24:6F-1 to 24:6F-5

LEGISLATIVE HISTORY CHECKLIST

NJSA 24:6F-1 to 24:6F-5 (Legalization of laetrile)

Laws of 1977 Chapter 318

Bill No. A3295

Sponsor(s) Gregorio, Deverin & Karcher

Date Introduced May 2, 1977

Committee: Assembly Institutions, Health & Welfare

Senate " " " "

Amended during passage Yes ~~No~~ Amendments during passage denoted by asterisks

Date of passage: Assembly June 20, 1977

Senate Jan. 5, 1978

Date of approval Jan. 10, 1978

Following statements are attached if available:

Sponsor statement Yes ~~No~~

Committee Statement: Assembly Yes ~~No~~

Senate Yes ~~No~~

Fiscal Note ~~Yes~~ No

Veto message ~~Yes~~ No

Message on signing ~~Yes~~ No

Following were printed:

Reports ~~Yes~~ No

Hearings Yes ~~No~~

EJ

10/4/76

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ASSEMBLY, No. 3295

STATE OF NEW JERSEY

INTRODUCED MAY 2, 1977

By Assemblymen GREGORIO, DEVERIN and KARCHER

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning the **manufacturing, introducing, delivering,** prescribing, administering or dispensing of amygdalin.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. No duly licensed physician shall be subject to any penalty or disciplinary action by any State agency or private professional organization solely for prescribing, administering or dispensing amygdalin, also known as laetrile or vitamin B-17, to a patient who has made a written request for such substance on **[a]** ***the following*** form **[which shall contain the following statement: "Amygdalin has not been approved as a treatment or a cure of cancer by the United States Food and Drug Administration."]** **:**

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

Patient's name .....

Address .....

Age ..... *Sex* .....

Name and address of prescribing physician

.....

.....

Malignancy, disease, illness or physical condition diagnosed for medical treatment by amygdalin (laetrile) .....

.....

My physician has explained to me:

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

(a) That the manufacture and distribution of amygdalin (laetrile) has been banned by the Federal Food and Drug Administration.

(b) That neither the American Cancer Society, the American Medical Association, nor the Medical Society of New Jersey recommend 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)

.....

.....

That notwithstanding the foregoing, I hereby request prescription and use of amygdalin (laetrile) (a) in the medical treatment of the malignancy, disease, illness or physical condition from which I suffer ☐, *or (b) as a dietary supplement* ☐. *Check (a) or (b).*

.....

Patient or person signing for patient

Attest:

.....

*Prescribing physician***

2. No duly registered pharmacist shall be subject to any penalty or disciplinary action by any State agency or private professional organization for dispensing, upon receipt of a prescription, amygdalin, provided that the pharmacist shall affix to the container containing amygdalin a label which shall contain the following statement: "Amygdalin has not been approved as a treatment or cure of **[cancer]** ***any malignancy, disease, illness or physical condition*** by the United States Food and Drug Administration."

3. No health care facility or employee thereof may restrict or forbid the use of, refuse to administer or dispense, or be subject to any disciplinary action or penalty for administering or dispensing, amygdalin, also known as laetrile or vitamin B-17, when prescribed by a physician. For the purposes of this act, "health care facility" means any such facility as defined in the "Health Care Facilities Planning Act" (C. 26:2H–1 et seq.).

****[*3.*]** ***4.*** *No person shall be held liable for any civil or criminal penalty solely for the manufacture, introduction or delivery or introduction for intrastate commerce in this State, the substance known as amygdalin, also known as laetrile or vitamin*

*B-17; provided that such manufacture, introduction or delivery is conducted pursuant to chapters 6A and 6B of Title 24 of the New Jersey Statutes.**

5. The State Department of Health shall maintain records concerning the use of the substance amygdalin, also known as laetrile or vitamin B-17, and shall make periodic studies, based on such records, concerning the efficacy of such substance in the treatment of cancer. The Commissioner of Health is hereby authorized to promulgate rules and regulations to implement the provisions of this act, including: regulations to prohibit the use of amygdalin unless such substance is prescribed by a physician on the form set out in this act; and regulations to require copies of all such forms, when completed, to be sent to the Department of Health.

[**3.]** ***[**4.*] ***6.*** This act shall take effect immediately.

ASSEMBLY, No. 3295

STATE OF NEW JERSEY

INTRODUCED MAY 2, 1977

By Assemblymen GREGORIO, DEVERIN and KARCHER

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning the prescribing, administering or dispensing of amygdalin.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. No duly licensed physician shall be subject to any penalty or disciplinary action by any State agency or private professional organization solely for prescribing, administering or dispensing amygdalin, also known as laetrile or vitamin B-17, to a patient who has made a written request for such substance on a form which shall contain the following statement: "Amygdalin has not been approved as a treatment or a cure of cancer by the United States Food and Drug Administration."

2. No duly registered pharmacist shall be subject to any penalty or disciplinary action by any State agency or private professional organization for dispensing, upon receipt of a prescription, amygdalin, provided that the pharmacist shall affix to the container containing amygdalin a label which shall contain the following statement: "Amygdalin has not been approved as a treatment or cure of cancer by the United States Food and Drug Administration."

3. This act shall take effect immediately.

STATEMENT

This bill provides that no disciplinary action shall be taken by any State agency or private professional organization against physicians or pharmacists for the prescribing or dispensing of the substance commonly known as laetrile, provided that the patient has given written consent for such substance. The consent form and the container must carry a statement that the substance has not been approved by the United States Food and Drug Administration as a treatment or cure for cancer.

Laetrile, also known as amygdalin and vitamin B-17, is claimed by its manufacturer to be effective in the treatment of cancer. The FDA maintains that it is not effective and has banned its production in the United States. It is available from suppliers in other nations.

This bill takes no position on the efficacy of laetrile. It merely states that there should be no State interference with the physician-patient relationship as regards the use of this controversial substance. Persons suffering from cancer ought to have the right to request the use of laetrile, and physicians ought to have the right to use their judgment as to whether conditions warrant the use of the substance.

The State of Alaska has adopted a law allowing the prescribing of laetrile, and many other legislatures are considering action of this type.

ASSEMBLY INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

STATEMENT TO

ASSEMBLY, No. 3295

STATE OF NEW JERSEY

DATED: MAY 16, 1977

Since there has been considerable controversy about the substance commonly known as laetrile, the committee amended the bill to provide additional immunities for persons manufacturing, introducing or delivering laetrile for intrastate commerce.

The bill provides that no disciplinary action shall be taken by any State agency or private professional organization against physicians or pharmacists for prescribing or dispensing laetrile, provided that the patient has acknowledged in writing that he is aware that the U.S. Food and Drug Administration has not approved laetrile for the treatment or cure of cancer.

The amendment provides that persons manufacturing, introducing or delivering laetrile for intrastate commerce shall not be held liable for any civil or criminal penalties, provided that such actions shall be in accordance with present State law governing such substances.

SENATE INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

STATEMENT TO

ASSEMBLY, No. 3295

[OFFICIAL COPY REPRINT]

with Senate committee amendments

STATE OF NEW JERSEY

DATED: SEPTEMBER 19, 1977

PURPOSE OF THE BILL:

This bill would permit the prescription, use, manufacture and delivery of amygdalin in New Jersey, without liability or penalty. Amygdalin, or laetrile, is an anti-cancer drug.

BACKGROUND:

Laetrile is a controversial widely-publicized product. The Federal Food and Drug Administration (FDA) has prohibited it from being transported across state lines, effectively limiting its use. The FDA maintains that laetrile has not been proven both safe and effective (the test required by the Federal Food and Drug Act) and thus cannot be approved for interstate commerce. Proponents of laetrile, notably the Committee for Freedom of Choice in Cancer Therapy, contend that the FDA has never properly tested laetrile. Moreover, they assert that, whether or not laetrile is shown to be effective, citizens should at least be allowed the freedom to use it—to make their own choice.

Despite the FDA ban on laetrile, many cancer patients have continued to obtain laetrile and use it, illegally, with the help of various undercover distributors. However, one class of patients may obtain laetrile without penalty, due to a Federal District Court decision. These are the terminally ill. On April 8, 1977, a Federal judge ruled that terminally ill cancer patients may import laetrile for their use if they obtain an affidavit signed by their physician. The judge gave his ruling on the ground that the FDA had not provided sufficient evidence that laetrile was a drug (as opposed to a vitamin or dietary supplement), and therefore came under the jurisdiction of the FDA. The judge is presently reviewing an administrative record, prepared by the FDA

at his request, which attempts to justify the government's position in the matter. Meanwhile, his ruling stands.

New Jersey law does not make any reference to laetrile or amygdalin. New Jersey's "New Drug" law (C. 24:6A–1 et seq.) prescribes the standards which new drugs must meet before they can be approved for use here. Unlike the Federal law, the State's statute only requires that a drug be safe (not safe and effective) in order to be approved.

Aware of the importance of this legislation and the intense interest of the public in it, the Senate Institutions, Health and Welfare Committee held a public hearing on this bill and two similar Senate bills on July 19, 1977. The committee heard testimony from the sponsor of Assembly Bill No. 3295, the Commissioner of Health and representatives of the FDA, the American Cancer Society and the Committee for Freedom of Choice, among others.

COMMITTEE POSITION:

Testimony before the committee was divided as to whether or not laetrile is effective in treating malignancies. Moving accounts of recovery from cancer due to laetrile were countered by persuasive evidence and arguments denying any efficacy for the drug.

Nevertheless, the committee reports this bill favorably, with amendments, on the ground that, in a free society, people should be able to choose their own forms of treatment for disease as long as doing so does not expose them to harmful products. In other words, the safety of drugs needs to be assured by government but not necessarily the effectiveness of drugs. This is especially true when a drug such as laetrile is widely sought by the public. Testimony before the committee acknowledged that, if ingested orally in large doses, laetrile can be harmful, but otherwise confirmed that the drug is safe.

SUMMARY OF PROVISIONS:

As amended, Assembly Bill No. 3295 contains the following provisions: (1) A section guaranteeing physicians the freedom to prescribe, administer or dispense laetrile without being subject to penalty or disciplinary action. The section also sets out the form to be used by physicians in prescribing laetrile. The drug could be used as a treatment for cancer but also simply as a dietary supplement for those who believe it may prevent the onset of cancer. Furthermore, patients would be warned that laetrile has not been approved as a treatment for malignancies by the FDA or other authorities; (2) Language permitting pharmacists to dispense laetrile without fear of penalty or disciplinary action; (3) A new section with sanctions and protections

for health care facilities and their employees concerning the use of laetrile. In the course of its public hearing the committee learned that health care facilities in the State were effectively blunting the effect of the aforementioned court decision by refusing to permit laetrile to be given to terminal patients. One physician had even suffered temporary dismissal from his hospital post for prescribing laetrile to a patient; (4) A section permitting the manufacture of laetrile in New Jersey and its delivery or introduction for commerce within the State; and (5) A new section requiring the Department of Health to periodically study the efficacy of laetrile. The section also authorizes the commissioner to promulgate regulations necessary to implement the act's provisions, including any regulation to facilitate the preparation of the studies required by the bill.

The bill would take effect immediately upon enactment.

FROM THE OFFICE OF THE GOVERNOR

FOR IMMEDIATE RELEASE — FOR FURTHER INFORMATION

JANUARY 10, 1978 — ANNE BURNS

Governor Brendan Byrne today signed into law legislation legalizing the use of laetrile in New Jersey.

A-3295, sponsored by Assemblymen John Gregorio, Thomas Deverin and Alan Karcher, permits a physician to prescribe laetrile to a patient. It requires the patient to make an official request for the drug.

The request form will include a statement warning the patient that laetrile has not been approved as a treatment or a cure of cancer by the U. S. Food and Drug Administration.

The bill also requires the dispensing pharmacist to include this warning on the drug container.

"I recognize that the drug laetrile is not a proven cure for cancer. Clearly, it is no more than a source of psychic comfort to cancer patients," the Governor said.

"Yet, I do not believe that people should be deprived of its use; and I have faith in the medical profession that it will not be abused and that cancer patients will be advised of proven and recognized cancer treatment methods."

Under this legislation, no health care facility may restrict or forbid the use of or refuse to administer or dispense laetrile once it is prescribed by a physician.

It also allows for the manufacture, introduction or delivery for intrastate commerce of the drug subject to the regulations set down in Chapters 6A and 6B of Title 24 of the New Jersey Statutes.

The State Department of Health will maintain a record concerning the use of laetrile and will make periodic studies regarding the effectiveness of the drug in treating cancer.

* * *