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105TH CONGRESS
2D SESSION

H. R. 3938

To permit the approval and administration of drugs and devices to patients who are terminally ill.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 1998

Mr. SHAW (for himself, Mr. CHRISTENSEN, Mr. RAMSTAD, Mrs. JOHNSON of Connecticut, Mr. COBURN, Mr. ROMERO-BARCELÓ, Mr. HAYWORTH, Mr. NEAL of Massachusetts, Mr. BUNNING, Mr. BURTON of Indiana, and Mr. HILLIARD) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To permit the approval and administration of drugs and devices to patients who are terminally ill.

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 ''Terminally Ill Access to Treatment Act of 1998''.

SEC. 2. DRUGS AND DEVICES FOR TERMINALLY ILL.

(a) APPROVAL.—The Secretary of Health and Human Services shall approve, for purposes of treating the terminally ill only, drugs and devices which have not

received final approval from the Food and Drug Administration and which have not been shown to be unsafe.

(b) ADMINISTRATION.—It is not illegal for a health care practitioner to administer a drug or device approved under subsection (a) to a terminally ill patient if the practitioner—

(1) has given the patient sufficient notice that the drug or device has not received final approval from the Food and Drug Administration and should be considered experimental; and

(2) has received from such patient or the patient's legal representative written approval to administer such drug or device.

(c) UNSAFE DRUG OR DEVICE.—If a health care practitioner administers, in accordance with subsection (b), a drug or device approved under subsection (a) and determines the drug is unsafe and has caused acute harm to the practitioner's terminally ill patient, the practitioner shall cease the administration of the drug or device and shall report to the Secretary of Health and Human Services the practitioner's findings of acute harm.

(d) NOTICE.—The Secretary of Health and Human Services shall give timely public notice of—

(1) the benefits derived from a drug or device approved under subsection (a); and

(2) any harm caused by a drug or device approved under subsection (a).

(e) DEFINITIONS.—For purposes of this section—

(1) the term ''terminally ill'' means an individual who has been certified by a physician as having an illness or physical condition which can reasonably be expected to result in death in 24 months or less after the date of certification; and

(2) the term ''physician'' has the same meaning as is given that term by section 1861(r)(1) of the Social Security Act (42 U.S.C 1395x(r)(1)).

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