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108TH CONGRESS
2D SESSION

H. R. 4598

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, 2004

Mr. STUPAK (for himself, Mr. SMITH of New Jersey, Mr. WELDON of Florida, Ms. KILPATRICK, Mr. WAMP, Ms. DEGETTE, Mr. BURTON of Indiana, Ms. DELAURO, Mr. DOYLE, Mr. BACA, and Mr. GORDON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Accutane Safety and Risk Management Act''.

SEC. 2. FEDERAL FOOD, DRUG, AND COSMETIC ACT; RESTRICTIONS REGARDING DRUG ISOTRETINOIN.

(a) IN GENERAL.—Not later than the expiration of the 30-day period beginning on the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this Act as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall withdraw the approval under section 505 of the Federal Food, Drug, and Cosmetic Act of each application for a drug that contains isotretinoin as an active ingredient (including the drug marketed as Accutane). During or after such period, any holder of an application that is subject to the preceding sentence may file with the Secretary a supplemental application for such drug, and the Secretary may approve the supplemental application in accordance with subsection (b).

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

a single program, approved by the Secretary, that provides for the distribution of the drug in accordance with the following conditions:

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

(A) The pharmacist has registered with the program.

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

(C) The pharmacist agrees that the drug will be dispensed only pursuant to prescriptions issued by practitioners at treatment centers certified under paragraph (2).

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

tion in the program as a pharmacist, and will maintain compliance with the agreement described in subparagraph (C) and otherwise comply with applicable conditions.

(2) The program certifies clinics and medical offices as treatment centers regarding the drug, makes the certifications in accordance with the conditions described in subsection (c), provides that the certifications are effective for one year, and maintains a registry of treatment centers for which certifications are in effect.

(3) The program develops and makes available to practitioners materials for educating patients on the drug, including managing the risks associated with the drug, and such materials include a questionnaire, to be completed monthly by patients, that warns patients of the adverse side effects described in paragraph (1)(B) and monitors for the development of any such effects in patients.

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

(A) The drug is prescribed for severe, recalcitrant nodular acne that is unresponsive to conventional therapy, including antibiotics.

(B) The patient is registered with the program.

(C) Using the materials referred to in paragraph (3), the practitioner educates the patient on the drug, including providing one-on-one, in-person counseling.

(D) The practitioner provides to the patient the questionnaire referred to in paragraph (3), and the patient completes the questionnaire.

(E) The patient signs a statement providing the informed consent of the patient to undergo treatment with the drug (or a parent or guardian of the patient signs the statement, in the case of a patient who is a minor or otherwise lacks legal capacity).

(F) The patient undergoes the appropriate blood tests.

(G) In the case of a female patient—

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

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

an electronic verification, provided to the practitioner by an accredited laboratory, that the patient has undergone a pregnancy test and received a negative result.

(H) In the case of a male patient, the education under subparagraph (C) includes education on the need to avoid impregnating women while being treated with the drug.

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

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

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

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

(5) Such additional conditions as the Secretary may by regulation determine to be necessary to protect the public health with respect to the drug.

(c) CERTIFICATION OF TREATMENT CENTERS.—For purposes of subsection (b)(2), the conditions for the program to certify a clinic or medical office as a treatment center regarding a drug containing isotretinoin are as follows:

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

(A) The practitioner is authorized under the law of the State involved to administer prescription drugs.

(B) The practitioner has registered with the program and received education on the potential side effects referred to in subsection (b)(1)(B).

(C) The practitioner agrees as follows:

(i) The practitioner will prescribe the drug for a patient in accordance with subsection (b)(4).

(ii) If a female patient being treated with the drug becomes pregnant, the practitioner will immediately report the pregnancy to the program and provide follow-up in accordance with the program.

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

(iv) The practitioner will—

(I) report to the Secretary any information received by the practitioner on adverse events that are associated with the use of the drug by patients of the practitioner; and

(II) submit such reports quarterly, except in the case of a patient death associated with the drug, in which case the report will be submitted immediately, but in no case later than 15 days after the date on which the practitioner learns of the death.

(D) The practitioner has signed and filed with the program a statement that the practitioner understands the conditions for participation in the program as a practitioner, and will maintain compliance with the agreements described in subparagraph (C) and otherwise comply with applicable conditions.

(2) After the initial certification of the clinic or office, the program renews a certification for additional-one year periods only if the program has conducted an evaluation to determine whether, during the preceding one-year period, each practitioner at the center who prescribes the drug has maintained substantial compliance with applicable conditions of the program.

(3) Such additional conditions as the Secretary may by regulation determine to be necessary to protect the public health with respect to the drug.

(d) MONITORING BY SECRETARY.—The Secretary shall monitor the distribution of drugs containing isotretinoin under supplemental applications approved under subsection (b), including the prescribing and dispensing of the drug, to determine whether the drug is being distributed in accordance with the program approved by the Secretary under such subsection.

SEC. 3. REPORTING OF ADVERSE EVENTS BY MANUFACTURERS AND DISTRIBUTORS.

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

verse event to such person and states that the individual believes the drug is a factor in the event, the person shall consider the event to be associated with the drug for purposes of the preceding sentence.

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

SEC. 4. FURTHER STUDIES.

(a) IN GENERAL.—The Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Director of the National Institute of Mental Health, shall continue to conduct and support appropriate studies to explore, in adolescents and adults—

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

(2) the behavioral effects of isotretinoin, including depression, suicidal ideation, suicide attempts, suicide, and aggressive or violent behavior.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of studies under subsection (a), there are authorized to be appropriated such sums as may be necessary for fiscal year 2005 and each subsequent fiscal year, in addition to any other authorizations of appropriations that are available for such purpose.

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