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To: *Charles* Date 5-5-50

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REMARKS:

The attached copy of a telephone conversation with Doctor John Gofman is being sent for your information.

(Fold here for return)

From *Wandske* Phone _____

To _____

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16-39884-2 GPO

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 Collection *Division of biology Medicines*
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May 4, 1950

Re: H-606(C)

The following long distance telephone conversation with Dr. John Gofman, May 3, 1950, 4:00 p.m., was recorded with and is being distributed with his permission: (Doctor Gofman has not had an opportunity to edit the following material, and parenthetical inserts are mine.)

Wandlyke
Director, National Heart Institute

Doctor Gofman speaking:-

We are just about ready to send out a second publication on our work and I have in mind sending you and Doctor Shields Warren, Atomic Energy Commission, a copy of this manuscript before it goes to publication for you to have the latest data. I hope to be able to have that in your hands by next Sunday, but I couldn't have it by May 5, 1950 which is Friday. I suppose that will be too late for this Committee (Study Section - *VanS*).

On page 2 of the report of the committee (Committee Report of May 1, 1950 which I have recently distributed. This Committee, Doctors Kendall, Neurath, Page and Shannon visited the Donner Laboratory at the request of the National Advisory Heart Council.)

"The group at the Donner Laboratory are quite convinced that, on a constant diet, these molecules (Sf 10-20) represent a stable entity, in terms of their concentration, being acutely unaffected in concentration by the ingestion of lipid substances. It is the feeling of the committee that this point could be fortified and should be fortified experimentally in rigidly controlled studies of a limited number of human subjects before embarking on an extensive program of screening where the potential short term effects of food intake are not amenable to control or to analysis. It may be that this point of view was not stressed sufficiently strongly at the time of the meetings and that the Donner Laboratory has more pertinent information than was alluded to in the discussions."

We are reporting in this paper on about 50 subjects that we tested either before meal and after meal on two occasions separately about the sore part without any treatment of any sort and we have 17 that were negative on one occasion - were negative on the second occasion too, that show no molecules present, and we have about 30 here that were positive on one occasion and were positive within the experimental area with almost the same value on the second occasion except for one case. We have in progress now, probably about 200 people that we are doing the same thing on without any sort of dietary restrictions so that we will have to add to these 40 or 50 another 200 within a matter of a couple of weeks. We have

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checked on some individuals, we have taken as many as 8 samples and found no variations before and after a meal, we have 6 individuals who are studied every three hours around the clock after a huge meal containing lots of fats cholesterol in it and the positives remain positive in about the same degree, and the negatives negative. I pointed this out to the Committee, I feel sure and I don't quite understand why this point wasn't clarified before this report, but, perhaps, it was my error in not pointing it out completely adequately.

Doctor Van Slyke: You expect me to editorialize your remarks ...?

Doctor Gofman: You can use anything I say on the phone - there isn't anything I want to hold back. I would like to take the blame for any inadequate explanation - etc.

Secondly, I would like to say if it were an inadvertent effect of the meal or something like this, it could not be that in 2,000 or so cases that we have analyzed already that our distribution would remain the same as we intentionally reported in our first paper if it were due to differences of times of drawing the blood because, we have drawn bloods at all times of the day with and without respect of the time of the meal and the figures still remain the same. For example, we certainly wouldn't be seeing a vast difference between young females and young males and between normals and the myocardial infarctions if this were the case. So, I feel we use more point in what we do on anyone that we are starting on some regimen now. At the present time, we have at least two baseline samples before starting a given dietary regimen. That's the group that I say we will have about 200 or so in a very short while. I can present these to the Committee (Study Section), if it would help them in their deliberations, within about 10 days, we will have them and I can present them.

Thirdly, in the dietary series where we have checked people periodically once they are on a diet, if it were just an inadvertency, we would see just as many people going up as going down but, on 85 cases we haven't seen that. I feel that this question is under a good control. In this note we will include these 40 or 50 people which show the relationship between the two samples. It will show which are fasting and which are feasting, etc.

On page 3 of the Report:

"These molecules (Sf 10-20) are always present when the total cholesterol concentration of plasma is above 300 mg. percent."

In this report we are issuing now, the same paper, we are publishing the cholesterol values as well as the Sf 10-20 values in detail giving the cholesterol against these values for normal cholesterolemics in the category of normals, diabetics, and coronaries and, in the category of hypercholesterolemics. Now we mentioned in our first note in "Science" that one could be positive or negative with respect to these components at any cholesterol level below 300 mg percent, but that the cholesterol level itself told us nothing since one could have a lot of the molecules Sf 10-20 group and have the same cholesterols as in other persons who had none of these molecules. This was expressed in the "Science" paper although there we didn't give the details or figures since we were limited in the number of words allowed in the "Science" paper but we had all the 300 cases analyzed for cholesterol at that time. Now in the hypercholesterolemic group although - we have about 25 cases here - 33 cases of people whose cholesterols in various categories of diseases were over 300 mg. per cent and there is a range of a factor of 10 in the concentration of Sf 10-20 molecules so even with the cholesterols over 300, many people have much more of the molecules than many others independent of the cholesterol. We have in this category now 33 cases of people whose cholesterol is over 300, we have two that were negative, that is, showed none of the molecules. We feel as we stated in the paper and as I stated to the committee, that above 300 mg. percent most people by far are positive, but that the concentration of the special molecules is exceedingly variable and there again the cholesterol tells us very little.

The next subject on page 3:

"Many individual subjects with low total cholesterol concentrations are said to have rather high concentration of the Sf 10-20 factor."

This statement is not a matter of "are said to be" but they actually do have a high concentration. I had these data for the committee to look at at that time. Also it says:

"A total cholesterol concentrations below 200 mg. per cent in the rabbit and below 300 mg. percent in man, there would appear to be a crude correlation between total cholesterol concentration and the concentration of the Sf 10-20 molecules."

It is certainly true if I say at a cholesterol level of 200 to 250 mg. percent there are about as many people who are positive and positive in variable degree as there are who are negative, but below cholesterols of 200 there is a lower percentage of people who are positive although there is still a very definite one when it is about 30 percent in normal, so that what I want to say there is a cholesterol level of about 200 mg. percent does not tell us in any specific case whether or not this person has none of these molecules or whether he has a tremendous concentration of them. I think this point should be very clear and we have all these data presented on graphs which show the cholesterol level versus the actual concentration of Sf 10-20 in mg. percent which I hope to have in your hands, as I say, by May 8, maybe I could even have them before, I'll try.

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Right below that it is stated that:

"It is the general feeling of the committee that this correlation should be inquired into rather extensively early in the rational evolution of the program. It is the committee's understanding that such a program is actually underway at present and will be expanded during the coming year."

As a matter of fact we had the first 300 cases analyzed before the scientists came here and it is on this data we based our statements that the correlation isn't very good. We are not doing cholesterol level analytically on every patient now simply because we feel that they don't correlate well and we don't have enough money to do everything. That is why we have been forced to cut back on doing the cholesterol on every patient, we had hoped to at one time but this would be impossible.

The next point is on page 4, (1st paragraph) the statement about the 11 additional negatives that were not included in our compilation since it was known that they were already on a diet which, to some extent at least, was restricted in terms of fat and cholesterol for a period of from three months to three years, and the committee states here that they question whether we had the right to exclude these. Actually, the facts are, that I myself question whether we had the right to exclude them, and the committee assured me that they were not unhappy about this at all. These were patients who came to us from doctors who said, "Here is a case that has been on a very restricted regimen already, do you want to study them?" And I would say to them, "Doctor, this patient may have a low positive result or negative result but we are very interested in seeing these people who have been on restricted diets since they give us additional information to compare with the other myocardial infarction." But these myocardial infarctions are reported on the basis of those who have not been on severely restricted diets and if they are just moderately restricted we do not exclude them. Since, it is based on this fact, we knew in advance that we were going to see some people who might be negative since we know the effect of diet on these molecules. We could just have well have said to these doctors - "No, we will not study your new patients because they may be negative," and this way the question wouldn't have arisen. We will present all data whether positive or negative, and in any event the inclusion of even those who have been on restricted diets, cuts down the over-all incidence of positivity to about 90 percent instead of 95. It would seem to me a little foolish to include them without a statement of the previous circumstances because we now have many myocardial infarctions who were quite positive and who we put on diets and who are now negative. If we included them as negatives, we would be defeating ourselves, I believe.

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Now, the next point on page 4:

"The Committee discussed the above data in some detail, and in general believe that an important aspect of these correlations is missing, namely, the systematic quantitating of the Sf 10-20 factor. The Denner Laboratory group agreed that this is an important aspect of the study and indicated that they had quantitative information on a number of patients. They felt their measurements, being as they are, wholly objective in nature and recorded photographically, are amenable to review for quantitation at a later date."

Nothing could be further from the truth than that we were not quantitating these molecules. What I did when I reported the data on page 3 under "b" at this little meeting to the committee - I said, that 60 percent of normal males between 20 and 40 were positive to some extent, but before the committee came out, I hadn't had a chance to arrange them as to the degree of positivity and that they should keep this in mind as we enter these things as we go along. On the first succeeding 1,600 to 2,000 cases that I will send you in this report, we will have down an actual measurement of concentration on every one of these cases, and on the first 280 cases we reported in Science there was a measurement of concentration, not only whether they were positive or negative. It was given on a standard diagram. So that it is true that when you run a large number of cases you may be a week behind on having the answers on that week's work or on the previous week's work.

The next thing is, again, the Committee raised the question of excluding half the negatives. I brought this point up and said I don't know whether we have the right to exclude them though I'm pretty sure they have to be treated separately. We don't throw those cases out, we just put them in a separate category so as to get the data as they truly are. (Page 4, paragraph 5) and they said it was again emphasized, by the Committee, in relation to these data, that rigidly controlled experiments in the human on the effect of diet on the presence or absence of these molecules and on their concentration are an essential for a reasonable approach to the problem. Since we are doing dietary studies, I reported to the Committee that we have many more dietary studies and in this paper, we are reporting on something like 85 people that have been on the diet long enough to see an effect. So, we have been carrying this on; I told the committee this, and this report indicates that we were not aware, or might not be aware that we have to know the effect of diet before we can exclude cases. We were quite aware of this, and are aware of it. I thought I had explained the thing adequately to the committee but, possibly, in trying to cover a lot of material in a short while, I did not do as good a job of it as I might have.

Now the next thing that is said on page 5, the committee recommends some delay in the field studies and states their belief that definitive information on the stability of the concentration of molecules in relation to diet is essential. This I say (as I told you earlier in the conversation, we have these 40 or 50 patients that we are reporting on and have some 300 that we're doing tests samples before anything is done to their diet) we are fully aware of and I expressed this to the committee. We are quite assured already that there is no effect if there is no change in diet. They said that specific studies should assess the ability or other substances, by they lipotropic, hormonal, or other chemical agents, to modify the concentration of the molecules. This, I don't understand, in view of the fact that I had mentioned in our "Science" report and mentioned to the committee later that we already had 50 people on choline, 50 people on methionine, 50 people on some other regimen that were drug possibilities - these are small controlled groups, and we had already started these, but that no results were available in respect to these agents - they will be available, I hope, within a couple of weeks. These are not field studies, we do not plan to go out and put 1,000 people on methionine. These are small groups of 25 or 50 to see the effect, but we had no intention of going out and putting 1,000 people on anyone of these lipotropic agents and until and unless we had thoroughly evaluated its effect, in 25 to 50 patients, but we had already had these studies under control before the committee suggested that we ought to try these agents we were very interested in them. I got the opinion that the committee felt that we were going to do field studies on choline before doing any small studies on this and other lipotropic agents.

What I wanted to make clear was that we were not going to go out and try 1,000 people on choline indiscriminately; that would be a horrible thing to do, and we already have, going now for five weeks, these experimental series on choline, methionine and we're starting a series on inositol, and we have a group on a mixed preparation.

These are all being done on small groups that are well controlled, and so far as one can possibly be assured they are not changing their diet at the same time. These are people who work at the radiation laboratory and who are cooperating.

There is one other point I would like to make about this, and I feel perfectly free to have this in the record. I have at no time ever expressed to anyone that I think getting rid of these molecules is a cure, a prophylaxis, or anything else against atherosclerosis. When we put people on a diet, or on these drugs, I express to them this is wholly experimental. I state that we are trying to evaluate this, that we have no idea whatever that we will do them any good and make it clear to every person that we have no illusions that we're doing anything for them. I fear that the committee may have gotten the impression that we were assuring people that we're curing them, or something like that.

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I hope that this misunderstanding is cleared up so that the Study Sections and the Heart Council will not feel that we are advocating these things. I cannot help what science writers or broadcasters claim when I do not state these things.

Further, on page 5, at the bottom, it is stated it was the opinion of the Committee, that to try to study 2,000 to 5,000 who had a myocardial infarction; to put them on the diet and then reject them would be a difficult if not impossible task. I have discussed this with the Alameda County Medical Association and gone through official channels on this. They are very enthusiastic about cooperating. The doctors in the area are going to put the patients on the diet we suggest, and we will check their blood periodically and then evaluate them. To do 2,000 to 5,000 myocardial infarctions will be a very simple task from a technical point of view, rather than a difficult or impossible one, in my opinion.

Doctor Van Slyke: Well, Doctor Gofman, the point I think the Committee was concerned about was the inability to keep people under dietetic control in home conditions. Doctor Gofman: Well, then I think the Committee missed the point I made about that - mainly, that the entire point of such a study is it doesn't matter if they stay on the diet or not, because we no longer care what the patient says - we are interested in what his blood shows. We are interested in evaluating out of this 2,000 to 5,000 cases how many become negative; is their recurrence rate of myocardial infarction the same, or isn't it? And, if somebody doesn't follow the diet or, for some other reason, say is metabolically unable to become negative, this is a separate category, and so, it doesn't matter whether they do follow it rigidly or not - just so they do become negative or, if they don't become negative, then we classify them as people still positive. The entire point of the study is not to see how many people we can get rigorously under diet, but how many people we can convert to negative and find out if they are any better off. So, it doesn't matter whether it is done in a hospital or not, actually.

Doctor Van Slyke: How often do you expect to check on these people? Doctor Gofman: We are going to check these people once every six weeks at the start and then once every three months so we will know what these people are doing. I realize fully that we could do a smaller number of studies. We could do it on 200 patients and get the answer in ten years, but 200 patients won't give us the answer in a couple of years and that was the essence of the letter I wrote you before (April 15, 1950). So far as the use of choline, methionine and inositol or other lipotropic factors are concerned, we are not using any of those and would not until our control series indicate whether or not they decrease these molecules. We have these studies in progress and hope to have the results within 10 days on at least the first 25 patients of each group. But these are small groups, and we would never consider going out on a mass basis. I don't believe that we should. I believe drugs are dangerous items to use. I think the diet we are using is a quite safe one and really completely adequate.

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On page 6 the Committee states that we can best serve the problem of atherosclerosis and coronary disease if applied to an extension of our knowledge relative to these newly described factors rather than primarily to the application of information now available. We believe, honestly, that we are in a position to do both studies at once without in any way taxing our facilities inordinately, and we certainly do not plan to let the basic work grow in favor of clinical work but we feel that the clinical evaluation, right or wrong, must be done soon; and we feel that we can do it under conditions we can trust. We want to help any other group that will also do this study, and in fact, I am going to try to make arrangements with a couple of groups. We are very anxious to help others. We also think we can carry on fundamental studies, but I think that the clinical evaluation of this thing should not be delayed in spite of the committee's statement that it should.

Further, on comments by Doctor Irvine H. Page, he states that:

"The feeding of cholesterol to rabbits apparently increases this same peak. This work is less convincing."

It is absolutely true that this peak is never present in rabbits, in the approximately 75 rabbits here we have looked at, without feeding cholesterol, and though we don't have the correlation of the amount of disease with the amount of the molecules in over 17 or 18 rabbits now, we know that feeding cholesterol is the factor that produces this peak in well over 50 rabbits. So that I don't see from the statement that it is less convincing that the feeding of cholesterol apparently increases this same type of peak. I believe this is convincing, to me at least. That again is a matter of opinion.

On point 4 of Doctor Page's comments:

"A diffuse, not too well integrated program of animal and clinical investigation has been started, which in my opinion, covers much too wide a range of uncontrolled materials."

I believe that we will have very excellent control data, we will get good clinical stories on everyone we investigate, and I think there will be no uncontrolled cases. We certainly don't accept as a myocardial infarction or any other disease just what somebody tells us. We ask that we see the evidence in detail. Doctor Thomas Lyons is a competent cardiologist and cardiographer and he checks all the records with the doctors, except for those doctors whom I know from their own competence absolutely reliable in their clinical material. Doctor Page goes on to say that there is a great danger that:

"The interpretations of applications of the test may far exceed the evidence on which it is based."

To this I say it is unfortunate that there are people who assume for some work more than its true merit, and more than its proven points.

(At this point Doctor Gofman stressed his efforts to stop "popular" articles but that certain writers had gone ahead on their own - VanS)

I agree with Doctor Page that, possibly, the people who are normal whose blood is positive are going to worry that they may be on the way to myocardial infarction. He says that grave harm may be done. I have certainly emphasized and re-emphasized to our subjects the experimental nature of this, and the fact that we have proven nothing, but I know that they will still misinterpret this and over-interpret it, but I don't know how we can get the test done unless we do use people.

On the comments by Doctor Neurath on question 2 on the relationship between refractive index gradients and concentration, I consider this is a well established feature about the ultracentrifugal analysis. We have checked this ourselves, we have checked the mixtures that he speaks of, and we have checked the effect in relation to density of medium that he speaks of, and I feel reasonably certain of the availability of this information, both from our public reports, and from some of my statements in the meeting, but again there it must have been my inadequacy in explaining which left these questions in his mind. We feel we have covered all the points mentioned in his paragraph 2.

In paragraph 3, Doctor Neurath questioned whether we might not be missing some of the positives by faulty collection of material. We have checked the remaining material after we have collected what we are interested in, and have seen that it contains a negligible or no concentration of the molecules that we are studying, so we do not believe that we have faulty collection. We have tested this at least 30 times at random.

Secondly, he asks whether tests were made to see how much of this or other "light" components may remain in the protein layer. We have tested this, and we have pointed out that these materials are not left in the tube, that we do get them out. We are quite convinced of this point. We have extensive data, I believe, on that. Doctor Neurath notes that the data are "not more than suggestive and informational, and that a great deal of work has yet to be done to arrive at an answer." We didn't find 100 percent agreement, and all we are asking for is the opportunity to work. We don't want to say we have proven anything, we just want to work and find out. He believes the success of the large-scale testing would depend on reliable clinical data. No one could disagree that one should have reliable clinical data, and I certainly would not use any that was not.

And point two (page 2, first paragraph of Doctor Neurath's comments.) that there should be a "more rigorous evaluation of fasting or feasting on the ultracentrifugal patterns." We have checked this - many individuals before and after a meal and convinced ourselves that there was no significant difference but we are, as I say, doing many more of these. Now, secondly, Doctor Neurath is not convinced that a random collection of blood, regardless of time or fasting, is a good procedure and he doesn't see why a fasting period of at least four hours could not be made a matter of compelling routine. Well, this would interfere with collecting many samples because of the difficulties of getting people at a standard interval after fasting, and since we are quite convinced that it doesn't matter, we aren't doing it this way but, apparently, we have not convinced him of this, and I would like for this reason to get, possibly, another 300 or 400 done this way and prove the point further. I believe the data we will present in this manuscript we are writing will show that.

And then, the following paragraph, Doctor Neurath notes:

"If the test shows an incidence of positivity in 'normal individuals' as high as 60 percent, it is necessary to demonstrate that this incidence can be reduced as low as 10 percent or less."

He recommends that we ought to go ahead with:

"An analysis of 1,000 males below twenty years of age."

We already have the data on young females on about 200 some cases under 20; and they are only about 13 percent positive. This shows that it is not 60 percent in everyone and if these molecules are related to atherosclerosis, we cannot alter the fact that young men from 20-40 show these molecules in their blood. So we are doing children now, and the younger age groups, and I reported this to the committee although the data was not then available. It is a matter of collecting first the most pertinent data, and that is why we did not emphasize this group at first.

And then Doctor Neurath's statement is that he feels:

"If it is true that the quantitative level of the 'critical' component can be influenced by diet to the extent of complete apparent disappearance, rigorous studies on the effect of the diet in a group of hospitalized patients appear to be absolutely essential."

Well, we already know that by putting people on diets at home and some in our controlled diet table at Cowell Hospital, (the University students' hospital) that they are showing the effects even without a completely rigorous restricted diet. Since we know that we can get this effect even on a home restriction, we feel this is more important than a hospital restriction because it shows what can be done with a reasonable approach that would have to be used ultimately if this were of any merit from the point of view of doing something about atherosclerosis. Therefore, we're much more interested, in many respects, in trying to find out how many people become negative or less positive even when some of them are fudging on this diet. But we definitely stated if we get the numbers we can definitely tell even though some don't respond. Many do respond. The majority do respond. We haven't seen any persistent rise in concentration of these molecules in any people that we've put on diet, and if this were a random affair, we would expect to see a rise of concentration as well as a lowering. So I don't know what to do about this hospitalized patient series group.

Doctor Kendall suggests that they give us some blood from patients in their hospital that are on the right diet and I said this would be a fine idea - so the arrangements are in progress for checking that particular group.

Doctor Van Slyke: "Oh, you are making those arrangements with Doctor Kendall?"

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Doctor Gofman: Well, they were already made when Doctor Kendall was here. He said he was interested in seeing this and I said we would be only too glad to run the ultracentrifugal analysis for them.

Doctor Van Slyke: Have you received any blood to date?

Doctor Gofman: He has sent to us already 12 samples of his dogs that they are studying with respect to (now a year or so) plus cholesterol, but none on the humans on the right diet.

Doctor Van Slyke: Oh, I see.

Doctor Gofman speaking - Then in Doctor Kendall's statement, he makes one point:

"That it is possible that the higher incidence of positives among their coronary patients is a reflection of the higher cholesterol level that was seen in this group and that practically the determination of the level of this factor will have little more significance than a determination of the total cholesterol level."

With this, I am in complete disagreement because we have the evidence in the form of the cholesterol levels on all of our coronaries of the first 100 or so cases and we have the cholesterol levels on many of our normals. And the point I made in the paper in "Science" and which will make again by presenting the cholesterol levels, is that many of our coronaries have the same cholesterol level as many of our normals but their percentage of positivity is on the order of 95 percent as compared to the order of 50 percent or 60 percent among normals of the same cholesterol level. So that there again I don't see how that point could have been missed, namely, that one can have a 225 mg. cholesterol level in the coronary group if there is a 95 percent chance there will be molecules (Sf 10-25) whereas in the normal group it's a 50 percent to 60 percent chance. And furthermore, from the data we're presenting in this present manuscript, when the coronary patients are positive, they are on the average, the concentration is higher than in the normal - even when the normals are positive. I do not believe that phospholipid determinations are really of such moment, just as I no longer believe even the cholesterol to be of such moment since it involves adding up a whole lot of molecules and saying the total is this.

I think that one of the major points that we have shown is that one shouldn't base things on the total of adding up any molecules if you're trying to find out what the individual molecules mean.

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I believe that the large scale study that we are proposing can be done without compromising our fundamental research program. I sincerely believe that the evaluation of this thing should be done at an early time, and that there are sufficiently cogent reasons for doing the study rapidly. I think we should go ahead.

Doctor Van Slyke: If you go into the field study, how much is it going to penalize your work on the basic components of the problem?

Doctor Gofman: We have several excellent graduate students and men who are M.D.'s that are back working for a Ph.D., who are handling the fundamental aspects and working with me. I think they are doing a reasonably good job. I think that that work will go ahead and, it is going ahead. They are not being involved in these field studies, they are allowed to go ahead with their fundamental studies. We are able, by organizing this thing properly, to use just technician level help on the field study, and this is what we are doing, and this is why we need the support because if we didn't do the field study in this way, we would, if we were going to go ahead with it, have to use our graduate students which would penalize their fundamental program.

Doctor Van Slyke: What is the Medical Society that is working with you?

Doctor Gofman: I have spoken with the officials of the Executive Council, Alameda County Medical Society. They say they think it would be a fine idea if every doctor would send their myocardial infarctions for study, just to study their blood, and then the doctor would take care of their patients, and we would check their bloods after the patient goes on a diet and, as I said, if the patients do not stay on the diets and their blood does not come down to negative, this would in no way invalidate the results we are trying to find out, namely, whether negativity with respect to these tests is a valuable thing. The collection of 2000 myocardial infarctions that are studied in this manner is by no means the difficult or impossible task suggested by the committee, because I honestly think we are well on our way to getting this done.