AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2891 OFFERED BY MR. NADLER OF NEW YORK

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preserve Access to Affordable Generics and Biosimilars Act''.

SEC. 2. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 44 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c–2) the following:

''SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS.

''(a) IN GENERAL.—

''(1) ENFORCEMENT PROCEEDING.—The Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent claim, in connection with the sale of a drug product or biological product.

''(2) PRESUMPTION AND VIOLATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and shall be a violation of this section if—

''(i) an ANDA filer or a biosimilar biological product application filer receives anything of value, including an exclusive license; and

''(ii) the ANDA filer or biosimilar biological product application filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product or biosimilar biological product, as applicable, for any period of time.

''(B) EXCEPTION.—Subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that—

''(i) the value described in subparagraph (A)(i) is compensation solely for other goods or services that the ANDA filer or biosimilar biological product application filer has promised to provide; or

''(ii) the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

''(b) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

''(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

''(2) that the agreement's provision for entry of the ANDA product or biosimilar biological product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive.

''(c) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration that the ANDA filer or biosimilar biological product application filer, respectively, receives as part of the resolution or settlement includes only one or more of the following:

''(1) The right to market and secure final approval in the United States for the ANDA product or biosimilar biological product at a date, whether certain or contingent, prior to the expiration of—

''(A) any patent that is the basis for the patent infringement claim; or

''(B) any patent right or other statutory exclusivity that would prevent the marketing of such ANDA product or biosimilar biological product.

''(2) A payment for reasonable litigation expenses not to exceed— (A) for calendar year 2021, $7,500,000; or (B) for calendar year 2022 and each subsequent calendar year, the amount determined for the preceding calendar year adjusted to reflect the percentage increase (if any) in the Producer Price Index for Legal Services published by the Bureau of Labor Statistics of the Department of Labor for the most recent calendar year.

''(3) A covenant not to sue on any claim that the ANDA product or biosimilar biological product infringes a United States patent.

''(d) ENFORCEMENT.—

''(1) ENFORCEMENT.—A violation of this section shall be treated an unfair method of competition under section 5(a)(1).

''(2) JUDICIAL REVIEW.—

''(A) IN GENERAL.—Any party that is subject to a final order of the Commission, issued

in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order 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 successor thereto, of the NDA holder or biological product license holder is incorporated as of the date that the NDA or biological product license application, as applicable, is filed with the Commissioner of Food and Drugs; or

''(iii) the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer or biosimilar biological product application filer is incorporated as of the date that the ANDA or biosimilar biological product application is filed with the Commissioner of Food and Drugs.

''(B) TREATMENT OF FINDINGS.—In a proceeding for judicial review of a final order of the Commission, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

''(e) 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 this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of an ANDA filer or biosimilar biological product application filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

''(f) PENALTIES.—

''(1) FORFEITURE.—Each party that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to the violation of this section. If no such value has been received by the NDA holder, the biological product license hold-

er, the ANDA filer, or the biosimilar biological product application filer, the penalty to the NDA holder, the biological product license holder, the ANDA filer, or the biosimilar biological product application filer shall be sufficient to deter violations, but in no event shall be greater than 3 times the value given to an ANDA filer or biosimilar biological product application filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any party that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

''(2) CEASE AND DESIST.—

''(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a party in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such party at any time before the expiration of 1

year after such order becomes final pursuant to section 5(g).

''(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to the violation of this section by a party shall be conclusive unless—

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

''(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

''(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

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

''(B) 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 holder, the biological product license holder, the ANDA filer, or the biosimilar biological product application filer, compensation received by the ANDA filer or biosimilar biological product application filer, and the amount of commerce affected; and

''(C) other matters that justice requires.

''(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. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

''(g) DEFINITIONS.—In this section:

''(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

''(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is oth-

erwise related to the resolution or settlement of the claim.

''(3) ANDA.—The term 'ANDA' means an abbreviated new drug application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application filed under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)).

''(4) ANDA FILER.—The term 'ANDA filer' means a party that owns or controls an ANDA filed with the Food and Drug Administration or has the exclusive rights under such ANDA to distribute the ANDA product.

''(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)).

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

''(8) BIOLOGICAL PRODUCT LICENSE HOLDER.—The term 'biological product license holder' means—

''(A) the holder of an approved biological product license application for a biological product;

''(B) a person owning or controlling enforcement of any patents that claim the biological product that is the subject of such approved application; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (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.

''(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means the product to be manufactured under the biosimilar biological product application that is the subject of the patent infringement claim.

''(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term 'biosimilar biological product ap-

plication' means an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

''(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FILER.—The term 'biosimilar biological product application filer' means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration or has the exclusive rights under such application to distribute the biosimilar biological product.

''(12) DRUG PRODUCT.—The term 'drug product' has the meaning given such term in section 314.3(b) of title 21, Code of Federal Regulations (or any successor regulation).

''(13) MARKET.—The term 'market' means the promotion, offering for sale, selling, or distribution of a drug product.

''(14) NDA.—The term 'NDA' means a new drug application filed under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

''(15) NDA HOLDER.—The term 'NDA holder' means—

"(A) the holder of an approved NDA application for a drug product;

"(B) a person owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

"(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (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.

"(16) PARTY.—The term 'party' means any person, partnership, corporation, or other legal entity.

"(17) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, including any extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition, and extensions thereof.

''(18) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer or biosimilar biological product application filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product, or biosimilar biological product license application or biosimilar biological product, may infringe any patent held by, or exclusively licensed to, the NDA holder, biological product license holder, ANDA filer, or biosimilar biological product application filer of the drug product or biological product, as applicable.

''(19) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, 355a), or on the licensing of biological product applications under section 351(k)(7) (12-year exclusivity) or paragraph (2) or (3) of section 351(m) (pediatric exclusivity) of the Public Health Service Act (42 U.S.C. 262) or under section 527 of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 360cc) (orphan drug exclusivity).''.

(b) EFFECTIVE DATE.—Section 27 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 27(a)(1) of that Act entered into on or after the date of enactment of this Act.

SEC. 3. 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 the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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), within 30 days after such

filing, shall 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 subtitle B of title XI 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, 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. 4. NOTIFICATION OF AGREEMENTS.

Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note), as amended by section 3(b), is further amended by adding at the end the following:

''(e) RULE OF CONSTRUCTION.—

''(1) IN GENERAL.—An agreement that is required under subsection (a) or (b) shall include agreements resolving any outstanding disputes, including agreements resolving or settling a Patent Trial and Appeal Board proceeding.

''(2) DEFINITION.—For purposes of subparagraph (A), the term 'Patent Trial and Appeal Board proceeding' means a proceeding conducted by the Patent Trial and Appeal Board of the United States Patent and Trademark Office, including an inter partes review instituted under chapter 31 of title 35, United States Code, a post-grant review instituted under chapter 32 of that title (including a proceeding instituted pursuant to the transitional program for covered business method patents, as described in section 18 of the Leahy-Smith America Invents Act (35 U.S.C. 321 note)), and a derivation proceeding instituted under section 135 of that title.''.

SEC. 5. 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 27 of the Federal Trade

Commission Act or'' after ''that the agreement has violated''.

SEC. 6. 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) inserting after subparagraph (E) the following:

''(F) under section 27,''.

SEC. 7. REPORT ON ADDITIONAL EXCLUSION.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Federal Trade Commission shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a recommendation, and the Commission's basis for such recommendation, regarding a potential amendment to include in section 27(c) of the Federal Trade Commission Act (as added by section 2 of this Act) an additional exclusion for consideration granted by an NDA holder to a ANDA filer or by a biological product license holder to a biosimilar biological product application filer as part of the resolution or settlement, a re-

lease, waiver, or limitation of a claim for damages or other monetary relief.

(b) DEFINITIONS.—In this section, the terms ''ANDA filer'', ''biological product license holder'', ''biosimilar biological product application filer'', and ''NDA holder'' have the meanings given such terms in section 27(g) of the Federal Trade Commission Act (as added by section 2 of this Act).

SEC. 8. STATUTE OF LIMITATIONS.

The Federal Trade Commission shall commence any enforcement proceeding described in section 27 of the Federal Trade Commission Act, as added by section 2, except for an action described in section 27(f)(2) of the Federal Trade Commission Act, not later than 6 years after the date on which the parties to the agreement file the certification under section 1112(d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. 9. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such

Act or amendments to any person or circumstance shall not be affected.

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