

106TH CONGRESS
2D SESSION

S. 2501

To provide access and choice for use of generic drugs instead of nongeneric drugs under Federal health care programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 3, 2000

Mr. JOHNSON introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide access and choice for use of generic drugs instead of nongeneric drugs under Federal health care programs, 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,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Generic Pharmaceutical Access and Choice for Con-
6 sumers Act of 2000”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purposes.

TITLE I—ENCOURAGEMENT OF THE USE OF GENERIC DRUGS

- Sec. 101. Encouragement of the use of generic drugs under the Public Health Service Act.
- Sec. 102. Application to Federal employees health benefits program.
- Sec. 103. Application to medicare program.
- Sec. 104. Application to medicaid program.
- Sec. 105. Application to Indian Health Service.
- Sec. 106. Application to veterans programs.
- Sec. 107. Application to recipients of uniformed services health care.
- Sec. 108. Application to Federal prisoners.

TITLE II—THERAPEUTIC EQUIVALENCE REQUIREMENTS FOR
GENERIC DRUGS

- Sec. 201. Therapeutic equivalence of generic drugs.

TITLE III—GENERIC PHARMACEUTICALS AND MEDICARE
REFORM

- Sec. 301. Sense of the Senate regarding a preference for the use of generic pharmaceuticals under the medicare program.

1 SEC. 2. FINDINGS AND PURPOSES.

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) Generic pharmaceuticals are approved by
5 the Food and Drug Administration on the basis of
6 testing and other information establishing that such
7 pharmaceuticals are therapeutically equivalent to
8 brand-name pharmaceuticals, ensuring consumers a
9 safe, efficacious, and cost-effective alternative to
10 brand-name pharmaceuticals.

11 (2) The pharmaceutical market has become in-
12 creasingly competitive during the last decade be-
13 cause of the increasing availability and accessibility
14 of generic pharmaceuticals.

15 (3) The Congressional Budget Office estimates
16 that—

1 (A) the substitution of generic pharma-
2 ceuticals for brand-name pharmaceuticals will
3 save purchasers of pharmaceuticals between
4 \$8,000,000,000 and \$10,000,000,000 each
5 year; and

6 (B) quality generic pharmaceuticals cost
7 between 25 percent and 60 percent less than
8 brand-name pharmaceuticals, resulting in an es-
9 timated average savings of \$15 to \$30 on each
10 prescription filled.

11 (4) Generic pharmaceuticals are widely accepted
12 by both consumers and the medical profession, as
13 the market share held by generic pharmaceuticals
14 compared to brand-name pharmaceuticals has more
15 than doubled during the last decade, from approxi-
16 mately 19 percent to 43 percent, according to the
17 Congressional Budget Office.

18 (b) PURPOSES.—The purposes of this Act are—

19 (1) to reduce the cost of prescription drugs to
20 the United States Government and to beneficiaries
21 under Federal health care programs while maintain-
22 ing the quality of health care by encouraging the use
23 of generic drugs rather than nongeneric drugs under
24 those programs whenever feasible; and

1 (2) to increase the utilization of generic phar-
 2 maceuticals by requiring the Food and Drug Admin-
 3 istration, where appropriate, to determine that a ge-
 4 neric pharmaceutical is the therapeutic equivalent of
 5 its brand-name counterpart, and by affording na-
 6 tional uniformity to that determination.

7 **TITLE I—ENCOURAGEMENT OF**
 8 **THE USE OF GENERIC DRUGS**

9 **SEC. 101. ENCOURAGEMENT OF THE USE OF GENERIC**
 10 **DRUGS UNDER THE PUBLIC HEALTH SERV-**
 11 **ICE ACT.**

12 (a) IN GENERAL.—Part B of title II of the Public
 13 Health Service Act (42 U.S.C. 238 et seq.) is amended
 14 by adding at the end the following new section:

15 **“SEC. 247. USE OF GENERIC DRUGS ENCOURAGED.**

16 “(a) Each grant or contract entered into under this
 17 Act that involves the provision of health care items or serv-
 18 ices to individuals shall include provisions to ensure that,
 19 to the extent feasible, any prescriptions provided for under
 20 such grant or contract are filled by providing the generic
 21 form of the drug involved, unless the nongeneric form of
 22 the drug is—

23 “(1) specifically ordered by the prescribing pro-
 24 vider; or

1 “(2) requested by the individual for whom the
2 drug is prescribed.

3 “(b) In this section:

4 “(1) The term ‘generic form of the drug’ means
5 a drug that is the subject of an application approved
6 under section 505(j) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 355(j)), for which the Sec-
8 retary has made a determination that the drug is
9 the therapeutic equivalent of a listed drug under sec-
10 tion 505(j)(5)(E) of that Act (21 U.S.C.
11 355(j)(5)(E)).

12 “(2) The term ‘nongeneric form of the drug’
13 means a drug that is the subject of an application
14 approved under section 505(b) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 355(b)).”.

16 (b) EFFECTIVE DATE.—The amendment made by
17 this section shall apply with respect to any drug furnished
18 on or after the date of enactment of this Act.

19 **SEC. 102. APPLICATION TO FEDERAL EMPLOYEES HEALTH**
20 **BENEFITS PROGRAM.**

21 (a) IN GENERAL.—Section 8902 of title 5, United
22 States Code, is amended by adding at the end the fol-
23 lowing new subsection:

24 “(p) To the extent feasible, if a contract under this
25 chapter provides for the provision of, the payment for, or

1 the reimbursement of the cost of any prescription drug,
2 the carrier shall provide, pay, or reimburse the cost of the
3 generic form of the drug (as defined in section 247(b)(1)
4 of the Public Health Service Act), except, if the nongeneric
5 form of the drug (as defined in section 247(b)(2) of such
6 Act) is—

7 “(1) specifically ordered by the prescribing pro-
8 vider; or

9 “(2) requested by the individual for whom the
10 drug is prescribed.”.

11 (b) EFFECTIVE DATE.—The amendment made by
12 this section shall apply to any drug furnished during con-
13 tract years beginning on or after January 1, 2001.

14 **SEC. 103. APPLICATION TO MEDICARE PROGRAM.**

15 (a) IN GENERAL.—Section 1861(t) of the Social Se-
16 curity Act (42 U.S.C. 1395x(t)) is amended by adding at
17 the end the following new paragraph:

18 “(3) For purposes of paragraph (1), the term ‘drugs’
19 means, to the extent feasible, the generic form of the drug
20 (as defined in section 247(b)(1) of the Public Health Serv-
21 ice Act), unless the nongeneric form of such drug (as de-
22 fined in section 247(b)(2) of such Act) is—

23 “(A) specifically ordered by the health care pro-
24 vider; or

1 “(B) requested by the individual to whom the
2 drug is provided.”.

3 (b) EFFECTIVE DATE.—

4 (1) IN GENERAL.—Except as provided in para-
5 graph (2), the amendment made by this section shall
6 apply with respect to any drug furnished on or after
7 the date of enactment of this Act.

8 (2) MEDICARE+CHOICE PLANS.—In the case of
9 a Medicare+Choice plan offered by a
10 Medicare+Choice organization under part C of title
11 XVIII of the Social Security Act (42 U.S.C. 1395w-
12 21 et seq.), the amendment made by this section
13 shall apply to any drug furnished during contract
14 years beginning on or after January 1, 2001.

15 **SEC. 104. APPLICATION TO MEDICAID PROGRAM.**

16 (a) IN GENERAL.—Section 1902(a) of the Social Se-
17 curity Act (42 U.S.C. 1396a(a)) is amended—

18 (1) in paragraph (64), by striking “and” at the
19 end;

20 (2) in paragraph (65), by striking the period at
21 the end and inserting “; and”; and

22 (3) by adding the following new paragraph:

23 “(66) provide that the State shall, in conjunc-
24 tion with the program established under section
25 1927(g), to the extent feasible, provide for the use

1 of a generic form of a drug (as defined in section
2 247(b)(1) of the Public Health Service Act), unless
3 the nongeneric form of the drug (as defined in sec-
4 tion 247(b)(2) of such Act is—

5 “(A) specifically ordered by the provider;

6 or

7 “(B) requested by the individual to whom
8 the drug is provided.”.

9 (b) **EFFECTIVE DATE.**—The amendment made by
10 this section shall apply with respect to any drug furnished
11 under State plans that are approved or renewed on or
12 after the date of enactment of this Act.

13 **SEC. 105. APPLICATION TO INDIAN HEALTH SERVICE.**

14 (a) **IN GENERAL.**—Title II of the Indian Health Care
15 Improvement Act (25 U.S.C. 1621 et seq.) is amended by
16 adding at the end the following new subsection:

17 **“SEC. 225. USE OF GENERIC DRUGS ENCOURAGED.**

18 “In providing health care items or services under this
19 Act, the Indian Health Service shall ensure that, to the
20 extent feasible, any prescriptions that are provided for
21 under this Act are filled by providing the generic form of
22 the drug (as defined in section 247(b)(1) of the Public
23 Health Service Act) involved, unless the nongeneric form
24 of the drug (as defined in section 247(b)(2) of such Act)
25 is—

1 “(1) specifically ordered by the prescribing pro-
2 vider; or

3 “(2) requested by the individual for whom the
4 drug is prescribed.”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 this section shall apply with respect to any drug furnished
7 on or after the date of enactment of this Act.

8 **SEC. 106. APPLICATION TO VETERANS PROGRAMS.**

9 (a) USE OF GENERIC DRUGS ENCOURAGED.—Sub-
10 chapter III of chapter 17 of title 38, United States Code,
11 is amended by inserting after section 1722A the following
12 new section:

13 **“§ 1722B. Use of generic drugs encouraged**

14 “When furnishing a prescription drug under this
15 chapter, the Secretary shall furnish a generic form of the
16 drug (as defined in section 247(b)(1) of the Public Health
17 Service Act), unless the nongeneric form of the drug (as
18 defined in section 247(b)(2) of such Act) is—

19 “(1) specifically ordered by the prescribing pro-
20 vider; or

21 “(2) requested by the individual for whom the
22 drug is prescribed.”.

23 (b) CLERICAL AMENDMENT.—The table of sections
24 at the beginning of chapter 17 of such title is amended
25 by inserting after the item relating to section 1722A the

1 following new item:

“1722B. Use of generic drugs encouraged.”.

2 (c) EFFECTIVE DATE.—The amendments made by
3 this section shall apply with respect to any drug furnished
4 on or after the date of enactment of this Act.

5 **SEC. 107. APPLICATION TO RECIPIENTS OF UNIFORMED**
6 **SERVICES HEALTH CARE.**

7 (a) USE OF GENERIC DRUGS ENCOURAGED.—Chap-
8 ter 55 of title 10, United States Code, is amended by add-
9 ing at the end the following new section:

10 **“§ 1110. Use of generic drugs encouraged**

11 “The Secretary of Defense shall ensure that, when-
12 ever feasible, each health care provider who furnishes a
13 drug furnishes the generic form of the drug (as defined
14 in section 247(b)(1) of the Public Health Service Act), un-
15 less the nongeneric form of the drug (as defined in section
16 247(b)(2) of such Act) is—

17 “(1) specifically ordered by the prescribing pro-
18 vider; or

19 “(2) requested by the individual for whom the
20 drug is prescribed.”.

21 (b) CLERICAL AMENDMENT.—The table of sections
22 at the beginning of such chapter is amended by inserting
23 after the item relating to section 1109 the following new
24 item:

“1110. Use of generic drugs encouraged.”.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply with respect to any drug furnished
3 on or after the date of enactment of this Act.

4 **SEC. 108. APPLICATION TO FEDERAL PRISONERS.**

5 (a) IN GENERAL.—Section 4006(b) of title 18,
6 United States Code, is amended by adding at the end the
7 following new paragraph:

8 “(3) USE OF GENERIC DRUGS ENCOURAGED.—

9 The Attorney General shall ensure that, whenever
10 feasible, each health care provider who furnishes a
11 drug to a prisoner charged with or convicted of an
12 offense against the United States furnishes the ge-
13 neric form of the drug (as defined in section
14 247(b)(1) of the Public Health Service Act), unless
15 the nongeneric form of the drug (as defined in sec-
16 tion 247(b)(2) of such Act) is—

17 “(A) specifically ordered by the prescribing
18 provider; or

19 “(B) requested by the prisoner for whom
20 the drug is prescribed.”.

21 (b) EFFECTIVE DATE.—The amendment made by
22 this section shall apply with respect to any drug furnished
23 on or after the date of enactment of this Act.

1 **TITLE** **II—THERAPEUTIC**
2 **EQUIVALENCE REQUIRE-**
3 **MENTS FOR GENERIC DRUGS**

4 **SEC. 201. THERAPEUTIC EQUIVALENCE OF GENERIC**
5 **DRUGS.**

6 (a) IN GENERAL.—Section 505(j) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is
8 amended—

9 (1) in paragraph (5), by adding at the end the
10 following new subparagraph:

11 “(E)(i) For each abbreviated application filed under
12 paragraph (1), the Secretary shall determine whether the
13 new drug for which the application is filed is the thera-
14 peutic equivalent of the listed drug referred to in para-
15 graph (2)(A)(i) prior to the approval of the application.

16 “(ii) For purposes of clause (i), a new drug is the
17 therapeutic equivalent of a listed drug if—

18 “(I) each active ingredient of the new drug and
19 the listed drug is the same;

20 “(II) the new drug and the listed drug (aa) are
21 of the same dosage form; (bb) have the same route
22 of administration; (cc) are identical in strength or
23 concentration; (dd) meet the same compendial or
24 other applicable standards, except that the drugs
25 may differ in shape, scoring, configuration, pack-

1 aging, excipient, expiration time, or, subject to para-
2 graph (2)(A)(v), labeling; and (ee) are expected to
3 have the same clinical effect and safety profile when
4 administered to patients under conditions specified
5 in the labeling; and

6 “(III) the new drug does not (aa) present a
7 known or potential bioequivalence problem and
8 meets an acceptable in vitro standard; or (bb) if the
9 new drug presents a known or potential bioequiva-
10 lence problem, the drug is shown to meet an appro-
11 priate bioequivalence standard.

12 “(iii) With respect to a new drug for which an abbrevi-
13 ated application is filed under paragraph (1), the provi-
14 sions of this subparagraph shall supersede any provisions
15 of the law of any State relating to the determination of
16 the therapeutic equivalence of the drug to a listed drug.”;
17 and

18 (2) in paragraph (7)(A), by adding at the end
19 the following:

20 “(iv) The Secretary shall include in each revision
21 of the list under clause (ii) on or after the date
22 of enactment of this clause the official and propri-
23 etary name of each listed drug that is therapeuti-
24 cally equivalent to a new drug approved under this

1 subsection during the preceding 30-day period, as
 2 determined under paragraph (5)(E).”.

3 (b) EFFECTIVE DATE.—The amendments made by
 4 this section shall take effect on the date of enactment of
 5 this Act.

6 **TITLE III—GENERIC PHARMA-**
 7 **CEUTICALS AND MEDICARE**
 8 **REFORM**

9 **SEC. 301. SENSE OF THE SENATE REGARDING A PREF-**
 10 **ERENCE FOR THE USE OF GENERIC PHARMA-**
 11 **CEUTICALS UNDER THE MEDICARE PRO-**
 12 **GRAM.**

13 It is the sense of the Senate that legislative language
 14 requiring, to the extent feasible, a preference for the safe
 15 and cost-effective use of generic pharmaceuticals should
 16 be considered in conjunction with any legislation that adds
 17 a comprehensive prescription drug benefit to the medicare
 18 program under title XVIII of the Social Security Act (42
 19 U.S.C. 1395 et seq.).

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