

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Competitive Deals Re-
3 sulting in Unleashed Generics and Savings Act of 2019”
4 or the “Competitive DRUGS Act of 2019”.

5 **SEC. 2. CLAWBACK OF RESEARCH AND DEVELOPMENT TAX**

6 **BENEFITS FOR MANUFACTURERS ENGAGING**
7 **IN PAY-FOR-DELAY.**

8 (a) IN GENERAL.—Section 41 of the Internal Rev-
9 enue Code of 1986 is amended by adding at the end the
10 following new subsection:

11 “(i) RECAPTURE.—

12 “(1) IN GENERAL.—If the Federal Trade Com-
13 mission determines under section 27 of the Federal
14 Trade Commission Act that the taxpayer violated
15 section 5 of such Act in connection with the sale of
16 a drug product (as defined in such section), then the
17 tax under this chapter for the taxable year which in-
18 cludes the date of such determination shall be in-
19 creased by the sum of the product for each of the
20 2 relevant years of—

21 “(A) the aggregate decrease in the credits
22 allowed under section 38 for such relevant year
23 which would have resulted solely from reducing
24 to zero any credit determined under this sec-
25 tion, multiplied by

1 “(B) the sales ratio for such drug product
2 for such relevant year.

3 “(2) RELEVANT YEAR.—For purposes of this
4 subsection, the term ‘relevant year’ means, with re-
5 spect to any determination by the Federal Trade
6 Commission described in paragraph (1), a taxable
7 year in which the aggregate decrease in the credits
8 allowed under section 38 which would have resulted
9 solely from reducing to zero any credit determined
10 under this section is one of the two highest such de-
11 creases during the 10-year period ending with the
12 last taxable year that ended before the date of such
13 determination.

14 “(3) SALES RATIO.—For purposes of this sub-
15 section, the term ‘sales ratio’ means, with respect to
16 a drug product sold by a taxpayer in a taxable year,
17 the ratio of—

18 “(A) the revenue from sales of such drug
19 product by such taxpayer during such taxable
20 year, to

21 “(B) the total revenue from sales of all
22 drug products by such taxpayer during such
23 taxable year.

24 “(4) CONSENT DECREES DEEMED TO BE VIOLA-
25 TIONS.—If a taxpayer enters into a consent decree

1 with respect to any proceeding initiated by the Fed-
2 eral Trade Commission under section 27 of the Fed-
3 eral Trade Commission Act, such consent decree
4 shall be treated for purposes of this subsection as if
5 the Commission had determined under such section
6 that the taxpayer violated section 5 of such Act in
7 connection with the sale of the drug product to
8 which such proceeding relates.

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

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

17 **SEC. 3. TAX ON RECEIPT OF PAY-FOR-DELAY PAYMENTS;**
18 **DENIAL OF DEDUCTION FOR PAY-FOR-DELAY**
19 **PAYMENTS.**

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

23 **“CHAPTER 37—PAY-FOR-DELAY**

“Sec. 4501. Imposition of tax.

1 **“SEC. 4501. IMPOSITION OF TAX.**

2 “There is hereby imposed, on each taxpayer who is
3 party to an agreement that is determined by the Federal
4 Trade Commission under section 27 of the Federal Trade
5 Commission Act to be a violation of section 5 of such Act,
6 a tax equal to 50 percent of the amount paid to such tax-
7 payer under such agreement.”.

8 (b) DENIAL OF DEDUCTION.—Section 162(c) is
9 amended by adding at the end the following new para-
10 graph:

11 “(4) PAY-FOR-DELAY PAYMENTS.—No deduc-
12 tion shall be allowed under subsection (a) for any
13 payment under an agreement that is determined by
14 the Federal Trade Commission under section 27 of
15 the Federal Trade Commission Act to be a violation
16 of section 5 of such Act.”.

17 (c) CONFORMING AMENDMENT.—The table of chap-
18 ters for the Internal Revenue Code of 1986 is amended
19 by inserting after the item relating to chapter 36 the fol-
20 lowing new item:

“CHAPTER 37—PAY-FOR-DELAY”.

21 **SEC. 4. UNLAWFUL COMPENSATION FOR DELAY.**

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

1 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE**
2 **GENERICS.**

3 “(a) IN GENERAL.—

4 “(1) ENFORCEMENT PROCEEDING.—The Com-
5 mission may initiate a proceeding to enforce the pro-
6 visions of this section against the parties to any
7 agreement resolving or settling, on a final or interim
8 basis, a patent infringement claim, in connection
9 with the sale of a drug product.

10 “(2) VIOLATION.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (B), in such a proceeding, an agreement
13 shall be an unfair method of competition in or
14 affecting commerce and be a violation of section
15 5 if pursuant to the agreement—

16 “(i) an ANDA filer receives anything
17 of value, including an exclusive or non-ex-
18 clusive license, an agreement regarding the
19 marketing of a product, or any other com-
20 mercial opportunity or benefit; and

21 “(ii) the ANDA filer agrees to limit or
22 forgo research, development, manufac-
23 turing, marketing, or sales of the ANDA
24 product for any period of time.

25 “(B) EXCEPTION.—Subparagraph (A)
26 shall not apply if the parties to such agreement

1 demonstrate by clear and convincing evidence
2 that—

3 “(i) the value described in subpara-
4 graph (A)(i) is compensation solely for
5 other goods or services that the ANDA
6 filer has promised to provide; or

7 “(ii) the procompetitive benefits of the
8 agreement outweigh the anticompetitive ef-
9 fects of the agreement.

10 “(b) LIMITATIONS.—In determining whether the set-
11 tling parties have met their burden under subsection
12 (a)(2)(B), the fact finder may not presume—

13 “(1) that entry of the ANDA product into
14 interstate commerce would not have occurred until
15 the expiration of the relevant patent or statutory ex-
16 clusivity; or

17 “(2) that the agreement’s provision for entry of
18 the ANDA product into interstate commerce prior to
19 the expiration of the relevant patent or statutory ex-
20 clusivity means that the agreement is procom-
21 petitive.

22 “(c) EXCLUSIONS.—Nothing in this section shall pro-
23 hibit a resolution or settlement of a patent infringement
24 claim in which the consideration granted to the ANDA

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

3 “(1) The right to market the ANDA product in
4 the United States prior to the expiration of—

5 “(A) any patent that is the basis for the
6 patent infringement claim; or

7 “(B) any patent right or other statutory
8 exclusivity that would prevent the marketing of
9 such drug.

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

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

15 “(d) JUDICIAL REVIEW.—

16 “(1) IN GENERAL.—Any party that is subject
17 to a final order of the Commission, issued in an ad-
18 ministrative adjudicative proceeding under the au-
19 thority of subsection (a)(1), may, within 30 days
20 after the issuance of such order, petition for review
21 of such order in—

22 “(A) the United States Court of Appeals
23 for the District of Columbia Circuit; or

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

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

3 “(2) TREATMENT OF FINDINGS.—In a pro-
4 ceeding for judicial review of a final order of the
5 Commission, the findings of the Commission as to
6 the facts, if supported by evidence, shall be conclu-
7 sive.

8 “(e) CONSTRUCTION.—

9 “(1) ANTITRUST LAWS AND CONSUMER PRO-
10 TECTION LAWS.—Nothing in this section shall be
11 construed to modify, impair, or supersede the oper-
12 ation of—

13 “(A) the antitrust laws as defined in sub-
14 section (a) of the first section of the Clayton
15 Act (15 U.S.C. 12(a)), or any State law sub-
16 stantially similar to any of such antitrust laws;
17 or

18 “(B) section 5 of this Act or any substan-
19 tially similar State law.

20 “(2) CLAIMS AND COUNTERCLAIMS.—Nothing
21 in this section shall modify, impair, or supersede the
22 right of an ANDA filer to assert a claim or counter-
23 claim against any person under any law referred to
24 in paragraph (1).

25 “(f) PENALTIES.—

1 “(1) FORFEITURE.—Each party that violates
2 subsection (a)(2)(A) shall forfeit and pay to the
3 United States a civil penalty sufficient to deter such
4 violation, but in no event greater than 3 times the
5 value received by the party that is reasonably attrib-
6 utable to such violation. Such penalty shall accrue to
7 the United States and may be recovered in a civil
8 action brought by the Commission, in its own name
9 by any of its attorneys designated by it for such pur-
10 pose, in a district court of the United States against
11 any party that commits such violation. In such ac-
12 tions, the United States district courts are empow-
13 ered to grant mandatory injunctions and such other
14 and further equitable relief as the courts determine
15 to be appropriate.

16 “(2) CEASE AND DESIST.—

17 “(A) IN GENERAL.—If the Commission has
18 issued a cease and desist order with respect to
19 a party in an administrative adjudicative pro-
20 ceeding under the authority of subsection
21 (a)(1), an action brought pursuant to para-
22 graph (1) may be commenced against such
23 party at any time before the expiration of 1
24 year after such order becomes final pursuant to
25 section 5(g).

1 “(B) EXCEPTION.—In an action under
2 subparagraph (A), the findings of the Commis-
3 sion as to the material facts in the administra-
4 tive adjudicative proceeding with respect to a
5 violation described in subsection (a)(2)(A) by a
6 party shall be conclusive unless—

7 “(i) the terms of such cease and de-
8 sist order expressly provide that the Com-
9 mission’s findings shall not be conclusive;
10 or

11 “(ii) the order became final by reason
12 of section 5(g)(1), in which case such find-
13 ing shall be conclusive if supported by evi-
14 dence.

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

18 “(A) the nature, circumstances, extent,
19 and gravity of the violation, including the
20 amount of commerce affected;

21 “(B) with respect to the violator, in addi-
22 tion to the value received, the degree of culpa-
23 bility, any history of violations, the ability to
24 pay, and any effect on the ability to continue
25 doing business; and

1 “(C) other matters that justice requires.

2 “(4) REMEDIES IN ADDITION.—Remedies pro-
3 vided in this subsection are in addition to any other
4 remedy provided by Federal or State law. Nothing in
5 this paragraph shall be construed to affect any au-
6 thority of the Commission under any other provision
7 of law.

8 “(g) DEFINITIONS.—In this section:

9 “(1) AGREEMENT RESOLVING OR SETTling A
10 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
11 ment resolving or settling a patent infringement
12 claim’ includes any agreement that is entered into
13 within 30 days before or after the resolution or the
14 settlement of a patent infringement claim, or any
15 other agreement that can be shown to be contingent
16 upon, to provide a contingent condition for, or to be
17 otherwise related to the resolution or settlement of
18 the claim.

19 “(2) ANDA.—The term ‘ANDA’ means an ab-
20 breviated new drug application filed under section
21 505(j) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 355(j)) or a new drug application filed
23 under section 505(b)(2) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355(b)(2)).

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

6 “(4) ANDA PRODUCT.—The term ‘ANDA
7 product’ means the product to be manufactured
8 under the ANDA that is the subject of the patent
9 infringement claim.

10 “(5) DRUG PRODUCT.—The term ‘drug prod-
11 uct’ has the meaning given such term in section
12 314.3(b) of title 21, Code of Federal Regulations (or
13 any successor regulation).

14 “(6) NDA.—The term ‘NDA’ means a new
15 drug application filed under section 505(b) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355(b)).

18 “(7) PATENT INFRINGEMENT CLAIM.—The
19 term ‘patent infringement claim’ means any allega-
20 tion made to an ANDA filer, whether or not in-
21 cluded in a complaint filed with a court, that the
22 ANDA filer’s ANDA or ANDA product may infringe
23 any of the following held by, or exclusively licensed
24 to, the NDA holder of the drug product:

25 “(A) Any patent.

1 “(B) Any filed patent application.

2 “(C) Any extension, reissue, renewal, divi-
3 sion, continuation, continuation in part, or reex-
4 amination of a patent.

5 “(D) Any patent term restoration, patents
6 of addition, or extensions thereof.

7 “(E) Any other patent interest.

8 “(8) STATUTORY EXCLUSIVITY.—The term
9 ‘statutory exclusivity’ means those prohibitions on
10 the approval of drug applications under clauses (ii)
11 through (iv) of section 505(c)(3)(E) (5- and 3-year
12 data exclusivity), section 527 (orphan drug exclu-
13 sivity), section 505A (pediatric exclusivity), or sec-
14 tion 505E (qualified infectious disease product ex-
15 clusivity) of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 355(c)(3)(E), 360cc, 355a, 355f).”.

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

1 **SEC. 5. NOTICE AND CERTIFICATION OF AGREEMENTS.**

2 (a) NOTICE OF ALL AGREEMENTS.—Section
3 1112(c)(2) of the Medicare Prescription Drug, Improve-
4 ment, and Modernization Act of 2003 (21 U.S.C. 355
5 note) is amended by—

6 (1) striking “the Commission the” and insert-
7 ing the following: “the Commission—

8 “(A) the”;

9 (2) striking the period and inserting “; and”;
10 and

11 (3) inserting at the end the following:

12 “(B) any other agreement the parties enter
13 into within 30 days after entering into an
14 agreement covered by subsection (a) or (b).”.

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

17 “(d) CERTIFICATION.—The Chief Executive Officer
18 or the company official with primary responsibility for ne-
19 gotiating any agreement under subsection (a) or (b) that
20 is required to be filed under subsection (c) shall execute
21 and file with the Assistant Attorney General and the Com-
22 mission a certification as follows: ‘I declare that the fol-
23 lowing is true, correct, and complete to the best of my
24 knowledge: The materials filed with the Federal Trade
25 Commission and the Department of Justice under section
26 1112 of subtitle B of title XI of the Medicare Prescription

1 Drug, Improvement, and Modernization Act of 2003, with
2 respect to the agreement referenced in this certification—

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

5 ““(2) include any ancillary agreements that are
6 contingent upon, provide a contingent condition for,
7 or are otherwise related to, the referenced agree-
8 ment; and

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

14 **SEC. 6. COMMISSION LITIGATION AUTHORITY.**

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

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

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

21 (3) by inserting after subparagraph (E) the fol-
22 lowing new subparagraph:

23 ““(F) under section 27;”.

1 **SEC. 7. STATUTE OF LIMITATIONS.**

2 The Federal Trade Commission shall commence any
3 enforcement proceeding described in section 27 of the
4 Federal Trade Commission Act, as added by section 3, ex-
5 cept for an action described in section 27(f)(2) of such
6 Act, not later than 6 years after the date on which the
7 parties to the agreement file the other agreements under
8 section 1112(c)(2) or the certification required by section
9 1112(d) of the Medicare Prescription Drug Improvement
10 and Modernization Act of 2003 (21 U.S.C. 355 note).

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