

MOTION TO RECOMMIT H.R. 987

OFFERED BY M__ . _____

M__ . _____ moves to recommit the bill H.R. 987 to the Committee on Energy and Commerce with instructions to report the same back to the House forthwith with the following amendment:

Strike title I and insert the following:

1 **TITLE I—LOWERING**
2 **PRESCRIPTION DRUG COSTS**

3 **SEC. 100. SHORT TITLE.**

4 This title may be cited as the “CREATES Act”.

5 **Subtitle A—Bringing Low-cost Op-**
6 **tions and Competition While**
7 **Keeping Incentives for New**
8 **Generics**

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

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

14 (1) in subclause (I), by striking “180 days
15 after” and all that follows through the period at the

1 end and inserting the following: “180 days after the
2 earlier of—

3 “(aa) the date of the first com-
4 mercial marketing of the drug (includ-
5 ing the commercial marketing of the
6 listed drug) by any first applicant; or

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

9 (2) by adding at the end the following new sub-
10 clause:

11 “(III) APPLICABLE DATE.—The appli-
12 cable date specified in this subclause, with
13 respect to an application for a drug de-
14 scribed in subclause (I), is the date on
15 which each of the following conditions is
16 first met:

17 “(aa) The approval of such an
18 application could be made effective,
19 but for the eligibility of a first appli-
20 cant for 180-day exclusivity under
21 this clause.

22 “(bb) At least 30 months have
23 passed since the date of submission of
24 an application for the drug by at least
25 one first applicant.

1 “(cc) Approval of an application
2 for the drug submitted by at least one
3 first applicant is not precluded under
4 clause (iii).

5 “(dd) No application for the drug
6 submitted by any first applicant is ap-
7 proved at the time the conditions
8 under items (aa), (bb), and (cc) are
9 all met, regardless of whether such an
10 application is subsequently ap-
11 proved.”.

12 **Subtitle B—Protecting Consumer**
13 **Access to Generic Drugs**

14 **SEC. 111. UNLAWFUL AGREEMENTS.**

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

21 (1) a subsequent filer directly or indirectly re-
22 ceives from such holder (or in the case of such an
23 agreement between two subsequent filers, the other
24 subsequent filer) anything of value, including a li-
25 cense; and

1 (2) the subsequent filer agrees to limit or fore-
2 go research on, or development, manufacturing,
3 marketing, or sales, for any period of time, of the
4 covered product that is the subject of the application
5 described in subparagraph (A) or (B) of subsection
6 (g)(8).

7 (b) EXCLUSION.—It shall not be unlawful under sub-
8 section (a) if a party to an agreement described in such
9 subsection demonstrates by clear and convincing evidence
10 that the value described in subsection (a)(1) is compensa-
11 tion solely for other goods or services that the subsequent
12 filer has promised to provide.

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

19 (1) The right to market the covered product
20 that is the subject of the application described in
21 subparagraph (A) or (B) of subsection (g)(8) in the
22 United States before the expiration of—

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

1 (B) any patent right or other statutory ex-
2 clusivity that would prevent the marketing of
3 such covered product.

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

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

8 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-
9 SION.—

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

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

17 (B) a person, partnership, or corporation
18 over which the Commission would have author-
19 ity pursuant to such section but for the fact
20 that such person, partnership, or corporation is
21 not organized to carry on business for its own
22 profit or that of its members.

23 (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES
24 ENFORCEMENT AUTHORITY.—

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

6 (B) POWERS OF COMMISSION.—Except as
7 provided in subparagraph (C) and paragraphs
8 (1)(B) and (3)—

9 (i) the Commission shall enforce this
10 section in the same manner, by the same
11 means, and with the same jurisdiction,
12 powers, and duties as though all applicable
13 terms and provisions of the Federal Trade
14 Commission Act (15 U.S.C. 41 et seq.)
15 were incorporated into and made a part of
16 this section; and

17 (ii) any NDA or BLA holder or subse-
18 quent filer that violates this section shall
19 be subject to the penalties and entitled to
20 the privileges and immunities provided in
21 the Federal Trade Commission Act.

22 (C) JUDICIAL REVIEW.—In the case of a
23 cease and desist order issued by the Commis-
24 sion under section 5 of the Federal Trade Com-
25 mission Act (15 U.S.C. 45) for violation of this

1 section, a party to such order may obtain judi-
2 cial review of such order as provided in such
3 section 5, except that—

4 (i) such review may only be obtained
5 in—

6 (I) the United States Court of
7 Appeals for the District of Columbia
8 Circuit;

9 (II) the United States Court of
10 Appeals for the circuit in which the
11 ultimate parent entity, as defined in
12 section 801.1(a)(3) of title 16, Code
13 of Federal Regulations, or any suc-
14 cessor thereto, of the NDA or BLA
15 holder (if any such holder is a party
16 to such order) is incorporated as of
17 the date that the application described
18 in subparagraph (A) or (B) of sub-
19 section (g)(8) or an approved applica-
20 tion that is deemed to be a license for
21 a biological product under section
22 351(k) of the Public Health Service
23 Act (42 U.S.C. 262(k)) pursuant to
24 section 7002(e)(4) of the Biologics
25 Price Competition and Innovation Act

1 of 2009 (Public Law 111–148; 124
2 Stat. 817) is submitted to the Com-
3 missioner of Food and Drugs; or

4 (III) the United States Court of
5 Appeals for the circuit in which the
6 ultimate parent entity, as so defined,
7 of any subsequent filer that is a party
8 to such order is incorporated as of the
9 date that the application described in
10 subparagraph (A) or (B) of subsection
11 (g)(8) is submitted to the Commis-
12 sioner of Food and Drugs; and

13 (ii) the petition for review shall be
14 filed in the court not later than 30 days
15 after such order is served on the party
16 seeking review.

17 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

18 (A) CIVIL PENALTY.—The Commission
19 may commence a civil action to recover a civil
20 penalty in a district court of the United States
21 against any NDA or BLA holder or subsequent
22 filer that violates this section.

23 (B) SPECIAL RULE FOR RECOVERY OF
24 PENALTY IF CEASE AND DESIST ORDER
25 ISSUED.—

1 (i) IN GENERAL.—If the Commission
2 has issued a cease and desist order in a
3 proceeding under section 5 of the Federal
4 Trade Commission Act (15 U.S.C. 45) for
5 violation of this section—

6 (I) the Commission may com-
7 mence a civil action under subpara-
8 graph (A) to recover a civil penalty
9 against any party to such order at
10 any time before the expiration of the
11 1-year period beginning on the date
12 on which such order becomes final
13 under section 5(g) of such Act (15
14 U.S.C. 45(g)); and

15 (II) in such civil action, the find-
16 ings of the Commission as to the ma-
17 terial facts in such proceeding shall be
18 conclusive, unless—

19 (aa) the terms of such order
20 expressly provide that the Com-
21 mission's findings shall not be
22 conclusive; or

23 (bb) such order became final
24 by reason of section 5(g)(1) of
25 such Act (15 U.S.C. 45(g)(1)), in

1 which case such findings shall be
2 conclusive if supported by evi-
3 dence.

4 (ii) RELATIONSHIP TO PENALTY FOR
5 VIOLATION OF AN ORDER.—The penalty
6 provided in clause (i) for violation of this
7 section is separate from and in addition to
8 any penalty that may be incurred for viola-
9 tion of an order of the Commission under
10 section 5(l) of the Federal Trade Commis-
11 sion Act (15 U.S.C. 45(l)).

12 (C) AMOUNT OF PENALTY.—

13 (i) IN GENERAL.—The amount of a
14 civil penalty imposed in a civil action under
15 subparagraph (A) on a party to an agree-
16 ment described in subsection (a) shall be
17 sufficient to deter violations of this section,
18 but in no event greater than—

19 (I) if such party is the NDA or
20 BLA holder (or, in the case of an
21 agreement between two subsequent fil-
22 ers, the subsequent filer who gave the
23 value described in subsection (a)(1)),
24 the greater of—

1 (aa) 3 times the value re-
2 ceived by such NDA or BLA
3 holder (or by such subsequent
4 filer) that is reasonably attrib-
5 utable to the violation of this sec-
6 tion; or

7 (bb) 3 times the value given
8 to the subsequent filer (or to the
9 other subsequent filer) reason-
10 ably attributable to the violation
11 of this section; and

12 (II) if such party is the subse-
13 quent filer (or, in the case of an
14 agreement between two subsequent fil-
15 ers, the subsequent filer who received
16 the value described in subsection
17 (a)(1)), 3 times the value received by
18 such subsequent filer that is reason-
19 ably attributable to the violation of
20 this section.

21 (ii) FACTORS FOR CONSIDERATION.—
22 In determining such amount, the court
23 shall take into account—

24 (I) the nature, circumstances, ex-
25 tent, and gravity of the violation;

1 (II) with respect to the violator,
2 the degree of culpability, any history
3 of violations, the ability to pay, any
4 effect on the ability to continue doing
5 business, profits earned by the NDA
6 or BLA holder (or, in the case of an
7 agreement between two subsequent fil-
8 ers, the subsequent filer who gave the
9 value described in subsection (a)(1)),
10 compensation received by the subse-
11 quent filer (or, in the case of an
12 agreement between two subsequent fil-
13 ers, the subsequent filer who received
14 the value described in subsection
15 (a)(1)), and the amount of commerce
16 affected; and

17 (III) other matters that justice
18 requires.

19 (D) INJUNCTIONS AND OTHER EQUITABLE
20 RELIEF.—In a civil action under subparagraph
21 (A), the United States district courts are em-
22 powered to grant mandatory injunctions and
23 such other and further equitable relief as they
24 deem appropriate.

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

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

9 (e) FEDERAL TRADE COMMISSION RULEMAKING.—
10 The Commission may, in its discretion, by rule promul-
11 gated under section 553 of title 5, United States Code,
12 exempt from this section certain agreements described in
13 subsection (a) if the Commission finds such agreements
14 to be in furtherance of market competition and for the
15 benefit of consumers.

16 (f) ANTITRUST LAWS.—Nothing in this section shall
17 modify, impair, limit, or supersede the applicability of the
18 antitrust laws as defined in subsection (a) of the first sec-
19 tion of the Clayton Act (15 U.S.C. 12(a)), and of section
20 5 of the Federal Trade Commission Act (15 U.S.C. 45)
21 to the extent that such section 5 applies to unfair methods
22 of competition. Nothing in this section shall modify, im-
23 pair, limit, or supersede the right of a subsequent filer
24 to assert claims or counterclaims against any person,

1 under the antitrust laws or other laws relating to unfair
2 competition.

3 (g) DEFINITIONS.—In this section:

4 (1) AGREEMENT RESOLVING OR SETTLING A
5 COVERED PATENT INFRINGEMENT CLAIM.—The
6 term “agreement resolving or settling a covered pat-
7 ent infringement claim” means any agreement
8 that—

9 (A) resolves or settles a covered patent in-
10 fringement claim; or

11 (B) is contingent upon, provides for a con-
12 tingent condition for, or is otherwise related to
13 the resolution or settlement of a covered patent
14 infringement claim.

15 (2) COMMISSION.—The term “Commission”
16 means the Federal Trade Commission.

17 (3) COVERED PATENT INFRINGEMENT CLAIM.—
18 The term “covered patent infringement claim”
19 means an allegation made by the NDA or BLA hold-
20 er to a subsequent filer (or, in the case of an agree-
21 ment between two subsequent filers, by one subse-
22 quent filer to another), whether or not included in
23 a complaint filed with a court of law, that—

24 (A) the submission of the application de-
25 scribed in subparagraph (A) or (B) of para-

1 graph (9), or the manufacture, use, offering for
2 sale, sale, or importation into the United States
3 of a covered product that is the subject of such
4 an application—

5 (i) in the case of an agreement be-
6 tween an NDA or BLA holder and a sub-
7 sequent filer, infringes any patent owned
8 by, or exclusively licensed to, the NDA or
9 BLA holder of the covered product; or

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

13 (B) in the case of an agreement between
14 an NDA or BLA holder and a subsequent filer,
15 the covered product to be manufactured under
16 such application uses a covered product as
17 claimed in a published patent application.

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

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

1 (A) the holder of—

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

7 (ii) a biologics license application filed
8 under section 351(a) of the Public Health
9 Service Act (42 U.S.C. 262(a)) with re-
10 spect to a biological product;

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

13 (i) the list published under section
14 505(j)(7) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-
16 nection with the application described in
17 subparagraph (A)(i); or

18 (ii) any list published under section
19 351 of the Public Health Service Act (42
20 U.S.C. 262) comprised of patents associ-
21 ated with biologics license applications filed
22 under section 351(a) of such Act (42
23 U.S.C. 262(a)); or

24 (C) the predecessors, subsidiaries, divi-
25 sions, groups, and affiliates controlled by, con-

1 trolling, or under common control with any en-
2 tity described in subparagraph (A) or (B) (such
3 control to be presumed by direct or indirect
4 share ownership of 50 percent or greater), as
5 well as the licensees, licensors, successors, and
6 assigns of each of the entities.

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

10 (7) STATUTORY EXCLUSIVITY.—The term
11 “statutory exclusivity” means those prohibitions on
12 the submission or approval of drug applications
13 under clauses (ii) through (iv) of section
14 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)
15 through (iv) of section 505(j)(5)(F) (5-year and 3-
16 year exclusivity), section 505(j)(5)(B)(iv) (180-day
17 exclusivity), section 527 (orphan drug exclusivity),
18 section 505A (pediatric exclusivity), or section 505E
19 (qualified infectious disease product exclusivity) of
20 the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),
22 360cc, 355a, 355f), or prohibitions on the submis-
23 sion or licensing of biologics license applications
24 under section 351(k)(6) (interchangeable biological
25 product exclusivity) or section 351(k)(7) (biological

1 product reference product exclusivity) of the Public
2 Health Service Act (42 U.S.C. 262(k)(6), (7)).

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

5 (A) in the case of a drug, a party that
6 owns or controls an abbreviated new drug appli-
7 cation submitted pursuant to section 505(j) of
8 the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 355(j)) or a new drug application sub-
10 mitted pursuant to section 505(b)(2) of the
11 Federal Food, Drug, and Cosmetic Act
12 (21U.S.C. 355(b)(2)) and filed under section
13 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or
14 has the exclusive rights to distribute the cov-
15 ered product that is the subject of such applica-
16 tion; or

17 (B) in the case of a biological product, a
18 party that owns or controls an application filed
19 with the Food and Drug Administration under
20 section 351(k) of the Public Health Service Act
21 (42 U.S.C. 262(k)) or has the exclusive rights
22 to distribute the biological product that is the
23 subject of such application.

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

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

5 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)
6 of the Medicare Prescription Drug, Improvement, and
7 Modernization Act of 2003 (21 U.S.C. 355 note) is
8 amended by inserting “or the owner of a patent for which
9 a claim of infringement could reasonably be asserted
10 against any person for making, using, offering to sell, sell-
11 ing, or importing into the United States a biological prod-
12 uct that is the subject of a biosimilar biological product
13 application” before the period at the end.

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

17 “(d) CERTIFICATION.—The Chief Executive Officer
18 or the company official responsible for negotiating any
19 agreement under subsection (a) or (b) that is required to
20 be filed under subsection (c) shall, within 30 days of such
21 filing, execute and file with the Assistant Attorney General
22 and the Commission a certification as follows: ‘I declare
23 that the following is true, correct, and complete to the best
24 of my knowledge: The materials filed with the Federal
25 Trade Commission and the Department of Justice under

1 section 1112 of the Medicare Prescription Drug, Improve-
2 ment, and Modernization Act of 2003, with respect to the
3 agreement referenced in this certification—

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

6 ““(2) include any ancillary agreements that are
7 contingent upon, provide a contingent condition for,
8 were entered into within 30 days of, or are otherwise
9 related to, the referenced agreement; and

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

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

16 Section 505(j)(5)(D)(i)(V) of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))
18 is amended by inserting “section 111 of the Lowering Pre-
19 scription Drug Costs and Extending Community Health
20 Centers and Other Public Health Priorities Act or” after
21 “that the agreement has violated”.

22 **SEC. 114. COMMISSION LITIGATION AUTHORITY.**

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

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

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

5 (3) by inserting after subparagraph (E) the fol-
6 lowing:

7 “(F) under section 111(d)(3)(A) of the
8 Lowering Prescription Drug Costs and Extend-
9 ing Community Health Centers and Other Pub-
10 lic Health Priorities Act;”.

11 **SEC. 115. STATUTE OF LIMITATIONS.**

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

20 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND
21 DESIST ORDER.—If the Commission has issued a cease
22 and desist order under section 5 of the Federal Trade
23 Commission Act (15 U.S.C. 45) for violation of section
24 111 of this Act and the proceeding for the issuance of
25 such order was commenced within the period required by

1 subsection (a) of this section, such subsection does not
2 prohibit the commencement, after such period, of a civil
3 action under section 111(d)(3)(A) against a party to such
4 order or a civil action under subsection (l) of such section
5 for violation of such order.

6 **Subtitle C—Creating and Restoring**
7 **Equal Access to Equivalent**
8 **Samples**

9 **SEC. 121. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
10 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

11 (a) DEFINITIONS.—In this section—

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

14 (A) a nondiscriminatory price for the sale
15 of the covered product at or below, but not
16 greater than, the most recent wholesale acquisi-
17 tion cost for the drug, as defined in section
18 1847A(c)(6)(B) of the Social Security Act (42
19 U.S.C. 1395w–3a(c)(6)(B));

20 (B) a schedule for delivery that results in
21 the transfer of the covered product to the eligi-
22 ble product developer consistent with the timing
23 under subsection (b)(2)(A)(iv); and

24 (C) no additional conditions are imposed
25 on the sale of the covered product;

1 (2) the term “covered product”—

2 (A) means—

3 (i) any drug approved under sub-
4 section (c) or (j) of section 505 of the Fed-
5 eral Food, Drug, and Cosmetic Act (21
6 U.S.C. 355) or biological product licensed
7 under subsection (a) or (k) of section 351
8 of the Public Health Service Act (42
9 U.S.C. 262);

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

12 (iii) when reasonably necessary to
13 support approval of an application under
14 section 505 of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 355), or sec-
16 tion 351 of the Public Health Service Act
17 (42 U.S.C. 262), as applicable, or other-
18 wise meet the requirements for approval
19 under either such section, any product, in-
20 cluding any device, that is marketed or in-
21 tended for use with such a drug or biologi-
22 cal product; and

23 (B) does not include any drug or biological
24 product that appears on the drug shortage list
25 in effect under section 506E of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 356e), unless—

3 (i) the drug or biological product has
4 been on the drug shortage list in effect
5 under such section 506E continuously for
6 more than 6 months; or

7 (ii) the Secretary determines that in-
8 clusion of the drug or biological product as
9 a covered product is likely to contribute to
10 alleviating or preventing a shortage.

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

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

22 (5) the term “license holder” means the holder
23 of an application approved under subsection (c) or
24 (j) of section 505 of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355) or the holder of a li-

1 cense under subsection (a) or (k) of section 351 of
2 the Public Health Service Act (42 U.S.C. 262) for
3 a covered product;

4 (6) the term “REMS” means a risk evaluation
5 and mitigation strategy under section 505–1 of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355–1);

8 (7) the term “REMS with ETASU” means a
9 REMS that contains elements to assure safe use
10 under section 505–1(f) of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 355–1(f));

12 (8) the term “Secretary” means the Secretary
13 of Health and Human Services;

14 (9) the term “single, shared system of elements
15 to assure safe use” means a single, shared system
16 of elements to assure safe use under section 505–
17 1(f) of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 355–1(f)); and

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

22 (A) conduct testing to support an applica-
23 tion under—

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

4 (ii) section 351(k) of the Public
5 Health Service Act (42 U.S.C. 262(k));
6 and

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

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

11 (1) IN GENERAL.—An eligible product developer
12 may bring a civil action against the license holder
13 for a covered product seeking relief under this sub-
14 section in an appropriate district court of the United
15 States alleging that the license holder has declined
16 to provide sufficient quantities of the covered prod-
17 uct to the eligible product developer on commercially
18 reasonable, market-based terms.

19 (2) ELEMENTS.—

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

24 (i) that—

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

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

5 (aa) the eligible product de-
6 veloper has obtained a covered
7 product authorization from the
8 Secretary in accordance with sub-
9 paragraph (B); and

10 (bb) the eligible product de-
11 veloper has provided a copy of
12 the covered product authorization
13 to the license holder;

14 (ii) that, as of the date on which the
15 civil action is filed, the product developer
16 has not obtained sufficient quantities of
17 the covered product on commercially rea-
18 sonable, market-based terms;

19 (iii) that the eligible product developer
20 has submitted a written request to pur-
21 chase sufficient quantities of the covered
22 product to the license holder and such re-
23 quest—

24 (I) was sent to a named cor-
25 porate officer of the license holder;

1 (II) was made by certified or reg-
2 istered mail with return receipt re-
3 quested;

4 (III) specified an individual as
5 the point of contact for the license
6 holder to direct communications re-
7 lated to the sale of the covered prod-
8 uct to the eligible product developer
9 and a means for electronic and writ-
10 ten communications with that indi-
11 vidual; and

12 (IV) specified an address to
13 which the covered product was to be
14 shipped upon reaching an agreement
15 to transfer the covered product; and

16 (iv) that the license holder has not de-
17 livered to the eligible product developer
18 sufficient quantities of the covered product
19 on commercially reasonable, market-based
20 terms—

21 (I) for a covered product that is
22 not subject to a REMS with ETASU,
23 by the date that is 31 days after the
24 date on which the license holder re-

1 ceived the request for the covered
2 product; and

3 (II) for a covered product that is
4 subject to a REMS with ETASU, by
5 31 days after the later of—

6 (aa) the date on which the
7 license holder received the re-
8 quest for the covered product; or

9 (bb) the date on which the
10 license holder received a copy of
11 the covered product authorization
12 issued by the Secretary in ac-
13 cordance with subparagraph (B).

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

16 (i) REQUEST.—An eligible product de-
17 veloper may submit to the Secretary a
18 written request for the eligible product de-
19 veloper to be authorized to obtain suffi-
20 cient quantities of an individual covered
21 product subject to a REMS with ETASU.

22 (ii) AUTHORIZATION.—Not later than
23 120 days after the date on which a request
24 under clause (i) is received, the Secretary
25 shall, by written notice, authorize the eligi-

1 ble product developer to obtain sufficient
2 quantities of an individual covered product
3 subject to a REMS with ETASU for pur-
4 poses of—

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

10 (II) development and testing that
11 involves human clinical trials, if the
12 eligible product developer has—

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

21 (BB) otherwise satisfied the
22 Secretary that such protections
23 will be provided; and

1 (bb) met any other require-
2 ments the Secretary may estab-
3 lish.

4 (iii) NOTICE.—A covered product au-
5 thorization issued under this subparagraph
6 shall state that the provision of the covered
7 product by the license holder under the
8 terms of the authorization will not be a
9 violation of the REMS for the covered
10 product.

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

15 (A) that, on the date on which the eligible
16 product developer requested to purchase suffi-
17 cient quantities of the covered product from the
18 license holder—

19 (i) neither the license holder nor any
20 of its agents, wholesalers, or distributors
21 was engaged in the manufacturing or com-
22 mercial marketing of the covered product;
23 and

24 (ii) neither the license holder nor any
25 of its agents, wholesalers, or distributors

1 otherwise had access to inventory of the
2 covered product to supply to the eligible
3 product developer on commercially reason-
4 able, market-based terms;

5 (B) that—

6 (i) the license holder sells the covered
7 product through agents, distributors, or
8 wholesalers;

9 (ii) the license holder has placed no
10 restrictions, explicit or implicit, on its
11 agents, distributors, or wholesalers to sell
12 covered products to eligible product devel-
13 opers; and

14 (iii) the covered product can be pur-
15 chased by the eligible product developer in
16 sufficient quantities on commercially rea-
17 sonable, market-based terms from the
18 agents, distributors, or wholesalers of the
19 license holder; or

20 (C) that the license holder made an offer
21 to the individual specified pursuant to para-
22 graph (2)(A)(iii)(III), by a means of commu-
23 nication (electronic, written, or both) specified
24 pursuant to such paragraph, to sell sufficient
25 quantities of the covered product to the eligible

1 product developer at commercially reasonable
2 market-based terms—

3 (i) for a covered product that is not
4 subject to a REMS with ETASU, by the
5 date that is 14 days after the date on
6 which the license holder received the re-
7 quest for the covered product, and the eli-
8 gible product developer did not accept such
9 offer by the date that is 7 days after the
10 date on which the eligible product devel-
11 oper received such offer from the license
12 holder; or

13 (ii) for a covered product that is sub-
14 ject to a REMS with ETASU, by the date
15 that is 20 days after the date on which the
16 license holder received the request for the
17 covered product, and the eligible product
18 developer did not accept such offer by the
19 date that is 10 days after the date on
20 which the eligible product developer re-
21 ceived such offer from the license holder.

22 (4) REMEDIES.—

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

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

6 (ii) award to the eligible product de-
7 veloper reasonable attorney's fees and costs
8 of the civil action; and

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

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

22 (II) that the license holder failed
23 to comply with an order issued under
24 clause (i).

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

6 (i) beginning on—

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

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

16 (aa) the date on which the
17 license holder received the re-
18 quest; or

19 (bb) the date on which the
20 license holder received a copy of
21 the covered product authorization
22 issued by the Secretary in ac-
23 cordance with paragraph (2)(B);
24 and

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

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

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

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

23 “(1) PROVISION OF SAMPLES NOT A VIOLATION OF
24 STRATEGY.—The provision of samples of a covered prod-
25 uct to an eligible product developer (as those terms are

1 defined in section 121(a) of the Lowering Prescription
2 Drug Costs and Extending Community Health Centers
3 and Other Public Health Priorities Act) shall not be con-
4 sidered a violation of the requirements of any risk evalua-
5 tion and mitigation strategy that may be in place under
6 this section for such drug.”.

7 (e) RULE OF CONSTRUCTION.—

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

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

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

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

20 **SEC. 122. REMS APPROVAL PROCESS FOR SUBSEQUENT**
21 **FILERS.**

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

25 (1) in subsection (g)(4)(B)—

1 (A) in clause (i) by striking “or” after the
2 semicolon;

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

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

6 “(iii) accommodate different, com-
7 parable aspects of the elements to assure
8 safe use for a drug that is the subject of
9 an application under section 505(j), and
10 the applicable listed drug.”;

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

13 “(C)(i) Elements to assure safe use, if re-
14 quired under subsection (f) for the listed drug,
15 which, subject to clause (ii), for a drug that is
16 the subject of an application under section
17 505(j) may use—

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

20 “(II) a different, comparable aspect of
21 the elements to assure safe use under sub-
22 section (f).

23 “(ii) The Secretary may require a drug
24 that is the subject of an application under sec-
25 tion 505(j) and the listed drug to use a single,

1 shared system under subsection (f), if the Sec-
2 retary determines that no different, comparable
3 aspect of the elements to assure safe use could
4 satisfy the requirements of subsection (f).”;

5 (3) in subsection (i), by adding at the end the
6 following:

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

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

19 “(m) SEPARATE REMS.—When used in this section,
20 the terms ‘different, comparable aspect of the elements to
21 assure safe use’ or ‘different, comparable approved risk
22 evaluation and mitigation strategies’ means a risk evalua-
23 tion and mitigation strategy for a drug that is the subject
24 of an application under section 505(j) that uses different
25 methods or operational means than the strategy required

1 under subsection (a) for the applicable listed drug, or
2 other application under section 505(j) with the same such
3 listed drug, but achieves the same level of safety as such
4 strategy.”.

5 **SEC. 123. RULE OF CONSTRUCTION.**

6 (a) IN GENERAL.—Nothing in this subtitle, the
7 amendments made by this subtitle, or in section 505–1
8 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 355–1), shall be construed as—

10 (1) prohibiting a license holder from providing
11 an eligible product developer access to a covered
12 product in the absence of an authorization under
13 this subtitle; or

14 (2) in any way negating the applicability of a
15 REMS with ETASU, as otherwise required under
16 such section 505–1, with respect to such covered
17 product.

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

Strike title II and insert the following:

1 **TITLE II—SUPPORTING**
2 **PEDIATRIC CANCER RESEARCH**

3 **SEC. 201. FINDING; SENSE OF CONGRESS.**

4 According to the Congressional Budget Office, the bi-
5 partisan provisions of title I of this Act decrease Federal
6 spending by over \$4,000,000,000. It is the sense of Con-
7 gress that these savings should be redirected to the Na-
8 tional Institutes of Health Innovation Account to be made
9 available to support pediatric cancer research as provided
10 by the amendments made by section 202.

11 **SEC. 202. PEDIATRIC CANCER RESEARCH.**

12 Section 1001(b) of the 21st Century Cures Act (Pub-
13 lic Law 114–255) is amended—

14 (1) in paragraph (3), by amending subpara-
15 graph (A) to read as follows:

16 “(A) AUTHORIZATION OF APPROPRIA-
17 TIONS.—For each of the fiscal years 2017
18 through 2026, there is authorized to be appro-
19 priated from the Account to the Director of
20 NIH, for the purpose of carrying out the NIH
21 Innovation Projects, an amount not to exceed
22 the total amount transferred to the Account
23 under paragraph (2)(A), plus \$4,963,000,000
24 for the period of fiscal years 2020 through
25 2024, to remain available until expended.”; and

1 (2) in paragraph (4), by adding at the end the
2 following new subparagraph:

3 “(E) For pediatric cancer research, not to
4 exceed a total of \$4,963,000,000 for the period
5 of fiscal years 2020 through 2024.”.

