**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):

# TITLE VI—FOOD AND DRUG ADMINISTRATION

## Subtitle A—CREATES Act

### SEC. 601. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term "commercially reasonable, market-based terms" means—

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

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

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

(2) the term "covered product"—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

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

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

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage;

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

(4) the term "eligible product developer" means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 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—

(A) conduct testing to support an application under—

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

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

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

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

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

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

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has submitted a written request to purchase sufficient quantities of the covered product to the license holder and such request—

(I) was sent to a named corporate officer of the license holder;

(II) was made by certified or registered mail with return receipt requested;

(III) specified an individual as the point of contact for the license holder to direct communications related to the sale of the covered product to the eligible product developer and a means for electronic and written communications with that individual; and

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

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

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

date on which the license holder received the request for the covered product; and

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

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

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

shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

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

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

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

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

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

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

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

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

otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms;

(B) that—

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

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to the individual specified pursuant to paragraph (2)(A)(iii)(III), by a means of communication (electronic, written, or both) specified pursuant to such paragraph, to sell sufficient quantities of the covered product to the eligible

product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product developer received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) REMEDIES.—

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

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

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

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

(i) beginning on—

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

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

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

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

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

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

"(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are

defined in section 601(a) of the Lower Drug Costs Now Act of 2019) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under this section for such drug.".

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term "antitrust laws"—

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

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

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

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

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking "or" after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 505(j), and the applicable listed drug.";

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:

"(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 505(j) may use—

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

"(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

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

under section 505(j) and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).";

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

"(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug."; and

(4) by adding at the end the following:

"(m) SEPARATE REMS.—When used in this section, the terms 'different, comparable aspect of the elements to assure safe use' or 'different, comparable approved risk evaluation and mitigation strategies' means a risk evaluation and mitigation strategy for a drug that is the subject

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

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

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

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

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

(b) DEFINITIONS.—In this section, the terms "covered product", "eligible product developer", "license holder", and "REMS with ETASU" have the meanings given such terms in section 601(a).

# Subtitle B—Pay-for-Delay

**SEC. 611. UNLAWFUL AGREEMENTS.**

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

(1) a subsequent filer directly or indirectly receives from such holder (or in the case of such an agreement between two subsequent filers, the other subsequent filer) anything of value, including a license; and

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

(b) EXCLUSION.—It shall not be unlawful under subsection (a) if a party to an agreement described in such subsection demonstrates by clear and convincing evidence that the value described in subsection (a)(1) is compensation solely for other goods or services that the subsequent filer has promised to provide.

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

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

(A) any patent that is the basis of the covered patent infringement claim; or

(B) any patent right or other statutory exclusivity that would prevent the marketing of such covered product.

(2) A payment for reasonable litigation expenses not to exceed $7,500,000 in the aggregate.

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

(d) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

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

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

(B) a person, partnership, or corporation over which the Commission would have authority pursuant to such section but for the fact that such person, partnership, or corporation is not organized to carry on business for its own profit or that of its members.

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

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

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

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

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

(ii) any NDA or BLA holder or subsequent filer that violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act.

(C) JUDICIAL REVIEW.—In the case of a cease and desist order issued by the Commission under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section, a party to such order may obtain judicial review of such order as provided in such section 5, except that—

(i) such review may only be obtained in—

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

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

cessor thereto, of the NDA or BLA holder (if any such holder is a party to such order) is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (g)(8) or an approved application that is deemed to be a license for a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148; 124 Stat. 817) is submitted to the Commissioner of Food and Drugs; or

(III) the United States Court of Appeals for the circuit in which the ultimate parent entity, as so defined, of any subsequent filer that is a party to such order is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (g)(8) is submitted to the Commissioner of Food and Drugs; and

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

(3) ADDITIONAL ENFORCEMENT AUTHORITY.—

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

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

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

(I) the Commission may commence a civil action under subparagraph (A) to recover a civil penalty against any party to such order at any time before the expiration of the 1-year period beginning on the date on which such order becomes final

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

(II) in such civil action, the findings of the Commission as to the material facts in such proceeding shall be conclusive, unless—

(aa) the terms of such order expressly provide that the Commission's findings shall not be conclusive; or

(bb) such order became final by reason of section 5(g)(1) of such Act (15 U.S.C. 45(g)(1)), in which case such findings shall be conclusive if supported by evidence.

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

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The amount of a civil penalty imposed in a civil action under subparagraph (A) on a party to an agreement described in subsection (a) shall be sufficient to deter violations of this section, but in no event greater than—

(I) if such party is 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)), the greater of—

(aa) 3 times the value received by such NDA or BLA holder (or by such subsequent filer) that is reasonably attributable to the violation of this section; or

(bb) 3 times the value given to the subsequent filer (or to the other subsequent filer) reasonably 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)), compensation received by 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)), and the amount of commerce affected; and

(III) other matters that justice requires.

(D) INJUNCTIONS AND OTHER EQUITABLE RELIEF.—In a civil action under subparagraph (A), the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

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

(5) PRESERVATION OF AUTHORITY OF COMMISSION.—Nothing in this section shall be construed to affect any authority of the Commission under any other provision of law.

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

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

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

(g) DEFINITIONS.—In this section:

(1) AGREEMENT RESOLVING OR SETTLING A COVERED PATENT INFRINGEMENT CLAIM.—The term ''agreement resolving or settling a covered patent infringement claim'' means any agreement that—

(A) resolves or settles a covered patent infringement claim; or

(B) is contingent upon, provides for a contingent condition for, or is otherwise related to the resolution or settlement of a covered patent infringement claim.

(2) COMMISSION.—The term "Commission" means the Federal Trade Commission.

(3) COVERED PATENT INFRINGEMENT CLAIM.—The term "covered patent infringement claim" means an allegation made by the NDA or BLA holder to a subsequent filer (or, in the case of an agreement between two subsequent filers, by one subsequent filer to another), whether or not included in a complaint filed with a court of law, that—

(A) the submission of the application described in subparagraph (A) or (B) of paragraph (9), or the manufacture, use, offering for sale, sale, or importation into the United States of a covered product that is the subject of such an application—

(i) in the case of an agreement between an NDA or BLA holder and a subsequent filer, infringes any patent owned by, or exclusively licensed to, the NDA or BLA holder of the covered product; or

(ii) in the case of an agreement between two subsequent filers, infringes any patent owned by the subsequent filer; or

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

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

(4) COVERED PRODUCT.—The term "covered product" means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) NDA OR BLA HOLDER.—The term "NDA or BLA holder" means—

(A) the holder of—

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

(ii) a biologics license application filed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product;

(B) a person owning or controlling enforcement of the patent on—

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

Cosmetic Act (21 U.S.C. 355(j)(7)) in connection with the application described in subparagraph (A)(i); or

(ii) any list published under section 351 of the Public Health Service Act (42 U.S.C. 262) comprised of patents associated with biologics license applications filed under section 351(a) of such Act (42 U.S.C. 262(a)); or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any entity described in subparagraph (A) or (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(6) PATENT.—The term "patent" means a patent issued by the United States Patent and Trademark Office.

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

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

(8) SUBSEQUENT FILER.—The term "subsequent filer" means—

(A) in the case of a drug, a party that owns or controls an abbreviated new drug application submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21U.S.C. 355(b)(2)) and filed under section 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or has the exclusive rights to distribute the cov-

ered product that is the subject of such application; or

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

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

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

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

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

"(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement under subsection (a) or (b) that is required to be filed under subsection (c) shall, within 30 days of such filing, execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

"'(1) represent the complete, final, and exclusive agreement between the parties;

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

"'(3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

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

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

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

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

(1) in subparagraph (D), by striking "or" after the semicolon;

(2) in subparagraph (E), by inserting "or" after the semicolon; and

(3) by inserting after subparagraph (E) the following:

"(F) under section 611(d)(3)(A) of the Lower Drug Costs Now Act of 2019;".

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

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

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

# Subtitle C—BLOCKING Act

**SEC. 621. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.**

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking "180 days after" and all that follows through the period at the end and inserting the following: "180 days after the earlier of—

"(aa) the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

"(bb) the applicable date specified in subclause (III).''; and

(2) by adding at the end the following new subclause:

"(III) APPLICABLE DATE.—The applicable date specified in this subclause, with respect to an application for a drug described in subclause (I), is the date on which each of the following conditions is first met:

"(aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

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

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

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

proved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved.".

# Subtitle D—Purple Book

**SEC. 631. PUBLIC LISTING.**

Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended by adding at the end the following:

"(9) PUBLIC LISTING.—

"(A) IN GENERAL.—

"(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of the Lower Drug Costs Now Act of 2019, the Secretary shall publish and make available to the public in a searchable, electronic format—

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

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

"(II) the date of approval of the marketing application and the application number; and

"(III) the marketing or licensure status of the biological product for which a biologics license under subsection (a) or this subsection is in effect or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

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

"(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7),

has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

"(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period that is applicable and has not con-

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

"(B) WITHDRAWAL OR SUSPENSION OF LICENSURE.—If the licensing of a biological product was withdrawn or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If the withdrawal or suspension occurred after its publication in such list, the reference product sponsor shall notify the Secretary that—

"(i) the biological product shall be immediately removed from such list—

"(I) for the same period as the withdrawal or suspension; or

"(II) if the biological product has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety, purity, or potency reasons; and

"(ii) a notice of the removal shall be published in the Federal Register.".

**SEC. 632. REVIEW AND REPORT ON TYPES OF INFORMATION TO BE LISTED.**

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

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

(2) transmit to Congress an evaluation of such comments, including any recommendations about the types of information that should be added to or removed from the list.

# Subtitle E—Orange Book

**SEC. 641. ORANGE BOOK.**

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

"(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

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

"(B) a full list of the articles used as components of such drug;

"(C) a full statement of the composition of such drug;

"(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

"(E) such samples of such drug and of the articles used as components thereof as the Secretary may require;

"(F) specimens of the labeling proposed to be used for such drug;

"(G) any assessments required under section 505B; and

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

"(i) The applicant shall file with the application the patent number and the expiration date of—

"(I) any patent which claims the drug for which the applicant submitted the application and is a drug substance (including active ingredient) patent or a drug product (including formulation and composition) patent; and

"(II) any patent which claims the method of using such drug.

"(ii) If an application is filed under this subsection for a drug and a patent of the type described in clause (i) which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include such patent information.

Upon approval of the application, the Secretary shall publish the information submitted under subparagraph (H). The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and

minorities in clinical trials required by subparagraph (A).".

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

(1) by inserting after "the patent number and the expiration date of any patent which" the following: "fulfills the criteria in subsection (b) and";

(2) by inserting after the first sentence the following: "Patent information that is not the type of patent information required by subsection (b) shall not be submitted."; and

(3) by inserting after "could not file patent information under subsection (b) because no patent" the following: "of the type required to be submitted in subsection (b)".

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

"(iv) For each drug included on the list, the Secretary shall specify each exclusivity period that is applicable and has not concluded under—

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

"(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

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

"(IV) section 505A;

"(V) section 505E; or

"(VI) section 527(a).".

(d) REMOVAL OF INVALID PATENTS.—

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

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

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

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

"(ii) The holder of an approved application shall include in any notification under clause (i) a copy of the decision described in subclause (I) or (II) of clause (i).

"(iii) The Secretary shall remove from the list any patent that is determined to be invalid in a decision described in subclause (I) or (II) of clause (i)—

"(I) promptly; but

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

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(e) REVIEW AND REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

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

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

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

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Comptroller General of the United States (referred to in this section as the "Comptroller General") shall submit to the Committee on Energy and Commerce of the House of Representatives a report on the patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)), including an analysis and evaluation of the types of patents included in such list and the claims such patents make about the products they claim.

(b) CONTENTS.—The Comptroller General shall include in the report under subsection (a)—

(1) data on the number of—

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

gether comprising the finished dosage form of the drug; and

(B) claims in each patent that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient or formulation of a drug;

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

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

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

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

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

# Subtitle F—Advancing Education on Biosimilars

**SEC. _51. EDUCATION ON BIOLOGICAL PRODUCTS.**

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

**"SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

"(a) INTERNET WEBSITE.—

"(1) IN GENERAL.—The Secretary shall maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

"(2) CONTENT.—Educational materials provided under paragraph (1) may include—

"(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

"(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

"(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

"(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), includ-

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

"(3) FORMAT.—The educational materials provided under paragraph (1) may be—

"(A) in formats such as webinars, continuing medical education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

"(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

"(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish the following information:

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

"(B) The summary review of each biological product licensed under subsection (a) or (k).

"(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential com-

mercial or financial information, or other matter described in section 552(b) of title 5.

"(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.".

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

"(iv) CLINICAL MEDICAL EDUCATION PROGRAM ON BIOSIMILAR BIOLOGICAL PRODUCTS.—Completion of a clinical medical education program developed or improved under section 352A(b) of the Public Health Service Act by a MIPS eligible professional during a performance period shall earn such eligible professional one-half of

the highest potential score for the performance category described in paragraph (2)(A)(iii) for such performance period. A MIPS eligible professional may only count the completion of such a program for purposes of such category one time during the eligible professional's lifetime.".

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