

109TH CONGRESS
1ST SESSION

H. R. 2956

To provide for the establishment of certain restrictions with respect to drugs containing isotretinoin (including the drug marketed as Accutane).

IN THE HOUSE OF REPRESENTATIVES

JUNE 16, 2005

Mr. STUPAK introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for the establishment of certain restrictions with respect to drugs containing isotretinoin (including the drug marketed as Accutane).

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.**

4 This Act may be cited as the “Accutane Safety and
5 Risk Management Act”.

6 **SEC. 2. FEDERAL FOOD, DRUG, AND COSMETIC ACT; RE-**
7 **STRICTIONS REGARDING DRUG**
8 **ISOTRETINOIN.**

9 (a) IN GENERAL.—Not later than the expiration of
10 the 30-day period beginning on the date of the enactment

1 of this Act, the Secretary of Health and Human Services
2 (referred to in this Act as the “Secretary”), acting
3 through the Commissioner of Food and Drugs, shall with-
4 draw the approval under section 505 of the Federal Food,
5 Drug, and Cosmetic Act of each application for a drug
6 that contains isotretinoin as an active ingredient (includ-
7 ing the drug marketed as Accutane). During or after such
8 period, any holder of an application that is subject to the
9 preceding sentence may file with the Secretary a supple-
10 mental application for such drug, and the Secretary may
11 approve the supplemental application in accordance with
12 subsection (b).

13 (b) RESTRICTIONS.—Any approval by the Secretary
14 of a supplemental application for a drug containing
15 isotretinoin pursuant to subsection (a) shall provide that
16 such drug is being approved as a drug subject to subpart
17 H of part 314 of title 21, Code of Federal Regulations.
18 The Secretary shall under such subpart H establish re-
19 strictions on the distribution of the drug. Such restrictions
20 shall require that distribution of the drug under all the
21 approved supplemental applications be exclusively through
22 a single program, approved by the Secretary, that provides
23 for the distribution of the drug in accordance with the fol-
24 lowing conditions:

1 (1) Distribution of the drug by manufacturers
2 is directly to pharmacists (without the involvement
3 of entities engaged in the wholesale distribution of
4 drugs), and each pharmacist receiving the drug is in
5 compliance with the following:

6 (A) The pharmacist has registered with the
7 program.

8 (B) The pharmacist has received education
9 on potential side effects of the drug relating to
10 birth defects and mental health or behavioral
11 issues that, as of the day before the date of the
12 enactment of this Act, were described on the
13 approved labeling for the drug (including de-
14 pression, suicidal ideation, suicide attempts,
15 suicide, and aggressive or violent behavior).

16 (C) The pharmacist agrees that the drug
17 will be dispensed only pursuant to prescriptions
18 issued by practitioners at treatment centers cer-
19 tified under paragraph (2).

20 (D) The pharmacist has signed and filed
21 with the program a statement that the phar-
22 macist understands the conditions for participa-
23 tion in the program as a pharmacist, and will
24 maintain compliance with the agreement de-

1 scribed in subparagraph (C) and otherwise com-
2 ply with applicable conditions.

3 (2) The program certifies clinics and medical
4 offices as treatment centers regarding the drug,
5 makes the certifications in accordance with the con-
6 ditions described in subsection (c), provides that the
7 certifications are effective for one year, and main-
8 tains a registry of treatment centers for which cer-
9 tifications are in effect.

10 (3) The program develops and makes available
11 to practitioners materials for educating patients on
12 the drug, including managing the risks associated
13 with the drug, and such materials include a ques-
14 tionnaire, to be completed monthly by patients, that
15 warns patients of the adverse side effects described
16 in paragraph (1)(B) and monitors for the develop-
17 ment of any such effects in patients.

18 (4) The drug is prescribed for a patient by a
19 practitioner only in accordance with the following:

20 (A) The drug is prescribed for severe, re-
21 calcitrant nodular acne that is unresponsive to
22 conventional therapy, including antibiotics.

23 (B) The patient is registered with the pro-
24 gram.

1 (C) Using the materials referred to in
2 paragraph (3), the practitioner educates the pa-
3 tient on the drug, including providing one-on-
4 one, in-person counseling.

5 (D) The practitioner provides to the pa-
6 tient the questionnaire referred to in paragraph
7 (3), and the patient completes the question-
8 naire.

9 (E) The patient signs a statement pro-
10 viding the informed consent of the patient to
11 undergo treatment with the drug (or a parent
12 or guardian of the patient signs the statement,
13 in the case of a patient who is a minor or other-
14 wise lacks legal capacity).

15 (F) The patient undergoes the appropriate
16 blood tests.

17 (G) In the case of a female patient—

18 (i) the education under subparagraph
19 (C) includes education on the need to avoid
20 becoming pregnant while being treated
21 with the drug; and

22 (ii) the practitioner determines that
23 the patient is not pregnant, as indicated by
24 an electronic verification, provided to the
25 practitioner by an accredited laboratory,

1 that the patient has undergone a preg-
2 nancy test and received a negative result.

3 (H) In the case of a male patient, the edu-
4 cation under subparagraph (C) includes edu-
5 cation on the need to avoid impregnating
6 women while being treated with the drug.

7 (I) The prescription is issued only after
8 compliance with subparagraphs (B) through
9 (H).

10 (J) The prescription is for a 30-day supply
11 of the drug, with no refills.

12 (K) Each further prescription for the drug
13 is issued by the practitioner to the patient only
14 pursuant to another in-person consultation with
15 the practitioner, and prior to issuing the pre-
16 scription, compliance with subparagraphs (C)
17 through (I) is repeated.

18 (L) The patient undergoes the appropriate
19 blood tests 30 days after the conclusion of
20 treatment with the drug.

21 (5) Such additional conditions as the Secretary
22 may by regulation determine to be necessary to pro-
23 tect the public health with respect to the drug.

24 (c) CERTIFICATION OF TREATMENT CENTERS.—For
25 purposes of subsection (b)(2), the conditions for the pro-

1 gram to certify a clinic or medical office as a treatment
2 center regarding a drug containing isotretinoin are as fol-
3 lows:

4 (1) The program determines that each of the
5 practitioners at the clinic or office who will prescribe
6 the drug is in compliance with the following:

7 (A) The practitioner is authorized under
8 the law of the State involved to administer pre-
9 scription drugs.

10 (B) The practitioner has registered with
11 the program and received education on the po-
12 tential side effects referred to in subsection
13 (b)(1)(B).

14 (C) The practitioner agrees as follows:

15 (i) The practitioner will prescribe the
16 drug for a patient in accordance with sub-
17 section (b)(4).

18 (ii) If a female patient being treated
19 with the drug becomes pregnant, the prac-
20 titioner will immediately report the preg-
21 nancy to the program and provide follow-
22 up in accordance with the program.

23 (iii) The practitioner will not issue
24 prescriptions for the drug by telephone or

1 facsimile transmission, or through the
2 Internet.

3 (iv) The practitioner will—

4 (I) report to the Secretary any
5 information received by the practi-
6 tioner on adverse events that are asso-
7 ciated with the use of the drug by pa-
8 tients of the practitioner; and

9 (II) submit such reports quar-
10 terly, except in the case of a patient
11 death associated with the drug, in
12 which case the report will be sub-
13 mitted immediately, but in no case
14 later than 15 days after the date on
15 which the practitioner learns of the
16 death.

17 (D) The practitioner has signed and filed
18 with the program a statement that the practi-
19 tioner understands the conditions for participa-
20 tion in the program as a practitioner, and will
21 maintain compliance with the agreements de-
22 scribed in subparagraph (C) and otherwise com-
23 ply with applicable conditions.

24 (2) After the initial certification of the clinic or
25 office, the program renews a certification for addi-

1 tional one-year periods only if the program has con-
2 ducted an evaluation to determine whether, during
3 the preceding one-year period, each practitioner at
4 the center who prescribes the drug has maintained
5 substantial compliance with applicable conditions of
6 the program.

7 (3) Such additional conditions as the Secretary
8 may by regulation determine to be necessary to pro-
9 tect the public health with respect to the drug.

10 (d) MONITORING BY SECRETARY.—The Secretary
11 shall monitor the distribution of drugs containing
12 isotretinoin under supplemental applications approved
13 under subsection (b), including the prescribing and dis-
14 pensing of the drug, to determine whether the drug is
15 being distributed in accordance with the program ap-
16 proved by the Secretary under such subsection.

17 (e) ADDITIONAL APPROVED USES.—

18 (1) IN GENERAL.—With respect to a drug that
19 contains isotretinoin as an active ingredient, this
20 section may not be construed as prohibiting the Sec-
21 retary from approving an application under section
22 505 of the Federal Food, Drug, and Cosmetic Act
23 for such a drug for a use different than the use de-
24 scribed in subsection (b)(4)(A) (which different use
25 is referred to in this subsection as a “new use”).

1 (2) CONDITIONS.—For purposes of paragraph
2 (1):

3 (A) An approval by the Secretary of a new
4 use is subject to the same conditions as apply
5 under subsection (b) with respect to the use de-
6 scribed in paragraph (4)(A) of such subsection.

7 (B) In applying such conditions to the new
8 use, the Secretary may authorize the program
9 under subsection (b) to be expanded to include
10 the new use, or the Secretary may require the
11 establishment of a separate program for the
12 new use.

13 (C) The requirement of monitoring under
14 subsection (d) applies with respect to the new
15 use to the same extent and in the same manner
16 as the requirement applies with respect to the
17 use described in subsection (b)(4)(A).

18 (D) Section 3 applies with respect to the
19 new use.

20 **SEC. 3. REPORTING OF ADVERSE EVENTS BY MANUFAC-**
21 **TURERS AND DISTRIBUTORS.**

22 (a) IN GENERAL.—Each person who is a manufac-
23 turer or distributor of a drug containing isotretinoin shall
24 report to the Secretary any information received by such
25 person on adverse events that are associated with such

1 drug. In any case in which an individual reports an ad-
2 verse event to such person and states that the individual
3 believes the drug is a factor in the event, the person shall
4 consider the event to be associated with the drug for pur-
5 poses of the preceding sentence.

6 (b) TIMEFRAME FOR REPORTING.—A person de-
7 scribed in subsection (a) shall submit reports under such
8 subsection to the Secretary on a quarterly basis, except
9 that in the case of a death associated with isotretinoin,
10 the report shall be submitted immediately, but in no case
11 later than 15 days after the date on which the person
12 learns of the death.

13 **SEC. 4. FURTHER STUDIES.**

14 (a) IN GENERAL.—The Secretary, in consultation
15 with the Director of the Centers for Disease Control and
16 Prevention, the Director of the National Institutes of
17 Health, and the Director of the National Institute of Men-
18 tal Health, shall continue to conduct and support appro-
19 priate studies to explore, in adolescents and adults—

20 (1) the effects of isotretinoin and retinoid acid
21 on the central nervous system, including the brain;
22 and

23 (2) the behavioral effects of isotretinoin, includ-
24 ing depression, suicidal ideation, suicide attempts,
25 suicide, and aggressive or violent behavior.

1 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of studies under subsection (a), there are author-
3 ized to be appropriated such sums as may be necessary
4 for fiscal year 2006 and each subsequent fiscal year, in
5 addition to any other authorizations of appropriations that
6 are available for such purpose.

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