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107TH CONGRESS
1ST SESSION

H. R. 386

To amend the Federal Food, Drug, and Cosmetic Act with respect to orphan drugs.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2001

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

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to orphan drugs.

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 ''Orphan Drug Program Improvement Act of 2001''.

SEC. 2. FEDERAL FOOD, DRUG, AND COSMETIC ACT; AMENDMENTS TO PROGRAM FOR ORPHAN DRUGS.

(a) CONFORMING ORPHAN-DRUG DESIGNATION TO REFLECT LABELING OF APPROVED DRUG.—Section

526(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bb(a)) is amended—

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by inserting after paragraph (1) the following paragraph:

''(2) In approving an application filed pursuant to section 505 for a drug designated under paragraph (1), or approving the issuance of a license under section 351 of the Public Health Service Act for a drug so designated, the Secretary shall, with respect to the intended use of the drug, conform the designation of the drug under paragraph (1) to reflect the labeling that is approved for the drug.''.

(b) CLINICAL SUPERIORITY OF SUBSEQUENT DRUG.—Section 527 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), by striking ''subsection (b)'' and inserting ''subsections (b) and (c)''; and

(2) by adding at the end the following:

''(c)(1) In a case in which the Secretary approves an application filed pursuant to section 505, or issues a license under section 351 of the Public Health Service Act, for a drug designated under section 526 for a rare disease or condition, and such drug is approved or licensed be-

cause it is considered to be clinically superior to a previously approved or licensed drug designated under section 526, the seven-year period of prohibition against approval described in subsection (a) shall apply only to prohibit approval of drugs that exhibit the same clinically superior features.

''(2) In paragraph (1), the term 'clinically superior' means a drug (that is otherwise the same drug) that is shown to provide better safety or better efficacy, or to provide a major contribution to patient care.

''(3) In making a determination of whether a drug is clinically superior for purposes of this subsection, the Secretary, upon request of the applicant involved, shall refer a determination as to whether the drug provides a major contribution to patient care to an advisory committee.''.

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