

Thurs 1:20 pm  
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**AMENDMENT**  
**OFFERED BY MR. RUSH OF ILLINOIS**

At the appropriate place, insert the following:

1 **SEC. \_\_\_\_ . PROTECTING CONSUMER ACCESS TO GENERIC**  
2 **DRUGS.**

3 (a) **IN GENERAL.**—Section 505 of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 355) is amended by  
5 adding at the end the following:

6 “(w) **PROTECTING CONSUMER ACCESS TO GENERIC**  
7 **DRUGS.**—

8 “(1) **UNFAIR AND DECEPTIVE ACTS AND PRAC-**  
9 **TICES RELATED TO NEW DRUG APPLICATIONS.**—

10 “(A) **CONDUCT PROHIBITED.**—It shall be  
11 unlawful for any person to directly or indirectly  
12 be a party to any agreement resolving or set-  
13 tling a patent infringement claim in which—

14 “(i) an ANDA filer receives anything  
15 of value; and

16 “(ii) the ANDA filer agrees to limit or  
17 forego research, development, manufac-  
18 turing, marketing, or sales, for any period  
19 of time, of the drug that is to be manufac-

1           tured under the ANDA involved and is the  
2           subject of the patent infringement claim.

3           “(B) EXCEPTIONS.—Notwithstanding sub-  
4           paragraph (A)(i), subparagraph (A) does not  
5           prohibit a resolution or settlement of a patent  
6           infringement claim in which the value received  
7           by the ANDA filer includes no more than—

8                   “(i) the right to market the drug that  
9                   is to be manufactured under the ANDA in-  
10                  volved and is the subject of the patent in-  
11                  fringement claim, before the expiration  
12                  of—

13                   “(I) the patent that is the basis  
14                   for the patent infringement claim; or

15                   “(II) any other statutory exclu-  
16                   sivity that would prevent the mar-  
17                   keting of such drug; and

18                   “(ii) the waiver of a patent infringe-  
19                   ment claim for damages based on prior  
20                   marketing of such drug.

21           “(C) ENFORCEMENT.—

22                   “(i) IN GENERAL.—A violation of sub-  
23                   paragraph (A) shall be treated as an un-  
24                   fair and deceptive act or practice and an  
25                   unfair method of competition in or affect-

1           ing interstate commerce prohibited under  
2           section 5 of the Federal Trade Commission  
3           Act and shall be enforced by the Federal  
4           Trade Commission in the same manner, by  
5           the same means, and with the same juris-  
6           diction as though all applicable terms and  
7           provisions of the Federal Trade Commis-  
8           sion Act were incorporated into and made  
9           a part of this subsection.

10           “(ii) Subchapter A of chapter VII  
11           shall not apply with respect to this sub-  
12           section.

13           “(D) DEFINITIONS.—In this subsection:

14           “(i) AGREEMENT.—The term ‘agree-  
15           ment’ means anything that would con-  
16           stitute an agreement under section 5 of the  
17           Federal Trade Commission Act.

18           “(ii) AGREEMENT RESOLVING OR SET-  
19           TLING.—The term ‘agreement resolving or  
20           settling’, in reference to a patent infringe-  
21           ment claim, includes any agreement that is  
22           contingent upon, provides a contingent  
23           condition for, or is otherwise related to the  
24           resolution or settlement of the claim.

1                   “(iii) ANDA.—The term ‘ANDA’  
2 means an abbreviated new drug application  
3 for the approval of a new drug under sec-  
4 tion (j).

5                   “(iv) ANDA FILER.—The term  
6 ‘ANDA filer’ means a party that has filed  
7 an ANDA with the Food and Drug Admin-  
8 istration.

9                   “(v) PATENT INFRINGEMENT.—The  
10 term ‘patent infringement’ means infringe-  
11 ment of any patent or of any filed patent  
12 application, extension, reissuance, renewal,  
13 division, continuation, continuation in part,  
14 reexamination, patent term restoration,  
15 patent of addition, or extension thereof.

16                   “(vi) PATENT INFRINGEMENT  
17 CLAIM.—The term ‘patent infringement  
18 claim’ means any allegation made to an  
19 ANDA filer, whether or not included in a  
20 complaint filed with a court of law, that its  
21 ANDA or drug to be manufactured under  
22 such ANDA may infringe any patent.

23                   “(2) FTC RULEMAKING.—The Federal Trade  
24 Commission may, by rule promulgated under section  
25 553 of title 5, United States Code, exempt certain

1 agreements described in paragraph (1) from the re-  
2 quirements of this subsection if the Commission  
3 finds such agreements to be in furtherance of mar-  
4 ket competition and for the benefit of consumers.  
5 Consistent with the authority of the Commission,  
6 such rules may include interpretive rules and general  
7 statements of policy with respect to the practices  
8 prohibited under paragraph (1).”.

9 (b) NOTICE AND CERTIFICATION OF AGREE-  
10 MENTS.—

11 (1) NOTICE OF ALL AGREEMENTS.—Section  
12 1112(c)(2) of the Medicare Prescription Drug, Im-  
13 provement, and Modernization Act of 2003 (21  
14 U.S.C. 3155 note) is amended by—

15 (A) striking “the Commission the” and in-  
16 serting the following: “the Commission—

17 “(A) the”;

18 (B) striking the period at the end and in-  
19 serting “; and”; and

20 (C) adding at the end the following:

21 “(B) any other agreement the parties enter  
22 into within 30 days of entering into an agree-  
23 ment covered by subsection (a) or (b).”.

1           (2) CERTIFICATION OF AGREEMENTS.—Section  
2       1112 of such Act is amended by adding at the end  
3       the following:

4       “(d) CERTIFICATION.—The chief executive officer or  
5       the company official responsible for negotiating any agree-  
6       ment required to be filed under subsection (a), (b), or (c)  
7       shall execute and file with the Assistant Attorney General  
8       and the Commission a certification as follows: ‘I declare  
9       under penalty of perjury that the following is true and  
10      correct: The materials filed with the Federal Trade Com-  
11      mission and the Department of Justice under section 1112  
12      of subtitle B of title XI of the Medicare Prescription Drug,  
13      Improvement, and Modernization Act of 2003, with re-  
14      spect to the agreement referenced in this certification: (1)  
15      represent the complete, final, and exclusive agreement be-  
16      tween the parties; (2) include any ancillary agreements  
17      that are contingent upon, provide a contingent condition  
18      for, or are otherwise related to, the referenced agreement;  
19      and (3) include written descriptions of any oral agree-  
20      ments, representations, commitments, or promises be-  
21      tween the parties that are responsive to subsection (a) or  
22      (b) of such section 1112 and have not been reduced to  
23      writing.’”.

24      (c) GAO STUDY.—

1           (1) STUDY.—Beginning 2 years after the date  
2 of enactment of this Act, and each year for a period  
3 of 4 years thereafter, the Comptroller General shall  
4 conduct a study on the litigation in United States  
5 courts during the period beginning years prior to the  
6 date of enactment of this Act relating to patent in-  
7 fringement claims involving generic drugs, the num-  
8 ber of patent challenges initiated by manufacturers  
9 of generic drugs, and the number of settlements of  
10 such litigation. The Comptroller General shall trans-  
11 mit to Congress a report of the findings of such a  
12 study and an analysis of the effect of the amend-  
13 ments made by subsections (a) and (b) on such liti-  
14 gation, whether such amendments have had an effect  
15 on the number and frequency of claims settled, and  
16 whether such amendments resulted in earlier or de-  
17 layed entry of generic drugs to market, including  
18 whether any harm or benefits to consumers has re-  
19 sulted.

20           (2) DISCLOSURE OF AGREEMENTS.—Notwith-  
21 standing any other law, agreements filed under sec-  
22 tion 1112 of the Medicare Prescription Drug, Im-  
23 provement, and Modernization Act of 2003 (21  
24 U.S.C. 355 note), or unaggregated information from  
25 such agreements, shall be disclosed to the Comp-

1 troller General for purposes of the study under para-  
2 graph (1) within 30 days of a request by the Comp-  
3 troller General.

