

.....
(Original Signature of Member)

108TH CONGRESS
2D SESSION

H. R. _____

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

Mr. STUPAK introduced the following bill; which was referred to the Committee on _____

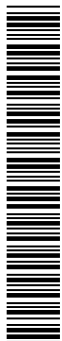
A BILL

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.**

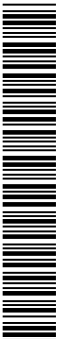
4 This Act may be cited as the “Accutane Safety and
5 Risk Management Act”.



1 **SEC. 2. FEDERAL FOOD, DRUG, AND COSMETIC ACT; RE-**
2 **STRICTIONS REGARDING DRUG**
3 **ISOTRETINOIN.**

4 (a) IN GENERAL.—Not later than the expiration of
5 the 30-day period beginning on the date of the enactment
6 of this Act, the Secretary of Health and Human Services
7 (referred to in this Act as the “Secretary”), acting
8 through the Commissioner of Food and Drugs, shall with-
9 draw the approval under section 505 of the Federal Food,
10 Drug, and Cosmetic Act of each application for a drug
11 that contains isotretinoin as an active ingredient (includ-
12 ing the drug marketed as Accutane). During or after such
13 period, any holder of an application that is subject to the
14 preceding sentence may file with the Secretary a supple-
15 mental application for such drug, and the Secretary may
16 approve the supplemental application in accordance with
17 subsection (b).

18 (b) RESTRICTIONS.—Any approval by the Secretary
19 of a supplemental application for a drug containing
20 isotretinoin pursuant to subsection (a) shall provide that
21 such drug is being approved as a drug subject to subpart
22 H of part 314 of title 21, Code of Federal Regulations.
23 The Secretary shall under such subpart H establish re-
24 strictions on the distribution of the drug. Such restrictions
25 shall require that distribution of the drug under all the
26 approved supplemental applications be exclusively through



1 a single program, approved by the Secretary, that provides
2 for the distribution of the drug in accordance with the fol-
3 lowing conditions:

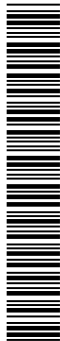
4 (1) Distribution of the drug by manufacturers
5 is directly to pharmacists (without the involvement
6 of entities engaged in the wholesale distribution of
7 drugs), and each pharmacist receiving the drug is in
8 compliance with the following:

9 (A) The pharmacist has registered with the
10 program.

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

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

23 (D) The pharmacist has signed and filed
24 with the program a statement that the phar-
25 macist understands the conditions for participa-



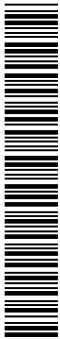
1 tion in the program as a pharmacist, and will
2 maintain compliance with the agreement de-
3 scribed in subparagraph (C) and otherwise com-
4 ply with applicable conditions.

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

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

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

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



1 (B) The patient is registered with the pro-
2 gram.

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

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

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

17 (F) The patient undergoes the appropriate
18 blood tests.

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

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

24 (ii) the practitioner determines that
25 the patient is not pregnant, as indicated by



1 an electronic verification, provided to the
2 practitioner by an accredited laboratory,
3 that the patient has undergone a preg-
4 nancy test and received a negative result.

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

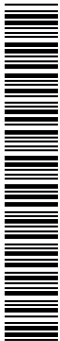
9 (I) The prescription is issued only after
10 compliance with subparagraphs (B) through
11 (H).

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

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

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

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



1 (c) CERTIFICATION OF TREATMENT CENTERS.—For
2 purposes of subsection (b)(2), the conditions for the pro-
3 gram to certify a clinic or medical office as a treatment
4 center regarding a drug containing isotretinoin are as fol-
5 lows:

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

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

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

16 (C) The practitioner agrees as follows:

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

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



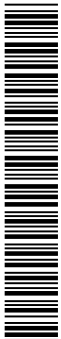
1 (iii) The practitioner will not issue
2 prescriptions for the drug by telephone or
3 facsimile transmission, or through the
4 Internet.

5 (iv) The practitioner will—

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

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

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



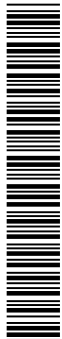
1 (2) After the initial certification of the clinic or
2 office, the program renews a certification for addi-
3 tional-one year periods only if the program has con-
4 ducted an evaluation to determine whether, during
5 the preceding one-year period, each practitioner at
6 the center who prescribes the drug has maintained
7 substantial compliance with applicable conditions of
8 the program.

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

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

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

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



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

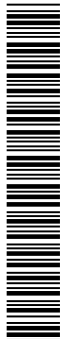
5 (b) TIMEFRAME FOR REPORTING.—A person de-
6 scribed in subsection (a) shall submit reports under such
7 subsection to the Secretary on a quarterly basis, except
8 that in the case of a death associated with isotretinoin,
9 the report shall be submitted immediately, but in no case
10 later than 15 days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

12 **SEC. 4. FURTHER STUDIES.**

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

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

22 (2) the behavioral effects of isotretinoin, includ-
23 ing depression, suicidal ideation, suicide attempts,
24 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 2005 and each subsequent fiscal year, in
5 addition to any other authorizations of appropriations that
6 are available for such purpose.

