APPROVED AND SIGNED BY THE GOVERNOR

Date 4-28-81

Time

No. 720

WEST VIRGINIA LEGISLATURE

REGULAR SESSION, 1981

—●—

ENROLLED

Com. Sub. for

HOUSE BILL No. 720

(By Mr. Kawras + Mr. Farley)

—●—

Passed April 8, 1981

In Effect Ninety Days From Passage

ENROLLED

COMMITTEE SUBSTITUTE

FOR

H. B. 720

(MR. KARRAS and MR. FARLEY)

[Passed April 8, 1981; in effect ninety days from passage.]

AN ACT to amend article five-a, chapter sixteen of the code of West Virginia, one thousand nine hundred thirty-one, as amended, by adding thereto a new section, designated section nine-a, and to amend article five, chapter thirty of said code by adding thereto a new section, designated section sixteen-a, all relating to the manufacture, prescription, and use of amygdalin (laetrile) under certain circumstances; requiring informed consent of the patient; allowing the parent or guardian of a minor child to consent to the use of amygdalin (laetrile); forwarding copy of the written informed request to state registrar of vital statistics; providing for the regulation, inspection, and licensing of persons or facilities producing, manufacturing, delivering or selling amygdalin (laetrile); and providing for certain immunities for physicians, pharmacists, chemists, and hospitals acting in compliance with this statute.

Be it enacted by the Legislature of West Virginia:

That article five-a, chapter sixteen of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended by adding thereto a new section, designated section nine-a; and that article five, chapter thirty of said code be amended by adding thereto a new section, designated section sixteen-a, all to read as follows:

CHAPTER 16. PUBLIC HEALTH.

ARTICLE 5A. CANCER CONTROL.

§16-5A-9a. Laetrile use; informed consent.

A hospital or other health care facility may not interfere with the physician-patient relationship by restricting or forbidding the intravenous use of amygdalin (laetrile) as certified in accordance with section sixteen-a, article five, chapter thirty of this code, as an adjunct to recognized, customary or accepted modes of therapy in the treatment of any malignancy for terminally ill cancer patients when it is prescribed or administered by a physician holding an unlimited license for the practice of medicine in the state of West Virginia and the patient has signed the "written informed request" therefor as set forth in this section: *Provided,* That a parent or guardian may sign the "written informed request" on a minor's behalf.

In the event that no recognized, customary or accepted mode of therapy is available for the treatment of any malignancy for a terminally ill cancer patient, the physician may prescribe or administer intravenous amygdalin (laetrile), as certified in accordance with section sixteen-a, article five, chapter thirty of this code, as the sole mode of therapy, providing further that said patient executed the "written informed request" as set forth in this section.

Any physician, hospital or other health care facility participating in any act permitted or required by this section is immune from any civil or criminal liability that otherwise might result by reason of such actions. A physician may not be subjected to disciplinary action by the state board of medicine of West Virginia for prescribing or administering intravenous amygdalin (laetrile), in compliance with the provisions of this section.

Nothing in this section shall be construed as constituting an endorsement of amygdalin (laetrile), as certified in accordance with section sixteen-a, article five, chapter thirty of this code, for the treatment of any malignancy, disease, illness or physical condition.

The "written informed request" referred to in this section

shall be on a form prepared by and obtained from the state department of health and shall be in substance as follows:

"WRITTEN INFORMED REQUEST"
FOR PRESCRIPTION OF INTRAVENOUS AMYGDALIN
(LAETRILE) FOR MEDICAL TREATMENT

Patient's name: .....

Address .....

Age ..... Sex .....

Name and address of prescribing physician:

.....

Nature of malignancy diagnosed for medical treatment by amygdalin (laetrile):

.....

.....

.....

My physician has explained to me:

(a) That the manufacture and distribution of amygdalin (laetrile) has not been approved by the Federal Food and Drug Administration.

(b) That neither the American Cancer Society, the American Medical Association nor the West Virginia State Medical Association recommends use of amygdalin (laetrile) in the treatment of any malignancy, disease, illness or physical condition.

(c) That there are alternative recognized treatments for the malignancy, disease, illness or physical condition from which I suffer which he has offered to provide for me including:

(here describe) (state "none" if applicable) .....

.....

.....

(d) That I have the right to refuse or terminate the intravenous use of laetrile at any time.

I understand that physicians, hospitals or health care facilities

are immune from civil and criminal liability for prescribing or administering amygdalin (laetrile) in compliance with state statutes.

That notwithstanding the foregoing, I hereby request prescription and use of intravenous amygdalin (laetrile) in the medical treatment of the malignancy from which I suffer.

Patient or person signing for patient

Date of execution of request ----------

ATTEST: ----------

Prescribing physician

The prescribing physician shall forward a copy of the written informed request to the state registrar of vital statistics within ten days of the execution of such request and shall retain a copy of the request in the patient's medical file.

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 5. PHARMACISTS, ASSISTANT PHARMACISTS AND DRUGSTORES.

§30-5-16a. Manufacture of laetrile.

The manufacture, distribution, delivery, possession, sale and use of amygdalin (laetrile) is lawful under specified conditions within the state of West Virginia unless the United States food and drug administration shall make a formal finding that the substance is harmful: *Provided,* That no person shall manufacture, distribute, sell or deliver amygdalin (laetrile) for the purpose of transporting such substance to any other state, district or territory beyond the borders of West Virginia.

The director of the state department of health and the state board of pharmacy shall regulate the manufacture, distribution and sale of amygdalin (laetrile) for use within the state to ensure that the substance is not adulterated in accordance with the provisions of article seven, chapter sixteen of this code: *Provided,* That amygdalin (laetrile) manufactured under the provisions of this section shall be certified as to composition and purity by the director of the state department of health or a qualified testing laboratory approved to make

such certification by the director of the state department of health. The board of pharmacy shall have all necessary authority for the regulation, inspection and licensing of any person or facility producing, manufacturing, delivering or selling any amygdalin (laetrile) in this state in accordance with the provisions of this article and shall promulgate and adopt rules and regulations outlining minimum standards for manufacturers in preparing, packaging, processing and compounding amygdalin (laetrile) and for the enforcement of such standards: *Provided, however,* That application for a permit to manufacture amygdalin (laetrile) shall be accompanied by the permit fee of five thousand dollars and by a bond of the applicant in the surety sum of one million dollars with a corporate surety authorized to transact business in the state of West Virginia, which bond shall be conditioned on the payment of all fees herein prescribed and on the faithful performance of and compliance with the provisions of this section and of the regulations issued hereunder by the board of pharmacy.

Any physician, pharmacist or chemist is immune from civil or criminal liability and from disciplinary actions for activities which comply with the provisions of this section or regulations promulgated pursuant thereto.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originated in the House.

Takes effect ninety days from passage.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker House of Delegates

The within is approved this the 28 day of April, 1981.

Governor

C-641