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106TH CONGRESS
2D SESSION

H. R. 3677

To amend the Federal Food, Drug, and Cosmetic Act to restrict the authority of the Food and Drug Administration to issue clinical holds regarding investigational drugs or to deny patients expanded access to such drugs.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2000

Mr. BURTON of Indiana (for himself, Mr. BARR of Georgia, Mr. BARTON of Texas, Mr. DOOLITTLE, Mr. GILMAN, Mr. HORN, Mr. JONES of North Carolina, Mr. LAHOOD, Mr. MCHUGH, Mr. MCINTOSH, Mrs. MEEK of Florida, Mr. PAUL, Mr. RYUN of Kansas, Mr. SCARBOROUGH, and Mr. STUMP) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to restrict the authority of the Food and Drug Administration to issue clinical holds regarding investigational drugs or to deny patients expanded access to such 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 ''Thomas Navarro FDA Patient Rights Act''.

SEC. 2. INVESTIGATIONAL NEW DRUGS; RESTRICTIONS ON AGENCY AUTHORITY REGARDING CLINICAL HOLDS ON TRIALS AND EXPANDED ACCESS FOR PATIENTS.

(a) CLINICAL HOLDS.—Section 505(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3)) is amended by adding at the end the following subparagraph:

''(D) The Secretary may not under clause (i) or (ii) of subparagraph (B) place a clinical hold on an investigation of a drug on the basis that the Secretary has determined that—

''(i) there is another drug (including another investigational drug) that is or may be a safe and effective therapy for the disease or condition involved; or

''(ii) there is a comparable or satisfactory alternative therapy available for a patient who is receiving or will receive the drug as a clinical subject in the investigation, except that such restriction on the authority of the Secretary applies only if the patient declares in writing that the patient is aware of the comparable or satisfactory alternative therapy, is aware of the risk involved in receiving the drug in the

investigation, and chooses to receive the drug notwithstanding such risk and notwithstanding the comparable or satisfactory alternative therapy.''.

(b) EXPANDED ACCESS.—

(1) INDIVIDUAL PATIENT ACCESS.—Section 561(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)(1)) is amended by inserting before the semicolon the following: '', except that such conditions for the receipt by the person of the investigational drug do not apply if the person declares in writing that the person is aware that there is a comparable or satisfactory alternative therapy, is aware of the risk involved in receiving the investigational drug, and chooses to receive the drug notwithstanding such risk and notwithstanding the comparable or satisfactory alternative therapy''.

(2) TREATMENT APPLICATION.—Section 561(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(c)(2)) is amended by inserting before the semicolon the following: '', except that such condition for the receipt by a patient of an investigational drug does not apply if the patient declares in writing that the patient is aware that there is a comparable or satisfactory alternative therapy,

is aware of the risk involved in receiving the investigational drug, and chooses to receive the drug notwithstanding such risk and notwithstanding the comparable or satisfactory alternative therapy''.

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