

116TH CONGRESS  
1ST SESSION

# H. R. 2700

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.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2019

Mr. BURGESS (for himself, Mr. WALDEN, Mr. UPTON, Mr. MCKINLEY, Mr. CARTER of Georgia, Mr. BUCSHON, Mr. BILIRAKIS, Mr. MULLIN, Mrs. RODGERS of Washington, Mr. LONG, Mr. FLORES, Mr. HUDSON, Mr. SHIMKUS, Mr. WALBERG, Mr. KINZINGER, Mr. OLSON, Mr. JOHNSON of Ohio, Mr. GUTHRIE, Mr. GRIFFITH, Mr. DUNCAN, Mrs. BROOKS of Indiana, Mr. GIANFORTE, Mr. LATTA, Mr. SCALISE, Mr. SENSENBRENNER, Mr. COLLINS of Georgia, Mr. STIVERS, Mr. HILL of Arkansas, Mr. MITCHELL, and Mr. HURD of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## 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.

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 “Lowering Prescription  
3 Drug Costs and Extending Community Health Centers  
4 and Other Public Health Priorities Act”.

5 **SEC. 2. TABLE OF CONTENTS.**

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

- Sec. 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-

ably attributable to the violation  
of this section; and

(II) if such party is the subsequent filer (or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1)), 3 times the value received by such subsequent filer that is reasonably attributable to the violation of this section.

(ii) FACTORS FOR CONSIDERATION.—

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

(I) the nature, circumstances, extent, and gravity of the violation;

(II) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA or BLA holder (or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the 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”  
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 Lowering Pre-  
12 scription Drug Costs and Extending Community Health  
13 Centers and Other Public Health Priorities Act or” after  
14 “that the agreement has violated”.

15 **SEC. 114. COMMISSION LITIGATION AUTHORITY.**

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

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

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

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

24 “(F) under section 111(d)(3)(A) of the  
25 Lowering Prescription Drug Costs and Extend-

1           ing Community Health Centers and Other Pub-  
2           lic Health Priorities Act;”.

3 **SEC. 115. STATUTE OF LIMITATIONS.**

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

12           (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND  
13 DESIST ORDER.—If the Commission has issued a cease  
14 and desist order under section 5 of the Federal Trade  
15 Commission Act (15 U.S.C. 45) for violation of section  
16 111 of this Act and the proceeding for the issuance of  
17 such order was commenced within the period required by  
18 subsection (a) of this section, such subsection does not  
19 prohibit the commencement, after such period, of a civil  
20 action under section 111(d)(3)(A) against a party to such  
21 order or a civil action under subsection (l) of such section  
22 5 for violation of such order.

1 **Subtitle C—Creating and Restoring**  
2 **Equal Access to Equivalent**  
3 **Samples**

4 **SEC. 121. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**  
5 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

6 (a) DEFINITIONS.—In this section—

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

9 (A) a nondiscriminatory price for the sale  
10 of the covered product at or below, but not  
11 greater than, the most recent wholesale acquisi-  
12 tion cost for the drug, as defined in section  
13 1847A(c)(6)(B) of the Social Security Act (42  
14 U.S.C. 1395w–3a(c)(6)(B));

15 (B) a schedule for delivery that results in  
16 the transfer of the covered product to the eligi-  
17 ble product developer consistent with the timing  
18 under subsection (b)(2)(A)(iv); and

19 (C) no additional conditions are imposed  
20 on the sale of the covered product;

21 (2) the term “covered product”—

22 (A) means—

23 (i) any drug approved under sub-  
24 section (c) or (j) of section 505 of the Fed-  
25 eral Food, Drug, and Cosmetic Act (21



1 U.S.C. 355) or biological product licensed  
2 under subsection (a) or (k) of section 351  
3 of the Public Health Service Act (42  
4 U.S.C. 262);

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

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

18 (B) does not include any drug or biological  
19 product that appears on the drug shortage list  
20 in effect under section 506E of the Federal  
21 Food, Drug, and Cosmetic Act (21 U.S.C.  
22 356e), unless—

23 (i) the drug or biological product has  
24 been on the drug shortage list in effect

1 under such section 506E continuously for  
2 more than 6 months; or

3 (ii) the Secretary determines that in-  
4 clusion of the drug or biological product as  
5 a covered product is likely to contribute to  
6 alleviating or preventing a shortage.

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

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

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

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

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

9           (8) the term “Secretary” means the Secretary  
10 of Health and Human Services;

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

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

19                   (A) conduct testing to support an applica-  
20 tion under—

21                           (i) subsection (b)(2) or (j) of section  
22 505 of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 355); or

1 (ii) section 351(k) of the Public  
2 Health Service Act (42 U.S.C. 262(k));  
3 and

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

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

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

16 (2) ELEMENTS.—

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

21 (i) that—

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

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

1 (aa) the eligible product de-  
2 veloper has obtained a covered  
3 product authorization from the  
4 Secretary in accordance with sub-  
5 paragraph (B); and

6 (bb) the eligible product de-  
7 veloper has provided a copy of  
8 the covered product authorization  
9 to the license holder;

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

15 (iii) that the eligible product developer  
16 has submitted a written request to pur-  
17 chase sufficient quantities of the covered  
18 product to the license holder and such re-  
19 quest—

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

22 (II) was made by certified or reg-  
23 istered mail with return receipt re-  
24 quested;

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

9 (IV) specified an address to  
10 which the covered product was to be  
11 shipped upon reaching an agreement  
12 to transfer the covered product; and

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

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

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

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

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

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

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

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

1 subject to a REMS with ETASU for pur-  
2 poses of—

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

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

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

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

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



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

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

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

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

21 (ii) neither the license holder nor any  
22 of its agents, wholesalers, or distributors  
23 otherwise had access to inventory of the  
24 covered product to supply to the eligible

1 product developer on commercially reason-  
2 able, market-based terms;

3 (B) that—

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

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

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

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

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

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

20 (4) REMEDIES.—

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

24 (i) order the license holder to provide  
25 to the eligible product developer without

1 delay sufficient quantities of the covered  
2 product on commercially reasonable, mar-  
3 ket-based terms;

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

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

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

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

23 (B) MAXIMUM MONETARY AMOUNT.—A  
24 monetary amount awarded under subparagraph  
25 (A)(iii) shall not be greater than the revenue

1           that the license holder earned on the covered  
2           product during the period—

3                   (i) beginning on—

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

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

13                                   (aa) the date on which the  
14                                   license holder received the re-  
15                                   quest; or

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

22                           (ii) ending on the date on which the  
23                           eligible product developer received suffi-  
24                           cient quantities of the covered product.

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

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

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

20           “(1) PROVISION OF SAMPLES NOT A VIOLATION OF  
21          STRATEGY.—The provision of samples of a covered prod-  
22          uct to an eligible product developer (as those terms are  
23          defined in section 121(a) of the Lowering Prescription  
24          Drug Costs and Extending Community Health Centers  
25          and Other Public Health Priorities Act) shall not be con-

1 sidered a violation of the requirements of any risk evalua-  
 2 tion and mitigation strategy that may be in place under  
 3 this section for such drug.”.

4 (e) RULE OF CONSTRUCTION.—

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

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

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

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

17 **SEC. 122. REMS APPROVAL PROCESS FOR SUBSEQUENT**  
 18 **FILERS.**

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

22 (1) in subsection (g)(4)(B)—

23 (A) in clause (i) by striking “or” after the  
 24 semicolon;

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

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

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

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

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

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

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

21 “(ii) The Secretary may require a drug  
22 that is the subject of an application under sec-  
23 tion 505(j) and the listed drug to use a single,  
24 shared system under subsection (f), if the Sec-  
25 retary determines that no different, comparable



1 aspect of the elements to assure safe use could  
2 satisfy the requirements of subsection (f).”;

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

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

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

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

1 listed drug, but achieves the same level of safety as such  
2 strategy.”.

3 **SEC. 123. RULE OF CONSTRUCTION.**

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

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

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

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

1           **TITLE II—EXTENSION OF**  
2           **PUBLIC HEALTH PROGRAMS**

3   **SEC. 201. EXTENSION FOR COMMUNITY HEALTH CENTERS,**  
4                   **THE NATIONAL HEALTH SERVICE CORPS,**  
5                   **AND TEACHING HEALTH CENTERS THAT OP-**  
6                   **ERATE GME PROGRAMS.**

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

12          (b) **NATIONAL HEALTH SERVICE CORPS.**—Section  
13 10503(b)(2)(F) of the Patient Protection and Affordable  
14 Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by  
15 striking “2018 and 2019” and inserting “2018, 2019, and  
16 2020”.

17          (c) **TEACHING HEALTH CENTERS THAT OPERATE**  
18 **GRADUATE MEDICAL EDUCATION PROGRAMS.**—Section  
19 340H(g)(1) of the Public Health Service Act (42 U.S.C.  
20 256h(g)(1)) is amended by striking “2018 and 2019” and  
21 inserting “2018, 2019, and 2020”.

22          (d) **APPLICATION.**—Amounts appropriated pursuant  
23 to this section for fiscal year 2020 are subject to the re-  
24 quirements contained in Public Law 115–245 for funds

1 for programs authorized under sections 330 through 340  
2 of the Public Health Service Act (42 U.S.C. 254b–256).

3 (e) CONFORMING AMENDMENT.—Section 3014(h)(4)  
4 of title 18, United States Code, is amended by striking  
5 “and section 50901(e) of the Advancing Chronic Care, Ex-  
6 tenders, and Social Services Act” and inserting “, section  
7 50901(e) of the Advancing Chronic Care, Extenders, and  
8 Social Services Act, and section 201(d) of the Lowering  
9 Prescription Drug Costs and Extending Community  
10 Health Centers and Other Public Health Priorities Act”.

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

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

17 (b) SPECIAL DIABETES PROGRAM FOR INDIANS.—  
18 Section 330C(c)(2)(D) of the Public Health Service Act  
19 (42 U.S.C. 254c–3(c)(2)(D)) is amended by striking  
20 “2018 and 2019” and inserting “2018, 2019, and 2020”.

21 **SEC. 203. EXTENSION FOR FAMILY-TO-FAMILY HEALTH IN-**  
22 **FORMATION CENTERS.**

23 (a) IN GENERAL.—Section 501(c) of the Social Secu-  
24 rity Act (42 U.S.C. 701(c)(1)(A)(vii)) is amended by strik-

1 ing “2018 and 2019” and inserting “2018, 2019, and  
2 2020”.

3 (b) CONFORMING CHANGE.—Section 501(c)(3)(C) of  
4 the Social Security Act (42 U.S.C. 701(c)(3)(C)) is  
5 amended by striking “2018 and 2019” and inserting  
6 “2018, 2019, and 2020”.

7 **SEC. 204. EXTENSION FOR SEXUAL RISK AVOIDANCE EDU-**  
8 **CATION AND PERSONAL RESPONSIBILITY**  
9 **EDUCATION.**

10 (a) SEXUAL RISK AVOIDANCE EDUCATION.—Sub-  
11 sections (a) and (f) of section 510 of the Social Security  
12 Act (42 U.S.C. 710) are amended by striking “2018 and  
13 2019” each place it appears and inserting “2018, 2019,  
14 and 2020”.

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

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

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

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

○