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106TH CONGRESS
2D SESSION

H. R. 4242

To amend section 527 of the Federal Food, Drug and Cosmetic Act with respect to clinically superior modifications to previously approved or licensed drugs.

IN THE HOUSE OF REPRESENTATIVES

APRIL 11, 2000

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

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A BILL

To amend section 527 of the Federal Food, Drug and Cosmetic Act with respect to clinically superior modifications to previously approved or licensed drugs.

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

SECTION 1. SHORT TITLE; PURPOSE.

(a) SHORT TITLE.—This Act may be cited as the ''Orphan Drug Innovation Act''.

(b) PURPOSE.—The purpose of the amendments made by this Act is to increase patient choice and ensure appropriate market protections under the orphan drug provisions of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. AMENDMENT TO THE FEDERAL FOOD, DRUG AND COSMETIC ACT.

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 because 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 claim the same clinical superiority.

''(2) In paragraph (1), the term 'clinically superior' means a drug (that is otherwise the same drug) that is shown to provide a significant therapeutic advantage over and above that provided by an approved orphan drug.

''(3) Paragraph (1) shall apply to any drug designated on or after January 1, 1990.''.

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