26:2L-1 to 26:2L-9

LEGISLATIVE HISTORY CHECKLIST

NJSA 26:2L-1 to 26:2L-9 (Controlled dangerous substances--therapeutic uses--est. program in Department of Health--approp. $25,000)

LAWS 1981 CHAPTER 72

Bill No. A819

Sponsor(s) Bassano, McQuire and Burgio

Date Introduced Feb. 4, 1980

Committee: Assembly Institutions, Health and Welfare

Senate Judiciary

Amended during passage Yes ~~No~~ Amendments denoted by asterisks
according to Governor's recommendations Substituted for S1434 (attached)
Date of Passage: Assembly Oct. 16, 1980 Re-enacted 2-2-81

Senate Nov. 10, 1980 Re-enacted 2-19-81

Date of approval March 23, 1981

Following statements are attached if available:

| | | | |
|---|---|---|---|
| Sponsor statement | | Yes | ~~No~~ Also attached: Assembly amendment, adopted 10-6-90 (with statement) |
| 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 |

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3-23-81

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# ASSEMBLY, No. 819

# STATE OF NEW JERSEY

INTRODUCED FEBRUARY 4, 1980

By Assemblymen BASSANO, MAGUIRE and
Assemblywoman BURGIO

Referred to Committee on Institutions, Health and Welfare

AN ACT authorizing a program for research into the therapeutic use of certain Schedule I controlled dangerous substances in certain situations *[and]* *,* supplementing Title 26 of the Revised Statutes *and making an appropriation therefor*.

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

1. This act shall be known and may be cited as the "Controlled Dangerous Substances Therapeutic Research Act."

2. The Legislature finds and declares that recent medical research has shown that the therapeutic use of certain Schedule I controlled dangerous substances may alleviate the nausea and ill-effects of certain medical treatment, such as cancer chemotherapy, and, additionally, may alleviate the ill-effects of certain diseases, such as glaucoma. The Legislature further recognizes that there is a need for further therapeutic research with regard to the use of such controlled dangerous substances for these purposes under strictly controlled circumstances. It is for this purpose that the "Controlled Dangerous Substances Therapeutic Research Act" is hereby enacted.

3. As used in this act:

a. "Board" means the Therapeutic Research Qualification Review Board established in section 5 of this act.

b. "Commissioner" means the State Commissioner of Health.

c. "Schedule I controlled dangerous substance" means a controlled dangerous substance having a high addiction liability; no accepted medical use in the United States; and listed in New Jersey Administrative Code 8:65-10.1.

d. "Drugs" means drugs as defined in section 2 of P. L. 1970, c. 226 (C. 24:21-2).

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

e. "Practitioner" means a physician licensed to prescribe and administer drugs which are subject to the "New Jersey Controlled Dangerous Substance Act" (P. L. 1970, c. 226).

f. "Program" means the controlled dangerous substances therapeutic research program established in this act.

4. a. There is hereby established *[in the Division of Laboratories, Epidemiology and Research,]* in the State Department of Health, the controlled dangerous substances therapeutic research program. The program shall be limited to therapeutic research programs presently conducted by the Bureau of *[New]* Drugs in the Food and Drug Administration of the U. S. Department of Health*[, Education and Welfare]* *and Human Services* or its successor and shall be administered by the commissioner who shall promulgate rules and regulations necessary for the administration of this act. In making such promulgations, the commissioner shall take into consideration all Federal controlled dangerous substances laws and rules adopted pursuant to such laws.

b. The program shall be limited to patients who are certified to the board, established by section 5 of this act, by a practitioner as being involved in a life-threatening or sense-threatening situation and who are not responding to drugs or where the drugs administered have proven to be effective but where the patient has incurred severe side effects.

5. a. The commissioner, after consulting with the *[New Jersey]* Medical Society *of New Jersey*, shall appoint a Therapeutic Research Qualification Review Board to serve at his pleasure. The board shall be comprised of physicians licensed to practice medicine and surgery in New Jersey and who are well qualified in their specialities. Members of the board may be reimbursed for their attendance at meetings at the rate of $35.00 per day.

b. The board shall review all practitioners applying for participation in the program and certify their participation in the program.

c. The board shall have the authority to approve for participation in the program any patient who is certified to it by a practitioner, pursuant to the provisions of section 4b. of this act.

6. a. The commissioner shall enter into an agreement with the National Institute on Drug Abuse for receipt of a Schedule I controlled dangerous substance for the purposes prescribed in this act, subject to the provisions of all Federal controlled dangerous substances laws and rules adopted pursuant to such laws.

b. The commissioner shall provide for a Schedule I controlled dangerous substance received pursuant to subsection a. of this section to be transferred to those practitioners certified by the board to participate in the program.

7. The board shall review all reports of use of Schedule I controlled dangerous substances in such cases, and the commissioner, in conjunction with the board, shall report his findings and recommendations to the Legislature and Governor on an annual basis regarding the effectiveness of the program.

8. Notwithstanding any laws to the contrary, nothing in the laws dealing with controlled dangerous substances shall be construed to prohibit a program of therapeutic research with regard to the use of certain Schedule I controlled dangerous substances in certain situations, as provided in section 4b. of this act.

*9. *There is appropriated $25,000.00 or so much thereof as is necessary to carry out the purposes of this act.**

*[9.]* *10.* This act shall take effect immediately.

b. The commissioner shall provide for a Schedule I controlled dangerous substance received pursuant to subsection a. of this section to be transferred to those practitioners certified by the board to participate in the program.

7. The board shall review all reports of use of Schedule I controlled dangerous substances in such cases, and the commissioner, in conjunction with the board, shall report his findings and recommendations to the Legislature and Governor on an annual basis regarding the effectiveness of the program.

8. Notwithstanding any laws to the contrary, nothing in the laws dealing with controlled dangerous substances shall be construed to prohibit a program of therapeutic research with regard to the use of certain Schedule I controlled dangerous substances in certain situations, as provided in section 4b. of this act.

9. This act shall take effect immediately.

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STATEMENT

The purpose of this bill is to create a highly controlled program in the State Department of Health for research into therapeutic use of certain Schedule I controlled dangerous substances in certain situations.

Recent medical research has shown that the therapeutic use of certain Schedule I controlled dangerous substances may alleviate the nausea and ill-effects of certain medical treatment, such as heroin for cancer chemotherapy, and, additionally, may alleviate the ill-effects of certain diseases, such as marihuana for glaucoma. Only patients who are certified by a practitioner as being involved in a life-threatening or sense-threatening situation and are not responding to drugs, or where the drugs administered have proven to be effective but where the patient has incurred severe side effects, can participate in this program.

Not all Schedule I controlled dangerous substances may be utilized for therapeutic research programs, however. Only such substances used in research programs presently being conducted by the Bureau of New Drugs in the Food and Drug Administration of the U.S. Department of Health, Education and Welfare are permissible. The State Commissioner of Health would have to apply for application and full particulars concerning therapeutic research programs presently conducted by the Bureau of New Drugs, and then proceed for receipt of a required Schedule I controlled dangerous substance for a specified program with the National Institute on Drug Abuse.

A819 (1981)

The State Department of Health will incur expenses in purchasing the required Schedule I controlled dangerous substances and in covering the costs of physicians who participate in a therapeutic research program. However, federal funds may be available to support such programs upon application of the State Department of Health to the appropriate federal agency.

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# SENATE, No. 1434

# STATE OF NEW JERSEY

INTRODUCED JULY 28, 1980

By Senators SCARDINO, HAGEDORN and A. RUSSO

Referred to Committee on Institutions, Health and Welfare

AN ACT authorizing a program for research into the therapeutic use of certain Schedule I controlled dangerous substances in certain situations, supplementing Title 26 of the Revised Statutes and making an appropriation therefor.

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

1. This act shall be known and may be cited as the "Controlled Dangerous Substances Therapeutic Research Act."

2. The Legislature finds and declares that recent medical research has shown that the therapeutic use of certain Schedule I controlled dangerous substances may alleviate the nausea and ill-effects of certain medical treatment, such as cancer chemotherapy, and, additionally, may alleviate the ill-effects of certain diseases, such as glaucoma. The Legislature further recognizes that there is a need for further therapeutic research with regard to the use of such controlled dangerous substances for these purposes under strictly controlled circumstances. It is for this purpose that the "Controlled Dangerous Substances Therapeutic Research Act" is hereby enacted.

3. As used in this act:

a. "Board" means the Therapeutic Research Qualification Review Board established in section 5 of this act.

b. "Commissioner" means the State Commissioner of Health.

c. "Schedule I controlled dangerous substance" means a controlled dangerous substance having a high addiction liability; no accepted medical use in the United States; and listed in New Jersey Administrative Code 8:65–10.1.

d. "Drugs" means drugs as defined in section 2 of P. L. 1970, c. 226 (C. 24:21–2).

e. "Practitioner" means a physician licensed to prescribe and administer drugs which are subject to the "New Jersey Controlled Dangerous Substance Act" (P. L. 1970, c. 226).

f. "Program" means the controlled dangerous substances therapeutic research program established in this act.

4. a. There is hereby established in the State Department of Health, the controlled dangerous substances therapeutic research program. The program shall be limited to therapeutic research programs presently conducted by the Bureau of Drugs in the Food and Drug Administration of the U. S. Department of Health and Human Services or its successor and shall be administered by the commissioner who shall promulgate rules and regulations necessary for the administration of this act. In making such promulgations, the commissioner shall take into consideration all Federal controlled dangerous substances laws and rules adopted pursuant to such laws.

b. The program shall be limited to patients who are certified to the board, established by section 5 of this act, by a practitioner as being involved in a life-threatening or sense-threatening situation and who are not responding to drugs or where the drugs administered have proven to be effective but where the patient has incurred severe side effects.

5. a. The commissioner, after consulting with the Medical Society of New Jersey, shall appoint a Therapeutic Research Qualification Review Board to serve at his pleasure. The board shall be comprised of physicians licensed to practice medicine and surgery in New Jersey and who are well qualified in their specialities. Members of the board may be reimbursed for their attendance at meetings at the rate of $35.00 per day.

b. The board shall review all practitioners applying for participation in the program and certify their participation in the program.

c. The board shall have the authority to approve for participation in the program any patient who is certified to it by a practitioner, pursuant to the provisions of section 4b. of this act.

6. a. The commissioner shall enter into an agreement with the National Institute on Drug Abuse for receipt of a Schedule I controlled dangerous substance for the purposes prescribed in this act, subject to the provisions of all Federal controlled dangerous substances laws and rules adopted pursuant to such laws.

b. The commissioner shall provide for a Schedule I controlled dangerous substance received pursuant to subsection a. of this section to be transferred to those practitioners certified by the board to participate in the program.

*c. *Patients and practitioners receiving Schedule I controlled dangerous substances through the National Cancer Institute's In-*

*vestigational Drug Branch shall not be subject to the provisions of this act.**

7. The board shall review all reports of use of Schedule I controlled dangerous substances in such cases, and the commissioner, in conjunction with the board, shall report his findings and recommendations to the Legislature and Governor on an annual basis regarding the effectiveness of the program.

8. Notwithstanding any laws to the contrary, nothing in the laws dealing with controlled dangerous substances shall be construed to prohibit a program of therapeutic research with regard to the use of certain Schedule I controlled dangerous substances in certain situations, as provided in section 4b. of this act.

9. There is appropriated $25,000.00 or so much thereof as is necessary to carry out the purposes of this act.

10. This act shall take effect immediately.

ASSEMBLY AMENDMENT TO

# ASSEMBLY, No. 819

[OFFICIAL COPY REPRINT]

# STATE OF NEW JERSEY

ADOPTED OCTOBER 6, 1980

Amend page 3, section 6, after line 9, insert subsection c. as follows:

"c. Patients and practitioners receiving Schedule I controlled dangerous substances through the National Cancer Institute's Investigational Drug Branch shall not be subject to the provisions of this act.".

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STATEMENT

This amendment is necessary to preclude the possibility that Assembly, No. 819 (OCR) might interfere with the National Cancer Institute's new tetrahydrocannabinol (THC) distribution program. Without this amendment, receipt of THC by patients and doctors might be delayed by interposing the restrictions inherent in the bill between the National Cancer Institute and New Jersey's cancer patients.

ASSEMBLY INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

STATEMENT TO

# ASSEMBLY, No. 819

with Assembly committee amendments

# STATE OF NEW JERSEY

DATED: JUNE 16, 1980

This legislation creates a highly controlled program in the State Department of Health for research into the therapeutic use of certain Schedule I controlled dangerous substances in certain situations. The Department of Health would serve to facilitate research in the State as the sponsor of a drug therapy research program and as a middleman between the Federal Government and participating physicians. Approval for patients to participate in this program is given by the Therapeutic Research Qualification Review Board, appointed by the Commissioner of Health, after consulting with the Medical Society of New Jersey.

Only those Schedule I controlled dangerous substances approved by the Bureau of Drugs in the Food and Drug Administration may be used in a therapeutic research program. Once approved, the substance will be supplied by the National Institute on Drug Abuse (NIDA) to the State at no cost.

In order to defray the administrative costs of the program as much as possible, the Department of Health is encouraged to seek grant funds from the Federal Government.

The committee supports the purpose of this legislation and released the bill with an appropriation not to exceed $25,000.00.

SENATE JUDICIARY COMMITTEE

STATEMENT TO

# ASSEMBLY, No. 819

# STATE OF NEW JERSEY

DATED: NOVEMBER 10, 1980

A-819 creates a highly controlled program in the State Department of Health for research into the therapeutic use of certain Schedule I controlled dangerous substances in certain situations. The Department of Health would serve to facilitate research in the State as the sponsor of a drug therapy research program and as a middleman between the Federal government and participating physicians.

Schedule I controlled dangerous substances have no currently accepted medical use in treatment in the United States. Recent medical research indicates, however, that heroin is capable of alleviating the nausea and ill-effects of chemotherapy. Marihuana has also been proven capable of alleviating the pain or ill-effects of certain diseases or treatments thereof.

Participation in the program is limited to patients who are certified by a practitioner as being involved in a life-threatening or sense-threatening situation and are not responding to drugs, or to patients receiving drugs which have proven to be effective but which also create severe side effects. Final approval for a patient to participate in this program must be given by the Therapeutic Research Qualification Review Board appointed by the Commissioner of Health, after consulting with the New Jersey Medical Society.

Only those Schedule I controlled dangerous substances approved by the Bureau of New Drugs in the Food and Drug Administration of the U. S. Department of Health and Human Services may be utilized in a therapeutic research program. Once approved, the substance will be supplied to the State Department of Health by the National Institute on Drug Abuse (NIDA). Controlled dangerous substances are supplied by NIDA at no cost. However, to help defray administrative costs incurred by the Department of Health as a result of this program, A-819 appropriates $25,000.00.

STATE OF NEW JERSEY
EXECUTIVE DEPARTMENT January 22, 1981

ASSEMBLY BILL NO. 819 (2 OCR)

To the Assembly:

Pursuant to Article V, Section 1, Paragraph 14(b) of the Constitution, I am returning Assembly Bill No. 819 (2 OCR) with my objections, for reconsideration.

This bill would establish in the Department of Health a highly regulated program for research into the therapeutic use of certain Schedule I controlled dangerous substances in certain situations. Only those substances which have been approved by the Bureau of Drugs in the Food and Drug Administration may be utilized in the State's program.

The purpose of the bill is to provide some relief for patients involved in life-threatening situations, such as cancer, where the drugs administered have severe side effects.

I believe that this bill merits enactment, however I am concerned about certain technical defects. The bill does not clearly provide the Commissioner of Health the authority to require patients desiring to participate in the program to release their medical records or follow-up reports. In addition, the bill fails to provide safeguards to an individual's privacy regarding such records. Finally, the bill does not clearly require participating physicians to submit follow-up reports. This lack of clarity may create unnecessary litigation.

Accordingly, I am returning Assembly Bill No. 819 (2 OCR) for reconsideration and recommend that it be amended as follows:

Page 2, section 4, line 10: Insert after "act":

", including but not limited to rules and regulations which may be necessary to require patients desiring certification pursuant to section 5 of this act to release their medical records for the purposes of certification and follow-up reports."

Page 2, section 4, line 18: Insert new subsection:

"c. The names and medical records of individual patients who have either requested certification or have been certified pursuant to section 5 of this act shall not be released in any form which identifies the individual, except that the names and records of such individuals shall be made available upon request for use in the enforcement of laws regarding controlled dangerous substances (P.L. 1970, c. 226; C. 24:21-1 et seq.)."

Page 3, section 7 line 1: Insert as section 7 and renumber sections 7-10 accordingly:

"7. Participating practitioners shall submit to the commissioner reports on the use of Schedule I controlled dangerous substances received by their patients pursuant to this act."

Resepctfully,

/s/ Brendan Byrne

GOVERNOR

Attest:

/s/ Harold L. Hodes

CHIEF OF STAFF, SECRETARY