SENATE COMMITTEE ON HUMAN
RESOURCES AND FACILITIES

The meeting was called to order at 9:43 a.m., in Room 323 on Monday, April 4, 1977, with Senator Jack Schofield in the Chair.

PRESENT: Chairman Jack Schofield
Vice-Chairman Joe Neal
Senator William Raggio
Senator Richard Blakemore
Senator Wilbur Faiss
Senator William Hernstadt

GUESTS: Assemblyman Nash Sena, A.B. 300
Senator Thomas Wilson, A.B. 121
Mr. Al Edmundson, State Division of Health
Mr. Orville Wahrenbrock, Dept. of Human Resources
Assemblyman Danny Demers, A.B. 121
Michael Clasen, Attorney General Deputy, Human Resources
Roger Trounday, Director, Dept. of Human Resources

A.B. 300

Assemblyman Nash Sena: Mr. Sena said that the original bill was to provide that each school district set aside a period for prayers. The bill has now been amended to include the words "meditation" and "reflection". Also, the attorney staff felt the bill should be amended so that "all persons must be silent during this period". Mr. Sena said that numerous states have already passed this type of legislation, i.e., Arkansas, Connecticut, Delaware and Maine.

Mr. Sena read a letter to the Committee to verify the constitutionality of this legislation. The letter sited several cases on this issue. He read in part from an opinion submitted by Mr. Frank Daykin of the Legislative Counsel Bureau, "The pupil who chooses not to pray during the period of silence, cannot be distinguished from those who do pray, for all must observe the same silence."

Senator Hernstadt: The Senator asked if a student wished to be excused from the room, wouldn't that create a stigma, and by requiring all the students to stay in the room that keeps it "even-handed"?

Mr. Sena: Mr. Sena said that it was his intention that if all participate, no one can be pointed out.

Senator Hernstadt: The Senator requested that a public hearing be held on this so that his Jewish constitutents could air their views.

Mr. Sena: The Assemblyman had no objection to a public hearing, and he noted that the only objection the Assembly had heard was from the American Civil Liberties Union.

A.B. 121 (Exhibit "A")

Senator Wilson: The Senator discussed his proposed Amendment 69 to A.B. 121 and said that the only additions to the existing Amendment would be on Page Two of the Amendment, under Section 3, Item 1 - B, and Item 2 - D and E (Exhibit "B"). Senator Wilson said we need to give the State Board of Health, or another competent agency, the jurisdiction to inquire and limit, for the public interest, and the power to adopt and amend regulations.

Senator Hernstadt: The Senator said that he was in accord with the first two changes, but opposed Item 2 - E of Section 3, because he did not feel there should be involvement with drug-drug interaction. He suggested the following change in wording, "Adopt and may amend regulations which warn of toxic or allergic reactions from using licensed substances in conjuntion with any other substances."

Orville Wahrenbrock: Mr. Wahrenbrock said the Division of Health would like to raise some questions for clarification on A.B. 121: (1) How is the State Board of Health going to establish the 'minimum' standards? (2) The Department is concerned about the liability to the State. If something goes wrong in the usage of the substance, who has the liability? (3) The Department is concerned about the language in the bill which makes the Division's Commissioner able to establish regulations regarding qualifications of physicians to use the material. The Department of Human Resources does not feel that the Commissioner of Food and Drug is in a position to establish regulations regarding any physician, and (4) The Fiscal Note is predicated on an unknown factor of how many manufacturers there are going to be in the State. The Department is concerned about the amount of money needed to do the research to establish the minimum standards, as stated in A.B. 121.

Senator Hernstadt: The Senator did not understand the Department's concern about standards. The standards are not concerned with efficacy, but whether the substance is toxic or causes allergic reactions.

Mr. Wahrenbrock: He said that the minimum standard of use with other drugs is their concern, as brought up by Senator Wilson.

Al Edmundson: He commented that Laetrile contains a certain amount of cyanide, and the amount would have to be set to determine toxicity. At this point, all drugs coming into the State have been checked by the Federal Food and Drug Administration, and the Division of Health has been relying on the F.D.A.'s research.

Assemblyman Danny Demers: The Assemblyman said that the F.D.A. contracts out their laboratory work, and with regards to Laetrile and Gerovital H3, there is a great deal of research material available. Mr. Demers said that on Page 2, Line 16 of A.B. 121, the language could be expanded to say, 'defray the costs involved so that fees could be charged in advance for work which involved other than inspections, as required by the F.D.A.'. He also commented that the University System has laboratory equipment that could be available on a contract basis.

Senator Neal: The Senator asked if the Division was concerned because they have not previously been involved in determining the properties of substances.

Mr. Edmundson: He said yes, they were concerned.

Senator Neal: The Senator inquired as to the foreseen duties of the Division of Health if A.B. 121 were passed?

Mr. Edmundson: He replied that the Commissioner is currently responsible for the purity of drugs, but if new drugs are manufactured in this State, the determination of purity would not come from the research of the F.D.A., but from the Division itself. He further commented to Senator Neal that there are presently in the Food and Drug section of the Division, eight inspectors, who are on call 24 hours/day.

Senator Neal: The Senator pointed out that he understood that the Health Division would not be able to establish standards for Laetrile and Gerovital H3, but only for additional substances which might be manufactured.

Mr. Wahrenbrock: He asked what 'minimum' standards do we adopt?

Mr. Demers: The formulas of Laetrile and Gerovital H3 (GH3) are fairly well known, the Assembly said, and the Health Division has the responsibility of establishing minimum standards in preparing compound processing and substance for the manufacturers.

Senator Hernstadt: He said that in reference to Laetrile and Gerovital H3, research documents could probably be obtained from the many responsible countries where approval of usage of these substances has been given. He stated there shouldn't be any concern about funding the manufacture of a new substance if all the 'reasonable' fees are being carried by the requestors, and in addition, the State will receive a 10% tax in the future.

Mr. Wahrenbrock: He commented that it is not the position of the Department to fight A.B. 121. The Department concurs with Mr. Demers amendment to expand the fee capability. However,

they are still concerned about having to regulate the actions of physicians.

Mr. Demers: He suggested that perhaps the State Medical Examiners Board or the Licensing Board could be amended in to do the regulating.

Senator Hernstadt: He said that he was concerned that certain categories of doctors who are not qualified to prescribe certain substances would be able to prescribe Laetrile and GH3.

Mr. Demers: He answered that if only Onycologists could give the prescription, they tend to follow the direction of the National Cancer Institute.

Mr. Wahrenbrock: He questioned if the Committee saw any liability in the passage of this bill?

Mike Clasen: In his opinion, if any action were brought, the Legislature would be liable and the State might be considered a party to the suit. Mr. Clasen suggested that a 'disclaimer' section might be included.

Senator Schofield: The Chairman questioned that perhaps this type of action could be taken on any issue passed by the Legislature under any circumstances.

Senator Raggio: He said that he felt there was a real distinction between this and other legislation, because the Legislature makes a specific finding that these drugs (Laetrile and GH3) should be licensed.

Roger Trounday: Mr. Trounday said that the Department's concern is that if they state in their regulations what is a reasonable amount for prescription based on hearing input, and someone questions the research or the laboratory examinations, the Department or the State might be liable, as all research done on Laetrile and GH3 will come from sources outside of their Division.

Senator Raggio: He said that the Legislature by its own action finding that a substance is viable, is different from a drug by prescription, and that is why he opposes the whole idea. He emphasized that this is an area we have no business being in.

Senator Blakemore: He suggested to Senator Raggio that maybe the Legislature ought to take the opposite approach they have been taking, and merely say that the substances Laetrile and GH3 are legal.

Senator Raggio: He said that the Legislature cannot disclaim something that they are actually doing.

Senator Hernstadt: The Senator said that the prescribing physician and the manufacturer of the substance should be responsible, and he asked Senator Raggio if he would be 'happy' if the Committee passed a substance act, and it didn't mention Laetrile or GH3.

Senator Raggio: He responded that it is not a question if the Legislature would be 'happy', he simply did not believe that the Legislature should be engaged in this area. If anything is done, he felt that the responsibility should be given to the local authorities, and the duties should be the same as are prescribed at the Federal level.

Senator Neal: Motion to amend A.B. 121 and Do Pass
Senator Faiss: 2nd the Motion

Senator Raggio: He requested that the amendments be read into the minutes.

Senator Hernstadt: Section 3, Item 1 - B from Amendment 69, "Can safely be used pursuant to regulations prescribed by the board."; Section 3, Item 2 - D from Amendment 69, "Adopt and may amend regulations governing the qualifications of physicians to administer or prescribe the substance."; and Section 3, Item 3 - E would be changed to read, "May make warnings of toxic or allergic reactions from the use of licensed substances in conjunction with any other substance.". The Senator also read from Page Two, Lines 15 and 16 of A.B. 121 to be changed to "Establish fees which may be collected in advance for the purpose of defraying the costs of the enforcement of this act."

The Motion passed. (Senator Raggio voted "NO")

Chairman Schofield said that the meeting for Tuesday, April 5, would be scheduled for 8:00 a.m., and Senator Hernstadt suggested that since the Committee would not be meeting on Friday, April 8, that the hearing for that date be re-scheduled for Thursday, April 7th.

The meeting adjourned at 10:57 a.m.

SEN. JACK SCHOFIELD, CHAIRMAN SHEBA LYNN WOOLLEY, SECRETARY

EXHIBIT "A"

(REPRINTED WITH ADOPTED AMENDMENTS)
SECOND REPRINT **A. B. 121**

ASSEMBLY BILL NO. 121—ASSEMBLYMEN DEMERS, SCHOFIELD, VERGIELS, HAYES, GOMES AND HARMON

JANUARY 21, 1977

Referred to Committee on Commerce

SUMMARY—Requires public hearing for disqualification of laetrile in cancer treatment. (BDR 40-362)
FISCAL NOTE: Local Government Impact: No.
State or Industrial Insurance Impact: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to substances; providing for the licensing and inspection of manufacturers under certain conditions; imposing a tax; providing that prescriptions for these substances by trade name may be filled by the generic equivalents; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. Chapter 41 of NRS is hereby amended by adding thereto a new section which shall read as follows:

The purchaser of a substance which has not been approved as a drug by the Food and Drug Administration of the United States Department of Health, Education and Welfare but which has been licensed for manufacture in this state has a cause of action against the seller or manufacturer for any misrepresentation of its therapeutic effect made directly to him or by publication.

SEC. 2. NRS 454.201 is hereby amended to read as follows:

454.201 "Dangerous drug" means any drug, other than a controlled substance as defined in chapter 453 of NRS, unsafe for self-medication or unsupervised use, and includes the following:

1. Any drug which has been approved by the Food and Drug Administration for general distribution and bears the legend: "Caution: Federal law prohibits dispensing without prescription"; [or]

2. *Any substance which has been licensed by the state board of health for manufacture in this state but has not been approved as a drug by the Food and Drug Administration; or*

3. Any drug which may be sold only by prescription because of regulations adopted by the board because the board has found such drugs to be dangerous to public health or safety.

Original bill is 3 pages long.
Contact the Research Library for
a copy of the complete bill.

EXHIBIT "B"

ASSEMBLY AMENDMENT

SENATE AMENDMENT

ASSEMBLY BILL NO. 121
ASSEMBLY JOINT RESOLUTION NO.

SENATE BILL NO.
SENATE JOINT RESOLUTION NO.

Sec. 3. Chapter 585 of NRS is hereby amended by adding thereto a new section which shall read as follows:

1. The state board of health may from time to time license for manufacture in this state one or more substances which are not at that time approved as drugs by the Food and Drug Administration of the United States Department of Health, Education and Welfare, if the board finds after a hearing that the substance:

(a) Is not allergenic or toxic if used in reasonable amounts; and

(b) Can safely be used pursuant to regulations prescribed by the board.

Such licensing does not require a finding, or constitute a representation, that the substance has any therapeutic effect.

2. If the board so licenses any substance, the commissioner shall:

(a) Adopt and may amend regulations which prescribe minimum standards for manufacturers in preparing, compounding, processing and packaging the substance.

(b) Conduct inspections of manufacturers of the substance.

(c) Establish fees, to be collected from the manufacturer, for the purpose of paying the costs of the inspections.

(d) Adopt and may amend regulations governing the qualifications of physicians to administer or prescribe the substance.

(e) Adopt and may amend regulations which prescribe standards for the use of licensed substances and for the use of the licensed substances in conjunction with any other substance.

3. There is hereby imposed upon the gross receipts of a manufacturer from the sale of each substance licensed for manufacture pursuant to this section a tax of 10 percent, payable quarterly to the department of taxation. The Nevada tax commission shall prescribe by regulation