

Members present:

Chairman Jeffrey
Vice Chairman Robinson
Assemblyman Bennett
Assemblyman Bremner
Assemblyman Chaney
Assemblyman Horn

Assemblyman Sena
Assemblyman FitzPatrick
Assemblyman Rusk
Assemblyman Tanner
Assemblyman Weise

The meeting was called to order at 3:10 p.m. by Chairman Jeffrey. He stated that the bills would not be called in order of their listing on the agenda.

SB 92: Lester Goddard, Commissioner of Savings and Loan Associations, stated that this bill was introduced at the request of Family Savings and Loan which has been active in the northern part of Nevada and which is now expanding to the Las Vegas area. He stated that they currently have 15 members on the board of directors in the northern area and they would like to increase the number which would be allowed because they wished to have other directors appointed for the southern region, yet none of those in the north wanted to step down. He stated that the only drawback he could see to this type of a move would be that it might increase travel and other expenses incidental to the meetings of the board.

AB 762: Assemblyman Weise first addressed the committee on this bill as prime sponsor and stated that one of the reasons for its introduction was that he felt the passage of the bill which allowed the manufacture and distribution of Gerovital in the last session was done in a manner which did not allow real investigation of the facts relative to the drug. He also stated that it had been presented to the committee which recommended it be passed that it would be treated as a controlled substance and be issued by prescription only and since there had been a bill introduced to make it an over-the-counter-drug, he felt that this bill was needed. He stated that he wasn't sure Gerovital shouldn't be sold over the counter, but that if it should be then the current regulations in the law should be taken from the books. He read to the committee from several newspaper reports relative to this issue and also from newspaper advertising which was sponsored by Rom-Amer Pharmaceuticals, Ltd., the only licensed manufacturer in the state.

Robert A. Grayson, attorney of Carson City, representing Rom-Amer Pharmaceuticals, Ltd., stated that passage of this bill would destroy one of Nevada's newest industries which had been established by the action of the legislature last session. He further pointed out that that company had invested great sums in fees to comply with strict regulations which had been established and to set up manufacturing and inspections facilities. He also pointed out that the company has a spotless reputation with Mr. Edmundson's office at the Department of Human Resources. Mr. Grayson stated that if this bill were to pass, it would also result in the loss of revenues to the state from the tax on sales

of the drug. He stated in conclusion that the bill which had been proposed for over-the-counter sales was not a direct result of efforts by Rom-Amer, but that it had been a request of the people who were using the drug and who were being charged exorbitant prices by the doctors prescribing the drug, for preliminary examinations before writing the prescriptions, etc.

In answer to a question from Mr. Weise, Mr. Grayson stated that if the provisions in the law requiring Gerovital to be sold only by prescription and manufactured under strict regulations were removed, then it would not be lawful to distribute it within the state because it was not an approved substance under the FDA guidelines. He also stated that if over-the-counter sales were permitted by the passage of the Senate bill in question, the law would have to be altered from what it is presently.

In answer to a question from Mr. Tanner, Max Shapiro stated that if the committee wished to know the exact chemical makeup of Gerovital, they should refer to Remington's Practice of Pharmacy, a text used by pharmacists.

Irvin Rivkin was next to speak in opposition to the bill and told them that he had been afflicted with crippling arthritis and that over the past six months, while using the drug Gerovital, he had experienced far less pain than over the past three or four years. He also stated that he, nor anyone in his family, had stock in Rom-Amer.

Jean Pardini, resident of Las Vegas, stated that he had been suffering from high cholesterol, gout and diabetes and that since he had been taking Gerovital he had felt much better and that upon returning to his doctor who had been treating him for many years, the doctor found that many of his symptoms and problems had cleared up to a great extent. He asked that this bill not pass.

Leo Henrikson stated that he was not appearing on behalf of nor did he have an interest in Rom-Amer, but as a private citizen wanted to tell the committee how much benefit he had received since beginning treatment with the drug some four to five months ago. He stated that in view of the relief it had afforded him from his arthritis, he felt that if this bill passed and Gerovital were to be taken off the market, people would simply go outside the country to get more because they would not want to go back to the pain and incapacity they had before beginning to use it. He pointed out that the drug was used commonly in other countries such as Sweden; however, he stated that he felt, personally, that it should probably remain as a prescription drug so that it could be well regulated. He urged the committee to defeat the bill.

In answer to questions from the committee, Mr. Grayson stated that there is only one dosage being produced at this time and it is the exact same formula as was developed in Romania originally and that the only difference between what is sold in Europe and in Nevada, is that the drug is sold in capsule form in Nevada and in

Europe it is sold in tablet form.

Mr. Edward Seremba, president of the Save Our Seniors, Inc. organization, was next to address the committee and urged that the committee not pass the bill. His remarks are attached and marked as Exhibit "A".

Mr. Grayson also submitted to the committee a letter addressed to physicians and pharmacists from Rom-Amer dated February 23, 1979 which contains informational material and background on Gerovital. That is attached and marked as Exhibit "B".

AB 712: Jim Wadhams, Director of Commerce, stated that he was appearing on behalf of Joseph Sevigny, Commissioner of Banking, and that this bill was an agency bill which had been requested by the Ways and Means committee so that there could be adjustments made in the fee schedule in an attempt to offset the losses which had been occurring in this area and to result in a slight surplus. He stated that they had contacted those in the industry and that they had concurred with this change.

Bob Demmick, Deputy Legislative Auditor, submitted to the committee an amendment and letter from his office explaining its necessity. That is attached and marked as Exhibit "C" and was agreed with by Mr. Wadhams.

AB 717: Jack McElwee, Manager of rates and regulations for Sierra Pacific Power Company, stated the they were concerned with some of the language in the bill in that connection fees are not clearly defined. He stated that they currently have the ability to charge each unit of a complex for connection of service and bill that separate tenant on an individual basis if the landlord so desires. He said that they do not want to bill to preclude them from being able to bill the individual tenants pursuant to current rules and regulations. He stated that he felt this bill would address only the cost of the physical installation of the service connection to the customer and the utility service facility and, if that was the intent of the bill, he would like to see it clarified in the bill. He stated that as a result of the water meter issue in the last session they had rules adopted and have been installing water meters in commercial hookups and had planned to expand that to residential hookups during this session based upon certain criteria which had been established during the last session. He said that when making hookups to multiple dwellings, it is their intention to run common lines through the complex and then run individual lines to the separate units; this would lower the cost of piping the projects.

Mr. Weise stated that requiring every apartment or office or condominium to have separate metered systems would be contrary to energy conservation. He stated that when the water meter matter was discussed their prime concern was the conservation of water by using meters to regulate its usage and be able to charge properly for its use. He stated that having to install a separate meter for every office in a complex or every unit in a building

was an effective way to implement that conservation idea.

David Hoy, attorney representing DiLoreto Construction, stated that they had submitted plans to Sierra Pacific Power Company for an apartment complex with 338 units which would be used for housing by a casino for its workers. He stated that when they submitted those plans they found out about the new tariff which required separate meters on each unit. He explained to the committee how this would greatly increase their costs and affect their construction plans. He pointed out that usually in a complex such as apartments there is one meter for usage of water by the apartments and one meter for water used outside them for irrigation, etc. The committee discussed with Mr. Hoy the various new systems which could be employed in construction which would facilitate conservation techniques. Mr. Hoy told the committee that he would supply them with language to amend the bill subsequent to their discussion and that information is attached and marked as Exhibit "D".

Heber Hardy, Chairman of the PSC, stated that they would oppose the bill as it was written, but they would support it with the suggested changes from Mr. Hoy. He stated that originally SPPC did not want to change the existing tariff regulation, but that after discussion regarding this, they decided to petition the commissioner for clarification of the point.

SB 184: It was commented that this bill was referred to Commerce from Environment because they thought that the bill would have an effect on the business community.

Lew Dodge stated that this was an agency bill introduced by the state Health Division. His remarks are attached and marked as Exhibit "E".

Mr. Ernie Gregory was next to speak and he discussed the necessity and bureaucratic intricacies of this bill with the committee and Mr. Dodge. After the discussion Chairman Jeffrey stated that the matter would be reviewed by a sub-committee consisting of himself and Mr. Weise together with Mr. Dodge and Mr. Gregory.

AB 716: Assemblyman Rhodes stated that this bill would extend authority for rural utilities to run power lines along the state roads as they had been allowed to in the past.

Mr. Bob Vaughan, Wells Rural Electric and Mount Wheeler Power and Nevada Rural Electric Association, stated that this bill would permit continuation of putting in power lines along the roads of Nevada. He stated that the organizations which he represents would suggest a clarifying amendment to the bill and it is attached and marked as Exhibit "F". Bill Raymon pointed out that you do not have to include the telephone companies in the provisions of this bill because they are already covered under other sections of NRS. It was also pointed out that if the lines have to be moved due to relocation of the roadways, that the utility companies must bear the cost of that relocation.

Brent Howerton, Highway Department offered an amendment to the committee relative to this bill and it is attached and marked as Exhibit "G" which would provide that the use would have to be compatible with use of the road and by approval of permit.

SB 385: Mr. David Russell, representing Southwest Gas proposed to the committee an amendment to this bill which is attached and marked as Exhibit "H" and otherwise stated that he supported passage of the bill.

Heber Hardy stated that he would concur with the bill with the proposed amendment from Mr. Russell, otherwise as written.

Stan Warren stated that Nevada Bell would concur with the bill as amended also.

SB 386: Jack McElwee stated that this bill would provide for increasing the size of power lines which would not have to be put underground and would also cut down on certain paperwork relative to environmental impact studies which are done on a routine basis in an area outside an incorporated city or town.

Heber Hardy stated that this bill would only change the KV factor relative to undergrounding lines and he would have no objection to the change.

Stan Warren for Nevada Bell stated that they were in favor of the bill and he introduced Mr. John Holmes who submitted to the committee that they had been excluded from the requirements of the bill in the original printing, but that the reprint had had excluded from line 12, the original wording on lines 22 and 23 of the original bill which should be included. Mr. Hardy stated that it may have been the concern of the Senate Committee that new annexations of areas into cities might have caused them to eliminate this wording, but that he saw no problem with using those words. Chairman Jeffrey pointed out that any facility in an outlying area would still have to comply with county ordinances regarding building regulations and impact studies and he stated that the bill could be amended to reflect Mr. McElwee's change and that he would discuss it with Senator Wilson.

That concluded testimony on this bill and the meeting was briefly adjourned at 6:00, prior to the beginning of an action meeting.

Respectfully submitted,

Linda D. Chandler
Linda D. Chandler
Secretary

ASSEMBLY COMMERCE COMMITTEE

GUEST LIST

NAME (Please print)	REPRESENTING (organization)	WISH TO SPEAK	
		Yes	No.
AB Dave Hoy	Di Loreto Construction	X	
Edward Seremba	Save our Seniors	X	
STAN WARRIN	NEV BELL	SB 385 586	
HEBER HARDY	P.S.C.	X	
ROBERT O. VAUGHAN	WELLS RURAL ELECTRIC MT WHEELER POWER + NREA	X	
ROBERT O. DIMMICK	LEGIS. COUNSEL BUREAU-AUDIT DIV.	SB 72 X	
KENT WICK	NEVADA RURAL ELECTRIC ASSOC.	X	
ADUE RUSSELL	SW GAS	SB 385 X	
JOHN HOLMES	NEV BELL	X	
IRVING PIVKIN	SELF	X	
Max Shapiro	Self		
James Davidson	Self	✓	
Carol A. Grayson	Gen. Amer. Pharmaceuticals	✓	
Brent Howerton	Nevada Highway Dept.	✓	766
Wm Raymond	Nevada Hwy Dept	✓	

My name is Edward Seramba. I am President of the Save Our Seniors, Incorporated. My address is P.O. Box 3181, North Las Vegas, Nevada 89030. Thank you for the opportunity of testifying before you today with regard to Gerovital.

I should like to preface my statement with a few, brief remarks about the elderly and their problems with the health care delivery system in this country.

Those of us who have survived into our fifties, sixties and seventies and beyond are experts at medical care. If we break a hip or suffer some other misfortune, we perhaps get mended or, sometimes, we sort of mend ourselves. Very little is done by way of anticipating the health problems of the older people, and very little is done by way of preventive medical care. We break. We are mended. We go on. We do not need a university study or a medical survey to tell us about the facts of health care. We have learned about this through experience.

Responsible new attempts to improve our medical care are deserving of broad legislative support. I am speaking today in support of Gerovital because it is something whose time has come, and something which deserves our timely consideration. I address myself specifically to the need to eliminate the costly and time-consuming procedure of going through the process of obtaining a medical prescription, preceded by a physical examination, in order to purchase this health care substance.

The cost, time and transportation involved simply remove

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this product from the reach of the elderly. I need not dwell on the difficulties older people have in getting about -- going to a doctor's office, getting the physical, paying the bill and going over to have the prescription filled.

In my daily contacts with seniors, the **BIGGEST** problem that comes up has to do with transportation. Those of us who drive cars or fly on airplanes understandably find it difficult to **SEE** a person who lacks personal transportation and personal funds and he just tries to get downtown or out to see a friend or even for an airing to see a park or some scenery or whatever. It is difficult to imagine what a bill for \$25 or \$50 or \$100 for a physical examination, tacked on top of the cost to fill the prescription, can do to the budget of an older person when, in fact, that budget is sometimes nonexistent. In brief, he or she is in a hand-to-mouth situation. Anything to make his problems more difficult, anything done to further deplete his purse, is **A SIN**

I find it of great interest that Gerovital is used in some 60 countries today. Countries such as Switzerland, West Germany, France and Great Britain require NO prescription. Holland requires no prescription. Gerovital is used perhaps most extensively in clinical practice in Romania, where it was originally developed -- it is administered in almost 70 clinics and industries in Romania. I believe the correct number is 67 clinics and industries in that small country of Romania.

We like to think we in the United States are ahead of the world in medical practice and in humane treatment of our population, including the old and the young. I have lived some considerable time and I am not so sure. Attitudes of various countries toward drugs and remedies are constantly changing. The simplest of medicines can be the cause of shocking controversy. I think back to the resumption of international relations between America and Mainland China and I think it interesting that when the presidential delegation and all the news correspondents got to China they found that the common

aspirin tablet is considered to be a prescription drug in China! The New York Times wrote extensively about the fact that in China you need a doctor's prescription in order to buy an aspirin. In our country, the very first doctor to use ether to put his patients to sleep during an operation was the president of the American Medical Association. He was from Philadelphia, a highly-respected medical man and surgeon, and he lost his presidency and his membership in the AMA because of using ether. I think also about the first stethoscope and how long it was withheld from general medical useage, and during World War II of the discovery and use of penicilin overseas and its slow acceptance here.

Change is always resisted. That is the natural, cautious side of people the world everywhere. But there comes a time for change.

The older citizens do not have all that much time to cool their heels, so to speak.

In all my readings about Gerovital, I find no literature supporting the notion that through the device of prescriptions it should be controlled from general useage by those who need it most -- the seniors. I find no use of it recorded as a stimulant or a depressant or a drug of the mind-altering kind. I see in Gerovital a product of vast potential benefit to our population, primarily the older people. I see no need to remove the public's access to it, PARTICULARLY that part of the public which would benefit greatly by it; our pharmacies themselves are licensed and the druggists are professionals and in vending this product through the pharmacies we have a built-in protection against abuse.

There is one need I do see. It is to remove the hindrances and the red tape. It is to refrain from interference with access to this product by those so urgently need of it.

Should the product be established as in some way nonproductive of good and adequate medical care for a person of whatever age and of whatever financial circumstance, ample time will be available to legislate the remedies necessary to impose the necessary controls.

I have talked with hundreds of people about Gerovital. Some have used it. Many are wondering about it.

I regret to say there are many, many honorable and deserving people who wish so very much to try it but who are kept from this by the high cost and the very real inconvenience of going to a doctor's office and taking off their clothes and having their chests thumped.

I trust that this honorable body will remove the necessity of going through such folderol. Whatever any one's view of Gerivotal or any other medical product or substance may be, I doubt that he or she can make much of a case for putting the elderly to such inconvenience and such pesky bother. To me, the matter involves application of good sense to resolve a situation that really isn't helpful to anyone including the doctors, whose services are so urgently needed in more important areas of the health care delivery system. I wish to conclude by confiding in you that I am 73 years old. I will be 74 in August. I am an active person. I enjoy organizational work. I also enjoy active sports. I have won the last 3 golf tournaments I've entered, including the Las Vegas Muscular Dystrophy and the Ely, Nevada Open. Against many younger players. I have been taking Gerovital regularly. I feel young. I feel spry. I feel mentally alert. I am so mentally alert that I do not need my chest thumped and a costly medical examination if I am to continue taking this product, Good luck and God speed to this august body. I hope to be back next year and the year after, at 75. Thank you.

ROM-AMER PHARMACEUTICALS, LTD.

300 SOUTH 4th ST. • SUITE 1603 • LAS VEGAS, NEVADA 89101

TELEPHONE (702) 386-0391

TWX 910-397-6952

February 23, 1979

Dear Physician or Pharmacist:

It has been brought to our attention that members of the medical and pharmacy professions in Nevada are interested in obtaining additional background and clinical information about GEROVITAL CAPSULES.

In this connection, we have researched our files carefully and prepared the enclosed presentation which sets forth, in condensed form, some of the observations derived from various clinical and laboratory investigations, together with excerpts from statements which have appeared in public newspapers or magazines and/or various professional journals. The Gerovital preparations which were used in the various investigations were either injectable or tablet dosage forms, of Romanian origin. The composition of the capsule dosage form we are manufacturing and making available in Nevada contains the same chemical ingredients in the same proportions as were used in the investigational preparations. In this connection, please refer to the paragraph under "DESCRIPTION:" in the body of the package insert appearing at the end of the accompanying presentation.

If you require any further information, please feel free to call the undersigned at (702) 384-6619, or in the Northern Nevada area, (702) 329-4259 for any clarification or further information which we may be able to supply in connection with our product.

As you are probably aware, GEROVITAL in injectable and tablet dosage forms of Romanian origin has been sold in approximately 60 countries of the world for periods of 10 to 20 years, and particularly in certain, highly regulated countries such as Switzerland, West Germany, France, Great Britain and Holland where no prescription is required. GEROVITAL is very extensively used in Romania (where it was originally conceived) and is administered in approximately 67 clinics and various industrial establishments throughout that country.

We trust that you will be able to find time in your busy days to look at the enclosures, and we hope that your perusal of them will enable you to make a value judgment in connection with your possible professional prescription and/or dispensing of our product.

A telephone referral list is maintained in our Las Vegas offices to enable individuals who wish to use GEROVITAL to locate physicians who are prescribing it. This list is primarily a telephone list and is not published or released in any way, and if, after your examination of the presentation, you would like to have your name added to the list of physicians who are presently prescribing GEROVITAL, please drop us a note to that effect or telephone Ms. Mary DeVilbiss at 384-6619.

Very truly yours,

ROM-AMER PHARMACEUTICALS, LTD.

EXHIBIT "B"

By Edward J. Grossman, Ph.D.
Edward J. Grossman, Ph.D.
Vice President

EJG:mlh
Enclosures

GEROVITAL INFORMATION

February, 1979

In the interest of brevity and in order not to impose unduly upon your reading time, we have taken the liberty of excerpting from various journals and articles certain portions which our scientific people believe are relevant and cogent to your understanding of our product. The cover letter, transmitting the information to you, should be considered as part of this presentation.

Upon your request, we will be glad to furnish the full article, or reprint of any report or article, so that you may make your own determination of both the relevancy and sufficiency of the excerpts. In all cases, underscoring of the various excerpts was added by us for emphasis.

- I. Zung, William W. K., M.D. (Duke University Medical Center and Veterans Administration Hospital, Durham, North Carolina): Pharmacology of Depression in the Aged. Evaluation of Gerovital H3 as an Antidepressant Drug. *Psychosomatics*, 15: 127-131 (1974).

"The results of this double-blind study comparing Gerovital H3 versus imipramine and placebo showed that by comparing pre- and post-treatment scores on several rating scales measuring depression, both GH3 and imipramine treated patients improved significantly with respect to their depressive disorders, while placebo treated patients did not. Further, the results of this study showed that using the clinical global impression and the Zung self depression scale, the change scores obtained from calculating pre-treatment to post-treatment differences showed GH3 to be superior to imipramine since the GH3-placebo differences were significantly different, while the imipramine-placebo differences were not."

In a separate study report prepared for submission to the FDA, Dr. Zung also stated:

"Evidence in support of safety was provided using the following measurements: 1. Vital signs: a. Blood pressure, b. Pulse. 2. Laboratory tests: a. Blood chemistry, b. Hematology, c. Urinalysis, d. Electrocardiogram. In addition, special studies using electroencephalographic recordings were performed. Based upon a within treatment group comparison of pre-treatment and post-treatment test results, no significant pathological changes were found for patients studied in the Gerovital H3-injectable group, nor were any significant pathological changes found in the imipramine and placebo treated groups.

Further evidence in support of safety for Gerovital H3-injectable was provided in a tabulation of adverse reactions found during the study. Patients in the GH3 group did not experience any more side effects than patients in the imipramine and placebo treated groups. Of those side effects that were experienced in the GH3 treated group, only the complaint of dizziness from two patients were thought to be drug attributable.

(continued)

It is our conclusion, based on the investigation conducted in this study, that Gerovital H3-injectable is an efficacious drug in the treatment of depressive disorders, and that it is a safe drug."

- II. Cohen, S., M.D. (Professor of Psychiatry, Neuropsychiatric Institute, University of California at Los Angeles, Los Angeles, California) and Ditman, Keith S. (Medical Director, Vista Hill Psychiatric Foundation, San Diego, California): Gerovital H3 in the treatment of the depressed aging patient. *Psychosomatics*, 14: 15-19 (1974).

"Eighty-five percent of forty-one subjects reported some improvement from a series of twelve GH3 intramuscular injections. Their response was prompt and dramatic, but mainly subjective. Most felt a greater sense of well-being and relaxation, slept better at night, and many obtained some relief from depression and the discomforts of chronic inflammatory or degenerative disease. Such broad and definite claims of improvement are intriguing and encouraging, but caution in their interpretation is indicated. The possibility of a psychogenic effect cannot be ruled out from the study and could explain the improvement in this group of patients. The need for double-blind, controlled studies is apparent. The lowering of the blood cholesterol in eight of nine cases of hypercholesterolemia is encouraging and warrants further scrutiny. The relief of chronic pain reported by our medical patients is also worth further investigation"

"None of the normal subjects reported any side effects. There were no pathological laboratory changes attributable to Gerovital H3 administration. It was our definite impression that it was a safe drug in the dosage given."

- III. Hayman, Max, M.D., et al. (Desert Psychiatric Medical Group, Palm Springs, California; Research Psychiatrist (Professor), University of California at Los Angeles, School of Medicine, Los Angeles, California): Gerovital H3 in the treatment of depression in a private practice population: A double-blind study. Presented at the Annual Meeting of the Academy of Psychosomatic Medicine - Scottsdale, Arizona (November 20, 1974).

"A double-blind study comparing Gerovital H3 against placebo in an out-patient private practice population with diagnosis of depressive disorders was performed. The results demonstrated that Gerovital H3 was significantly better than placebo in all three variables measured. A tabulation of adverse reactions showed minimal side effects reported for both the Gerovital H3 treated and placebo treated groups. We conclude from the data presented that Gerovital H3 is an efficacious drug in the treatment of depressive disorders in an adult population, and that it is also a safe drug."

- IV. Reports from: Dr. Bernard M. Wagner
Departments of Pathology, College of
Physicians and Surgeons
Columbia University and Beekman
Downtown Hospital
New York, N.Y.

"A five-day acute intramuscular toxicity study of Gerovital-H3 in rats, dogs and mice, at dose levels of 0, 15, 30 and 60 mg/kg of body weight, revealed no abnormalities upon neurologic and ophthalmic examination. Hematologic studies, clinical chemistry tests and urinalyses were all within normal limits.

A separate thirteen-week subacute intramuscular toxicity study of Gerovital H3 in rats and dogs at dose levels of 0, 15, 30 and 60 mg/kg/day also revealed no abnormalities upon neurologic and ophthalmic examinations. Hematologic studies, clinical chemistry and urinalyses all were within normal limits. Gross and microscopic studies of all organs revealed no drug related toxic manifestations."

- V. Report from: Dr. Bernard M. Wagner
Director of Laboratories
National Veterinary Laboratory Inc.
Franklin Lakes, N.J.
and
Dr. S. Carson
Biometric Testing, Inc.

"An acute oral toxicity assay was performed using varied oral doses of Gerovital-H3 in rats and dogs. Rats receiving 0.94g/kg body weight, and dogs receiving 1.2g/kg body weight showed no significant pathological changes."

- VI. MacFarlane, David M., Ph.D. (School of Pharmacy, University of Southern California, Los Angeles, California): Procaine HCl (Gerovital H3): A weak, reversible, fully competitive inhibitor of monoamine oxidase. Federation Proceedings, 34: 108-110 (1975).

"The data presented here indicates that GH3 is a weak, reversible, fully competitive inhibitor of MAO.

This mode of action is in marked contrast to that exhibited by other known inhibitors of MAO that are used clinically for the treatment of depression and hypertension. For example, it has been demonstrated that compounds like pargyline (EUTONYL), phenelzine (NARDIL), and tranylcypromine (PARNATE) are irreversible inhibitors of MAO and produce, for all intents and purposes, a noncompetitive inhibition, probably due to formation of covalent bonds between the drug and MAO.

(continued)

It has been widely reported that patients who are given irreversible inhibitors of MAO may experience hypertensive reactions manifested by chest pain, headache, and, on occasion, fatal intracranial hemorrhage; particularly after eating certain tyramine-containing foods such as cheese and wine, after taking tricyclic antidepressants, and after ingesting certain commonly-used sympathomimetic amines that are found in common cold remedies. On the other hand, hypertensive reactions have not been reported to occur in patients being treated with GH3, and consequently, there are no restrictions as to the types of food that may be enjoyed while taking GH3.

The absence of hypertensive reactions with GH3 may be related to the reversible, competitive inhibition of MAO produced by this agent. With the use of this type of inhibitor, the presence of additional and/or excessive quantities of substrate for MAO such as tyramine, norepinephrine, or serotonin could result in an alleviation of the GH3-induced inhibition of MAO with displacement of the drug from its binding sites on the enzyme. This would allow the enzyme to metabolize and reduce the elevated levels of substrate and thereby reduce a hypertension that could be hazardous to the patient."

- VII. Robinson, D. S. (University of Vermont) et al.: Aging, monoamines and monoamine oxidase levels. *Lancet*, 1: 290 (1972).

Robinson, D. S. (University of Vermont) et al.: Relation of sex and aging to monoamine oxidase activity of human brain, plasma and platelets. *Archives General Psychiatry*, 24: 536 (1971).

"Robinson et al. have shown that there is an age-dependent increase in MAO activity of human brain, plasma, and platelets and a corresponding decrease in central monoamines. These correlations could explain some of the manifestations of aging, especially as related to CNS function. The ability of GH3 to inhibit MAO may explain why the agent is effective in the alleviation of some of the signs and symptoms of aging."

- VIII. Jancar, V. G., M.D. (Psychiatrist), Apony, A. J., M.D., and Hrachovec, J. P., M.D. (Department of Biological Sciences, University of Southern California, Los Angeles, California): Recent clinical experience with treatment of depression with Gerovital H3 tablets. Abstract - Gerontological Society (1974).

"Patients were all over forty-five years of age and suffering from symptoms of depression from various causes. They received GH3 tablets in increasing dosage over six weeks, starting with three tablets a day, up to optimum response, but not more than six tablets daily. Blood chemistry, urinalysis, and EKG were taken before and after the study. The following symptoms were very much improved: decisiveness, sexual libido, mental and physical energy, and sleeping patterns."

- IX. Long, Robert F., Ph.D. (Chief Psychologist, St. Peter State Hospital, St. Peter, Minnesota) and Gislason, Solveig S., M.D. (St. Peter State Hospital, St. Peter, Minnesota): The effect of Procaine on orientation, attention, memory and weight of aged psychiatric patients, *Journal of Neuro-Psychiatry*, 5: 186-196 (1964).

"Seventeen patients received intramuscular Procaine injections for one year in a double-blind study. Sixteen matched patients served as control receiving saline. After one year of treatment, Procaine group showed significantly greater improvement than the control in orientation, memory and attention. Procaine group also gained weight significantly in comparison with the control group."

- X. Cammer, Leonard, M.D. (Associate Attending Psychiatrist, Flower and Fifth Avenue Hospitals, N.Y.C., N.Y.; Chairman, Section on Psychiatry, New York State Medical Society; Life Fellow, American Psychiatric Association): A double-blind clinical trial of Gerovital H3-Injectable as an Antidepressant drug. IND Submission No. 8681 (Form FD-1573), Statement of Investigator. 23 pp. (March 25, 1975).

"A double-blind placebo-controlled clinical trial of Gerovital H3-Injectable was conducted to evaluate the efficacy and safety of this drug in the treatment of depressive disorders Results showed that GH3 was significantly better than placebo in the treatment of the patients' depressive disorders Evidence of safety of GH3 was provided by the laboratory tests measuring blood chemistries, blood counts, and urinalysis. Results of statistical comparisons for pre-treatment and post-treatment values for GH3 and placebo-treated patients showed no major significant changes."

- XI. Yau, Tom M., Ph.D. (Ohio Mental Health and Mental Retardation Research Center, Cleveland, Ohio): Gerovital H3, monoamine oxidases, and brain monoamines. Presented at the Symposium on Theoretical Aspects of Aging - Miami, Florida (February 7-8, 1974).

"Based on previous reports and additional results presented herein, the following conclusions can be made regarding the basic mechanisms of GH3:

1. GH3 is a weak, reversible and competitive inhibitor of MAO;
2. GH3 may function as an antidepressant by gently modifying the level of brain monoamines;
3. Compared with a few classical MAO inhibitors, GH3 is quite selective in inhibiting the oxidative deamination of certain important brain monoamines, especially serotonin;
4. Due to the minimal inhibition of GH3 on the oxidative deamination of liver tyramine and tryptamine, the normal physiological function of liver MAO to inactivate excess amounts of ingested or endogenously synthesized toxic amines is not impaired, thereby eliminating the toxic 'hypertensive crisis' so typical of other MAO inhibitors."

- XII. Bucci, Luigi, M.D. (Rockland State Hospital, Orangeburg, New York, N.Y.): Procaine: A monoamine oxidase inhibitor in schizophrenia. Diseases of the Nervous System: A Practical Journal on Psychiatry and Neurology. Physicians Postgraduate Press, Inc., 34: 389-391 (1973).

"The fifty years of history of Procaine indicates many potential applications for the drug. Its pharmacological properties and its clinical actions have indicated use in the following: Hypertension, cardiac arrhythmias, angina pectoris, serum sickness, urticaria, dermatitis, narcotic substitute for severe pains and for the treatment of addiction. This author has emphasized the usefulness of the various MAO inhibitors, combined with one of the phenothiazines, for the treatment of chronic, apathetic schizophrenic patients who have only partially responded therapeutically to other psychopharmacological agents. Procaine . . . is also a MAO inhibitor, therefore it is reasonable to assume that its usefulness in psychiatry may be due to some of the pharmacological properties that this drug shares with other MAO inhibitors . . . As a rule, it is quite safe and well tolerated."

- XIII. Abrams, Arnold, Ph.D. (Division of Behavioral Sciences, The Chicago Medical School Institute for Medical Research, Chicago, Illinois), et al.: The effects of a European Procaine preparation in an aged population. I. Psychological effects. Journal of Gerontology, 20: 139-43 (1965).

"By a double-blind technique the effects of an experimental European Procaine preparation (Gerovital) were compared to those from a standard American Procaine preparation, with use of residents in a Home for the Aged. After treatment, the direction (on the four sets of assessments) was toward improvement in the group who had been given the European drug, as compared to the group who received the American Procaine preparation. When evaluations were combined into scores, the differences between the two groups were found to be statistically significant. While caution is necessary in the interpretation of these results, they suggest that the European drug had a beneficial effect on psychological functioning, and that the drug merits further exploration to determine the nature and extent of its effect."

- XIV. Jancar, V. G., M.D. (Psychiatrist), Lando, S. F., M.D. (Psychiatrist), and Apony, A. J., M.D. (Chief of Staff, St. Clare's Hospital, Schenectady, New York): Recent clinical experience with treatment of depression in elderly with Gerovital H3 tablets.

"We report the following results:

1. We noticed that the onset of the beneficial effect of Gerovital H3 tablets was in most cases faster than with other anti-depressants currently in use. In general, improvement began a week to ten days after beginning the course of treatment, as compared to an average two weeks' time lag with other drugs used in our practice.
2. We experienced fewer side effects with GH3 than with other forms of medication used in our practice. We didn't experience any 'cheese syndrome' usually encountered with 'classical' MAOI, mainly high blood pressure, tachycardia, loss of libido, increase in weight, excessive sleepiness, loss of acuity, constipation, dryness of mouth, congestion of the nasal passages or blurry vision. The only side effects we encountered were few cases of palpitations and restlessness. Both disappeared when the amount of medication was reduced. Fourteen patients finished the course.

(continued)

3. In clinical improvement of the patients, of the fourteen patients, two reported feeling uncomfortable on the medication with no improvement. One returned to her previous monoamine oxidase antidepressant. The second had no previous exposure to antidepressants and felt no change while on GH3.

A third patient obtained the same results with GH3 as he had with imipramine.

The remaining eleven showed good to significant improvement. As a rule, the first beneficial symptoms were: increased decisiveness, liveliness, enrichment of thought processes and disappearance of psychomotor retardation. Later in the course of treatment, patients showed signs of improved memory, a change in dream content from a pattern of victimization to a positive image, and improved performance on the job, including increased creativity and the ability to carry more complicated tasks to completion on their own. At the end of the treatment, most patients indicated their somatic complaints had diminished or disappeared, especially those characterized by pain. Two male patients reported increased libido, and one female patient reported loss of profuse sweating, which she claimed she had had all her life.

All eleven patients would choose to continue on Gerovital H3 as an antidepressant if needed for further control of depression.

In our experience the optimum results were achieved in most cases by 300 to 400 mg. a day, that is, 3 to 4 GH3 tablets. This equals dosage commonly used in our outpatient practice of tricyclic antidepressant (25 mg. per tablet), three or four times a day."

XV. The following statements are excerpts from various publications and letters:

- A. MEDICAL WORLD NEWS — April 6, 1973, Vol. 14, No. 14

"Research done in the past has shown that Procaine alone has little effect on the aging process, but work at the Chicago Medical School in 1965 convinced some that Gerovital itself was definitely worth further study as an agent to combat depression. Said Chicago pharmacologist Paul Gordon: 'We found that Procaine doesn't do a damned thing, but Procaine plus the additives do — that's a fact' (Medical World News, December 12, 1969). According to Elmer Gardner of the FDA's Bureau of Drugs: 'There's no safety problem with the drug.'"

- B. THE CLEVELAND PRESS — April 3, 1975, No. 24712

"Last year, about 38,000 persons got the drug in the Romanian clinics. Among them were about 1,000 Americans who paid \$1,400.00 each for a two-week tour of the country with Gerovital treatments thrown in."

C. BOSTON HERALD AMERICAN — April 27, 1975

"FDA's Dr. Frank A. Hayes says first results of the American tests indicate Gerovital seems to have some ability to treat mild depression. If further results confirm this, the FDA may have no choice but to license Gerovital."

D. FOOD AND DRUG COMMISSIONER — Alexander M. Schmidt, M.D. —
October 21, 1976
Letter to Senator Howard W. Cannon

"Procaine Hydrochloride is a rather safe drug when used in appropriate doses and in patients who are not allergic to it . . . et cetera."

E. MEDICAL WORLD NEWS — July 14, 1975

"The Palm Springs team also did an open study of fifty patients to investigate dosage and side effects. They found 'hardly any side effects,' but one incidental result they don't have statistics on because they weren't studying it (and weren't authorized to): 'Patients with arthritic pain often reported less pain and better mobility.'

'There's more good news for boosters of the controversial, Procaine-based Romanian "youth drug," Gerovital H3 (GH3). Results of double-blind clinical trials in the U.S. are coming in and they tend to confirm the impression of earlier laboratory studies and at least one open clinical study (Medical World News, December 14, 1973, p. 15) that the compound does have some effect on the pathophysiology of aging. The latest of these are two double-blind controlled studies done at Duke University's aging studies center, reported by Dr. William W. K. Zung, Professor of Psychiatry, and Dr. H. S. Wang, Associate Professor, at the Annual Meeting of the American Geriatrics Society in Miami Beach.'

'Pointing out that no significant reduction of CBF and no marked slowing of EEG frequency were observed in patients on GH3, Dr. Wang suggests it may be safer than imipramine for elderly patients.' "

XVI. The following text, from the package insert, should be carefully considered for both contraindications, method of use and capsule content:

Gerovital Capsules

Distributed by:

ROM-AMER PHARMACEUTICALS, LTD.

300 South 4th Street

Las Vegas, Nevada 89101

DESCRIPTION: Each capsule contains 100 mg. of procaine hydrochloride with 6 mg. benzoic acid, 0.5 mg. dibasic sodium phosphate and 5 mg. potassium metabisulfite as preservatives and stabilizers. These capsules are manufactured in Nevada by Rom-Amer Pharmaceuticals, Ltd.

Gerovital, in injectable and tablet dosage forms, is distributed by others in a number of European nations, including West Germany, Switzerland and the United Kingdom. In the United States, Gerovital is considered subject to "new drug" classification by the Food and Drug Administration. The injectable and tablet forms of the drug containing the same quantities of procaine hydrochloride, benzoic acid, dibasic sodium phosphate and potassium metabisulfite as are in the capsule have been the subject of Investigational New Drug exemptions, and clinical studies on the injectable form have been performed in the United States to determine its usefulness in the treatment of certain types of depression in a population over 50 years old. These clinical studies have not been considered conclusive by the Food and Drug Administration.

The manufacture of Gerovital capsules in Nevada is authorized under the provisions of a state law enacted in 1977. The state law specifically requires notice that Gerovital has not been approved as a drug by the Food and Drug Administration of the United States Department of Health, Education and Welfare and that the State of Nevada has not approved the substance. Gerovital is made available in Nevada in the belief that physicians and their patients should have the freedom to make their own determination of its usefulness. No claims are made or authorized by Rom-Amer Pharmaceuticals, Ltd. that Gerovital in any dosage form, including these capsules, has any therapeutic or other benefit.

ADMINISTRATION: Suggested regimen for Gerovital capsules is two daily, two or three hours after meals, over a period of 30 days. After 30 days, provide a 15 days pause, then resume serially.

PRECAUTIONS: Gerovital should not be administered simultaneously with sulfonamides. Specific allergy to procaine is a contraindication and individual tolerance should be tested in all cases by administering only one capsule per day for the first two days.

STATE OF NEVADA
LEGISLATIVE COUNSEL BUREAU

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April 16, 1979

Assemblyman John E. Jeffrey
Chairman, Committee on Commerce
Legislative Building
Carson City, Nevada 89710

Dear Assemblyman Jeffrey:

A.B. 712 is currently before your Committee on Commerce. This bill is the result of our audit of the Banking Division for the fiscal year ended June 30, 1976.

Section 1, Page 2, lines 10-14, of A.B. 712 are not in complete accord with our audit recommendation. Therefore, we are submitting to you a proposed amendment for A.B. 712. We have discussed this with Mr. Joe Sevigny, Superintendent of Banks, who is in agreement with the proposal.

When this bill is heard by your committee, we will be in attendance to explain our proposed amendment.

Sincerely yours,

JOHN R. CROSSLEY, C.P.A.
LEGISLATIVE AUDITOR

By Robert O. Dimmick
Robert O. Dimmick
Deputy Legislative Auditor

JRC:ROD:hjr
pc: James Wadhams
Joe Sevigny
Attachment

EXHIBIT "C"

1509

AB 712
PROPOSED AMENDMENT

Delete the present wording of Section 10 and replace with the following:

"All money received by the superintendent under this chapter must be deposited with the state treasury for credit to the appropriate account within the general fund for use of the banking division to be used to carry out the provisions of this chapter. At the close of each fiscal year, any remaining balance must lapse within the general fund."

HOY & MILLER, CHARTERED
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April 27, 1979

The Honorable James Jeffrey
Chairman, Assembly Commerce Committee
Nevada State Legislature
Carson City, Nevada

Re: AB 717

Dear Mr Jeffrey:

Pursuant to my testimony before the Assembly Commerce Committee on April 26, 1979 regarding AB 717 and the committee's request for amendments to the bill, I enclose herewith the proposed amendments to AB 717.

You will note that, as requested, the amendment provides that the owner of the "water system" may request separate delivery or metering systems. I used the term "owner of the water system" to include both the owner of an apartment house or other rental housing and the owner of the system in a cooperative, condominium or townhouse situation. In the latter case, if the water system is owned by the condominium association, the association, acting through its members, would have to elect for separate meters. If, however, the condo or townhouse was built so that the water system were not part of the common area, then each unit owner could make his own election.

If there are any questions concerning this, please contact me.

Very truly yours,

HOY & MILLER, CHARTERED

By _____
David R. Hoy

DRH:bc

Enclosure

Bob: Thank you very much for your help. Anything you can do to push this along will be appreciated.

EXHIBIT "D"

Dave

1511

AMENDMENTS TO AB 717

Title is amended to read as follows:

An act relating to public utility regulation; prohibiting public utilities which provide water from charging more than one fee or requiring more than one water meter for connecting to multiple dwellings; and providing other matters properly relating them.

Strike lines 3 - 6 and insert in lieu thereof the following:

Unless the owner of the water system within a building requests in writing that a utility provide multiple delivery or metering systems, a public utility must provide water through a single connection to a building containing multiple dwellings and may charge a fee for its connection to the entire building and may, subject to the provisions of NRS 704.230(4) require a single water meter or water meter facility but must not charge a separate fee or require a separate water meter or water meter facility for the individual dwellings within it.

Strike lines 12 - 14 and insert in lieu thereof:

Section 3: This act shall become effective on passage and approval

April 26, 1979

S. B. 184

BEFORE THE ASSEMBLY COMMITTEE ON COMMERCE

The purpose of this bill is to clarify the responsibilities and authority of the Health Division and the Division of Environmental Protection regarding sewage disposal and the certification of subdivisions.

The 1977 Legislature reorganized several State agencies. This reorganization took the Environmental Protection Section from the Bureau of Environmental Health of the Health Division and created the Division of Environmental Protection in the Department of Conservation and Natural Resources.

Statutes were changed to transfer authority and responsibility from the Health Division to the Division of Environmental Protection.

We feel that some of those changes were incomplete and this is an attempt to rectify that.

NRS 439.200, Section 1 (d), was amended to delete the control of sewage disposal from the Board of Health's authority to adopt regulations.

I assume that this was done because the primary control of municipal

EXHIBIT "E"

sewage systems is with the Division of Environmental Protection and is covered under water pollution laws.

However, of all factors influencing public health in both rural and urban areas, no single item is of greater importance than the proper disposal of sewage!

NRS 439.150 declares the State Board of Health to be supreme in all non-administrative health matters.

We are requesting that NRS 439.200 1 (d) be amended to restore the specific authority for controlling sewage disposal but with wording to clarify the Board's authority with respect to the water pollution control law administered by the Environmental Commission. This is reflected in the change shown on page 1, lines 9-12.

While the environmental functions were removed from the Health Division, the subdivision and condominium statutes - NRS 117 and 278 - were not amended and still require the Health Division to certify approval of water pollution and sewage disposal for all new subdivisions and condominiums.

This bill would transfer the responsibility for certifying approval of water pollution and sewage disposal by public systems to the Division of Environmental Protection while retaining the responsibility for

certifying water quality~~and~~ water supply facilities with the Health
Division. This is reflected in the change shown on page 2, lines
29-34 and page 4, lines 33-38.

April 19, 1979

Assemblyman Dean Rhoads
Nevada State Legislature
Carson City, Nevada 89710

Dear Dean:

Thank you for introducing AB716. It is in quite brief form and I am afraid if not clarified might lead to disputes as to what was intended.

Therefore, I am suggesting that the new paragraph be amended to read as follows:

" ^{NOW-~~Part~~} A/rural electric cooperative ~~which has been formed pursuant to NRS 31.410 to 31.540,~~ inclusive, may erect, bury, maintain and operate power lines, and telephone lines in connection therewith, along public highways, roads, streets and alleys, within the service area of the cooperative, as certificated by the Nevada Public Service Commission, provided, that such use shall not obstruct the natural and proper use of such highways, roads, streets and alleys."

I suggest "highways, roads, streets and alleys" rather than just "roads" as chapter 405 which is being amended does not define what a road is.

I am adding "and telephone lines in connection therewith", as there is frequently quite a savings in cost to serve the rural telephone subscribers to be able to rent poles from the power company, and that of course uses the same right of way. Without that added wording there would be no right to attach the telephone lines.

I am adding that it would only be "within the service area of the cooperative as certificated by the Nevada Public Service Commission", to make the bill more palatable as it would confine the area in which a cooperative had this particular right. If they have to build a line outside of the certificated area, such as a power supply line, it would be reasonable that they would seek normal rights of way for that purpose. This would answer the objections of a Reno or Las Vegas legislation, who would worry that the cooperative had the right to go down main street.

Assemblyman Dean Rhoads
April 19, 1979
Page Two

I added that "the use shall not obstruct the natural and proper use of such highways, roads, streets and alleys", to make the bill more palatable.

We and our clients certainly appreciate your support of this legislation as it can be very helpful to hold down costs of power to the rural areas, where it is particularly expensive to provide such power.

I have told you before, and I wish to reiterate that I think you and Norman carry a tremendous amount of influence, particularly being from rural areas. I am amazed at what you have been able to accomplish on a number of matters, particularly the Public Lands Bill.

Thank you again and kind personal regards.

Very truly yours,

ROBERT O. VAUGHAN

dlb

cc: Senator Norman Glaser
Mr. Daniel Bryan
Mr. D. Vernon Dalton
Ms. Ester Quilici
Mr. B. Kent Wick
Mr. Thomas A. Bath
Mr. J. Dean Baker

Mrs. Margaret E. Rowe

PROPOSED AMENDMENT TO ASSEMBLY BILL NO. 716
OFFERED BY THE NEVADA HIGHWAY DEPARTMENT

Section 1. Chapter 405 of NRS is hereby amended by adding thereto a new section which shall read as follows:

A rural electric cooperative which has been formed pursuant to NRS 81.410 to 81.540, inclusive, may erect or bury power lines along public roads provided that provisions of N.R.S. 408.955 and local governmental franchise requirements governing occupancy of public roads are observed.

EXHIBIT "G"

Amendment to SB 385

Delete present language of subsection 5, page 2, line 10 and substitute:

" 5. If the commission receives an application which appears to be within the prohibition of subsection 3, it shall make a determination as to whether the application violates the prohibition within 45 days and only after the public utility is given notice and opportunity to be heard on the application."

EXHIBIT "H"