Committee in Session at 8:40 am on Friday, May 11, 1979.

Senator Keith Ashworth in the Chair.

PRESENT: Chairman Keith Ashworth
Vice-Chairman Joe Neal
Senator Clifton Young
Senator Wilbur Faiss

ABSENT: Senator Rick Blakemore
Senator Jim Kosinski

GUESTS: Mr. Tom Huddleston, State Fire Marshal
Dr. George Bennett, Executive Secretary, State Board of Pharmacy
Dr. John Carr, Health Officer, Health Division
Mr. Marvin Kratter, Rom-Amer Pharmaceuticals, Ltd.
Mr. Leo Henrickson, Citizen
Ms. Elizabeth Hecker, Citizen
Dr. Art Singer, Citizen
Ms. Ruth Becker, Citizen
Ms. Joyce Bartmus, Citizen
Ms. Mary Ann Weatherwax, Citizen
Mr. Edward Seremba, President, Save Our Seniors, Inc.
Ms. Ruby Frankfort, Citizen
Ms. Francis Struzel, Citizen

Chairman Ashworth opened the hearing on S.B. 540 and stated that the Fire Marshal had submitted amendments (Exhibit "A") to the bill.

Mr. Tom Huddleston, State Fire Marshal, stated that he had eliminated the provisions of S.B. 540 and changed it to an enabling act in line with the present law for any other industry regulated by the office of the State Fire Marshal. He said that it now simply sets up the right for the State Fire Marshal to license various aspects of fireworks and to write regulations. He emphasized Section 7 of Exhibit "A" as to city or county jurisdiction.

Senator Young questioned the statutory authority to write regulations. Mr. Huddleston stated the authority is contained under NRS Chapter 477 and S.B. 198 passed this session; S.B. 198 said that the Fire Marshal shall write regulations pertaining to fireworks but did not give the authority to license.

Chairman Ashworth questioned if the Fiscal Note would be the same with the amended version as with the original bill. Mr. Huddleston stated that it would. Chairman Ashworth questioned if there was adequate time in the session to address this issue. Mr. Huddleston stated that he did not believe so. He stated that he could handle most of the problems by regulation but still had the problem of uncontrolled manufacturers shipping fireworks into the state.

Chairman Ashworth questioned if this problem could be addressed during the interim and the issue presented at the beginning of the next legislative session. Mr. Huddleston stated that it could.

There being no further testimony, Chairman Ashworth closed the hearing on S.B. 540.

Chairman Ashworth opened the hearing on S.B. 574. He stated, for the record, that the committee has received 66 telephone calls, 84 letters, 3,904 original signatures on petitions for a total of 4,054 responses in favor of gerovital from the citizens of Nevada. He noted that the State Board of Pharmacy, Nevada Medical Association, Rom-Amer Pharmaceuticals and the State Health Division had been notified on this hearing; the Health Division had also been requested to notify the federal Food and Drug Administration.

Senator Blakemore arrived for the meeting (8:48 am).

Dr. George Bennett, Executive Secretary, State Board of Pharmacy, stated that the Board of Pharmacy is in opposition to S.B. 574 because procaine/gerovital is presently by state law allowed to be a prescription drug. He said that the federal Food and Drug Administration has taken a position in opposition to the sale of this product without prescription. He said that the Board does not argue with the position that the drug is allowed in Nevada; he said the position of the Board is that the drug is available through prescription and that is a proper control. He said the drug has been known as a local anesthetic, has been widely used and has many drawbacks to it; the reactions to any drug that is a prescription drug is determined by the federal Food and Drug Administration (FDA). Dr. Bennett stated that the question of efficacy is not the point; the Board feels that if the FDA feels it should be a prescription drug, the Board concurs. He said that there has been no problem in the administration of the law since it was passed last session.

Senator Neal questioned if the Board is aware that approximately 25 european counties currently have over-the-counter sale of gerovital. Dr. Bennett stated that they are aware that it is used in many countries. Senator Neal questioned if the metabolism of european people is any different than that of people in America. Dr. Bennett stated that his personal belief is that the metabolism of all human beings is essentially the same.

Dr. John Carr, Health Officer, Health Division, read into the record the statement received from the FDA (Exhibit "B").

Senator Faiss questioned if Dr. Carr had any idea of how long it would be before the FDA endorsed the product. Dr. Carr stated that he had no idea.

Dr. Carr stated that the Health Division has taken no position on the drug either during this session or during the last session. Chairman Ashworth questioned if it was difficult to have a new drug approved by the FDA and if drug manufacturers were attempting

to have their drugs proven in Europe due to this difficulty. Dr. Carr stated that it is difficult to have new drugs approved but was uncertain as to the degree of having drugs proven in Europe because of that fact.

Senator Blakemore questioned if this country was possibly too restrictive in allowing drugs that seem to be beneficial to the people. He questioned why it takes so long to have a drug approved. Dr. Carr stated that the preponderance of feeling is that it takes too long to have a new drug approved in this country; he said the FDA feels they have shortened the time to some extent.

Dr. Carr stated that Rom-Amer has been the only company that has been producing any product which was the outgrowth of the laetrile/gerovital legislation last session. In relation to the budget, Dr. Carr stated the Division has not spent as much money as was expected; of the $81,772 per year, approximately 3/8ths of that money has been spent to date. He also stated that the Division has received very good cooperation with Rom-Amer Pharmaceuticals, Ltd.

Mr. Marvin Kratter, Rom-Amer Pharmaceuticals, Ltd., stated that upon close examination of the FDA statement, they have not raised any questions regarding the safety of the drug. Also, he said that approximately 600,000 capsules have been distributed since January 10, 1979 and have yet to receive any complaints about side-effects or problems with the drug. He said that any side-effects may be attributable to the contents, such as novocaine, but the labeling of the drug clearly indicates that if there are any allergies to novocaine or xylocaine, the drug should not be used. He said that he was aware of no drug that did not have some manifestations of reactions in some people; however, there is a 20-year history on gerovital. He said that due to the drug's increased popularity, it is being "bath tubbed" in Mexico which has not been inspected by the State nor any taxes paid. He said that he believes the State has saved a great deal of money due to their effective cooperation; also, the 3/8ths of the budget expended by the State was covered by Rom-Amer's licensing fee. He stated that he believed the State will benefit based upon the increased sales rates, even under prescription. In response to the FDA's statement, Mr. Kratter noted that the FDA has not as yet appeared before the Nevada Legislature on the proposed legislation to delegalize the drug. He said the FDA has attempted to assert jurisdiction over Rom-Amer but has been unsuccessful. Mr. Kratter stated that he withdrew their clinical research activities because after he testified before the 1977 session of the legislature, he received notification from the FDA stating that his testimony was in violation of the Food and Drug Act; he said that as this constituted a violation of the permission given to clinically test the drug, he felt there was no sense in remaining under their jurisdiction.

Chairman Ashworth questioned if Mr. Kratter felt it was important to have a statement from the FDA. Mr. Kratter stated that he believed so but felt a representative should have been present.

Mr. Kratter stated that he had supplied the past session of the legislature with a study conducted by Duke University that indicated a time period of 8 years and $24 million until the drug is admitted, if ever, for use in country. He also said that American pharmaceutical companies are using tax-free dollars to gain acceptance for their products in other countries. He stated that since the FDA has acquired the right to rule on efficacy of a drug, as distinguished from safety, the rate of new drug innovation in this country has decreased almost 75 percent. He said this problem is being addressed by an attempt to obtain Congressional approval for what is termed, "break through drugs." He said he could not understand why a product that is being sold in 60 countries and has a 20-year history cannot be approved by the FDA. He noted that the oral form of the drug is being addressed, not the injectible form.

Mr. Kratter stated, for the record, that Rom-Amer Pharmauceticals, Ltd., is a publicly-owned company; he emphasized that he believes in the product and has no personal profit motive. He said that the FDA has never declared gerovital to be unsafe; he said his company has not been able to prove its efficacy to their satisfaction despite the fact that the FDA gave permission to inject this drug into over 1,000 patients, without one adverse reaction.

Senator Neal questioned how the drug would be sold over-the-counter and whether or not it will be sold at a reduced rate than the present cost. He questioned the cost of producing the drug and what the cost will be to the public. Mr. Kratter stated that the drug is being marketed at a price of $.30 per capsule; the pharmacies have been selling it at a price of $.50 per capsule. He said that as the useage has increased, the retail price has dropped to $.40 per capsule in some pharmacies. He said, as to the future costs, that this would be based upon the volume. He projected that making the drug available over-the-counter could increase the present sales by double or triple the amount. He felt the price of the product could be reduced by 1/3 or perhaps more; the price could be approximately $.20 per capsule to market. He said that eventually the cost could be between $.12 and $.15 per capsule to produce dependent upon the volume; the present cost is approximately between $.20 to $.22.

Mr. Kratter stated that Rom-Amer's plant is now subject to the equivalent of FDA's regulations; in addition, the employees are subject to a background investigation. Mr. Kratter said that he believed it significant that a member of the Nevada Medical Association is not present to speak in opposition to S.B. 574. Chairman Ashworth stated, for the record, that he had received word that the State Medical Association has no position for or against the bill and chooses not to appear.

Mr. Kratter stated that a difficulty encountered to lower the price of the drug was the inability to obtain products' liability insurance. He said they have since succeeded in obtaining this insurance from Lloyd's of London who wrote it, he stated, because

they were aware of the British government's experience with the drug. Senator Neal questioned the amount of the coverage. Mr. Kratter stated that it was for $500,000 per incident.

Senator Kosinski arrived for the meeting (9:23 am).

Mr. Kratter requested the committee's support of S.B. 574. He stated that he had not previously met many of the individuals who were present to testify in support of the bill. He said that they called to volunteer based upon a newspaper statement made that many senior citizens could not afford to come and appear; he said they are not being paid for their testimony but their transportation costs are being paid.

Senator Neal questioned if the product liability insurance would apply should over-the-counter sales be instituted. Mr. Kratter stated that it would.

Chairman Ashworth questioned if the bill only addresses the issue of gerovital. Dr. Bennett stated that it did.

Mr. Leo Henrickson, Citizen, gave testimony to the committee in support of the merits of gerovital. He stated that in addition to aiding arthritic conditions, he has found his concentration and retention facilities have improved. He stated that his contemporaries with the Teamsters Union, retired members, have also expressed their support. He spoke in support of S.B. 574 so the drug would be available to individuals on a fixed income that would be assisted by obtaining gerovital.

Senator Young questioned if Mr. Henrickson believed the cost would decrease should the drug be available over-the-counter. Mr. Henrickson stated that he believed it would. Senator Young questioned if many of these people would not receive a physical prior to taking the drug. Mr. Henrickson said that he believed they would not.

Ms. Elizabeth Hecker, Citizen, spoke in support of the merits of gerovital. She stated that she went to see a doctor who gave her a prescription for 3 bottles of the drug at a cost of $105. Chairman Ashworth questioned if she had been examined and she responded, "No, not at all." She stated that she believed the cost was too high for people on fixed incomes who need the drug. She requested the committee support for over-the-counter sales of gerovital. She said she has lived in the senior citizen center for the last 11 years and is 74 years of age.

Dr. Art Singer, Citizen, who is an attorney and certified public accountant, stated that he is not a shareholder in Rom-Amer and has no financial interest in the outcome of S.B. 574. He said that his health and continuing well-being is at stake giving him a different type of interest. He said that he is 56 years old and enumerated the merits of gerovital to the committee. He advocated the committee's support of S.B. 574.

Senator Young expressed concern about the long-range effects of the drug. He questioned the long-range affects and the accessibility of making it an over-the-counter drug. He questioned how to be certain that something made available this easily might not become a "nightmare" later. He questioned justification in proceeding without the guidelines that may come from the FDA.

Dr. Singer stated that there is a history of the use of this drug in european countries for the past 20 years with no adverse effects. He said that most people utilizing the drug are older and would settle for an additional 20 or 30 years. Senator Young expressed concern that, as an over-the-counter drug, younger people will be utilizing the drug. Dr. Singer stated that its intent is to inhibit the effects of aging and until these effects are experienced, the drug would probably not be utilized. Senator Young took exception as he believed this would be impossible to predict. Dr. Singer stated that there is no substance available, including air and water, that may not eventually have an effect on health.

Ms. Ruth Becker, Citizen, stated that she is an active volunteer in health-orientated organizations. She said that she has a crippling cervical spine condition due to an illness. She stated that she was taking large doses of codine and valium that were not effective. She said that since taking gerovital, it is on rare occasion that she utilizes any other drug. Ms. Becker stated that she works with senior citizens and handicapped individuals and would like to see the drug available at an affordable cost as she believes it would be beneficial to them. She requested the committee's support of S.B. 574.

Ms. Joyce Bartmus, Citizen, stated that she went to Romania over four years ago to obtain the drug. She stated that she has a severe arthritic condition and is allergic to many other drugs but has found relief with gerovital. She stated that she has had no adverse side-effects with the drug and her doctor hesitates to prescribe any other medication. She stated that she believed gerovital to be a "safe drug."

Ms. Mary Ann Weatherwax, Citizen, gave testimony to the committee as to how gerovital had helped her physical condition since experiencing a coronary and other ailments. She stated that she takes no other medication.

Senator Young questioned if she believed individuals should see a physician as to taking gerovital. Ms. Weatherwax stated that she did not believe so based on the amount of prescribed medication she had taken in the past, which she should not have taken. She said she did not believe it would do a youngster any harm should they take the drug.

Mr. Edward Seremba, President of Save Our Seniors, stated that the members insisted he come and testify in support of S.B. 574 on their behalf. He submitted Exhibit "C" for the record.

Ms. Ruby Frankfort, Citizen, stated that she would like to refute

the fact that you have to be a senior citizen to enjoy the benefits of gerovital. She gave testimony to the committee as to how the drug had helped her physical problem and stated her belief that the drug should be more readily available to people.

Mr. Kratter stated that he wished to respond to Senator Young's concerns. He said that he shared his concerns but said he would not, under any circumstances, lend his name or expend his time or investment to anything that would harm other human beings. He stated that the questions raised are valid but should the principle be followed that no drug can ever be used in this country until it has been tried for 30 years, he believed that individuals will die this year because they are not allowed to use drugs of choice. He stressed that there is no safety problem with this drug. He said he did not believe that senior citizens or people who can be helped by this drug should be deprived of it because someone may misuse it. He stated that he did not believe legislation would stop that possibility regardless.

Mr. Kratter stated that he could understand the pharmacists point of view. He said that at the present time, the pharmacists have absolute control of gerovital. He stated that if it is legal to do so, he does not intend to have the drug sold anywhere but in pharmacies; he was not certain as to the legality. Chairman Ashworth questioned if he would be agreeable to amending the bill in that manner. Mr. Kratter stated that he would be agreeable but expressed concern that the bill may be unconstitutional. He stated that he has gone on record with the pharmacists that they do not intend to change the distribution technique; however, if they are forced, they may have to do so. He said it was not of benefit to the company to have exposure of the type referenced by Senator Young.

Senator Young questioned why the drug had not been processed through the FDA. Mr. Kratter stated that it would take 8 years and $24 million; also, his predecessors had so offended the FDA that he believed the drug would never be approved.

Dr. George Bennett stated that the Board of Pharmacy exists for the protection of the public; this statement is in reference to Mr. Kratter's testimony that the Board of Pharmacy is interested in seeing the drug sold in pharmacies. He stated that the pharmacists' association would be interested in seeing the drug sold only in pharmacies; the Board of Pharmacy has not discussed this position. He also felt there may be a constitutional problem should the drug only be sold in pharmacies.

Dr. Bennett stated that the basic philosophical question regarding drugs is should they be "safe and efficacious" or should they be only "safe." He stated that Congress determined that they should be both safe and efficacious. He said that Rom-Amer makes no claim for a specific use of their product but, based on testimony, he enumerated the uses of the drug. He questioned the use of this drug when individuals should be under a physician's care and expressed

concern that people will be diagnosing their own conditions thereby denying themselves the proper medical care. He said that he shared the concern as to the cost of the product. He concluded by stating the Board agrees with the position of the FDA and stated his belief that it is in the interest of the public that the drug be sold by prescription as it is now.

Senator Neal questioned the price per capsule that the pharmacies charge. Dr. Bennett stated that he believed the prices were between somewhere above $.30 to $.50 per capsule. He said that more than one-third of the pharmacies in the State distribute the drug. He said that he believed that as the competition increases, the price will decrease.

As to the product liability insurance, Senator Neal stated that there appeared to be a great deal of credibility as to the safety placed on the drug. Dr. Bennett stated that there was no question as to the safety during the hearing; rather, if the drug is efficacious. He said the issue is if the drug should be sold over-the-counter.

Senator Faiss questioned if the Board had received any complaints on the drug. Dr. Bennett stated that there had been no official complaints of any kind concerning the sale of the drug. Senator Faiss questioned if he believed this to be in the drug's favor. Dr. Bennett stated that he did to the degree that the sales have been made up to this point.

Senator Kosinski stated that he was confused as to Dr. Bennett's comment that it was not in the interest of the public to have the drug sold over-the-counter. He stated that testimony had indicated that the drug is being prescribed without a physical examination and questioned how individuals are served by having a law in effect that requires a prescription. Dr. Bennett stated that he believes the criticism should be of the physician as the proper examinations are not being conducted. Senator Kosinski questioned if a provision should be in the law stating that a physical examination is a pre-requisite to prescribing the drug. Dr. Bennett stated that it is inferred in the Medical Practice Act and the physician can be subject to charges of malpractice. Senator Kosinski questioned justification to making the drug available over-the-counter; however, should the safety of the drug be established to his satisfaction, he stated that he could not justify requiring the drug to be available by prescription only. Dr. Bennett stated that he did not believe the safety of the drug was in question; rather, that individuals will diagnose their own ailments. Senator Kosinski stated that is presently the case with any vitamins or minerals that are readily available. Dr. Bennett stated that the FDA's position is that there has not been widespread testing to prove the efficacy of the product for many of the conditions for which it is used. He acknowledged that it does take a considerable amount of time and money but stated that the drug's efficacy has still not been proven.

Senator Young questioned if there was any problem of synergistic

reactions with other drugs. Dr. Bennett stated that there was a warning of that possibility; he stated that he was uncertain. Senator Young questioned if there had been any testing in this area. Mr. Kratter stated that tests were conducted prior to their receiving the INDs (Investigational New Drug Permit).

Ms. Francis Struzel, Citizen, stated that there is a book that completely explains gerovital and its effects. She stated that she was convinced the product is beneficial and requested that the committee read the book.

Chairman Ashworth closed the hearing on S.B. 574.

There being no further business, the meeting was adjourned at 10:24 am.

Respectfully submitted,

Roni Ronemus
Committee Secretary

Approved:

Chairman
Senator Keith Ashworth

EXHIBIT "A"

SECTION 1. Title 42 of NRS is hereby amended by adding thereto a new chapter to consist of the provisions set forth as sections 2 to 7, inclusive, of this act.

SEC. 2. 1. A license, issued by the state fire marshal, is required for
(a) manufacturer of fireworks
(b) wholesaler of fireworks
(c) importer and exporter of fireworks
(d) public display of any type of fireworks
(e) pyrotechnic operator
(f) pyrotechnic operator for special effects
2. Applications for licenses must be made on a form prescribed by the state fire marshal.
3. The state fire marshal may conduct inspections, examinations or hearings before the issuance of licenses.

SEC. 3. The state fire marshal may charge a reasonable fee, to be fixed by regulation, for inspection and issuance of license and testing and approval of fireworks.

SEC. 4. If any person is denied a license by the state fire marshal, he is entitled to a hearing, upon request, before the state fire marshal's advisory board. Failure to pass tests or examination does not constitute grounds for hearing.

SEC. 5. The state fire marshal may appoint, within the limits of legislative appropriations, deputies and such staff as is necessary to the performance of his duties as required in this chapter.

SEC. 6. 1. Any person who sells, gives or delivers any dangerous fireworks to a person who is under the age of 18 years:
(a) is guilty of a gross misdemeanor; and
(b) if convicted of a second or subsequent violation of this subsection, shall be punished by imprisonment in the county jail for 1 year and by a fine of not less than $500 nor more than $1,000. No court may grant probation to a person convicted of a violation of this paragraph, or suspend a sentence imposed upon such a person.
2. Any person who violates any other provision of this chapter or any regulation adopted pursuant to this chapter is guilty of a gross misdemeanor.

SEC. 7. NRS 244.367 is hereby amended to read as follows:
244.367 The governing political body of any city or county jurisdiction within the state of Nevada may pass ordinances prohibiting, restricting, suppressing or otherwise regulating the sale, use, storage and possession of fireworks that are more restrictive than the regulations contained within this provision.

NDR 32

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3:45 pm

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EXHIBIT "B"

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OAAUIJAZ RUEVFJQ0008 1302050-UUUU--RUWLSKP.
HWFD
FM FDA/EDRO/FRANK D ARNOLD, PH D/HFO-310/DHEW/ROCKVILLE MD
TO RUWLSKP/ATTN: ROD WILKS/ACTG CH/BUREAU OF CONSUMER
HEALTH PROTECTION SERVICES
INFO: SAN FRANCISCO REGIONAL OFFICE
INFO: SAN FRANCISCO DISTRICT OFFICE
BT

IN RESPONSE TO A REQUEST FROM SENATOR KEITH ASHWORTH, CHAIRMAN, HUMAN RESOURCES COMMITTEE, NEVADA STATE SENATE, RELAYED TO THIS OFFICE BY MR JAMES A. EDMUNDSON, CHIER, BUREAU OF CONSUMER HEALTH PROTECTION SERVICE, WE ARE PROVIDING THE FOLLOWING FOOD AND DRUG STATEMENT ON GEROVITAL. SENATOR ASHWORTH DESIRED RECEIPT OF THE STATEMENT BY 8:30 A.M. FRIDAY, MAY 11, 1979.

PAGE TWO RUEVFJQ0008

"FOOD AND DRUG ADMINISTRATION STATEMENT ON GEROVITAL H3"

GEROVITAL H3 IS THE TRADE NAME FOR A PRODUCT PROMOTED FOR MANY YEARS AS BEING EFFECTIVE IN TREATMENT OF VARIOUS MANIFESTATIONS OF THE AGING PROCESS. ALTHOUGH MANY ARTICLES HAVE APPEARED IN THE LAY PRESS ON THE USE AND EFFECTIVENESS OF GEROVITAL AS A REJUVENANT IN ELDERLY INDIVIDUALS THERE HAS BEEN NO SCIENTIFIC OR MEDICAL EVIDENCE TO SUPPORT SUCH CLAIMS.

GEROVITAL H3 IS THE TRADE NAME FOR AN INJECTABLE, LOCAL ANESTHETIC, PROCAINE HYDROCHLORIDE, WHICH HAS BEEN USED IN THIS COUNTRY FOR LOCAL ANESTHESIA, SPINAL ANESTHESIA AND NERVE BLOCK AND IS SOLD UNDER THE BRAND NAME OF NOVOCAINE AS WELL AS OTHER NAMES.

SEVERAL YEARS AGO, ROM-AMER SUBMITTED AN IND TO FDA SEEKING PERMISSION TO STUDY GEROVITAL H3 IN DEPRESSION IN ELDERLY PATIENTS. FDA WAS INTERESTED IN ASCERTAINING WHETHER THE DRUG IS EFFECTIVE IN THE TREATMENT OF MENTAL DEPRESSION NOT ONLY IN THE ELDERLY BUT IN OTHER PATIENTS AS WELL. FDA'S DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS SPEND CONSIDERABLE TIME ADVISING THE SPONSOR ON APPROPRIATE STUDY DESIGNS.

ROM-AMER SPONSORED SEVERAL CONTROLLED DOUBLE-BLIND STUDIES BUT TO DATE NO ACCEPTABLE STUDIES HAVE CLEARLY DEMONSTRATED EFFICACY. ON DECEMBER 30, 1976, THE MANAGEMENT OF ROM-AMER SOLD THE MAJORITY OF ITS STOCK TO MARVIN KRATTER, A NEVADA RESIDENT.

EXHIBIT B

IN 1977, THE NEVADA STATE LEGISLATURE ENACTED A LAW TO LEGALIZE GEROVITAL H3 WITHIN THE STATE (IT WAS PART OF A LAETRILE LEGLIZATION LAW). IN MAY 1977, AFTER THE LAW PASSED, MR KRATTER NOTIFIED FDA THAT ROM-AMER WAS DISCONTINUING ITS CLINICAL RESEARCH PROGRAM AND WITHDRAWING ITS IND. IN A PUBLIC STATEMENT MR. KRATTER HAD INDICATED HIS INTENTION TO MARKET GEROVITAL H3 IN NEVADA.

AT PRESENT TIME THERE IS NO SCIENTIFICALLY ACCEPTABLE EVIDENCE THAT GEROVITAL H3 IS SAFE AND EFFECTIVE FOR TREATING MENTAL DEPRESSION OR MANIFESTATIONS OF AGING. FDA IS CONCERNED ABOUT THE PROMOTION AND USE OF THIS PREPARATION BEFORE ADEQUATE TESTING IS DONE.

BECAUSE THERE HAS BEEN NO VALID EVIDENCE TO ESTABLISH THAT THE DRUG IS EFFECTIVE FOR USE OTHER THAN AS A LOCAL ANESTHETIC IT REMAINS AN UNPROVEN NEW DRUG FOR ANY OTHER USE AND IS SUBJECT TO THE REQUIREMENTS OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT. GEROVITAL H3 MAY NOT BE INTRODUCED INTO INTERSTATE COMMERCE, USED TO TREAT HUMANS, SOLD OR PROMOTED FOR USES WHICH HAVE NOT BEEN APPROVED BY FDA IN ACCORDANCE WITH FEDERAL STATUTES. IN ADDITION, DRUGS DISTRIBUTED WITHIN A PARTICULAR STATE THAT ARE MADE FROM COMPONENTS THAT HAVE MOVED IN INTERSTATE COMMERCE FALL WITHIN THE JURISDICTION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AS WELL. THE SHIPMENT OF GEROVITAL, H3 FROM OR INTO ANY STATE IS NOW ILLEGAL UNDER FEDERAL LAW AND THE

SPONSORS, PROMOTERS, DISTRIBUTORS, DISPENSERS, OR SELLERS OF THE DRUG, ARE SUBJECT TO THE APPLICABLE PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

IN SUMMARY, GEROVITAL H3 IS NOT AN APPROVED DRUG FOR ANY INDICATION. ITS ENTRY INTO INTERSTATE COMMERCE IS A VIOLATION OF FEDERAL LAW. STATE LEGISLATION OFFERS GREAT POTENTIAL FOR PROMOTING ITS ILLICIT USE IN PURPORTING TO TREAT THE MANIFESTATIONS OF OLD AGE. THIS SITUATION IS BEING CLOSELY MONITORED BY THE FOOD AND DRUG ADMINISTRATION.

GR: 580/DVU

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EXHIBIT "C"

Good morning! 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

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 ~~most prevalent~~ 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 ~~envision~~ SEE on a person who lacks personal transportation an d personal funds and he just trys 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 ~~unconscionable.~~ 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.

I am not, personally, a stranger to the laboratories and to pharmacology. I studied for some years the use of new pharmaceutical developments on livestock. I have ~~amputed~~ amputated the legs of ~~any~~ MANY an animal, and kept them in the deepfreeze, and looked into them to see what could have happened to make this particular animal lame and that one walk with a limp.

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, ~~that part of the~~ PARTICULARLY 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.

EXHIBIT C

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 in 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.

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