

117TH CONGRESS  
1ST SESSION

# H. R. 153

To prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 4, 2021

Mr. RUSH (for himself, Mr. CASTEN, Mr. COHEN, Mr. CONNOLLY, Mr. DESAULNIER, Mr. NEGUSE, Mr. RUIZ, Ms. UNDERWOOD, and Mr. VAN DREW) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on 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

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## A BILL

To prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, 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 “Protecting Consumer  
3 Access to Generic Drugs Act of 2021”.

4 **SEC. 2. UNLAWFUL AGREEMENTS.**

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

11 (1) a subsequent filer directly or indirectly re-  
12 ceives from such holder (or in the case of such an  
13 agreement between two subsequent filers, the other  
14 subsequent filer) anything of value, including a li-  
15 cense; and

16 (2) the subsequent filer agrees to limit or fore-  
17 go research on, or development, manufacturing,  
18 marketing, or sales, for any period of time, of the  
19 covered product that is the subject of the application  
20 described in subparagraph (A) or (B) of subsection  
21 (g)(8).

22 (b) **EXCLUSION.**—It shall not be unlawful under sub-  
23 section (a) if a party to an agreement described in such  
24 subsection demonstrates by clear and convincing evidence  
25 that the value described in subsection (a)(1) is compensa-

1 tion solely for other goods or services that the subsequent  
2 filer has promised to provide.

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

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

13 (A) any patent that is the basis of the cov-  
14 ered patent infringement claim; or

15 (B) any patent right or other statutory ex-  
16 clusivity that would prevent the marketing of  
17 such covered product.

18 (2) A payment for reasonable litigation ex-  
19 penses not to exceed \$7,500,000 in the aggregate.

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

22 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
23 SION.—

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

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

8           (B) a person, partnership, or corporation  
9 over which the Commission would have author-  
10 ity pursuant to such section but for the fact  
11 that such person, partnership, or corporation is  
12 not organized to carry on business for its own  
13 profit or that of its members.

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

16           (A) IN GENERAL.—A violation of this sec-  
17 tion shall be treated as an unfair or deceptive  
18 act or practice in violation of section 5(a)(1) of  
19 the Federal Trade Commission Act (15 U.S.C.  
20 45(a)(1)).

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

24           (i) the Commission shall enforce this  
25 section in the same manner, by the same

1 means, and with the same jurisdiction,  
2 powers, and duties as though all applicable  
3 terms and provisions of the Federal Trade  
4 Commission Act (15 U.S.C. 41 et seq.)  
5 were incorporated into and made a part of  
6 this section; and

7 (ii) any NDA or BLA holder or subse-  
8 quent filer that violates this section shall  
9 be subject to the penalties and entitled to  
10 the privileges and immunities provided in  
11 the Federal Trade Commission Act.

12 (C) JUDICIAL REVIEW.—In the case of a  
13 cease and desist order issued by the Commis-  
14 sion under section 5 of the Federal Trade Com-  
15 mission Act (15 U.S.C. 45) for violation of this  
16 section, a party to such order may obtain judi-  
17 cial review of such order as provided in such  
18 section 5, except that—

19 (i) such review may only be obtained  
20 in—

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

24 (II) the United States Court of  
25 Appeals for the circuit in which the

1 ultimate parent entity, as defined in  
2 section 801.1(a)(3) of title 16, Code  
3 of Federal Regulations, or any suc-  
4 cessor thereto, of the NDA or BLA  
5 holder (if any such holder is a party  
6 to such order) is incorporated as of  
7 the date that the application described  
8 in subparagraph (A) or (B) of sub-  
9 section (g)(8) or an approved applica-  
10 tion that is deemed to be a license for  
11 a biological product under section  
12 351(k) of the Public Health Service  
13 Act (42 U.S.C. 262(k)) pursuant to  
14 section 7002(e)(4) of the Biologics  
15 Price Competition and Innovation Act  
16 of 2009 (Public Law 111–148; 124  
17 Stat. 817) is submitted to the Com-  
18 missioner of Food and Drugs; or

19 (III) the United States Court of  
20 Appeals for the circuit in which the  
21 ultimate parent entity, as so defined,  
22 of any subsequent filer that is a party  
23 to such order is incorporated as of the  
24 date that the application described in  
25 subparagraph (A) or (B) of subsection

1 (g)(8) is submitted to the Commis-  
2 sioner of Food and Drugs; and

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

7 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

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

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

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

21 (I) the Commission may com-  
22 mence a civil action under subpara-  
23 graph (A) to recover a civil penalty  
24 against any party to such order at  
25 any time before the expiration of the

1 1-year period beginning on the date  
2 on which such order becomes final  
3 under section 5(g) of such Act (15  
4 U.S.C. 45(g)); and

5 (II) in such civil action, the find-  
6 ings of the Commission as to the ma-  
7 terial facts in such proceeding shall be  
8 conclusive, unless—

9 (aa) the terms of such order  
10 expressly provide that the Com-  
11 mission's findings shall not be  
12 conclusive; or

13 (bb) such order became final  
14 by reason of section 5(g)(1) of  
15 such Act (15 U.S.C. 45(g)(1)), in  
16 which case such findings shall be  
17 conclusive if supported by evi-  
18 dence.

19 (ii) RELATIONSHIP TO PENALTY FOR  
20 VIOLATION OF AN ORDER.—The penalty  
21 provided in clause (i) for violation of this  
22 section is separate from and in addition to  
23 any penalty that may be incurred for viola-  
24 tion of an order of the Commission under

1 section 5(l) of the Federal Trade Commis-  
2 sion Act (15 U.S.C. 45(l)).

3 (C) AMOUNT OF PENALTY.—

4 (i) IN GENERAL.—The amount of a  
5 civil penalty imposed in a civil action under  
6 subparagraph (A) on a party to an agree-  
7 ment described in subsection (a) shall be  
8 sufficient to deter violations of this section,  
9 but in no event greater than—

10 (I) if such party is the NDA or  
11 BLA holder (or, in the case of an  
12 agreement between two subsequent fil-  
13 ers, the subsequent filer who gave the  
14 value described in subsection (a)(1)),  
15 the greater of—

16 (aa) 3 times the value re-  
17 ceived by such NDA or BLA  
18 holder (or by such subsequent  
19 filer) that is reasonably attrib-  
20 utable to the violation of this sec-  
21 tion; or

22 (bb) 3 times the value given  
23 to the subsequent filer (or to the  
24 other subsequent filer) reason-

ably 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)),

1 compensation received by the subse-  
2 quent filer (or, in the case of an  
3 agreement between two subsequent fil-  
4 ers, the subsequent filer who received  
5 the value described in subsection  
6 (a)(1)), and the amount of commerce  
7 affected; and

8 (III) other matters that justice  
9 requires.

10 (D) INJUNCTIONS AND OTHER EQUITABLE  
11 RELIEF.—In a civil action under subparagraph  
12 (A), the United States district courts are em-  
13 powered to grant mandatory injunctions and  
14 such other and further equitable relief as they  
15 deem appropriate.

16 (4) REMEDIES IN ADDITION.—Remedies pro-  
17 vided in this subsection are in addition to, and not  
18 in lieu of, any other remedy provided by Federal  
19 law.

20 (5) PRESERVATION OF AUTHORITY OF COMMIS-  
21 SION.—Nothing in this section shall be construed to  
22 affect any authority of the Commission under any  
23 other provision of law.

24 (e) FEDERAL TRADE COMMISSION RULEMAKING.—  
25 The Commission may, in its discretion, by rule promul-

1 gated under section 553 of title 5, United States Code,  
2 exempt from this section certain agreements described in  
3 subsection (a) if the Commission finds such agreements  
4 to be in furtherance of market competition and for the  
5 benefit of consumers.

6 (f) ANTITRUST LAWS.—Nothing in this section shall  
7 modify, impair, limit, or supersede the applicability of the  
8 antitrust laws as defined in subsection (a) of the first sec-  
9 tion of the Clayton Act (15 U.S.C. 12(a)), and of section  
10 5 of the Federal Trade Commission Act (15 U.S.C. 45)  
11 to the extent that such section 5 applies to unfair methods  
12 of competition. Nothing in this section shall modify, im-  
13 pair, limit, or supersede the right of a subsequent filer  
14 to assert claims or counterclaims against any person,  
15 under the antitrust laws or other laws relating to unfair  
16 competition.

17 (g) DEFINITIONS.—In this section:

18 (1) AGREEMENT RESOLVING OR SETTLING A  
19 COVERED PATENT INFRINGEMENT CLAIM.—The  
20 term “agreement resolving or settling a covered pat-  
21 ent infringement claim” means any agreement  
22 that—

23 (A) resolves or settles a covered patent in-  
24 fringement claim; or

1 (B) is contingent upon, provides for a con-  
2 tingent condition for, or is otherwise related to  
3 the resolution or settlement of a covered patent  
4 infringement claim.

5 (2) COMMISSION.—The term “Commission”  
6 means the Federal Trade Commission.

7 (3) COVERED PATENT INFRINGEMENT CLAIM.—  
8 The term “covered patent infringement”  
9 means an allegation made by the NDA or BLA hold-  
10 er to a subsequent filer (or, in the case of an agree-  
11 ment between two subsequent filers, by one subse-  
12 quent filer to another), whether or not included in  
13 a complaint filed with a court of law, that—

14 (A) the submission of the application de-  
15 scribed in subparagraph (A) or (B) of para-  
16 graph (8), or the manufacture, use, offering for  
17 sale, sale, or importation into the United States  
18 of a covered product that is the subject of such  
19 an application—

20 (i) in the case of an agreement be-  
21 tween an NDA or BLA holder and a sub-  
22 sequent filer, infringes any patent owned  
23 by, or exclusively licensed to, the NDA or  
24 BLA holder of the covered product; or

1 (ii) in the case of an agreement be-  
2 tween two subsequent filers, infringes any  
3 patent owned by the subsequent filer; or

4 (B) in the case of an agreement between  
5 an NDA or BLA holder and a subsequent filer,  
6 the covered product to be manufactured under  
7 such application uses a covered product as  
8 claimed in a published patent application.

9 (4) COVERED PRODUCT.—The term “covered  
10 product” means a drug (as defined in section 201(g)  
11 of the Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 321(g))), including a biological product (as  
13 defined in section 351(i) of the Public Health Serv-  
14 ice Act (42 U.S.C. 262(i))).

15 (5) NDA OR BLA HOLDER.—The term “NDA  
16 or BLA holder” means—

17 (A) the holder of—

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

22 or

23 (ii) a biologics license application filed  
24 under section 351(a) of the Public Health

1 Service Act (42 U.S.C. 262(a)) for a cov-  
2 ered product;

3 (B) a person owning or controlling enforce-  
4 ment of the patent on—

5 (i) the list published under section  
6 505(j)(7) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-  
8 nection with the application described in  
9 subparagraph (A)(i); or

10 (ii) any list published under section  
11 351 of the Public Health Service Act (42  
12 U.S.C. 262) comprised of patents associ-  
13 ated with biologics license applications filed  
14 under section 351(a) of such Act (42  
15 U.S.C. 262(a)); or

16 (C) the predecessors, subsidiaries, divi-  
17 sions, groups, and affiliates controlled by, con-  
18 trolling, or under common control with any en-  
19 tity described in subparagraph (A) or (B) (such  
20 control to be presumed by direct or indirect  
21 share ownership of 50 percent or greater), as  
22 well as the licensees, licensors, successors, and  
23 assigns of each of the entities.

1           (6) PATENT.—The term “patent” means a pat-  
2           ent issued by the United States Patent and Trade-  
3           mark Office.

4           (7) STATUTORY EXCLUSIVITY.—The term  
5           “statutory exclusivity” means those prohibitions on  
6           the submission or approval of drug applications  
7           under clauses (ii) through (iv) of section  
8           505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)  
9           through (iv) of section 505(j)(5)(F) (5-year and 3-  
10          year exclusivity), section 505(j)(5)(B)(iv) (180-day  
11          exclusivity), section 527 (orphan drug exclusivity),  
12          section 505A (pediatric exclusivity), or section 505E  
13          (qualified infectious disease product exclusivity) of  
14          the Federal Food, Drug, and Cosmetic Act (21  
15          U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),  
16          360cc, 355a, 355f), or prohibitions on the submis-  
17          sion or licensing of biologics license applications  
18          under section 351(k)(6) (interchangeable biological  
19          product exclusivity) or section 351(k)(7) (biological  
20          product reference product exclusivity) of the Public  
21          Health Service Act (42 U.S.C. 262(k)(6), (7)).

22          (8) SUBSEQUENT FILER.—The term “subse-  
23          quent filer” means—

24                 (A) in the case of a drug, a party that  
25                 owns or controls an abbreviated new drug appli-

1 cation submitted pursuant to section 505(j) of  
2 the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 355(j)) or a new drug application sub-  
4 mitted pursuant to section 505(b)(2) of the  
5 Federal Food, Drug, and Cosmetic Act (21  
6 U.S.C. 355(b)(2)) and filed under section  
7 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or  
8 has the exclusive rights to distribute the cov-  
9 ered product that is the subject of such applica-  
10 tion; or

11 (B) in the case of a biological product, a  
12 party that owns or controls an application filed  
13 with the Food and Drug Administration under  
14 section 351(k) of the Public Health Service Act  
15 (42 U.S.C. 262(k)) or has the exclusive rights  
16 to distribute the biological product that is the  
17 subject of such application.

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

21 **SEC. 3. NOTICE AND CERTIFICATION OF AGREEMENTS.**

22 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)  
23 of the Medicare Prescription Drug, Improvement, and  
24 Modernization Act of 2003 (21 U.S.C. 355 note) is  
25 amended by inserting “or the owner of a patent for which

1 a claim of infringement could reasonably be asserted  
2 against any person for making, using, offering to sell, sell-  
3 ing, or importing into the United States a biological prod-  
4 uct that is the subject of a biosimilar biological product  
5 application” before the period at the end.

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

9 “(d) CERTIFICATION.—The Chief Executive Officer  
10 or the company official responsible for negotiating any  
11 agreement under subsection (a) or (b) that is required to  
12 be filed under subsection (c) shall, within 30 days of such  
13 filing, execute and file with the Assistant Attorney General  
14 and the Commission a certification as follows: ‘I declare  
15 that the following is true, correct, and complete to the best  
16 of my knowledge: The materials filed with the Federal  
17 Trade Commission and the Department of Justice under  
18 section 1112 of the Medicare Prescription Drug, Improve-  
19 ment, and Modernization Act of 2003, with respect to the  
20 agreement referenced in this certification—

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

23 “(2) include any ancillary agreements that are  
24 contingent upon, provide a contingent condition for,

1 were entered into within 30 days of, or are otherwise  
2 related to, the referenced agreement; and

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

8 **SEC. 4. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

9 Section 505(j)(5)(D)(i)(V) of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))  
11 is amended by inserting “section 2 of the Protecting Con-  
12 sumer Access to Generic Drugs Act of 2021 or” after  
13 “that the agreement has violated”.

14 **SEC. 5. 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:

23 “(F) under section 2(d)(3)(A) of the Pro-  
24 tecting Consumer Access to Generic Drugs Act  
25 of 2021;”.

1 **SEC. 6. STATUTE OF LIMITATIONS.**

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

10 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND  
11 DESIST ORDER.—If the Commission has issued a cease  
12 and desist order under section 5 of the Federal Trade  
13 Commission Act (15 U.S.C. 45) for violation of section  
14 2 of this Act and the proceeding for the issuance of such  
15 order was commenced within the period required by sub-  
16 section (a) of this section, such subsection does not pro-  
17 hibit the commencement, after such period, of a civil ac-  
18 tion under section 2(d)(3)(A) against a party to such  
19 order or a civil action under subsection (l) of such section  
20 5 for violation of such order.

○