IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

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UNITED STATES OF AMERICA, Plaintiff, vs. An article of food consisting of the following: 60 cases, more or less, each containing 12/50-tablet bottles ... all labeled in part: ... (bottle) "Aangamik 15 Calcium Pangamate (a salt of Pangamic Acid)", Defendant. FOODSCIENCE LABORATORIES INCORPORATED, Claimant.	CONSOLIDATED CASES Nos. 77C 662, 77C 3314, 77C 1647, 77C 1526, 77C 4219, 77C 3210

DEPOSITION OF:

JERZY W. MEDUSKI

November 7, 1978

REPORTED BY:
ROBERT MORRIS
CSR No. 3318

SCHILLER & COMBS, INC.
COURT AND DEPOSITION REPORTERS
625 POLK, SUITE 305
SAN FRANCISCO, CALIFORNIA 94102

p37 - type of tests necessary but not performed.
p39 - didn't know how someone else worked it
p.40 - [illegible]
p42 - no subchronic feeding studies w/ di-methylglycine + other studies.
p43 - not conducting general toxicity studies
p50 - other scientists struck

I N D E X

Deposition of Jerzy W. Meduski
November 7, 1978

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EXHIBITS

For the Plaintiff:

No.	Description	Iden.
1	Document entitled "Calcium Pangamate, A Comparative Report, DaVinci Laboratories"	32
2	Copy of document entitled "United States Patent Office," No. 3,033,868, Patented May 7, 1963	47
3	Document bearing the heading "The Metabolism of Dimethyglycine by Liver Mitochondria," Vol. 232, 1958	58
4	16-page document from The American Journal of Clinical Nutrition, entitled "Biosynthesis of Choline and Betaine"	59

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BE IT REMEMBERED that, pursuant to Notice of Taking Deposition, and on Tuesday, November 7, 1978, commencing at the hour of 10:15 a.m. thereof, at Morgan Hall, Room 238, University of California, Berkeley, Berkeley, California, before me, ROBERT MORRIS, a Notary Public in and for the County of Alameda, State of California, personally appeared

JERZY W. MEDUSKI,

called as a witness herein, who, having been first duly sworn, was examined and testified as hereinafter set forth.

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JAMES T. HYNES, ESQ., Assistant United States Attorney, Northern District of Illinois, 219 South Dearborn Street, Room 1500, Chicago, Illinois 60604; and RONALD L. CRAIG, ESQ., Trial Attorney, Food and Drug Administration, Office of the General Counsel, GCF-1, 5600 Fishers Lane, Rockville, Maryland 20857, appeared as counsel on behalf of Plaintiff United States of America.

BASS, ULLMAN & LUSTIGMAN, by ROBERT ULLMAN, ESQ., 747 Third Avenue, New York, New York 10017, appeared as counsel on behalf of Claimant Food Sciences Laboratories, Incorporated.

ALSO PRESENT: ROGER V. KENDALL.

It is stipulated and agreed by counsel for the respective parties that the deposition be taken pursuant to the Federal Rules of Civil Procedure.

It is further stipulated and agreed by counsel for the respective parties that all objections, except as to the form, would be reserved until the time of trial and that said objections would have the same force and effect as if interposed at the time of the taking of the deposition.

It is further stipulated and agreed by and between counsel for the respective parties and the witness that the reading and signing of the deposition is expressly reserved, and that the signing of the deposition will be obtained within 30 days after delivery by the reporter to counsel.

It is further stipulated and agreed by and between counsel for the respective parties that the deposition will be deemed signed and filed with the clerk of the respective court after the 30-day period.

It is further stipulated and agreed by and between counsel for the respective parties that in the event additional time is required by use of the mails the 30-day period will be extended accordingly.

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EXAMINATION BY MR. CRAIG

MR. CRAIG: Q. Please state your name for the record.

A. Jerzy W. Meduski, Ph.D.

Q. Would you give us your home address and your business address?

A. Home address, 1066 South Genessee Avenue, Los Angeles 90019.

And the business address is S.C., School of Medicine, 1411 Eastlake Avenue, Los Angeles 90033.

Q. Dr. Meduski, have you ever been deposed before?

A. No.

Q. Have you ever testified before?

A. No.

Q. By whom are you employed, Dr. Meduski?

A. USC, School of Medicine.

Q. Any particular department?

A. Neurology.

Q. Department of Neurology?

A. Neurology.

Q. Are you working there full time --

A. Yeah.

Q. -- in the Department of Neurology?

A. Yeah.

Q. Are you affiliated with any other particular

department?

A. Yes, I am teaching outside of the daywork in the Department of Biological Sciences.

Q. Okay. Now, the Department of Neurology is under the School of Medicine; is that correct?

A. Yes.

Q. But the Department of Biological Sciences, that's separate?

A. It's preparing pre-med, pre-dent and pre-pharmacy students and any other biology majors, all the people taking biology classes.

Q. How long have you worked with the Department of Neurology?

A. Since -- I think it was about four years or five years -- four years.

Q. Who is your supervisor?

A. Dr. Van der Meulen, who is Chairman of the Department of Neurology and also Vice-President of USC for Health Sciences in charge of medicine, dentistry and pharmacy.

Q. Who is your supervisor at the Department of Biological Sciences?

A. I don't have a supervisor in the Department of Biological Sciences. I teach three classes without any supervision as an independent scientist.

Q. How long have you been with the Department of

Biological Science?

A. I -- I never was a member of the Department of Biological Science, never.

Q. How long have you been teaching those three classes?

A. About four years, more or less, or five years.

I was teaching -- if this is interesting to you, I was teaching Principles of Biochemistry, which is four credit class. I'm teaching Introduction to Biochemistry and Cellular Physiology, a credit class, and I teach also the class which I introduced at USC, Nutritional Biochemistry, Advanced Biochemistry class with lab for credit point 438LX.

Q. What is the nature of your work with the Department of Neurology?

A. I am doing research dealing with interaction of molecular oxygen with living organisms under influence of nutrients, active biological substances or the conditions of the living organism. I am studying on the cellular level and organic level and subcellular level the events.

Q. What other departments under the School of Medicine have you worked with at USC?

A. I was in the Department of Pharmacology, because I am both M.D. and Ph.D., Biochemistry; and I am specially trained in pharmacology. I worked in the Department of Pharmacology.

Q. Who was your supervisor in the Department of

Pharmacology?

A. The Chairman of the Department of Pharmacology is Dr. Samuel Bessman.

Q. And how long did you work with Dr. Bessman?

A. I think one year or one -- not more than one or one and a half years.

Q. What was the nature of your work with Dr. Bessman?

A. I didn't work with him directly. I was studying the problem, my nine-year-old studies on the mechanism of activity of certain bacterial toxins. I was studying the hemolysis caused by certain bacterial toxins. And as a result of those studies I prepared and defended new explanation of activity of certain gangrene-producing microorganisms.

Q. The nature of this work, was it laboratory research or was it library research?

A. Pure laboratory research and ended with publication in Switzerland in Experientia as a scientific journal published in Switzerland. And this work, by the way, was later on discussed. And if you would like to have the opinion of other people about this work, you should read one of the issues of Bacteriological Review where this work is discussed.

Q. Why did you leave the Department of Pharmacology?

A. Because I suggested to the Department of Pharmacology that they should be interested in nutrition besides pharmacology.

I gave the first course in pharmacology in nutrition in the Department of Pharmacology.

I gave them the outline, that they should expand in the area of pharmacology, and they decided to do this work without my help. And in the same time I got the possibility to study laboratory, new laboratory work in nutrition with a grant, governmental grant on Vitamin B12. And I was studying this using the grant, governmental grant awarded to Dr. Dubinoff. He was -- he was studying B12, and he died because of retro-ocular neoplastic growth.

And after checking my credentials, NIH agreed for me to continue until expiration of this grant study. And I was given the chance to be independent. I was given the complete lab, and I moved over there, and I started to build up my own lab. At the moment I have my own independent lab within the Department of Neurology. I recently received utilization of new premises. I expanded, sort of, so I'm very happy with this.

Q. Have you worked with any other departments?

A. Not in the University, no.

Q. Never worked with the Department of Physiology?

A. No, never.

Q. Where did you work previous to the Department of Pharmacology?

A. I worked at USC, that's how I know.

Q. Previous to your working with USC, where did you work?

A. At UCLA.

Q. UCLA?

A. Uh-huh. I worked in UCLA in the Department of Medical Microbiology and Immunology. The Chairman was Dr. Rasmussen, and I worked over there on problems of testing -- I was studying synthesis of tryptophane in certain micro-organisms, and I discovered new pathway leading to tryptophane formation. This discovery has been recognized, and in this book (indicating) they recognize this discovery. They wrote the fact that I discovered this while working at UCLA, and you could get this (indicating).

MR. ULLMAN: Do you want to identify the book, Doctor?

THE WITNESS: Yes. An Introduction to Metabolic Pathways by Dagley and Nicholson, published by John Wiley.

MR. CRAIG: Can you --

MR. HYNES: I'd like the date of the publication, that's all.

THE WITNESS: One moment. This transition was discovered by me, and you could --

MR. CRAIG: Q. What page?

A. Page 237.

Q. I think you've answered the question.

A. No. No. No. I will try to answer it completely.

Oh, here it is here, Meduski and Zamenhof, 1969 studies on tryptophane synthesis from various strains of bacillus subtilis, published in Britain Journal of Biochemistry, Volume 112, Page 285.

Q. The reference is on Page 317?

A. Page 317.

And at this time when I was at UCLA I worked out a micromethod which makes possible the discovery because the methods in existence were not scientific enough.

Q. Can you tell me, Dr. Meduski, between what years you worked at UCLA?

A. Between 1965 and 1969, I believe.

Q. Was there any other department other than Microbiology that you worked at UCLA?

A. Officially employed, I was not. I was -- yes, in the very, very beginning I worked in the Department of Bacteriology. I worked as a technician for $500 monthly. I was at this time not yet a citizen of this country and none of my credentials were recognized by people from UCLA.

Q. Where did you work previous to UCLA?

A. Previous to UCLA I worked at the Scripps Clinic and Research Foundation in La Jolla. This is one of the best clinical centers in this country.

Q. What state is that in?

A. It is in California.

Q. California?

A. In San Diego. It is north of San Diego. It is Scripps Clinical and Research Foundation, is the place where I could meet -- among the patients, wife of Goldwater; this is the place.

Q. What kind of work did you do there?

A. I was studying -- I was doing two things: One, I was cooperating in work where my money came from; and the other I was given opportunity to do my original work.

In the work where I cooperated, I worked on the polarization of florescence at the heat which makes it possible to determine combination of two proteins together or protein or non-protein tied together. It is highly sophisticated biophysical technique which uses instrumentation not available, so to speak, on the market but constructed in the laboratory.

And in the work of which I was doing my own work, I was studying the same toxin, which I later on was studying at USC, the toxin which is called alpha toxin of gas gangrene producing microorganism, and I discovered the presence in human serum of the proteins which are active this toxin.

Q. Doctor, you mentioned that you had a Ph.D. and M.D.; is that correct?

A. Uh-huh.

Q. Can you tell us where you received your M.D.?

A. I received M.D. in the University of Warsaw in

Poland, and all that data connected with my M.D. you can find out in AMA because I was checked by American Medical Association and entered in the Master File of Physicians of this country. And if you'd go to the list of physicians in California, you will find out my name.

Q. You received that degree in 1946?

A. In November 1946. Later on I received practitioner's certificate after doing necessary internships and residencies. I have practitioner's certificate in Poland.

Q. What states in the United States are you licensed to practice?

A. I am theoretician, and I never practiced in Poland. I don't intend to practice here.

Q. So you're not licensed in any state?

A. I am. There are states where I would be able to practice and while practicing passing Federal Board Examination but I am theoretician.

Q. I just want to get this: Are you saying that as of now presently you are not licensed to practice in any state?

MR. ULLMAN: He answered your question, Mr. Craig. Do you want to hear it back?

Off the record one moment, please.

(Record read.)

MR. CRAIG: Q. Could you tell me then, Doctor, what states you are licensed to practice?

A. No, no. This is wrong question, which means that you misunderstood my previous answer.

I said that I have chosen not to follow the life of the practitioner. I was trained many years. Five years after I received my Medical Degree, I received another degree in Biochemistry; it's called exactly Doctor in Philosophy of Animal Physiology, specialty Biochemistry; another university in October '51. I was trained specially, sent by United Nations to Poland to the Dutch State Institute of Hygiene to study the way to check correctness of drugs in a country.

I received fellowship, and I have the Xeroxed copies to support this. And I organized in Poland Division of Pharmacology in Polish Institute of Hygiene. I was responsible between 1946 and 1952 for quality control of all drugs marketed in Poland.

Q. Doctor, I do not have reference to your Medical Degree and not the Ph.D. in Biochemistry.

Wait just a second.

I asked first where you were licensed to practice in any particular state, and I think you answered that you had taken the Federal Board --

MR. ULLMAN: He did not answer that. That is an improper question.

THE WITNESS: You don't -- I simply -- please write down. You simply don't understand the problems involved.

You should prepare yourself better for this type of discussion.

What I wanted to say, that AMA checked my medical preparation, offered me membership in AMA, and I was informed and sent folder about this, that there are states in the country where foreign trained physicians can start practicing while preparing for Federal Board.

In other words, if I wanted -- if I wanted to enter life as a practitioner, I had door open. But I disliked this endeavor. I am theoretician dealing with the theory of diseases and the factors which make a person healthy.

MR. CRAIG: Q. Thank you.

You mentioned, Doctor, that in Poland you were -- you worked with pharmacology?

A. No, I didn't work with pharmacology. After the Second World War I organized Division of Pharmacology of the State Institute of Hygiene in Poland because this division did not exist because of the war catastrophes, and I was in charge of this division. And I was responsible for pharmacological evaluations of all drugs marketed in Poland.

Q. Were you performing toxicity tests?

A. I was performing toxicity tests, biological activity tests, biological standardization tests, all tests which Dr. Kakoski requires at this moment for anybody who would apply for any application to do any decent preparation and put on the market, obviously.

Q. What are some of those tests that you just referred to?

A. Buy a book of toxicology and read it. I don't want to spend several hours going around all those pages. It's a waste of time. Or ask a consultant.

Q. You mentioned tests, the normal tests that should be done on a substance before it could be marketed.

MR. ULLMAN: Excuse me --

THE WITNESS: One moment. I received and I have in my pocket -- I received a letter from Dr. Charles Kakoski, and he listed on two pages all literature which is required in this country, which list requires of this country to be fulfilled before anybody can make any valuable application for any substance marketed not as a drug, for instance.

MR. CRAIG: Q. Now, when you were in Poland, were these the same kinds of tests that were --

A. You are --

Q. Let me finish.

Were these the same kind of tests that were required in Poland before a substance could be marketed?

A. Qualitatively they were the same. There were differences in details. But all those tests are basically following the rules of Biological Standardization Commission of the World Health Organization of the United Nations. And any country belonging to the United Nations and the World

Health Organization follows the advice with local modifications.

Q. Okay. When were you first contacted by Foodscience Laboratories?

A. They should correct me if I'm wrong, about three years ago. Two men arrived to my laboratory, one of them by the name Joe DeSilva and the other by the name of Guido Orlandi, and they asked me whether I am the man who gave in pharamacology a seminar discussing problems of so-called B15. I said, yes, I was the guy who did this because Pharmacology Department, USC, didn't know nothing about problems connected with pangamic acid. I asked them how they know about this? They said that DeSilva's co-worker has an uncle who was present at the seminar and he told them about this.

Q. Were you at that time asked to do work for Foodscience Laboratory?

A. No. No, they wanted me to -- first, we talked, and they said that they are interested in knowing something theoretical about the compound which they either, I don't remember, market or intending to market.

I said that I disliked to do practical work, but I have certain theoretical problems common with area of so-called -- why I say "so-called" because this is false name -- so-called B15.

Now, what are the common problems?

Q. I think you have answered the question.

A. But I will tell you something for just your benefit.

Do you remember when I said about Dubinoff that I was doing research on B12?

Q. Yes.

A. B12 and so-called area of B15 have one thing in common, one carbon unit metabolism.

Q. Doctor, I think we're going to get into that later on.

A. All right. All right. All right. I just wanted to explain to you.

Q. Right. Now, I'd like to kind of pursue this line of questioning. When were you first -- are you now contracted to do work for Foodscience Laboratories?

MR. ULLMAN: I'm going to object to the form of the question.

THE WITNESS: I can defend myself.

MR. CRAIG: Q. Are you now doing work for Foodscience Laboratory?

A. I received a yearly grant, and within this yearly grant I plan and I design the experiments which I want to do, which when completed will be published and which they consider important for them enough to give me this grant.

Q. When did you first receive this grant?

A. Last year. Last year, '77, I think. Yeah.

I recall '77.

Q. Are you also doing work for DaVinci Laboratories?

A. The grant was given to the University, not to me personally. The University established an account for me, and I can give you the number, if you like. And after the blessing of the University, after the money deposited at USC for my disposal through the University according to the rules of the University, I started to do research. And this is it.

Q. Doctor, my question -- my question was -- my question was: Are you doing work for DaVinci Laboratories?

A. The whole grant was signed and given by DaVinci. Yeah, it was DaVinci Laboratories research. And in my -- if you would look at my University activity chart, you will find that certain percent of my time is devoted to research sponsored by DaVinci Laboratories through the University. It doesn't go to me. It goes to the University. And I don't remember the account number.

Q. Okay. Doctor, what kind of work are you doing for them?

A. I am studying -- very simple, I can show you --

MR. ULLMAN: Answer the question.

THE WITNESS: I'm studying the metabolic effects of dimethylglycine in laboratory animals.

MR. CRAIG: Q. What do you hope to show by this?

A. Scientist doesn't work in order to hope to show

something. Scientist works in order to find out what occurs.

Q. So, Doctor, can you tell me what kind of tests you are running on dimethylglycine?

A. Again, this is very primitive question. I'm not running tests. I am designing experiments where one of the parameters sometimes is and sometimes is not dimethylglycine.

Q. Can you tell me some of the experiments? Could you describe them for me?

A. I take a rabbit, and I put this rabbit after anesthesia on the controlled respiration. I measure -- I set -- I'm setting up the measuring devices to measure venous blood pressure of this rabbit, arterial blood pressure of this rabbit, respiration of this rabbit. And I am introducing solution of, neutralized solution of, dimethylglycine into venous system of this rabbit, and I am following the changes of blood pressure, for instance. This is a very simple example.

Q. Okay. Are you conducting studies, safety studies on -- toxicity studies on dimethylglycine?

A. Before carrying out experiments of any metabolic value on any substance, the scientist must know within what range he can safely operate. I have not -- I cannot start any pharmacological studies without knowing beforehand the toxicity level of the substance I am studying. Therefore, it is obligatory for any work to find out the toxicity range

of the substances studied.

Q. Doctor, can you tell me what is pangamic acid -- excuse me. What is calcium pangamate?

A. Calcium pangamate, it is a name derived according to the rules of chemistry from an acid, pangamic acid, and it means calcium salt of pangamic acid, in the way as calcium sulfate means calcium salt of sulfuric acid.

Q. What is pangamic acid?

A. Pangamic acid according to definition accepted by some scientists is an ester of dimethylglycine and D-gluconic acid.

Q. Okay. Doctor, you mentioned that this is what some scientists in their opinion say pangamic acid is.

Can you tell me, is it your opinion, then, that there is no one generally recognized chemical structure for pangamic acid or calcium pangamate?

A. I would say that I did not read any dissenting work proving this factor of pangamic acid. I cannot --

Q. So there is some disagreement as to --

A. I think that this is correct. The structure of pangamic acid was never scientifically completely proven.

Q. So in the opinion of other scientists do some -- are there other scientists that believe that calcium pangamate or pangamic acid has a different structure other than D-gluconic acid and dimethylglycine?

A. No, I think that when somebody says pangamic acid, he must understand the ester structure, but how this ester is formed finally has not been, according to my opinion, irrevocably established.

Q. Doctor, are there some scientists that feel that pangamic acid is a mixture or is a -- excuse me -- is a mixture of calcium gluconate, diisopropylamine, dichloroacetate and glycine?

A. No scientist can put one name -- one compound on other compound. There are probably some people who are motivated by other -- other points of view than scientific who would use this type of name, but no scientist would put name of one compound and start calling something else this compound.

Q. Is calcium pangamate a mixture of -- can it be a mixture of gluconic acid and dimethylglycine?

A. If somebody is using scientific nomenclature correctly, when somebody says "calcium pangamate," it's a compound; it's a salt of pangamic acid; it means calcium salt of pangamic acid. It is not -- scientifically speaking this name cannot be used for a mixture.

Q. Can you describe for me how calcium pangamate, the compound, is made?

A. I don't know because I'm not interested in the making of compounds.

You should ask an organic chemist who is making this. I'm not.

Q. Can you explain for me how the mixture calcium pangamate and dimethylglycine is made?

A. Oh, most likely by putting those two compounds together and mixing them.

Q. There is no chemical reaction?

A. Mixture differs from a compound by the fact that in the mixture initially there is no chemical reaction, just mixture.

Q. Doctor, have you ever analyzed any samples of the seized product?

MR. ULLMAN: Objection. I don't know if the witness understands what you mean by the "seized product."

Are you referring now to specific lots of the article under seizure? Because I don't think the doctor has any idea of what the lot numbers are, if there are lot numbers or specific lots.

MR. CRAIG: Q. First of all, have you ever analyzed any official samples taken from the specific products that have been put under seizure?

MR. ULLMAN: Objection to "official samples." I don't think the doctor would have the slightest idea what you mean by that.

MR. CRAIG: Q. Any sample at all, Doctor?

Q. Yeah, I work out a method to find out whether a given sample represents an ester of dimethylglycine, and I worked out this method as a new approach. And when I worked out this method, I did some analysis, indeed.

MR. ULLMAN: Off the record.

(Discussion off the record.)

MR. ULLMAN: In the discussion that was just had off the record, it was clarified that Dr. Meduski did not have specific samples of lots of any of the products that were specifically seized in each of the actions that have been consolidated.

MR. CRAIG: Q. Doctor, have you ever analyzed Aangamik 15 tablets, calcium pangamate produced, manufactured by, distributed by Foodscience Laboratories?

A. Yeah.

Q. What did you find when you made your analysis?

A. I found very small amount of ester in the preparations.

Q. Can you then draw a conclusion that this is a mixture as opposed to a compound?

A. On the basis of this negative results, lack of esters, I could not say. For this it was necessary to identify the components of the mixture, which I did not do. I just wanted to know whether it is an ester or not, and I found there is very little.

Q. So you did not determine what the ingredients of

the mixture were?

MR. ULLMAN: He did not say that, Mr. Craig.

MR. CRAIG: Could you read it back? Would you read back his answer, please?

(Record read.)

THE WITNESS: Very simple. I was not interested.

MR. CRAIG: Q. Okay. What tests did you use, Doctor?

A. To get --

Q. To identify the ester content.

A. The color formation based on the production of hydroxamic acid derivative, the color formulation, colormetric test.

Q. Is that infra-red spectroscopy?

A. No, it was visual.

Q. Doctor, you said there was minimal ester content. Can you tell me how much in percentage?

A. I don't remember, but it was in some preparation two percent, I remember in one between two and nine, something like this.

Q. Two and zero?

A. No, two and nine.

Q. Nine.

A. As far as I remember. In some there was zero.

Q. Doctor, is it possible to conduct a study on a mixture, let's say a mixture of calcium gluconate and dimethylglycine and draw conclusions as to the safety of a

compound made up of calcium gluconate and dimethylglycine?

MR. ULLMAN: Object to the form of the question.

MR. CRAIG: I beg your pardon?

MR. ULLMAN: Object to the word "possible."

THE WITNESS: All right. All right.

MR. CRAIG: I was just asking if in his opinion can that be done?

THE WITNESS: It is possible, but it is scientifically unsound. It is much better to work with purified substances and simplified conditions.

MR. CRAIG: Q. Now, the reverse of that -- is it possible to conduct -- in your opinion, is it possible to conduct a study on the compound, let's say a compound of calcium gluconate and dimethylglycine and to draw conclusions as to the safety of a mixture, dimethylglycine and calcium gluconate?

A. If you know components of mixture and if you know response of living organism to each of the members of the mixture, then when you are working in the situation when there is no interaction within the mixture, you could say certain prediction about toxicity of the mixture.

Did I make it clear?

Q. Yes, I think so.

Why is it different conducting a study on the mixture and drawing conclusions and not be able to draw conclusions

as to the compound, and yet one can draw conclusions conducting a study on compounds?

MR. ULLMAN: Don't answer the question. I'm going to object to the form of the question because the doctor did not say it was not possible.

He said it was possible but scientifically that another procedure would be preferable.

If you want that read back, let's go back.

You asked him whether it was possible to conduct a study on a compound and to draw a conclusion on a mixture. His answer was that it is possible but scientifically something else is more desirable.

THE WITNESS: I wouldn't do it myself. I wouldn't do investigations where I would spend my time dealing with the stuff. Very simple.

MR. ULLMAN: There's no question pending, Doctor.

MR. CRAIG: Q. Isn't it true, Doctor, that the biological activity and toxicity of a mixture of two ingredients is not always the same as those same two ingredients when they're formed in a compound?

A. This is why I say no decent scientist would work with the mixture when he is able to work with separate ingredients because it is true that there are divisions. It is obvious. Yeah, it's true. I agree with you. I personally wouldn't do this type of research.

Q. But you would do the kind of research which involved a study on the compound itself?

A. One compound --

MR. ULLMAN: Object to the question.

THE WITNESS: One moment.

MR. ULLMAN: Just a moment.

Mr. Craig, I'm going to have to ask you not to put words into the witness's mouth.

Now, the doctor did not say this.

MR. CRAIG: I didn't characterize it. I'm asking him would he conduct --

MR. ULLMAN: Rephrase the question. The objection is the form. All other objections are reserved because I have a continuing objection as to the entire line of questioning as to the status of a compound. It is totally irrelevant.

THE WITNESS: Look --

MR. ULLMAN: There's no question pending.

MR. CRAIG: Q. The question pending is would you conduct studies on the compound, one compound, let's say a compound of calcium gluconate and dimethylglycine and be able to draw conclusions as to the safety of the ingredients, particular ingredients in the mixture?

MR. ULLMAN: I'm sorry. I'm going to object to the form of the question.

You didn't ask him would he do it, follow that

procedure. You're now asking would he be able to do it if he did it.

If you want to rephrase the question -- please do.

If your question is would you follow such a procedure to do so, fine.

If you're asking him if he was able to do so, that is a different question.

MR. CRAIG: Well --

MR. ULLMAN: Could you read the question back, please, Mr. Reporter?

And, Doctor, please, we do have a record that has to be made here.

Mr. Reporter, read the question back, please.

(Record read.)

MR. ULLMAN: Now, if you will change "able" for "purpose of." I think that's what you're asking for, the purpose of.

MR. CRAIG: No, I want to know would he be able to draw those conclusions. I don't want to know whether he's done it in the past. I want to know if he were to conduct it, the safety study or studies on the compound itself, calcium gluconate and dimethylglycine, could he draw conclusions as to the safety of the individual ingredients in the mixture of calcium gluconate and dimethylglycine.

MR. ULLMAN: Didn't he already answer that question

by saying to you that it could be done but that it is scientifically unsound?

MR. CRAIG: He did not answer the question that he could.

He answered the question that other scientists could.

I want to know whether he could.

MR. ULLMAN: In the face of him telling you that it's scientifically unsound, he's already told you that.

MR. CRAIG: He spoke as to the scientifically unsound nature of taking the mixture and drawing conclusions as to the compound. I have reversed it now on the compound, drawing conclusions as to the ingredients in the mixture.

MR. ULLMAN: I object to the form of the question. If you want to continue --

THE WITNESS: I have the feeling that the person who talks to me -- I have forgotten your name -- will learn something from the discussion.

There are two approaches to experimentation with drugs. One of them is purely theoretical where we aim at simplifying conditions so our results will be easy to interpret.

The other approach is not purely theoretical but practical approach, dictated by the practical aims.

In school of pharamacy there's a big area of investigations which deals with precisely the question you asked me, whether it is possible knowing components of a

mixture to predict its activity as a whole. This is a very big field and very difficult because there are very many additional factors involved when you can reach the mixture. Very often a tablet or a solution or a serum or something before final composition of a mixture is established is modified many times because although components of the mixture are known to the person who is compounding, the results of mixing bring new aspects of the story.

This is why I say when you must solve this practical problem you spend a lot of studies on it and the approach is the practical, satisfactory solution.

But this is not theoretical work; it is practical work. I am a theoretician, and I dislike the type of work. And I dislike dealing with this type of problem. That simple.

(A short recess was taken.)

MR. CRAIG: Q. Dr. Meduski, have you ever seen this document before?

It is entitled "Calcium Pangamate, A Comparative Report." Down at the bottom, "DaVinci Laboratories."

A. I may have in passing just looked at it without paying much attention, but I believe that I looked at it.

Q. Could you look at Page 2?

MR. ULLMAN: Okay. I'm going to object to any questions about that document insofar as it has not been established to be labeled for any of the articles under seizure in

this case.

MR. CRAIG: It doesn't have to be labeling.

MR. ULLMAN: It has nothing to do with any of the articles under seizure in this case.

MR. CRAIG: We'll see when I ask him a question. You haven't heard the question yet.

MR. ULLMAN: Have you heard my objection yet?

MR. CRAIG: You don't have a question to object to.

MR. ULLMAN: Would you read back my objection, please, Mr. Reporter?

MR. CRAIG: I heard the objection. We don't have to go through that.

The reason I've given this to Dr. Meduski is because I want him to be able to tell me whether or not the chemical structure on Page 2 is the correct chemical structure for calcium pangamate.

Do you object to that?

MR. ULLMAN: Yes. Go ahead and answer the question. All objections are reserved except as to form.

MR. CRAIG: Fine. Fine.

Q. Dr. Meduski, is the chemical structure on Page 2 the correct chemical structure for calcium pangamate, the compound?

A. Do you remember what I said in the beginning? That the chemical structure of calcium pangamate has been never satisfactorily established.

How can I say something whether it's correct or not?

Q. But you also said, Doctor, and correct me if I'm wrong, that in your opinion --

A. It's an ester.

Q. An ester of D-gluconic acid and dimethylglycine?

A. Yes.

Q. Is this the chemical structure for an ester?

A. I don't know because there are several possibilities to make this ester, very frankly.

Q. Do you know whether this is the chemical structure not of an ester but of D-gluconic acid and dimethylglycine?

A. Very frankly, I don't know. And this way of writing makes it very difficult to know exactly. For instance, this is -- this way of chemical notation seems to be a mixture of -- not clear mixture of at least two notations, but I cannot say nothing about the correctness of something which I have very general doubts about existing.

MR. CRAIG: I'd like to introduce this as an exhibit, Exhibit 1.

MR. ULLMAN: That is objected to.

(Document entitled "Calcium Pangamate, A Comparative Report, DaVinci Laboratories," consisting of 17 pages, marked Plaintiff's Exhibit No. 1 for identification.)

MR. CRAIG: Q. Could you draw for me the chemical structure of the mixture of calcium pangamate -- I mean the

mixture of calcium gluconate and dimethylglycine?

A. The mixture doesn't have structure. Mixture is coexistence of two compounds without interreacting amongst themselves.

MR. ULLMAN: One moment.

(Discussion off the record.)

MR. CRAIG: Q. Is calcium pangamate commonly added to food?

A. No. And for a very simple reason, because I didn't see practically anybody having it in pure form, and I see no reason to add it to food.

Q. Is calcium gluconate and dimethylglycine commonly added to food?

A. Calcium gluconate is not, but D-gluconic acid is a metabolite of very many foodstuffs of plant origin.

Dimethylglycine is a metabolite of the very many plant and animal foodstuffs.

Q. But is it commonly added to food?

MR. ULLMAN: As distinguished from any food substances?

MR. CRAIG: I understand what he's saying, it's in food.

THE WITNESS: It's commonly not added.

MR. CRAIG: Q. What food substances have dimethylglycine in them? Can you give me some examples?

MR. ULLMAN: You mean what foods contain the food substance dimethylglycine; is that your question?

MR. CRAIG: Q. What food substances contain dimethylglycine?

MR. ULLMAN: You said -- you're saying what food substances. You mean what foods?

MR. CRAIG: What foods.

MR. ULLMAN: Okay.

THE WITNESS: Look (indicating). Here we have interrelationship of metabolated glycine and derivatives. It means -- this picture gives us the coexistence of certain compounds in the tissues. And whenever I can find compound called betalin and compound called sarcosine, I know that transition between them involves formulation of dimethylglycine.

MR. CRAIG: Q. But can you specifically answer my question of what foods contain --

A. All foods which are muscles or organs of animals to start with and very many tissues of plants. For instance, beets, red beets.

Q. Is it your opinion, Doctor, that the mixture of calcium gluconate and dimethylglycine is safe for human consumption as a dietary supplement?

MR. ULLMAN: Object to dietary, the characterization of dietary supplement.

THE WITNESS: Whether it's safe for human consumption,

D-gluconic acid and its salt, calcium gluconate?

MR. CRAIG: I didn't have reference to that.

Q. I had asked you whether it's your opinion that the mixture of calcium gluconate and dimethylglycine --

A. Within the dosages below one gram daily, I think it is completely safe for an average, grown-up person when given orally.

Q. On what do you base that opinion?

A. I base it on my knowledge of behavior of calcium gluconate in the human body and on my own experiments of toxicity of dimethylglycine and on my own self-experimentation; I just have eaten one gram of dimethylglycine and waited to see what happens. It didn't, anything.

Q. What if I were to ask you this question, this same question, and have reference to the compound calcium pangamate, not the mixture, calcium gluconate and dimethylglycine?

A. Then I would say --

MR. ULLMAN: Object to the form.

THE WITNESS: There is no information whatsoever to answer this question.

MR. ULLMAN: Okay. Withdraw the objection.

MR. CRAIG: Q. What is an LD-50 test?

A. It is a test which determines conditions at which a given substance causes death of 50 percent of the population of experimental animals.

Q. Tell me what kinds of tests other than -- in your opinion, what kind of tests should be conducted on a particular substance, for example, a mixture of calcium gluconate and dimethylglycine, what kinds of tests ought to have been conducted on that or should be conducted?

Let me withdraw that question. Let me start over. I'll start over.

In your opinion, what tests should be performed on a substance before it can be recognized as safe?

MR. ULLMAN: Objection. What substance are you talking about? I object to the form of the question. We're not here about a substance. We're here about dimethylglycine and calcium gluconate.

MR. CRAIG: I have reference to a substance that is being added to food and that has no common history of being added to food.

MR. ULLMAN: Your question is not directed to calcium gluconate and dimethylglycine; is that correct?

MR. CRAIG: It's more general than that.

MR. ULLMAN: Object to the question.

MR. CRAIG: Objection noted.

THE WITNESS: You want me to answer very generally?

MR. CRAIG: Q. Yes, generally.

A. Whenever you deal with a substance which is continuously during long range, long periods of time added to

human consumption, the tests should be very stringent and should stress possible accumulation of the activities and the long-range effects.

Q. What kinds of tests?

A. Very generally, answering, there should be four types of tests, but I'm answering very generally your question.

There should be acute, subacute, chronical, and tests delineating the embryo-pathic effects on pregnant females, very generally answering.

Q. Have you conducted those kinds of tests on calcium pangamate?

A. I'm not working with calcium pangamate. I would not touch calcium pangamate.

Q. Have you conducted those kinds of tests on any tablets labeled Aangamik 15, calcium gluconate and dimethylglycine?

A. I was not carrying any tests on any preparations, no.

Q. Have you conducted those kinds of tests on dimethylglycine by itself?

A. I would like to conduct such a test if I would be properly granted.

Q. In your opinion can one rely on an LD-50 test alone to determine whether a substance is safe for human consumption?

A. In certain cases the results of LD-50 test plus background knowledge would form a general opinion about the

substance, in certain cases, very generally. In very many cases, no.

Q. Concerning the substance dimethylglycine, would you in your opinion think that an LD-50 test and the background knowledge of dimethylglycine is sufficient to show or establish that it is safe for human consumption?

A. In the condition 1 referred to earlier, in means -- in the amounts I just said orally and in the amounts not exceeding one gram per grown-up adult, I think it is safe within this -- within those limitations.

Q. Okay. I understand that you think that it's safe within those limitations. But do you think that it is safe to conduct an LD-50 -- the conclusions from an LD-50 test and background knowledge of dimethylglycine, is that sufficient for you to make the determination that there is -- that this is safe, below one gram daily, when taken below one gram daily?

MR. ULLMAN: I'm going to ask the reporter to read the answer back because he just specifically answered that direct question by telling you yes. I don't know why you have to reask it.

MR. CRAIG: Go ahead and read it back.

(Record read.)

MR. CRAIG: Okay. He thinks it's safe, but he did not say that those tests themselves are sufficient to establish that it is safe. That's my question.

MR. ULLMAN: What tests?

MR. CRAIG: The tests that I asked him about, the LD-50, an LD-50 and the background knowledge; that's what I asked him.

THE WITNESS: There's an easy answer. When you ask a specialist of an opinion, you are getting biased opinion formed by the background of the specialist.

I have certain scientific background. I am deeply rooted, so to speak, in certain scientific ways of thinking. And for me when I have those premises, I am not afraid to reach certain conclusions. Somebody else maybe reaches other conclusion. But for me personally, it is enough to answer in the way as I answered very simply.

MR. CRAIG: Q. Doctor, that still doesn't --

A. Very simple answer.

Q. My question is this: Based on --

A. My --

Q. -- your background knowledge of dimethylglycine and conclusions from an LD-50 test --

A. Based on my background knowledge, I personally -- the answer is yes to this question. I don't know how somebody else would answer it.

Q. Thank you. All right.

Now, I want to explore your background knowledge of dimethylglycine.

What does that consist of?

A. What?

Q. You were referring to your background knowledge of dimethylglycine.

A. It consists of knowing practically all written papers about dimethylglycine in six languages in original without translations and performing about one year experiments on this pure compound obtained from a Swiss producer named Pflueger.

Q. Can you go into some of the scientific studies?

A. I can send you a list of references, and you can do that yourself.

Q. Now --

MR. HYNES: Is it agreed that the doctor will compile such a list that he used and submit it to us?

MR. ULLMAN: We'd be very happy to do that.

MR. CRAIG: A list of studies in foreign languages or whatever?

THE WITNESS: Whatever.

MR. HYNES: We can always get it translated.

MR. ULLMAN: If we have some in the English language, we'll throw those in too.

MR. HYNES: Just for laughs.

MR. ULLMAN: Not for laughs, just for common knowledge.

MR. CRAIG: Q. Now, I want to talk about -- ask you

a question about your personal experimentation with the compound.

MR. ULLMAN: What compound?

MR. CRAIG: With the compound of calcium pangamate --

THE WITNESS: I didn't do any experiments with calcium pangamate.

MR. CRAIG: Q. When you refer to compound, then, are you sometimes referring to dimethylglycine as a compound?

A. I am using the chemical nomenclature as any educated, English speaking person is using. When I say "compound," I mean chemical entity.

Q. Okay. Are you referring to dimethylglycine then when you say "compound"?

A. Of course.

Q. Can you tell me about your own personal experimentation with dimethylglycine?

A. I just -- before we had the break, I told you about one of those experiments.

Q. Yes. I want to know some of the other studies that you've conducted.

A. I didn't finish any other studies. Any interpretation would be premature. I would hate to give you results which in my opinion may be not of final formulation.

Q. Have you conducted any sub-chronic feeding studies on dimethylglycine?

A. Yeah, I did. And I think you have in one of your Answers of Interrogatories, you have a table taken from such of my studies. There was, if I am correct -- maybe not. No. No.

No, I don't think I did such experiments with pure dimethylglycine. No, I didn't.

Q. You say "pure dimethylglycine."

Is there any other kind of dimethylglycine that you did do sub-chronic feeding studies on?

A. It exists on the market, all chemicals exist in different degrees of purity. And in certain types of experiments the very high degree of purity is required. The purity achieved, for instance, by repeated crystallization, something like that.

Q. But my question is: Did you conduct the sub-chronic feeding study on any other kind of dimethylglycine other than that?

A. No. No. No.

Q. Okay. Have you conducted any lifetime feeding studies in rodents?

A. No.

Q. Have you conducted any short-term feeding studies of non-rodents involving dimethylglycine?

A. Non-rodents? No, I didn't. No.

Q. Have you conducted any multi-generation reproduction

feeding studies?

A. No. No.

Q. Any teratology studies?

A. Also not. I told you, all those studies are possible but I didn't do it.

May I add now -- one moment. I was, as I said in the beginning, following my own scientific interests and not doing studies up to now for anybody else.

I was doing the things which I needed for my own experiments when I wanted to design and experiment, and I wanted to be sure that I am within the right dose from toxicity point of view, and I looked into toxicity. But I was not conducting any general toxicological studies. That simple.

Q. Fine. Are you presently in the process of conducting any of these types of studies that I've mentioned?

A. No. No.

Q. Have you conducted an LD-50 test on dimethylglycine?

A. Yeah, I did.

Q. Can you give me the results?

MR. ULLMAN: Just a moment, Mr. Craig. In the supplemental Answers to your first set of Interrogatories -- I don't know -- I think I furnished you with a copy this morning, I think you have two of them there.

MR. HYNES: This one (indicating)?

MR. ULLMAN: That is correct. Off the record.

(Discussion off the record.)

MR. CRAIG: Q. Doctor, other than the two LD-50 tests that are submitted in the supplemental Answers to Interrogatory --

A. Three.

Q. This one that you just gave us. Have you conducted any other LD-50 tests on dimethylglycine?

A. I did, I think. I don't remember at this moment. Maybe four or five additional tests because I was not sure at which range of the dosages the response will be. In order to do LD-50 tests, you must find a range where the lowest dose does not kill any animal, the highest dose kills all animals and the dosages between kills different animals. You have those two extreme points, and the calculations are very difficult. So before I reach the right points, it was necessary to do some --

Q. Would you take a look at this document?

It's entitled "United States Patent Office," No. 3,033,868, Patented May 7, 1963.

A. Okay. As far as I remember --

Q. First of all, have you ever seen this before, this document?

A. This document as it is, I did not. But chemical abstract, abstract published in Chemical Abstracts have this document. And the fact that you are looking at this is

because I found it.

Q. How does this -- could you continue looking over it?

A. Read it to yourself. I'm not tested in my ability of reading. Do what you want.

Q. Doctor, I'm trying to find out how this patent evidences the safety of calcium pangamate.

A. I'm not talking about calcium pangamate; how many times I'm repeating this. I don't care about calcium pangamate at all. Very simple.

How many times should I repeat this?

Q. Could I get an answer, then?

A. Answer about what?

Q. Whether or not this document evidences the safety of calcium pangamate.

A. Send me this document; I will study two weeks, and I will give you answer. I hate giving unprepared answer out of which better trained person can have bad conclusions, for the record.

Q. Let the record show that --

Are you saying -- are you saying that you're not familiar enough with the document to be able to give me an answer?

MR. ULLMAN: He didn't say that at all.

THE WITNESS: I said precisely what I said.

MR. CRAIG: Q. Doctor, can you tell me whether or

not this document evidences the safety of dimethylglycine?

A. I must look again, then I will be able to say because I don't remember.

MR. ULLMAN: Take all the time you want, Doctor.

Where in these Interrogatories is that patent referred to? Do you have a note?

MR. CRAIG: Answer to Interrogatory No. 12.

MR. ULLMAN: Okay.

THE WITNESS: This patent numbered 3,033,868, from May 7th, '63, mentions dimethylglycine on Page No. 3. And it says that this compound could be used to --

MR. CRAIG: Q. Are you reading?

A. Look. This is the paragraph where there are premises, and this is where they mention dimethylglycine.

Q. Oh. This particular paragraph right here (indicating) does mention dimethylglycine. But how does this evidence that dimethylglycine -- how was this evidenced that dimethylglycine is safe?

A. I assume, and you probably will be able to correct me, that before they granted this patent they were checking on which basis this statement is made. Otherwise, they probably should not grant the patent.

Q. Other than that assumption, is there anything else that --

A. You --

Q. Wait a minute.

Other than that assumption, is there anything else in this patent that would establish or evidence the safety of dimethylglycine?

A. If this patent does not indicate that NN-dimethyl-glycine is relatively safe, then I must presume that Patent Office did bad job granting this patent.

Q. But, Dr. Meduski, could you answer my specific question?

Other than that assumption that you made, is there anything else in this patent that evidences the safety of dimethylglycine?

A. This patent gives us the results of something, which I think are some tests. It doesn't give any way to know how those results were obtained. I don't know. Very frankly, I don't know.

MR. ULLMAN: I believe you also pointed our attention to some reference on the first page having to do with non-toxic --

THE WITNESS: I marked this (indicating).

(Discussion off the record.)

(Copy of document entitled "United States Patent Office," No. 3,033,868, Patented May 7, 1963, marked Plaintiff's Exhibit No. 2 for identification.)

- - -

MR. CRAIG: Q. Doctor, do you know what nitrosamines are?

A. Yeah, I teach about this. If you would take my lecture notes that students read, you would know what.

Q. Are nitrosamines considered by the scientific community to be known carcinogens?

A. Look, this question is stupid because you know it's considered carcinogens. I consider this question personally offending; you know, personally offending.

Q. I don't mean to offend.

A. I feel offended. And, please, put this on the record. I will have --

MR. ULLMAN: Let's go --

MR. CRAIG: Let's go off the record for a second.

(Discussion off the record.)

MR. CRAIG: Q. Do you know what nitrososarcosine is, Doctor?

MR. ULLMAN: I'm going to object to that. That is so far beyond the scope of this examination --

THE WITNESS: I have --

MR. ULLMAN: Doctor, I'm objecting. Please.

MR. CRAIG: Objection noted.

MR. ULLMAN: I'm going to direct him not to answer that unless you want to point out to me the possible connection to anything in this case.

MR. HYNES: I don't think you can direct him not to answer any question unless it involves a personal privilege or attorney-client privilege or work product privilege.

MR. ULLMAN: I can direct him not to answer any question simply by exercising my powers of speech.

Now, I'll let him answer this question, but we're going very far afield.

Do you want the question read back, Doctor?

THE WITNESS: No, I remember. I know this question. And I know -- what you want to know about this?

MR. CRAIG: Q. Is nitrososarcosine a nitrosamine?

A. Of course. And it's nitroso group, just a little of organic chemistry.

Q. Do you know of any scientists qualified by scientific training and experience to evaluate the safety of dimethylglycine who are of the opinion that dimethylglycine has been shown through scientific studies to be safe for human consumption other than yourself?

A. I think nobody was interested in this problem, but some people approached very close to this problem, and I know about toxicological studies on laboratory animals which are closely related to the toxicity of dimethylglycine.

Q. No. I asked do you know of any scientists, scientists other than yourself?

A. When I'm talking toxicological studies, I can,

obviously, name the scientists.

Q. Would you name those scientists for me?

A. I will get it from my briefcase. The names of the scientists who did toxicity studies, including the group of compounds very closely related to dimethylglycine are Professor Strack --

Q. Doctor, what did he do his study on, toxicity study on?

A. He did the toxicity studies on the whole family of betaines, carnitines and their derivatives. The studies were published in German in the journal which is called Acta biol. med. germ., Volume 3, Pages 28 to 36, 1959.

Q. Okay. Doctor, can you tell me what other scientists-- can you name some other scientists other than Dr. Strack?

A. Doing toxicity studies?

Q. Who are of the opinion that dimethylglycine has been shown to be safe for human consumption?

A. No one ever approached dimethylglycine from the point of view of adding to foods because this compound was scientifically very neglected. Nobody was --

Q. Are you then saying, Doctor, that you don't know of any other scientists who are of the opinion that dimethyl-glycine has been shown to be safe?

A. No, I want to answer this question differently.

I don't think any other scientist posed to himself

the question of toxicity of dimethylglycine to humans.

Q. Doctor, do you know of any scientists who are of the opinion that dimethylglycine has not been shown to be safe?

A. For humans?

Q. For human consumption.

A. I didn't talk with any scientists about the subject, and I didn't read any paper dealing with evaluation of dimethylglycine from this point of view.

Q. Do you know Thomas Jukes?

A. I don't know him personally. He phoned me once, and I talked by phone with him.

Q. Do you know whether Dr. Jukes is recognized in the scientific community as an expert in this field?

MR. ULLMAN: What field is that?

MR. CRAIG: The field of --

THE WITNESS: Which field?

MR. CRAIG: The field of vitamins, nutrients.

THE WITNESS: I know that Dr. Jukes, as far as I know, never dealt with dimethylglycine in his scientific career.

MR. CRAIG: Q. Do you know a George Briggs?

A. I know of him, but I don't know him.

Q. Do you know whether George Briggs is recognized in the scientific community as an expert in this field?

A. In which field?

Q. In the field I mentioned earlier.

A. Nutrition?

Q. Yes.

A. Yeah. I know that neither Dr. Jukes nor Dr. Briggs are physicians; this I know. Second, I know that both Dr. Jukes and Dr. Briggs in their opinion, which I read, did not mention once dimethylglycine. They were dealing with B15 and pangamic acid.

In their opinion, I did not read one word about dimethylglycine. And, please, correct me if I'm wrong.

MR. ULLMAN: Do you wish to correct the doctor, Mr. Craig?

MR. CRAIG: I'm moving on.

MR. ULLMAN: Surely. Please do.

MR. CRAIG: I don't want to get into an argument. I don't agree with him, but I don't want to get into an argument.

MR. ULLMAN: If you don't agree, would you like to show it?

MR. CRAIG: Q. Isn't it true, Doctor, that there's no consensus in the scientific community that dimethylglycine is safe for human consumption?

A. Very frankly, I don't know about any public discussion about adaptability of dimethylglycine for human consumption except for today, now we're making, very frankly.

Q. When I say dimethylglycine for human consumption, what I'm talking about is dimethylglycine being put in tablet form to be taken several times a day.

A. I answered about dimethylglycine. When you put dimethylglycine in a big bottle and drink everything, you will be dead for sure, especially 500 grams, you would be taking.

Q. Doctor, is your answer then the same whether or not dimethylglycine is mixed with any other substances, such as calcium gluconate or whatever?

MR. ULLMAN: You mean at the 500-gram level; is that your question?

MR. CRAIG: Q. At the 500-gram level -- where did you get the figure 500?

MR. ULLMAN: Because that was his last answer, 500 grams.

MR. CRAIG: Q. Now --

MR. ULLMAN: Do you want to hear it back?

MR. CRAIG: I have reference to -- just one second.

Q. I want to go back to a question. I'm not talking about the 500-gram level, no.

MR. ULLMAN: Because the doctor was.

MR. CRAIG: Q. I'm not talking about the 500-gram level. I'm talking about taking dimethylglycine, mixing it with calcium gluconate, whatever, taking it --

MR. ULLMAN: Excuse me. Object to the form of the

question.

Now, is your question mixing dimethylglycine and calcium gluconate, or is it dimethylglycine and whatever?

MR. CRAIG: Mixing calcium gluconate and dimethylglycine.

Q. Are you still of the opinion that there is no --

A. I can answer in the following way: When I would take a tablet containing 20 milligrams of dimethylglycine and about 30 milligrams of calcium gluconate mixed in the dry state I could take in this tablet without any negative results.

Q. Okay. My question --

A. My personal opinion.

Q. My question, though, went to the consensus in the scientific community as to the safety of dimethylglycine.

A. My answer is that scientific community was so blind by the attention to nonexisting vitamin B15 and nonexisting pangamic acid and nonexisting calcium pangamate that it was never virtually interested in exploring biological properties of dimethylglycine.

Q. Does the human body produce dimethylglycine?

A. Yeah, constantly.

Q. Can you tell me where, in any particular organ?

A. In all organs which contain both sarcosine and betalin.

Q. Is it produced in the liver?

A. Oh, yeah.

Q. Is it produced in the stomach?

A. I don't know whether I have data supporting this because I gave you and you probably have somewhere the list of compounds based on an American publication in the early '20's, list of organs based on the American publication from the early '20's, which contain both sarcosine and betalin. All those organs contain also dimethylglycine because it is a metabolic link between those organs.

Q. Does the fact that a substance may be found naturally in food mean that it is safe for human consumption when added to the diet?

MR. ULLMAN: I'm sorry. May I hear that question back, please?

(Record read.)

THE WITNESS: The answer must put many restrictions in order to be positive, many restrictions because any component of foods when given out of proportion or with interacting with other substances may have negative effects.

MR. CRAIG: Q. Does the fact that dimethylglycine is found naturally in food necessarily mean that it is safe for human consumption when added to the diet?

A. The answer is precisely the same; within limitations because out of proportion and in the negatively synergistically active situation it could have negative effects.

Q. Is dimethylglycine a vitamin?

A. No, not at all.

Q. Is calcium pangamate a vitamin?

A. Absolutely not.

Q. Is pangamic acid a vitamin?

A. Absolutely not. I told you several times about this.

Q. Would the mixture of calcium gluconate and dimethylglycine be a vitamin?

A. No. No, absolutely not.

Q. Is dimethylglycine needed in the diet?

A. No, it's not needed.

Q. Is calcium gluconate needed?

A. No, it's not needed. There is nothing needed in the diet.

Q. Do you have an opinion as to the level of dimethylglycine that should be in the normal diet?

MR. ULLMAN: Should be for what purpose?

THE WITNESS: Should be?

MR. CRAIG: Yes.

MR. ULLMAN: Object to the form of the question, "should be."

THE WITNESS: I'm sorry.

MR. ULLMAN: There's an objection to form, Doctor.

THE WITNESS: Excuse me.

MR. CRAIG: Q. "Should be" meaning for a normal,

healthy body.

A. You're rephrasing the question, which I already answered negatively, which means that either you are unable to catch up the difference between your questions or that you are considering the fellow you're talking to also on your level.

Q. Doctor, are you familiar with the American Institute of Nutrition?

A. Yes.

Q. Are you a member?

A. I was invited by Dr. Roslyn Alfin-Slater and Dr. Steven Zamenhof to become member; they wanted to sponsor me. I was too busy to go to them.

Q. So you're not presently a member?

A. I am member of so many societies and I pay so much membership fees that with my salary I must think twice. I am member of the oldest biochemical society in the world, of the British Biochemical Society, starting 1949, and I pay too much for it.

Q. That answers the question.

A. Oh, good.

Q. Is it your opimion that the American Institute of Nutrition is an expert body in the field of nutrition?

MR. ULLMAN: Object to the form of that question.

THE WITNESS: Why not? Of course.

MR. CRAIG: Q. Are you aware that the American Institute of Nutrition Committee on Nomenclature has reviewed the nutrient status of pangamic acid, so-called vitamin B15?

A. I repeated many times that I won't use the name of pangamic acid in a decent society, in a decent talk. Why you come back to it?

Q. Doctor, let me show you a copy of these two articles.

A. Yeah, I know them. I also would say you have them because I found them.

Q. In the Answers, in the claimant's Answers to Interrogatories, they cite these two articles as allegedly demonstrating the biological role of dimethylglycine in transmethylation.

A. That's true. This is also quoted in this, and those two papers are referred to in this book (indicating).

MR. ULLMAN: Let the record show that the doctor was just referring to An Introduction to Metabolic Pathways.

MR. CRAIG: Q. My question, Doctor, is whether either of these articles address the safety of dimethylglycine.

A. Those articles were not from general point of view of impact of the compound on animal metabolism; they were not thinking about any non-animal application.

(Document entitled "The Metabolism of Dimethylglycine by Liver Mitochondria," Vol. 232, 1958, marked Plaintiff's Exhibit No. 3 for identification.)

(Document entitled "Biosynthesis of Choline and Betaine," from The American Journal of Clinical Nutrition, marked Plaintiff's Exhibit No. 4 for identification.)

MR. CRAIG: Q. Doctor, you mentioned earlier that the University, correct me if I'm wrong, was given a grant by the DaVinci Laboratories for you to conduct certain studies?

A. Yeah, that's true.

Q. Was the University also given a grant by Foodscience Laboratories for you to conduct certain studies?

A. As far as I remember, in the University files the donor of the grant is DaVinci.

Q. Do you happen to know the relationship between DaVinci and Foodscience Laboratories?

A. No. No.

MR. CRAIG: No further questions.

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EXAMINATION BY MR. ULLMAN

MR. ULLMAN: One or two questions.

Q. Dr. Meduski, is there a chemical interaction in a mixture of dimethylglycine and calcium gluconate?

A. When they are in the dry state, the interaction is minimized.

Q. Would a dry mixture of dimethylglycine and calcium gluconate require in your opinion any separate test for safety of that mixture?

A. If only those two components are taken, I don't think personally that any extra precautions should be necessary.

MR. ULLMAN: Thank you, Doctor.

I don't have any further questions.

JERZY W. MEDUSKI

STATE OF CALIFORNIA)
) ss
County of Alameda)

I, ROBERT MORRIS, a Notary Public in and for the State of California, hereby certify:

That the witness in the foregoing deposition, named Jerzy W. Meduski, was by me duly sworn to tell the truth, the whole truth and nothing but the truth in the within entitled cause.

That said deposition was taken down in shorthand by me, a Certified Shorthand Reporter and a disinterested person, at the time and place therein stated, and that the testimony of the said witness was thereafter reduced to typewriting under my direction and supervision;

That if the deposition has not been signed by the time of trial, a reasonable opportunity having been given the witness to do so, signature has been waived in accordance with stipulation between counsel.

I further certify that I am not of counsel or attorney for either or any of the parties to the said deposition, nor in any way interested in the event of this cause, and that I am not related to any of the parties thereto.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal this ___ day of _____, 19____.

_____
Notary Public