

AMENDMENT TO
RULES COMMITTEE PRINT 116-14
OFFERED BY MR. BURGESS OF TEXAS

Strike section 2 and all that follows and insert the following:

1 SEC. 2. TABLE OF CONTENTS.

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

Section 1. Short title.

Sec. 2. Table of contents.

TITLE I—LOWERING PRESCRIPTION DRUG COSTS

Subtitle A—Bringing Low-cost Options and Competition While Keeping
Incentives for New Generics

Sec. 101. Change conditions of first generic exclusivity to spur access and competition.

Subtitle B—Protecting Consumer Access to Generic Drugs

Sec. 111. Unlawful agreements.

Sec. 112. Notice and certification of agreements.

Sec. 113. Forfeiture of 180-day exclusivity period.

Sec. 114. Commission litigation authority.

Sec. 115. Statute of limitations.

Subtitle C—Creating and Restoring Equal Access to Equivalent Samples

Sec. 121. Actions for delays of generic drugs and biosimilar biological products.

Sec. 122. REMS approval process for subsequent filers.

Sec. 123. Rule of construction.

TITLE II—EXTENSION OF PUBLIC HEALTH PROGRAMS

Sec. 201. Extension for community health centers, the National Health Service Corps, and teaching health centers that operate GME programs.

Sec. 202. Extension for special diabetes programs.

Sec. 203. Extension for family-to-family health information centers.

Sec. 204. Extension for sexual risk avoidance education and personal responsibility education.

1 **TITLE I—LOWERING**
2 **PRESCRIPTION DRUG COSTS**
3 **Subtitle A—Bringing Low-cost Op-**
4 **tions and Competition While**
5 **Keeping Incentives for New**
6 **Generics**

7 **SEC. 101. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**
8 **SIVITY TO SPUR ACCESS AND COMPETITION.**

9 Section 505(j)(5)(B)(iv) of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amend-
11 ed—

12 (1) in subclause (I), by striking “180 days
13 after” and all that follows through the period at the
14 end and inserting the following: “180 days after the
15 earlier of—

16 “(aa) the date of the first com-
17 mercial marketing of the drug (includ-
18 ing the commercial marketing of the
19 listed drug) by any first applicant; or

20 “(bb) the applicable date speci-
21 fied in subclause (III).”; and

22 (2) by adding at the end the following new sub-
23 clause:

24 “(III) APPLICABLE DATE.—The appli-
25 cable date specified in this subclause, with

1 respect to an application for a drug de-
2 scribed in subclause (I), is the date on
3 which each of the following conditions is
4 first met:

5 “(aa) The approval of such an
6 application could be made effective,
7 but for the eligibility of a first appli-
8 cant for 180-day exclusivity under
9 this clause.

10 “(bb) At least 30 months have
11 passed since the date of submission of
12 an application for the drug by at least
13 one first applicant.

14 “(cc) Approval of an application
15 for the drug submitted by at least one
16 first applicant is not precluded under
17 clause (iii).

18 “(dd) No application for the drug
19 submitted by any first applicant is ap-
20 proved at the time the conditions
21 under items (aa), (bb), and (cc) are
22 all met, regardless of whether such an
23 application is subsequently ap-
24 proved.”.

1 **Subtitle B—Protecting Consumer**
2 **Access to Generic Drugs**

3 **SEC. 111. UNLAWFUL AGREEMENTS.**

4 (a) AGREEMENTS PROHIBITED.—Subject to sub-
5 sections (b) and (c), it shall be unlawful for an NDA or
6 BLA holder and a subsequent filer (or for two subsequent
7 filers) to enter into, or carry out, an agreement resolving
8 or settling a covered patent infringement claim on a final
9 or interim basis if under such agreement—

10 (1) a subsequent filer directly or indirectly re-
11 ceives from such holder (or in the case of such an
12 agreement between two subsequent filers, the other
13 subsequent filer) anything of value, including a li-
14 cense; and

15 (2) the subsequent filer agrees to limit or fore-
16 go research on, or development, manufacturing,
17 marketing, or sales, for any period of time, of the
18 covered product that is the subject of the application
19 described in subparagraph (A) or (B) of subsection
20 (g)(8).

21 (b) EXCLUSION.—It shall not be unlawful under sub-
22 section (a) if a party to an agreement described in such
23 subsection demonstrates by clear and convincing evidence
24 that the value described in subsection (a)(1) is compensa-

1 tion solely for other goods or services that the subsequent
2 filer has promised to provide.

3 (c) LIMITATION.—Nothing in this section shall pro-
4 hibit an agreement resolving or settling a covered patent
5 infringement claim in which the consideration granted by
6 the NDA or BLA holder to the subsequent filer (or from
7 one subsequent filer to another) as part of the resolution
8 or settlement includes only one or more of the following:

9 (1) The right to market the covered product
10 that is the subject of the application described in
11 subparagraph (A) or (B) of subsection (g)(8) in the
12 United States before the expiration of—

13 (A) any patent that is the basis of the cov-
14 ered patent infringement claim; or

15 (B) any patent right or other statutory ex-
16 clusivity that would prevent the marketing of
17 such covered product.

18 (2) A payment for reasonable litigation ex-
19 penses not to exceed \$7,500,000 in the aggregate.

20 (3) A covenant not to sue on any claim that
21 such covered product infringes a patent.

22 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-
23 SION.—

1 (1) GENERAL APPLICATION.—The requirements
2 of this section apply, according to their terms, to an
3 NDA or BLA holder or subsequent filer that is—

4 (A) a person, partnership, or corporation
5 over which the Commission has authority pur-
6 suant to section 5(a)(2) of the Federal Trade
7 Commission Act (15 U.S.C. 45(a)(2)); or

8 (B) a person, partnership, or corporation
9 over which the Commission would have author-
10 ity pursuant to such section but for the fact
11 that such person, partnership, or corporation is
12 not organized to carry on business for its own
13 profit or that of its members.

14 (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES
15 ENFORCEMENT AUTHORITY.—

16 (A) IN GENERAL.—A violation of this sec-
17 tion shall be treated as an unfair or deceptive
18 act or practice in violation of section 5(a)(1) of
19 the Federal Trade Commission Act (15 U.S.C.
20 45(a)(1)).

21 (B) POWERS OF COMMISSION.—Except as
22 provided in subparagraph (C) and paragraphs
23 (1)(B) and (3)—

24 (i) the Commission shall enforce this
25 section in the same manner, by the same

1 means, and with the same jurisdiction,
2 powers, and duties as though all applicable
3 terms and provisions of the Federal Trade
4 Commission Act (15 U.S.C. 41 et seq.)
5 were incorporated into and made a part of
6 this section; and

7 (ii) any NDA or BLA holder or subse-
8 quent filer that violates this section shall
9 be subject to the penalties and entitled to
10 the privileges and immunities provided in
11 the Federal Trade Commission Act.

12 (C) JUDICIAL REVIEW.—In the case of a
13 cease and desist order issued by the Commis-
14 sion under section 5 of the Federal Trade Com-
15 mission Act (15 U.S.C. 45) for violation of this
16 section, a party to such order may obtain judi-
17 cial review of such order as provided in such
18 section 5, except that—

19 (i) such review may only be obtained
20 in—

21 (I) the United States Court of
22 Appeals for the District of Columbia
23 Circuit;

24 (II) the United States Court of
25 Appeals for the circuit in which the

1 ultimate parent entity, as defined in
2 section 801.1(a)(3) of title 16, Code
3 of Federal Regulations, or any suc-
4 cessor thereto, of the NDA or BLA
5 holder (if any such holder is a party
6 to such order) is incorporated as of
7 the date that the application described
8 in subparagraph (A) or (B) of sub-
9 section (g)(8) or an approved applica-
10 tion that is deemed to be a license for
11 a biological product under section
12 351(k) of the Public Health Service
13 Act (42 U.S.C. 262(k)) pursuant to
14 section 7002(e)(4) of the Biologics
15 Price Competition and Innovation Act
16 of 2009 (Public Law 111–148; 124
17 Stat. 817) is submitted to the Com-
18 missioner of Food and Drugs; or

19 (III) the United States Court of
20 Appeals for the circuit in which the
21 ultimate parent entity, as so defined,
22 of any subsequent filer that is a party
23 to such order is incorporated as of the
24 date that the application described in
25 subparagraph (A) or (B) of subsection

1 (g)(8) is submitted to the Commis-
2 sioner of Food and Drugs; and

3 (ii) the petition for review shall be
4 filed in the court not later than 30 days
5 after such order is served on the party
6 seeking review.

7 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

8 (A) CIVIL PENALTY.—The Commission
9 may commence a civil action to recover a civil
10 penalty in a district court of the United States
11 against any NDA or BLA holder or subsequent
12 filer that violates this section.

13 (B) SPECIAL RULE FOR RECOVERY OF
14 PENALTY IF CEASE AND DESIST ORDER
15 ISSUED.—

16 (i) IN GENERAL.—If the Commission
17 has issued a cease and desist order in a
18 proceeding under section 5 of the Federal
19 Trade Commission Act (15 U.S.C. 45) for
20 violation of this section—

21 (I) the Commission may com-
22 mence a civil action under subpara-
23 graph (A) to recover a civil penalty
24 against any party to such order at
25 any time before the expiration of the

1 1-year period beginning on the date
2 on which such order becomes final
3 under section 5(g) of such Act (15
4 U.S.C. 45(g)); and

5 (II) in such civil action, the find-
6 ings of the Commission as to the ma-
7 terial facts in such proceeding shall be
8 conclusive, unless—

9 (aa) the terms of such order
10 expressly provide that the Com-
11 mission's findings shall not be
12 conclusive; or

13 (bb) such order became final
14 by reason of section 5(g)(1) of
15 such Act (15 U.S.C. 45(g)(1)), in
16 which case such findings shall be
17 conclusive if supported by evi-
18 dence.

19 (ii) RELATIONSHIP TO PENALTY FOR
20 VIOLATION OF AN ORDER.—The penalty
21 provided in clause (i) for violation of this
22 section is separate from and in addition to
23 any penalty that may be incurred for viola-
24 tion of an order of the Commission under

1 section 5(l) of the Federal Trade Commis-
2 sion Act (15 U.S.C. 45(l)).

3 (C) AMOUNT OF PENALTY.—

4 (i) IN GENERAL.—The amount of a
5 civil penalty imposed in a civil action under
6 subparagraph (A) on a party to an agree-
7 ment described in subsection (a) shall be
8 sufficient to deter violations of this section,
9 but in no event greater than—

10 (I) if such party is the NDA or
11 BLA holder (or, in the case of an
12 agreement between two subsequent fil-
13 ers, the subsequent filer who gave the
14 value described in subsection (a)(1)),
15 the greater of—

16 (aa) 3 times the value re-
17 ceived by such NDA or BLA
18 holder (or by such subsequent
19 filer) that is reasonably attrib-
20 utable to the violation of this sec-
21 tion; or

22 (bb) 3 times the value given
23 to the subsequent filer (or to the
24 other subsequent filer) reason-

1 ably attributable to the violation
2 of this section; and

3 (II) if such party is the subse-
4 quent filer (or, in the case of an
5 agreement between two subsequent fil-
6 ers, the subsequent filer who received
7 the value described in subsection
8 (a)(1)), 3 times the value received by
9 such subsequent filer that is reason-
10 ably attributable to the violation of
11 this section.

12 (ii) FACTORS FOR CONSIDERATION.—

13 In determining such amount, the court
14 shall take into account—

15 (I) the nature, circumstances, ex-
16 tent, and gravity of the violation;

17 (II) with respect to the violator,
18 the degree of culpability, any history
19 of violations, the ability to pay, any
20 effect on the ability to continue doing
21 business, profits earned by the NDA
22 or BLA holder (or, in the case of an
23 agreement between two subsequent fil-
24 ers, the subsequent filer who gave the
25 value described in subsection (a)(1)),

1 compensation received by the subse-
2 quent filer (or, in the case of an
3 agreement between two subsequent fil-
4 ers, the subsequent filer who received
5 the value described in subsection
6 (a)(1)), and the amount of commerce
7 affected; and

8 (III) other matters that justice
9 requires.

10 (D) INJUNCTIONS AND OTHER EQUITABLE
11 RELIEF.—In a civil action under subparagraph
12 (A), the United States district courts are em-
13 powered to grant mandatory injunctions and
14 such other and further equitable relief as they
15 deem appropriate.

16 (4) REMEDIES IN ADDITION.—Remedies pro-
17 vided in this subsection are in addition to, and not
18 in lieu of, any other remedy provided by Federal
19 law.

20 (5) PRESERVATION OF AUTHORITY OF COMMIS-
21 SION.—Nothing in this section shall be construed to
22 affect any authority of the Commission under any
23 other provision of law.

24 (e) FEDERAL TRADE COMMISSION RULEMAKING.—
25 The Commission may, in its discretion, by rule promul-

1 gated under section 553 of title 5, United States Code,
2 exempt from this section certain agreements described in
3 subsection (a) if the Commission finds such agreements
4 to be in furtherance of market competition and for the
5 benefit of consumers.

6 (f) ANTITRUST LAWS.—Nothing in this section shall
7 modify, impair, limit, or supersede the applicability of the
8 antitrust laws as defined in subsection (a) of the first sec-
9 tion of the Clayton Act (15 U.S.C. 12(a)), and of section
10 5 of the Federal Trade Commission Act (15 U.S.C. 45)
11 to the extent that such section 5 applies to unfair methods
12 of competition. Nothing in this section shall modify, im-
13 pair, limit, or supersede the right of a subsequent filer
14 to assert claims or counterclaims against any person,
15 under the antitrust laws or other laws relating to unfair
16 competition.

17 (g) DEFINITIONS.—In this section:

18 (1) AGREEMENT RESOLVING OR SETTling A
19 COVERED PATENT INFRINGEMENT CLAIM.—The
20 term “agreement resolving or settling a covered pat-
21 ent infringement claim” means any agreement
22 that—

23 (A) resolves or settles a covered patent in-
24 fringement claim; or

1 (B) is contingent upon, provides for a con-
2 tingent condition for, or is otherwise related to
3 the resolution or settlement of a covered patent
4 infringement claim.

5 (2) COMMISSION.—The term “Commission”
6 means the Federal Trade Commission.

7 (3) COVERED PATENT INFRINGEMENT CLAIM.—
8 The term “covered patent infringement claim”
9 means an allegation made by the NDA or BLA hold-
10 er to a subsequent filer (or, in the case of an agree-
11 ment between two subsequent filers, by one subse-
12 quent filer to another), whether or not included in
13 a complaint filed with a court of law, that—

14 (A) the submission of the application de-
15 scribed in subparagraph (A) or (B) of para-
16 graph (9), or the manufacture, use, offering for
17 sale, sale, or importation into the United States
18 of a covered product that is the subject of such
19 an application—

20 (i) in the case of an agreement be-
21 tween an NDA or BLA holder and a sub-
22 sequent filer, infringes any patent owned
23 by, or exclusively licensed to, the NDA or
24 BLA holder of the covered product; or

1 (ii) in the case of an agreement be-
2 tween two subsequent filers, infringes any
3 patent owned by the subsequent filer; or

4 (B) in the case of an agreement between
5 an NDA or BLA holder and a subsequent filer,
6 the covered product to be manufactured under
7 such application uses a covered product as
8 claimed in a published patent application.

9 (4) COVERED PRODUCT.—The term “covered
10 product” means a drug (as defined in section 201(g)
11 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 321(g))), including a biological product (as
13 defined in section 351(i) of the Public Health Serv-
14 ice Act (42 U.S.C. 262(i)).

15 (5) NDA OR BLA HOLDER.—The term “NDA
16 or BLA holder” means—

17 (A) the holder of—

18 (i) an approved new drug application
19 filed under section 505(b)(1) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21
21 U.S.C. 355(b)(1)) for a covered product;
22 or

23 (ii) a biologics license application filed
24 under section 351(a) of the Public Health

1 Service Act (42 U.S.C. 262(a)) with re-
2 spect to a biological product;

3 (B) a person owning or controlling enforce-
4 ment of the patent on—

5 (i) the list published under section
6 505(j)(7) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-
8 nection with the application described in
9 subparagraph (A)(i); or

10 (ii) any list published under section
11 351 of the Public Health Service Act (42
12 U.S.C. 262) comprised of patents associ-
13 ated with biologics license applications filed
14 under section 351(a) of such Act (42
15 U.S.C. 262(a)); or

16 (C) the predecessors, subsidiaries, divi-
17 sions, groups, and affiliates controlled by, con-
18 trolling, or under common control with any en-
19 tity described in subparagraph (A) or (B) (such
20 control to be presumed by direct or indirect
21 share ownership of 50 percent or greater), as
22 well as the licensees, licensors, successors, and
23 assigns of each of the entities.

1 (6) PATENT.—The term “patent” means a pat-
2 ent issued by the United States Patent and Trade-
3 mark Office.

4 (7) STATUTORY EXCLUSIVITY.—The term
5 “statutory exclusivity” means those prohibitions on
6 the submission or approval of drug applications
7 under clauses (ii) through (iv) of section
8 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)
9 through (iv) of section 505(j)(5)(F) (5-year and 3-
10 year exclusivity), section 505(j)(5)(B)(iv) (180-day
11 exclusivity), section 527 (orphan drug exclusivity),
12 section 505A (pediatric exclusivity), or section 505E
13 (qualified infectious disease product exclusivity) of
14 the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),
16 360cc, 355a, 355f), or prohibitions on the submis-
17 sion or licensing of biologics license applications
18 under section 351(k)(6) (interchangeable biological
19 product exclusivity) or section 351(k)(7) (biological
20 product reference product exclusivity) of the Public
21 Health Service Act (42 U.S.C. 262(k)(6), (7)).

22 (8) SUBSEQUENT FILER.—The term “subse-
23 quent filer” means—

24 (A) in the case of a drug, a party that
25 owns or controls an abbreviated new drug appli-

1 cation submitted pursuant to section 505(j) of
2 the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 355(j)) or a new drug application sub-
4 mitted pursuant to section 505(b)(2) of the
5 Federal Food, Drug, and Cosmetic Act
6 (21U.S.C. 355(b)(2)) and filed under section
7 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or
8 has the exclusive rights to distribute the cov-
9 ered product that is the subject of such applica-
10 tion; or

11 (B) in the case of a biological product, a
12 party that owns or controls an application filed
13 with the Food and Drug Administration under
14 section 351(k) of the Public Health Service Act
15 (42 U.S.C. 262(k)) or has the exclusive rights
16 to distribute the biological product that is the
17 subject of such application.

18 (h) EFFECTIVE DATE.—This section applies with re-
19 spect to agreements described in subsection (a) entered
20 into on or after the date of the enactment of this Act.

21 **SEC. 112. NOTICE AND CERTIFICATION OF AGREEMENTS.**

22 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)
23 of the Medicare Prescription Drug, Improvement, and
24 Modernization Act of 2003 (21 U.S.C. 355 note) is
25 amended by inserting “or the owner of a patent for which

1 a claim of infringement could reasonably be asserted
2 against any person for making, using, offering to sell, sell-
3 ing, or importing into the United States a biological prod-
4 uct that is the subject of a biosimilar biological product
5 application” before the period at the end.

6 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
7 of such Act (21 U.S.C. 355 note) is amended by adding
8 at the end the following:

9 “(d) CERTIFICATION.—The Chief Executive Officer
10 or the company official responsible for negotiating any
11 agreement under subsection (a) or (b) that is required to
12 be filed under subsection (c) shall, within 30 days of such
13 filing, execute and file with the Assistant Attorney General
14 and the Commission a certification as follows: ‘I declare
15 that the following is true, correct, and complete to the best
16 of my knowledge: The materials filed with the Federal
17 Trade Commission and the Department of Justice under
18 section 1112 of the Medicare Prescription Drug, Improve-
19 ment, and Modernization Act of 2003, with respect to the
20 agreement referenced in this certification—

21 “(1) represent the complete, final, and exclu-
22 sive agreement between the parties;

23 “(2) include any ancillary agreements that are
24 contingent upon, provide a contingent condition for,

1 were entered into within 30 days of, or are otherwise
2 related to, the referenced agreement; and

3 ““(3) include written descriptions of any oral
4 agreements, representations, commitments, or prom-
5 ises between the parties that are responsive to sub-
6 section (a) or (b) of such section 1112 and have not
7 been reduced to writing.’”.

8 **SEC. 113. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

9 Section 505(j)(5)(D)(i)(V) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))
11 is amended by inserting “section 111 of the Strengthening
12 Health Care and Lowering Prescription Drug Costs Act
13 or” after “that the agreement has violated”.

14 **SEC. 114. COMMISSION LITIGATION AUTHORITY.**

15 Section 16(a)(2) of the Federal Trade Commission
16 Act (15 U.S.C. 56(a)(2)) is amended—

17 (1) in subparagraph (D), by striking “or” after
18 the semicolon;

19 (2) in subparagraph (E), by inserting “or”
20 after the semicolon; and

21 (3) by inserting after subparagraph (E) the fol-
22 lowing:

23 “(F) under section 111(d)(3)(A) of the
24 Strengthening Health Care and Lowering Pre-
25 scription Drug Costs Act;”.

1 **SEC. 115. STATUTE OF LIMITATIONS.**

2 (a) IN GENERAL.—Except as provided in subsection
3 (b), the Commission shall commence any administrative
4 proceeding or civil action to enforce section 111 of this
5 Act not later than 6 years after the date on which the
6 parties to the agreement file the Notice of Agreement as
7 provided by section 1112(c)(2) and (d) of the Medicare
8 Prescription Drug, Improvement, and Modernization Act
9 of 2003 (21 U.S.C. 355 note).

10 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND
11 DESIST ORDER.—If the Commission has issued a cease
12 and desist order under section 5 of the Federal Trade
13 Commission Act (15 U.S.C. 45) for violation of section
14 111 of this Act and the proceeding for the issuance of
15 such order was commenced within the period required by
16 subsection (a) of this section, such subsection does not
17 prohibit the commencement, after such period, of a civil
18 action under section 111(d)(3)(A) against a party to such
19 order or a civil action under subsection (l) of such section
20 5 for violation of such order.

21 **Subtitle C—Creating and Restoring**
22 **Equal Access to Equivalent**
23 **Samples**

24 **SEC. 121. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
25 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

26 (a) DEFINITIONS.—In this section—

1 (1) the term “commercially reasonable, market-
2 based terms” means—

3 (A) a nondiscriminatory price for the sale
4 of the covered product at or below, but not
5 greater than, the most recent wholesale acquisi-
6 tion cost for the drug, as defined in section
7 1847A(c)(6)(B) of the Social Security Act (42
8 U.S.C. 1395w-3a(c)(6)(B));

9 (B) a schedule for delivery that results in
10 the transfer of the covered product to the eligi-
11 ble product developer consistent with the timing
12 under subsection (b)(2)(A)(iv); and

13 (C) no additional conditions are imposed
14 on the sale of the covered product;

15 (2) the term “covered product”—

16 (A) means—

17 (i) any drug approved under sub-
18 section (c) or (j) of section 505 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21
20 U.S.C. 355) or biological product licensed
21 under subsection (a) or (k) of section 351
22 of the Public Health Service Act (42
23 U.S.C. 262);

24 (ii) any combination of a drug or bio-
25 logical product described in clause (i); or

1 (iii) when reasonably necessary to
2 support approval of an application under
3 section 505 of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 355), or sec-
5 tion 351 of the Public Health Service Act
6 (42 U.S.C. 262), as applicable, or other-
7 wise meet the requirements for approval
8 under either such section, any product, in-
9 cluding any device, that is marketed or in-
10 tended for use with such a drug or biologi-
11 cal product; and

12 (B) does not include any drug or biological
13 product that appears on the drug shortage list
14 in effect under section 506E of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 356e), unless—

17 (i) the drug or biological product has
18 been on the drug shortage list in effect
19 under such section 506E continuously for
20 more than 6 months; or

21 (ii) the Secretary determines that in-
22 clusion of the drug or biological product as
23 a covered product is likely to contribute to
24 alleviating or preventing a shortage.

1 (3) the term “device” has the meaning given
2 the term in section 201 of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 321);

4 (4) the term “eligible product developer” means
5 a person that seeks to develop a product for ap-
6 proval pursuant to an application for approval under
7 subsection (b)(2) or (j) of section 505 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
9 for licensing pursuant to an application under sec-
10 tion 351(k) of the Public Health Service Act (42
11 U.S.C. 262(k));

12 (5) the term “license holder” means the holder
13 of an application approved under subsection (c) or
14 (j) of section 505 of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
16 cense under subsection (a) or (k) of section 351 of
17 the Public Health Service Act (42 U.S.C. 262) for
18 a covered product;

19 (6) the term “REMS” means a risk evaluation
20 and mitigation strategy under section 505–1 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355–1);

23 (7) the term “REMS with ETASU” means a
24 REMS that contains elements to assure safe use

1 under section 505–1(f) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 355–1(f));

3 (8) the term “Secretary” means the Secretary
4 of Health and Human Services;

5 (9) the term “single, shared system of elements
6 to assure safe use” means a single, shared system
7 of elements to assure safe use under section 505–
8 1(f) of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 355–1(f)); and

10 (10) the term “sufficient quantities” means an
11 amount of a covered product that the eligible prod-
12 uct developer determines allows it to—

13 (A) conduct testing to support an applica-
14 tion under—

15 (i) subsection (b)(2) or (j) of section
16 505 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 355); or

18 (ii) section 351(k) of the Public
19 Health Service Act (42 U.S.C. 262(k));
20 and

21 (B) fulfill any regulatory requirements re-
22 lating to approval of such an application.

23 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-
24 CIENT QUANTITIES OF A COVERED PRODUCT.—

1 (1) IN GENERAL.—An eligible product developer
2 may bring a civil action against the license holder
3 for a covered product seeking relief under this sub-
4 section in an appropriate district court of the United
5 States alleging that the license holder has declined
6 to provide sufficient quantities of the covered prod-
7 uct to the eligible product developer on commercially
8 reasonable, market-based terms.

9 (2) ELEMENTS.—

10 (A) IN GENERAL.—To prevail in a civil ac-
11 tion brought under paragraph (1), an eligible
12 product developer shall prove, by a preponder-
13 ance of the evidence—

14 (i) that—

15 (I) the covered product is not
16 subject to a REMS with ETASU; or

17 (II) if the covered product is sub-
18 ject to a REMS with ETASU—

19 (aa) the eligible product de-
20 veloper has obtained a covered
21 product authorization from the
22 Secretary in accordance with sub-
23 paragraph (B); and

24 (bb) the eligible product de-
25 veloper has provided a copy of

1 the covered product authorization
2 to the license holder;

3 (ii) that, as of the date on which the
4 civil action is filed, the product developer
5 has not obtained sufficient quantities of
6 the covered product on commercially rea-
7 sonable, market-based terms;

8 (iii) that the eligible product developer
9 has requested to purchase sufficient quan-
10 tities of the covered product from the li-
11 cense holder; and

12 (iv) that the license holder has not de-
13 livered to the eligible product developer
14 sufficient quantities of the covered product
15 on commercially reasonable, market-based
16 terms—

17 (I) for a covered product that is
18 not subject to a REMS with ETASU,
19 by the date that is 31 days after the
20 date on which the license holder re-
21 ceived the request for the covered
22 product; and

23 (II) for a covered product that is
24 subject to a REMS with ETASU, by
25 31 days after the later of—

1 (aa) the date on which the
2 license holder received the re-
3 quest for the covered product; or

4 (bb) the date on which the
5 license holder received a copy of
6 the covered product authorization
7 issued by the Secretary in ac-
8 cordance with subparagraph (B).

9 (B) AUTHORIZATION FOR COVERED PROD-
10 UCT SUBJECT TO A REMS WITH ETASU.—

11 (i) REQUEST.—An eligible product de-
12 veloper may submit to the Secretary a
13 written request for the eligible product de-
14 veloper to be authorized to obtain suffi-
15 cient quantities of an individual covered
16 product subject to a REMS with ETASU.

17 (ii) AUTHORIZATION.—Not later than
18 120 days after the date on which a request
19 under clause (i) is received, the Secretary
20 shall, by written notice, authorize the eligi-
21 ble product developer to obtain sufficient
22 quantities of an individual covered product
23 subject to a REMS with ETASU for pur-
24 poses of—

1 (I) development and testing that
2 does not involve human clinical trials,
3 if the eligible product developer has
4 agreed to comply with any conditions
5 the Secretary determines necessary; or

6 (II) development and testing that
7 involves human clinical trials, if the
8 eligible product developer has—

9 (aa)(AA) submitted proto-
10 cols, informed consent docu-
11 ments, and informational mate-
12 rials for testing that include pro-
13 tections that provide safety pro-
14 tections comparable to those pro-
15 vided by the REMS for the cov-
16 ered product; or

17 (BB) otherwise satisfied the
18 Secretary that such protections
19 will be provided; and

20 (bb) met any other require-
21 ments the Secretary may estab-
22 lish.

23 (iii) NOTICE.—A covered product au-
24 thorization issued under this subparagraph
25 shall state that the provision of the covered

1 product by the license holder under the
2 terms of the authorization will not be a
3 violation of the REMS for the covered
4 product.

5 (3) AFFIRMATIVE DEFENSE.—In a civil action
6 brought under paragraph (1), it shall be an affirma-
7 tive defense, on which the defendant has the burden
8 of persuasion by a preponderance of the evidence—

9 (A) that, on the date on which the eligible
10 product developer requested to purchase suffi-
11 cient quantities of the covered product from the
12 license holder—

13 (i) neither the license holder nor any
14 of its agents, wholesalers, or distributors
15 was engaged in the manufacturing or com-
16 mercial marketing of the covered product;
17 and

18 (ii) neither the license holder nor any
19 of its agents, wholesalers, or distributors
20 otherwise had access to inventory of the
21 covered product to supply to the eligible
22 product developer on commercially reason-
23 able, market-based terms;

24 (B) that—

1 (i) the license holder sells the covered
2 product through agents, distributors, or
3 wholesalers;

4 (ii) the license holder has placed no
5 restrictions, explicit or implicit, on its
6 agents, distributors, or wholesalers to sell
7 covered products to eligible product devel-
8 opers; and

9 (iii) the covered product can be pur-
10 chased by the eligible product developer in
11 sufficient quantities on commercially rea-
12 sonable, market-based terms from the
13 agents, distributors, or wholesalers of the
14 license holder; or

15 (C) that the license holder made an offer
16 to sell sufficient quantities of the covered prod-
17 uct to the eligible product developer at commer-
18 cially reasonable market-based terms—

19 (i) for a covered product that is not
20 subject to a REMS with ETASU, by the
21 date that is 14 days after the date on
22 which the license holder received the re-
23 quest for the covered product, and the eli-
24 gible product developer did not accept such
25 offer by the date that is 7 days after the

1 date on which the eligible product devel-
2 oper received such offer from the license
3 holder; or

4 (ii) for a covered product that is sub-
5 ject to a REMS with ETASU, by the date
6 that is 20 days after the date on which the
7 license holder received the request for the
8 covered product, and the eligible product
9 developer did not accept such offer by the
10 date that is 10 days after the date on
11 which the eligible product developer re-
12 ceived such offer from the license holder.

13 (4) METHODS FOR TRANSMISSION OF RE-
14 QUESTS FOR COVERED PRODUCTS.—A written re-
15 quest for a covered product, offer to sell a covered
16 product, or acceptance of such an offer between the
17 eligible product developer and the license holder
18 shall be made by—

19 (A) certified or registered mail with return
20 receipt requested;

21 (B) personal delivery; or

22 (C) electronic means.

23 (5) REMEDIES.—

1 (A) IN GENERAL.—If an eligible product
2 developer prevails in a civil action brought
3 under paragraph (1), the court shall—

4 (i) order the license holder to provide
5 to the eligible product developer without
6 delay sufficient quantities of the covered
7 product on commercially reasonable, mar-
8 ket-based terms;

9 (ii) award to the eligible product de-
10 veloper reasonable attorney’s fees and costs
11 of the civil action; and

12 (iii) award to the eligible product de-
13 veloper a monetary amount sufficient to
14 deter the license holder from failing to pro-
15 vide eligible product developers with suffi-
16 cient quantities of a covered product on
17 commercially reasonable, market-based
18 terms, if the court finds, by a preponder-
19 ance of the evidence—

20 (I) that the license holder delayed
21 providing sufficient quantities of the
22 covered product to the eligible product
23 developer without a legitimate busi-
24 ness justification; or

1 (II) that the license holder failed
2 to comply with an order issued under
3 clause (i).

4 (B) MAXIMUM MONETARY AMOUNT.—A
5 monetary amount awarded under subparagraph
6 (A)(iii) shall not be greater than the revenue
7 that the license holder earned on the covered
8 product during the period—

9 (i) beginning on—

10 (I) for a covered product that is
11 not subject to a REMS with ETASU,
12 the date that is 31 days after the date
13 on which the license holder received
14 the request; or

15 (II) for a covered product that is
16 subject to a REMS with ETASU, the
17 date that is 31 days after the later
18 of—

19 (aa) the date on which the
20 license holder received the re-
21 quest; or

22 (bb) the date on which the
23 license holder received a copy of
24 the covered product authorization
25 issued by the Secretary in ac-

1 cordance with paragraph (2)(B);

2 and

3 (ii) ending on the date on which the
4 eligible product developer received suffi-
5 cient quantities of the covered product.

6 (C) AVOIDANCE OF DELAY.—The court
7 may issue an order under subparagraph (A)(i)
8 before conducting further proceedings that may
9 be necessary to determine whether the eligible
10 product developer is entitled to an award under
11 clause (ii) or (iii) of subparagraph (A), or the
12 amount of any such award.

13 (c) LIMITATION OF LIABILITY.—A license holder for
14 a covered product shall not be liable for any claim under
15 Federal, State, or local law arising out of the failure of
16 an eligible product developer to follow adequate safeguards
17 to assure safe use of the covered product during develop-
18 ment or testing activities described in this section, includ-
19 ing transportation, handling, use, or disposal of the cov-
20 ered product by the eligible product developer.

21 (d) NO VIOLATION OF REMS.—Section 505–1 of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–
23 1) is amended by adding at the end the following new sub-
24 section:

1 “(1) PROVISION OF SAMPLES NOT A VIOLATION OF
2 STRATEGY.—The provision of samples of a covered prod-
3 uct to an eligible product developer (as those terms are
4 defined in section 121(a) of the Strengthening Health
5 Care and Lowering Prescription Drug Costs Act) shall not
6 be considered a violation of the requirements of any risk
7 evaluation and mitigation strategy that may be in place
8 under this section for such drug.”.

9 (e) RULE OF CONSTRUCTION.—

10 (1) DEFINITION.—In this subsection, the term
11 “antitrust laws”—

12 (A) has the meaning given the term in
13 subsection (a) of the first section of the Clayton
14 Act (15 U.S.C. 12); and

15 (B) includes section 5 of the Federal
16 Trade Commission Act (15 U.S.C. 45) to the
17 extent that such section applies to unfair meth-
18 ods of competition.

19 (2) ANTITRUST LAWS.—Nothing in this section
20 shall be construed to limit the operation of any pro-
21 vision of the antitrust laws.

1 **SEC. 122. REMS APPROVAL PROCESS FOR SUBSEQUENT**
2 **FILERS.**

3 Section 505–1 of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355–1), as amended by section 121,
5 is further amended—

6 (1) in subsection (g)(4)(B)—

7 (A) in clause (i) by striking “or” after the
8 semicolon;

9 (B) in clause (ii) by striking the period at
10 the end and inserting “; or”; and

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

12 “(iii) accommodate different, com-
13 parable aspects of the elements to assure
14 safe use for a drug that is the subject of
15 an application under section 505(j), and
16 the applicable listed drug.”;

17 (2) in subsection (i)(1), by striking subpara-
18 graph (C) and inserting the following:

19 “(C)(i) Elements to assure safe use, if re-
20 quired under subsection (f) for the listed drug,
21 which, subject to clause (ii), for a drug that is
22 the subject of an application under section
23 505(j) may use—

24 “(I) a single, shared system with the
25 listed drug under subsection (f); or

1 “(II) a different, comparable aspect of
2 the elements to assure safe use under sub-
3 section (f).

4 “(ii) The Secretary may require a drug
5 that is the subject of an application under sec-
6 tion 505(j) and the listed drug to use a single,
7 shared system under subsection (f), if the Sec-
8 retary determines that no different, comparable
9 aspect of the elements to assure safe use could
10 satisfy the requirements of subsection (f).”;

11 (3) in subsection (i), by adding at the end the
12 following:

13 “(3) SHARED REMS.—If the Secretary ap-
14 proves, in accordance with paragraph (1)(C)(i)(II), a
15 different, comparable aspect of the elements to as-
16 sure safe use under subsection (f) for a drug that
17 is the subject of an abbreviated new drug application
18 under section 505(j), the Secretary may require that
19 such different comparable aspect of the elements to
20 assure safe use can be used with respect to any
21 other drug that is the subject of an application
22 under section 505(j) or 505(b) that references the
23 same listed drug.”; and

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

1 “(m) SEPARATE REMS.—When used in this section,
2 the terms ‘different, comparable aspect of the elements to
3 assure safe use’ or ‘different, comparable approved risk
4 evaluation and mitigation strategies’ means a risk evalua-
5 tion and mitigation strategy for a drug that is the subject
6 of an application under section 505(j) that uses different
7 methods or operational means than the strategy required
8 under subsection (a) for the applicable listed drug, or
9 other application under section 505(j) with the same such
10 listed drug, but achieves the same level of safety as such
11 strategy.”.

12 **SEC. 123. RULE OF CONSTRUCTION.**

13 (a) IN GENERAL.—Nothing in this subtitle, the
14 amendments made by this subtitle, or in section 505–1
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355–1), shall be construed as—

17 (1) prohibiting a license holder from providing
18 an eligible product developer access to a covered
19 product in the absence of an authorization under
20 this subtitle; or

21 (2) in any way negating the applicability of a
22 REMS with ETASU, as otherwise required under
23 such section 505–1, with respect to such covered
24 product.

1 (b) DEFINITIONS.—In this section, the terms “cov-
2 ered product”, “eligible product developer”, “license hold-
3 er”, and “REMS with ETASU” have the meanings given
4 such terms in section 121(a).

5 **TITLE II—EXTENSION OF**
6 **PUBLIC HEALTH PROGRAMS**

7 **SEC. 201. EXTENSION FOR COMMUNITY HEALTH CENTERS,**
8 **THE NATIONAL HEALTH SERVICE CORPS,**
9 **AND TEACHING HEALTH CENTERS THAT OP-**
10 **ERATE GME PROGRAMS.**

11 (a) COMMUNITY HEALTH CENTERS FUNDING.—Sec-
12 tion 10503(b)(1)(F) of the Patient Protection and Afford-
13 able Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended
14 by striking “fiscal year 2019” and inserting “each of fiscal
15 years 2019 and 2020”.

16 (b) NATIONAL HEALTH SERVICE CORPS.—Section
17 10503(b)(2)(F) of the Patient Protection and Affordable
18 Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by
19 striking “2018 and 2019” and inserting “2018, 2019, and
20 2020”.

21 (c) TEACHING HEALTH CENTERS THAT OPERATE
22 GRADUATE MEDICAL EDUCATION PROGRAMS.—Section
23 340H(g)(1) of the Public Health Service Act (42 U.S.C.
24 256h(g)(1)) is amended by striking “2018 and 2019” and
25 inserting “2018, 2019, and 2020”.

1 (d) APPLICATION.—Amounts appropriated pursuant
2 to this section for fiscal year 2020 are subject to the re-
3 quirements contained in Public Law 115–245 for funds
4 for programs authorized under sections 330 through 340
5 of the Public Health Service Act (42 U.S.C. 254b–256).

6 (e) CONFORMING AMENDMENT.—Section 3014(h)(4)
7 of title 18, United States Code, is amended by striking
8 “and section 50901(e) of the Advancing Chronic Care, Ex-
9 tenders, and Social Services Act” and inserting “, section
10 50901(e) of the Advancing Chronic Care, Extenders, and
11 Social Services Act, and section 201(d) of the Strength-
12 ening Health Care and Lowering Prescription Drug Costs
13 Act”.

14 **SEC. 202. EXTENSION FOR SPECIAL DIABETES PROGRAMS.**

15 (a) SPECIAL DIABETES PROGRAM FOR TYPE I DIA-
16 BETES.—Section 330B(b)(2)(D) of the Public Health
17 Service Act (42 U.S.C. 254e–2(b)(2)(D)) is amended by
18 striking “2018 and 2019” and inserting “2018, 2019, and
19 2020”.

20 (b) SPECIAL DIABETES PROGRAM FOR INDIANS.—
21 Section 330C(c)(2)(D) of the Public Health Service Act
22 (42 U.S.C. 254e–3(c)(2)(D)) is amended by striking
23 “2018 and 2019” and inserting “2018, 2019, and 2020”.

1 **SEC. 203. EXTENSION FOR FAMILY-TO-FAMILY HEALTH IN-**
2 **FORMATION CENTERS.**

3 (a) IN GENERAL.—Section 501(c) of the Social Secu-
4 rity Act (42 U.S.C. 701(c)(1)(A)(vii)) is amended by strik-
5 ing “2018 and 2019” and inserting “2018, 2019, and
6 2020”.

7 (b) CONFORMING CHANGE.—Section 501(c)(3)(C) of
8 the Social Security Act (42 U.S.C. 701(c)(3)(C)) is
9 amended by striking “2018 and 2019” and inserting
10 “2018, 2019, and 2020”.

11 **SEC. 204. EXTENSION FOR SEXUAL RISK AVOIDANCE EDU-**
12 **CATION AND PERSONAL RESPONSIBILITY**
13 **EDUCATION.**

14 (a) SEXUAL RISK AVOIDANCE EDUCATION.—Sub-
15 sections (a) and (f) of section 510 of the Social Security
16 Act (42 U.S.C. 710) are amended by striking “2018 and
17 2019” each place it appears and inserting “2018, 2019,
18 and 2020”.

19 (b) PERSONAL RESPONSIBILITY EDUCATION.—Sec-
20 tion 513 of the Social Security Act (42 U.S.C. 713) is
21 amended—

22 (1) in subsection (a)(1)(A), by striking “2019”
23 and inserting “2020”; and

24 (2) in subsection (a)(4), by striking “2019”
25 each place it appears and inserting “2020”; and

1 (3) in subsection (f), by striking “2019” and
2 inserting “2020”.

Amend the title so as to read: “A bill to incentivize low-cost drug options and generic competition, and to provide extensions for community health centers and the National Health Service Corps, and for other purposes.”.

