”.

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

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

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

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

21 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—

22 (1) INFLATION ADJUSTMENT.—Section  
23 736(c)(1)(B)(ii) of the Federal Food, Drug, and  
24 Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is  
25 amended by striking “Washington-Baltimore, DC–

1 MD–VA–WV” and inserting “Washington–Arlington–  
2 Alexandria, DC–VA–MD–WV”.

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

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

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

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

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

19 “(B) For each of fiscal years 2024 through  
20 2027, \$4,000,000.”.

21 (3) CAPACITY PLANNING ADJUSTMENT.—Para-  
22 graph (3), as redesignated, of section 736(c) of the  
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 379h(e)) is amended to read as follows:

25 “(3) CAPACITY PLANNING ADJUSTMENT.—

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

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

1 risk evaluation and mitigation strategies, and  
2 the direct review of annual reports for approved  
3 prescription drug products. Subject to the ex-  
4 ceptions in the preceding sentence, the Sec-  
5 retary shall not include as workload categories  
6 in applying such methodology in forecasting any  
7 non-core review activities, including those activi-  
8 ties that the Secretary referenced for potential  
9 future use in such notice but did not utilize in  
10 setting fees for fiscal year 2021.

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

21 “(D) PUBLICATION IN FEDERAL REG-  
22 ISTER.—The Secretary shall publish in the Fed-  
23 eral Register notice under paragraph (6) of the  
24 fee revenue and fees resulting from the adjust-



1           ment and the methodologies under this para-  
2           graph.”.

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

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

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

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

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

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

1 (B) in subparagraph (C), by striking  
2 “paragraph (5)” and inserting “paragraph  
3 (6)”.

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

8 “(5) ADDITIONAL DIRECT COST ADJUST-  
9 MENT.—

10 “(A) INCREASE.—The Secretary shall, in  
11 addition to adjustments under paragraphs (1),  
12 (2), (3), and (4), further increase the fee rev-  
13 enue and fees—

14 “(i) for fiscal year 2023, by  
15 \$44,386,150; and

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

1           “(B) APPLICABLE AMOUNTS.—The  
2 amounts referred to in subparagraph (A)(ii) are  
3 the following:

4           “(i) For fiscal year 2024,  
5 \$60,967,993.

6           “(ii) For fiscal year 2025,  
7 \$35,799,314.

8           “(iii) For fiscal year 2026, \$35,799,  
9 314.

10           “(iv) For fiscal year 2027,  
11 \$35,799,314.”.

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

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

22           (e) WRITTEN REQUESTS FOR WAIVERS, REDUC-  
23 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-  
24 CERNING FEES.—Section 736(i) of the Federal Food,

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

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

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

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

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

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

22 (2) by amending paragraph (2) to read as fol-  
23 lows:

24 “(2) EVIDENCE OF QUALIFICATION.—An ex-  
25 emption under paragraph (1) applies with respect to

1 a drug only if the applicant involved submits a cer-  
2 tification that the applicant’s gross annual revenues  
3 did not exceed \$50,000,000 for the last calendar  
4 year ending prior to the fiscal year for which the ex-  
5 emption is requested. Such certification shall be sup-  
6 ported by—

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

9 “(B) as necessary, other appropriate finan-  
10 cial information.”.

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

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

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

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

20 (3) in subsection (a)(3)(A), by striking “Not  
21 later than 30 calendar days after the end of the sec-  
22 ond quarter of fiscal year 2018, and not later than  
23 30 calendar days after the end of each quarter of  
24 each fiscal year thereafter” and inserting “Not later  
25 than 30 calendar days after the end of each quarter

1 of each fiscal year for which fees are collected under  
2 this part”;

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

5 “(v) For fiscal years 2023 and 2024,  
6 of the meeting requests from sponsors for  
7 which the Secretary has determined that a  
8 face-to-face meeting is appropriate, the  
9 number of face-to-face meetings requested  
10 by sponsors to be conducted in person (in  
11 such manner as the Secretary shall pre-  
12 scribe on the internet website of the Food  
13 and Drug Administration), and the num-  
14 ber of such in-person meetings granted by  
15 the Secretary.”;

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

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

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

22 (8) in subsection (f)—

23 (A) in paragraph (1), in the matter pre-  
24 ceding subparagraph (A), by striking “fiscal

1           year 2022” and inserting “fiscal year 2027”;  
2           and

3                   (B) in paragraph (5), by striking “January  
4           15, 2022” and inserting “January 15, 2027”.

5 **SEC. 105. SUNSET DATES.**

6           (a) **AUTHORIZATION.**—Sections 735 and 736 of the  
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;  
8 379h) shall cease to be effective October 1, 2027.

9           (b) **REPORTING REQUIREMENTS.**—Section 736B of  
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 379h–2) shall cease to be effective January 31, 2028.

12           (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-  
13 ber 1, 2022, subsections (a) and (b) of section 104 of the  
14 FDA Reauthorization Act of 2017 (Public Law 115–52)  
15 are repealed.

16 **SEC. 106. EFFECTIVE DATE.**

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

1 **SEC. 107. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,  
3 part 2 of subchapter C of chapter VII of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 379g 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 human  
7 drug applications and supplements (as defined in such  
8 part as of such day) that on or after October 1, 2017,  
9 but before October 1, 2022, were accepted by the Food  
10 and Drug Administration for filing with respect to assess-  
11 ing and collecting any fee required by such part for a fiscal  
12 year prior to fiscal year 2023.

13 **TITLE II—FEES RELATING TO**  
14 **DEVICES**

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

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

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



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

5 **SEC. 202. DEFINITIONS.**

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

8 (1) in paragraph (9)—

9 (A) in the matter preceding subparagraph  
10 (A), by striking “and premarket notification  
11 submissions” and inserting “premarket notifica-  
12 tion submissions, and de novo classification re-  
13 quests”;

14 (B) in subparagraph (D), by striking “and  
15 submissions” and inserting “submissions, and  
16 requests”;

17 (C) in subparagraph (F), by striking “and  
18 premarket notification submissions” and insert-  
19 ing “premarket notification submissions, and de  
20 novo classification requests”;

21 (D) in each of subparagraphs (G) and (H),  
22 by striking “or submissions” and inserting  
23 “submissions, or requests”; and

24 (E) in subparagraph (K), by striking “or  
25 premarket notification submissions” and insert-

1           ing “premarket notification submissions, or de  
2           novo classification requests”; and  
3           (2) in paragraph (11), by striking “2016” and  
4           inserting “2021”.

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

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

9           (1) in paragraph (1), by striking “fiscal year  
10          2018” and inserting “fiscal year 2023”; and

11          (2) in paragraph (2)—

12           (A) in subparagraph (A)—

13           (i) in the matter preceding clause (i),  
14           by striking “October 1, 2017” and insert-  
15           ing “October 1, 2022”;

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

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

20           (B) in subparagraph (B)(iii), by striking  
21           “or premarket notification submission” and in-  
22           serting “premarket notification submission, or  
23           de novo classification request”; and

24           (C) in subparagraph (C), by striking “or  
25           periodic reporting concerning a class III device”

1 and inserting “periodic reporting concerning a  
 2 class III device, or de novo classification re-  
 3 quest”.

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

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

9 (2) by amending paragraph (2) to read as fol-  
 10 lows:

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

| “Fee Type                        | Fiscal<br>Year<br>2023 | Fiscal<br>Year<br>2024 | Fiscal<br>Year<br>2025 | Fiscal<br>Year<br>2026 | Fiscal<br>Year<br>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                    |

14 (3) by amending paragraph (3) to read as fol-  
 15 lows:

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

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

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

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

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

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

1 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section  
2 738(c) of the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 379j(c)) is amended—

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

6 (2) in paragraph (2)—

7 (A) in subparagraph (A), by striking  
8 “2018” and inserting “2023”;

9 (B) in subparagraph (B)—

10 (i) in the matter preceding clause (i),  
11 by striking “fiscal year 2018” and insert-  
12 ing “fiscal year 2023”; and

13 (ii) in clause (ii), by striking “fiscal  
14 year 2016” and inserting “fiscal year  
15 2022”;

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

20 (D) in subparagraph (D), in the matter  
21 preceding clause (i), by striking “fiscal years  
22 2018 through 2022” and inserting “fiscal years  
23 2023 through 2027”;

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

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

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

5           “(4) PERFORMANCE IMPROVEMENT ADJUST-  
6 MENT.—

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

20           “(i) For fiscal year 2025, the product  
21 of—

22           “(I) the amount determined  
23 under subparagraph (B)(i)(I); and

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

4 “(ii) For fiscal year 2026, the product  
5 of—

6 “(I) the sum of the amounts de-  
7 termined under subparagraphs  
8 (B)(i)(II), (B)(ii)(I), and (B)(iii)(I);  
9 and

10 “(II) the applicable inflation ad-  
11 justment under paragraph (2)(B) for  
12 such fiscal year.

13 “(iii) For fiscal year 2027, the prod-  
14 uct of—

15 “(I) the sum of the amounts de-  
16 termined under subparagraphs  
17 (B)(i)(III), (B)(ii)(II), and  
18 (B)(iii)(II); and

19 “(II) the applicable inflation ad-  
20 justment under paragraph (2)(B) for  
21 such fiscal year.

22 “(B) AMOUNTS.—

23 “(i) PRE-SUBMISSION AMOUNT.—For  
24 purposes of subparagraph (A), with respect  
25 to the pre-submission written feedback

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

3 “(I) For fiscal year 2025,  
4 \$15,396,600 if such goal for fiscal  
5 year 2023 is met.

6 “(II) For fiscal year 2026:

7 “(aa) \$15,396,600 if such  
8 goal for fiscal year 2023 is met  
9 and such goal for fiscal year  
10 2024 is not met.

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

13 “(III) For fiscal year 2027:

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

18 “(bb) \$36,792,200 if such  
19 goal for fiscal year 2024 is met  
20 and such goal for fiscal year  
21 2025 is not met.

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

24 “(ii) DE NOVO CLASSIFICATION  
25 AMOUNT.—For purposes of subparagraph

1 (A), with respect to the de novo decision  
2 goal, the amounts determined under this  
3 subparagraph are as follows:

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

7 “(II) For fiscal year 2027:

8 “(aa) \$6,323,500 if such  
9 goal for fiscal year 2023 is met  
10 and such goal for fiscal year  
11 2024 is not met.

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

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

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



1 “(II) For fiscal year 2027:

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

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

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

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

19 “(I) for fiscal year 2023, March  
20 31, 2024;

21 “(II) for fiscal year 2024, March  
22 31, 2025; and

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

1           “(ii) The performance of the de novo  
2           decision goal, 510(k) decision goal, 510(k)  
3           shared outcome total time to decision goal,  
4           PMA decision goal, and PMA shared out-  
5           come total time to decision goal shall be  
6           based on data available as of—

7                       “(I) for fiscal year 2023, March  
8                       31, 2025; and

9                       “(II) for fiscal year 2024, March  
10                      31, 2026.

11           “(D) GOALS DEFINED.—For purposes of  
12           this paragraph, the terms ‘pre-submission writ-  
13           ten feedback goal’, ‘de novo decision goal’,  
14           ‘510(k) decision goal’, ‘510(k) shared outcome  
15           total time to decision goal’, ‘PMA decision  
16           goal’, and ‘PMA shared outcome total time to  
17           decision goal’ refer to the goals identified by the  
18           same names in the letters described in section  
19           201(b) of the Medical Device User Fee Amend-  
20           ments of 2022.

21           “(5) HIRING ADJUSTMENT.—

22                       “(A) IN GENERAL.—For each of fiscal  
23           years 2025 through 2027, after the adjust-  
24           ments under paragraphs (2), (3), and (4), if ap-  
25           plicable, if the number of hires to support the

1 process for the review of device applications  
2 falls below the thresholds specified in subpara-  
3 graph (B) for the applicable fiscal years, the  
4 base establishment registration fee amounts  
5 shall be decreased as the Secretary determines  
6 necessary to achieve a reduction in total fee col-  
7 lections equal to the hiring adjustment amount  
8 under subparagraph (C).

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

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

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

15 “(iii) For fiscal year 2027, the thresh-  
16 old is—

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

22 “(II) 75 hires for fiscal year  
23 2025 if such fees are so increased.

24 “(C) HIRING ADJUSTMENT AMOUNT.—The  
25 hiring adjustment amount for fiscal year 2025

1 and each subsequent fiscal year is the product  
2 of—

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

7 “(ii) \$72,877; and

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

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

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

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

16 “(iii) For fiscal year 2025:

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

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

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

6           “(6) OPERATING RESERVE ADJUSTMENT.—

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

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

22                   “(i) 13 weeks of operating reserves of  
23 carryover user fees; and

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

1           “(C) EXCLUDED AMOUNT.—For the period  
2           of fiscal years 2023 through 2026, a total  
3           amount equal to \$118,000,000 shall not be con-  
4           sidered part of the designated amount under  
5           subparagraph (B) and shall not be subject to  
6           the decrease under subparagraph (A).”.

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

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

15                 (1) in paragraph (1)(A), by striking  
16                 “\$320,825,000” and inserting “\$398,566,000”; and

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

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

22                 “(3) AUTHORIZATION OF APPROPRIATIONS.—

23                         “(A) IN GENERAL.—For each of fiscal  
24                         years 2023 through 2027, there is authorized to  
25                         be appropriated for fees under this section an

1 amount equal to the revenue amount deter-  
2 mined under subparagraph (B), less the  
3 amount of reductions determined under sub-  
4 paragraph (C).

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

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

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

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

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

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

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

2 (a) PERFORMANCE REPORTS.—Section 738A(a) of  
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4 379j–1(a)) is amended—

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

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

11 (3) in paragraph (1)—

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

15 (B) in subparagraph (A)(iv), by striking  
16 “fiscal year 2020” and inserting “fiscal year  
17 2023”; and

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

20 (b) REAUTHORIZATION.—Section 738A(b) of the  
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
22 1(b)) is amended—

23 (1) in paragraph (1), by striking “2022” and  
24 inserting “2027”; and

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5           “(3) IMPLEMENTATION AND REPORTING.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 (1) in paragraph (1)—

22 (A) in subparagraph (A)—

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

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

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

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

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

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

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

22 (2) in paragraph (2)—

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

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

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

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

10 (1) in paragraph (1)—

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

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

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

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



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

3           “(2) CAPACITY PLANNING ADJUSTMENT.—

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

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

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

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

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

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

11 “(C) LIMITATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15                  “(3) OPERATING RESERVE ADJUSTMENT.—

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

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

3                   “(i) 8 weeks for fiscal year 2024;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17              (7) in subsection (f)—

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 **SEC. 402. DEFINITIONS.**

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

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

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

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

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

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

3 (a) TYPES OF FEEES.—

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

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

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

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

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

3 (B) in clause (iii)—

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

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

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

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

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

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

23 “(D) REACTIVATION FEE.—

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

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

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

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

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

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

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

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

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

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



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

3 (A) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24           (1) by striking paragraph (1);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)—

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

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

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

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

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

24 “(3) CAPACITY PLANNING ADJUSTMENT.—

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

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

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

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

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

25           “(4) OPERATING RESERVE ADJUSTMENT.—



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

10           “(B) DECREASE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18           (7) in subsection (f)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1           “(ii) the sponsor’s rationale for such goals; and  
2           “(iii) an explanation of how the sponsor intends  
3           to meet such goals.

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

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 new drug.

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

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

19          “(9)(A)(i) In order for a device in a clinical study  
20          for which submission of an application for an investiga-  
21          tional device exemption is required to be exempt under this  
22          subsection, the sponsor of such study shall submit to the  
23          Secretary in such application a diversity action plan in the  
24          form and manner specified in the guidance required by  
25          section 524B.

1       “(ii) In order for a device in a clinical study for which  
2 submission of an application for an investigational device  
3 exemption is not required, except for a device being stud-  
4 ied as described in section 812.2(c) of title 21, Code of  
5 Federal Regulations (or successor regulations), to be ex-  
6 empt under this subsection, the sponsor of such study  
7 shall develop and implement a diversity action plan. Such  
8 diversity action plan shall be submitted to the Secretary  
9 in any premarket notification under section 510(k), re-  
10 quest for classification under section 513(f)(2), or applica-  
11 tion for premarket approval under section 515 for such  
12 device.

13       “(B) A diversity action plan under clause (i) or (ii)  
14 of subparagraph (A) shall include—

15               “(i) the sponsor’s goals for enrollment in the  
16 clinical study;

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

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

20       “(C) The Secretary may waive the requirement in  
21 subparagraph (A) or (B) if the Secretary determines that  
22 a waiver is necessary based on what is known about the  
23 prevalence of the disease in terms of the patient popu-  
24 lation that may use the device.



1 “(D) No diversity action plan shall be required for  
2 a submission described in section 561.”.

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

6 **“SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR**  
7 **CLINICAL STUDIES.**

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

10 “(1) the format and content of the diversity ac-  
11 tion plans required by sections 505(i)(5) and  
12 520(g)(9) pertaining to the sponsor’s goals for clin-  
13 ical study enrollment, disaggregated by age group,  
14 sex, race, geographic location, socioeconomic status,  
15 and ethnicity, including with respect to—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 (a) IN GENERAL.—Not later than 2 years after the  
19 date of publication of final guidance pursuant to section  
20 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act,  
21 as added by section 501(c) of this Act, the Secretary of  
22 Health and Human Services shall commence an evaluation  
23 to assess whether additions or changes to statutes or regu-  
24 lations are warranted to ensure that sponsors conduct  
25 post-approval studies or postmarket surveillance where—



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

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

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

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

19                   (A) the establishment of inclusion and ex-  
20 clusion criteria for certain subgroups, such as  
21 pregnant and lactating women and individuals  
22 with disabilities, including intellectual or devel-  
23 opmental disabilities or mental illness;

24                   (B) considerations regarding informed con-  
25 sent with respect to individuals with intellectual

1 or developmental disabilities or mental illness,  
2 including ethical and scientific considerations;

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

5 (D) clinical endpoints;

6 (E) biomarker selection; and

7 (F) studying analysis.

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

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

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

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

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

14 (2) contains information on—

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



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

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

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

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

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

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

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

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

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

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

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

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

19          **SEC. 506. DECENTRALIZED CLINICAL STUDIES.**

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

22                 (1) not later than 12 months after the date of  
23                 enactment of this Act, issue draft guidance that ad-  
24                 dresses considerations for decentralized clinical stud-  
25                 ies, including considerations regarding the engage-

1       ment, enrollment, and retention of a meaningfully  
2       diverse clinical population, with respect to race, eth-  
3       nicity, age, sex, and geographic location, when ap-  
4       propriate; and

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

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

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

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

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

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

## 8           **TITLE VI—GENERIC DRUG** 9           **COMPETITION**

### 10       **SEC. 601. INCREASING TRANSPARENCY IN GENERIC DRUG** 11       **APPLICATIONS.**

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

15           “(H)(i) Upon request (in controlled correspondence  
16           or otherwise) by a person that has submitted or intends  
17           to submit an abbreviated application for a new drug under  
18           this subsection for which the Secretary has specified in  
19           regulation, including in section 314.94(a)(9) of title 21,  
20           Code of Federal Regulations (or any successor regula-  
21           tions), or recommended in applicable guidance, certain  
22           qualitative or quantitative criteria with respect to an inac-  
23           tive ingredient, or on the Secretary’s own initiative during  
24           the review of such abbreviated application, the Secretary

1 shall inform the person whether such new drug is quali-  
2 tatively and quantitatively the same as the listed drug.

3 “(ii) Notwithstanding section 301(j), if the Secretary  
4 determines that such new drug is not qualitatively or  
5 quantitatively the same as the listed drug, the Secretary  
6 shall identify and disclose to the person—

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

10 “(II) for any ingredient for which there is an  
11 identified quantitative deviation, the amount of such  
12 deviation.

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

18 “(I) the formulation of the listed drug has been  
19 changed and the Secretary has determined that the  
20 prior listed drug formulation was withdrawn for rea-  
21 sons of safety or effectiveness; or

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

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

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

8       (b) GUIDANCE.—

9           (1) IN GENERAL.—Not later than 1 year after  
10 the date of enactment of this Act, the Secretary of  
11 Health and Human Services shall issue draft guid-  
12 ance, or update guidance, describing how the Sec-  
13 retary will determine whether a new drug is quali-  
14 tatively and quantitatively the same as the listed  
15 drug (as such terms are used in section  
16 505(j)(3)(H) of the Federal Food, Drug, and Cos-  
17 metic Act, as added by subsection (a)), including  
18 with respect to assessing pH adjusters.

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

22                   (A) publish draft guidance;

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

1           (C) after considering any comments re-  
2           ceived, and not later than one year after the  
3           close of the comment period on the draft guid-  
4           ance, publish final guidance.

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

10 **SEC. 602. ENHANCING ACCESS TO AFFORDABLE MEDI-**  
11 **CINES.**

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

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

20           “(ii) the sponsor of the application agrees to  
21           submit revised labeling for the drug that is the sub-  
22           ject of the application not later than 60 days after  
23           approval under this subsection of the application;



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

4       **TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN**  
5           **IMPROVEMENTS**

6           **Subtitle A—In General**

7       **SEC. 701. ANIMAL TESTING ALTERNATIVES.**

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

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

12           (2) in subsection (i)—

13           (A) in paragraph (1)(A), by striking “pre-  
14           clinical tests (including tests on animals)” and  
15           inserting “nonclinical tests”; and  
16           (B) in paragraph (2)(B), by striking “ani-  
17           mal” and inserting “nonclinical tests”; and

18           (3) after subsection (y), by inserting the fol-  
19           lowing:

20           “(z) NONCLINICAL TEST DEFINED.—For purposes  
21           of this section, the term ‘nonclinical test’ means a test con-  
22           ducted in vitro, in silico, or in chemico, or a nonhuman  
23           in vivo test, that occurs before or during the clinical trial  
24

1 phase of the investigation of the safety and effectiveness  
2 of a drug. Such test may include the following:

3 “(1) Cell-based assays.

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

6 “(3) Computer modeling.

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

9 “(5) Animal tests.”.

10 **SEC. 702. EMERGING TECHNOLOGY PROGRAM.**

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

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

16 “(a) PROGRAM ESTABLISHMENT.—

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

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

23 “(A) facilitate and increase communication  
24 between public and private entities, consortia,

1 and individuals with respect to innovative drug  
2 product design and manufacturing;

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

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

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

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

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

22 “(G) convene or participate in working  
23 groups to support the harmonization of inter-  
24 national regulatory requirements related to in-

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

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

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

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

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

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

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

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

22                 “(1) issue or update guidance to help facilitate  
23                 the adoption of, and advance the development of, in-  
24                 novative approaches to drug product design and  
25                 manufacturing; and

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

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

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

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

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

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

23 “(3) the number of public meetings held or par-  
24 ticipated in by the Food and Drug Administration  
25 pursuant to this section, including meetings con-

1 vened as part of a working group described in sub-  
2 paragraph (D) or (G) of subsection (a)(2), and the  
3 topics of each such meeting; and

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

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

12 **SEC. 703. IMPROVING THE TREATMENT OF RARE DISEASES**  
13 **AND CONDITIONS.**

14 (a) REPORT ON ORPHAN DRUG PROGRAM.—

15 (1) IN GENERAL.—Not later than September  
16 30, 2026, the Secretary shall submit to the Com-  
17 mittee on Energy and Commerce of the House of  
18 Representatives and the Committee on Health, Edu-  
19 cation, Labor, and Pensions of the Senate a report  
20 summarizing the activities of the Food and Drug  
21 Administration related to designating drugs under  
22 section 526 of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 360bb) for a rare disease or  
24 condition and approving such drugs under section  
25 505 of such Act (21 U.S.C. 355) or licensing such

1 drugs under section 351 of the Public Health Serv-  
2 ice Act (42 U.S.C. 262), including—

3 (A) the number of applications for such  
4 drugs under section 505 of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 355) or  
6 section 351 of the Public Health Service Act  
7 (42 U.S.C. 262) received by the Food and Drug  
8 Administration, the number of such applica-  
9 tions accepted and rejected for filing, and the  
10 number of such applications pending, approved,  
11 and disapproved by the Food and Drug Admin-  
12 istration;

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

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

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

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

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

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

14 (3) INFORMATION DISCLOSURE.—Nothing in  
15 this subsection shall be construed to authorize the  
16 disclosure of information that is prohibited from dis-  
17 closure under section 1905 of title 18, United States  
18 Code, or subject to withholding under paragraph (4)  
19 of section 552(b) of title 5, United States Code  
20 (commonly referred to as the “Freedom of Informa-  
21 tion Act”).

22 (b) STUDY ON EUROPEAN UNION SAFETY AND EFFI-  
23 CACY REVIEWS OF DRUGS FOR RARE DISEASES AND CON-  
24 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 entering into such contract—

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–  
25 8(a)(2)) 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) related to applications  
13 for rare diseases or conditions;

14 (B) examine tools or mechanisms to im-  
15 prove efforts and initiatives of the Food and  
16 Drug Administration to collect and consider  
17 such external expertise with respect to applica-  
18 tions for rare diseases or conditions throughout  
19 the application review and approval or licensure  
20 processes, including within internal benefit-risk  
21 assessments, advisory committee processes, and  
22 postapproval safety monitoring; and

23 (C) examine processes or alternatives to  
24 address or resolve conflicts of interest that im-  
25 pede the Food and Drug Administration in

1           gaining external expert input on rare diseases  
2           or conditions with a limited set of clinical and  
3           research experts.

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

7                   (A) complete the study under paragraph  
8                   (1);

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

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

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

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

23           (a) DRAFT GUIDANCE.—Not later than 3 years after  
24           the date of the enactment of this Act, the Secretary of  
25           Health and Human Services, acting through the Commis-

1 sioner of Food and Drugs, shall issue draft guidance for  
2 industry for the purposes of assisting entities seeking ap-  
3 proval under section 505 of the Federal Food, Drug, and  
4 Cosmetic Act (21 U.S.C. 355) or licensure under section  
5 351 of the Public Health Service Act (42 U.S.C. 262) of  
6 antifungal therapies designed to treat coccidioidomycosis  
7 (commonly known as Valley Fever).

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

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

18 **SEC. 705. ADVANCING QUALIFIED INFECTIOUS DISEASE**

19 **PRODUCT INNOVATION.**

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

23 (1) in subsection (c)—

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



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

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

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

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

9 (3) by amending subsection (g) to read as fol-  
10 lows:

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

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

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

20 “(A) an antibacterial or antifungal resist-  
21 ant pathogen, including novel or emerging in-  
22 fectious pathogens; or

23 “(B) qualifying pathogens listed by the  
24 Secretary under subsection (f).”.

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

7 **SEC. 706. NATIONAL CENTERS OF EXCELLENCE IN AD-**  
8 **VANCED AND CONTINUOUS PHARMA-**  
9 **CEUTICAL MANUFACTURING.**

10 (a) IN GENERAL.—Section 3016 of the 21st Century  
11 Cures Act (21 U.S.C. 399h) is amended to read as follows:

12 **“SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN AD-**  
13 **VANCED AND CONTINUOUS PHARMA-**  
14 **CEUTICAL MANUFACTURING.**

15 “(a) IN GENERAL.—The Secretary of Health and  
16 Human Services, acting through the Commissioner of  
17 Food and Drugs—

18 “(1) shall solicit and, beginning not later than  
19 one year after the date of enactment of the Prescrip-  
20 tion Drug User Fee Amendments of 2022, receive  
21 requests from institutions of higher education, or  
22 consortia of institutions of higher education, to be  
23 designated as a National Center of Excellence in Ad-  
24 vanced and Continuous Pharmaceutical Manufac-  
25 turing (in this section referred to as a ‘National

1 Center of Excellence’) to support the advancement,  
2 development, and implementation of advanced and  
3 continuous pharmaceutical manufacturing; and

4 “(2) shall so designate not more than 5 institu-  
5 tions of higher education or consortia of such insti-  
6 tutions that—

7 “(A) request such designation; and

8 “(B) meet the criteria specified in sub-  
9 section (c).

10 “(b) REQUEST FOR DESIGNATION.—A request for  
11 designation under subsection (a) shall be made to the Sec-  
12 retary at such time, in such manner, and containing such  
13 information as the Secretary may require. Any such re-  
14 quest shall include a description of how the institution of  
15 higher education, or consortium of institutions of higher  
16 education, meets or plans to meet each of the criteria spec-  
17 ified in subsection (c).

18 “(c) CRITERIA FOR DESIGNATION DESCRIBED.—The  
19 criteria specified in this subsection with respect to an in-  
20 stitution of higher education, or consortium of institutions  
21 of higher education, are that the institution or consortium  
22 has, as of the date of the submission of a request under  
23 subsection (a) by such institution or consortium—

24 “(1) physical and technical capacity for re-  
25 search, development, implementation, and dem-

1 onstration of advanced and continuous pharma-  
2 ceutical manufacturing;

3 “(2) manufacturing knowledge-sharing net-  
4 works with other institutions of higher education,  
5 large and small pharmaceutical manufacturers, ge-  
6 neric and nonprescription manufacturers, contract  
7 manufacturers, and other relevant entities;

8 “(3) proven capacity to design, develop, imple-  
9 ment, and demonstrate new, highly effective tech-  
10 nologies for use in advanced and continuous phar-  
11 maceutical manufacturing;

12 “(4) a track record for creating, preserving,  
13 and transferring knowledge with respect to advanced  
14 and continuous pharmaceutical manufacturing;

15 “(5) the proven ability to facilitate training of  
16 an adequate future workforce for research on, and  
17 implementation of, advanced and continuous phar-  
18 maceutical manufacturing; and

19 “(6) experience in participating in and leading  
20 advanced and continuous pharmaceutical manufac-  
21 turing technology partnerships with other institu-  
22 tions of higher education, large and small pharma-  
23 ceutical manufacturers, generic and nonprescription  
24 manufacturers, contract manufacturers, and other  
25 relevant entities—

1           “(A) to support companies seeking to im-  
2           plement advanced and continuous pharma-  
3           ceutical manufacturing in the United States;

4           “(B) to support Federal agencies with  
5           technical assistance and employee training,  
6           which may include regulatory and quality met-  
7           ric guidance as applicable, and hands-on train-  
8           ing, for advanced and continuous pharma-  
9           ceutical manufacturing;

10           “(C) with respect to advanced and contin-  
11           uous pharmaceutical manufacturing, to orga-  
12           nize and conduct research and development ac-  
13           tivities needed to create new and more effective  
14           technology, develop and share knowledge, create  
15           intellectual property, and maintain technological  
16           leadership;

17           “(D) to develop best practices for design-  
18           ing and implementing advanced and continuous  
19           pharmaceutical manufacturing processes; and

20           “(E) to assess and respond to the national  
21           workforce needs for advanced and continuous  
22           pharmaceutical manufacturing, including the  
23           development and implementing of training pro-  
24           grams.

1       “(d) TERMINATION OF DESIGNATION.—The Sec-  
2 retary may terminate the designation of any National Cen-  
3 ter of Excellence designated under this section if the Sec-  
4 retary determines such National Center of Excellence no  
5 longer meets the criteria specified in subsection (c). Not  
6 later than 90 days before the effective date of such a ter-  
7 mination, the Secretary shall provide written notice to the  
8 National Center of Excellence, including the rationale for  
9 such termination.

10       “(e) CONDITIONS FOR DESIGNATION.—As a condi-  
11 tion of designation as a National Center of Excellence  
12 under this section, the Secretary shall require that an in-  
13 stitution of higher education or consortium of institutions  
14 of higher education enter into an agreement with the Sec-  
15 retary under which the institution or consortium agrees—

16               “(1) to collaborate directly with the Food and  
17 Drug Administration to publish the reports required  
18 by subsection (g);

19               “(2) to share data with the Food and Drug Ad-  
20 ministration regarding best practices and research  
21 generated through the funding under subsection (f);

22               “(3) to develop, along with industry partners  
23 (which may include large and small biopharma-  
24 ceutical manufacturers, generic and nonprescription  
25 manufacturers, and contract research organizations

1 or contract manufacturers that carry out drug devel-  
2 opment and manufacturing activities) and another  
3 institution or consortium designated under this sec-  
4 tion, if any, a roadmap for developing an advanced  
5 and continuous pharmaceutical manufacturing work-  
6 force;

7 “(4) to develop, along with industry partners  
8 and other institutions or consortia of such institu-  
9 tions designated under this section, a roadmap for  
10 strengthening existing, and developing new, relation-  
11 ships with other institutions of higher education or  
12 consortia thereof; and

13 “(5) to provide an annual report to the Food  
14 and Drug Administration regarding the institution’s  
15 or consortium’s activities under this section, includ-  
16 ing a description of how the institution or consor-  
17 tium continues to meet and make progress on the  
18 criteria specified in subsection (c).

19 “(f) FUNDING.—

20 “(1) IN GENERAL.—The Secretary shall award  
21 funding, through grants, contracts, or cooperative  
22 agreements, to the National Centers of Excellence  
23 designated under this section for the purpose of  
24 studying and recommending improvements to ad-  
25 vanced and continuous pharmaceutical manufac-

1 turing, including such improvements as may enable  
2 the Centers—

3 “(A) to continue to meet the conditions  
4 specified in subsection (e);

5 “(B) to expand capacity for research on,  
6 and development of, advanced and continuous  
7 pharmaceutical manufacturing; and

8 “(C) to implement research infrastructure  
9 in advanced and continuous pharmaceutical  
10 manufacturing suitable for accelerating the de-  
11 velopment of drug products needed to respond  
12 to emerging medical threats, such as emerging  
13 drug shortages, quality issues disrupting the  
14 supply chain, epidemics and pandemics, and  
15 other such situations requiring the rapid devel-  
16 opment of new products or new manufacturing  
17 processes.

18 “(2) CONSISTENCY WITH FDA MISSION.—As a  
19 condition on receipt of funding under this sub-  
20 section, a National Center of Excellence shall agree  
21 to consider any input from the Secretary regarding  
22 the use of funding that would—

23 “(A) help to further the advancement of  
24 advanced and continuous pharmaceutical manu-



1 facturing through the National Center of Excel-  
2 lence; and

3 “(B) be relevant to the mission of the  
4 Food and Drug Administration.

5 “(3) RULE OF CONSTRUCTION.—Nothing in  
6 this section shall be construed as precluding a Na-  
7 tional Center for Excellence designated under this  
8 section from receiving funds under any other provi-  
9 sion of this Act or any other Federal law.

10 “(g) ANNUAL REVIEW AND REPORTS.—

11 “(1) ANNUAL REPORT.—Beginning not later  
12 than one year after the date on which the first des-  
13 ignation is made under subsection (a), and annually  
14 thereafter, the Secretary shall—

15 “(A) submit to Congress a report describ-  
16 ing the activities, partnerships and collabora-  
17 tions, Federal policy recommendations, previous  
18 and continuing funding, and findings of, and  
19 any other applicable information from, the Na-  
20 tional Centers of Excellence designated under  
21 this section;

22 “(B) include in such report an accounting  
23 of the Federal administrative expenses de-  
24 scribed in subsection (i)(2) over the reporting  
25 period; and

1           “(C) make such report available to the  
2           public in an easily accessible electronic format  
3           on the website of the Food and Drug Adminis-  
4           tration.

5           “(2) REVIEW OF NATIONAL CENTERS OF EX-  
6           CELLENCE AND POTENTIAL DESIGNEES.—The Sec-  
7           retary shall periodically review the National Centers  
8           of Excellence designated under this section to ensure  
9           that such National Centers of Excellence continue to  
10          meet the criteria for designation under this section.

11          “(3) REPORT ON LONG-TERM VISION OF FDA  
12          ROLE.—Not later than 2 years after the date on  
13          which the first designation is made under subsection  
14          (a), the Secretary, in consultation with the National  
15          Centers of Excellence designated under this section,  
16          shall submit a report to the Congress on the long-  
17          term vision of the Department of Health and  
18          Human Services on the role of the Food and Drug  
19          Administration in supporting advanced and contin-  
20          uous pharmaceutical manufacturing, including—

21                 “(A) a national framework of principles re-  
22                 lated to the implementation and regulation of  
23                 advanced and continuous pharmaceutical manu-  
24                 facturing;

1           “(B) a plan for the development of Federal  
2 regulations and guidance for how advanced and  
3 continuous pharmaceutical manufacturing can  
4 be incorporated into the development of phar-  
5 maceuticals and regulatory responsibilities of  
6 the Food and Drug Administration;

7           “(C) a plan for development of Federal  
8 regulations or guidance for how advanced and  
9 continuous pharmaceutical manufacturing will  
10 be reviewed by the Food and Drug Administra-  
11 tion; and

12           “(D) appropriate feedback solicited from  
13 the public, which may include other institutions  
14 of higher education, large and small biopharma-  
15 ceutical manufacturers, generic and non-  
16 prescription manufacturers, and contract manu-  
17 facturers.

18           “(h) DEFINITIONS.—In this section:

19           “(1) ADVANCED.—The term ‘advanced’, with  
20 respect to pharmaceutical manufacturing, refers to  
21 an approach that incorporates novel technology, or  
22 uses an established technique or technology in a new  
23 or innovative way, that enhances drug quality or im-  
24 proves the performance of a manufacturing process.

1           “(2) CONTINUOUS.—The term ‘continuous’,  
2 with respect to pharmaceutical manufacturing, re-  
3 fers to a process—

4           “(A) where the input materials are con-  
5 tinuously fed into and transformed within the  
6 process, and the processed output materials are  
7 continuously removed from the system; and

8           “(B) that consists of an integrated process  
9 that consists of a series of two or more simulta-  
10 neous unit operations.

11           “(3) INSTITUTION OF HIGHER EDUCATION.—  
12 The term ‘institution of higher education’ has the  
13 meaning given such term in section 101(a) of the  
14 Higher Education Act of 1965 (20 U.S.C. 1001(a)).

15           “(4) SECRETARY.—The term ‘Secretary’ means  
16 the Secretary of Health and Human Services, acting  
17 through the Commissioner of Food and Drugs.

18           “(i) AUTHORIZATION OF APPROPRIATIONS.—

19           “(1) IN GENERAL.—There is authorized to be  
20 appropriated to carry out this section \$100,000,000  
21 for the period of fiscal years 2023 through 2027.

22           “(2) FEDERAL ADMINISTRATIVE EXPENSES.—  
23 Of the amounts made available to carry out this sec-  
24 tion for a fiscal year, the Secretary shall not use  
25 more than eight percent for Federal administrative

1 expenses, including training, technical assistance, re-  
2 porting, and evaluation.”.

3 (b) **TRANSITION RULE.**—Section 3016 of the 21st  
4 Century Cures Act (21 U.S.C. 399h), as in effect on the  
5 day before the date of the enactment of this section, shall  
6 apply with respect to grants awarded under such section  
7 before such date of enactment.

8 (c) **CLERICAL AMENDMENT.**—The item relating to  
9 section 3016 in the table of contents in section 1(b) of  
10 the 21st Century Cures Act (Public Law 114–255) is  
11 amended to read as follows:

“Sec. 3016. National Centers of Excellence in Advanced and Continuous Phar-  
maceutical Manufacturing.”.

12 **SEC. 707. ADVANCED MANUFACTURING TECHNOLOGIES**  
13 **DESIGNATION PILOT PROGRAM.**

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

18 **“SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES**  
19 **DESIGNATION PILOT PROGRAM.**

20 “(a) **IN GENERAL.**—Not later than 1 year after the  
21 date of enactment of this section, the Secretary shall ini-  
22 tiate a pilot program under which persons may request  
23 designation of an advanced manufacturing technology as  
24 described in subsection (b).

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

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

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

17                           “(A) a drug that is described in section  
18                   506C(a) and is intended to treat a serious or  
19                   life-threatening condition; or

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

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

24                   “(1) SUBMISSION.—A person who requests des-  
25           ignation of a method of manufacturing as an ad-

1 vanced manufacturing technology under this section  
2 shall submit to the Secretary data or information  
3 demonstrating that the method of manufacturing  
4 meets the criteria described in subsection (b) in a  
5 particular context of use. The Secretary may facili-  
6 tate the development and review of such data or in-  
7 formation by—

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

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

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

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

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

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



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

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

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

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

16       “(2) PILOT PROGRAM GUIDANCE.—

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

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

23           “(ii) not later than 2 years after the  
24 date of enactment of this section, issue

1 final guidance regarding the implementa-  
2 tion of such program.

3 “(B) CONTENT.—The guidance described  
4 in subparagraph (A) shall address—

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

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

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

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

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

1 a report containing a description and evaluation of  
2 the pilot program being conducted under this sec-  
3 tion, including the types of innovative manufacturing  
4 approaches supported under the program. Such re-  
5 port shall include the following:

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

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

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

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

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

1           under this section, and the number of such ap-  
2           plications approved.

3           “(f) SUNSET.—The Secretary—

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

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

13   **SEC. 708. PUBLIC WORKSHOP ON CELL THERAPIES.**

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

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

3 **SEC. 709. REAUTHORIZATION OF BEST PHARMACEUTICALS**  
4 **FOR CHILDREN.**

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

8 **SEC. 710. REAUTHORIZATION FOR HUMANITARIAN DEVICE**  
9 **EXEMPTION AND DEMONSTRATION GRANTS**  
10 **FOR IMPROVING PEDIATRIC AVAILABILITY.**

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

15 (b) PEDIATRIC MEDICAL DEVICE SAFETY AND IM-  
16 PROVEMENT ACT.—Section 305(e) of the Pediatric Med-  
17 ical Device Safety and Improvement Act of 2007 (Public  
18 Law 110–85) is amended by striking “2018 through  
19 2022” and inserting “2023 through 2027”.

20 **SEC. 711. REAUTHORIZATION OF PROVISION RELATED TO**  
21 **EXCLUSIVITY OF CERTAIN DRUGS CON-**  
22 **TAINING SINGLE ENANTIOMERS.**

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

1 **SEC. 712. 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. 713. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

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

11 (1) in subsection (a)—

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

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

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

22 **SEC. 714. RESEARCH INTO PEDIATRIC USES OF DRUGS; AD-**  
23 **DITIONAL AUTHORITIES OF FOOD AND DRUG**  
24 **ADMINISTRATION REGARDING MOLECU-**  
25 **LARLY TARGETED CANCER DRUGS.**

26 (a) IN GENERAL.—

1           (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-  
2           PLICATION DRUG; LIMITATION REGARDING NOVEL-  
3           COMBINATION       APPLICATION       DRUG.—Section  
4           505B(a)(3) of the Federal Food, Drug, and Cos-  
5           metic Act (21 U.S.C. 355c(a)(3)) is amended—

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

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

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

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

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

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

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

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

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

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

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

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

22 “(B) ADDITIONAL REQUIREMENTS.—

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



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

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

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

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

21 “(iii) RESULTS OF ALREADY-COM-  
22 PLETED PRECLINICAL STUDIES OF APPLI-  
23 CATION DRUG.—The Secretary may re-  
24 quire that reports on an investigation re-  
25 quired pursuant to paragraph (1)(B) in-

1           clude the results of all preclinical studies  
2           on which the decision to conduct such in-  
3           vestigation was based.

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

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

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

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

1           subparagraph (B) shall be subject to the re-  
2           quirements of subparagraph (A), and no appli-  
3           cation (or supplement to an application) that is  
4           subject to the requirements of subparagraph  
5           (A) shall be subject to the requirements of sub-  
6           paragraph (B).”.

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

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

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

20           (b) GUIDANCE.—The Secretary shall—

21           (1) not later than 12 months after the date of  
22           enactment of this Act, issue draft guidance on the  
23           implementation of the requirements in subsection  
24           (a); and

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

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

11          (d) REPORTS TO CONGRESS.—

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

22           (2) GAO STUDY AND REPORT.—

23           (A) STUDY.—Not later than 3 years after  
24           the date of enactment of this Act, the Comp-  
25           troller General of the United States shall con-

1           duct a study of the effectiveness of requiring  
2           assessments and investigations described in sec-  
3           tion 505B of the Federal Food, Drug, and Cos-  
4           metic Act (21 U.S.C.355c), as amended by sub-  
5           section (a), in the development of drugs and bi-  
6           ological products for pediatric cancer indica-  
7           tions.

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

## 16           **Subtitle B—Inspections**

### 17   **SEC. 721. FACTORY INSPECTION.**

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

#### 22          (b) RECORDS OR OTHER INFORMATION.—

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

1 (A) by striking “an establishment that is  
2 engaged in the manufacture, preparation, prop-  
3 agation, compounding, or processing of a drug”  
4 and inserting “an establishment that is engaged  
5 in the manufacture, preparation, propagation,  
6 compounding, or processing of a drug or device,  
7 or that is subject to inspection under paragraph  
8 (5)(C),”; and

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

14 (2) GUIDANCE.—

15 (A) IN GENERAL.—The Secretary of  
16 Health and Human Services shall issue or up-  
17 date guidance describing—

18 (i) circumstances in which the Sec-  
19 retary intends to issue requests for records  
20 or other information in advance of, or in  
21 lieu of, an inspection under section  
22 704(a)(4) of the Federal Food, Drug, and  
23 Cosmetic Act, as amended by paragraph  
24 (1);

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

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

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

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

17 (ii) not later than 1 year after the  
18 close of the comment period for such draft  
19 guidance, issue final guidance under sub-  
20 paragraph (A).

21 (c) BIORESEARCH MONITORING INSPECTIONS.—

22 (1) IN GENERAL.—Section 704(a) of the Fed-  
23 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
24 374(a)) is amended by adding at the end the fol-  
25 lowing:

1           “(5) BIORESEARCH MONITORING INSPEC-  
2           TIONS.—

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

11          “(B) INFORMATION SUBJECT TO INSPEC-  
12          TION.—An inspection under this paragraph  
13          shall extend to all records and other informa-  
14          tion related to the studies and submissions de-  
15          scribed in subparagraph (E), including records  
16          and information related to the conduct, results,  
17          and analyses of, and the protection of human  
18          and animal trial participants participating in,  
19          such studies.

20          “(C) SITES AND FACILITIES SUBJECT TO  
21          INSPECTION.—

22          “(i) SITES AND FACILITIES DE-  
23          SCRIBED.—The sites and facilities subject  
24          to inspection by the Secretary under this  
25          paragraph are those owned or operated by



1 a person described in clause (ii) and which  
2 are (or were) utilized by such person in  
3 connection with—

4 “(I) developing an application or  
5 other submission to the Secretary  
6 under this Act or the Public Health  
7 Service Act related to marketing au-  
8 thorization for a product described in  
9 paragraph (1);

10 “(II) preparing, conducting, or  
11 analyzing the results of a study de-  
12 scribed in subparagraph (E); or

13 “(III) holding any records or  
14 other information described in sub-  
15 paragraph (B).

16 “(ii) PERSONS DESCRIBED.—A person  
17 described in this clause is—

18 “(I) the sponsor of an application  
19 or submission specified in subpara-  
20 graph (E);

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

1                   “(III) an institutional review  
2                   board, or other individual or entity,  
3                   engaged by contract, grant, or other  
4                   business arrangement with a non-  
5                   sponsor in preparing, collecting, or  
6                   analyzing records or other information  
7                   described in subparagraph (B); or

8                   “(IV) any person not otherwise  
9                   described in this clause that conducts,  
10                  or has conducted, a study described in  
11                  subparagraph (E) yielding records or  
12                  other information described in sub-  
13                  paragraph (B).

14                  “(D) CONDITIONS OF INSPECTION.—

15                  “(i) ACCESS TO INFORMATION SUB-  
16                  JECT TO INSPECTION.—Subject to clause  
17                  (ii), an entity that owns or operates any  
18                  site or facility subject to inspection under  
19                  this paragraph shall provide the Secretary  
20                  with access to records and other informa-  
21                  tion described in subparagraph (B) that is  
22                  held by or under the control of such entity,  
23                  including—

1           “(I) permitting the Secretary to  
2           record or copy such information for  
3           purposes of this paragraph;

4           “(II) providing the Secretary  
5           with access to any electronic informa-  
6           tion system utilized by such entity to  
7           hold, process, analyze, or transfer any  
8           records or other information described  
9           in subparagraph (B); and

10          “(III) permitting the Secretary  
11          to inspect the facilities, equipment,  
12          written procedures, processes, and  
13          conditions through which records or  
14          other information described in sub-  
15          paragraph (B) is or was generated,  
16          held, processed, analyzed, or trans-  
17          ferred.

18          “(ii) NO EFFECT ON APPLICABILITY  
19          OF PROVISIONS FOR PROTECTION OF PRO-  
20          PRIETARY INFORMATION OR TRADE SE-  
21          CRETS.—Nothing in clause (i) shall negate,  
22          supersede, or otherwise affect the applica-  
23          bility of provisions, under this or any other  
24          Act, preventing or limiting the disclosure  
25          of confidential commercial information or

1 other information considered proprietary or  
2 trade secret.

3 “(iii) REASONABLENESS OF INSPEC-  
4 TIONS.—An inspection under this para-  
5 graph shall be conducted at reasonable  
6 times and within reasonable limits and in  
7 a reasonable manner.

8 “(E) STUDIES AND SUBMISSIONS DE-  
9 SCRIBED.—The studies and submissions de-  
10 scribed in this subparagraph are each of the fol-  
11 lowing:

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

19 “(ii) Postmarket safety activities con-  
20 ducted under this Act or the Public Health  
21 Service Act.

22 “(iii) Any other clinical investigation  
23 of—

1                   “(I) a drug subject to section  
2                   505 or 512 of this Act or section 351  
3                   of the Public Health Service Act; or

4                   “(II) a device subject to section  
5                   520(g).

6                   “(iv) Any other submissions made  
7                   under this Act or the Public Health Serv-  
8                   ice Act with respect to which the Secretary  
9                   determines an inspection under this para-  
10                  graph is warranted in the interest of public  
11                  health.

12                  “(F) CLARIFICATION.—This paragraph  
13                  clarifies the authority of the Secretary to con-  
14                  duct inspections of the type described in this  
15                  paragraph and shall not be construed as a basis  
16                  for inferring that, prior to the date of enact-  
17                  ment of this paragraph, the Secretary lacked  
18                  the authority to conduct such inspections, in-  
19                  cluding under this Act or the Public Health  
20                  Service Act.”.

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

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

1 (i) review processes and practices in  
2 effect as of the date of enactment of this  
3 Act applicable to inspections of foreign and  
4 domestic sites and facilities described in  
5 subparagraph (C)(i) of section 704(a)(5) of  
6 the Federal Food, Drug, and Cosmetic  
7 Act, as added by paragraph (1); and

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

11 (B) GUIDANCE.—

12 (i) IN GENERAL.—The Secretary of  
13 Health and Human Services shall issue  
14 guidance describing the processes and  
15 practices applicable to inspections of sites  
16 and facilities described in subparagraph  
17 (C)(i) of section 704(a)(5) of the Federal  
18 Food, Drug, and Cosmetic Act, as added  
19 by paragraph (1), including with respect to  
20 the types of records and information re-  
21 quired to be provided, best practices for  
22 communication between the Food and  
23 Drug Administration and industry in ad-  
24 vance of or during an inspection or request  
25 for records or other information, and other

1 inspections-related conduct, to the extent  
2 not specified in existing publicly available  
3 Food and Drug Administration guides and  
4 manuals for such inspections.

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

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

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

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

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

19 “(c) APPLICABILITY.—The limitations on the Sec-  
20 retary’s use of evidence obtained under this section, or any  
21 evidence which is directly or indirectly derived from such  
22 evidence, in a criminal prosecution of the person from  
23 whom such evidence was obtained shall not apply to evi-  
24 dence, including records or other information, obtained  
25 under authorities other than this section, unless such limi-

1 tations are specifically incorporated by reference in such  
2 other authorities.”.

3 **SEC. 723. IMPROVING FDA INSPECTIONS.**

4 (a) RISK FACTORS FOR ESTABLISHMENTS.—Section  
5 510(h)(4) of the Federal Food, Drug, and Cosmetic Act  
6 (21 U.S.C. 360(h)(4)) is amended—

7 (1) by redesignating subparagraph (F) as sub-  
8 paragraph (G); and

9 (2) by inserting after subparagraph (E) the fol-  
10 lowing:

11 “(F) The compliance history of establish-  
12 ments in the country or region in which the es-  
13 tablishment is located that are subject to regu-  
14 lation under this Act, including the history of  
15 violations related to products exported from  
16 such country or region that are subject to such  
17 regulation.”.

18 (b) USE OF RECORDS.—Section 704(a)(4) of the  
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 374(a)(4)) is amended—

21 (1) by redesignating subparagraph (C) as sub-  
22 paragraph (D); and

23 (2) by inserting after subparagraph (B) the fol-  
24 lowing:



1       “(C) The Secretary may rely on any records or other  
2 information that the Secretary may inspect under this sec-  
3 tion to satisfy requirements that may pertain to a  
4 preapproval or risk-based surveillance inspection, or to re-  
5 solve deficiencies identified during such inspections, if ap-  
6 plicable and appropriate.”.

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

10           (1) in subsection (a)(1), by inserting  
11 “preapproval or” before “risk-based inspections”;  
12 and

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

14       “(c) PERIODIC REVIEW.—

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

22           “(2) REPORTS TO CONGRESS.—Beginning not  
23 later than 4 years after the date of the enactment  
24 of the Food and Drug Amendments of 2022, and  
25 every 4 years thereafter, the Secretary shall submit

1 to the Committee on Energy and Commerce of the  
2 House of Representatives and the Committee on  
3 Health, Education, Labor, and Pensions of the Sen-  
4 ate a report describing the findings and conclusions  
5 of each review conducted under paragraph (1).”.

6 **SEC. 724. GAO REPORT ON INSPECTIONS OF FOREIGN ES-**  
7 **TABLISHMENTS MANUFACTURING DRUGS.**

8 (a) IN GENERAL.—Not later than 18 months after  
9 the date of the enactment of this Act, the Comptroller  
10 General of the United States shall submit to the Com-  
11 mittee on Energy and Commerce of the House of Rep-  
12 resentatives and the Committee on Health, Education,  
13 Labor, and Pensions of the Senate a report on inspections  
14 conducted by—

15 (1) the Secretary of Health and Human Serv-  
16 ices (in this section referred to as the “Secretary”)  
17 of foreign establishments pursuant to subsections (h)  
18 and (i) of section 510 and section 704 of the Fed-  
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360;  
20 374); or

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

24 (b) CONTENTS.—The report conducted under sub-  
25 section (a) shall include—

1           (1) what alternative tools, including remote in-  
2           spections or remote evaluations, other countries are  
3           utilizing to facilitate inspections of foreign establish-  
4           ments;

5           (2) how frequently trusted foreign regulators  
6           conduct inspections of foreign facilities that could be  
7           useful to the Food and Drug Administration to re-  
8           view in lieu of its own inspections;

9           (3) how frequently and under what cir-  
10          cumstances, including for what types of inspections,  
11          the Secretary utilizes existing agreements or ar-  
12          rangements under section 809 of the Federal Food,  
13          Drug, and Cosmetic Act (21 U.S.C. 384e) and  
14          whether the use of such agreements could be appro-  
15          priately expanded;

16          (4) whether the Secretary has accepted reports  
17          of inspections of facilities in China and India con-  
18          ducted by entities with which they have entered into  
19          such an agreement or arrangement;

20          (5) what additional foreign governments or  
21          agencies of foreign governments the Secretary has  
22          considered entering into a mutual recognition agree-  
23          ment with and, if applicable, reasons why the Sec-  
24          retary declined to enter into a mutual recognition

1 agreement with such foreign governments or agen-  
2 cies;

3 (6) what tools, if any, the Secretary used to fa-  
4 cilitate inspections of domestic facilities that could  
5 also be effectively utilized to appropriately inspect  
6 foreign facilities;

7 (7) what steps the Secretary has taken to iden-  
8 tify and evaluate tools and strategies the Secretary  
9 may use to continue oversight with respect to inspec-  
10 tions when in-person inspections are disrupted;

11 (8) how the Secretary is considering incor-  
12 porating alternative tools into the inspection activi-  
13 ties conducted pursuant to the Federal Food, Drug,  
14 and Cosmetic Act (21 U.S.C. 301 et seq.); and

15 (9) what steps the Secretary has taken to iden-  
16 tify and evaluate how the Secretary may use alter-  
17 native tools to address workforce shortages to carry  
18 out such inspection activities.

19 **SEC. 725. UNANNOUNCED FOREIGN FACILITY INSPECTIONS**  
20 **PILOT PROGRAM.**

21 (a) IN GENERAL.—The Secretary of Health and  
22 Human Services (referred to in this section as the “Sec-  
23 retary”) shall conduct a pilot program under which the  
24 Secretary increases the conduct of unannounced surveil-  
25 lance inspections of foreign human drug establishments

1 and evaluates the differences between such inspections of  
2 domestic and foreign human drug establishments, includ-  
3 ing the impact of announcing inspections to persons who  
4 own or operate foreign human drug establishments in ad-  
5 vance of an inspection. Such pilot program shall evalu-  
6 ate—

7           (1) differences in the number and type of viola-  
8 tions of section 501(a)(2)(B) of the Federal Food,  
9 Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))  
10 identified as a result of unannounced and announced  
11 inspections of foreign human drug establishments  
12 and any other significant differences between each  
13 type of inspection;

14           (2) costs and benefits associated with con-  
15 ducting announced and unannounced inspections of  
16 foreign human drug establishments;

17           (3) barriers to conducting unannounced inspec-  
18 tions of foreign human drug establishments and any  
19 challenges to achieving parity between domestic and  
20 foreign human drug establishment inspections; and

21           (4) approaches for mitigating any negative ef-  
22 fects of conducting announced inspections of foreign  
23 human drug establishments.

24           (b) PILOT PROGRAM SCOPE.—The inspections evalu-  
25 ated under the pilot program under this section shall be

1 routine surveillance inspections and shall not include in-  
2 spections conducted as part of the Secretary's evaluation  
3 of a request for approval to market a drug submitted  
4 under the Federal Food, Drug, and Cosmetic Act (21  
5 U.S.C. 301 et seq.) or the Public Health Service Act (42  
6 U.S.C. 201 et seq.).

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

10 (d) REPORT.—The Secretary shall, not later than  
11 180 days following the completion of the pilot program  
12 under this section, make available on the website of the  
13 Food and Drug Administration a final report on the pilot  
14 program under this section, including—

15 (1) findings and any associated recommenda-  
16 tions with respect to the evaluation under subsection  
17 (a), including any recommendations to address iden-  
18 tified barriers to conducting unannounced inspec-  
19 tions of foreign human drug establishments;

20 (2) findings and any associated recommenda-  
21 tions regarding how the Secretary may achieve par-  
22 ity between domestic and foreign human drug in-  
23 spections; and



1 (1) IN GENERAL.—Section 506C–1(a)(2) of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 356c–1(a)(2)) is amended to read as follows:

4 “(2)(A) describes the communication between  
5 the field investigators of the Food and Drug Admin-  
6 istration and the staff of the Center for Drug Eval-  
7 uation and Research’s Office of Compliance and  
8 Drug Shortage Program, including the Food and  
9 Drug Administration’s procedures for enabling and  
10 ensuring such communication;

11 “(B) provides the number of reports described  
12 in section 704(b)(2) that were required to be sent to  
13 the appropriate offices of the Food and Drug Ad-  
14 ministration and the number of such reports that  
15 were sent; and

16 “(C) describes the coordination and alignment  
17 activities undertaken pursuant to section 506D(g);”.

18 (2) APPLICABILITY.—The amendment made by  
19 paragraph (1) shall apply with respect to reports  
20 submitted on or after March 31, 2023.

21 **SEC. 728. REPORTING OF MUTUAL RECOGNITION AGREE-**  
22 **MENTS FOR INSPECTIONS AND REVIEW AC-**  
23 **TIVITIES.**

24 (a) IN GENERAL.—Not later than December 31,  
25 2022, and annually thereafter, the Secretary of Health



1 and Human Services (referred to in this section as the  
2 “Secretary”) shall publish a report on the public website  
3 of the Food and Drug Administration on the utilization  
4 of agreements entered into pursuant to section 809 of the  
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e)  
6 or otherwise entered into by the Secretary in the previous  
7 fiscal year to recognize inspections between drug regu-  
8 latory authorities across countries and international re-  
9 gions with analogous review criteria to the Food and Drug  
10 Administration, such as the Pharmaceutical Inspection  
11 Co-Operation Scheme, the Mutual Recognition Agreement  
12 with the European Union, and the Australia-Canada-  
13 Singapore-Switzerland-United Kingdom Consortium.

14 (b) CONTENT.—The report under subsection (a) shall  
15 include each of the following:

16 (1) The total number of establishments that are  
17 registered under section 510(i) of the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the  
19 number of such establishments in each region of in-  
20 terest.

21 (2) The total number of inspections conducted  
22 at establishments described in paragraph (1),  
23 disaggregated by inspections conducted—

24 (A) pursuant to an agreement or other rec-  
25 ognition described in subsection (a); and

1 (B) by employees or contractors of the  
2 Food and Drug Administration.

3 (3) Of the inspections described in paragraph  
4 (2), the total number of inspections in each region  
5 of interest.

6 (4) Of the inspections in each region of interest  
7 reported pursuant to paragraph (3), the number of  
8 inspections in each FDA inspection category.

9 (5) Of the number of inspections reported  
10 under each of paragraphs (3) and (4)—

11 (A) the number of inspections which have  
12 been conducted pursuant to an agreement or  
13 other recognition described in subsection (a);  
14 and

15 (B) the number of inspections which have  
16 been conducted by employees or contractors of  
17 the Food and Drug Administration.

18 (c) DEFINITIONS.—In this section:

19 (1) FDA INSPECTION CATEGORY.—The term  
20 “FDA inspection category” means the following in-  
21 spection categories:

22 (A) Inspections to support approvals of  
23 changes to the manufacturing process of drugs  
24 approved under section 505 of the Federal  
25 Food, Drug, and Cosmetic Act (21 U.S.C. 355)

1 or section 351 of the Public Health Service Act  
2 (42 U.S.C. 262).

3 (B) Surveillance inspections.

4 (C) For-cause inspections.

5 (2) REGION OF INTEREST.—The term “region  
6 of interest” means China, India, the European  
7 Union, and any other geographic region as the Sec-  
8 retary determines appropriate.

9 **SEC. 729. ENHANCING TRANSPARENCY OF DRUG FACILITY**  
10 **INSPECTION TIMELINES.**

11 Section 902 of the FDA Reauthorization Act of 2017  
12 (21 U.S.C. 355 note) is amended to read as follows:

13 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

14 “Not later than 120 days after the end of each fiscal  
15 year, the Secretary of Health and Human Services shall  
16 post on the public website of the Food and Drug Adminis-  
17 tration information related to inspections of facilities nec-  
18 essary for approval of a drug under subsection (c) or (j)  
19 of section 505 of the Federal Food, Drug, and Cosmetic  
20 Act (21 U.S.C. 355), approval of a device under section  
21 515 of such Act (21 U.S.C. 360e), or clearance of a device  
22 under section 510(k) of such Act (21 U.S.C. 360(k)) that  
23 were conducted during the previous fiscal year. Such infor-  
24 mation shall include the following:

1           “(1) The median time following a request from  
2 staff of the Food and Drug Administration review-  
3 ing an application or report to the beginning of the  
4 inspection, including—

5                   “(A) the median time for drugs described  
6 in section 505(j)(11)(A)(i) of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C.  
8 355(j)(11)(A)(i));

9                   “(B) the median time for drugs described  
10 in section 506C(a) of such Act (21 U.S.C.  
11 356c(a)) only; and

12                   “(C) the median time for drugs on the  
13 drug shortage list in effect under section 506E  
14 of such Act (21 U.S.C. 356e).

15           “(2) The median time from the issuance of a  
16 report pursuant to section 704(b) of such Act (21  
17 U.S.C. 374(b)) to the sending of a warning letter,  
18 issuance of an import alert, or holding of a regu-  
19 latory meeting for inspections for which the Sec-  
20 retary concluded that regulatory or enforcement ac-  
21 tion was indicated, including the median time for  
22 each category of drugs listed in subparagraphs (A)  
23 through (C) of paragraph (1).

24           “(3) The median time from the sending of a  
25 warning letter, issuance of an import alert, or hold-

1 ing of a regulatory meeting to resolution of the ac-  
2 tions indicated to address the conditions or practices  
3 observed during an inspection.

4 “(4) The number of facilities that failed to im-  
5 plement adequate corrective or preventive actions  
6 following a report pursuant to such section 704(b),  
7 resulting in a withhold recommendation, including  
8 the number of such times for each category of drugs  
9 listed in subparagraphs (A) through (C) of para-  
10 graph (1).”.

11 **TITLE VIII—TRANSPARENCY,**  
12 **PROGRAM INTEGRITY, AND**  
13 **REGULATORY IMPROVE-**  
14 **MENTS**

15 **SEC. 801. PROMPT REPORTS OF MARKETING STATUS BY**  
16 **HOLDERS OF APPROVED APPLICATIONS FOR**  
17 **BIOLOGICAL PRODUCTS.**

18 (a) IN GENERAL.—Section 506I of the Federal Food,  
19 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

20 (1) in subsection (a)—

21 (A) in the matter preceding paragraph (1),  
22 by striking “The holder of an application ap-  
23 proved under subsection (c) or (j) of section  
24 505” and inserting “The holder of an applica-  
25 tion approved under subsection (c) or (j) of sec-

1           tion 505 of this Act or subsection (a) or (k) of  
2           section 351 of the Public Health Service Act”;

3           (B) in paragraph (2), by striking “estab-  
4           lished name” and inserting “established name  
5           (for biological products, by proper name)”; and

6           (C) in paragraph (3), by striking “or ab-  
7           breviated application number” and inserting “,  
8           abbreviated application number, or biologics li-  
9           cense application number”; and  
10          (2) in subsection (b)—

11           (A) in the matter preceding paragraph (1),  
12           by striking “The holder of an application ap-  
13           proved under subsection (c) or (j)” and insert-  
14           ing “The holder of an application approved  
15           under subsection (c) or (j) of section 505 of  
16           this Act or subsection (a) or (k) of section 351  
17           of the Public Health Service Act”;

18           (B) in paragraph (1), by striking “estab-  
19           lished name” and inserting “established name  
20           (for biological products, by proper name)”; and

21           (C) in paragraph (2), by striking “or ab-  
22           breviated application number” and inserting “,  
23           abbreviated application number, or biologics li-  
24           cense application number”.

1 (b) ADDITIONAL ONE-TIME REPORT.—Subsection  
2 (c) of section 506I of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 356i) is amended to read as follows:

4 “(c) ADDITIONAL ONE-TIME REPORT.—Within 180  
5 days of the date of enactment of the Food and Drug  
6 Amendments of 2022, all holders of applications approved  
7 under subsection (a) or (k) of section 351 of the Public  
8 Health Service Act shall review the information in the list  
9 published under section 351(k)(9)(A) and shall submit a  
10 written notice to the Secretary—

11 “(1) stating that all of the application holder’s  
12 biological products in the list published under sec-  
13 tion 351(k)(9)(A) that are not listed as discontinued  
14 are available for sale; or

15 “(2) including the information required pursu-  
16 ant to subsection (a) or (b), as applicable, for each  
17 of the application holder’s biological products that  
18 are in the list published under section 351(k)(9)(A)  
19 and not listed as discontinued, but have been discon-  
20 tinued from sale or never have been available for  
21 sale.”.

22 (c) PURPLE BOOK.—Section 506I of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-  
24 ed—

1           (1) by striking subsection (d) and inserting the  
2 following:

3           “(d) FAILURE TO MEET REQUIREMENTS.—If a hold-  
4 er of an approved application fails to submit the informa-  
5 tion required under subsection (a), (b), or (c), the Sec-  
6 retary may—

7           “(1) move the application holder’s drugs from  
8 the active section of the list published under section  
9 505(j)(7)(A) to the discontinued section of the list,  
10 except that the Secretary shall remove from the list  
11 in accordance with section 505(j)(7)(C) drugs the  
12 Secretary determines have been withdrawn from sale  
13 for reasons of safety or effectiveness; and

14           “(2) identify the application holder’s biological  
15 products as discontinued in the list published under  
16 section 351(k)(9)(A) of the Public Health Service  
17 Act, except that the Secretary shall remove from the  
18 list in accordance with section 351(k)(9)(B) of such  
19 Act biological products for which the license has  
20 been revoked or suspended for reasons of safety, pu-  
21 rity, or potency.”; and

22           (2) in subsection (e)—

23           (A) by inserting after the first sentence the  
24 following: “The Secretary shall update the list  
25 published under section 351(k)(9)(A) of the



1 Public Health Service Act based on information  
2 provided under subsections (a), (b), and (c) by  
3 identifying as discontinued biological products  
4 that are not available for sale, except that bio-  
5 logical products for which the license has been  
6 revoked or suspended for safety, purity, or po-  
7 tency reasons shall be removed from the list in  
8 accordance with section 351(k)(9)(B) of the  
9 Public Health Service Act.”;

10 (B) by striking “monthly updates to the  
11 list” and inserting “monthly updates to the lists  
12 referred to in the preceding sentences”; and

13 (C) by striking “and shall update the list  
14 based on” and inserting “and shall update such  
15 lists based on”.

16 (d) TECHNICAL CORRECTIONS.—Section 506I(e) of  
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 356i(e)) is amended—

19 (1) by striking “subsection 505(j)(7)(A)” and  
20 inserting “section 505(j)(7)(A)”; and

21 (2) by striking “subsection 505(j)(7)(C)” and  
22 inserting “section 505(j)(7)(C)”.

1 **SEC. 802. ENCOURAGING BLOOD DONATION.**

2 (a) STREAMLINING PATIENT AND BLOOD DONOR  
3 INPUT.—Section 3003 of the 21st Century Cures Act (21  
4 U.S.C. 360bbb–8c note) is amended to read as follows:

5 **“SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR**  
6 **INPUT.**

7 “Chapter 35 of title 44, United States Code, shall  
8 not apply to the collection of information to which a re-  
9 sponse is voluntary, to solicit—

10 “(1) the views and perspectives of patients  
11 under section 569C of the Federal Food, Drug, and  
12 Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended  
13 by section 3001) or section 3002; or

14 “(2) information from blood donors or potential  
15 blood donors to support the development of rec-  
16 ommendations by the Secretary of Health and  
17 Human Services acting through the Commissioner of  
18 Food and Drugs concerning blood donation.”.

19 (b) CLERICAL AMENDMENT.—The table of contents  
20 in section 1(b) of the 21st Century Cures Act is amended  
21 by striking the item relating to section 3003 and inserting  
22 the following:

“Sec. 3003. Streamlining patient and blood donor input.”.

1 **SEC. 803. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

2 Section 503 of the Federal Food, Drug, and Cosmetic  
3 Act (21 U.S.C. 353) is amended by adding at the end the  
4 following:

5 “(h)(1) Any contrast agent, radioactive drug, or OTC  
6 monograph drug shall be deemed to be a drug under sec-  
7 tion 201(g) and not a device under section 201(h).

8 “(2) For purposes of this subsection:

9 “(A) The term ‘contrast agent’ means an arti-  
10 cle that is intended for use in conjunction with a  
11 medical imaging device, and—

12 “(i) is a diagnostic radiopharmaceutical, as  
13 defined in sections 315.2 and 601.31 of title  
14 21, Code of Federal Regulations (or any suc-  
15 cessor regulations); or

16 “(ii) is a diagnostic agent that improves  
17 the visualization of structure or function within  
18 the body by increasing the relative difference in  
19 signal intensity within the target tissue, struc-  
20 ture, or fluid.

21 “(B) The term ‘radioactive drug’ has the mean-  
22 ing given such term in section 310.3(n) of title 21,  
23 Code of Federal Regulations (or any successor regu-  
24 lations), except that such term does not include—

25 “(i) an implant or article similar to an im-  
26 plant;

1           “(ii) an article that applies radiation from  
2           outside of the body; or

3           “(iii) the radiation source of an article de-  
4           scribed in clause (i) or (ii).

5           “(C) The term ‘OTC monograph drug’ has the  
6           meaning given such term in section 744L.

7           “(3) Nothing in this subsection shall be construed as  
8           allowing for the classification of a product as a drug (as  
9           defined in section 201(g)) if such product—

10           “(A) is not described in paragraph (1); and

11           “(B) meets the definition of a device under sec-  
12           tion 201(h),

13           unless another provision of this Act otherwise indicates a  
14           different classification.”.

15   **SEC. 804. POSTAPPROVAL STUDIES AND PROGRAM INTEG-**  
16                                   **RITY FOR ACCELERATED APPROVAL DRUGS.**

17           (a) IN GENERAL.—Section 506(c) of the Federal  
18           Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is  
19           amended—

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

22           “(2) LIMITATION.—

23           “(A) IN GENERAL.—Approval of a product  
24           under this subsection may be subject to 1 or  
25           both of the following requirements:

1           “(i) That the sponsor conduct an ap-  
2           propriate postapproval study or studies  
3           (which may be augmented or supported by  
4           real world evidence) to verify and describe  
5           the predicted effect on irreversible mor-  
6           bidity or mortality or other clinical benefit.

7           “(ii) That the sponsor submit copies  
8           of all promotional materials related to the  
9           product during the preapproval review pe-  
10          riod and, following approval and for such  
11          period thereafter as the Secretary deter-  
12          mines to be appropriate, at least 30 days  
13          prior to dissemination of the materials.

14          “(B) STUDIES NOT REQUIRED.—If the  
15          Secretary does not require that the sponsor of  
16          a product approved under accelerated approval  
17          conduct a postapproval study under this para-  
18          graph, the Secretary shall publish on the  
19          website of the Food and Drug Administration  
20          the rationale for why such study is not appro-  
21          priate or necessary.

22          “(C) POSTAPPROVAL STUDY CONDI-  
23          TIONS.—Not later than the time of approval of  
24          a product under accelerated approval, the Sec-  
25          retary shall specify the conditions for a post-

1 approval study or studies required to be con-  
2 ducted under this paragraph with respect to  
3 such product, which may include enrollment  
4 targets, the study protocol, and milestones, in-  
5 cluding the target date of study completion.

6 “(D) STUDIES BEGUN BEFORE AP-  
7 PROVAL.—The Secretary may require such  
8 study or studies to be underway prior to ap-  
9 proval.”; and

10 (2) by striking paragraph (3) and inserting the  
11 following:

12 “(3) EXPEDITED WITHDRAWAL OF AP-  
13 PROVAL.—

14 “(A) IN GENERAL.—The Secretary may  
15 withdraw approval of a product approved under  
16 accelerated approval using expedited procedures  
17 described in subparagraph (B), if—

18 “(i) the sponsor fails to conduct any  
19 required postapproval study of the product  
20 with due diligence, including with respect  
21 to conditions specified by the Secretary  
22 under paragraph (2)(C);

23 “(ii) a study required to verify and  
24 describe the predicted effect on irreversible  
25 morbidity or mortality or other clinical

1 benefit of the product fails to verify and  
2 describe such effect or benefit;

3 “(iii) other evidence demonstrates  
4 that the product is not shown to be safe or  
5 effective under the conditions of use; or

6 “(iv) the sponsor disseminates false or  
7 misleading promotional materials with re-  
8 spect to the product.

9 “(B) EXPEDITED PROCEDURES DE-  
10 SCRIBED.—Expedited procedures described in  
11 this subparagraph shall consist of, prior to the  
12 withdrawal of accelerated approval—

13 “(i) providing the sponsor with—

14 “(I) due notice;

15 “(II) an explanation for the pro-  
16 posed withdrawal;

17 “(III) an opportunity for a meet-  
18 ing with the Commissioner of Food  
19 and Drugs or the Commissioner’s des-  
20 ignee; and

21 “(IV) an opportunity for written  
22 appeal to—

23 “(aa) the Commissioner of  
24 Food and Drugs; or

1                   “(bb) a designee of the  
2                   Commissioner who has not par-  
3                   ticipated in the proposed with-  
4                   drawal of approval (other than a  
5                   meeting pursuant to subclause  
6                   (III)) and is not a subordinate of  
7                   an individual (other than the  
8                   Commissioner) who participated  
9                   in such proposed withdrawal;

10                   “(ii) providing an opportunity for  
11                   public comment on the notice proposing to  
12                   withdraw approval;

13                   “(iii) the publication of a summary of  
14                   the public comments received, and the Sec-  
15                   retary’s response to such comments, on the  
16                   website of the Food and Drug Administra-  
17                   tion; and

18                   “(iv) convening and consulting an ad-  
19                   visory committee on issues related to the  
20                   proposed withdrawal, if requested by the  
21                   sponsor and if no such advisory committee  
22                   has previously advised the Secretary on  
23                   such issues with respect to the withdrawal  
24                   of the product prior to the sponsor’s re-  
25                   quest.



1 “(4) LABELING.—

2 “(A) IN GENERAL.—Subject to subpara-  
3 graph (B), the labeling for a product approved  
4 under accelerated approval shall include—

5 “(i) a statement indicating that the  
6 product was approved under accelerated  
7 approval;

8 “(ii) a statement indicating that con-  
9 tinued approval of the product is subject to  
10 postmarketing studies to verify clinical  
11 benefit;

12 “(iii) identification of the surrogate or  
13 intermediate endpoint or endpoints that  
14 supported approval and any known limita-  
15 tions of such surrogate or intermediate  
16 endpoint or endpoints in determining clin-  
17 ical benefit; and

18 “(iv) a succinct description of the  
19 product and any uncertainty about antici-  
20 pated clinical benefit and a discussion of  
21 available evidence with respect to such clin-  
22 ical benefit.

23 “(B) APPLICABILITY.—The labeling re-  
24 quirements of subparagraph (A) shall apply  
25 only to products approved under accelerated ap-

1           proval for which the predicted effect on irre-  
2           versible morbidity or mortality or other clinical  
3           benefit has not been verified.

4                   “(C) RULE OF CONSTRUCTION.—With re-  
5           spect to any application pending before the Sec-  
6           retary on the date of enactment of the Food  
7           and Drug Amendments of 2022, the Secretary  
8           shall allow any applicable changes to the prod-  
9           uct labeling required to comply with subpara-  
10          graph (A) to be made by supplement after the  
11          approval of such application.

12                   “(5) REPORTING.—Not later than September  
13          30, 2025, the Secretary shall submit to the Com-  
14          mittee on Energy and Commerce of the House of  
15          Representatives and the Committee on Health, Edu-  
16          cation, Labor, and Pensions of the Senate a report  
17          describing circumstances in which the Secretary con-  
18          sidered real world evidence submitted to support  
19          postapproval studies required under this subsection  
20          that were completed after the date of enactment of  
21          the Food and Drug Amendments of 2022.”.

22                   (b) REPORTS OF POSTMARKETING STUDIES.—Sec-  
23          tion 506B(a) of the Federal Food, Drug, and Cosmetic  
24          Act (21 U.S.C. 356b(a)) is amended—

1           (1) by redesignating paragraph (2) as para-  
2 graph (3); and

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

5           “(2) ACCELERATED APPROVAL.—Notwith-  
6 standing paragraph (1), a sponsor of a drug ap-  
7 proved under accelerated approval shall submit to  
8 the Secretary a report of the progress of any study  
9 required under section 506(c), including progress to-  
10 ward enrollment targets, milestones, and other infor-  
11 mation as required by the Secretary, not later than  
12 180 days after the approval of such drug and not  
13 less frequently than every 180 days thereafter, until  
14 the study is completed or terminated.”.

15       (c) GUIDANCE.—

16           (1) IN GENERAL.—The Secretary of Health and  
17 Human Services shall issue guidance describing—

18           (A) how sponsor questions related to the  
19 identification of novel surrogate or intermediate  
20 clinical endpoints may be addressed in early-  
21 stage development meetings with the Food and  
22 Drug Administration;

23           (B) the use of novel clinical trial designs  
24 that may be used to conduct appropriate post-  
25 approval studies as may be required under sec-

1           tion 506(c)(2)(A) of the Federal Food, Drug,  
2           and Cosmetic Act (21 U.S.C. 356(c)(2)(A)), as  
3           amended by subsection (a); and

4           (C) the expedited procedures described in  
5           section 506(c)(3)(B) of the Federal Food,  
6           Drug, and Cosmetic Act (21 U.S.C.  
7           356(c)(3)(B)).

8           (2) FINAL GUIDANCE.—The Secretary shall  
9           issue—

10           (A) draft guidance under paragraph (1)  
11           not later than 18 months after the date of en-  
12           actment of this Act; and

13           (B) final guidance not later than 1 year  
14           after the close of the public comment period on  
15           such draft guidance.

16           (d) RARE DISEASE ENDPOINT ADVANCEMENT  
17           PILOT.—

18           (1) IN GENERAL.—The Secretary of Health and  
19           Human Services shall establish a pilot program  
20           under which the Secretary will establish procedures  
21           to provide increased interaction with sponsors of  
22           rare disease drug development programs for pur-  
23           poses of advancing the development of efficacy  
24           endpoints, including surrogate and intermediate

1 endpoints, for drugs intended to treat rare diseases,  
2 including through—

3 (A) determining eligibility of participants  
4 for such a program; and

5 (B) developing and implementing a process  
6 for applying to, and participating in, such a  
7 program.

8 (2) PUBLIC WORKSHOPS.—The Secretary shall  
9 conduct up to 3 public workshops, which shall be  
10 completed not later than September 30, 2026, to  
11 discuss topics relevant to the development of  
12 endpoints for rare diseases, which may include dis-  
13 cussions about—

14 (A) novel endpoints developed through the  
15 pilot program established under this subsection;  
16 and

17 (B) as appropriate, the use of real world  
18 evidence and real world data to support the val-  
19 idation of efficacy endpoints, including surro-  
20 gate and intermediate endpoints, for rare dis-  
21 eases.

22 (3) REPORT.—Not later than September 30,  
23 2027, the Secretary shall submit to the Committee  
24 on Energy and Commerce of the House of Rep-  
25 resentatives and the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate a report  
2 describing the outcomes of the pilot program estab-  
3 lished under this subsection.

4 (4) GUIDANCE.—Not later than September 30,  
5 2027, the Secretary shall issue guidance describing  
6 best practices and strategies for development of effi-  
7 cacy endpoints, including surrogate and intermediate  
8 endpoints, for rare diseases.

9 (5) SUNSET.—The Secretary may not accept  
10 any new application or request to participate in the  
11 program established by this subsection on or after  
12 October 1, 2027.

13 **SEC. 805. FACILITATING THE USE OF REAL WORLD EVI-**  
14 **DENCE.**

15 (a) GUIDANCE.—Not later than 1 year after the date  
16 of the enactment of this Act, the Secretary of Health and  
17 Human Services shall issue, or revise existing, guidance  
18 on considerations for the use of real world data and real  
19 world evidence to support regulatory decisionmaking, as  
20 follows:

21 (1) With respect to drugs, such guidance shall  
22 address—

23 (A) the use of such data and evidence to  
24 support the approval of a drug application  
25 under section 505 of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 355) or a biological  
2 product application under section 351 of the  
3 Public Health Service Act (42 U.S.C. 262), or  
4 to support an investigational use exemption  
5 under section 505(i) of the Federal Food, Drug,  
6 and Cosmetic Act or section 351(a)(3) of the  
7 Public Health Service Act; and

8 (B) the use of such data and evidence ob-  
9 tained as a result of the use of drugs author-  
10 ized for emergency use under section 564 of the  
11 Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 360bbb-3) in such applications, submis-  
13 sions, or requests; and

14 (C) standards and methodologies which  
15 may be used for collection and analysis of real  
16 world evidence included in such applications,  
17 submissions, or requests, as appropriate.

18 (2) With respect to devices, such guidance shall  
19 address—

20 (A) the use of such data and evidence to  
21 support the approval, clearance, or classification  
22 of a device pursuant to an application or sub-  
23 mission submitted under section 510(k),  
24 513(f)(2), or 515 of the Federal Food, Drug,  
25 and Cosmetic Act (21 U.S.C. 360(k),

1 360c(f)(2), 360e), or to support an investiga-  
2 tional use exemption under section 520(g) of  
3 such Act (21 U.S.C. 360j(g));

4 (B) the use of such data and evidence ob-  
5 tained as a result of the use of devices author-  
6 ized for emergency use under section 564 of the  
7 Federal Food, Drug, and Cosmetic Act (21  
8 U.S.C. 360bbb-3), in such applications, submis-  
9 sions, or requests; and

10 (C) standards and methodologies which  
11 may be used for collection and analysis of real  
12 world evidence included in such applications,  
13 submissions, or requests, as appropriate.

14 (b) REPORT TO CONGRESS.—Not later than 2 years  
15 after the termination of the public health emergency deter-  
16 mination by the Secretary of Health and Human Services  
17 under section 564 of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 360bbb-3) on February 4, 2020,  
19 with respect to the Coronavirus Disease 2019 (COVID-  
20 19), the Secretary shall submit a report to the Committee  
21 on Energy and Commerce of the House of Representatives  
22 and the Committee on Health, Education, Labor, and  
23 Pensions of the Senate on—

24 (1) the number of applications, submissions, or  
25 requests submitted for clearance or approval under



1 section 505, 510(k), 513(f)(2), or 515 of the Fed-  
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355,  
3 360(k), 360c(f)(2), 360e) or section 351 of the Pub-  
4 lic Health Service Act, for which an authorization  
5 under section 564 of the Federal Food, Drug, and  
6 Cosmetic Act (21 U.S.C. 360bbb-3) was previously  
7 granted;

8 (2) of the number of applications so submitted,  
9 the number of such applications—

10 (A) for which real world evidence was sub-  
11 mitted and used to support a regulatory deci-  
12 sion; and

13 (B) for which real world evidence was sub-  
14 mitted and determined to be insufficient to sup-  
15 port a regulatory decision; and

16 (3) a summary explanation of why, in the case  
17 of applications described in paragraph (2)(B), real  
18 world evidence could not be used to support regu-  
19 latory decisions.

20 (c) INFORMATION DISCLOSURE.—Nothing in this  
21 section shall be construed to authorize the disclosure of  
22 information that is prohibited from disclosure under sec-  
23 tion 1905 of title 18, United States Code, or subject to  
24 withholding under subsection (b)(4) of section 552 of title

1 5, United States Code (commonly referred to as the  
2 “Freedom of Information Act”).

3 **SEC. 806. DUAL SUBMISSION FOR CERTAIN DEVICES.**

4 Section 513 of the Federal Food, Drug, and Cosmetic  
5 Act (21 U.S.C. 360c) is amended by adding at the end  
6 the following:

7 “(k) For a device authorized for emergency use under  
8 section 564 for which, in accordance with section 564(m),  
9 the Secretary has deemed a laboratory examination or pro-  
10 cedure associated with such device to be in the category  
11 of examinations and procedures described in section  
12 353(d)(3) of the Public Health Service Act, the sponsor  
13 of such device may, when submitting a request for classi-  
14 fication under section 513(f)(2), submit a single submis-  
15 sion containing—

16 “(1) the information needed for such a request;  
17 and

18 “(2) sufficient information to enable the Sec-  
19 retary to determine whether such laboratory exam-  
20 ination or procedure satisfies the criteria to be cat-  
21 egorized under section 353(d)(3) of the Public  
22 Health Service Act.”.

1 **SEC. 807. MEDICAL DEVICES ADVISORY COMMITTEE MEET-**  
2 **INGS.**

3 (a) IN GENERAL.—The Secretary shall convene one  
4 or more panels of the Medical Devices Advisory Committee  
5 not less than once per year for the purpose of providing  
6 advice to the Secretary on topics related to medical devices  
7 used in pandemic preparedness and response, including  
8 topics related to in vitro diagnostics.

9 (b) REQUIRED PANEL MEMBER.—A panel convened  
10 under subsection (a) shall include at least 1 population  
11 health-specific representative.

12 (c) SUNSET.—This section shall cease to be effective  
13 on October 1, 2027.

14 **SEC. 808. ENSURING CYBERSECURITY OF MEDICAL DE-**  
15 **VICES.**

16 (a) IN GENERAL.—Subchapter A of chapter V of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
18 et seq.), as amended by section 501, is further amended  
19 by adding at the end the following:

20 **“SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.**

21 “(a) IN GENERAL.—For purposes of ensuring cyber-  
22 security throughout the lifecycle of a cyber device, any per-  
23 son who submits a premarket submission for the cyber de-  
24 vice shall include such information as the Secretary may  
25 require to ensure that the cyber device meets such cyberse-  
26 curity requirements as the Secretary determines to be ap-

1 appropriate to demonstrate a reasonable assurance of safety  
2 and effectiveness, including at a minimum the cybersecu-  
3 rity requirements under subsection (b).

4 “(b) CYBERSECURITY REQUIREMENTS.—At a min-  
5 imum, the manufacturer of a cyber device shall meet the  
6 following cybersecurity requirements:

7 “(1) The manufacturer shall have a plan to ap-  
8 propriately monitor, identify, and address in a rea-  
9 sonable time postmarket cybersecurity vulnerabilities  
10 and exploits, including coordinated vulnerability dis-  
11 closure and procedures.

12 “(2) The manufacturer shall design, develop,  
13 and maintain processes and procedures to ensure the  
14 device and related systems are cybersecure, and shall  
15 make available updates and patches to the cyber de-  
16 vice and related systems throughout the lifecycle of  
17 the cyber device to address—

18 “(A) on a reasonably justified regular  
19 cycle, known unacceptable vulnerabilities; and

20 “(B) as soon as possible out of cycle, crit-  
21 ical vulnerabilities that could cause uncontrolled  
22 risks.

23 “(3) The manufacturer shall provide in the la-  
24 beling of the cyber device a software bill of mate-

1       rials, including commercial, open-source, and off-the-  
2       shelf software components.

3           “(4) The manufacturer shall comply with such  
4       other requirements as the Secretary may require to  
5       demonstrate reasonable assurance of the safety and  
6       effectiveness of the device for purposes of cybersecu-  
7       rity, which the Secretary may require by an order  
8       published in the Federal Register.

9           “(c) SUBSTANTIAL EQUIVALENCE.—In making a de-  
10      termination of substantial equivalence under section  
11      513(i) for a cyber device, the Secretary may—

12           “(1) find that cybersecurity information for the  
13      cyber device described in the relevant premarket  
14      submission in the cyber device’s use environment is  
15      inadequate; and

16           “(2) issue a nonsubstantial equivalence deter-  
17      mination based on this finding.

18           “(d) DEFINITION.—In this section:

19           “(1) CYBER DEVICE.—The term ‘cyber device’  
20      means a device that—

21           “(A) includes software, including software  
22      as or in a device;

23           “(B) has the ability to connect to the  
24      internet; or

1           “(C) contains any such technological char-  
2           acteristics that could be vulnerable to cyberse-  
3           curity threats.

4           “(2) LIFECYCLE OF THE CYBER DEVICE.—The  
5           term ‘lifecycle of the cyber device’ includes the  
6           postmarket lifecycle of the cyber device.

7           “(3) PREMARKET SUBMISSION.—The term ‘pre-  
8           market submission’ means any submission under  
9           section 510(k), 513, 515(e), 515(f), or 520(m).

10          “(e) EXEMPTION.—The Secretary may identify de-  
11         vices or types of devices that are exempt from meeting  
12         the cybersecurity requirements established by this section  
13         and regulations promulgated pursuant to this section. The  
14         Secretary shall publish in the Federal Register, and up-  
15         date, as appropriate, a list of the devices and types of de-  
16         vices so identified by the Secretary.”.

17          (b) PROHIBITED ACT.—Section 301(q) of the Fed-  
18         eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(q))  
19         is amended by adding at the end the following:

20          “(3) The failure to comply with any requirement  
21         under section 524C (relating to ensuring device cyberse-  
22         curity).”.

23          (c) ADULTERATION.—Section 501 of the Federal  
24         Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-  
25         ed by inserting after paragraph (j) the following:

1 “(k) If it is a device subject to the requirements set  
2 forth in section 524C (relating to ensuring device cyberse-  
3 curity) and fails to comply with any requirement under  
4 that section.”.

5 (d) MISBRANDING.—Section 502(t) of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is  
7 amended—

8 (1) by striking “or (3)” and inserting “(3)”;  
9 and

10 (2) by inserting before the period at the end the  
11 following: “, or (4) to furnish a software bill of ma-  
12 terials as required under section 524C (relating to  
13 ensuring device cybersecurity)”.

14 **SEC. 809. PUBLIC DOCKET ON PROPOSED CHANGES TO**  
15 **THIRD-PARTY VENDORS.**

16 (a) IN GENERAL.—

17 (1) OPENING PUBLIC DOCKET.—Not later than  
18 90 days after the date of enactment of this Act, the  
19 Secretary of Health and Human Services shall open  
20 a single public docket to solicit comments on factors  
21 that generally should be considered by the Secretary  
22 when reviewing requests from sponsors of drugs sub-  
23 ject to risk evaluation and mitigation strategies to  
24 change third-party vendors engaged by sponsors to

1 aid in implementation and management of the strat-  
2 egies.

3 (2) FACTORS.—Such factors include the poten-  
4 tial effects of changes in third-party vendors on—

5 (A) patient access; and

6 (B) prescribing and administration of the  
7 drugs by health care providers.

8 (3) CLOSING PUBLIC DOCKET.—The Secretary  
9 of Health and Human Services may close such pub-  
10 lic docket not earlier than 90 days after such docket  
11 is opened.

12 (4) NO DELAY.—Nothing in this section shall  
13 delay agency action on any modification to a risk  
14 evaluation and mitigation strategy.

15 (b) GAO REPORT.—Not later than December 31,  
16 2026, the Comptroller General of the United States shall  
17 submit to the Committee on Energy and Commerce of the  
18 House of Representatives and the Committee on Health,  
19 Education, Labor, and Pensions of the Senate a report  
20 on—

21 (1) the number of changes in third-party ven-  
22 dors (engaged by sponsors to aid implementation  
23 and management of risk evaluation and mitigation  
24 strategies) for an approved risk evaluation and miti-  
25 gation strategy the Secretary of Health and Human



1 Services has approved under section 505–1(h) of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 355–1(h));

4 (2) any issues affecting patient access to the  
5 drug that is subject to the strategy or considerations  
6 with respect to the administration or prescribing of  
7 such drug by health care providers that arose as a  
8 result of such modifications; and

9 (3) how such issues were resolved, as applica-  
10 ble.

11 **SEC. 810. FACILITATING EXCHANGE OF PRODUCT INFOR-**  
12 **MATION PRIOR TO APPROVAL.**

13 (a) IN GENERAL.—Section 502 of the Federal Food,  
14 Drug, and Cosmetic Act (21 U.S.C. 352) is amended—

15 (1) in paragraph (a)—

16 (A) by striking “drugs for coverage” and  
17 inserting “drugs or devices for coverage”; and

18 (B) by striking “drug” each place it ap-  
19 pears and inserting “drug or device”, respec-  
20 tively;

21 (2) in paragraphs (a)(1) and (a)(2)(B), by  
22 striking “under section 505 or under section 351 of  
23 the Public Health Service Act” and inserting “under  
24 section 505, 510(k), 513(f)(2), or 515 of this Act or  
25 section 351 of the Public Health Service Act”;

1 (3) in paragraph (a)(1)—

2 (A) by striking “under section 505 or  
3 under section 351(a) of the Public Health Serv-  
4 ice Act” and inserting “under section 505,  
5 510(k), 513(f)(2), or 515 of this Act or section  
6 351 of the Public Health Service Act”; and

7 (B) by striking “in section 505(a) or in  
8 subsections (a) and (k) of section 351 of the  
9 Public Health Service Act” and inserting “in  
10 section 505, 510(k), 513(f)(2), or 515 of this  
11 Act or section 351 of the Public Health Service  
12 Act”; and

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

14 “(gg)(1) Unless its labeling bears adequate directions  
15 for use in accordance with paragraph (f), except that (in  
16 addition to drugs or devices that conform with exemptions  
17 pursuant to such paragraph) no drug or device shall be  
18 deemed to be misbranded under such paragraph through  
19 the provision of product information to a payor, formulary  
20 committee, or other similar entity with knowledge and ex-  
21 pertise in the area of health care economic analysis car-  
22 rying out its responsibilities for the selection of drugs or  
23 devices for coverage or reimbursement if the product infor-  
24 mation relates to an investigational drug or device or in-  
25 vestigational use of a drug or device that is approved,

1 cleared, granted marketing authorization, or licensed  
2 under section 505, 510(k), 513(f)(2), or 515 of this Act  
3 or section 351 of the Public Health Service Act (as appli-  
4 cable), provided—

5           “(A) the product information includes—

6                   “(i) a clear statement that the investiga-  
7                   tional drug or device or investigational use of a  
8                   drug or device has not been approved, cleared,  
9                   granted marketing authorization, or licensed  
10                   under section 505, 510(k), 513(f)(2), or 515 of  
11                   this Act or section 351 of the Public Health  
12                   Service Act (as applicable) and that the safety  
13                   and effectiveness of the drug or device or use  
14                   has not been established;

15                   “(ii) information related to the stage of de-  
16                   velopment of the drug or device involved, such  
17                   as—

18                           “(I) the status of any study or studies  
19                           in which the investigational drug or device  
20                           or investigational use is being investigated;

21                           “(II) how the study or studies relate  
22                           to the overall plan for the development of  
23                           the drug or device; and

24                           “(III) whether an application, pre-  
25                           market notification, or request for classi-

1           fication for the investigational drug or de-  
2           vice or investigational use has been sub-  
3           mitted to the Secretary and when such a  
4           submission is planned;

5           “(iii) in the case of information that in-  
6           cludes factual presentations of results from  
7           studies, which shall not be selectively presented,  
8           a description of—

9                   “(I) all material aspects of study de-  
10                   sign, methodology, and results; and

11                   “(II) all material limitations related  
12                   to the study design, methodology, and re-  
13                   sults;

14           “(iv) where applicable, a prominent state-  
15           ment disclosing the indication or indications for  
16           which the Secretary has approved, granted mar-  
17           keting authorization, cleared, or licensed the  
18           product pursuant to section 505, 510(k),  
19           513(f)(2), or 515 of this Act or section 351 of  
20           the Public Health Service Act, and a copy of  
21           the most current required labeling; and

22           “(v) updated information, if previously  
23           communicated information becomes materially  
24           outdated as a result of significant changes or as

1 a result of new information regarding the prod-  
2 uct or its review status; and

3 “(B) the product information does not in-  
4 clude—

5 “(i) information that represents that an  
6 unapproved product—

7 “(I) has been approved, cleared,  
8 granted marketing authorization, or li-  
9 censed under section 505, 510(k),  
10 513(f)(2), or 515 of this Act or section  
11 351 of the Public Health Service Act (as  
12 applicable); or

13 “(II) has otherwise been determined  
14 to be safe or effective for the purpose or  
15 purposes for which the drug or device is  
16 being studied; or

17 “(ii) information that represents that an  
18 unapproved use of a drug or device that has  
19 been so approved, granted marketing authoriza-  
20 tion, cleared, or licensed—

21 “(I) is so approved, granted mar-  
22 keting authorization, cleared, or licensed;  
23 or

1                   “(II) that the product is safe or effec-  
2                   tive for the use or uses for which the drug  
3                   or device is being studied.

4           “(2) For purposes of this paragraph, the term ‘prod-  
5 uct information’ includes—

6                   “(A) information describing the drug or device  
7                   (such as drug class, device description, and fea-  
8                   tures);

9                   “(B) information about the indication or indica-  
10                  tions being investigated;

11                  “(C) the anticipated timeline for a possible ap-  
12                  proval, clearance, marketing authorization, or licen-  
13                  sure pursuant to section 505, 510(k), 513, or 515  
14                  of this Act or section 351 of the Public Health Serv-  
15                  ice Act;

16                  “(D) drug or device pricing information;

17                  “(E) patient utilization projections;

18                  “(F) product-related programs or services; and

19                  “(G) factual presentations of results from stud-  
20                  ies that do not characterize or make conclusions re-  
21                  garding safety or efficacy.”.

22           (b) GAO STUDY AND REPORT.—Beginning on the  
23           date that is 5 years and 6 months after the date of enact-  
24           ment of this Act, the Comptroller General of the United  
25           States shall conduct a study on the provision and use of

1 information pursuant to section 502(gg) of the Federal  
2 Food, Drug, and Cosmetic Act, as added by this sub-  
3 section (a), between manufacturers of drugs and devices  
4 (as defined in section 201 of the Federal Food, Drug, and  
5 Cosmetic Act (21 U.S.C. 321)) and entities described in  
6 such section 502(gg). Such study shall include an analysis  
7 of the following:

8           (1) The types of information communicated be-  
9           tween such manufacturers and payors.

10           (2) The manner of communication between  
11           such manufacturers and payors.

12           (3)(A) Whether such manufacturers file an ap-  
13           plication for approval, marketing authorization,  
14           clearance, or licensing of a new drug or device or the  
15           new use of a drug or device that is the subject of  
16           communication between such manufacturers and  
17           payors under section 502(gg) of the Federal Food,  
18           Drug, and Cosmetic Act, as added by subsection (a).

19           (B) How frequently the Food and Drug Admin-  
20           istration approves, grants marketing authorization,  
21           clears, or licenses the new drug or device or new use.

22           (C) The timeframe between the initial commu-  
23           nications permitted under section 502(gg) of the  
24           Federal Food, Drug, and Cosmetic Act, as added by  
25           subsection (a), regarding an investigational drug or

1 device or investigational use, and the initial mar-  
2 keting of such drug or device.

3 **SEC. 811. BANS OF DEVICES FOR ONE OR MORE INTENDED**  
4 **USES.**

5 (a) IN GENERAL.—Section 516(a) of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360f(a)) is  
7 amended—

8 (1) in paragraph (1), by inserting “for one or  
9 more intended use” before the semicolon at the end;  
10 and

11 (2) in the matter following paragraph (2), by  
12 inserting “for any such intended use or uses. A de-  
13 vice that is banned for one or more intended uses is  
14 not a legally marketed device under section 1006  
15 when intended for such use or uses” after “banned  
16 device”.

17 (b) SPECIFIC DEVICES DEEMED BANNED.—Section  
18 516 of the Federal Food, Drug, and Cosmetic Act (21  
19 U.S.C. 360f) is further amended by adding at the end the  
20 following:

21 “(c) SPECIFIC DEVICE BANNED.—Electrical stimula-  
22 tion devices that apply a noxious electrical stimulus to a  
23 person’s skin intended to reduce or cease self-injurious be-  
24 havior or aggressive behavior are deemed to be banned de-  
25 vices, as described in subsection (a).



1       “(d) REVERSAL BY REGULATION.—Devices banned  
2 under this section are banned devices unless or until the  
3 Secretary promulgates a regulation to make such devices  
4 or use of such devices no longer banned based on a finding  
5 that such devices or use of such devices does not present  
6 substantial deception or an unreasonable and substantial  
7 risk of illness or injury, or that such risk can be corrected  
8 or eliminated by labeling.”.

9 **SEC. 812. CLARIFYING APPLICATION OF EXCLUSIVE AP-**  
10 **PROVAL, CERTIFICATION, OR LICENSURE**  
11 **FOR DRUGS DESIGNATED FOR RARE DIS-**  
12 **EASES OR CONDITIONS.**

13       (a) APPLICATION OF EXCLUSIVE APPROVAL, CER-  
14 TIFICATION, OR LICENSURE FOR DRUGS DESIGNATED  
15 FOR RARE DISEASES OR CONDITIONS.—Section 527 of  
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 360cc) is amended—

18           (1) in subsection (a), in the matter following  
19 paragraph (2), by striking “same disease or condi-  
20 tion” and inserting “same approved indication or  
21 use within such rare disease or condition”;

22           (2) in subsection (b)—

23               (A) in the matter preceding paragraph (1),  
24               by striking “same rare disease or condition”  
25               and inserting “same indication or use for which

1 the Secretary has approved or licensed such  
2 drug”; and

3 (B) in paragraph (1), by striking “with the  
4 disease or condition for which the drug was des-  
5 ignated” and inserting “for whom the drug is  
6 indicated”; and

7 (3) in subsection (c), by striking “same rare  
8 disease or condition” and inserting “same indication  
9 or use”.

10 (b) APPLICATION OF AMENDMENTS.—The amend-  
11 ments made by subsection (a) shall apply with respect to  
12 any drug designated under section 526 of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-  
14 less of the date on which the drug was so designated, and  
15 regardless of the date on which the drug was approved  
16 under section 505 of such Act (21 U.S.C. 355) or licensed  
17 under section 351 of the Public Health Service Act (42  
18 U.S.C. 262).

19 **SEC. 813. GAO REPORT ON THIRD-PARTY REVIEW.**

20 Not later than September 30, 2026, the Comptroller  
21 General of the United States shall submit to the Com-  
22 mittee on Energy and Commerce of the House of Rep-  
23 resentatives and the Committee on Health, Education,  
24 Labor, and Pensions of the Senate a report on the third-  
25 party review program described in section 523 of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360m).

2 Such report shall include—

3 (1) a description of the financial and staffing  
4 resources used to carry out such program;

5 (2) a description of actions taken by the Sec-  
6 retary pursuant section 523(b)(2)(C) of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C.  
8 360m(b)(2)(C)); and

9 (3) the results of an audit of the performance  
10 of select persons accredited under such program.

11 **SEC. 814. REPORTING ON PENDING GENERIC DRUG APPLI-**  
12 **CATIONS AND PRIORITY REVIEW APPLICA-**  
13 **TIONS.**

14 Section 807 of the FDA Reauthorization Act of 2017  
15 (Public Law 115–52) is amended, in the matter preceding  
16 paragraph (1), by striking “2022” and inserting “2027”.

17 **SEC. 815. FDA WORKFORCE IMPROVEMENTS.**

18 Section 714A of the Federal Food, Drug, and Cos-  
19 metic Act (21 U.S.C. 379d–3a) is amended—

20 (1) in subsection (a), by striking “medical prod-  
21 ucts” and inserting “products regulated by the Food  
22 and Drug Administration”; and

23 (2) by striking subsection (d) and inserting the  
24 following:

1       “(d) AGENCY-WIDE STRATEGIC WORKFORCE  
2 PLAN.—

3           “(1) IN GENERAL.—Not later than 1 year after  
4 the date of enactment of the Food and Drug  
5 Amendments of 2022, the Commissioner of Food  
6 and Drugs shall develop and begin implementation  
7 of an agency-wide strategic workforce plan at the  
8 Food and Drug Administration, which shall in-  
9 clude—

10           “(A) agency-wide human capital goals and  
11 strategies;

12           “(B) performance measures, benchmarks,  
13 or other elements to facilitate the monitoring  
14 and evaluation of the progress made toward  
15 such goals and the effectiveness of such strate-  
16 gies; and

17           “(C) a process for updating such plan  
18 based on timely and relevant information on an  
19 ongoing basis.

20           “(2) REPORT TO CONGRESS.—Not later than  
21 18 months after the date of enactment of the Food  
22 and Drug Amendments of 2022, the Secretary shall  
23 submit to the Committee on Energy and Commerce  
24 of the House of Representatives and the Committee  
25 on Health, Education, Labor, and Pensions of the

1 Senate a report describing the plan under paragraph  
2 (1) and the status of its implementation.”.

3 **TITLE IX—MISCELLANEOUS**

4 **SEC. 901. DETERMINATION OF BUDGETARY EFFECTS.**

5 The budgetary effects of this Act, for the purpose of  
6 complying with the Statutory Pay-As-You-Go Act of 2010,  
7 shall be determined by reference to the latest statement  
8 titled “Budgetary Effects of PAYGO Legislation” for this  
9 Act, submitted for printing in the Congressional Record  
10 by the Chairman of the House Budget Committee, pro-  
11 vided that such statement has been submitted prior to the  
12 vote on passage.

13 **SEC. 902. MEDICAID IMPROVEMENT FUND.**

14 Section 1941(b)(3)(A) of the Social Security Act (42  
15 U.S.C. 1396w–1(b)(3)(A)) is amended by striking “\$0”  
16 and inserting “\$450,000,000”.

Passed the House of Representatives June 8, 2022.

Attest:

*Clerk.*

117<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 7667**

---

**AN ACT**

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.