INSTANT MEMO

To: Steve Croft

From: Ingrid Stahlman, SSS

Subject: Attached Transcript

Date: 8/16/93

How are you doing ???

Here is the transcript & disk that Frank Wiesel requested be transcribed from his break-out group in Chantilly.

He asked that someone he knows do it so I requested that a copy of the transcript be sent along with the invoice. Anyhoo here it is! Please give me a call if you have any questions -

Hope all is going well (better?) over there -

TRANSCRIPTION OF

SEPTEMBER NATIONAL INSTITUTE

OF HEALTH MEETING

FW This will be casual. Everyone feel comfortable without suit coats and loosen our ties. We are going to move right into it I think this morning. Are there any questions about how this process is going to work. Does anyone have any questions. Does everyone have a list of our questions and the questions which were presented by the N.I.H. Two series of questions. I am going to go through our list only because I understand our questions and I'll be happy to hand our. I've got further lists of questions which we have prepared and if anyone has a question from the other list, we've incorporated many of them, but if they feel it's important to address a question on the other list, we'll do that to and as we have--as we go through this I'd like to also have questions which we haven't considered or the N.I.H. hadn't questions. There is obviously a lot of good minds here, we can come up with questions of our own. We are going to over this morning have a lot of ground to cover I think and we are going to have to really get through these things and sort of put a side whatever pet projects we may have and talk about the larger issue. I think that we have tremendous opportunity here and unless anyone has any questions, I think we should just get moving forward. What I would like to do first before we get to far into this is to read the Enabling Legislation. We went to Senator Harkin. We proposed to him this office and he wrote this up with an advisory panel in mind. So I am going to read this law. The Appropriations Committee in the United States Senate is not satisfied that the conventional medical community as symbolized by N.I.H. has fully explored the potential that exists in unconventional medical practices. Many routine and effective medical

procedures now considered common place were once considered unconventional and counter indicated. Cancer radiation therapy is such a procedure that is now common place, but once was considered to be quackery. In order to more adequately explore these conventional medical practices, the community request that N.I.H. establish an office within the director to fully investigate and validate. To investigate and validate these practices. The committee further directs that N.I.H. convene and establish an advisory panel to screen and select the procedures for investigation and to recommend a research program to fully test the most promising unconventional medical practices. The committee has added 2 million dollars for this purpose and asks for a report by the end of January, 1992 on the progress made to establish this office. So that is our charge, to establish the working motto by which we can evaluate these therapies. It's a very open mandate. It's a very--we have every reason to hope that they're going to follow our lead. So without further ado, I would like to start right into the list of questions that we have talked about and I've passed out. If anyone doesn't have a copy, let me know. Under defining the research agenda, question number one, what diseases or disease, conditions does your committee view as most likely to be benefited by alternative medical treatment? Do we want to start that out and open it up?

-- I think that whatever we say should be preface by the lack of progress made by the tremendous amount of the funds that have been spent up to date on these particular areas such as cardiovascular disease and go on from there.

FW We have three major killers, we have cancers, we have heart disease and we have AIDS which we have effectively not been able to astound the rising death resulting in those three diseases and illnesses and it has been suggested to me that they at least be a significant part of our focus because they represent 80% of the preventable causes of death in America. My point is we have a preface. With the lack of progress...

FW I understand because of the lack of progress.

-- I would say any chronic systemic metobol dysfunction or immunological challenge would be a target or what I would ya know we're going tangle the word alternative, say integrative medicine. It may be all pathology, but certainly those things should be targeted.

-- I think also is important stress what Dr. Caplans was saying yesterday about his research--Dr. Caplans about this sickel-cell anemia. ....which have been neglected because they are affecting minorities like....and I think they also need to be brought to the attention.

FW Certainly none of the--by defining the focus here, no one is going to exclude anything. I think that it's important--there was already some discussion in the diet-nutrition panel that we're not going to focus on these diseases, there's all kinds of other things. Well no one's going to exclude, it's just that we have to have focus and we have to prioritize and so we need to come to the larger group and to the Appropriations Committee with our research agenda. With what we feel should be first,

second, third, fourth and also.

-- I would say that ...invention, that would be such an example of general immune deficiency.... They are becoming more and more common in western industrial societies for whatever reasons.

-- I would agree with him and I think if we could make it a more general statement as immune deficiency diseases including AIDS chronic....

FW General immune deficiency diseases covering any immunological problems that exists.

-- You've also noted to include things like....

FW Ah hah

-- Look at ....disease because though....

-- So if we could make them general things like immune deficiency and cardiovascular.

-- Talking about immune deficiency, I think we should also add altering immune disease which effect majority of people. So you can say immune deficiency and altering immune disease.

-- Immune dysfunction

-- If you use the general topic of degenerate diseases, you may cover all but your one cardiovascular disease.

(several speaking)

-- You run the risk here, if you're going to site those diseases of....that you're concerned about. If you're there to site them as those that are best opportunities that alternative medicine may have using the term figuratively may actually have a benefit....But the view point of this question to try to specify those areas which would best be benefited as alluded to later in the questions or are you just going to mention everything because in the view in what you are hearing here, I think that every field is close cut. Every field is going to have a benefit depending upon what subtopic you're looking at. So by saying cardiovascular precluding ....for an example is doing an injustice to those people who are doing research in....and you're going to be running that risk as you go down these questions that anyone's project....

-- Well alternate immune disease is mentioned.

-- No I recognize that. What I'm trying to point out here is that you're going to be self-limiting. On the other hand, you're trying to pick those topics which are best suited.

-- Well we are very limited. We have ya know 2 million dollars all together for the committee this year and there going to--they're are five other panels and they're going to be coming up with many other projects. I think it's like somehow we have--it's not a matter of limiting, it's a matter of focusing now. Some success in the initial early stage of this complay will open the door towards

being able to deal with many other conditions and situation. Where as failure at this point means that nobody will succeed. So I think we have to focus, ya know pin point those areas that have been most likely to be successful.

FW We, at this point in this dynamic, we need a victory. We really need a victory. We need to show that there are therapies, alternative therapies. We need to show the public health service.

-- Do we need to come up with exact language as we move through this list?

FW Yes

-- Well than I would propose that we get something on the table that the language for one be that we focus on immune dysfunctions, plan cancer, AIDS, auto immune disease and cardiovascular diseases with language proceeding that indicating the comments about the failure of conventional medical research to come up with answers for these questions and also this is a focus, not a limitation.

-- May I recommend a modification instead of saying conventional medical research, let's say health care systems. Let's get away from using conventional verses unconventional. Alternative verses acceptable. We're in no innovate as opposed to traditional and that's what we should be using.

-- Is the writer that's working with this group going to come

up with permanent product or what's the actual mechanics of this?

FW We're going to put together ideas here and we're going to put them together in as close to the language that we can all agree upon and then we're going to draft them as resolutions to the larger group and then they'll be presented as such and they'll be a work product or a report which is the recommendations of this--which will make up recommendations of this committee and the other committees to the N.I.H. as to how to set up this office as to what diseases to look at as to how to prioritize their work.

-- Are we going to deal with actual biological/physiological diseases here or social conditions within the realm of what we are talking about cause I know a lot of the unconventional practices have a lot lower rate of malpractice insurance....finances the system a lot less.

FW Well I clearly think that you know, people say to me--I hear safety and efficacy a lot. I think that we have to go beyond that in 1992 America. I think we have to consider three things, one is safety, one is efficacy and one is economy because where there are two good say treatments for a disease or illness, I don't think we can afford to overlook the one which is purely economically better, it costs less. It doesn't have to pay as much. I think that we have to seriously look at these things. We're in serious trouble. I mean everyone has talked and talked and talked about health care crisis. You know it's now, I'm not sure how much money, 950 billion, I heard

that figure. It's astronomical. No one understand how much money this is. So we have to I think consider all these three things, you know safety, efficacy and economy and it can be part of the, you know we are looking at all of these things. We want to look at these things. Today we want to focus and we want to come up with language as to how we define what we research. I don't think we want to exclude anything. I think this is more of a series of priorities here, what do we do first, how do we set up the office and what do we do first when we get the office set up.

-- Well Frank where are the dickers in alternative medicine?

FW Where are they?

-- Where are the dickers currently. What do we have in our portfolio that...?

FW I think that's a good questions.

-- I would say that I think Frank, it has been done quite nicely. We feel that it is increasing at around 10 to 15 percent per year world wide. So it's a sign of great deal of the public's approach.

-- Natural Apathetic Arena has been a lot cheaper, it's running about a fifth the costs of standard medical care. The same kind of patient that rates results and a lot higher patient compliance rates. Their malpractice rate is about zero.

-- Homeopathic so, so almost never gets through except by a local medical association sometimes.

-- In writing my cancer therapy book, one of the things that astounded me was the degree to which the Japanese and people in other countries have dealt into the realm of non toxic medicine and especially herbs and natural products and I think we have to break out of sort of our nationalist mode and really realize there's a whole world of medical practice out there and a lot of the problems that we have in medicine is that the F.D.A. and the research establishment really thinks that the medical world or the world of health ends at our borders and this isn't so. There are many things going on, as I say in Japan and other countries that have followed the UN's Cult or their World Health Organization Cult for a new medicine which integrates western and traditional practices so and this of course relates to the human situation and so forth.

-- Excellent point, but we have to tie it to the economic situation here because we are dealing with N.I.H. This establishment here and we have to appeal to the public and to maybe establish an understatement what the public understands and realizes that health care has gotten out of hand. So that has to be tied to this, the economic issues.

-- My name is (can't understand her name-foreign female), good morning everybody. Kilation (phonetic) therapy one tenth of the cults long-lasting systemic, beneficial results, rejuvenation of the whole system, definitely the

most of all results.

-- Scientific data is important.

-- There is plenty of scientific data, unfortunately we have talked about the aborted double blind studies and why, don't we look over, aren't we going to talk about it, they allowed us, we're going to talk more about it.

FW This kilation has been brought up to me a lot and I had some discussions with a world renown cardiologist who is a member of our organization who himself said we cut and we patch, but we don't cure. He was telling me that the first cardiovascular thoracic surgeries that he did were not cures, so obviously we have alternatives in cardiovascular.

-- Our best model to really hang the tail on the donkey is AIDS. We've had 11 years of AIDS, we have a zero percent cure. In cancer, they can sleaze around about a eight or nine percent cure rate for metastic disease really when you look at the statistics. With AIDS, there's zero and the long term survivors of AIDS from anything we can follow, at least in North America, the long-term survivors have in common either that they are a total abandence, so called orthodoxy or they've mingled unorthodoxy with orthodoxy and I think that--and this is growing expeditiously. If we didn't even deviate from AIDS, we would be able to make the case for the abject failure of this allopathic model and the only thing out there that is helpful being these other kinds of therapies, so I think....zero percent cure rate.

FW Doctor B..?

-- I agree that AIDS is certainly going to increase daily and become one of the important problems we have in American with definitely a disease, but if you're looking for a quick answer, I believe that we take 100 patients who are doomed to death by a panel of experts within three to six months with cancer and put them on alternative medicine and it proves to work, you could have an answer that could give much credibility in six months and I don't think. I am not criticizing your statement, I think AIDS is one of the most problems we have in health care in America today, if not the most important, but I think to get an answer for AIDS might take a long time, whereas with cancer, we would chose only dying patients and get an answer in six months, I think we could give this group credibility and I think at a much quicker by providing the cure with alternative medicines for dying patients with cancer.

FW Now are you talking about outcomes, research to this kind of thing because I know you can't do a clinical trial in six months.

-- Why not?

FW Well, we are really looking for survival. One of the things that...

-- When it is a protocol that I am taking is patients who have six or less months to live with a proven diagnosis of cancer of the lung, brain, pancreas or colon, liver who have failed on standard methods, have been evaluated by a

group of medical oncologist who will certify that they will be dead in six months or less, put them on an alternative medicine and in six months or less you could have an answer. Because again, you take a patient with agleamal mextoma who has had surgery, radiation, chemotherapy and the tumor is growing and the standards methods have failed, they die quickly. All I am saying is that I have patients like this who have been cured by alternative medicine. When I say cured, alive and well five years later without evidence of disease.

-- Are you envisioning an possible controlled study, I mean would there be....

-- No because again what I am saying is five medical oncologist all certified, all university affiliated have agreed to work as a panel of evaluators of the patient before they go on the study and all five certify that these patients are incurable and will die in six months or less.

-- What Dr. B? is suggesting is completely acceptable... and very doable and would have a very dramatic result and that is perfectly within the...of N.I.H. approved meningology so that is a very important thing to look and I've read your materials on it and I know that's what you're talking about and I think that's something that would be very...Frank, I would also suggest as a structure, the way we look at this. I think we're dealing with two separate issues. One in a sense.....one has to do with underlying biological prophecies which we certainly have to look at. The other has to do with specific diseases, disease staff

and I think we have to separate these and deal with them spontaneously letting the rest of this group know that we feel that research has to be conducted simultaneously in both areas and underlying immune pathology...and also with regard to cancer or AIDS, or any illnesses.

FW Well people have suggested to me that perhaps these were chosen incorrectly that it should have been by disease. There have been others who have argued that it was chosen correctly because many therapies will impact positively on more than one disease condition and if we are looking at this as a chronic generative disease problem at least as the majority of these diseases, then what helps one will help another. I think Dr. Brezensky is an example. His antineoplaza has demonstrated to have a positive result in cancer and also now in AIDS. So there is two completely different diseases which are impacted by the same in a positive way by the same type of therapy.

-- Now they both should make that answer within six months. If you taken on a neoglastoma, the survival is usually six months or less on the basis there is relapse after the surgery....the people who are HIV...infection we can test on evaluation of ....disease within six months. There's got to be some idea.

FW I think this is going to be tremendously important to be able to demonstrate this because one of the problems has been, even in Nobel...had two evaluations done and it was struck by the way it was presented by National Cancer last night. These were their efforts. I mean they are generally perceived as the efforts to D6 vitamin C and

that's exactly what they did. They said vitamin C is not affective for any kind of disease or illness. That was their comment after the test. So think that clearly we need to demonstrate, one that we can put together an evaluation that can in good faith evaluate a therapy. One, we need one victory here. We need to do something within a six month or a one year period that can demonstrate in a very real way the potential in these alternatives and I agree that people with AIDS who have all of the recognized market who are very sick who get dramatically better. We don't know if we can eliminate the virus. We don't know if we can make a person convert zero negative. But we do know that we can take this person from a very sick person to a very well person and we have to measure that. We have to be able to demonstrate that in a group of people with a therapy. Now back to the question, are we then, have we then decided that without excluding any of the diseases or illness of what underlying disease conditions that the focus at least initially should be the major public health problems of untying such as cancer, AIDS and heart disease, does this make sense to everyone?

-- I particularly think it makes sense but why would you want to exclude a...

FW No, no without exclusion I said. Without excluding anything, but focus, as a focus.

-- These were massively complex diseases. How would you propose to tackle anyone of those diseases with any kind of scientific value but in fact billions of dollars instead. If you don't got the protocol to go along with

the...you're going to be...in the medical establishment and the scientifically...

-- Well that's a separate issue though.

(several speaking)

FW We're going to deal with those. These questions are, what we are trying to do is get through what one, two three four, yes those are issues that we are going to deal with, but what diseases, I mean the questions specifically ask what diseases does your committee feels most likely to be benefited.

-- I don't understand the question. If I have a cat scan on a patient who had surgery and had a brain tumor and the cat scan shows a large tumor mass in the brain and six months to a year later that cat scan is normal, no one is going to question the results.

-- That's a specific, that's fine.

-- Well that's what I am saying.

(several speaking)

-- I'm sure Dr. Brezensky has cancers he's curred. I think that Dr. Burton who has cured prostate cancer. I have visited Dr. Burton in the Bahamas...with prostate cancer, Dr. Ravesey in New York with all kinds of cancers and after all that we are now doing the study on one of the drug companies are doing the study with Dr. Ravesey on

AIDS in mice at Bethezda hospital in New York to see whether his medicine can affect raw AIDS with mice. Where to me because cancer has been a problem to the community for many, many more years than AIDS, I think we'd have no resistance if we said let's see if we can cure a disease that's killing 500,000 people a year and how we've made no progress according to many articles in the 40 years that I've been a physician, so I don't see why there would be any resistance to taking people with incurable cancer, such as lung cancer, brain cancer, pancreas cancer and putting them on this drug and as I say anybody who's dealt with this disease in six controlled months, the answer is there and it's simple enough to do.

(several speaking)

-- ...proves to you that they work. To change somebody's health standards that's doomed to die.

-- I wouldn't change the standards, but change the laboratory findings. As I say you have a patient with carcinoma of the lung which attaches to the liver and you have a cat scan on their brain, on their lung and on their liver and then you put them on a medicine and six months later that cat scan is normal, you're not just saying, you substantiating it with a scientific method. So what you can do before we start on this program is record all the tests that are necessary. The primary side and all areas ....

FW Excuse, we have another question down here. We got into a dialogue.

-- I listened quit avidly last night and I think it was very interesting and I am seeing what's happening this morning. I think we are loosing perspective. We were here to write policy or to attempt to write policy to allow all of us, all our research endeavors to forward unencumbered with whatever assistance are available and with as much as a lazy affair as possible in terms of a policy. What this is ending up being is try to afford their own scientific merit as being the particular evidence or example why they should go for it. With all do respect to the physicians that are here. Although they have provided evidence that their treatments or methodologies may be efficacious, if we were to put all eggs in that basket at god for bid that basket was not to provide any pruition, we probably would sink in the very basket that we were placing upon the water. We are here to write a policy. We are not here to explore or exploit or expound upon our own scientific endeavors.

-- The only thing that we've heard Mr. Wiewel say that we need an answer quickly to give us....

-- Provide a forum or provide example instruction without providing the particular examples. Rather than saying we should push forward.

-- I'm not sure what you mean by that.

-- For example, if you feel that it a six month trial, okay where you have a weld in your case, an end point that is irrevocable, okay or in a case a scenario for which you have an end point, if you say that you must have an answer

within twelve months, it's really moot to consider a cancer situation which has a survival of 12 months because we know by random deviation you are going to have some 15 months and you're going to have some 9 months.

-- If you have the proper selection, you could pick people out who....

-- I agree whole heartedly, but once again we are deviating from the original reason we are here. If in deed you wish to have a form of a particular group of experimentations or particular protocols for which you have answer so to speak within 12 months, than write the policy for that, but write in siting specific examples of such.

FW Once again I think that, we're going to have to do this all day because there's a lot of good ideas and a lot of people here to deal with. We need to discuss what diseases.

-- I would like to move here a motion....

-- As I understand all six groups are going to be answering these specific questions.

FW That's right.

-- Therefore, I think we ought to read the question and answer the question.

FW I think this is exactly what...

-- What disease, what is most like--none of us will question that these methods make the...the question is what is most likely. I would submit therefore, the most likely is the most curable of all kinds of diseases which is cancer. It is, I mean your odds are throwing the dice. That is the most likely. To me that's the answer to the question.

-- Excuse me but I think we have to talk in terms of specifics. Although I think we are here, I think there is two points to what Joseph was saying, one is that we have to get beyond ourselves and our particular and Cole? already agreed with that, but I think that realistically what this comes down to is a test of something. I mean the Congress and the public is looking to us and saying well do you really have anything and if you do let's test it according to the best scientific procedures and see if there's anything there. I don't see how we can get away with that. It does come down to a question of specifics eventually. Not general procedures.

-- You know one way without spending much money, if you have something is to make a...Dr. Brezensky's result, my result on kilation. Tons of physicians in this country do very good work and ....is not very expensive and can come ome to some conclusions. As for the methodology, I am perturbed by the concepts... underlying biological process and...if we stay we get language of orthodox medicine, we're going to be lost in the yonder of the faulty thinking processes. First for instance chronic fatigue recently is being demonstrated to relate to food allergies, before that to....I say that's related to many things. So what I am saying is, if you look at chronic

fatigue as a disease or virus and never find the specific virus or you find them.....whatever and don't look at the disease process from the biological pin point which in my opinion is....can stop allergy, from stress with toxic metals whatever. Once an allergy, food allergy, once you reach the point of no return of the resistance, the disease appears. I propose that we look at this concept of how we look at disease, we must set new terms of dialogue and not go with their terms.

FW I think I am hearing at least that none of us wants to say, we're going to exclude this condition or exclude that condition from the discussion. I think what we are also hearing is that we must focus on the questions that we have at hand, what diseases are disease conditions. I think that what I am hearing is that obviously alternative medicine offers great promise for the full range of diseases or illnesses that we face in this country and that today we should focus on some of them as an initial focus. So, I would say that bar any objection that we should concentrate on cancer, AIDS and cardiovascular diseases which represent approximately 80% of the preventable causes of death. Not to exclude, we will not and never will we exclude, because I don't think it make sense to exclude a wonderful treatment which might exist for sickl--cell anemia or a wonderful treatment might exist for any kind of disease or illness. I think that we need to focus here and I think also without excluding anyone, we should probably move on to the next question.

-- I so move that wording with the addition of because of the failure of the medical field to solve these problems. I

would also like to speak to that motion one more time as I said last night, a lot of people were not listening to the message. Dr. Friedman said last night, "at best" they will evaluate eight to ten procedures per year. At best we cannot afford to get bogged down in individual items. We have to focus on the key issues because this is our best shot at it.

Berk I don't think we ought to pay any attention when he said that. Let me tell you why. This is a new movement and if we start to let conventional N.I.H. determine what we are going to do, we just in my opinion might as well close up shop. But I believe that the question is what do you mean by evaluating and I think that starts with simply finding out what Dr. Berzensky been doing and what Dr. Ravesey been doing and what Dr. Latino knows and so on around the horn. Then it moves step by step by step up to where if you do what they want you to do, it's going to be a test that's going to cost millions and millions of dollars and take a long time oand their going to eight or ten of them per year. I don't think that the public feels that you have to do that. I think what the public--if you were to go to the public and say we've got a treatment that is shown to be affective in 30% of the cases, in AIDS cases, I think you'd have a clamer, let's pursue this further and therefore I think what we have here is the opportunity in this organization to set up protocols of our own as to how we should look at these items and we can either go all the way to those eight or ten or we can go part way to those eight or ten and I think if we can show efficacy of not scientifically proven, but efficacy that satisfies the public, I think we are going to be able through Congress

and so on to get these things moved forward. So I just think that the day we start to let Dr. Friedman tell us how much we are going to be able to do, I think we're sunk.

-- I agree with you whole heartedly Congressman but we must admit that this point N.I.H. is in control of this meeting.

(several speaking)

-- No I don't think so at all and I think I am a good one to judge that because I have been close to the Congress as mandating that this had to be done and I don't think N.I.H. is in control of this meeting. I think we're in control of this meeting.

-- On the other hand, I don't think it's necessary for rugged games through the scientific orders at N.I.H. that they haven't even solved something that by and large are very serious and well contended group of scientist.

-- Excuse me, but I think Friedman gave us the mandate to do that because if I remember correctly his last point was that we must compare the effectiveness of the alternative therapy to the conventional therapy. I think he thinks of it in exactly diametrically opposite terms than we do. He thinks that conventional therapy, it works so well that even if you're unconventional treatment comes up and has some benefit, it can't possibly be as good as the conventional. I see exactly opposite terms. I see the object failure of conventional medicine to deal with let's

say metastasize cancer.

-- You don't have to destroy them to prove our point.

FW I understand that.

-- They are offering to make the comparison. I think that inevitably that comparison is going to be made because what happens is, this has happened with different alternative therapies that even if you prove that it is affective, they come back and say well you only got 42%, we get 46% so therefore we're going to junk your method. That comparison will be made whether we chose to make it or not.

(several speaking)

FW I do understand the comment, I see no point in rubbing any one's nose in anything. We are where we are, so I agree with you. I don't want to rub any one's nose in anything, but I also don't want to have my director of an agency or my deputy director or whatever position he held, tell me that we aren't going to give you any people, we aren't going to give you any funds. We aren't going to give you any special treatment. Well, I am sorry, but this is my National Cancer Institute. This isn't his National Cancer Institute, it isn't somebody else. This is our National Cancer Institute. If we say we want 25% of the budget next year, this will scare the day lights out of them. So I think we need to be serious about this, but I don't think we need to rub any one's nose in it. I think it's time that we move on to the next question unless we have

any problems.

-- I'd like to say and that is I am prepared to do the research at my expense if I can...

FW Okay, we are going to make note of that and there will be a time when we will take you up on that.

-- Here is another items which should be considered under one possibly which is the ....deatrogenic disease from ordinary allopathic treatment. I think a study done in Harvard of the New York State Hospital ...deatrogenic disease come up a perfectly astronomical number.

-- What kind of disease.

-- Caused by drugs, diseases caused by existing drugs.

FW Drugs by the doctors and their intervention.

-- I don't know if that should include in it if you can think....

-- Part of the overall picture of a disease certainly needs to be there because if you look at the impact, how do we impact something. You've got a lifestyle, we give some cancer patient ... and destroy their social structure and everything else.

(several speaking)

FW Well let's consider it because I mean it is something that

we consider in the whole range if issues that we are fasing. Okay, now the next one is going to be tough. These are all tough and...

-- Take a concensus, you better find out if you got concensus.

-- You'll never get consensus.

-- I made a motion.

-- I'll second it.

(several speaking)

-- The wording reads that without excluding anything else, either with or without because of the failure of medical therapy to successfully address these issues inspite of a tremendous amount of funding that the initial focus beyond the cancer, cardiovascular disease and what he said, AIDS.

-- AIDS and other immune deficiency...

-- Immune dysfunction

(several speaking)

FW We are never going to agree on exactly the words, do we have seconds.

-- I'll second.

FW All in favor? Opposed?

-- Guess it's unanimous.

(several speaking)

-- Okay, Ron did you get that down, or did the writer hear that.

FW Everything is being taped, so be careful what you say. Okay, we did write a letter last night and we did send it through Peter to David Keslin, the Commissioner of F.D.A. to ask him to come to our meeting. We don't know what the result of that letter is, but we have made the formal request to invite him. Question number two, this is going to be interesting, what general methods of treatment does your committee view as most promising. What we're going to have to do again is Steve Grubb described it as let the blood letting begin. I think that clearly there's going to be people, we're a diverse group here and I think that's wonderful, however we're going to have to cover the general methods of treatment that we feel, like the most promising as per pharmacological/biological treatments.

-- What is the distinction between general methods in your view and specific treatments as in the next question?

FW Obviously general methods would be a pharmacological intervention, a field of biological response modifiers verses chemotherapy. Those are two competing fields which are pharmacological in nature or biological verses pharmacological. Verses the specific treatments such as

antineoplastons or immunoaugmentative therapy or specific treatments.

-- I don't see there's any way in the world we can answer the question because we haven't come up--if not we had said, we had this particular glioma that we are going to deal with it and it would come up with a specific answer to have you deal with that, but cancer isn't a disease.

END OF SIDE ONE, TAPE NUMBER ONE

BEGINNING OF SIDE TWO, TAPE NUMBER ONE

(different speaker)...agree about is that combination therapy is probably the word of the day. I think any of the diseases that we mentioned thus far this morning are going to be less addressed by a multiplicity of approaches. For example, nutritional medicine, my field is AIDS for example. I think it is going to be very hard for us to come up with. Let's look at ozone therapy for AIDS. Granted I think that's a very promising area, but it seems to me in my clinical experience that a multiplicity of approaches is required for the complete healing of that condition and so I would like to have some language here about paying careful attention to treatments that are combinations and multimodality and that coming up with specific monotherapies is probably not going to be the answer.

FW General methods, I think what the question, what we're looking to is, if a general method encompasses a multifactorial approach, they die and nutrition and homeography. That's one approach, that's one general method of treatment.

-- So we're looking to--so question two is about modalities then.

FW Well three is more specific, it's specific treatments you see. I mean a specific treatment might be a specific treatment such as antineoplaston, a general method is ya know....

-- Let me homeopathy as one of the general methods which hopefully...

-- (foreign gentleman speaking-very difficult to understand)

-- ....you'd have to put in there too....cancers

FW What did you define the retenoic acid?

-- It's a differentiation in uses.

FW Differentiation

-- What I don't understand that many of these clinic using alternative, unapproved methods have been active for many years. Wouldn't it be simple enough to say to these clinics, give us evidence of your success rate that you achieved on illegal basis rather than give theoretical approaches.

(several speaking)

FW Well that's the next question. I just don't want to jump ahead here. What we're looking at is, in a general sense,

you see what they're coming to us and saying, well you see we have a mock okay it's the magic bullet mock okay we have fought the war on cancer in search of the magic bullet for thirty years. I think it's an exercise in futility. We haven't found the magic bullet. Perhaps in one or two three kinds of cancer in maybe 10 or 15 percent of the cancers have we found something which has helped extend life. There is no magic bullet. Anyone searching for that one particular thing which is going to hit all the whole arrange, I think we're not going to find it, but there are things which we have to look at in the whole focus, in the holism, ya know a person's diet, a person's lifestyle, a person's stress level, the person's ya know circulating level of antineoplastons. These are all parts of general methods of treatment and I think that as you said, the order of the day is that we don't exclude things. We don't say the patient doesn't need, you don't need to give them good nutrition when they are in the hospital because we are giving them good sound chemotherapy. I think you need to consider all these things in general methods of treatment. I think much more today now that we are looking holistically at these things. There is even some medical schools....

-- You say that's very important the first step have some degree of success so that we can get credibility and I'm saying rather than start out with experiments that have not been tested, for example when I went down to visit Dr. Burton, he showed me patients with data diagnosis bone scans, no bone scans that were abnormal initially with metastatic prostate cancer, so I know a man like that has evidence that he has cured patients who would have been

incurable on standards methods. I'm sure Dr. Brezensky has data where he has success in patients that he has treated with his methods. Dr. Ravesey has data on patients he has treated successfully with his methods. Why not use his data that is already available rather than settle for theoretical.

FW Well I think that--you're right, I mean I understand what you are saying, but I think we have to relate it to the question, what is Dr. Brezensky and Dr. Burton a fall under the umbrella of general method of treatment. People have said to me immunological treatments. This is what we are looking for in this question. We are looking for are there immunological treatments. People come to me and they say, I want a immune system treatment. I want something for the immune system, you know what I mean. The people are asking for therapies which they are only are sort of half understanding ya know. Like the immune system obviously is a general method of treatment.

-- I just want to make the observation that part of the difficulty I think is that science is reductionist and it gets easier and easier to do science the less items you have to deal with and the ideal situation for a scientist is when they are dealing with one item and they contest that against another item. Medicine is holistic, the more things that you can do for the patient, the more likely the patient is to get better and so when we look at, when we want to say, well what works in terms of the patient, we generally find that we are dealing with many factors. When you want to look at it from the point of view of a research project, it becomes more and more difficult to do

that. Barry did you want...

-- I think we're dealing with a furious argument here because the question itself is maybe we should consider I think we're having trouble finding the answer and we're dealing with...

-- You can go back to the original questions, but I don't think that they're going to...

FW Or just rephrase the question.

(several speaking)

-- You're making the point as has been made and I think it is a very important one that we want to take a more holistic approach and we don't want to say we're all going to be interested in this one way of, but on the other ha nd that is what this question is saying, get rid of that holistic approach and narrow it down. Maybe we should somehow rephrase it and answer it as has been suggested in a general sense.

FW See general methods of treatment could be--a general method of treatment could be a holistic approach to the treatment of cancer. It can not all be practiced in this country. I mean if you go to Mayo, you're not going to get a holistic approach to cancer therapy, so this would be a general method of treatment. I mean these are the things that we envisioned when we were talking about this, a general method for the treatment of heart disease...

-- (foreign gentleman hard to understand)....and that's what's happening right now, there's so many that I really fall asleep. Why don't we go around each member of the table and ask them...we have cancer, we have cardiovascular disease, we have immune dysfunction. Go around each member of the table rather than...back and forth, go through all the questions, answer all the questions, then you can debate the thing...we have to come out with an agenda, if we sit and haggle and debate like, excuse me Congressman, a member of parliament the congress. We are not to come up with an agenda at the end of the day. So why don't we ask what they want and list them and move on.

Berk I agree and I think we're making heavy war of this questions, which is not all that difficult. I am just going to propose that we say immuno-modifying methods. I mean...

(several speaking)

FW Can we ask for general systems of treatment?

-- Immuno therapy, differentiation therapy which is the use of differentiation in uses.

FW That's two differentiation...

-- Specific or general?

-- General, yes.

-- Dry state therapy.

-- Does that mean if a patient comes to see me and is dying of cancer, what do I do for them?

FW Pardon me?

-- What do you do for a patient who walks in and who is dying of cancer?

-- That's not the issue...

(several speaking)

-- We have to get a positive step forward to gain creditability and I'm saying if we start doing research with unproven methods, it will be five to ten years before you get an answer.

FW What do you feel are the general methods of treatment?

-- Well again..,

FW Immuno-therapy or we are not talking about here...

(several speaking)

-- I'm saying Dr. Brezensky's says he's had patients that he's helped, let him give a protocol of how to treat a certain kind of cancer. Say that doctor Ravesey has cancers that he's cured, let me give you a protocol...how they work.

(several speaking)

-- You want to get an asnwer so that we can gain credibility.

FW Okay, but general, we are asking the question on general methods.

-- All the panels are addressing these same questions.

FW Okay, around the table...

-- We've got two very difficult reviews here and I think it's intriguing. One is we want to gain credibility from the signs of the community, whatever that is. The other is and I certainly concur with Berkley Bedell is that this is not a scientific dispute. It may go on forever. It's a political problem and if we can go to the American public and accomplish what I call poly- factoriality, just to create new word, is the way to approach these things, we're going to get support in Congress and that's what we want. We can split hairs over science forever. We're firmly locked into a 17th century postulance here, that's cartesnia cartonia postulate are ridiculous in terms of medicine and we need a political statement, we need a conceptualization about what we're trying to save the population of the planet and it's not being done by splitting hairs over science and I bet we have to make that ultimately. We need, I don't care what we call it, polyfactoriality, multifactorial, multitherapy, whatever it is to get us off this dying, we need the freedom to do these things.

FW What would you suggest as a general methods of treatment?

-- A polyfactoriality and ....and management and

individualized protocols.

-- ....mentality, can we, do we have the liberty of changing the language and saying what the Brenner say, not what specific treatment, but what treatment have proved in the methonologies program or whatever analogies, they have been efficient and effective, then you do the thing...now they want to see how the Brezensky method works or the ....method, then they do the studies, not us. We opt to prove that when 1000, 54, 30 percent succeed or whatever, that we can do with the methodology method. We can not abide by their methodology request or we will sink.

FW Barry

-- We are being placed in our own time...questions that we developed these questions were not given to us by N.I.H. The questions that we are mere dealing with were developed by this group. So instead of arguing about the wording in the questions I think it's very important that we....which is an ancient saying, we cease the day we have a wonderful opportunity to do something and I think that we need to do that...

(several speaking)

FW Let's not get bogged down. I'm not in love these words, all I have done is to create a frame work that we, the group of people here, to create a frame work for discussion, so nothing is etched in stone here. I think that if we can, we've had suggestions about immunotherapytherapy, differentiation therapy,

polyfactorial or multifactorial therapy.

(serveral speaking)

-- What I'm hearing is the answer to question number two should be those methods of treatment the practitioners have proved to be successful in numerous cases and let them make their own choice of it.

-- Right, that' the way, very good.

-- The other issues here is that there is really two categories and answers to question number two. One is modality, or systems of medicine, for example homeopathic medicine, naturepathic medicine, acupuncture, I think those need to be mentioned as an answer to question two and then there are medical approaches, for example, differentiation of research has been mentioned, immunomogilation therapy, botanical medicine that's both anti vial and anti microbial in general. That we need to separate specific approaches from systems of medicine and I think we need to combine them both in this question.

-- Of course this is the pharmacological and biological meeting...

-- Yeh I know that, but I think it would be really great if every single committee mentioned homeopathic medicine. I think that homeopathic medicine needs to come--becoming emerging because it's so important from the basic science perspective.

FW Richard?

-- Let me see if I can put an idea forward. I agree with you that we should see it today, this is our moment to get something done. We are fighting the system. The system is proved by hundreds of thousands of doctors. It is respected by the majority of America to what they're using. If we went to upset the system, we better go on a very conservative, not a radical basis. No matter what I happen to think about visual imagery, if I exposed that, 98% of the people think I'm nuts. But, if I were going on a conservative tract and say I want to prove or disprove what ever others have found to work, the system has a hard job of saying we're not going to fool with that. Alright and that goes with the next question too. The minute we try to get specific treatments, we're going to argue, your treatment is better than your treatment, no his treatment is better than yours. Let's not get wrapped up in a minutiae argument, let's say let them prove or disprove whatever people who have tried and proved and I'll think you'll have a big point in putting this forward.

FW I don't think anyone here would argue with the fact that we all want to prove or disprove. I have no particular love for any particular idea that would go beyond a real good scientific evaluation. Let the chips fall where they may and I think everyone is agreement on that. Certainly we're fighting the system and certainly I don't want to...or try to over throw the American medical system. Perhaps the nonviolent overthrow, but any case I think...

Berk I think it would be helpful to all of us if I'd tell you a

little a bit about what's happened and at least my perception of what I would hope to see happen. The first I'm pretty sure of, the second I could be very wrong about. First of all, you need to know that when this legislation was passed and I went over and met with the people at N.I.H. and it was my strong feeling that we were tremendously understaffed and we needed to have what I'm going to call investigators to go out and do exactly what you're talking about here. To go out and visit Ravesey and go out and visit Burton and go and visit the people who are working with ozone and that sort of thing to check to see whether it looked like they really had something and then proceed forward from that. The result of that was that Senator Harkin's office sent a letter over to N.I.H. I think the proper word is telling them that they were supposed to hire five full-time investigators at N.I.H. to go out, well I guess that's it, full time investigators at N.I.H. That moved forward at a very slow pace, but at least I'm advised by Jay Moscowich is that within six weeks, he expects to have at least five more staffed people on board at this office at N.I.H. and I think, I'm not sure, but I think two of them will be investigators to go out and look at various treatments. My perception is and you may not agree with this or anything, but we need to talk about it. My perception is that if he has two full time investigators, that what those people would do would be as different treatments come into this office for attention, such as Jim, your sickle-cell anemia thing, such as what Dr. Ravesey is doing, such as some of the ozone treatments that seem to be working, that they would simply go out and look and see what sort of success it looks like those treatments are

having as compared to conventional treatments and then at least I had the impression from Jay and I talked to him again yesterday about it and at least he indicated to me that he was in agreement, that one of the things he would receptive to would be for us to come up with protocols as to how unconventional treatments should be evaluated because at least in my opinion if we're going to use the double blind studies and conventional types of protocols, they're not going to be appropriate for many of these types of treatments and at least it would be my hopes that we would end up with a type of protocol that depended primarily on what I guess we generally call it outcome research and that is that does the treatment, is there really proper evidence to indicate that this treatment is affective particularly in those types of diseases that you've mentioned for which at least--I think their general feeling that conventional treatments are far from as effective as we would like to have them be. I thought at least you should be aware of what is moving and what's happening as we look at how we want to go forward.

-- Just to compliment on Bill's statement. You're really looking for a inter-structure or framework to be able to embrace these particular modality treatments etc. rather than looking at specific treatments. One of the things that I've always and throughout my own research is been that at this juncture, the N.I.H. has been scientifically enable, unable I should say, to be able to educationally apprise themselves of the research, even thought I tend to believe that I write relatively clearly and the investigators that I work with do the same. There is a certain education risk that exist between the

investigators rather they be practitioners or actual researchers and what stands at the N.I.H. and since their legislating the policy and eventually the funds that are going to enable these researchers to go ahead. I don't mean research in terms of basic research, but to be applied to clinical, practical, it doesn't make a difference. I think this office really needs to afford a service such that these investigators just don't go out a assemble data and just bring it back, manipulate it into the black box and say it's ineffective as I ....last month, but rather afford a forum for such that there is a common grounds, meaning if we do not conform, it doesn't mean that there tenants have to be modulated or ours, but rather both. But there is a middle ground, it doesn't have to be the exact middle. There is an in-between grounds that we have to be able to provide more scientifically halusidating information. It may be their way in the case of what Dr. Brenner is suggesting, but it hasn't been presented as in a fashion that is easily assumable by them. Okay, in the case of other people's work, maybe there is an educational problem, they just don't understand. I'm not saying you can't stand on your..and basically say we'll it's up to them to understand because you're going to be the pulls apart, you're going to be diaposed and basically you're going to be abrased rather than to affect your goal. So maybe this office can provide a framework such that the data that comes in, either in a pre submission fashion or in a post submisson fashion whether it be prospective or retrospective, can afford a framework such the.data that it generated or has been generated can be presented in a fashion that can be weighed and evaluated appropriately

and fairly without preconceived notion, rather out any prejudged efficacy or treatment on safety.

FW I think that's a very good idea.

-- Back to...I have a firm that's competitive to the firm that Joe...those guys did a magnificent job taking an alternative therapy and bringing it at great costs, I hate to think what kind of money they spent, and I just sat back and sort of...but at great expense they brought that into traditional medicine to the point where they had an article...which was a ground breaking part for ozone therapy or use of ozone on any biological process. So that what he saying is that some agency is within N.I.H must be well funded with brilliant people to take these alternative therapies and strap their essence and then present them so that other researchers then can follow through in the traditional academic process otherwise we are up against an F.D.A. that will take you 200 million dollars and you will get nowhere and you'll find that you'll finally be shot down.

-- What your suggesting is sort of like an...

-- Right within N.I.H. where people who are on the fringe or in unconventional areas could go to and get a receptive hearing and get help in terms of translating their data into a form that could be acceptable to the main stream.

-- ..question, you present any therapy, it is strictly an intellectual, it's not an emotional or it's not a..it's strictly an intellectual question. You want to put the

money in brains to that question and

-- But we have a background in suspicion and hatred and fear in this area that kind of like anything in any other...

(several speaking)

-- ...not start off fresh or wipe the slate clean, but to avail us the opportunity to say we'll okay if they're going to afford us this form and we're going to assembly in such a fashion, then we have to move with the idea. Now that portions of our brain that there is a secret agenda that they're trying to keep a thumb on top of. That they're trying to move forward. They're trying to appropriate moneys. I think the two million dollars that they appropriated is a scan pimple on the face of what's going to be necessary, but a least it's some moneys to afford us the ability to come together.

-- I'm just making an observation that that's all...agreed and that's what we're trying to overcome. We here represent the people within the alternative community who are willing to walk the extra mile or are willing to enter into this process, right. There are others out there who are not and some of the things that some of the people that Brenner has mentioned for instance, there's a problem on the other side. The problem is not just with N.I.H. There's a problem that it's not going to be so easy to extract the date from those people...forty years of suspicion and paranoia and whatever.

-- ...have set up an oasis where this alternative work could

go forward. It maybe needs a hundred million dollars funding instead of two million funding but that...

Berk I'd also like to speak to the problem that Ralph just brought up about the fear of F.D.A. and should probably read you an amendment that we have proposed should go into the legislation that's now--the trouble is that's not a fast track and it went to the committee last week and it's going to go to the full floor of the Senate this week. I should read this to ya. It says "The director of the National Institutes of Health is authorized not withstanding the provision of any other law for the purpose of research only, to authorize physicians licensed to practice medicine to use any medicine or medical procedure for which there is no evidence or reason to believe that such medicine or medical procedure is unsafe for the investigation of such medicine or medical procedures. Any physician so authorized by the director may proceed with such medicine or medical procedure only if the patient is fully informed and provides written consent." Now the purpose of this was to say that if N.I.H wanted to look into some doctor that was treating people with ozone or with something that F.D.A. has not approved, that they would be able to tell that doctor that we want you to research this and you can go ahead and treat patients with it and find out how it works without having to worry about F.D.A. That was all set to go and no problem or anything else and they called me about the day before and they said they hit a real snag and I said what's the snag and the snag was that they were told that they didn't need this, that N.I.H. already, the director of N.I.H. already had that authority. Well if N.I.H does

already have that authority, then we should be well aware of it. If they don't have it, somebody was misinforming Harkins's staff and so at least as we go forward it seems to me that we should assume that N.I.H. does have that authority because they've been so advised that if they begin this investigation, if we do have investigators go out and they look at--keep using it, ozone and they believe that there's reason to believe that it is worth checking into, that the director would apparently have authority to tell a doctor that we are authorizing you to treat patients under these direct rules with ozone so that we can monitor it to see if it really is effective in the treatment of cancer, for example. At least this needs to be cleared up because Harkin's staff believed that they have that authority and if there's any question...

-- I think what they're eluding to, and I could be wrong, there is well documented policy of that compassionate use okay, but if that's what eluding to, if that's what they're refereNCIng in the fact that the policy is already within the you know, within the statutes compassionate use is predicated on a case by case basis. Okay, that means that on each and every individual patient that comes forth, that patient has to be evaluated for that particular therapy. That is not the same thing as what Senator Harkin was suggesting is that they could basically deputized a particular physician or group to investigate the potential treatment. Those are two distinctly different entities so we're reciting that as being, just be duplicity for that the...

-- The problem is everything is moving so fast, it's going to

the floor I think tomorrow.

(several speaking)

-- I think too that the National Cancer Institute does not have such authority. I was harassed by the State of Texas. They want to put me out of business, they want to take my license away after the N.C.I. proved my treatment was showing effectiveness. I was informed by the National Cancer Institute that they're not going to tell the State of Texas to leave me in peace, to let live and until this therapy is evaluated. So if such a therapy exist, I can write N.C.I. and they're not going to do anything to interfere with the State of Texas even to call and tell them leave the guy in peace and let us evaluate the treatment because the treatment may be lifesaving.

-- I have a real problem with the wording on that too. Any time you get a large set of licensed physicians doing such and such, you cut out nine tenths of the alternate medical practice. I've got four people on my staff with excellent therapies that work all over the place and not one of them will go out of the closet and say here's my data with his name on it because every time someone else in the nation has done that, they've shut them right down. The F.D.A. or someone has come in and said, we don't care if your stuff works or not, you're not licensed to do this. Well if no one licenses someone to do this.

Berk A licensed physician is--any licensed physician is a physician that is licensed to practice medicine.

-- But, what does that mean? That's my question, how do you license an lungthologist or a developmental neurologist or someone with mind-body practice or just knows a good technique he learned some place. You don't fit into the standard hierarchy some place.

Berk This would not include such people, but at least it's my belief it may be wrong if you've got all licensed practitioners into this, you would include a tremendous percent of the people that are doing it and you would not include nurse practitioners and this sort of thing.

-- Can I say something? I think you're raising an extremely important point, which I know Harris is an expert on it which is the medical practice is at and in our meeting we have to rewrite the questions and we talked about this a lot, but I'm not convinced that even though that sort of-- ya know the bottom line question in a lot of this that really is something we can address meeting. There's a lot to be said on that question...

-- I suggest the medical practice be...

(several speaking)

-- Berkley's bill would give us a foot in the door and things could move on from there, but at least that would protect Dr. Brezensky and it would protect Dr. Ravesey or somebody. Ya know there are many medical doctors who are doing these therapies who do need protection. I don't think it would stop there. We are reaching at this point to try to overturn the medical practices acts from this

committee..

-- ...what I'm saying is there is a huge wealth of data out there and I'm been in the business myself for ten years and have extract the date from random sources and I've had to promise so many people, I'm not going to tell anybody where I found this out. I know several methods that I've seen work on advanced breast cancer, just watched the stuff melt away in a couple of weeks. It would be phenomenal for people in the community at large to know, but I can't tell anybody how I found that out.

FW What I think what Dr. Moss is saying and I think I agree, ya know a lot of cases we're dealing with health care providers, health care practitioners, okay they may be not licensed under the existing laws of the state of whatever ya know and so there is no universal medical licensure here and while we have individual state licensures and some of the people in this room are having trouble with those and some people who were not able to come because they are having trouble with those state medical licensure boards. This is an issue which we can make a recommendation that ya know we begin to seriously look at the medical practices acts on a state wide basis, but I don't ink we can really discuss that kind of scope here. I mean this is a huge issue. Now technically, we have, if what Joseph was saying is correct, we have compassionate use, which is an inclusionary process which you can treat one patient at one time which we all know a patient who has had a therapy which has been denied to them through one thing through another, that's how I got involved here. A whole group of patients was denied therapy by actions of

the United States Public Health Service, but I think clearly that I 'm not aware of any law, I'm not aware of any power which has allowed, the Secretary of Health and Human Services to say that Dr. Brezensky should be able to treat the patients in the State of Texas. I'm just not aware of any such thing. I am aware of international law, which I believe supersedes all of what we're discussing here and that is, and there again we've got language again, but the declaration of Elsinky said that a physician should be able to--should be free to use any therapeutic measure which his judgment offers the help of savings lives, reestablishing health or alleviating suffering now this is a matter of international law. We are the signator of the Elsinky declaration. Also the American Medical Association has signed this declaration. So this is international law. I'm not aware of a national law, federal law.

-- It's not law, international.

FW Well the declaration was a treaty which we signed or a declaration which we have the signator on besides it's not a law.

-- ...supersedes domestic law.

(several speaking)

FW ...whether or not we practically applying this. Practically it's not being applied. If Berkley as you're say and as Mike Hall tells you that this exists, this power exists, I'm not aware of it. I've never been told about this and I don't know anyone else who is. Is anyone

else aware of such a law?

-- If I'm understanding correctly, your amendment is aimed at giving freedom to patients and physicians to use any alternative method be it two of them or three of them whatever, agreed upon. If this is what the amendment is, it will be splendous.

-- If is being that if the secretary of H.H.S. asks that that be so.

-- ...you have investigation, you can ask for an investigation protocol permission, this exists already. It doesn't change the realty that if you have to go through the progress and they deny to you, what are you going to do about it. If in deed the realty of medical intervention has to be a...relationship between patients and doctors providing that both agree on holy water, if a physician and a doctor have agreed on holy water and this is what the patient wants, why can't a physician have holy water. I making...

FW That's the larger question.

-- That's not fair...I think for a patient to bypass a proven method and go on unproven methods is just as wrong as to deny someone who has failed someone who has failed on proven methods, an alternative method. If someone is cured on proven method, why should they bypass that...

-- Why would they want to do that?

(several speaking)

-- This is not a question of our individual beliefs. It is a question of what the law is and the law is that the patient has the right to chose the--the mentally competent patient, adult patient has the right to choose the therapy or reject the therapy and that includes lifesaving procedures and this has been upheld over and over again by the courts in the case of people who have rejected blood transfusions and the courts say ya know we think you're going to die, we think you're crazy, but this is the most fundamental right of the Anglo-American tradition is the right to do with your body what you wish and that's the law. It's immaterial whether a doctor thinks you should do that or not do that. That's freedom of choice.

FW Now there is a problem and the problem that we're facing and that is the medical license sure boards, the state medical authorities and the federal authorities telling physicians that they can not use certain substances that are not "approved". These are issues that we can deal with. I think we are in very interesting territory, very pertinent territory, but I think we have to get back to point and that is we did discuss, and I don't think we were done discussing, the general methods of treatment. These are all issues which we were addressing under criteria for evaluations. We're into the barriers now area, so we need to keep coming back to the questions because we want to do this in some logical order. We were on the question of general methods of treatment. I don't think anyone here is going to solve what general methods of treatment will best address the major public health

issues of our time once and for all. But, we're trying to get a handle on--we want to go to people who don't understand our language and who don't understand what we're looking for essentially in the case of we have an anti viral substance, two or three anti viral substances approved for AIDS. We are talking about ozone, we're talking about kilation, we're talking about foreign concepts to these people. What we wanted to get a handle on by asking this question is what general methods are we going to approach disease with that are different than the methods now being used. I mean we're not going to, obviously I don't think anyone here is saying we should have the new and approved ADT to treat AIDS. So what methods would we put forward.

-- Dr. Bernan, who's our chairman who's here would be good to hear from.

FW Good

-- I just want to--it sounds like you're doing a very good job...if a person...barriers and problems that you are faced with. I just would like to stress what said last night is to...go through some of these, come up with some research priorities, criteria if you can do that, I think you'll be heard much better by the general group as a whole.

FW When you say that, you mean specific treatments?

-- There's a lot of questions here. You can spend several days on each question. All I'm hearing so far sitting

there which is not the whole time you've been together is question number six which involves barriers and I'm just saying to you. I've got only a couples hours left for your actual group as one group here. Go through all the questions, come up with some of these...

-- You have a different list than what they've been going by.

(several speaking)

FW Well lets do this, let's suggest that we go, try to stay on point. I know this is all very interesting conversation here and I'm not trying to limit anyone's comments, but I think it's important that we go around. Let me tell you what we have had. We have had Dr. Brezensky's suggest that differentiation agents and immunological therapies. We have multimodality...

-- Oxidative therapy and that will not preclude antioxidant verses oxidant. It won't preclude the vitamin C people, it won't preclude vitamin E people or vitamin A or the...

(several speaking)

-- I have a recommendation to one of your questions. We were stumbling over general methods of treatment and possibly maybe the general treatment strategies may be a reasonable replacement. All I'm trying to do is get away from the idea of method of treatment rather on more broad spectrum, kind of global approach.

FW General methods, strategies. Barry?

-- I would recommend that we deal with that question and use it as an opportunity to state our philosophical view and the view is that we want to, we do not want to be limited by this and intellectual signs of parameters. I think that's about all we need to say...long list of all the treatments which we believe might have efficacy. I don't think we'll be as effected if we do that. If we say it is our position in response to number two that we want to go inside or outside of the confines of existing scientific understanding to investigate what might work. We'd all be limited by current modality that's all we need to say. We don't need to list every approach. This is not the place for it.

-- Ya know I bet if we actually went around the table, I think the list is actually...I think we loose our power by not specifying what we think...I think what's happening is question number two and three are really being combined and let's just do that.

-- Can we go around and let's just take less than a minute a piece to just say what we think is top on the agenda because otherwise we'll eat up the entire...

END OF SIDE TWO, TAPE NUMBER ONE

BEGINNING OF SIDE ONE, TAPE NUMBER 1A

Berk ...well I'm quite surprised you folks don't have a better opinion of the federal government. But I really strongly support what Leanna trying to say as an individual and that is the reality is that the government is deeply involved in these things. Like it or not, they are and we can say we're going to give up and let the others be

involved, we're going to get out of the way or we can say we're going to try to have it participate and help us and use the leverage we have to see that it does it. Now I may be wrong, I think we've got quite a heck of a lot of leverage and I think that leverage comes from the fact that there are going to be more and more members of Congress that are going to say we're not happy with the way health care is going and we want to look at other possibilities of how we solve the problem and I'm surely in the minority, but I have to tell you I am much more favorably impressed with what the leaders of this office are doing and the rest of you are. I think they invited a heck of a wonderful group in here for this meeting. I think that shows that they really have some interests in doing it. Now we don't need to worry about whether their doing it cause the fear Congress or whether they're doing because they want to, that doesn't matter. The fact is that I think that there's some evidence that this office can really turn out to be something very beneficial to alternative medicine. I think it already has and I just can't imagine to being so pessimistic about.

FW I have a question about the proposal and so it will help to clarify for me. Are we talking about a center which is once again, are you talking about a center which is under the umbrella of this office for matonics.

-- Yes under the umbrella of this office.

FW So it would then function as a result of the recommendations of the advisory panels.

-- Right and would be staffed by people who would be recommended by the advisory panel.

FW It would be staffed by people recommended by the advisory panel and it would share educational opportunities, research opportunities and act as a liaison between the other, okay.

-- ...see how, unless we begin to put something like that in place...

FW Okay Michael.

-- Although I fully understand your point of view, both of you. Many times I've felt the same. If that attitude were to prevail, we shouldn't be here today. This is an opportunity. Whether it reaches fruition or not, we still don't know, but it's an opportunity. Now given that then, may I suggest that we take a look at number 4, which used to be, number 3 which used to be number 4 on the top of page 4. And it might be possible that at line 3 at the end of it by inserting " a center under the offices of unconventional medicine" would solve that there and then add on the end a further goal might be in the future an institution. Right into that paragraph.

FW So are you proposing create a fund administered by a center, is that what you are saying?

-- You create a center for research by the office of unconventional.

-- A center for research alternative medicine under the

auspices of the Office of ....

-- That's correct, yes. Yes, that might satisfy that need without going into a lot of additional verbiage. Since it seems to apply to that paragraph anyway.

FW James?

-- We are still on the point of an institute, right?

FW We're on a point of Leanna's.

-- The only issue that I have a recommendation is that I want it to be very clear that what we are talking about is a staffing by scientists. That this is a research center.

-- It's been added onto the paragraph because it seems to fit with what's being said in that paragraph.

-- Staffed by scientists selected by the advisory panel who are experts from the various fields of alternative medicine.

-- Fine. Whatever the wording you would like but it seems to fit with the message in that paragraph. So why add another paragraph.

FW Do we have further comment?

-- (Foreign female - cannot understand)

-- We just added another sentence onto that paragraph, that's all.

-- A comment on this concept. If you were doing arteriosclerosis research you would need a great infrastructure. Perhaps in thinking in terms of an institute for alternative medicine it's necessary to think of an institute that can do primary statistical screening methods to evaluate modalities on initial level. Not to go through the whole process, because after initial levels of significance are established, which you can't get established in this country at the present time for numerous reasons: money, manpower, so on and so forth, if they pass the initial screening process, i.e., they were statistically significant, then they could be taken out in many different avenues to be researched and developed further for F.D.A. approval. I feel it is necessary to have an institute that screens and evaluates modalities to develop levels of significance in the scientific manner such that further research can be carried on at that. Now there is another point. If Dr. Matino, at that point, can point to that institute and say as a result of this institute's work, this hematological modality shows promise, then he can write a grant proposal and use that as the first step in the pure review process to go further with that research. That would be my recommendation, in short, to have it an institute to do statistical evaluation to develop levels of significance of alternative modality.

Berk I don't think we're as far apart from what's going to happen as what we're talking here. You need to know that in February, Senator Harkin sent a letter over requesting that they hire five investigators to go out and check on unconventional medical practices that are being used. At

least it is my understanding that they are hiring five people at this time of whom two will be investigators to do just exactly what I think Jim is talking about.

-- Would they be the laboratory personnel?

Berk Well they may, I don't know. But the first thing is at least I would hope, and things don't happen the way I hope they do a lot of the time, but I would hope they would go out and visit the cancell people and the ozone people.

-- Or bring the cancell back and analyze it.

Berk ... And some sort of thing to look at them with the information that is already there to see if whether then there should be and effort for them to authorize the cancell people for example to treat 50 people under their supervision to be sure that they know what the situation is prior to treatment and what the situation is after treatment. So that if they can then document that this is a treatment that appears to be both safe and effective we would have real leverage to get it to move forward. That's my perception and I think that that is quite similar to what Leanna is saying except that it's manning it, but my point would be that I think it is further along that process than some of you may realize in terms of getting it accomplished.

FW I would like to call myself. I have no philosophical objection to either a center or, well to having a center at N.I.H., I have a certain problem though with the concept of an institute of alternative medicine because it

seems to me that while it may be politically necessary, what we want to do is eventually to integrate our ideas into the National Cancer Institute, into the various institutes as they exist...

-- But in the mean time...

FW Yeh, it the mean time it may be politically necessary to do that in expedience, and that's how we should look at this but eventually, I mean, we don't, we are not, the N.I.H. is organized along disease lines, and we are not a disease I hope...

-- That's right. And that is why I am not in favor of proposing that we have an institute of alternative medicine. But I do propose that we have an office.

-- I fully support your idea of a center and I think that we should hold in abeyance the question, if we get the center, we will then know based on this idea of outreach to the rest of N.I.H. whether we are getting nowhere with them in which case we need to review our situation.

-- And I would maintain our autonomy as well for a while.

FW Yes, what you are going to need because otherwise you could easily just get swallowed up by ...

-- Yes, I think Harris is completely correct in his analysis but I think we can prevent that too.

FW Well that's the struggle, the struggle is to prevent it.

-- Say that in something in order if this goes forth, every step that we make can preserve the autonomy of this operation, I don't know how, ...

-- To preserve autonomy ...

FW An autonomous center, can we do it with one descriptor?

-- Something like that. But otherwise, you know, the history of the N.I.C. or N.A.I.A.D. or whatever it is for both cancer and AIDS are abismal demonstrations of federal power.

FW Do we have the language here?

-- Yeh, how about this. We recommend the creation of an autonomous center for research in alternative medicine under the auspices of the Office of Unconventional Medical Practices staffed by scientists selected by the advisory panel who are experts from the various fields of alternative medicine. The purpose of this center for research in alternative medicine would be a statistical analysis of extent data, in vitro and in vivo testing, research, training, and education.

-- (several speaking)

FW Or even better than that is without exclusion cancer, AIDS and so without exclusion takes in everything else. This has been a new--are we talking now about a neww--we talked twice here ...

-- You are revising number 4, you will assume responsibility for the original drafting of number 4 should you can offer it as a friendly amendment and if you wish to accept it as a friendly amendment there is no need to go through any rigmarole over it.

FW Okay, and it would be inserted where? You just read something that is fine.

-- I just would put it at the end of number 4 or it could be its own recommendation I don't really care.

FW Let's talk about that because I have another resolution here which I would like to introduce which has to do with how we fund that. And just so, before we decide where we put it I think, is everyone in agreement that we should put this into 4? Okay we voted on that is that right? Do we have a motion to accept this and enter it into number 4?

-- I move the question.

FW Do we have a second?

-- Sure.

-- I'm not sure that you are not, that this isn't something separate from 4.

-- It feels like it's separate, and also, I don't want it to get lost because I think it is terribly important.

-- Because what I really wanted to mention, and I think that it really tends to indicate what James is saying is and yourself and everyone else. I'm afraid that what your're suggesting here is a tremendously powerful entity, but I'm not sure whether or not that is really not taking there research out of the hands of those people who have been looking at it and possibly relegating a good portion of it to a particular sector. You are talking about an autonomous center, on one hand what Groff was saying that you don't want an institute of alternative medicine because you want to remove that ... that is an alternative therapy. So you don't want to be put in that. Your alternative then is the fact that you want to mainstream these concepts as soon as possible, and you don't want to keep them in another track. Because to keep them in another track you ostracize them.

-- Then you could say to interface with existing disease centers at the N.I.H.

-- What I am trying to bring forth here is that in this office actually I had a first tier, a first tier was to screen statistically the data out there to give us an opportunity to best realize what our research opportunities were A. B, to provide seed money or intramural money to further expound upon the rationales of those therapies whether it be through in vivo, or clinical, or scientific, or ethnological studies sufficient that the seed money would provide data that would allow us to take that new data, in the confines of the old data that preceded it, to allow it to mainstream. It would be done in such a fashion that the new data that

was generated, since it was being embraced within the institute, per se, could never be questioned upon futility because it would be done within the institutional framework. And then it gives you the opportunity to mainstream, it gives you the opportunity to take advantage of the present branding institution decision. It is basically founded in the tenants that you will bring it forth in the first place and take advantage of the intramurals to a lesser extent and the other moneys to a greater extent.

-- To further complicate matters, we talked about the educational function which I am very concerned about. Would it be too complicating to also add something that the various ageNCIes of the N.I.H. consult with this new office in, before publishing materials.

-- God no! (Laughter and talking

-- No, now wait a minute, it is not micro-managing. We have a cancer information service that is virtually a quack-busting agency. They are issuing detailed literature on all of these therapies which get on to Compuserve and the PDQ system and so forth. I think that is a terrible contradiction and that really it should be this group and this office that issues the literature to the public on alternative therapy.

-- I think so too.

Berk Sure, but you sure as heck don't want the regular institutes having anything to say about what our

publication says.

-- We should say something about what there publications say. Most of the quack-busting literature that comes out of this country is coming from the N.I.H. and especially the N.C.I. and the Cancer Information Service.

-- I think it is quite unusual, in fact in never happens, it is unusual that one institute profudes it's own data.

-- Listen to what I have to say, please. The fact that you bring a modality into the center of excellence or the center of research or this office, okay and you start explorint it and it is within the basic paperwork trail...there is an internal newsletter that occurs. I'm quite sure...I think it would be quite an uncommon situation, you would be ... that quack-busting approach to large extent, not because .....

FW I think, I completely sympathize that most of the negative information that emanates in the public eye regarding alternative therapy comes straight from the N.I.H., let's just make a resolution, a separate resolution, that asks them to stop proliferating any information about alternative therapies and we will do that.

(several speaking)

-- Come on now, look, this is really getting, this is descending into somewhat of a ridiculous level. We cannot be telling scientists at the N.I.H. what they can say and what they cannot say.

(several speaking)

-- It doesn't matter, the guys who are going to get this document are going to laugh at us for passing such resolution.

-- You believe that.

-- I think so.

FW Any other comments?

Berk What I perceive is that if this office indeed ends up having its own publication, and if we research and check, say cancell, and we find cancell is effective, and we put out from this office a publication which says our check shows that cancell is effective, hang on to your hats, it isn't gonna matter what those other people say. And it is my belief, and we don't have to go through, we get stuck having to do what all of the scientists say we've got to do, I just believe that we have a tremendous opportunity here and the last thing we ought to do is be worrying about what they say. What matters is what we say and if we say the right things, things are going to change.

-- Amen.

-- Do you really think one agency of the N.I.H can produce and publish...directly contrary to some other...

Berk I can almost guarantee you that if we have findings that show that something is effective and we've checked that

and we want to publish it, that N.I.H. is not going to be able to keep us from publishing it because I think I can get help from (several talking) for god's sake.

-- Let me say one thing, the weapon we have is Congress.

Berk Sure, they aren't going to be able to stop us if we really have documentation that shows something we can publish it. I would just bet my life on that.

-- I sure hope you are right.

-- Just a suggestion about what Michael said before. We're here because we're thinking that it is not going to be business as usual. We are going to be able to do things differently. And if we constantly think that the N.I.H. is going to undermine everything that we are doing then we are wasting a lot of time, but if we take the initiative and keep on the initiatives of the advisory panel, then we are going to it out and that is why we are here. And I might say, I sat in on some of the cross-cutting committees yesterday. There is a cross-cutting panel on pure review. There is a cross-cutting panel on research, and a lot of things we are doing here and talk about now are being dealt with by other panels and maybe we are a half an hour away from adjourning this one and maybe we should get through the things.

-- Yes, okay, that's my point.

-- I will withdraw my addition to her recommendation.

-- I hate to be a stickler, but we have a motion on the floor, and unless, please correct me if I'm wrong, but I don't think I was asleep but were we not informed that an office cannot award funding but a center can and that is why I recommended that this, isn't that what was said.

Berk You were informed that I think that is the case but I am not at all sure of it.

-- Well I thought it was brought up and that is why I recommend this going into paragraph 3 that used to be paragraph 4 rather than second. But, if that is incorrect information, then our motion on the floor can reasonably be put into another section then.

(several speaking)

-- We had some discussion in the pure review panel and had two people from the N.I.H., we talked about the grant procedure and as far as then, a center or an office cannot award a grant.

-- Either one?

-- You can award supplements to an already existing grant if you feel the work is moving forward and you want to do it. But an institute ... and maybe we have to make changes to the existing guidelines.

FW Okay, with that in mind, might I just, there again I'm just trying to clarify this but if we have the funds couldn't we earmark, and I'm going to present here a

resolution which would provide us funds to do this, the committee recommends that 10 percent or more of the budget of the institutes within the National Institute of Health be earmarked for the activities of the Office of Alternative Medicine.

-- Point of order Mr. Chairman, we have a resolution on the floor at this time.

FW I understand. What I'm saying is that we don't know the answer to the question that we are posing. We don't know whether or not this office can fund or the center can fund. If we are just talking about a word, what I'm saying is...

-- Well I know about the Office for Research in Women's Health. And they most certainly do have a active research budget.

FW Okay then that's the answer.

-- And that is why I am proposing this because I am concerned about the funding ability of a, of the Office of Unconventional Medical Practices, so what I suggest we do right now is vote on this resolution and then go on to yours because I think this is very important.

-- Okay. Let's vote on the resolution and then can we decide that if an office can grant it that it will be put in that.

-- Okay

-- That would change the language of grant procedures here in the N.I.H., maybe it would be beneficial to see how they are attacking the issue.

-- I think that is a good point, however we don't really have time, I'm just concerned that there'd be this forceful input from all of the committees to the N.I.H. and that they'd get it, whether or not this is perfect procedurally, it probably isn't.

-- Point of clarification.

FW Yes, point of clarification.

-- Are we all, we left hanging yesterday what we are calling this thing we are involved in. Are we going to be locked into calling this alternative medicine and is this an appropriate time to set it up, or should we decide whatever we are going to call this?

-- Is that coming up in the general meeting?

-- They both--or is anything going to come up in the general meeting.

FW Let's talk about that in a moment. Now a point of clarification please, I will get to this. We have an amendment. We have ...

-- Actually it is a separate resolution I think at this point.

FW Okay, we have a resolution, it's been seconded, can we have a show of hands. All in favor? All those opposed? One opposed.

-- One abstained.

FW One abstained. This will then become number 9 and number 9 Leanna you will be responsible for getting to Rod, Okay.

-- I got it, uh huh.

FW Now I have number 10 which I would like to propose. And that is that the committee recommends that 10 percent or more of the budget of the institutes within the National Institute of Health be earmarked for the activities of the Office of Alternative Medicine.

(several speaking)

FW Well I started, let me tell you how I came to this, I started at 50 percent (loud laughter) to 25 (loud laughter).

-- Let's hear what the Congressmen have to say about this one, I want to hear this, I think it is ridiculous.

Berk I think that we've got the 2 million dollars, I think Congress, and we have a commitment that's in the budget also again for this next year. I think we've got that commitment. I think until we show how this office is working and that sort of thing with the federal government cutting back everywhere they are cutting back we better

hope to heck we can hold onto that 2 million dollars. N.I.H. is going to be cut pretty severely as I understand it this next year and if we can hold our own, I think we can be pretty proud of it and if you want to send a message you can but I'm sure of it that everyone would laugh at you. Sorry Mr. Chairman.

-- They are things we can reasonably achieve and there are things we can't reasonable achieve. If we start getting unreasonable then it is going to hurt the things we can reasonably achieve.

-- I agree with that.

FW I understand that, and I don't want to be unreasonable but I have to tell you I think we are in an absolutely unreasonable situation. They have given us a pittance. They have spent all of it on a place like this.

-- They don't even pay for drinks.

FW Besides that they don't pay for drinks. I just, I will defer to the wisdom of this panel but I do think that yes there may be some snickering.

-- ...we should have went from 2 million to 250 million or something like that.

-- Yeh, but how long did it take?

-- A very short time, a couple of years. No recently.

-- I think it behooves us to turn in some good science in the next six months to a year. Because if we don't start producing good stuff there's not much justification to going beyond what we have now.

-- Right

-- That's an important goal I believe.

-- We are going to cure cancer three times over by next year so.

-- You are in Washington. You are right within the shadow of Bethezda and Rockville. There is an awful lot of good science done here. You've got to match that level of science. And there is too little documentation, you hear too much anecdotal literature without proper documentation, I think that ought to be one type of resolution to ourselves that we ought to come up with better data.

-- I think we made that clear.

FW There's no question about that. I guess my opinion is that deservedly we would deserve to have 10 percent earmarked for the study of alternative medicine. I think it is totally deserved. I don't think there is any joke about it. I think right now, today, we deserve to have 10 percent of it. I mean look what we've gotten, look what we've done. Look at the level of progress. We do have evidence and we can't get it studied.
So, in any case, do we have further discussion?

-- You are withdrawing your amendment?

FW No. Do we have further discussion about the amendment?

FW No I'm not withdrawing it

-- I'm seconding it.

-- Wait a minute, well I don't think though that we, Mike, that we should trivialize the matter. You are quite right that there should be a considerable amount of money spent on alternative medicine. The question is how do you do that in a respectable manner.

-- Don't forget also, too, that to use Berkley against Berkley, Berkley was the one who taught us that if you want to get a radical reform to the F.D.A. you call for the abhorition of the efficacy clause.

-- Well I think Frank's idea is the same Iowa type of idea (laughter).

-- Ten percent of 8 billion dollars is 800 million dollars. That is a little bit exaggerated.

FW And like I said I don't think that that is enough. I don't. That's where I'm stumped. I don't think it is enough and you think it is exaggerated.

-- The big cry of the AIDS community has been throw more money, throw more money, throw more money. But when I go to AMFAR and look for support for certain research, I

don't get any help from all that money that they cry about. And guys like Larry Kramer in New York cry about more money. The answer is not just in money the answer is doing some good, solid science and sometimes that doesn't require a heck of a lot of money, it just takes an Otto Wartburg or an Albert Einstein or a Jonas Salk working in a modest laboratory to do that.

FW With all due respect I am not asking for new money. I am asking for ...

-- Two hundred million is what you are listing, it makes us look crazy. Maybe 10 million dollars.

-- Nobody's asking for it, if we take 800 million dollars away from the institution that is already there.

(several speaking)

-- Just one more thing. One more point why it was necessary. One more point. There is such a thing as intramural research at N.I.H. and extra mural research at N.I.H.

-- All covered by ...

-- Exactly, the problem is that there are leaders in each one of those disciplines who determine what will be studied in intramural research. And then you get an extra mural research if you are in consistency with the intramural research. However we may have to go to the intramural people and say, Hey fellas, we have come up with such, such, such, and such, we would like your assistance to

verify this data and bring it forward. We are going to need their facilities and their expertise. I don't want to come and be antagonistic to them. I would rather be complimentary and get the use of that facility. Look, I've been on the fifth floor of building ten at N.I.H. for many an afternoon begging to have them use millions of dollars of resources to verify the work that I had done in Cuba and I can't get them off of dead center and I've been polite to them every time because I still need their assistance.

FW I don't want to go begging.

-- Can I say something? But the AIDS activists have gotten 4 billion dollars for ...

-- But that is a cooperative movement. Every cent went to pose welcome research.

FW I disagree.

-- You might have well bought stock in Burrough's welcome rather than to throw that money to AMFAR.

-- I don't think we are here for radical trivialization about Frank Wiewel. But we all started out years ago on this course. It was radical, it was confrontational, it was this and that to even get the N.C.I. to have an O.T.A. study an alternative ... that was not done by being sweet and gentlemanly and we haven't gotten through to have this meeting which is historic anyway you look at it, but I'm not saying to burn down anything at all, I'm saying that there is a time to be confrontational, that time is now,

we are talking about a disaster of unmitigated dimensions and we are really talking details. To turn to the N.C.I. to save us from cancer, or AIDS, or the N.I.H. to do it is just a travesty. We need some good general confrontation with them. I don't think it is abnormal or trivializing the issue to say if we are going to have a federal budget at all, which is another point to be considered, that 10 percent of this health bill could go to so called alternative therapy, I don't think that that is irrational at all. It is a chance to make a statement. And I think it is a powerful statement, I think there is nothing wrong with that at all.

FW Do we have further discussion?

-- What do you think?

-- I feel that it is antagonistic in a way that it won't get the results that you want. It would be counter-productive, that's the word I was looking for.

(several speaking)

-- We have to face the problem here. In one hand you would like this particular office, this entity to be funded directly so that it can therefore grant moneys for research. That is one possibility. The other possibility, and as Jim mentioned to some of us, that need some short term victories real quick, in which case those moneys and the appropriations of those moneys into this office probably may not occur in a time period as commensurate with the victories that you are actually

looking for. So I think it is incumbent upon us to have a more tiered approach in a sense that our up front we should try to utilize the granting institution that is there in place already not looking for funds and make sure that scientists, practitioners, etc. are four of the most competitive ... that we can in terms of the science or the methodology we are bringing forth. And in the second tier try to become a self-granting institution. Because if you wait for the appropriations, what happens if it doesn't happen, are you going to say that you are not going to put your efforts into looking through the mainstream. When I say the mainstream, the pre-existing grant procedure.

FW So what are you suggesting?

-- I suggest that the idea of granting this particular office is probably premature at this juncture though it should be in the resolution as a second tier approach.

-- We already have it in a ...

-- Are you speaking in favor of the motion or opposed to it?

FW I'm sorry, Michael, we already have immediately created a fund administered by the office of alternative medicine for awarding research grants in number 4. So it is a moot point.

-- Couldn't we substitute a dollar figure for this that would be ...

Berk Just so you understand, we're not talking about what

N.I.H. does we're talking about what we are asking Congress to do in this case.

-- Well couldn't we ask for, wouldn't it make sense to ask for 5 or 10 million next year, would that be a start to ask for an increase.

Berk Yeh, I don't think you'd look crazy if you asked for 5 million. I think if you ask for 800 million at a time when they are cutting back everywhere.

-- We wouldn't know how to use 800 million dollars.

Berk I think that would be absolutely ludicrous is my personal opinion and I'm going to vote against the amendment as it is because we have enough of a problem keeping that 2 million dollars.

-- We don't want to undercut Berkley.

FW So what would a reasonable figure be that would give more money but wouldn't look stupid?

-- Four

FW Well I would like to amend the motion to say 4 or 5 million, I'm going to go hog wild here, so I say 5 million.

-- 49.99 million

(several speaking)

FW Five million dollars. That we ask for 5 million dollars.

Berk I'll live with whatever you do, but I want you to know that you made it so big and I don't think 4 or 5 million dollars is so bad, I don't think you're going to get it but I think ...

-- Your efforts are so important to this, if this is going to be derogatory to our efforts then maybe we shouldn't put it in.

-- Do you think we should put a cap,...(several talking)

Berk I don't think it matters one way or the other whether you put 4 or 5, I don't think it's going hurt anything, I don't think it is going to help it, but I don't think it is that big a thing. I think you ask for 800 million dollars and ...

-- I don't think it should be in there at all, at all.

FW Would you support 4 or 5?

Berk Yeh, I'll vote for it. I don't care that much.

FW Alright, I would amend it to, with everyone's permission, amend that to five million dollars and you are saying that we should not direct that to the institutes within N.I.H....

Berk Well it's just a resolution but you have to know that it is Congress that appropriates the money and we have to

have very good friends on the appropriations committee.

FW The committee recommends that the appropriation for the office be increased to five million dollars in the next fiscal year.

(several speaking)

FW Any other comments or anything? Okay by a show of hands all of those in favor? Opposed? It is unanimous.

-- I'm abstaining.

FW One abstention.

-- I don't think you should be going asking for money. You should be working with what you have to get the thing off the ground.

FW Okay, is everyone through the recommendations of this committee to there satisfaction? Do we have any recommendations? I have to tell you that they have passed me a note that says please, please remind all panel members they must complete there reimbursement voucher and return it along with there airline receipts which is the last page of your ticket to the registration desk today. Panel members will receive a flat rate of $75.00 ground transportation when they correctly complete there reimbursement voucher and their airline receipt is handed in. A sample reimbursement voucher has been provided with the reimbursement packet and should be followed exactly when completing the voucher. In addition we must check

out by one o'clock.

-- Today?

-- Yes, today.

FW So it is now twenty minutes after twelve we are going to need to adjourn for a period of time.

-- The cost panels meet at 1:45.

FW Thank you all. Thank you all.

-- One question, I just see where the reimbursement envelope is directed to N.I.H. in Bethezda. They....

BEGINNING OF NEW MEETING

SPEAKING OF A DR. WALKER (difficult to hear)

-- ...books and they collaborate on magazine articles and clinical journal articles. This results is being put together by some of the medical bureaus of the 21st century. Doctors indeed are on the cutting edge of new advances of medicine. I will bring to your attention just a couple of those. I will speak on four particular topics. Two advent and two in brief. In brief I will just mention gaulid which I know you folks are...of and kilation therapy which some of you folks use and practice. I will also speak to you about....the treatment of cancer... I will also speak to you about the use of carnavora....for the treatment of cancer, AIDS and other pathology. Let me just bring to your attention, gaulid that I'm most familiar with. It's a nutritional

supplement sold in health food stores in...and it has been used extensively for the treatment of belise syndrome which incidently is a book that I've written and over a million copies have printed and...I have also the investigated the use of gaulid towards the treatment of cancer and indeed it's useful for AIDS as the ozone therapy spoke for lowering high blood pressure and for high blood cholesterol. Research is very expensive around the world, especially in Japan but in the United States it is research that is a...through the microbiologist and has found that gaulid...the immune system remarkable when utilized in the treatment of degenerative disease and in later terms, it is not a clinical research, although through various associations, he has been able to use gaulid on humans extensively for therapy. James Duke, Ph.D. of the U.S. Department of Agriculture acknowledges that gaulid of the 900... pharmaceuticals the Department of Agriculture has investigated, gaulid is at the top of the list as being most effective. Next I will mentioned kilation therapy. I've investigated this area very extensively where as I've written some 18 clinical journal and magazine articles and two books and one of the books this moring was here whhere I've written both so extensively and at an equal amount on kilation. Here's a small book...I've written six major size books, one of them is called the "Kilation Answer" and it has 192,000 hard cover books in print published by the Evanston Company. So you see my work is to take the clinicians words, the medical views and turn them into consumer language before I write rather exclusively for the consumer. My idea is to bring these new advances of medicine to the consumers so that the individual can use

them for himself and so to his traditional physician, traditional practicing physician and saying this is available would you investigate it for me and help me with its application. It sort of...this causes orthodox physician to investigate so call alternatives. My claim as it was in yesterday's committee is that we must bring our meethod, of biological alternatives to the public directly. It's very difficult to change the minds of the medical community as they are so inbrained with what they learned from the pharmaceutical industry via the...it's just too much money involved and too many...supplier to physicians to change them except can we change in their pocket book by use of the pressures of people, their patients. So I bring you today a suggestion that we could produce literature for the consumer out of the N.I.H....and I am offering my offices for your purposes. I was, well my publisher is the Avery(?) Publishing Group and I was afforded the privilege of having my own publishing imprint at this publishing house

END OF SIDE 1, TAPE 1A

BEGINNING OF SIDE 2 TAPE 1B

....is a co-position devoted to holistic type help quotes that I will be involved with. Not necessarily that I will write the totally but I will be in charge of producing. Probably participating with coworkers who are in Md.'s, D.O., D.C's, Od.'s and D.D.S's, PHD's and so forth. The health book I'm contracted right now to do, seven books that are responsible for doing 24 books in the next year. So I am looking to this committee to bring to the publishing house a series of topics that you would want to have produced. Yesterday it was mentioned that a panel

would possible evolve from this committee and perhaps...draw books in individual therapy for the one encyclopedia type book that would describe therapies. This committee is in a very viable position to acquire these therapies and information on these therapies and I would say yes they do...who can take on these therapies and to get them published and out into the consumer area. Another topic that I'm moving to now is shark cartilage. Shark cartilage is an excellent for the treatment of cancer as a result of a particular...that cartilage can...some cancer in fact that is the title of the book...published by the Avery Publishing Group. It happens that cartilage protects sharks whereas one out of three Americans at least will be getting cancer. It is one out of one million sharks who might get cancer. As the particular ingredient in the cartilage, their skeleton in sharks, sharks have no gums, there skeleton is comprised strictly of cartilage, that one-sixth of their body weight is taken up by cartilage, this ingredient in...has an antiangiogenetic effect. That is when the tumors grow in human beings, the tumors have an in growth of capillaries, that's an angiogenesis effects. The capillaries nourish the tumor and if those capillaries were able to be diminished either by forcing them to shrink or having an intimidating effect so that they would not grow, well it is likely that the tumor would not expand and kill the patient. This is proven to be the case. In a series of tests which were conducted by ...Copland, M.D. of the Harvard Medical School it was found that shark cartilage causes an anti...angiogenetic affect and the capillaries failed to grow into the tumor and the tumor tends to shrink and fade. It might

disappear altogether It expands like cartilage, it has a...shark cartilage specifically is not a drug. It is a food supplement. It is food supplement sold in health food stores. These are the types of remedies that we should be bringing to the American people. My suggestion to you is that this sort of information about shark cartilage be brought to the National Cancer Institute for further investigation. They've done almost nothing upon this...they've done nothing period on shark cartilage and this is a time again for the people of the world because...is a viable cancer and AIDS treatment, incidentally is very-shark cartilage is very effective against...So I think this committee really has the text to educate officials at N.I.H. so that they'll put pressure on their associated organizations. The fourth treatment I want to bring to your attention is carnivore. It's a herbal remedy, an extract of the venus squad or plant that eats bugs, that eats the worms and of course...I've written extensively on all these subjects. Some of my articles are on the venus squad...I've written six articles on shark cartilage, one of them is covered in the last issued of Natural Magazine. In this issue which was out yesterday also Eastwest Natural Health also there is an article of mine on carnivora. Carnivora works highly effectively against degenerate disease of several...but it is especially useful in the treatment of skolic tumors, that is malignant tumors of all types. It even is used for the treatment of pancreatic cancer. My own wife was on carnivora and she has breast cancer. In fact Michael Shacter, M.D. of a Supple, New York, is her physician and administers carnivora to her, but not as a prescribing physician, only as a technician. He

administers it intravenously and he is able to do this because he discovered that carnivora...who in discovery that the use of carnivora when he was at a...oncologist in the laboratories of the Boston University School of Medicine in 1981. He, Dr. Keller, prescribes the carnivora for the patient who calls with records and you usually fax those records to him. He then provides the protocol to the patient, the patient buys...the carnivora for...and the patient then takes that carnivora that he received through the mail through his physician. They physician then follows the protocol that Dr. Keller has laid out and the patients then....in fact I've seen HIV patients who have had...have increased from 11, 10, 758 in one case and some 700 in other cases. Dr. Keller has set stats for the treatment of about 15 HIV patients to this point... is involved and it brings that ratio to normal and the patients, the HIV patient acquires no symptoms he's ever...the carnivora does not make an HIV negative positive patient negative but it does sustain the body to the point that the body develops no symptom of the disease. It works very well on all types of solid tumors, but not in blood...such as leukemia. The fact is my wife and I went to Germany cause we were told about a variety of American patients, 2,500 patients around the world and about 200 US patients who were treated by Dr. Keller. They did not need surgeries or chemotherapy or radiation. In fact chemotherapy radiation tends to diminish the effect of carnivora. So I must tell you that a patient who discovers that he or she has a malignancy should in deed look to the alternative of carnivora. We went to Germany, my wife...Stephanie but never chemotherapy radiation and she had been on a variety of metabolic

cancer therapies but when tested through a diagnostic technique or the cat scan it was found that imminently she was going...as a result of suppressed immunology. When administered, of course the treatment of carnivora, her immune systems held so boosted that today she only needs to intromuscular, no longer intravenous and even that I administer to her, she needs only two or three times a week.

FW Dr. Walker, in order to facilitate discussion and questions, we'll need to summarize if you can, we are at about 18 minutes.

Dr.W Alright I will tell you that carnivora is something that you folks should look at and it's important to the N.I.H. Well we buy carnivora and it comes in the mail, this week we were advised by the ah Tom Kelly that this district dirctor of Customs, Department of Health and Human Services, Food and Drug Administrations in ...Massachusetts. There are a shipment of carnivora vials, 50 cc per vial were seized and we can't have them. This happens frequently to American patients. I mean frequently. So my wife has written a letter to the F.D.A. and this is what it says: "Dr. Mr. Kelly, I am a victim of breast cancer who has experienced preservation of my life by use of the carnivora and...manufactured by Carnivore for...Republic of Germany. This herbal remedy, an extract of the...as has been prescribed by my physician doctor of medicine...(talking very fast) A photo copy of his mos recent prescription dated August 26, 1992, a prescription is enclosed. Based on this prescription, my husband went...acted on my behalf to purchase four 50 ml.

vials of carnivora, less than three months apart for my personal use. You then advised me by written notice...F.D.A....6829, a copy of the notice is enclosed, that these four 50 ml. vials of carnivora which are $800 each, have been seized and held at the Port of Washington, Massachusetts. Please be advised that the carnivora must be held under refrigeration for safeguard against potency I request that you return these four vials to me at once for I have run out of supplies...remedy. The action of the Department is endangering my health. Please return the four bottles of carnivora to me or at least let me have one of them...put it in your sampling..." Well this is a representative of other American patients who face similar problems of this nature. This is real. I mean, my wife is dependent on the substance so that her immune systems stay...and she does not develop a tumor. I say to you ladies and gentlemen that this committee and in fact the whole of the office for the study of unconventional medical practices is so important to help these types of patients. Please take it under your advisement that you have a most important mandate and I thank you. Oh, one more thing, I do have materials to supply you. I would be glad to leave with you information on particular topics that I spoke on today. There are on numerous articles on some 200 different therapeutically galleries considered unconventional and here are three books.

FW Dr. Walker, thank you very much and we'd like to ask you to send those materials to N.I.H. It's very important that they have them.

Dr.W I can't just leave them with you. I mean you are N.I.H.

FW We can certainly facilitate them being taken to the office, yes. Any questions.

Dr.W Who should I send these to?

FW You can leave them here, thank you very much.

-- I have a brief questions, I wonder if you could stand on your offer to assist the office on unconventional medical practicing in publishing whatever materials suitable to be published that might come out of this process and particular your offer to assist without charge. Is that for your services or do you somehow...

Dr.W Okay, there is no charge for my services. I am looking for publishable material to produce in book form for turning out for consumer purchases. It would be sold in book stores, health food stores and by mail order. I ask you to consider that you will be sifting into some very important informations that are not generally available. I would make those informations available to the public at large.

FW Thank you very much.

-- I'd just like to make one comment in relation to what Dr. Walker has said. I went over to Germany in November to look at some unconventional therapies that were being used to see if we could bring them over to the United States. I think it's imperative that this committee bring unconventional medical practices most as quickly as possible to bring therapies under our wing so that people

are not forced to leave the United States, go via the back door, have whatever modality is being used, seized. Every opportunity be afforded under the freedom of choice of the individual is there and not denied.

FW I second that and our committee has made a recommendation to stop the foreign migratory F.D.A. seizures of this sort. So we have done that and I urge you to take that F.D.A. regulations which guide the importation of this substance because I have read that regulation and I am aware of that and patients can under that provision bring these in for under three months.

(several speaking)

-- May I say something...directly to Dr. Keller, he will be in New York on the weekend of 24th, Saturday and Sunday talking about this. It is a symposium run by...and will be on cancer and all of the immune disorders. Dr. Keller is going to be one of the speakers from Europe and Dr. (?). So it is going to be a very fine symposium. Please come if you can. If you want information, ask me about it.

Dr.W Dr. Keller will be here October 24th and 25th at the Ramada Hotel..will be the speaker to the foundation for the advanced innovative medicine and you are certainly urged to come and listen to and question this.

-- I might incorporate Dr. Keller as one of the books....

FW Excuse me, thank you, we're not going to be able to take

questions from the outside, we just don't have time. But if you can talk to them after while on you, we would appreciate it.

-- What can that possibly be a benefit to you.

-- Sir but we are not taking questions from our...

-- Can you tell me how I can get those regulations you mentioned?

FW You can give me a buzz at my office, I've got a F.D.A., I will fax it to you. I've got the F.D.A. regulations. There are regulations coming, the importations of substances for individuals which are less than three months and I have them in my office.

-- You mean less than three months apart.

FW Less than three months apart for personal use only. You can import any drug unapproved by F.D.A. for your personal use.

-- As long it is approved in the foreign country.

FW As long as it is approved in the country of origin.

-- It is approved in Germany?

FW And not, I'm sorry and not under the import, the formal import alert. F.D.A. has a formal import alert policy which can stop a substance totally.

-- Substances is legal for use in Germany and many other European that is not approved by F.D.A. in the United States. It is not legal for an American physician to prescribe. You will get indicted for criminal.

-- Something which might be of use to you is the fact that this is in a homeopathic formacapea it was in fact discovered by Honoma, this particular medicine, not by the German mentioned. It is in the homeopathic formacapea, that might be of some help to you.

FW Okay, we are going to have to move on here. Thank you very much Dr. Walker. The next presenter is Ed Sabcheck(?), is Ed Sabcheck here? Mr. Sabcheck? Apparently Mr. Sabcheck is not with us this morning. We have Dr. Floyd Leaders, Dr. Leaders?

Dr.L I appreciate you letting me talk to you, this really spontaneous, I'm not on your list. I come from a little different background. I am a pharmacologist by training, pharmacist is my undergraduate degree, pharmacology is my graduate degree. I've been involved for the last 30 years of my life--and I think you will see when I tell you what I do why I feel like a stranger in paradise. I have working for the last 30 years producing or actually working with the pharmaceutical industry getting drug products approved by the F.D.A.. I am used to being in the middle between the drug investors and the regulatory uses. I would like you to point out before I go on--there are two different parts to the F.D.A.. I have not had the unfortunate experience of running into the compliance division which is what I believe...this morning. My

experience has been drug approval division which although I will not...I will not say the F.D.A. is easy to work with, but they are scientist and you can talk science to them. The compliance division is more of the...function. Anyway I have been doing for the last 25 years this particular task. The last 14 years I have been, as president of my own company, working for the pharmaceutical industry on parts of various...applications and other regulatory submissions. In associating in some way with over 50 of these submissions and talking to the ageNCIes the last 25 years. Earlier this year, late last year, I was exposed to alternative medicine who my mother-in-law that is a cancer victim. I don't like the word victim. She has cancer and we're in the process of taking care of that. I got a hold of Bernie Segul's(?) book of medicine miracles and prescreened it before I...and found in there a whole new approach to what I'm doing. Now I've been in the Washington area and devoted to what is Bernie claimed here. I am the result of the public interest. Dr. Walker's books that he talks about which are made for the public are what got me from the scientific literature in this field. I have gone through the literature extensively. I almost have reserve seat at the National Library of Medicine for going through the literature that was referenced in the...literature and much to my surprise and I guess all my pharmacology training, all of my pharmacy training, I find that there is a very large body of literature supporting on in unconventional, let me use. I don't live unconventional alternative medicine. So I put myself in the middle and that is why I want to talk to this group because I'm quite different then anybody else here. I do not come from any of the specialties. I do

not come from any particular way of doing things. I'm looking for a third option based upon what I call auto pharmacology. Now being a pharmocologist is not surprising I would call it auto pharmacology, but when you come right down to it, every mechanism except perhaps autobiotics, and amnioinfectants that work on the organism, every therapy we have works through the body systems whether it be ingrowthism or it be the immune system, whether it be...or whatever. There are...products either inhibit, stimulate or substitute for natural processes. That replaces the body for...therefore I need to be understanding that a little bit further. You all are looking as a group at changing the face of the industry through legislation, that's one option, that takes time. The N.I.H has decided to become involved as part of the government to bring...to bringing alternative medicine into the wider use. I'm looking for a third way. Some of you, this may rub the wrong way, but there is enough data out there for some active therapies or let's say interventions. Some invention that I believe that with my training and my experience in bringing products through the approval process, the golden process, are soon to put action through the F.D.A.. Now...so be it. We will sell ourselves an objection to bring 10 interventions into the conventional medicine before the end of the year 2000. Most of these will require F.D.A. approval. I have not been anyway minimizing that this is not...is what I do for a living. So I am here to ask you all for help if you will. I have been through the literature. I've been through the lay literature. I've been in debt through much of the literature. The more people I talk to...the more I realize that basically we will not be able to do

everything that needs to be done. I am looking for information on selective innovative interventions that have data. I'm talking about the...that you all say that you did not like...through F.D.A. regulations to get you through them. I've had a couple discussions with people that say you can't test my particular intervention. Try to, I would like very much to get into a discussion with you. There may be things that can be tested if you really have the desire to do so. I suspect it may be easier to bitch than to act. That would be a bridge between you and the industry. I believe this can be done with private funds the government has more money than the rest of us, but they're slow working getting it done. I look at my efforts...I look at myself and my efforts...in a parallel pathway to what this unconventional medical office is doing. I hope I can convince the N.I.H. that I am not in competition of working with them book work because I was at the first convention--it was at the first meeting I expressed my interests in participating and did not get an invitation. That tells you some things and I'm up here on my own. But, I look at myself not as competition, but as parallel. If I can help any of you, I would like to talk about it. If you have data or information that you didn't think that have a modality that has data behind it. come see me. The name of our company is the..Group..Maryland, the telephone number is (301) 394-7560, the fax is 294-7567. I would be glad to hear from any of you and I promise you that I will respond. I want to make a change in the way things are done and I think this is a wonderful time to be doing a part of that. Thank you very much, if you have any questions, I would be glad to answer them.

FW Very good, are there any other people here who would like to present information to this panel that are not on a list or have not spoken to us? I wish to thank those individuals who have presented the information. Once again, urge to them that the information that they have talked to us about and brought to us be given to the Office of Alternative Medicine, International Institute of Health or left here with us. I assure you that it will get to the proper place.

FW Okay, panel members, we have in front of us a draft of a summary. Does everyone have that summary? I have extra copies here for those who would like to have a copy of the draft. Yesterday we ended our session with the call for further resolutions for individuals to adjourn and draft any resolutions that they felt appropriate and I think it would be an appropriate time to talk about those and any new business at this time. Does anyone have any resolutions or have any thoughts about resolutions that should be made? Berkley?

Berk You said something about the importation of--that there was something about that our feeling in regard to opening up the opportunity for importation of drugs from foreign countries or medications from foreign countries and I don't find it in here. I don't know what you had in mind.

FW Okay, there is my--I was referring to the draft recommendation that we made to enter the F.D.A. searches and seizures. They may not be contained in this, I just got this morning. It was only finished and dropped off after I came to the meeting today. So I don't know

whether or not they've included this.

-- Paragraph 7

FW Number 7, "it is the recommendation of this committee that we express condemnation of recent F.D.A. regulatory activities to serve to intimidate the American citizens and shall make research into life saving therapies. To this end, we recommend to the Congress that the efficacy clauses of Food and Drug Administration Act appeal the...interpreted to us, do not involve the federal government in the practice of medicine." That covers an area, but that is not the moratoria clause. We called specifically for a moratorium and it apparently has not--I don't see it in here, so apparently that was either left out or inadvertently not included on this list.

-- That was pretty important.

FW Well it is. It's very important. Now can we...

-- Can we write that in now?

FW Yes, we'll write that in now. I think that I have a copy of the individual recommendations that we made as they were typed up by the individual. We don't as you see today, have a writer here. There was a problem and the writer was needed to go to one of the cross cutting issue panels afterwards so I didn't get these directly--done directly and he is not with us this morning. We haven't figured out quite where he is yet, but we'll have a writer here--we are taping so that he'll be able to write these

up. In any case, Berkley what I was referring to directly and indirectly I think we made a motion and passed a resolution regarding the moratorium and I'm looking for that now on the list of--the F.D.A. however, does have a policy. The policy does allow for the import for the personal use of these substances above and beyond the issue at hand. I don't have a copy of the recommendations for the moratorium. I will ask our writer to get us a copy of that as soon as we can. Are there any other suggestions?

Berk That will be added?

FW That will be added. I am going to make a note in the draft report to add the moratorium language that we voted on.

-- Paragraph 7?

FW Well that isn't precisely the language.

(several speaking)

-- Did we vote on number 7?

-- I agree, I don't think we did it. I don't know how that got in there.

-- I'm not so sure--I don't believe the point--there's a number of quotes here that I don't think we even discussed. I don't know where the subject comes from.