I

116TH CONGRESS
1ST SESSION

H. R. 1344

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2019

Mr. DOGGETT (for himself, Mr. BLUMENAUER, Mr. CARTWRIGHT, Ms. JUDY CHU of California, Mr. CUMMINGS, Ms. DELAURO, Mr. DESAULNIER, Mr. GRIJALVA, Ms. HILL of California, Ms. KAPTUR, Mr. KHANNA, Ms. MOORE, Mrs. NAPOLITANO, Ms. OCASIO-CORTEZ, Ms. NORTON, Ms. PINGREE, Mr. POCAN, Ms. WATERS, Mr. WELCH, and Mr. LANGEVIN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Energy and Commerce, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Competitive Deals Resulting in Unleashed Generics and Savings Act of 2019'' or the ''Competitive DRUGS Act of 2019''.

SEC. 2. CLAWBACK OF RESEARCH AND DEVELOPMENT TAX BENEFITS FOR MANUFACTURERS ENGAGING IN PAY-FOR-DELAY.

(a) IN GENERAL.—Section 41 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(i) RECAPTURE.—

''(1) IN GENERAL.—If the Federal Trade Commission determines under section 27 of the Federal Trade Commission Act that the taxpayer violated section 5 of such Act in connection with the sale of a drug product (as defined in such section), then the tax under this chapter for the taxable year which includes the date of such determination shall be increased by the sum of the product for each of the 2 relevant years of—

''(A) the aggregate decrease in the credits allowed under section 38 for such relevant year which would have resulted solely from reducing to zero any credit determined under this section, multiplied by

''(B) the sales ratio for such drug product for such relevant year.

''(2) RELEVANT YEAR.—For purposes of this subsection, the term 'relevant year' means, with respect to any determination by the Federal Trade Commission described in paragraph (1), a taxable year in which the aggregate decrease in the credits allowed under section 38 which would have resulted solely from reducing to zero any credit determined under this section is one of the two highest such decreases during the 10-year period ending with the last taxable year that ended before the date of such determination.

''(3) SALES RATIO.—For purposes of this subsection, the term 'sales ratio' means, with respect to a drug product sold by a taxpayer in a taxable year, the ratio of—

''(A) the revenue from sales of such drug product by such taxpayer during such taxable year, to

''(B) the total revenue from sales of all drug products by such taxpayer during such taxable year.

''(4) CONSENT DECREES DEEMED TO BE VIOLATIONS.—If a taxpayer enters into a consent decree

with respect to any proceeding initiated by the Federal Trade Commission under section 27 of the Federal Trade Commission Act, such consent decree shall be treated for purposes of this subsection as if the Commission had determined under such section that the taxpayer violated section 5 of such Act in connection with the sale of the drug product to which such proceeding relates.

''(5) RECAPTURE NOT TAKEN INTO ACCOUNT IN DETERMINING MAXIMUM PENALTY.—The increase in tax under this subsection shall not be treated as a penalty for purposes of section 27(f) of the Federal Trade Commission Act.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years ending after the date of the enactment of this Act.

SEC. 3. TAX ON RECEIPT OF PAY-FOR-DELAY PAYMENTS; DENIAL OF DEDUCTION FOR PAY-FOR-DELAY PAYMENTS.

(a) RECEIPT OF PAYMENT.—The Internal Revenue Code of 1986 is amended by inserting after chapter 36 the following new chapter:

''CHAPTER 37—PAY-FOR-DELAY

"SEC. 4501. IMPOSITION OF TAX.

''There is hereby imposed, on each taxpayer who is party to an agreement that is determined by the Federal Trade Commission under section 27 of the Federal Trade Commission Act to be a violation of section 5 of such Act, a tax equal to 50 percent of the amount paid to such taxpayer under such agreement.''.

(b) DENIAL OF DEDUCTION.—Section 162(c) is amended by adding at the end the following new paragraph:

''(4) PAY-FOR-DELAY PAYMENTS.—No deduction shall be allowed under subsection (a) for any payment under an agreement that is determined by the Federal Trade Commission under section 27 of the Federal Trade Commission Act to be a violation of section 5 of such Act.''.

(c) CONFORMING AMENDMENT.—The table of chapters for the Internal Revenue Code of 1986 is amended by inserting after the item relating to chapter 36 the following new item:

''CHAPTER 37—PAY-FOR-DELAY''.

SEC. 4. 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.

"(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 infringement claim, in connection with the sale of a drug product.

"(2) VIOLATION.—

"(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be an unfair method of competition in or affecting commerce and be a violation of section 5 if pursuant to the agreement—

"(i) an ANDA filer receives anything of value, including an exclusive or non-exclusive license, an agreement regarding the marketing of a product, or any other commercial opportunity or benefit; and

"(ii) the ANDA filer agrees to limit or forgo research, development, manufacturing, marketing, or sales of the ANDA product 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 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 may not presume—

''(1) that entry of the ANDA product into interstate commerce 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 into interstate commerce 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 granted to the ANDA

filer as part of the resolution or settlement includes one or more of the following and nothing else:

''(1) The right to market the ANDA product in the United States 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 drug.

''(2) A payment, not to exceed $7,500,000, if based on reasonable litigation expenses.

''(3) A covenant not to sue (including any agreement to dismiss) on any claim that the ANDA product infringes a United States patent.

''(d) JUDICIAL REVIEW.—

''(1) 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 after the issuance of such order, petition for review of such order in—

''(A) the United States Court of Appeals for the District of Columbia Circuit; or

''(B) the United States Court of Appeals for the circuit in which any party subject to

such final order is incorporated on the date that the petition for review is filed.

''(2) 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) CONSTRUCTION.—

''(1) ANTITRUST LAWS AND CONSUMER PROTECTION LAWS.—Nothing in this section shall be construed to modify, impair, or supersede the operation of—

''(A) the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), or any State law substantially similar to any of such antitrust laws; or

''(B) section 5 of this Act or any substantially similar State law.

''(2) CLAIMS AND COUNTERCLAIMS.—Nothing in this section shall modify, impair, or supersede the right of an ANDA filer to assert a claim or counterclaim against any person under any law referred to in paragraph (1).

''(f) PENALTIES.—

''(1) FORFEITURE.—Each party that violates subsection (a)(2)(A) shall forfeit and pay to the United States a civil penalty sufficient to deter such violation, but in no event greater than 3 times the value received by the party that is reasonably attributable to such violation. 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 commits such violation. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as the courts determine to be 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 a violation described in subsection (a)(2)(A) 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, including the amount of commerce affected;

"(B) with respect to the violator, in addition to the value received, the degree of culpability, any history of violations, the ability to pay, and any effect on the ability to continue doing business; and

''(C) other matters that justice requires.

''(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to any other remedy provided by Federal or State 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 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 before or after the resolution or the settlement of a patent infringement claim, or any other agreement that can be shown to be contingent upon, to provide a contingent condition for, or to be otherwise related to the resolution or settlement of the claim.

''(2) 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)).

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

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

''(5) 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).

''(6) 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)).

''(7) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court, that the ANDA filer's ANDA or ANDA product may infringe any of the following held by, or exclusively licensed to, the NDA holder of the drug product:

''(A) Any patent.

''(B) Any filed patent application.

''(C) Any extension, reissue, renewal, division, continuation, continuation in part, or reexamination of a patent.

''(D) Any patent term restoration, patents of addition, or extensions thereof.

''(E) Any other patent interest.

''(8) 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), 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), 360cc, 355a, 355f).''.

(b) APPLICABILITY.—Section 27 of the Federal Trade Commission Act, as added by this section, shall apply to any agreement described in section 27(a)(2)(A) of that Act entered into after June 17, 2013. Section 27(f) of the Federal Trade Commission Act, as added by this section, shall apply to agreements entered into on or after the date of enactment of this Act.

SEC. 5. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by—

(1) striking ''the Commission the'' and inserting the following: ''the Commission—

''(A) the'';

(2) striking the period and inserting ''; and''; and

(3) inserting at the end the following:

''(B) any other agreement the parties enter into within 30 days after entering into an agreement covered by subsection (a) or (b).''.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official with primary responsibility for negotiating any agreement under subsection (a) or (b) that is required to be filed under subsection (c) 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. 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) by inserting after subparagraph (E) the following new subparagraph:

"(F) under section 27;".

SEC. 7. 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 3, except for an action described in section 27(f)(2) of such Act, not later than 6 years after the date on which the parties to the agreement file the other agreements under section 1112(c)(2) or the certification required by section 1112(d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

○