

**Amendment to the Amendment in the Nature of a Substitute to H.R. 3  
Offered by Rep. Ferguson of Georgia**

The amendment would promote competition in the market for drugs and biological products by, among other policies, stopping anti-competitive practices and reforming certain exclusivity conditions.

**AMENDMENT**

**OFFERED BY M** \_\_\_\_\_

Add at the end the following (and conform the table of contents accordingly):

1           **TITLE VI—FOOD AND DRUG**  
2                           **ADMINISTRATION**  
3                           **Subtitle A—CREATES Act**

4   **SEC. 601. 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

1 (C) no additional conditions are imposed  
2 on the sale of the covered product;

3 (2) the term “covered product”—

4 (A) means—

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

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

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

1 (B) does not include any drug or biological  
2 product that appears on the drug shortage list  
3 in effect under section 506E of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C.  
5 356e), unless—

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

10 (ii) the Secretary determines that in-  
11 clusion of the drug or biological product as  
12 a covered product is likely to contribute to  
13 alleviating or preventing a shortage;

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

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

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

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

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

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

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

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

1 (A) conduct testing to support an applica-  
2 tion under—

3 (i) subsection (b)(2) or (j) of section  
4 505 of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 355); or

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

8 and

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

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

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

21 (2) ELEMENTS.—

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

1 (i) that—

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

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

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

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

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

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

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

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

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

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

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

23 (I) for a covered product that is  
24 not subject to a REMS with ETASU,  
25 by the date that is 31 days after the



1 date on which the license holder re-  
2 ceived the request for the covered  
3 product; and

4 (II) for a covered product that is  
5 subject to a REMS with ETASU, by  
6 31 days after the later of—

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

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

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

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

23 (ii) AUTHORIZATION.—Not later than  
24 120 days after the date on which a request  
25 under clause (i) is received, the Secretary

1 shall, by written notice, authorize the eligi-  
2 ble product developer to obtain sufficient  
3 quantities of an individual covered product  
4 subject to a REMS with ETASU for pur-  
5 poses of—

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

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

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

22 (BB) otherwise satisfied the  
23 Secretary that such protections  
24 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 601(a) of the Lower Drug Costs Now  
2 Act of 2019) shall not be considered a violation of the  
3 requirements of any risk evaluation and mitigation strat-  
4 egy that may be in place under this section for such  
5 drug.”.

6 (e) RULE OF CONSTRUCTION.—

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

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

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

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

19 **SEC. 602. REMS APPROVAL PROCESS FOR SUBSEQUENT**  
20 **FILERS.**

21 Section 505–1 of the Federal Food, Drug, and Cos-  
22 metic Act (21 U.S.C. 355–1), as amended by section 601,  
23 is further amended—

24 (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  
19 the listed drug under subsection (f);  
20 or

21 “(II) a different, comparable as-  
22 pect of the elements to assure safe use  
23 under subsection (f).

24 “(ii) The Secretary may require a  
25 drug that is the subject of an application

1 under section 505(j) and the listed drug to  
2 use a single, shared system under sub-  
3 section (f), if the Secretary determines  
4 that no different, comparable aspect of the  
5 elements to assure safe use could satisfy  
6 the requirements of subsection (f).”;

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

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

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

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

1 of an application under section 505(j) that uses different  
2 methods or operational means than the strategy required  
3 under subsection (a) for the applicable listed drug, or  
4 other application under section 505(j) with the same such  
5 listed drug, but achieves the same level of safety as such  
6 strategy.”.

7 **SEC. 603. RULE OF CONSTRUCTION.**

8 (a) IN GENERAL.—Nothing in this subtitle, the  
9 amendments made by this subtitle, or in section 505–1  
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 355–1), shall be construed as—

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

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

20 (b) DEFINITIONS.—In this section, the terms “cov-  
21 ered product”, “eligible product developer”, “license hold-  
22 er”, and “REMS with ETASU” have the meanings given  
23 such terms in section 601(a).

## 1           **Subtitle B—Pay-for-Delay**

### 2   **SEC. 611. UNLAWFUL AGREEMENTS.**

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

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

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

20           (b) **EXCLUSION.**—It shall not be unlawful under sub-  
21 section (a) if a party to an agreement described in such  
22 subsection demonstrates by clear and convincing evidence  
23 that the value described in subsection (a)(1) is compensa-  
24 tion solely for other goods or services that the subsequent  
25 filer has promised to provide.

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

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

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

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

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

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

20 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
21 SION.—

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

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

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

11 (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES  
12 ENFORCEMENT AUTHORITY.—

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

18 (B) POWERS OF COMMISSION.—Except as  
19 provided in subparagraph (C) and paragraphs  
20 (1)(B) and (3)—

21 (i) the Commission shall enforce this  
22 section in the same manner, by the same  
23 means, and with the same jurisdiction,  
24 powers, and duties as though all applicable  
25 terms and provisions of the Federal Trade

1 Commission Act (15 U.S.C. 41 et seq.)  
2 were incorporated into and made a part of  
3 this section; and

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

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

16 (i) such review may only be obtained  
17 in—

18 (I) the United States Court of  
19 Appeals for the District of Columbia  
20 Circuit;

21 (II) the United States Court of  
22 Appeals for the circuit in which the  
23 ultimate parent entity, as defined in  
24 section 801.1(a)(3) of title 16, Code  
25 of Federal Regulations, or any suc-



1           cessor thereto, of the NDA or BLA  
2           holder (if any such holder is a party  
3           to such order) is incorporated as of  
4           the date that the application described  
5           in subparagraph (A) or (B) of sub-  
6           section (g)(8) or an approved applica-  
7           tion that is deemed to be a license for  
8           a biological product under section  
9           351(k) of the Public Health Service  
10          Act (42 U.S.C. 262(k)) pursuant to  
11          section 7002(e)(4) of the Biologics  
12          Price Competition and Innovation Act  
13          of 2009 (Public Law 111-148; 124  
14          Stat. 817) is submitted to the Com-  
15          missioner of Food and Drugs; or  
16          (III) the United States Court of  
17          Appeals for the circuit in which the  
18          ultimate parent entity, as so defined,  
19          of any subsequent filer that is a party  
20          to such order is incorporated as of the  
21          date that the application described in  
22          subparagraph (A) or (B) of subsection  
23          (g)(8) is submitted to the Commis-  
24          sioner of Food and Drugs; and

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

5 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

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

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

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

19 (I) the Commission may com-  
20 mence a civil action under subpara-  
21 graph (A) to recover a civil penalty  
22 against any party to such order at  
23 any time before the expiration of the  
24 1-year period beginning on the date  
25 on which such order becomes final

1 under section 5(g) of such Act (15  
2 U.S.C. 45(g)); and

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

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

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

17 (ii) RELATIONSHIP TO PENALTY FOR  
18 VIOLATION OF AN ORDER.—The penalty  
19 provided in clause (i) for violation of this  
20 section is separate from and in addition to  
21 any penalty that may be incurred for viola-  
22 tion of an order of the Commission under  
23 section 5(l) of the Federal Trade Commis-  
24 sion Act (15 U.S.C. 45(l)).

25 (C) AMOUNT OF PENALTY.—

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

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

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

19 (bb) 3 times the value given  
20 to the subsequent filer (or to the  
21 other subsequent filer) reason-  
22 ably attributable to the violation  
23 of this section; and

24 (II) if such party is the subse-  
25 quent filer (or, in the case of an

1 agreement between two subsequent fil-  
2 ers, the subsequent filer who received  
3 the value described in subsection  
4 (a)(1)), 3 times the value received by  
5 such subsequent filer that is reason-  
6 ably attributable to the violation of  
7 this section.

8 (ii) FACTORS FOR CONSIDERATION.—

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

11 (I) the nature, circumstances, ex-  
12 tent, and gravity of the violation;

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

1 the value described in subsection  
2 (a)(1)), and the amount of commerce  
3 affected; and

4 (III) other matters that justice  
5 requires.

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

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

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

20 (e) FEDERAL TRADE COMMISSION RULEMAKING.—  
21 The Commission may, in its discretion, by rule promul-  
22 gated under section 553 of title 5, United States Code,  
23 exempt from this section certain agreements described in  
24 subsection (a) if the Commission finds such agreements

1 to be in furtherance of market competition and for the  
2 benefit of consumers.

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

14 (g) DEFINITIONS.—In this section:

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

20 (A) resolves or settles a covered patent in-  
21 fringement claim; or

22 (B) is contingent upon, provides for a con-  
23 tingent condition for, or is otherwise related to  
24 the resolution or settlement of a covered patent  
25 infringement claim.

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

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

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

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

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

24           (B) in the case of an agreement between  
25 an NDA or BLA holder and a subsequent filer,



1           the covered product to be manufactured under  
2           such application uses a covered product as  
3           claimed in a published patent application.

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

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

12                 (A) the holder of—

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

17                         or

18                         (ii) a biologics license application filed  
19                         under section 351(a) of the Public Health  
20                         Service Act (42 U.S.C. 262(a)) with re-  
21                         spect to a biological product;

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

24                         (i) the list published under section  
25                         505(j)(7) of the Federal Food, Drug, and

1           Cosmetic Act (21 U.S.C. 355(j)(7)) in con-  
2           nection with the application described in  
3           subparagraph (A)(i); or

4           (ii) any list published under section  
5           351 of the Public Health Service Act (42  
6           U.S.C. 262) comprised of patents associ-  
7           ated with biologics license applications filed  
8           under section 351(a) of such Act (42  
9           U.S.C. 262(a)); or

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

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

21          (7) STATUTORY EXCLUSIVITY.—The term  
22          “statutory exclusivity” means those prohibitions on  
23          the submission or approval of drug applications  
24          under clauses (ii) through (iv) of section  
25          505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)

1 through (iv) of section 505(j)(5)(F) (5-year and 3-  
2 year exclusivity), section 505(j)(5)(B)(iv) (180-day  
3 exclusivity), section 527 (orphan drug exclusivity),  
4 section 505A (pediatric exclusivity), or section 505E  
5 (qualified infectious disease product exclusivity) of  
6 the Federal Food, Drug, and Cosmetic Act (21  
7 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),  
8 360cc, 355a, 355f), or prohibitions on the submis-  
9 sion or licensing of biologics license applications  
10 under section 351(k)(6) (interchangeable biological  
11 product exclusivity) or section 351(k)(7) (biological  
12 product reference product exclusivity) of the Public  
13 Health Service Act (42 U.S.C. 262(k)(6), (7)).

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

16 (A) in the case of a drug, a party that  
17 owns or controls an abbreviated new drug appli-  
18 cation submitted pursuant to section 505(j) of  
19 the Federal Food, Drug, and Cosmetic Act (21  
20 U.S.C. 355(j)) or a new drug application sub-  
21 mitted pursuant to section 505(b)(2) of the  
22 Federal Food, Drug, and Cosmetic Act  
23 (21U.S.C. 355(b)(2)) and filed under section  
24 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or  
25 has the exclusive rights to distribute the cov-

1 ered product that is the subject of such applica-  
2 tion; or

3 (B) in the case of a biological product, a  
4 party that owns or controls an application filed  
5 with the Food and Drug Administration under  
6 section 351(k) of the Public Health Service Act  
7 (42 U.S.C. 262(k)) or has the exclusive rights  
8 to distribute the biological product that is the  
9 subject of such application.

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

13 **SEC. 612. NOTICE AND CERTIFICATION OF AGREEMENTS.**

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

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

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

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

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

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

1 **SEC. 613. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

2 Section 505(j)(5)(D)(i)(V) of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))  
4 is amended by inserting “section 611 of the Lower Drug  
5 Costs Now Act of 2019 or” after “that the agreement has  
6 violated”.

7 **SEC. 614. COMMISSION LITIGATION AUTHORITY.**

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

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

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

14 (3) by inserting after subparagraph (E) the fol-  
15 lowing:

16 “(F) under section 611(d)(3)(A) of the  
17 Lower Drug Costs Now Act of 2019;”.

18 **SEC. 615. STATUTE OF LIMITATIONS.**

19 (a) IN GENERAL.—Except as provided in subsection  
20 (b), the Commission shall commence any administrative  
21 proceeding or civil action to enforce section 611 of this  
22 Act not later than 6 years after the date on which the  
23 parties to the agreement file the Notice of Agreement as  
24 provided by section 1112(c)(2) and (d) of the Medicare  
25 Prescription Drug, Improvement, and Modernization Act  
26 of 2003 (21 U.S.C. 355 note).

1 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND  
2 DESIST ORDER.—If the Commission has issued a cease  
3 and desist order under section 5 of the Federal Trade  
4 Commission Act (15 U.S.C. 45) for violation of section  
5 611 of this Act and the proceeding for the issuance of  
6 such order was commenced within the period required by  
7 subsection (a) of this section, such subsection does not  
8 prohibit the commencement, after such period, of a civil  
9 action under section 611(d)(3)(A) against a party to such  
10 order or a civil action under subsection (l) of such section  
11 5 for violation of such order.

## 12 **Subtitle C—BLOCKING Act**

### 13 **SEC. 621. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-** 14 **SIVITY TO SPUR ACCESS AND COMPETITION.**

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

18 (1) in subclause (I), by striking “180 days  
19 after” and all that follows through the period at the  
20 end and inserting the following: “180 days after the  
21 earlier of—

22 “(aa) the date of the first com-  
23 mercial marketing of the drug (includ-  
24 ing the commercial marketing of the  
25 listed drug) by any first applicant; or

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

3 (2) by adding at the end the following new sub-  
4 clause:

5 “(III) APPLICABLE DATE.—The appli-  
6 cable date specified in this subclause, with  
7 respect to an application for a drug de-  
8 scribed in subclause (I), is the date on  
9 which each of the following conditions is  
10 first met:

11 “(aa) The approval of such an  
12 application could be made effective,  
13 but for the eligibility of a first appli-  
14 cant for 180-day exclusivity under  
15 this clause.

16 “(bb) At least 30 months have  
17 passed since the date of submission of  
18 an application for the drug by at least  
19 one first applicant.

20 “(cc) Approval of an application  
21 for the drug submitted by at least one  
22 first applicant is not precluded under  
23 clause (iii).

24 “(dd) No application for the drug  
25 submitted by any first applicant is ap-



1 proved at the time the conditions  
2 under items (aa), (bb), and (cc) are  
3 all met, regardless of whether such an  
4 application is subsequently ap-  
5 proved.”.

## 6 **Subtitle D—Purple Book**

### 7 **SEC. 631. PUBLIC LISTING.**

8 Section 351(k) of the Public Health Service Act (42  
9 U.S.C. 262(k)) is amended by adding at the end the fol-  
10 lowing:

11 “(9) PUBLIC LISTING.—

12 “(A) IN GENERAL.—

13 “(i) INITIAL PUBLICATION.—Not later  
14 than 180 days after the date of enactment  
15 of the Lower Drug Costs Now Act of  
16 2019, the Secretary shall publish and  
17 make available to the public in a search-  
18 able, electronic format—

19 “(I) a list in alphabetical order of  
20 the nonproprietary or proper name of  
21 each biological product for which a  
22 biologics license under subsection (a)  
23 or this subsection is in effect, or that  
24 has been deemed to be licensed under  
25 this section pursuant to section

1 7002(e)(4) of the Biologics Price  
2 Competition and Innovation Act of  
3 2009, as of such date of enactment;

4 “(II) the date of approval of the  
5 marketing application and the applica-  
6 tion number; and

7 “(III) the marketing or licensure  
8 status of the biological product for  
9 which a biologics license under sub-  
10 section (a) or this subsection is in ef-  
11 fect or that has been deemed to be li-  
12 censed under this section pursuant to  
13 section 7002(e)(4) of the Biologics  
14 Price Competition and Innovation Act  
15 of 2009.

16 “(ii) REVISIONS.—Every 30 days  
17 after the publication of the first list under  
18 clause (i), the Secretary shall revise the list  
19 to include each biological product which  
20 has been licensed under subsection (a) or  
21 this subsection during the 30-day period.

22 “(iii) PATENT INFORMATION.—Not  
23 later than 30 days after a list of patents  
24 under subsection (l)(3)(A), or a supple-  
25 ment to such list under subsection (l)(7),

1 has been provided by the reference product  
2 sponsor to the subsection (k) applicant re-  
3 specting a biological product included on  
4 the list published under this subparagraph,  
5 the reference product sponsor shall provide  
6 such list of patents (or supplement there-  
7 to) and their corresponding expiry dates to  
8 the Secretary, and the Secretary shall, in  
9 revisions made under clause (ii), include  
10 such information for such biological prod-  
11 uct. Within 30 days of providing any sub-  
12 sequent or supplemental list of patents to  
13 any subsequent subsection (k) applicant  
14 under subsection (l)(3)(A) or (l)(7), the  
15 reference product sponsor shall update the  
16 information provided to the Secretary  
17 under this clause with any additional pat-  
18 ents from such subsequent or supplemental  
19 list and their corresponding expiry dates.

20 “(iv) LISTING OF EXCLUSIVITIES.—

21 For each biological product included on the  
22 list published under this subparagraph, the  
23 Secretary shall specify each exclusivity pe-  
24 riod that is applicable and has not con-

1                   cluded under paragraph (6) or paragraph  
2                   (7).

3                   “(B) WITHDRAWAL OR SUSPENSION OF LI-  
4                   CENSURE.—If the licensing of a biological prod-  
5                   uct was withdrawn or suspended for safety, pu-  
6                   rity, or potency reasons, it may not be pub-  
7                   lished in the list under subparagraph (A). If the  
8                   withdrawal or suspension occurred after its  
9                   publication in such list, the reference product  
10                  sponsor shall notify the Secretary that—

11                  “(i) the biological product shall be im-  
12                  mediately removed from such list—

13                  “(I) for the same period as the  
14                  withdrawal or suspension; or

15                  “(II) if the biological product has  
16                  been withdrawn from sale, for the pe-  
17                  riod of withdrawal from sale or, if ear-  
18                  lier, the period ending on the date the  
19                  Secretary determines that the with-  
20                  drawal from sale is not for safety, pu-  
21                  rity, or potency reasons; and

22                  “(ii) a notice of the removal shall be  
23                  published in the Federal Register.”.

1 **SEC. 632. REVIEW AND REPORT ON TYPES OF INFORMA-**  
2 **TION TO BE LISTED.**

3 Not later than 3 years after the date of enactment  
4 of this Act, the Secretary of Health and Human Services  
5 shall—

6 (1) solicit public comment regarding the type of  
7 information, if any, that should be added to or re-  
8 moved from the list required by paragraph (9) of  
9 section 351(k) of the Public Health Service Act (42  
10 U.S.C. 262(k)), as added by section 631; and

11 (2) transmit to Congress an evaluation of such  
12 comments, including any recommendations about the  
13 types of information that should be added to or re-  
14 moved from the list.

15 **Subtitle E—Orange Book**

16 **SEC. 641. ORANGE BOOK.**

17 (a) **SUBMISSION OF PATENT INFORMATION FOR**  
18 **BRAND NAME DRUGS.**—Paragraph (1) of section 505(b)  
19 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 355(b)) is amended to read as follows:

21 “(b)(1) Any person may file with the Secretary an  
22 application with respect to any drug subject to the provi-  
23 sions of subsection (a). Such persons shall submit to the  
24 Secretary as part of the application—

1 “(A) full reports of investigations which have  
2 been made to show whether or not such drug is safe  
3 for use and whether such drug is effective in use;

4 “(B) a full list of the articles used as compo-  
5 nents of such drug;

6 “(C) a full statement of the composition of such  
7 drug;

8 “(D) a full description of the methods used in,  
9 and the facilities and controls used for, the manufac-  
10 ture, processing, and packing of such drug;

11 “(E) such samples of such drug and of the arti-  
12 cles used as components thereof as the Secretary  
13 may require;

14 “(F) specimens of the labeling proposed to be  
15 used for such drug;

16 “(G) any assessments required under section  
17 505B; and

18 “(H) patent information, with respect to each  
19 patent for which a claim of patent infringement  
20 could reasonably be asserted if a person not licensed  
21 by the owner engaged in the manufacture, use, or  
22 sale of the drug, and consistent with the following  
23 requirements:

1                   “(i) The applicant shall file with the appli-  
2                   cation the patent number and the expiration  
3                   date of—

4                   “(I) any patent which claims the drug  
5                   for which the applicant submitted the ap-  
6                   plication and is a drug substance (includ-  
7                   ing active ingredient) patent or a drug  
8                   product (including formulation and com-  
9                   position) patent; and

10                  “(II) any patent which claims the  
11                  method of using such drug.

12                  “(ii) If an application is filed under this  
13                  subsection for a drug and a patent of the type  
14                  described in clause (i) which claims such drug  
15                  or a method of using such drug is issued after  
16                  the filing date but before approval of the appli-  
17                  cation, the applicant shall amend the applica-  
18                  tion to include such patent information.

19 Upon approval of the application, the Secretary shall pub-  
20 lish the information submitted under subparagraph (H).  
21 The Secretary shall, in consultation with the Director of  
22 the National Institutes of Health and with representatives  
23 of the drug manufacturing industry, review and develop  
24 guidance, as appropriate, on the inclusion of women and

1 minorities in clinical trials required by subparagraph  
2 (A).”.

3 (b) CONFORMING CHANGES TO REQUIREMENTS FOR  
4 SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—  
5 Section 505(c)(2) of the Federal Food, Drug, and Cos-  
6 metic Act (21 U.S.C. 355(j)(7)) is amended—

7 (1) by inserting after “the patent number and  
8 the expiration date of any patent which” the fol-  
9 lowing: “fulfills the criteria in subsection (b) and”;

10 (2) by inserting after the first sentence the fol-  
11 lowing: “Patent information that is not the type of  
12 patent information required by subsection (b) shall  
13 not be submitted.”; and

14 (3) by inserting after “could not file patent in-  
15 formation under subsection (b) because no patent”  
16 the following: “of the type required to be submitted  
17 in subsection (b)”.

18 (c) LISTING OF EXCLUSIVITIES.—Subparagraph (A)  
19 of section 505(j)(7) of the Federal Food, Drug, and Cos-  
20 metic Act (21 U.S.C. 355(j)(7)) is amended by adding at  
21 the end the following:

22 “(iv) For each drug included on the list, the Sec-  
23 retary shall specify each exclusivity period that is applica-  
24 ble and has not concluded under—



1 “(I) clause (ii), (iii), or (iv) of subsection  
2 (c)(3)(E) of this section;

3 “(II) clause (iv) or (v) of paragraph (5)(B) of  
4 this subsection;

5 “(III) clause (ii), (iii), or (iv) of paragraph  
6 (5)(F) of this subsection;

7 “(IV) section 505A;

8 “(V) section 505E; or

9 “(VI) section 527(a).”.

10 (d) REMOVAL OF INVALID PATENTS.—

11 (1) IN GENERAL.—Section 505(j)(7) of the  
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 355(j)(7)) is amended by adding at the end the fol-  
14 lowing:

15 “(D)(i) The holder of an application approved under  
16 subsection (c) for a drug on the list shall notify within  
17 14 days the Secretary in writing if either of the following  
18 occurs:

19 “(I) The Patent Trial and Appeals Board issues  
20 a decision from which no appeal has been or can be  
21 taken that a patent for such drug is invalid.

22 “(II) A court issues a decision from which no  
23 appeal has been or can be taken that a patent for  
24 such drug is invalid.

1       “(ii) The holder of an approved application shall in-  
2 clude in any notification under clause (i) a copy of the  
3 decision described in subclause (I) or (II) of clause (i).

4       “(iii) The Secretary shall remove from the list any  
5 patent that is determined to be invalid in a decision de-  
6 scribed in subclause (I) or (II) of clause (i)—

7               “(I) promptly; but

8               “(II) not before the expiration of any 180-day  
9 exclusivity period under paragraph (5)(B)(iv) that  
10 relies on a certification described in paragraph  
11 (2)(A)(vii)(IV) that such patent was invalid.”.

12       (2) APPLICABILITY.—Subparagraph (D) of sec-  
13 tion 505(j)(7) of the Federal Food, Drug, and Cos-  
14 metic Act (21 U.S.C. 355(j)(7)), as added by para-  
15 graph (1), applies only with respect to a decision de-  
16 scribed in such subparagraph that is issued on or  
17 after the date of enactment of this Act.

18       (e) REVIEW AND REPORT.—Not later than one year  
19 after the date of enactment of this Act, the Secretary of  
20 Health and Human Services, acting through the Commis-  
21 sioner of Food and Drugs, shall—

22               (1) solicit public comment regarding the types  
23 of patent information that should be included on the  
24 list under section 507(j)(7) of the Federal Food,  
25 Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

1 (2) transmit to the Congress an evaluation of  
2 such comments, including any recommendations  
3 about the types of patent information that should be  
4 included on or removed from such list.

5 **SEC. 642. GAO REPORT TO CONGRESS.**

6 (a) IN GENERAL.—Not later than one year after the  
7 date of enactment of this Act, the Comptroller General  
8 of the United States (referred to in this section as the  
9 “Comptroller General”) shall submit to the Committee on  
10 Energy and Commerce of the House of Representatives  
11 a report on the patents included in the list published under  
12 section 505(j)(7) of the Federal Food, Drug and Cosmetic  
13 Act (21 U.S.C. 355(j)(7)), including an analysis and eval-  
14 uation of the types of patents included in such list and  
15 the claims such patents make about the products they  
16 claim.

17 (b) CONTENTS.—The Comptroller General shall in-  
18 clude in the report under subsection (a)—

19 (1) data on the number of—

20 (A) patents included in the list published  
21 under paragraph (7) of section 505(j) of the  
22 Federal Food, Drug and Cosmetic Act (21  
23 U.S.C. 355(j)), that claim the active ingredient  
24 or formulation of a drug in combination with a  
25 device that is used for delivery of the drug, to-

1           gether comprising the finished dosage form of  
2           the drug; and

3           (B) claims in each patent that claim a de-  
4           vice that is used for the delivery of the drug,  
5           but do not claim such device in combination  
6           with an active ingredient or formulation of a  
7           drug;

8           (2) data on the date of inclusion in the list  
9           under paragraph (7) of such section 505(j) for all  
10          patents under such list, as compared to patents that  
11          claim a method of using the drug in combination  
12          with a device;

13          (3) an analysis regarding the impact of includ-  
14          ing on the list under paragraph (7) of such section  
15          505(j) certain types of patent information for drug  
16          product applicants and approved application holders,  
17          including an analysis of whether—

18                 (A) the listing of the patents described in  
19                 paragraph (1)(A) delayed the market entry of  
20                 one or more drugs approved under such section  
21                 505(j); and

22                 (B) not listing the patents described in  
23                 paragraph (1)(A) would delay the market entry  
24                 of one or more such drugs; and

1 (4) recommendations about which kinds of pat-  
2 ents relating to devices described in paragraph  
3 (1)(A) should be submitted to the Secretary of  
4 Health and Human Services for inclusion on the list  
5 under paragraph (7) of such section 505(j) and  
6 which patents should not be required to be so sub-  
7 mitted.

## 8 **Subtitle F—Advancing Education** 9 **on Biosimilars**

### 10 **SEC. 51. EDUCATION ON BIOLOGICAL PRODUCTS.**

11 (a) WEBSITE; CONTINUING EDUCATION.—Subpart 1  
12 of part F of title III of the Public Health Service Act (42  
13 U.S.C. 262 et seq.) is amended by adding at the end the  
14 following:

#### 15 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

16 **“(a) INTERNET WEBSITE.—**

17 **“(1) IN GENERAL.—**The Secretary shall main-  
18 tain and operate an internet website to provide edu-  
19 cational materials for health care providers, patients,  
20 and caregivers, regarding the meaning of the terms,  
21 and the standards for review and licensing of, bio-  
22 logical products, including biosimilar biological prod-  
23 ucts and interchangeable biosimilar biological prod-  
24 ucts.

1 “(2) CONTENT.—Educational materials pro-  
2 vided under paragraph (1) may include—

3 “(A) explanations of key statutory and  
4 regulatory terms, including ‘biosimilar’ and  
5 ‘interchangeable’, and clarification regarding  
6 the use of interchangeable biosimilar biological  
7 products;

8 “(B) information related to development  
9 programs for biological products, including bio-  
10 similar biological products and interchangeable  
11 biosimilar biological products and relevant clin-  
12 ical considerations for prescribers, which may  
13 include, as appropriate and applicable, informa-  
14 tion related to the comparability of such biologi-  
15 cal products;

16 “(C) an explanation of the process for re-  
17 porting adverse events for biological products,  
18 including biosimilar biological products and  
19 interchangeable biosimilar biological products;  
20 and

21 “(D) an explanation of the relationship be-  
22 tween biosimilar biological products and inter-  
23 changeable biosimilar biological products li-  
24 censed under section 351(k) and reference  
25 products (as defined in section 351(i)), includ-

1           ing the standards for review and licensing of  
2           each such type of biological product.

3           “(3) **FORMAT.**—The educational materials pro-  
4           vided under paragraph (1) may be—

5                   “(A) in formats such as webinars, con-  
6           tinuing medical education modules, videos, fact  
7           sheets, infographics, stakeholder toolkits, or  
8           other formats as appropriate and applicable;  
9           and

10                   “(B) tailored for the unique needs of  
11           health care providers, patients, caregivers, and  
12           other audiences, as the Secretary determines  
13           appropriate.

14           “(4) **OTHER INFORMATION.**—In addition to the  
15           information described in paragraph (2), the Sec-  
16           retary shall continue to publish the following infor-  
17           mation:

18                   “(A) The action package of each biological  
19           product licensed under subsection (a) or (k).

20                   “(B) The summary review of each biologi-  
21           cal product licensed under subsection (a) or (k).

22           “(5) **CONFIDENTIAL AND TRADE SECRET IN-**  
23           **FORMATION.**—This subsection does not authorize  
24           the disclosure of any trade secret, confidential com-

1 commercial or financial information, or other matter de-  
2 scribed in section 552(b) of title 5.

3 “(b) CONTINUING EDUCATION.—The Secretary shall  
4 advance education and awareness among health care pro-  
5 viders regarding biological products, including biosimilar  
6 biological products and interchangeable biosimilar biologi-  
7 cal products, as appropriate, including by developing or  
8 improving continuing education programs that advance  
9 the education of such providers on the prescribing of, and  
10 relevant clinical considerations with respect to, biological  
11 products, including biosimilar biological products and  
12 interchangeable biosimilar biological products.”

13 (b) APPLICATION UNDER THE MEDICARE MERIT-  
14 BASED INCENTIVE PAYMENT SYSTEM.—Section  
15 1848(q)(5)(C) of the Social Security Act (42 U.S.C.  
16 1395w-4(q)(5)(C)) is amended by adding at the end the  
17 following new clause:

18 “(iv) CLINICAL MEDICAL EDUCATION  
19 PROGRAM ON BIOSIMILAR BIOLOGICAL  
20 PRODUCTS.—Completion of a clinical med-  
21 ical education program developed or im-  
22 proved under section 352A(b) of the Public  
23 Health Service Act by a MIPS eligible pro-  
24 fessional during a performance period shall  
25 earn such eligible professional one-half of



1 the highest potential score for the perform-  
2 ance category described in paragraph  
3 (2)(A)(iii) for such performance period. A  
4 MIPS eligible professional may only count  
5 the completion of such a program for pur-  
6 poses of such category one time during the  
7 eligible professional's lifetime.”.



