AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.

S. 1416

To amend the Federal Trade Commission Act to prohibit anticompetitive behaviors by drug product manufacturers, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. CORNYN

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Affordable Prescriptions for Patients Act of 2019''.

SEC. 2. PRODUCT HOPPING.

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 41 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c–2) the following:

''SEC. 27. PRODUCT HOPPING.

''(a) DEFINITIONS.—In this section:

''(1) ABBREVIATED NEW DRUG APPLICATION.—The term 'abbreviated new drug application' means an application under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

''(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

''(3) BIOSIMILAR BIOLOGICAL PRODUCT LICENSE APPLICATION.—The term 'biosimilar biological product license application' means an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

''(4) FOLLOW-ON PRODUCT.—The term 'follow-on product'—

''(A) means a drug approved through an application or supplement to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or a biological product licensed through an application or supplement to an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a change, modification, or reformulation to the

same manufacturer's previously approved drug or biological product that treats the same medical condition; and

"(B) excludes such an application or supplement to an application for a change, modification, or reformulation of a drug or biological product that is requested by the Secretary or necessary to comply with law, including sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

"(5) GENERIC DRUG.—The term 'generic drug' means a drug approved under an application submitted under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

"(6) LISTED DRUG.—The term 'listed drug' means a drug listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)).

"(7) MANUFACTURER.—The term 'manufacturer' means the holder, licensee, or assignee of—

"(A) an approved application for a drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

''(B) a biological product license under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

''(8) REFERENCE PRODUCT.—The term 'reference product' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

''(9) ULTIMATE PARENT ENTITY.—The term 'ultimate parent entity' has the meaning given the term in section 801.1 of title 16, Code of Federal Regulations, or any successor regulation.

''(b) PROHIBITION ON PRODUCT HOPPING.—

''(1) PRIMA FACIE.—Except as provided in paragraph (2), a manufacturer of a reference product or listed drug shall be considered to have engaged in an unfair method of competition in or affecting commerce in violation of section 5(a) if the Commission demonstrates by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that, during the period beginning on the date on which the manufacturer of the reference product or listed drug first receives notice that an applicant has submitted to the Commissioner of Food and Drugs

an abbreviated new drug application or biosimilar biological product license application and ending on the date that is 180 days after the date on which that generic drug or biosimilar biological product is first marketed, the manufacturer engaged in either of the following actions:

''(A) The manufacturer engaged in a hard switch, which shall be established by demonstrating that the manufacturer engaged in either of the following actions:

''(i) Upon the request of the manufacturer of the listed drug or reference product, the Commissioner of Food and Drugs withdrew the approval of the application for the listed drug or reference product or placed the listed drug or reference product on the discontinued products list and the manufacturer marketed or sold a follow-on product.

''(ii)(I) The manufacturer of the listed drug or reference product—

''(aa) announced withdrawal of, discontinuance of the manufacture of, or intent to withdraw the application with respect to the drug or reference

product in a manner that impedes competition from a generic drug or a biosimilar biological product, as established by objective circumstances; or

''(bb) destroyed the inventory of the listed drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, which may be established by objective circumstances; and

''(II) marketed or sold a follow-on product.

''(B) The manufacturer engaged in a soft switch, which shall be established by demonstrating that the manufacturer engaged in both of the following actions:

''(i) The manufacturer took actions with respect to the listed drug or reference product other than those described in subparagraph (A) that unfairly disadvantage the listed drug or reference product relative to the follow-on product described in clause (ii) in a manner that impedes competition from a generic drug or a biosimilar biological product that is highly

similar to, and has no clinically meaningful difference with respect to safety, purity, and potency from, the reference product, which may be established by objective circumstances.

''(ii) The manufacturer marketed or sold a follow-on product.

''(2) JUSTIFICATION.—

''(A) IN GENERAL.—Subject to paragraph (3), the actions described in paragraph (1) by a manufacturer of a listed drug or reference product shall not be considered to be an unfair method of competition in or affecting commerce if—

''(i) the manufacturer demonstrates to the Commission or a district court of the United States, as applicable, by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that—

''(I) the manufacturer would have taken the actions regardless of whether a generic drug that ref-

erences the listed drug or biosimilar biological product that references the reference product had already entered the market; and

''(II)(aa) with respect to a hard switch under paragraph (1)(A), the manufacturer took the action for reasons relating to the safety risk to patients of the listed drug or reference product;

''(bb) with respect to an action described in item (aa) or (bb) of paragraph (1)(A)(ii)(I), there is a supply disruption that—

''(AA) is outside of the control of the manufacturer;

''(BB) prevents the production or distribution of the applicable listed drug or reference product; and

''(CC) cannot be remedied by reasonable efforts; or

''(cc) with respect to a soft switch under paragraph (1)(B), the manufacturer had legitimate pro-com-

petitive reasons, apart from the financial effects of reduced competition, to take the action.

"(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) may be construed to limit the information that the Commission may otherwise obtain in any proceeding or action instituted with respect to a violation of this section.

"(3) RESPONSE.—With respect to a justification offered by a manufacturer under paragraph (2), the Commission may—

"(A) rebut any evidence presented by a manufacturer during that justification; or

"(B) establish by a preponderance of the evidence that, on balance, the pro-competitive benefits from the conduct described in subparagraph (A) or (B) of paragraph (1), as applicable, do not outweigh any anticompetitive effects of the conduct, even in consideration of the justification so offered.

"(c) ENFORCEMENT.—

"(1) IN GENERAL.—If the Commission has reason to believe that any manufacturer has violated, is violating, or is about to violate this section, the Commission may take any of the following actions:

"(A) Institute a proceeding—

"(i) that, except as provided in paragraph (2), complies with the requirements under section 5(b); and

"(ii) in which the Commission may impose on the manufacturer any penalty that the Commission may impose for a violation of section 5.

"(B) In the same manner and to the same extent as provided in section 13(b), bring suit in a district court of the United States to temporarily enjoin the action of the manufacturer.

"(C) Bring suit in a district court of the United States, in which the Commission may seek—

"(i) to permanently enjoin the action of the manufacturer;

"(ii) any of the remedies described in paragraph (3); and

"(iii) any other equitable remedy, including ancillary equitable relief.

"(2) JUDICIAL REVIEW.—

"(A) IN GENERAL.—Notwithstanding any provision of section 5, any manufacturer that is subject to a final order of the Commission that

is issued in a proceeding initiated under paragraph (1)(A) may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

"(i) the United States Court of Appeals for the District of Columbia Circuit; or

"(ii) the court of appeals of the United States for the circuit in which the ultimate parent entity of the manufacturer is incorporated.

"(B) TREATMENT OF FINDINGS.—In a review of an order issued by the Commission conducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

"(3) EQUITABLE REMEDIES.—

"(A) DISGORGEMENT.—

"(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, disgorgement of any unjust enrichment that a person obtained as a result of the violation that gives rise to the suit.

"(ii) CALCULATION.—Any disgorgement that is ordered with respect to a person under clause (i) shall be offset by any amount of restitution ordered under subparagraph (B).

"(iii) LIMITATIONS PERIOD.—The Commission may seek disgorgement under this subparagraph not later than 5 years after the latest date on which the person from which the disgorgement is sought receives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the disgorgement.

"(B) RESTITUTION.—

"(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, restitution with respect to the violation that gives rise to the suit.

"(ii) LIMITATIONS PERIOD.—The Commission may seek restitution under this subparagraph not later than 5 years after the latest date on which the person from which the restitution is sought re-

ceives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the restitution.

''(4) RULES OF CONSTRUCTION.—Nothing in this subsection may be construed as—

''(A) requiring the Commission to bring a suit seeking a temporary injunction under paragraph (1)(B) before bringing a suit seeking a permanent injunction under paragraph (1)(C); or

''(B) affecting any other authority of the Commission under this Act to seek relief or obtain a remedy with respect to a violation of this Act.''.

(b) APPLICABILITY.—Section 27 of the Federal Trade Commission Act, as added by subsection (a), shall apply with respect to any—

(1) conduct that occurs on or after the date of enactment of this Act; and

(2) action or proceeding that is commenced on or after the date of enactment of this Act.

(c) ANTITRUST LAWS.—Nothing in this section, or the amendments made by 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 it applies to unfair methods of competition.

(d) RULEMAKING.—The Federal Trade Commission may issue rules under section 553 of title 5, United States Code, to carry out section 27 of the Federal Trade Commission Act, as added by subsection (a), including by defining any terms used in such section 27 (other than terms that are defined in subsection (a) of such section 27).

SEC. 3. TITLE 35 AMENDMENTS.

(a) IN GENERAL.—Section 271(e) of title 35, United States Code, is amended—

(1) in paragraph (2)(C), in the flush text following clause (ii), by adding at the end the following: ''With respect to a submission described in clause (ii), the act of infringement shall extend to any patent that claims the biological product, a method of using the biological product, or a method or product used to manufacture the biological product.''; and

(2) by adding at the end the following:

''(7)(A) Subject to subparagraphs (C), (D), and (E), if the sponsor of an approved application for a reference product, as defined in section 351(i) of the Public Health

Service Act (42 U.S.C. 262(i)) (referred to in this paragraph as the 'reference product sponsor'), brings an action for infringement under this section against an applicant for approval of a biological product under section 351(k) of such Act that references that reference product (referred to in this paragraph as the 'subsection (k) applicant'), the reference product sponsor may assert in the action a total of not more than 20 patents of the type described in subparagraph (B), not more than 10 of which shall have issued after the date specified in section 351(l)(7)(A) of such Act.

''(B) The patents described in this subparagraph are patents that satisfy each of the following requirements:

''(i) Patents that claim the biological product that is the subject of an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) (or a use of that product) or a method or product used in the manufacture of such biological product.

''(ii) Patents that are included on the list of patents described in section 351(l)(3)(A) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)), including as provided under section 351(l)(7) of such Act.

''(iii) Patents that—

"(I) have an actual filing date of more than 4 years after the date on which the reference product is approved; or

"(II) include a claim to a method in a manufacturing process that is not used by the reference product sponsor.

"(C) The court in which an action described in subparagraph (A) is brought may increase the number of patents limited under that subparagraph—

"(i) if the request to increase that number is made without undue delay; and

"(ii)(I) if the interest of justice so requires; or

"(II) for good cause shown, which—

"(aa) shall be established if the subsection (k) applicant fails to provide information required under paragraph (2)(A) that would enable the reference product sponsor to form a reasonable belief with respect to whether a claim of infringement under this section could reasonably be asserted; and

"(bb) may be established—

"(AA) if there is a material change to the biological product (or process with respect to the biological product) of the sub-

section (k) applicant that is the subject of the application;

''(BB) if, with respect to a patent on the supplemental list described in section 351(l)(7)(A) of Public Health Service Act (42 U.S.C. 262(l)(7)(A)), the patent would have issued before the date specified in such section 351(l)(7)(A) but for the failure of the Office to issue the patent or a delay in the issuance of the patent, as described in paragraph (1) of section 154(b) and subject to the limitations under paragraph (2) of such section 154(b); or

''(CC) for another reason that shows good cause, as determined appropriate by the court.

''(D) In determining whether good cause has been shown for the purposes of subparagraph (C)(ii)(II), a court may consider whether the reference product sponsor has provided a reasonable description of the identity and relevance of any information beyond the subsection (k) application that the court believes is necessary to enable the court to form a belief with respect to whether a claim of infringement under this section could reasonably be asserted.

"(E) The limitation imposed under subparagraph (A)—

"(i) shall apply only if the subsection (k) applicant completes all actions required under paragraphs (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)); and

"(ii) shall not apply with respect to any patent that claims, with respect to a biological product, a method for using that product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.".

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply with respect to an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) on or after the date of enactment of this Act.