-- It comes from me. I gave it to the writer because it was a suggested thing.

-- But it wasn't discussed.

-- It was not discussed, no I had...

FW Do we want to discuss it now. We did request additional-- this was inadvertently put on to this...

-- I'm delighted that it was there, but I didn't plan to have it.

(several speaking)

FW Obviously we did not discuss it. We should discuss it and we should vote on it. Now part of this confusion as I said is we don't have a writer. The writer moves from panel to panel, so I didn't even have a chance to talk to him yesterday afternoon because he was in another panel. I think that it would be helpful to have a writer who is...

-- I've just been informed that the writer, that they were up so late last night, won't be here until 11:00.

FW I see, well we have it on tape and they'll give us assurances that they will transcribe, we'll now exactly the language that we voted on if there is a question about that and they're going to do a complete transcript but we need to deal with this now. This is something that has been introduced as a resolution or as a recommendation by

a member of the panel and we will entertain any other resolutions or recommendations which will be introduced at this time. I think we can do this anyway you'd like. Either we can go through the existing recommendations that we have here in front of us and then ask for new business or we can go through or we do this new resolution. Is there anyone who has a new resolution.

-- As an additional resolution?

FW An additional.

-- Well I'd like to return the discussions of environmental illness. I know that a number of people in the field, experts in the field, who would have liked to participate in the first session of the committee, did not do so for fear, they've been persecuted, they've been hounded and these are outstanding medical people. Therefore, it seems to me that ah--for example the editor of Lancet(?) has published a very substantial volume on this subject. A lot of very important work has been done on this subject and I think that it would be totally appropriate for the committee to take position recommending the secretary take public steps to recognize the importance of the field with medicine.

-- ...clinically, which is called clinically colleged, is that...

-- That's one term, I think they use environmental medicine now.

-- It used to be called clinics in colleged, that's right.

-- One of the most brilliant scientist that I've met has done outstanding work like this, Irish Bell, and she presented two proposals--a proposal for a grant from N.I.H. They came back and said please revise your proposal in this fashion. She did, well she's a professor and a research scientist of long experience, she submitted that the revised proposal and it was returned to her because the type style of her typewriter was not accepted. This is literally true.

FW I haven't heard of that excuse before, but that's a novel excuse. I think that this committee is going to recommend specific kinds of treatment to address. We've talked about this, we haven't come to a final decision but it is my feeling that at least in a general sense or in a specific sense, we are going to recommend that certain treatments be looked at. These will not be to the exclusion of any other treatment. We are going to be inclusive, not exclusive. We are going to recommend that they look at some therapies not to the exclusion of others. I will at this time put how would you...

-- I saw it environmental medicine.

FW Environmental medicine, on that list, do you have any objection to listing environmental medicine as a general group.

-- I think it's very important. I think that so much of the medicine that--so much of the medical problems that we do

so many we are dealing with are environmentally induced and I think to leave that out would be a major...

FW Okay, in my notes here I do have the particular therapies that we went around the table and discussed.

-- I have a point of order.

FW I'm sorry, Michael.

-- It was my impression we were going to address this number 7 here which is on the list already before we proceed, shouldn't that be done before we proceed to other resolutions or any other...

FW If that's how you'd like to proceed, that's how we will proceed.

-- It's not a matter of how I'd like to proceed.

(several speaking)

FW Well let's deal with this one because I don't think anyone has seen this. This is a new recommendation. First of all, I would just like to say I have read this recommendation and I have to be very straight forward and honest about this, this cuts to the heart of the problem. I have done a lot of studying about the Food, Drug and Cosmetic Act. Originally I believe it was Estes Keithoufer introduced a clause. His attempt was to limit the exponential expense of drugs in the market place. Initially his intention was very good. His intentions

were noble. By the time the amended version of his bill got to the floor and got voted on, he himself, Keithoufer would not support it and did not vote on it. The special interests hung clause after clause after clause on it and the language of the law no longer was what he originally intended. These are the policies of the past which so will serve us today. The efficacy clause is now responsible for a 231 million dollar drug approval process by ...University, 500 million dollars according to the Pharmaceutical Manufacturers Association. The barriers for the clinical approval of medicines and therapies in the United States are too high for any therapy that we have addressed. No one that I know of has the kind of money necessary to pass muster through this process. You are routinely seeing 30-day approval process turning into a six and one-half year nightmare as in Dr. Brezensky. He presented to them over six feet of documents. Hundreds of pounds of documents. The F.D.A. simply ran out of questions to ask Dr. Brezensky. As a wonderful scientist and a persistent person who doggedly pursued that to the end and received his I & D. This is an example just for an example. I think that this does cut to the heart of the matter and I would like to hear any comments that people might have on this particular subject.

-- I think there is a point in history that I think this is accurate. You're right that by the time the bill got to consideration, Keithhofer was...and sort of withdrew from the picture. Also I believe it's absolutely true that his interest was in the rising cost of medical--of pharmaceuticals and the only people interested in putting in this efficacy provision with the F.D.A. people, they

had procrastinating for this for some time. I don't believe he was personally interested in this.

FW If I might just address one concern which is brought up to me every single time we address this issue, I personally, it is my personal position that we should have safe and effective and economical therapies. I do not know want therapies which are not effective. What I am suggesting is that the current process does not produce effective drugs.

-- I would like to add to what you said Frank, in this book of mine, I discussed the...amendments and I just put a read of a line or a two. The Caforba-Harrison(?) amendments themselves mentioned only and I am quoting adequate and well controlled investigations including clinical investigations. That's how they say adequate and well controlled investigations including clinical investigations. Now the F.D.A. has taken the words here and interpreted in a way that it has. Therefore another is to make is much more strict, much...

FW First it became substantial evidence and then it became preponderance of a scientific evidence. Consensus of scientist agreeing on something before it can be approved when in fact we know that the evidence comes from the scientific process.

-- Well these are internal F.D.A. rights that have changed this. In other words, F.D.A. could change it back again if it wanted. If it were it would require an act of Congress to make this an easier mode of getting drugs

approved.

FW This is a very good point. The letter of the law is substantial evidence. The interpretation of the law by the F.D.A., the regulations which grew from the language of the law used preponderance of experts which they also interpret it to mean the F.D.A.. Now I would propose in addition to this that we insert three words. Three words would cure this deal. By two or more, I'm sorry, two or more, would say, two or more experts in the field. Because what we have to do here is we have to take this out of the hands of the F.D.A. and put it in the hands of two or more experts in the field. This then takes it out of the perfew of F.D.A., puts it in to the hand of two or more experts. We will never achieve consensus or the preponderance of evidence.

-- How about the expression, respectable minority of expert opinion. That's one which is subject to legal meaning I think.

FW Respectable minority, anyone have any feelings on this?

Berk I do, I don't understand what you are saying, where are you going to put it.

FW Well what we would be doing is is to add to, to suggest to add to this.

Berk Well I wouldn't add a darn thing if it were me. You got something that is very straight forward and says exactly and if people are opposed, alright, but I think the more you clutter it up, the more you mess everything up is my

opinion.

-- We are discussing number 7?

-- That's right.

Berk But I think it seems to me that what we ought to do is hear from the people that have disagreements with it or recommended changes because if that's the case then we can debate those, but I don't think--we're short on time for all of us to pontificate about how wonderful this is, I think is a mistake.

FW Excuse me Michael, but I think Joseph had his hand up before you did. I'm calling you after Joseph.

-- ...I think I know what you are getting at, you're just a little tired and I think we all are, but the repeal of the efficacy clause runs a trends risk and that is obviously so evident that any thing, and entity. any costs, etc. which is yet to be proven in what anyone's criteria is is going to run the risk for the light individual is not going to have any confidence or any security to that particular entity. is actually going to afford or affect the result their looking for. That's number one. So in terms of...

END OF SIDE TWO, TAPE 1B

BEGINNING OF TAPE 2, SIDE 1

FW Michael

-- Yes, the only addition I might consider would be and I don't know exactly how to word this, but environmental

concerns. Environmental hazards, environmental pollutants. How would we start...

-- environmental medicine

FW James

-- If you're done, we actually I'm wearing several hats, I'm here representing lungthologist which apparently nobody knows about, the induction of the dry state and that's had lots of affects on lots of different diseases and it's only represented by about three people in the United States right now. But also the whole spectrum of wellness and bringing everything together in a mutualistic whole. Ya know the multifactorial thing to me is just the way of life. I don't think of individual treatments ever really.

FW Gladys

-- I'm just wondering how we put compassion into this whole process. How we put the factor of loving patient into this. We get into the techniques and so on, but where does the fact that you care about your patient fit in. I don't know, I'm just putting this out on the table because that's where it starts and if we could start from the focus of care and love and concern and then build from that what we need to, maybe that would be a--it's certainly the point that pulls us together. There isn't a person here that doesn't come from that stand point that we care about what we're doing or we wouldn't be here. So this part of it is where--I don't know how to do that, but I would love to see us work into that focus.

-- Coming from none of the disciplines, consider the possibility of using the disciplines that are known. Homeopathy, naturpathy, acupuncture, neuroplastons, chemo yeh, but anyway consider the disciplines that are known, it may get more...

FW Cervene?

-- Okay I will focus on kilation therapy and I will say this will be a optimal general treatment not only for cardiovascular disorders, toxic metal states, auxiliator...but also it is a general rejuvenation and not necessarily...general systemic rejuvenation and lack extension methods, de methodology of designing the results is very easy in the case of cardiovascular. Non...techniques such as...before a doctor can very well validate. Levels of cholesterol, oxidize cholesterol, are very easy methods of validating the efficacy. Both on the clinical and scientific grounds.

FW Thank you.

-- I'm here just to learn more about other things. I use the same methods no matter what the disease problem would be. Some I'm here more to learn than to add much to.

-- We develop a model of sickel-cell anemia to introduce a oxidative therapy to numerous conditions that ah--that hiposia has their roots so I would say that this would be a nice convenient model to make some progress.

FW Barry

-- ...political invitation and I want to let you know the greatest strength are existing data you can build upon. We have a lot of that which is beyond this table.

FW Okay, George

-- I agree with kilation therapy anti...therapy. we have scientific modalities already available...(very hard to hear, can't get last couple sentences)

-- I would certainly put my support behind the antioxidant therapy. We currently have a proposal before the N.I.H. on oxidative stress in AIDS and theoretical pathology in the cause of stimulation of the virus and get the cells with antioxidants to prevent is cross the board and is certainly neutrogenic and deal with cancer. They certainly are promoted by heavy metals and cross the board kilation. So I think and they need it as a buffer when using the ozone therapy. So I think antioxidant is...

FW Seymour

-- I as a physician have said for 40 years I've been a doctor. We've made no progress with standard treatments in treating...our only progress has been in our diagnostic abilities where we diagnose cancer in earlier stages when certain cancers are curable such as cancer of the breasts. All I am saying is that if we are loosing 500,000 people a year, I have evidence that Dr. Ravesey's work can cure people who would have died under standard therapy, I am saying that anybody that wants to start an experiment with government approval should be able based on the work

they've done in their own laboratories to substantiate what they're saying and what I'm saying is if I can substantiate Dr. Ravesey's work and can save lives that are otherwise dying and save billions of dollars, why not try such a study.

FW Richard

-- I go along with what Barry and the others have said. I think we ought to recommend treatments that have been proven by others as a place to start.

FW Okay, Michael.

-- I say compassionate polyfactoriality, individualized protocols stressing detox and oxidated therapies and biochemical individuality and we ought to be looking seriously at a parallel thing for a quick payoff and I think it would be great since Dr. Brenner wants to do this that we would stand behind the idea of just validating that one thing as an illustration. It doesn't capture the essence of everything we're doing, but it points to something that is demonstrable and quick.

-- Yes...massive immunotherapytherapy and differentiation therapy, I think we have to some how classify Dr. Ravesey's treatment in general terms. I don't know what would be the best general term for Dr. Ravesey's treatment.

-- Antimetabaloy

-- Why don't we mention this also.

FW Yes Harrison.

-- Dietary nutrition treatment.

-- You know what is extraordinary here and I guess I am the last person and everything has been mentioned. I have nothing to add. It is a...and I think it's complete at the moment.

-- May I say a word about mental illness. It seems to me that any rational and effective approach through mental illness would have to comprehend through virtually all the specific techniques and quotes that have been mentioned around the table here especially the reference to environmental illness is ver important I think and ah I will say that as compared to I would say...way down the line and the physiological thing is very, very high in any effective approach to mental illness.

FW Peter

-- ...with the multifactoral view compared to the...and not only combined in therapy but...as well. Most of the approaches I have the opportunity to report on...all combined are a different variety of therapies and...to one. Brief example, the poxy herbal therapy which has been in use for many years and a number of other clinicians or components of that use simple herbal tonic and in my investigations to contact any type of results when it's used by its original components to combine a

kind of healing essence...level that goes along with the therapy and also just to add briefly what several people suggested of building upon...that there's a lot of data, a lot of studies out there ready to come to the public that are not valid enough for...was presented at the large convention of atheopathic physicians a couple of weeks ago in Arizona by Dr. Steve Austin. As an example, he's taken a look for a number of years at three of the healing clinics in Key Juan, Mexico that focus on...and found a lot of evidence...have many long terms of sirvivors and particularly the...that he found the greatest response in so. So he...individual of his study as well as others that are among others that are aware of the conserve of the beginning point for a series...(very difficult to hear)

FW Well I think generally I am a believer that we have real body, an existing body of evidence that demands to be evaluated. So I would say that we should look at what exists in the fields of immuno therapy and differentiation agents, oxidative therapies. We've got a lot of evidence out there and many of these things have been mentioned.

-- Just one thing I'd like to add to this discussion is we've certainly been focusing on the therapies and modalities that are already being used with effectiveness and I'd just like to point out a belief that I have and I think some of us around the table have as well is that probably the solutions to the serious medical conditions of our times, if they are already not extent are going to come from minds trained in natural medicine. So I don't want to exclude our endeavor with N.I.H. to the already

existing therapies but that the principals that underlie a lot of our work are going to go forward in time and lead us to new solutions in the future.

-- I'd like to just mention the urgency that I feel to put an umbrella over Dr. Brezensky's head and I think that that's one of the best treatments that's been developed in this country and he's behaved the way we want people to behave and I'm really upset because I think he's in imminent danger of being shut down and that could be a tremendous tragedy. I also want to mention historically what I think is the best treatment for cancer which is Coley's Toxants and there is an institute in New York Cancer Research Institute run by ...Coley Norts who is 85 years old which has demonstrated nearly a thousand cures of cancer, mostly at Memorial...through the use of his very radical immuno therapy. In addition I wanted to say that there is a treatment in Hungry right now in Phase III Multicenter Trials called M.T.H. 68 developed by Lazo Zatarie of Florida which is showing remarkable results through the use of viral and deference. Intenuated New Castle disease, it's a chicken virus aerosol spray and their getting very remarkable results and the treatment investigator on that study is the current president of the International Union Against Cancer. So I think it's the kind of thing that I was talking about that there is a big world out there and this committee, when we grow a bit and reach out to these other therapies that are going on. The immunotherapytherapy would be my overall...

FW Which I think leads us into the next question which will perhaps, I don't want to spend a lot of time on this. I

don't want everyone's pet therapy necessarily, but I do want, we do want ideas and the reason we want ideas is so we can look at what--I mean I've learned a lot already and we've only been here an hour and a half about other things that I don't understand. New ideas, Berkley said ya know we have to keep our eyes open because just about the time we think we know something, something comes along that might be better, it might be safer, it might be more effective. So the key here is to keep our eyes and ears open. Obviously I think it's tremendously important that we view this thing in the big picture, but I also think that we are going to need to be specific about what it is we're going to recommend. Now this brings me to a subject which Ralph raised and what I would like to do is to have Dr. Brezensky at this time tell us just a little bit about what he's doing and the reason I'm doing this is because it is a specific treatment with which I know and I am familiar with and I have many members in my organization of people against cancer who have benefited from his therapy. He is now in crisis because of the regulatory situation which exists in the country and he serves as an example of on one hand a man who has passed muster with the testing procedure that they've put out and on the other hand is now under attack by the officials in the regulatory areas and I think National Cancer Institute has agreed that what he is doing apparently has value and they want to evaluate. Perhaps you can give us a little bit of background.

-- Can I just make one point please, one other point. I am astounded that Dr. was it Freidman, the man from N.C.I. could get up and use Dr. Brezensky as an example of the

success of the system and at the same time N.C.I. and N.I.H. refuses to make a phone call to go to bat for him in order to stop him from being shut down in Texas. That is exploitation.

FW I think that co-optation is a very real factor here. That is that they will bring us in under their benevolent wings until we all comply some how to their wishes. They have the funds for the war on cancer and if we believe we have something which could be an important weapon in the war on cancer, I think it's tremendously important that we as individuals, that we as individuals let them know what these things are, what they can do, that we feel that these things are as important as the things that they are doing, perhaps more important. Perhaps they represent the future. Dr. Brezensky would you like to tell us a little bit about...

-- (very difficult to understand) Sure I'd like to be brief because obviously the time is very valuable. Our theory is that the human body possess the system of defense which is parallel the immune system...chemical defense system. Whereas immune system was designed to protect us from invasion from the outside, from the invasion by natural organisms. Biochemical defense systems protect us against certain rebellions it's guarding proper differentiation and developmental disservice. Both systems are enormously important with...in both of them are cooperating and we've got the costs of the diseases which can be managed by the proper use of the immune system and the possible diseases which can be managed by the proper use of biochemical defense system. The main crucial difference between

biochemical defense system and the immune system is that instead of killing the environment agents which is the principal action of immune system, biochemical defense is trying to reprogram the cells which developed in their own way. These are the cells which will give rise to cancer. These are the cells which may give the rise to...basically I'm talking about billions of cells which are developing every day...and these cells need to develop according to certain problem if we don't...police force which will guard proper development of the cells, we will develop a cost of different diseases. This is a police force...and the immune system can be compared to the...which is guarding us from invading from the outside. I came out with the idea about 25 yeas when I was a medical student and most of my life I spent in academics surrounding. Initially I was working on this research project as a student in medical schooling. I was enjoying the great fun. I had great freedom to do research, well only because nobody no what I was doing. My...department knew exactly what I was doing, but when it mentioned didn't know about it. So for six years, I had a great time. I was receiving grants from medical school. I was able to do research. I was enjoying my freedom, but ultimately the news broke through. I graduated as the best student of the entire class. I made the...by the youngest man in the history of the medical school but honestly there was tremendous pressure coming from your government to make me a member from his...so what they are telling me, well look here is this beautiful labs we are going to give you, a nice salary, beautiful area but there is a price to pay, your freedom. I refused, I decided that I wasn't going to be member of Ernest Barkley and I quickly come to the

conclusion that I have no rights in the government system because in the government, you can not win with the...system. So I decided to immigrate to US and I got enough history in itself for seven years I was working in the practice of medicine. I became a facility member, I was receiving grants from N.C.I., from medical schools, from various organizations, I was enjoying a great chance. I didn't make much money, this wasn't important, but I was enjoying freedom. Again I was enjoying freedom because nobody exactly knew what I was doing except for a few people. ...On one side I was offered beautiful lab, very nice area, very nice salary, a lot of money and the other hand I was asked to give them my freedom. I was told you have to do what we what we tell you to do. I refused, I selected freedom. I decided to open my own laboratory. So that was the greatest idea...because my entire possession of $5,000 of a debt, I was trying to...it costs 250 million dollars for a single drug okay and I was trying to bring ten different from...to do in scientific way...human tumors and animal tumors, we did...genetics...that is required by F.D.A. we compiled the data in order to proceed with...ultimately we did 20 different phase one clinical studies and six phase two clinical studies. We were able to obtain I&D approval from F.D.A. for the people with breast cancer...approval three other I&Ds for the treatment of cancer and AIDS. We didn't keep anything secret. As soon as I decided to open my laboratory, I was not allowed anymore to present my...at various conventions in the United States. I was not allowed to bring my papers in the medical journals of the United States. It left me only one possibility, to do it abroad. That's why I published in Geneva, in Paris, in

Tokyo, where ever. Altogether there are about 230 publications of my research at this moment and about six of these publications have gone by researches which have nothing to do with their individual resources. Within the last two years there were five papers which were articles by...Cancer Institute about molecular basis of our treatment so you can imagine that doing all of this I probably should be congratulated by the National Cancer Institute, by the state govenment because I stick to American spirit. That's what American spirit is about. Do it yourself without the government for the big money...do it yourself...and that's what I tried to do and I went through hell through the last 15 years. I was exposed to harassment, to prejudice at every level. Beginning at....beginning from state level to federal level and finally went through all this, we pass successfully inspection. The National Cancer Institute, it was founded that every case which we presented for the National Cancer Institute group...and these are the tumors which everybody knows are deadly tumors. These are...malignant brain tumors, such as...there's nothing you can do. These people will die within a few months. It will...that in a group of seven cases which we presented, the tumors disappeared, the tumors decreased in size, the patients were able to live normal life. I was happy to present many more cases, but of course they won't give me the time to review all of these cases. Ultimately when the...N.C.I. had approved our produce for clinical testing, I said well finally that's the end of harassment, that's the beginning of great times, then we have our treatment tested, then we prove that it's working, we benefit a lot of people. I was wrong, two

months exactly after our treatment approved by N.C.I. was viciously attacked by the state government, by the office of Attorney General in the State of Texas and they wanted me stop making medicine. They wanted me to stop treating people. they wanted me to destroy the...N.C.I. did not help us. They didn't call the Attorney General to tell them to leave the guy in peace, we would like to do...the state government knew for 15 years what we were doing, they did not attack us They attack us just two months ago. If they would be not enough, about one month ago I tell you attack again by the state general attorney office....office, this time there was a complaint from Texas Board of Medical Examiners that they are after my license, they like to cancel my license and the only reason why they would like to do it, there is not a place for the patients who are on...treatment...of people who are involved in state government to defend us. The only complaint about us is that there we are using treatment which is alternative. The treatment is not yet approved by F.D.A. or by the state government. The way it is going now, it looks like they may be successful. They may be able to shut us down, but again National Cancer Institute does not wish to call them, does not wish to tell them how important this product and this product is enormously because 200 we got patients who are taking the treatment now, if we stop the treatment, most of are going to die. There is no...for people who have...to die. We start the treatment...we have tons of people who are better in few months. If this is what you'd like to prove, then this would prove that the treatment is effective because the people who where free from cancer before, but it's not going to save the lives of these people. My idea is that

the government is the first place should protect the lives of the people who are responding to the treatment. These people should be allowed to receive the treatment and we should to receive the freedom to exist, freedom to live...most of the harassment against us began once it was founded...then we are...by the state to put us out of business.

-- This is the contradiction that we're in. That we don't want to be the ones to set up alternative practitioners to be attacked by state boards and if this convention, this meeting can't come up with a way to put an umbrella over the alternative practitioners and I don't care what kind of fine documents come out of this panel, it's going to be a failure.

Dr.B In my opinion, my perspective, it is my experience with governmental is that...for government is that it would leave me in peace, let me live and let me do what I was doing was not expecting miracles..who could help government officials put together idea because...to help N.C.I. put all the papers together for our I&D. I going to spend with out company, millions of dollars to produce medicine which will be given free to the patients with...so we are asking them for a little freedom. Let us get certain degree of freedom so that we can continue to save people lives...on the other hand, I take the compliments to..from National Cancer Institute because their view of our product was for the objective. I was very hesitant to let them do it because previously there are some other groups of doctors which were sent by insurance companies and instead of...they did a...so what

we are looking for is sudden belief...to be able to...

FW Well I think that this demonstrates that this is the answer to the argument. They don't have the data, you do have the data. They haven't done the studies, well you've done the studies. They haven't published the papers, well you published the papers. Still we have a system which rejects new important ideas. We're going to move on to the next question and perhaps this is the essence of what it is we're going to do and that is to establish criteria to evaluate. One of the charges of the law is to investigate, to explore these unconventional medical practices and to fully investigate and validate them. We are, our charge is to convene, we have convened and established an advisory to screen and to select procedures for investigation. As hard of job as this is going to be to screen and to select, we're going to have to do it. Now we already have a program and Dr. Brezensky's program, which is underway and I think that we could do a great service by providing safeguard, providing a watch dog over the policies which have so ill served us in the past. I think that we, no matter how well intentioned the Public Health Service might be, I think that there have been, there is clear evidence that in the past we've had problems. We need to establish new criteria for evaluating these methods. So I'm going to open that up for discussion in terms of criteria.

-- Speaking for my group here kind of three basic principals you got to look at. First of all antidote has been the big brother here, you can always look at anybody who's done something and has the result and they'll get their

testimonials from whoever same. Gee this worked great, I did such and such with so and so, that's...certain success rate. So you can't have a certain level of suspicion based on antidotes to tell you something needs to be investigated. The second thing is I think we need to really drop out of the old scientific period...cause a lot of the alternate medicine simply doesn't work that way. You know what you've been training on and there's no way you can...so we have to think of a new paradatas and validate things that doesn't require the old, well it says on hypothesis this test is going...lets come back and say this data didn't work and what that's going to be, I don't know. The third thing is that the individual practitioners are all very adamant about saying, let us set up our own methods for validating what we're doing. I can't say I particularly agree with that either because it depends on what their scientific level of understanding is and if a homeopath says let's do it this way because its the way we've always done, the rest of the scientific community doesn't accept that. It simply won't be accepted. We've got to find some means for melding the processes together...all of us are going to catch as a valid scientific methodology to prove.

FW Speaking the same language.

-- Yes

FW Michael

-- There's a way out of this. The first principal of the scientific method is careful observation of clinical

events. The difference between that and anecdotal is simply proper documentation. I think that if we use that and focus on clinical evidence as opposed to the double blind, etc., this is a valid and legitimate part of scientific method and there certainly is a wealth of information out there as everybody has already noted on this...

-- Just on coat tails of what you're saying, I think it would be wise of us to endorse the N.C.I.'s 10 best case series at the methodology, specific methodology for doing what you're proposing.

-- What is that?

-- That is we, where an investigator is simply asked to provide ten cases demonstrating effectiveness of a particular therapy. It is not ten consecutive cases which is interesting. It is ten best, choosing ten cases out of an entire clientele if you will and I think it is quite significant that it is ten best and not ten consecutive. I would also push for using the consecutive case approach. Look at a series of you know ten people come into your office, you treat them, ten consecutive cases and you look at the outcomes on those consecutive cases and not just choosing the best.

FW Well this brings up an interesting subject because for criteria, over three years ago I met with the National Cancer Institute Director Broder and Commission Young of Food and Drug and suggested to them that they adopt a strategy for the best case series and they've done this.

So I think this is important they've done this. This is something that we can all do. This is something that every practitioner treating every disease or illness can begin to do. Since you've suggested to me that there is no standard mechanism for data collection, it had been suggested to me, so I went and I did a little look around the land...to find out and I was amazed to find that the criteria for collecting information was not standard anywhere. The "scientific" or "proven" therapies were not, the criteria to evaluate them were not standard and if you went from Mayo Clinic to N.B. Anderson to Malloy...you couldn't even evaluate the data side by side because they didn't even collect the same data. Now on a case of designing a method, I suggested this in the last meeting that instead of teaching the practitioner, instead of giving the practitioner a fish and feed him for a day, you teach him to fish. So what is it the practitioner has to do. Dr. Brezensky has done the method and the methodology, but not everyone has the financial wealth to do that. We're facing a system which demands huge resources in terms of time, energy and money. So perhaps the best case study is an important place to start and perhaps ten cases is something we can all do. Berkley had suggested to me at one time that perhaps even five cases. Now Houston is written in repression and reform and incidentally I have a book for everyone and I will bring it down in our next meeting. The...and reform of the evaluation of alternative cancer therapies, he suggests that even one case in an advanced cancer represents a significant piece of evidence. Even one case with a terminal cancer, so best case series may be a good place where we can start. What I think we need to do in terms

of criteria is to establish a questionnaire which will cover all of the things that you need. Obviously in cancer, you need a pathology report. You need to know that the patient had cancer because the argument is always going to be made, well the patient got better, but maybe they didn't have cancer so ya know a pathology report, a questionnaire which collects time and data that each practitioner can collect and to guide the practitioner in collecting this kind of data, that would help us to establish criteria for validating these methods.

-- From my experience, ten cases may be difficult to review for the group of nci experts in one day. It took them almost an entire day to review five patients when they came to us. I showed them many more cases, but they didn't get enough time. They reviewed a couple more cases, that's was about all they were able to do in one day. So I think five cases is probably more reasonable to review within just one short visit unless you'd like a group of experts to study for two or three days and of course we have to obey to accept the principal, what needs to be evaluated in the first place of course we need to get...pathology report or slides if we are talking about cancer. We need data regarding the treatment to make sure that this is what the treatment you said being used and the patient was not being used heavy dose chemotherapy at the same and we need to evaluate those optional treatments according to a general accepted criteria. But on the top of that we've got add a few other things. These are typical for alternative treatment. Of course as far as evaluation of the cancer is concerned, the main principal for evaluation is the measurement of the size of tumor or

the debt of the tumor. I think we should still stick with to this principal, but on the top of that we also should consider, for instance the performances stages of patient is good, okay it could be that for instances certain alternative treatment may not eliminate the tumor and may not be...the tumor, but the patient may live comfortable lives...this is also very important, so this will be taken under consideration. Also obviously survival is extremely important. The patient may live with the tumor and basically he may...but he can live for long period of time. So that's why I think we should establish that we should use whatever criteria already there in medical science to evaluate the results but we have to work up specific criteria which are used in alternative treatment and it should add to it. Like a patient's performance...is very important.

FW Right, in the People Against Cancer, we have developed a questionnaire such as the one as I discussed and it includes performance statutes using the Carnowsky(?) scale. What's important is the patient can actually tell you, ya know on the Carnowsky scale where they stand when they began therapy and the doctor can also then assess it, sometimes it's different, sometimes it's the same, but it is a measure and then we can assess it in six months and then we can assess in another six months. Now you mentioned these, I just want to point them out before we go on. You mentioned tumor regression, okay, I think we have to use tumor regression as a point of measure. However, there is evidence that even when you do make the tumor get smaller, it can be an expense of patients survival, so it shouldn't be the only criteria. Tumor

stabilization is tremendously important. I had a good friend who lived for ten years with a tumor the size of a pear in his lung and he said it never got any worse and I lived a normal life, a productive life. Survival data is something that I don't hear coming out of the conventional medical model because rarely are protocols used for five years. By the time you get a year or two year protocol and then they've gone on to a new drug and they don't have any five-year survival data. It's important that we use survival data as a method of criteria and the performance is something we mentioned and I think that that's also an important criteria. Michael?

-- Every hospital in Tijuana at least in certain should be able to produce the lung parameter that casts and I think it's the only one and that is amount of disease free survival time. Nothing else is very important. A lot has been documented and if we do that, I can't imagine any of the long-term clinics in Tijuana not being able to put on a show that would charm Congress.

Berk The problem is that if we're going to do perspective research as well if what we say is we're going to use survival time, I fear we're talking about ten years to check that and I think maybe in perspective types of research we...

-- There are three or four for key cases are just so dramatic that it doesn't take them long to...

FW Barry

-- Well there are different...and combinations to look at and the end point, one of our end points that have been mentioned are the crucial ones, these are the standard ones in the environmental model as well. Survival of...like tumor regression, performance status, performance is one of the best predictors of survival. So these things are very well established and I think that it's...to look at those same end points Mr. Bedell's point is well taken when we move as surely we will, the prospective studies, then we know much longer time to look out and we learn to modify. But the point is we are all very clear. I didn't hear anyone being against this what the...have to do and it is interesting that they are the...medical therapies today.

FW Good point, it has been requested that we take a short break. We have one scheduled and should have had one some time ago. So there are those that would like to have a short break, what should we say ah...

(break--several speaking informally)

-- Can I make a quick statement?

FW Yes you can.

Berk I think we have an opportunity we should all be aware of and that is that we have the opportunity and I talked to both our Chairman, Dr. Berman and I think to Steve Droth(?), we have the opportunity at the conclusion of this total meeting to pass some resolutions and I think it is quite important for us if we possibly can come to

agreement to pass some rather strong resolutions because my past experience is you have these meetings of these groups and they all talk about everything and then they go home and nothing is changed. It may not be changed, but if we get resolutions passed and in writing, I think it has much greater chance of bringing about some change. So I hope as we discuss these things, we would focus on the possibility of trying to get together, I would hope rather strong resolutions. Because unless I misread the other people at this total meeting, my guess is that they're probably going to tend to be supportive of whatever resolutions are brought forth in support of alternative medicine treatment.

FW Okay, we were--I agree whole heartedly, we have--I have drafted some preliminary resolutions on the basis of the suggestions, comments, discussion today, we will draft further resolutions and we will run them by everyone and get general agreement. Hopefully we can then present these resolutions to the larger group. We were in the area of criteria. We had not yet finished the criteria. I think that everyone essentially feels that we're not going to ask for special treatment, just different treatment and that we don't want different standards, just a fair chance. So with that in mind, should we go through further sets of criteria for validating these methods.

-- Let me call attention to one factor which I think is an interesting methodologically. In evaluatingthis was mentioned before in the break that in evaluating what you call the ordinary...evaluation of cancer therapies for instance, the tumor regression is considered a good thing

general speaking in tumor. That's not necessarily the case at all, I mean in homeopathic theory for instance, the tumor is regarded as a kind of a counter balancing factor externalizing the cancer which is in the body especially if it's needed near the surface of the the organism. Alexander...had a stomach cancer in the 1950's and this has stayed, he shows me, he's a quite...he showed me and he still had it...and it's a bulge on it's abdomen wall and it's been forty years since that time. He's lived perfectly a comfortable life with that and still so the reason I mentioned is for the...point of view, we don't necessary want in evaluating cancer therapies to you said in one of each well don't be treated exactly...according to the same standards as the ordinary method of cancer treatment is evaluated because we may decide that tumor regressions aren't a bad thing, maybe tumor regression is a good thing, it might be considered a bad thing in some cases. It depends on how it regresses, I would say perhaps more than whether it regressed or not. Just finally let me mention the book by Abels, a German's book on evaluation of cancer chemical therapy, he concluded in that book that the people who tumors regressed the most rapidly...the ones who died...

FW Well we spoke to two individuals who were familiar with Abel and we did distributed that report, so I....

END OF SIDE ONE, TAPE TWO

BEGINNING OF SIDE TWO, TAPE TWO

FW ...v-measure...now and what were charged here to do is are there better ventures, are there more important things. In the last meeting I was struck by the fact that we had a

long discussion about this, that and the other criteria for whether the person with AIDS was actually "0" positive or not and I remember that in the final analysis the question was raised, did the patient get better. Ya know, did the patient get well. After all that's what we're all looking for. So we're just looking here for ideas. Pain is something that I have mentioned often to me. Pain is something that patients will do anything to stop the pain. They will take drugs which numb their lives which put them out of commission, which don't allow them to walk or carry on a normal life to stop the pain with disease or illness. So if we have alternative ways to deal with pain, they're tremendously important. Pain has to be a criteria. If the pain stops, the patient feels better, ya know that's an important criteria to judge whether or not we've had success.

-- One important issue is also what the evaluator as far as of medicine concerned...of conventional medicine is purity we are striving to have the medicine as pure as possible. Close to 100% pure. But in biological advocatious of the cases, not always we can accomplish this because biological molecules are very complex. For instance I have experience with N.C.I. when we submitted some of our chemicals which later would become medicine to N.C.I. for evaluation. Some of them were rejected because the purity was not 99%, but was 98.6%...here means nothing because the purities which consisted of sight...0.4% were common amino acids which wouldn't have helped patients at all. So I think we should introduce certain idea to evaluation processes that we don't necessarily need to evaluate pure chemicals in the treatment of the disease. It's difficult

to determine the structure of certain biological chemicals and the mixture of biological chemicals still...it should be tested. It should not be rejected simply because we don't know all of the ingredients of the biological mixture. Providing that we are able to...that this mixture be pretty much the same from one test to another. Also the combination of treatment and multifactoral factors needs to be taken under consideration. It's entirely possible that we may still use for instance psychopathic chemotherapy but very much we use dosage level in combination with some other treatment like for instance, immunotherapy...back to the chemotherapy by using very small dosage, but such combination may be both benefit because of...so the treatment which fall into alternative therapy should not be discredited simply because there are certain combination of the medicine which is being used. We know very well that in some chemotherapy regiment there are eight different drugs are used in the same patient. So why would, for instance alternative treatment be discredited if we are talking about testing of seven combinations of two or three different agents. They should be tested the same way as, for instance the combination of the...and if they work, they should be approved.

FW Correct, well Jay Moscowitz, who is the Associate Director, and I have talked about a way in which we can possible deal with these kinds of issues and I think an important way is outcomes research. You assess the outcome, irrespective of what happens in between the doctor and the patient coming together for therapy and I think it's important that we look at this because one, it

is a completely viable method of evaluation which is not only--can not only determine safety and efficacy, but economy in doing it economically. I mean we can no longer expect--we can't expect to come out of this meeting or any other meeting like this and get granulized clinical...on all of the suggested therapies that we're going to do. Currently drug approval is 200 to 400 million dollars in this county. There's not that kind of money to evaluate these therapies in that way. So if outcomes can be done, this sort of supersedes the minutiae, does the patient get better. You had a question.

-- Just a quick comment. In our own staff, some of the criteria that we use, one is reproducibility and anybody anywhere in the world should really do the same thing and get exactly the same results. As long as that happens, then you take things like personality conflicts and budgeting data and all that so whatever you're doing whether it's bizarre or not, should be reproducible. The second thing is that we're trying to develop a kind of across the board wellness scale that they would fit into. It's got social factors, how much did it cost, do I feel better or not, did the tumor regress whatever. You got to look at everything all at once. It doesn't do any good to eliminate the guys tumor...doesn't exist any more because they couldn't afford to live there. The third thing is to have some kind of validity to the process and that's the thing that we've always hung up on and I like this ya know ten best cases or ten consecutive or 100 consecutive cases idea because so much of what we're dealing with is not standard.

FW Right

-- I don't understand what we're doing. If I gave you 100 best cases, that will do nothing in the United States. What does that have to do with F.D.A. and the final approval to use that modality in the United States. You could satisfy the N.I.H. with a lot of intellectual case history, what does best case mean in the eyes of Jay Moscowitz or Tony (?)

FW Well me just explain that. There are people who come to the National Cancer Institute with absolutely no evidence whatsoever that what they're proposing works. They don't have pathology reports. They don't have, I mean not everyone comes with your level of expertise. So we are talking about screening these methods. We have to have some way to do that. One is to determine that there have been ten cases treated.

-- We're drifting to the mountain and the mountain is two hundred million dollars.

FW Well I understand that the two to four hundred million dollars clinical trial process is the process with which we have had to live. I think it has ill-served us. I think as people we can no longer accept it. We should demand new processes. I'm not saying that we're going to get them overnight, but we are talking about a new ball game here. We are calling the shots. How do we want these new therapies evaluated. Design a new medicine. That's what we're doing here. Okay?

-- I also have a...there are 500, maybe 600 physicians out there already gathering the data doing the science physiology, biochemistry. What this group for the National Institute of Health should be doing is using that data and making the data available to the public because that is where the problem arises. You can't keep them in sectors. You've got to focus on the agenda.

FW Yes, well it's a good point, it's been suggested and this is James, to what you are talking about is perhaps what this office could serve as is an unbiased broker of information. What is the state of evidence on XYZ therapy. Well XYZ therapy has presented a series of ten best cases to the N.I.H. and here's the theories. You be the judge. I mean in the final analysis I am a believer in patient rights. I believe that the patient should decide whatever it is they're going to do based upon the information, but if they don't have good information and if they don't have that kind of information that you're suggesting already exists, they can't make that informed choice. So I think part of what we're dealing with also is as Berkley has pointed out, there's a lot of information out there and the patient should have it. How do we get it to them. How do we act as...Berkley?

Berk I'm disturbed that I'm not sure we're headed towards anything that is going to be meaningful in terms of accomplishment. It seems to me that what we need to do is start to discuss in each of these areas what sort of a resolution we would like to see this total group come out with. Now yesterday it goes further than that, but I'll read the first part. It's something I wrote up while

they're speaking. It goes as follows: where as many types of alternative medical practices are not appropriately evaluated by current methods. It is the directive of this group that such unconventional practices be evaluated using outcomes protocols I got here with proper documentation. Now, if we agree that that's what we want to do, that's great. If we feel we should add to that all this different list, then that's something we should do or if we think we just want to leave it general like that so we don't have a limiting situation of the tumor for example, that's fine, but I would hope we would start to direct our discussion towards one proposal and then another proposal so that when we get through tomorrow, we will have some resolutions that we have brought forth and unless I miss my guess, we're not going to have very much trouble getting the resolution passed in that group out there because I think they're very supportive of trying to support such a thing and I would hope that we might start with this as a point to begin and see whether that's what we would to have or whether we would like to change it or we would like to add it and direct it towards accomplishment of various types of resolutions that we can bring forth.

(several speaking)

-- I would like to make a motion that we accept your proposal.

-- But I have a question about when you say evaluate. I'm not sure what you mean. As I see this situation, you are working without some concern. What you really want in out

come demonstrate certain results and I feel for example and I could mention any number of good results that come out or experienced. What I would like the scientist to do is not evaluate the results but explain why those results occur if you see what I mean.

Berk I see what you men, but I think in reality that this office is an office and even the legislation says that to evaluate alternative types of treatment. I think that what we're looking at is somehow to say to the public, we have evaluated this and it looks good to us.

-- There are two points there. If you follow the proof procedurally, what you're then blatantly saying is that we support particular alternative therapies to go ahead. Present this with a seed data and hence we will then evaluate it and I don't think that's really what we want to say here, but rather the fact that there is a form for conceptualizing that if--let's talk about not the alternative therapy that exists now, but the innovator that exists tomorrow. Do you suggest that innovator onto himself whether it be a a prac--let's say it is a medical practitioner, physician, he should go out and provide the seed data or are you suggesting that we continue with those therapies that are ongoing now. That whatever pure review processes that we decide upon may not make the grade, may not cut the mustard, but you want to still provide seed data possible challenging their patients against untorn affects. I'm not quite sure what you're asking for. Are you asking for just some basic head scenario on ten best cases are you going back look retrospectively or do you expect the practitioners

continue going on their job as usual staying underneath the carpet so to speak because they are afraid to come forth.

Berk What I had in mind here and I may be wrong, but I have in mind here is that in my opinion we are going to get cornered with the double blind studies and this sort of thing as you all know when we went to N.I.H. on ozone with that sort of thing. At least Moscowitz has indicated to me that one of the things that we could consider is what sort of protocols we should have in terms of evaluating unconventional types of treatment.

-- ...or degenerated?

Berk No either one, either already generated or to be generated in the future. Now my perception and it may be very wrong, we've got these investigators that are going to be hired and on staff as I understand it. My perception is that they could go out and visit the Brezenky's and the Ravesey's and the people who are using ozone and the people who are using...maybe and look at those treatments and see what sort of success they're having and I would think they should do it with outcomes measurement rather than anything else and then if they see that as sufficiently encouraging that they would then go back to that practitioner and say now what we would like you to do is treat another 20 patients and we'll supervise that and be sure that you get the proper records to begin with. To be sure that they really had AIDS for example and we will monitor that to see whether it's really true and if they do enmonor and see that it looks as if it is efficacious

and effective, then I think we have come a long, long way towards what we need to and even then we can go to N.I.H. and ask them to proceed or if they won't, we can publish information as to what we have already found and I think we've still accomplished what we wished to do. Now maybe I'm talking too much, but my big plea is for god's sakes let's try to put together some resolutions if we can possibly agree upon them so that when we get done, we have really had some accomplishments rather than just a lot of talk.

(several speaking)

FW Would you like to read it again, Berkley?

Berk Yeh, anybody that want's to amend it, I'm not here to try to sell this. Where at an insight of alternative medical practices are not appropriately evaluated by current methods, it is the directive of this group that such unconventional practices be evaluated using outcomes protocols with proper documentation.

FW Might I make one suggestion about...are in place of are have not-alternative, he says alternative.

-- May I suggest a friendly amendment?

Berk Let's try to break these, medical practices whereas many types of alternative medical practices are not appropriately evaluated by current methods. Somebody wants to change that.

FW Has not been appropriately evaluated?

-- Cannot be.

(several speaking)

FW Okay, we're going to vote, any other amendments, all those in favor of this resolution, raise your hand, all those opposed.

-- I have an additional thing to say. I think that it's very good that we propose this resolution, but for the wording. I just want to get us back to our focus here which is trying answer question number four. I would propose--I have written something here I would like to read to you. This committee advocates the use of conventional state of the art measures in each field for evaluating effectiveness of alternative innovative treatments in cancer, AIDS and cardiovascular disease. In addition, it must recognized the quality of life, pain control and overall functioning of the patient be measured in order to fully evaluate effectiveness. We endorse the basic research principals of reproducibility, objective clinical observation and the research designs of ten best case series outcomes evaluation and consecutive case analysis in addition to the costly large sample control trials. Further we endorse the resolution introduced by Congressmen Bedell as you've just voted.

-- I have fortunately an objection to that Leanna.

-- What's that?

-- I don't in reference to the control clinical trials. I think they're a bunch of...and I'd really--I have written a book on it and ah--

-- I've read your book.

(several speaking)

FW Okay, I think--what I would like to do and if everyone disagrees, that's fine, what I would like to do is to try to get through these questions upon which we can make resolutions. We have two very big questions a head of us and we can make resolutions as we go. I have a whole series of them I would like to introduce, but does anyone have a problem with that getting through these, we've got a lot of work and we've got a very little time. We've got 45--

-- May I make one small suggestion?

FW Yes

-- We have on the list outcome research as a way of--

FW That's right, that's a--

(several speaking)

FW Berkley the argument has always been made when you bring in the historical data that it's invalid and you can't judge by what happened in the past and you can't match the controls etc., so you have to do prospective trials which

costs a lot of money and take a lot of time.

(several speaking)

Berk I disagree with you. It seems to me that Leanna has brought an amendment for us. I don't think I agree with it, but she brought it before us.

FW You mean an amendment to yours?

Berk No, no a separate one and I guess my worry is if we spend our time talking about questions and so on, we're going to get up to the last ten minutes and then we're going to try to have some amendments. It seems to me if people have amendments that they think are resolutions right now is the time to bring them forward and discuss them and decide on it rather than to spend all our time talking about some theoretical questions.

FW That's fine if the panel decides that's how we want to proceed. My point was this that there are issues raised in these other two questions and we have gone through the first five and made no resolutions.

-- Well I think that resolution answers five and six basically. Our roll is to advise them. Make resolutions and say let's handle it this way.

FW Okay, well then if we're making resolutions based on--I guess my point is just this. Do we want to walk through the questions, discuss them and then make the resolutions or do we want to make the resolutions we have tomorrow's

sessions, is that right.

-- I don't think we have time to do that.

(several speaking)

FW Can you read your resolution again.

-- Well actually, it's no--what I was attempting to do was to try to find some language that will make whatever written document that this committee comes up with more effective. But if our purpose now is to come up with say four or five resolutions then forget this. This is just introductory language for this. So with...we decided to go with powerful, short, distinct resolutions that we're going to do in the next 50 minutes.

-- Well is that the sense of what people want to do?

FW That's basically what we want to do. Okay if that's the sense of what we want to do, that's what we'll do. With that in mind, we have one and we have that done and I think we can probably get that typed up, our writers there might make a note here of Berkley's resolution and we had a resolution before which was also passed regarding a letter to Dr. Kester which he will type up.

Berk That was not a resolution. It was a motion of our group and to me we should be aware that Steve Groff violently is upset with that amendment and he is upset because he feels that from a protocol standpoint it needed to go through his office rather than through us directly to do that and

I have to assume that his concern is that he is going to get in trouble with some other, excuse the word bureaucrats, over arguing that directly and we were going to try to apologize to him, so to say.

FW As the question comes up on autonomy. Are we truly autonomist, we probably should advised him that we were doing that. I think it made him tremendously nervous that we were asking the Secretary of F.D.A., or the Commissioner. I think it is tremendously appropriate. I think it's appropriate for him to be here. I would have liked Dr. Broder to be here, Dr. Kessler to be here and the heads of the institutes to be here so they could see what it is we have to say, but since they are not, we invited one, we probably should have asked Steve about it. In terms of resolutions, where are we, do we have--

Berk I've got another one.

FW Berkley

Berk This comes from the fact, I'm going to hopefully get that sorted out some yet today, but I told you that I had an amendment that I think was all set to go into law and we were advised that the Secretary already had that authority and now because things are moving so fast, it's almost for sure not in the law. Maybe we don't want this amendment, but let me read it to you again. I wrote it up quickly during the speeches last night. That the Secretary use his or her authority to give permission, this was following this other and I have changed a little but, permission to use such treatment for research purposes and

that only and if such physicians be free of censure from licensing state boards on patients not withstanding any other laws or regulations provided there is no evidence that such treatments are dangerous and further provided that any patient so treated has been advised that such treatment has not been proven to be safe and effective and the patient has acknowledged in writing being so advised.

-- Move to accept.

-- Wait a second, I don't understand this. Does it mean that upon doing something innovative, I keeping on bringing up kilation because ya know everybody, that I have to ask permission now to administer kilation.

Berk Let me tell you what it says as I understand it. What is says is that the Secretary will have authority to tell you that you can treat with kilation for research purposes because they think there is some benefit to it and they want to find out and then you will then be free to treat with such treatment as they supervise what's happening with patients regardless of F.D.A. or a medical board interference.

-- Even it's not F.D.A. approved, you can do it.

Berk You don't have to get an I&D, you don't have to do all those things. That it would say if they--if N.I.H. feels that this is worth investigation, that they're free to have you go ahead and investigate it even though you have not gone through F.D.A..

-- Included in this would be outcome research that would be included.

Berk Yes, Richard

-- I'm not an attorney, but it's my understanding that under the as a constitution that the Federal Government has no right to order a state to do anything with the state's laws. If the state prohibits something, the state would ignore that. Now I agree with what you're trying to do. I'm not disagreeing with the intent, but I think it's...

Berk Where I'm coming from is this is almost word for word for what I was trying to get into law and I was advised that the reason that they didn't feel that they could do it was they were--

(several speaking)

-- Well it's interstate congress thing though.

-- She's not practicing an interstate congress.

-- No but she's practicing something that could be done interstate.

-- That doesn't make it interstate.

-- It's already in the federal register complay that says any position can use for whatever modality, therapy, advise that they consider to benefit the treatment for an individual. It's already a law.

-- Yeh but it's ignored by the state boards.

-- The interstate there is an individual. It's on a case by case basis. So that you are going to be defeated if you were to suggest that a new innovative therapy was going to be tried--I'm say that limited well designed on protocol for 20 patients. Okay and that you had very, very specific inclusion criteria that you went to a quality insurance control individual that had no vested interest in the project whatsoever so that you were not compromising your protocol whatsoever. The fact that you were opening it up to 20 patients and actually requesting or actually submitting for patients to include...that portion of the register and that's what Mr. Bedell was trying to get passed. It's not to be done on a case to case basis. You are not allowed to put protocol through for clinical trials. When I say not allowed, I'm not agreeing with them, I'm just telling you I'm reading it as facts. On a case by case basis, however, a physician can do anything he likes.

-- Isn't it proper that we're not allowed to as a federal agency to give...state board, but you're not trying to do that, but it's just kind of the sense of the meeting isn't it--

Berk ...this gives correction and made that this is the--Leanna added this actually and if you're talking about such a position to be free of censure from licensing state boards, if that's the concern then I don't know Leanna felt that this was sure be beneficial from Mr. Brezensky if that were in it. I'm not here to argue for it or

against it.

FW Understand this is a resolution recommending things. We're recommending these things to help free patients and doctors. These are just recommendations, these will not carry the weight of law. I think we should make this recommendation because irrespective or whether or not it may be legal or illegal, the intent is the statement, isn't it and we know what we're asking for.

-- It should be expanded to cover also the State Health Department because we have two agencies in the trade one the State Board of Medical Examiners and another one is State Health Department.

FW Would it be covered by state health authorities, state regulatory agencies.

Berk I don't think you have to do that. The only way they do it is by law, is it not.

-- But in our case, we are backed up by Texas Health Department and then by Texas Board.

FW I understand

Berk Not withstanding any other laws is what this is.

-- I have a resolution that I would like to introduce.

-- We've got a motion on--

-- ...explaining something. The think I have a resolution

on, I'm going to suggest particularly pertaining to your case. So I'm not sure that we need to amend the general--

FW One for this particular situation. Do we have any other concerns, discussion, comments? Do we have a second.

-- I'll second it.

FW All those in favor, opposed. It's like the Soviet central committee.

Berk We might change the words to make it fit better.

FW And Berkley, incidentally anyone who phrases these when we pass resolutions should go to Ron, is that right and take them directly to them and explain your handwriting. Ralph?

-- I'd like to introduce a resolution about Dr. Brezensky's situation. I could use some help on the wording here, but here's what I wrote. Where as the National Cancer Institute has decided to conduct controlled clinical trials of Staslar R. Brezensky's antineoplastons and this method is currently under scrutiny by the Office of Unconventional Medicines of the National Institute of Health. The call on the regulatory agencies of the State of Texas including the Attorney General and the Texas Board of Medical Examiners to declare a more moratorium on any legal action against Dr. Brezensky for the duration of these medical investigations.

Berk Amendment under scrutiny, I think it has a sort of

negative connotation, unconsideration.

FW Unconsideration

-- You'll probably have to put the Health Department in there.

-- Well we have regulatory agencies that you mentioned including the--

-- Texas Health Department

-- The Attorney General, the Texas Health Department.

-- And the Texas State Board of Medical Examiners.

(several speaking)

FW Okay, Joseph.

-- I am really sympathizing, quite empathetic about Brezensky's fight, I think it's a travesty and it's...scientific blasphemy, however I do not think that this panel does specifically sight a particular example at the preclusion of other particular projects and I think you are asking people of we do not ratify it, it looks as if we're oppositionists. If we do ratify it, but we don't know all the data surrounding the situation other than the testimony that was given today, we're not doing our our do diligence

-- Can you make it more general.

FW Barry

(several speaking)

-- ...I think that the concept is important and I think we need to carry it through, but I think we'd be better off and be better served Dr. Brezensky and everyone else by saying that any treatment or regiment that is currently under investigation by a government sponsored body, has to be hands off. That's legal terminology but that's

-- That's what I meant by more general.

-- I'm sorry, I don't agree because I think the specific case in hand--first of all I think we know enough from what we've heard last night and today to be able to say exactly what the resolution states which is we heard from the N.C.I. itself that it had looked into--it had sent sight visitors to Brezensky, it had found evidence of effectiveness and Ed wanted to go--Ed Wanton is planning to go forward with the clinical trials. I mean that being the case, I don't think, I don't think this resolution goes beyond that. It does not make any claims for Dr. Brezensky or for the effectiveness beyond what N.C.I. itself says and secondly, I mean I don't think that the general resolution is going to have the impact that the specific...

-- This is a general resolution and perhaps that of a specific...

FW Well if you want to do that, that would be fine. It is

such as the case of Dr. Brezensky, now do--

-- Your question about impact is self-limiting by the fact your using him as an example.

FW Well if we can solve this by saying in a general sense this would apply across the board which we have determined that we're going to evaluate a therapy and in a specific case of Dr. Brezensky, can we do that?

-- Can we do this as a friendly amendment. If you will accept that as a friendly amendment there is no need to...

FW I certain would accept.

-- There is evidence by the case of the Brezensky.

FW As long as the Brezensky case is mentioned in the resolution as a specific of the...

-- I agree with you, we definitely have to make a statement.

FW Okay, then is it, I have one question, is this, does this relate then, is it going to be the larger resolution for the moratorium, for the F.D.A. moratorium which we have requested. Well I think then we have to make it more general even with putting Brezensky's in because we have to deal with the seizures, the raids and the ya know...

Berk Why don't we just make it specific.

-- In this case lay it to them and say we as a committee

would like to request this and then make a general statement about similar cases. So they're two completely separate issues.

FW How would we phrase this particular...

-- No it's a specific example...

-- The more impact if you keep them together and they're not specific issues. They are the same issue, you're just using this as an example. Putting your additional wording that you think.

Berk I think they are separate issues. I think from what I understand he's going to talk about. I think he's going to talk about F.D.A. are you not.

-- We need a general statement. General about moratorium...

FW That was my question.

-- It is very important to make it as general as you can because as we said last night and today we are trying to encourage other physicians to come forward under a protective umbrella and if we have that kind of language out there I know several physicians who would probably feel more comfortable about talking about what they are doing and knowing that they may then avail themselves with N.C.I.'s help or N.I.H. help without running the risk of investigation.

FW Okay...

-- There's a general feeling I can here in some speakers that is not right to single out one person when there is a lot of deserving candidates out there, but I don't agree with that. First of all Dr. Brezensky is really under the gun at this present moment to agree that no one else probably is and secondly his record is long and very extensive and third if Dr. Brezensky wins his case, this will reverberate and help all the others anyway and I think it's very important to concentrate by fire just at this moment.

(several speaking)

FW What I would like to do and I need help with the language here, but I would like to formally and respectively request, to make this request in writing that the we have a moratorium on F.D.A. seizures and state regulatory authority, F.D.A. and state regulatory authority seizures, raids on clinics, practitioners or therapies which have been chosen by the LEM for evaluation as pilot studies or for evaluation. Does that...

-- ...because first when you are dealing with F.D.A. and raids, I mean I am for what you are saying, but I think that is it--in my opinion we have to come up with a resolution that addresses the imminent danger of Brezensky being shut down.

(several speaking)

-- ...can we have two, can we have two separate ones.

FW If we need a--I think we need a general statement. Does everyone agree?

-- To protect everybody and then we need more...

FW Regarding F.D.A. and state regulatory authority raids seizures, licensure, I don't know how...regulatory action, I don't know.

-- Well we have a writer to work on this.

FW Just a general statement regarding moratorium on F.D.A. and state regulatory action on those therapies which we are investigating.

Berk It's really what the amendment what I have says, but it doesn't hurt to say it again.

(several speaking)

Berk The only think different is that I say that the Secretary has to use his or her authority to accomplish this. What he is saying is that...

-- Couldn't we use the body of your resolution and just have a different preface saying that well you said the Secretary should do XYZ, we say the F.D.A. should do XYZ.

Berk I think that's a separate amendment, I think...

(several speaking)

FW Excuse me, could we have one conversation please.

-- ...language was I think is excellent, why not use it as a general statement and specifically name Dr. Brezensky and that way we don't have to come back and do this every time someone comes forward.

FW Well then we'd have to change it to whereas the office of Confidential Medical Practice for Alternative Medicine of National Institutes of Health has decided to...

(several speaking)

FW Consider to evaluate certain alternative medical practices. We call on the regulatory authorities including the Attorney General, the State and the Health authorities and the Boards of Medical Examiners to declare a moratorium of any legal action against practitioners of these methods for the duration of the N.I.H. investigation.

-- That's fine, you just need to change the first word where as to when.

-- But you also have to have the Secretary named as the person to do this action and we're not in session until after this meeting so...

(several speaking)

-- Okay we've urged the Secretary to appeal to state medical authorities including the Attorney General, the Board of Medical Examiners, the Board of Health.

(several speaking)

FW We have to make it to specifically call on the Secretary to appeal to the Texas Medical authorities in the case of Dr. Brezensky.

Berk I have a little amendment I'd like to add. Before you got to the legal part, no legal action, I think that should say legal action which would jeopardize such research.

(several speaking)

FW Harris have you written this?

-- Whereas the, what are we calling ourselves, the...

FW The pops of alternative medicine.

-- Pops of alternative meedicine, N.I.H. has decided. Now where is the N.I.H., is it the office of Alternative Medicine, that's evaluating Dr. Brezensky...

Berk We really don't say that. I'm sorry, but you've got to say the Office of Unconventional Medical Practices. That's what it is until we change it but that's...

-- Maybe one's that evaluate Dr. Brezensky...

(several speaking)

-- To evaluate certain alternative medical practices specifically the neoplastoms of Dr...

FW Well you see there we're running back into the same problem is that do we want to make this a general.

-- Do we want to mention Dr. Brezensky?

FW Yes I think as a second sentence.

-- Isn't this committee work that you an do after the meeting?

FW I think so.

(several speaking)

FW Are there any other comments on the resolution? Can I see a show of hands all those who are in favor of the resolution, all those opposed.

FW Two abstains, one...three abstains...Leanna?

-- No I just want to move on.

FW Alright, so we passed this unanimous...

-- Um, I ya know we have I think a half an hour, right. I have an issue that I think is of great importance that came up in the June meeting which is pure review and I don't want to leave this morning's session without discussing it.

FW That's a different committee, I think this afternoon. From two to six there is a purity process.

FW You can attend that. You see that's why they split it up into cross cutting issues. I have a resolution which probably should have gone before the discussion here. I think that clearly alternative medicine, the terms alternative medicine become the defining terms. I see it written in the pure review literature, I see it written in the Popular Press. It was written up in the Congressional Record, in the Congressional Quarterly, the Office of Alternative Medicine. I would like to make a resolution that we've spoken to Harkin and his office and we've spoken to Jay Moscowitz here and Steven Groff and they're all in agreement that if we come to a consensus regarding a new name for this office that they will change the name. I think it's important that we do that. I don't want to be un-anything. I don't want to be for the study of anything. I don't want to have all these useless descriptors typed on. I would just resolve that this office be called the Office of Alternative Medicine.

(several speaking)

FW Please one at a time. Joseph?

-- Do you usually crank that the word alternative is a relative term that may be...that alternative to what...and that's the problem that I have with the word alternative and possibly I would consideration of novel and innovative.

-- ...innovative as well because that's something that's fine now and remains...

(several speaking)

FW Innovative means new. Of course there is innovative chemotherapy and...

END OF SIDE 2, TAPE #2

BEGINNING OF SIDE 1, TAPE #2A

Berk Can I speak, as you know I am a strong supporter of this, but I should tell you that Dr. Matino, that's why I was out, he's got some real concerns about it and at least I would like for him to state what he would like for this to say for us to listen to it. I think it's my personal opinion that it accomplishes exactly the same thing and might be more acceptable generally in terms of the--and he had a long time coming to this as far as I think you know how strong I feel about this issue. Could you quickly say what you had in mind.

FW Well before we do that, we have voted and we do have I understand..

Berk We didn't vote to re...

FW That's right, but what I mean is as long as everyone's final with accepting this as...

-- Absolutely

FW Fine, everybody fine.

-- ...set of recommendations and the board's spoke of positive, but we haven't made a negative statement. We

made positive recommendations okay. My major concern is the efficacy clause as it stands now is seen by all of us as to bring new alternative or innovative technology with a modifier in front of it to the public. So I thought that it would be conceivable that we could have rephrased this particular clause to say that we recommend an...we recommend that the F.D.A. statues of Food and Drug and Cosmetic Act be revised, be written as not to place an impedance into the path of bringing alternative methodologies or any methodologies or therapy conventions to the forefront and hence to the community and the patient population at large.

FW Do we have comments.

-- Will all due respect to Congressman Bedell and Mr. Latino I think you know that's--we have a specific resolution which is much better. What you're proposing is much general, it's much more profuse. What we have is specific wording which is optimate of any ambiguity or misinterpretation. I think specifically is better than generality in this case.

FW Michael

-- What I was going say is we touched while you were out of the...that this does not mean that there is no efficacy at all because there is still some efficacy contained in this. The key...amendments added to the efficacy. So we are not really striking at the concept of zero efficacy and there's not great virtue of being positive all the time. The ten commandments is a negative document.

FW I think that--may I ask you just--hold on one second--may I ask you if you would feel comfortable in making a general statement that we could add as a recommendation. I don't want to exclude anyone here. I don't my verses your. I don't us verses them. We've got enough of that in the existing system. I want to include, is there a language that you can write which would not in regard to this particular resolution, but in regard to the issue say that we could adopt. Could you do that for the committee?

-- As an additional recommendation?

FW As an additional recommendation for the committee.

-- ...I think would be coming a redundant statement that actually would become a statement so that you actually tend to negate or modify previous recommendation hence would be exercised as...as far as I am concerned. The board is going to protect it but we don't...

FW I would like to ask a question. Do you, are you aware of the language that we adopted?

Berk They changed it...

-- ...the last revisions, I'm not.

FW Before we talk, I would like to read to you the as adopted resolution. It is the recommendation of this committee that we express condemnation of the recent F.D.A. regulatory activities which have served to intimidate American citizens and violate their human and

constitutional rights in so needed research into life saving modalities. To this then we recommend to the congress that the efficacy clauses of the Food, Drug and Cosmetic Act be repealed or significantly reinterpreted to read, we require substantial evidence of efficacy as determined by two or more experts in the field. That is the language as adopted.

-- It seems to me that you could follow that by saying the intent of this recommendation is and then just add your own.

(several speaking)

FW I'm sorry, once again...

-- All suggested in response to your request is that a statement, an interpreted statement...the inclusive intent here is not to afford, not to place impedatives of the basic clause before, that's what was suggested as to not negate the statement, not to believe the statement, but rather make it a positive interpreter statement. Now you may feel the recommendation...

-- The purpose of any regulation is to place impediments. I mean you can't simply not place impediments. In other words you are saying that let's not have any regulations.

-- ...as impediments or as, I'm using to word very brief. I'm thinking in general terms. So those impediments replace there for the purposes of...

-- Yeh but they don't admit that for goodness sakes. We can't tell them to admit that you're are doing this deliberately to...

-- Yeh but you are admitting it by the sense that you're talking about the combination of...so you are already taking them out of the...

FW Can you, can we resolve this by including the general language in the committee report which I would assure you that would be or in another resolution. Is that an alternative that you could live with? Incidentally does anyone have a problem we have not--we are now 20 minutes into our break. I am perfectly willing to go through our break. I am more than willing to go through our break. Does anyone else have a problem with going through the break.

-- I need a short sandbox break.

FW That's find we'll do that.

-- Ed? was one of the people we've called and he's come in from Michigan to present to this committee and he explained to Steve Groff that he was coming and couldn't possibly be here before 9:00 and his plane was held up and I'd hate to have him to come all this way and not have a chance to have 10 or 15 minutes to address the group.

FW I agree, is there any objection to hearing Mr. Sabcheck? now and then proceeding with the recommendation with what we have--before we do that, does anyone want a break right

now.

(several speaking)

FW Okay very good, does anyone have any objection to hearing Mr. Sabcheck now?

(several speaking)

Berk Have we settled the other problem though so we don't have to come back to it.

FW Okay, have we settled the other problem so we don't have to come back to it before we start new business here. Can we introduce here into the language of the committee into our report, language that you can live with or in the alternative can you write an additional recommendation.

-- I have no problem with writing--I have no problem with the...that's not a problem. What I'm saying is that placing it as an additional recommendation you propose is going to have to induce the previous recommendation, otherwise it is standing by itself.

FW That's fine, I can accept that.

-- ...I think that I like the wording that you added which you have referred to before we left the room and I gladly...this recommendation. I am not sure that an additional recommendation is...one of the concerns you had was that this really belongs in a wider context, but now I understand there is not going to be an opportunity for...

FW That's right.

Berk Can I quickly explain that to people because I think I mislead you. Earlier I thought we were going to take these before the group and have a chance to have the whole group vote on these resolutions. I find that that is not the case and that we will have a chance to have our report made a part of the report language which accomplishes roughly the same thing and it is important what we've done here in terms of our resolutions and so on but just so you know that that is not going to happen.

-- I find it an intolerable situation that the Brezensky resolution or recommendation passed by this panel will not be raised to the entire group. I find that intolerable. Only because that we mean--it's an immediate situation of a person, member of our complay who is in imminent danger of having his medical license pulled at the time that N.I.H. has already agreed to investigate his method. I think we are being bureaucratically obstructed by the leadership, the NIC leadership and their appointed leadership in keeping this from being a fully democratic assembly.

-- The only way that could be...is if you had a representative of the F.D.A. present their argument for or rather the Texas Department of Health present their argument because we haven't heard both sides of that story.

FW Okay, if I may address that. The issue is not whether or not Dr. Brezensky should have these therapies approved or

not. The decision is just should we be able as an organization to evaluate them and in order to do that we have to stop this proceeding. If the proceeding goes on, the evaluation will be negated. There will be no way to conduct the evaluation of this therapy. It is a test case and I will put to you that if we fail with Brezensky, we fail.

-- No but we could also make a very valid point that we want to see science on both sides of this issue. That's a far more valid point than just saying we'll accept his word at face value. If the Texas Department of Health had to present their argument, they could really have egg on their face to the whole world.

FW Well I agree with you. I am not questioning whether or not the Texas Board should be able to present their argument and the Brezensky people should be able to present their argument. What I am proposing and I think what we are proposing here is to extend the moratorium while we evaluate. Only stop at while we are evaluating this and that is the thing that I am so concerned about is that if we don't do that, we as an organization will be impotent. Richard?

Berk We're short on--we're terribly short on time, let's hear from Dr. Sabcheck. I can tell you without a whole lot of debate on the issue. I can tell you that if you want to get it before the group. The only chance you got is there's microphones there and if you want to go to those microphones and propose an amendment or resolution in spite of the fact you're not supposed to do it, you can

try to do it. They haven't told us that we can't do it and I don't know what we're going to gain by debating a lot here except to maybe go try to do it if you want to.

FW Okay, Richard?

-- I don't believe this has anything to do with Texas. I don't think it has anything to do with whatever program he wants to try. I think it has to do with the fact that the Congress told the N.I.H. we want to look at alternative therapies. The N.I.H. is putting on this committee. I want to know whether it's for real or strictly a dog and pony show. I don't believe the N.I.H. has any authority over the Texas Attorney General and what the Texas Attorney General wants to do or will do has nothing...I do believe the N.C.I. would not participate in a trial unless it was absolutely safe with all kinds of safety precautions. In any trial they participate in, it is absolutely safe and that's not an issue. Therefore the N.I.H...

-- It would be the F.D.A. that would require phase one studies for process...

FW No, no, no

-- James, you missed the speech that Freidman gave on the first night we were here because he explained that the N.C.I. has initiated, has done a sight visit to Brezensky, has found seven cases of tumors that seems to regress and is now initiated four clinical trials on brain cancer that N.C.I. approved or is trying to arrange for trials at

N.C.I. approved institutions. If N.C.I. wants to investigate, one of our unconventional methods and this is the one that has gotten furthest in their investigation, then we would be absolutely remised not to extend the umbrella of this group over that person and show the point where N.C.I. has completed it's investigation. That's all we're asking for. We make no value records whatsoever on the value of Brezensky's treatment. It may be worthless. It may be crackpot or it may be the greatest break through in history. We don't know, that's why we have trials in these things. If we allowed these two concurrent things to go on, we fought for N.C.I. and N.I.H. evaluation and we let the man be destroyed by Neanderthal life and state authorities, than all we've done is set him up for destruction and I'm sorry I ever got involved, that I ever found out the name of Brezensky because I was the one pushing all these years for him to be evaluated and now I am supposed to participate in a situation which may lead to his destruction and I personally...

-- But we're also here to set up a structure for everyone in the future to be able to present and legally carry out meaningful and efficacious modalities. Now I wouldn't want to see the defense--if there were data that we were not privy to where certain negative outcomes were known to the authorities in Texas, I wouldn't want to condone or--

-- If all were asking you to do is to support N.C.I. judgment and we can have validation from N.C.I. people--

-- But that is an intellectual question of science. N.C.I. follows science--

FW We can't have this. We have voted on the resolution. The resolution has passed. The question now is to whether we're going to introduce this is as a resolution or whether it's going to be simply one of our recommendations. Do we need to vote on this as to whether we need to or do we need to simply go into--do we have a motion to introduce this?

-- I would say resolution. I would like to introduce this as a resolution and as a sense of this group that we be allowed to introduce this is a resolution to the whole body of our conference.

Berk Make it that the resolution that this group will try to offer it as...that way you don't have to get permission or anything.

-- Sure that's sensible that this group will attempt to offer.

-- But I would encourage (several speaking)...as we see just because that is...one individual but I am more worried about all of us.

FW I see what you are saying. Absolutely that this has implications for--far reaching implications for the future of our look and for the evaluation of all therapies that come after this.

-- We had discussed the other day that it would be a generalized statement that this...

-- Right now we're told that can't have resolutions brought

to the full group. That's what we're being told.

-- It's the very nature of what the problem has been if we allow ourselves to become part...into small groups and the whole group never knows what everybody else is doing, we really...we can't do that.

-- That seems to be the game plan.

FW There are serious concerns which have been expressed throughout this conference in every committee that I have seen. About co-optation and about the dog and pony show that they are putting on here and that they are going to bring all these people in and we'll all pretend that we have some sort of policy. Okay, what I think we're referring to here and what I want to bring us back to because we are way off mark and we're way down the track and I thinks it tremendously important this is the language that we have adopted and we have adopted this language. Is everyone...

-- Are you talking about number three...no I believe that the words specifically should be changed to the word includes.

FW This has been voted on and adopted.

-- No we voted on a general statement to include Brezensky. Not a specific inclusion of Brezensky.

FW The language was taken off the tape recording.

-- Alright then it should read, this recommendation includes

the case of Dr. Stanislaw Brezensky of Texas.

FW Would you like to make a motion to change the language.

-- I make a motion.

-- The specific language that is being recommended is we...

-- This recommendation includes the case of Dr. Stanislaw? Brezensky of Texas.

-- I think...because more than just include it. I think that we want to--to me this is weak, but I think even as it stands and I think we can incur there by just say include because I think we want to point the attention to the fact that this is the case that will turn this one way.

-- We got the general statement in the first five lines.

-- I agree with you that we do have the statement in the first five lines and if that was the truth to this committee, than we wouldn't even have this...so the point is that you want...this particular statement by case in point.

FW Now I asked originally for resolution on this...people said would you accept this..

-- ...consensus of opinion that we would attempt to bring some light onto this particular case by including it in the recommendation. Just thinking in terms of group being realistically precise by saying refer specifically to me

making true an exclusionary.

FW That's a good point, but how would suggest changing it without...

-- I would suggest the last sentence to read, the situation of Dr. Brezensky of Texas in an urgent case in point.

FW That's fine with me.

Berk That sounds like a good compromise.

FW The situation...

-- Would you like to put that in a form of an amendment to the motion.

-- I would put it in the form of altering the final sentence.

FW That the situation of Dr. S.R. Brezensky of Texas is an urgent case in point.

-- Right

-- That's fine with me.

-- I second it.

-- I have one question, I'm not moving this, would you want to say to demonstrate the sincerity of the N.I.H.?

(several speaking)

-- The amendment has been moved and seconded.

FW All those in favor of the amendment, opposed. Again the soviet central committee is...

(several speaking)

FW Okay, I think in all fairness to Mr. Sabcheck, we need to hear his.

-- I still have one issue on...we haven't resolved the language with what we are doing with that last number seven and I might disagree..

FW We have. We have to do two mechanical things here. Because we have no writer.

-- I am not at all sure about this situation...

(several speaking)

FW Okay I just didn't want anyone to testify.

(several speaking)

FW Okay Mr. Sabcheck has come a long way. We would like, Mr. Sabcheck, tell you that you have ten minutes, five minutes for questions, any of the length of time of your presentation goes into the question period, we want to give you an opportunity to hear all the questions, but bear that in mind.

Sab. (difficult to hear at times) I have come to make you aware of a product and some of you are already aware of that product and the name of it is cancell. If you think you've got problems with your products or your therapies or modalities, when I was at Texas Medical Center and introducing this, the medical center did a computer readout on some of my studies we had done in Africa using cancell on the AIDS virus. Dr. ?Anderson was nice enough to make a comment and the comment was that cancell is so far ahead of the mental community that we do not even have a vocabulary to explain it. We have the...of the product. My attempt to explain it goes like this. Cancell happens to be a vibrational capitalist and once you realize that everything on the face of the earth is vibrational, Einstein said that in his little formula and everything is motion we find out the realization is that all illnesses or diseases are vibrational densities and what the...does is allow the vibration density of the cells of the body to be raised and if you raise the vibrational frequency of the cell structure of the body it would have to be above the vibrational density of the disease, then the body reverses itself and eliminates the disease. In other words Cancell cures nothing at all. All Cancell does is raise the vibrational treatment of the cell structure of the body and...we have--the National Cancer Institute did make a study of Cancell. In December of 1990 they put out a report to us to debate...cannot be presented without the request. They found that they tried it on eight different human tumors and 58 strings of those human tumors and it either reduced or eliminated all 58. I have a copy of that report. We did at least 1,000...studies in Africa

and some in England on the AIDS virus and the indicatattion is that the AIDS virus is destroyed by the vibrational treatment of Cancell. In some...in 21 days. Now the problem that you get into of course and that is AIDS is a three pronged problem. You have the virus, because of the virus you get a impair immune system, because of the impair system, you get...once you get rid of the virus, you will still have the impair immune system and the opportunity of infections and they have to be dealt with. Cancell does effectively or does affect positively things like tripulsey? and also...pneumonia affected by the material. So basically that's what it is and that's how simple it is and we can put it to you this way. The material is nontoxic it has no side affects and you do not even have to take it internally. All you have to do is to get it to go through the ora of the body and it will change the vibration frequency of the cell...at that point it will have a beneficial effect. Question?

-- I have one point and one question. You might want to add also that...alright this is rather crucial that we are dealing with. The question that I have pertains to particularly to your comment...what happened to it.

Sab ...to do therapy was that when called and ask for a phone call, if this was the most affective compound we have ever tested on cancer on a three hundred and some thousand things that they've tested at that time and therefore they have refused to do any further...because of its toxicity. We suggested that it was not toxic, untoxic. We had reports to that effect and the researchers said anything that is that effective has to be toxic and therefore we

refused to do a toxicity study.

-- Do you have a copy of the N.C.I. report with you. Do you have copies of...

Sab Not...

-- Could I look at one right now?

FW Mr. Sabcheck, what is Cancell, how, could you tell us exactly what it is.

-- How is it administered.

FW Could you tell us what it is made of?

Sab Originally what I did was, let me do this here while I am talking. Originally what I did is none of this is detectable to that...what I did I started out with a non toxic six ring compound. Now we're talking chemistry and it is not realized in science or the chemical industries that as you manipulate the ring by force coming to a five-ring compound and some use a three-ring compound and in doing that it raises the vibrational frequency of the complex material itself. Until I see the frequency is high enough and still non toxic that we could use that material...

FW Would we find these compounds in the merc index, is it bigger than a gray box?

Sab ...like this I never lie. We could sit back and say there

are three basic chemical compounds that were entered. But that's not really true because what really happened was that if you penetrate this thing slowly you always will get the power curve, the power curve on this...will get two plateaus, two power plateaus. Now if you do it on a high speed electronic...devise, instead of those nice flat plateaus, what you get are peeks and these are run from 19 to 18 peeks on each plateau. Each one of those peeks happens to be a chemical compound. What the plateaus do is you allow them...so basically I have never gone back and tried to identify the compound because the material constantly changes. It is affected by the atmosphere of the temperature of the...

-- What do you start with though, what do you begin with.

(gentleman asking question-can not hear)

-- When you are talking about...I am just curious in what type of resolve in basically by looking at the are of the peek in other words...I'm curious of what type are you actually resolving or isolating specific entities within...

Sab Um, no, we have...let me put it this way. M.I.T. has attempted to analyze Cancell in folks that is impossible...attempted to the Food and Drug Administration attempted, all of the health...it is impossible...because they are all on...

-- Can you tell us what your starting point is. What is your...

Sab My starting point is nothing more than an obstacle.

FW And that's it.

-- Is this a a homeopathic...

Sab No it is not homeopathic, what it does--it is not homeopathic, but the present material is an advance in homeopathy.

-- My I ask a little question. I have a nine year old who has immune deficiency syndrome acquired prenatal period two transfusion. He has failure to strive, is approximately the growth of a five year old. The family has kept him alive through good and bodied management and guidance aminoes and herbs. They apply your product and you are asking me to give the green light. I haven't...because don't know enough and I am concerned. What I understand that he has to stop everything while he does Cancell. All the things that...

Sab You have to...not

-- Herbs and vitamins and all that.

Sab Yes those things, yes those are all vibrational therapies.

-- See the things the medical person has never realized is--the pharmaceutical industry has never realized. Homeopathic medicine verses vibration, it does not...and of course their data is...go out and try things until they get an effect. But the effect is definitely vibration.

Nothing...

-- Okay to finish this case, it is correct then that have to stop vitamins and amino acid therapy and everything before we start Cancell or the time they start Cancell.

Sab They should yes because...

-- What is going to happen to the ya know, all the therapies that we are doing which as much pain is chemobolic and abolic balance to some degree.

Sab I don't know, each case is different.

-- I am afraid they are going to lose so much weight...that's what I am afraid...

Sab You can put into the diet as many calories...

FW Berkley has a question.

Berk You face some serious legal problems do you not with the F.D.A. or somebody?

Sab Well the F.D.A. uses, ya know is going to drag me in at the end of this month here to try to enforce an injunction and I don't feel until my--I'm not a lawyer, but I happen to see forth to setting laws and they've made their attacks upon me and they are still making them. Well basically what happened is, and I'll do this real quick, the F.D.A. filed a brief and in the brief they were very, very specific in the fact that cancell was not a drug

under their definition of a drug, was not encountered because I had never taken...at least 30-40,000 frequencies in the way of my dispense. They...and tore apart, that meant that the F.D.A. did not have...because the federal courts were very careful in who they chose. They were very nice gentlemen by...and they chose the...federal cases in front of him before in his life and he was very much at the mercy of his...and he proceeded with the trial and he was so frightened that they went through this entire trial and never bothered to have a hearing. When I attempted to appeal the...I was told I could not appeal the case because had to have a transcript of the hearing. Since there was no hearing, why it was impossible for me to...

FW Mr. Sabcheck so we can clarify this. I would like to know, you said the F.D.A. is dragging us in this mud. What are they actually charging you with so we can understand?

Sab They are charging me with violating the injunction not to ship a drug in interstate...I did file with the court by the way an affidavit stating this was not a drug. It was non classified because...and they...

FW If it is not a drug, what is it, how would you classify it?

Sab I would classify it as a vibrating catalyst because I know--Dr...

FW See I don't know what a vibrational catalyst is so it's

kind of hard to know.

Sab Well see that's the problem with this thing, it's probably 20-50 years ahead of medical research for...

FW Okay

Sab So it's hard to say because their aren't any words for it.

-- We all know that...it's well known that vibrational frequencies can be seen in...

-- Not all of them.

-- Many of them. There have been real active, long...that's what we're looking for, effects. When you tell me that MIT cannot, does not have documentation to support that we...F.D.A. documentation that we are not capable of and have you appointed...when you have keys in this field that no one else probably has. Have you reported your insights to these people and to try to afford them the opportunity to assist you...the opposition saying do your best.

Sab No I...the way that they might be...has been very likely with a family in Massachusetts that had a brain--one of the men had a brain tumor in the family and then took Cancell three or four years ago for the brain tumor and it's gone and they were the ones that submitted to N.I.T. at Harvard to find out what is in it.

-- Would it be in your best interest?

Sab I don't know. What I get into, we have a consistent pattern and that is anybody who gets involved in the scientific community, with the medical community or the pharmaceutical community, 26...have already contacted us and asked to establish cancell. They become very enthused for about three to four weeks and then all of the sudden they do 180.

-- (questioned asked but could not hear)

Sab I find that here that I was...ya know I think I can say because it's true. Well one of the representatives from...when they look at it and they were ah--they thought this was the greatest...they flew people in for meetings to do all kinds of things and when they ended up with this thing, they decided that they were not interested. My question was that...there were here to tell you why they were not interested and...the school because they are not interested on the basis this is a cure and can not make any...

-- Are you saying...

Sab Well no, almost everything is except the fact that...is what I did for the court and on the issues of conjunction I think they put out a letter which...I gave away that said send a letter to Judge? giving him your experiences with...

FW Next

-- Mr. Sabcheck, is your...available?

Sab I'm going to tell you that.

FW Joseph--let's keep

(several speaking)

-- Leanna had her hand up, have you had a chance to look at the.

-- Yes there's mostly just some in vitro data here that's very hard for me to interpret.

Sab Well what they did if you read toxicologist, it says the percent growth in tumors and in the three columns that they have here...if you go done the negative it means there was negative growth rate. It was easier to eliminate the two because 100% means the tumor is no longer there.

-- How do we know that this is cancell?

Sab Read the letters.

-- My question is, you mentioned that there's been 1000 clinical trials done in both Europe and Africa.

Sab Primarily in Africa.

-- Have any of those been published in the Pure Review journals?

Sab Just one...do you have a copy of the?

-- Yes I do, where was that published.

Sab ...(can't not hear)

Berk If the F.D.A. prevails in their court case, what will happen to you and your?

Sab The thing that going to happen to me is that I am going to get back my life and save a heck of a lot of money and there is a lot of people in the United States and throughout the world because this is being used in every...

-- What is your profession?

Sab Pardon

-- What do you do?

Sab I work in a foundage

-- You what?

(several speaking)

-- ...you say cancell has been around for 40-50 years?

Sab Yeh the original material that...1936...40,000 animals...well documented and just got sick and tired of everything and after 47 years...just quit and I think...

-- How do you use it?

Sab Basically all you really have to do, the easiest way to use it is to just put it on the top...place it over any...material itself...

-- Any cross point?

Sab Yeh cross point...and so basically that's all you have to do because people are used to taking medicine in therapy, we always tell them to take a half of teaspoon internally every 12 hours and we also tell them 1/2 teaspoon on top of that and place it over...

FW What do you think we can do for your, how do you see it?

Sab Well basically what you got to understand and that is the Food and Drug Administration's whole argument with you people because they can set up and they are very efficient in what they are doing. They're function is to create a monopoly for the pharmaceutical medical complex and they've done that. Now they're every year the cost of medicine in the United States...

-- ...well but what do you specifically?

Sab All you have to do is what I would like to do is that have somebody put a...bill in Congress...you know that would solve a lot of problems and that's not going to happen.

-- But you see there is a big conceptual problem here because I've heard your tape and so forth and in effect you are telling people to off all their medicines, conventional and unconventional.

Sab No really.

-- Well practically speaking, most of the things that people in this room and this convention use plus most of the things that are used at N.I.H. and go onto a truly unproven method. I mean the evidence that you've wrote us, it's not, I don't know how to say this, I starting to sound like N.I.H., but some of it is innuendo, some of it you saying something, some of it ya know remember we spoke on the phone and I wanted you to send me cases and you said that you had the cases in shoe boxes of letters that people had sent you and I should come out to...

Sab We do get back the thing we put in--in each bottle we put in we do put in a thing called a reorder form in case they want to.

-- But what I am trying to say is that before you are going to get anybody, any sane person in the world to go to bat in Congress for you, you've got to present more than you've done because you've got thousands of people who take this medicine and you haven't presented 10 cases.

Sab ...what I brought...just on this treatment alone, I got...of people of testimonials since treatment.

-- Testimonials do not cut the mustard and you know that.

Sab Let me say this so you understand what I have done. Every time I run across any medical...that show some interests, I give them a challenge and the challenge is straight

forward and that is to take any number of patients you desire, you've all got them in your medical clinics that have taken chemo, radiation and surgical...and you have done them no good and you're now sending them home to so call get the repair...my challenge is once you have gone through the entire...you have drug up, nothing you can do, nothing you can do. Then lets take those people and put them on cancell and see what happens. Now you made the interest that I probably should have challenged 15 or 20 times the reputable institution and not one will take it up.

FW Mr. Sabcheck I would like to thank you for coming before this committee and let you know that I personally and I think my co-chair are both interested as is everyone here in good solid information cancell. If you can submit this to this panel, I assure you that it will get to the N.I.H. right away, thanks very much.

Berk I asked that item two in draft be deleted. That was not supposed to be in there. I had to go downtown and I left the list with Frank of the things that were supposed to be on this. This was still on the list. I had meant to have it deleted. I am trying to do it legislatively and I would ask that it would please be deleted.

FW Do we have a second

-- I don't understand what we are saying here, we are on point number two.

Berk First of all they don't have that authority which I...and secondly it is much better to do it legislatively if we

can.

FW Do we have a second? All in favor, all opposed. Unanimous we have deleted number two. Joseph?

-- (very difficult to hear)...the original of Berkley's report, the original charge of this committee...supposed to look at more global issues regardless...the committee as a whole, not as a subcommittee and also to make some specific recommendations to the large committee regards the position of biological pharmaceuticals. Will we be afforded the opportunity to those particular items so that we are not placing ourselves in jeopardy of not at least addressing some of the particular reasons that this...

FW The answer is yes, you will have the opportunity...

END OF SIDE #1 OF TAPE 2A

BEGINNING OF SIDE #2 TAPE 2A

-- We have discussed a number of compounds that many of us think are a great interests for pursuit and I think the N.I.H. is hoping and waiting that some of the committees that are meeting over these three days are going to come up with specific recommendations of what compounds are worthy of study because I don't think they have a clue and I think they think that we do. I know that's it's dangerous for us to sit around and discuss, ya know make a list of things that we think are the most potential and the most exciting, but I would us to make an active decision whether or not we are going to do that and I would like to propose that we at least try.

-- We talked about this last night...

-- I found that the difficulty in doing that and I don't think it's an avoidable difficulty is that we all have our interests. We all have things we've been either emotionally or in other ways vested in and if we're going to do that and I really urge everybody to put--to really put aside their personal things and try to think what's the best for the committee as a whole and for the group as a whole because otherwise it becomes a ya know kind of intramural, ya know and none of us intend to do that but as I say we've all put a lot of our lives into specific areas and so I would be in favor of having such a meeting, but I hope that we could all keep it very objective in terms of what is the best thing to develop at this point. Yes Michael.

-- Certainly this is something to look forward, however it would be obvious the time it would take to do something like this would be prohibited for us at this particular meeting. If we wish to fulfill our obligation to the request of Dr. Burman, than we might simply list the ones that as many as we can and say that time did not permit categorization of these and that might satisfy the fact that we addressed it but also point out reasonably that time is not available. Well certainly...we could get into a...over any one let along dozens.

FW To remind the committee, on the first day we did address one of the general methods of treatment and then when got to one of the specific treatments, we decided that we would classify these and go around the table and each

person put in their particular point of view regarding oxidative or ozone therapy, environmental medicine, methodology. Mrs. McGrevey I believe said loving and caring existing. Alternative therapies were discussed. Kilation, oxidative, etc. We went down a list and each person had a chance to talk about these things.

(several speaking)

FW It's going to be included--are we now suggesting...

-- I'm making a proposal that between recommendation four and five, we say that the committee believes that some of the compounds that immediately deserve research attention on the part of the N.I.H. include, but are not limited to, the list that you just went over.

-- The list does not includes any compounds unfortunately.

-- Make it modalities or something of that nature, methodology or whatever.

-- Well I think actually it does--there are some compounds. I think the ozone certainly needs to be mentioned there.

(several speaking)

FW We're walking a thin line here. I don't have an opinion about this. I've heard opinions on both sides. One is we keep them general like oxygen therapy. The other we say ...

-- I guess what I am proposing is just that list that you just read.

(several speaking)

FW Michael has a point to make.

-- There was one that you mentioned there that more properly belongs with another committee that address very issue. We were...

FW The loving?

-- Yes that more properly belongs with the mind body committee rather than...pharmacological and biological.

-- It's not in this list. The way this list is given, it's right here, the first part of the draft.

FW What does it say?

-- It says the consensus was the combination multimodality therapy was the order of the day. Nutritional therapy, ozone therapy were mentioned as promising treatments. Also discussed were immune and modifying therapies, dry state therapy, polyfunctional approaches, kilation therapies, differentiation therapy and polyfactorial therapy. The panel agreed that a more basic approach considering the entire patient was desirable.

-- More holistic approach it says here.

-- Right

-- I would like to move that the word homeopathic be included there. We did--it was--just got left out of the...

-- It said differentiation therapy I think just to be clarifying there.

FW Barry, do you feel that we should name specific products?

-- I'll tell you my concern and I agree that...I'm not quite sure what the...might be helpful to N.I.H. will guide them and...modalities to look at. It's not going to help them a lot if we given them an...we're concerned with. On the other hand, I don't think that we can be too specific that that would be unfair. So I think we're kind of caught in the middle. I would like N.I.H. to not have total...I think we should guide them to some degree and how we can do that and still be as inclusive as we would like, I don't really know.

FW So yours is the general verses the specific. You're making the point for the general verses the specific?

-- I'm really not...

-- When we mention something specific and then we say something like this does not exclude all the therapy that might come...

-- Then we get into which specific and I am afraid that...

-- I ought to think it's premature...to Leanna had said,

that's premature for...group of 120 people to start right...I mean, lets wait for the committee to be...and let the committee decide on what things are going to be researched. I don't think it's up to us to be...

-- You do have a point because one of our recommendations, number four, if number four were adopted then what would happen is those researchers that are promoting various compounds would come forth with grant proposals that would be reviewed by people such as are in this room and would be awarded. So I consider recommendation number four really critical.

-- Which recommendation four?

-- It's the recommendation that N.I.H. start awarding grants and that pure review be established on the basis of people that are at this meeting.

-- There's not any specific therapy mentioned there.

-- I know, that's what, I am agreeing with you.

-- What you're saying that the normal process of selection, once you get that going, we'll find the specific products in the general categories that would be of most interest. Joseph?

-- It says various fields of innovative alternative medicine. I mean it couldn't be more general than that.

-- She's agreeing.

-- I'm agreeing with you.

-- It would be helpful if we were to provide the most current framework for this screening procedure such that it would not preclude the very therapies that they're trying to bring to scientific valuable process. Meaning to say I guess that if many of the therapies the way they're structured now in terms the way they're presented, the way they're constructed etc., would not be a full prey in a larger...it just could not compete. Okay, it couldn't compete not because of essence, because of the way it is constructed and the way it was presented. The charge would be for this Office of Alternative Medicine on unconventional medical practices is to afford a strategy and framework over then which these particular modalities can become competitive such that they can then enter the more, I think you used the terminology mainstream of the grand view process. Do you think it would be--at this juncture I don't--I believe that there is a lot of essence but I don't believe that it's going to be at a competitive level. You think you may in deed be helpful if you were to provide a strategy framework that we would...

FW Are you suggesting an amendment to one of the existing recommendations or are you suggesting that we add a new recommendation?

-- New recommendation.

-- One of the committees that I was in yesterday, I guess it was a committee, one of the things that we spent a lot of time talking about was issues related to this in that. We

suggested that there be training programs for physicians or for people in the field who don't know how the heck to go about this. In other words, those of us who have gathered information, I have 40 years of information in my office that amounts to not anything excepts patient's lives have been changed. Research wise I have gathered the research. I don't know how, but we need to--what we were saying was the clinicians need training in this just as the N.I.H. needs training in what we are doing. So what we were suggesting here was a combination of training programs, symposia, work shops, whatever to get this process going and I think that's a little different.

-- I agree I guess in basic premise I am agree in what you are suggesting. I just don't think that someone who has been kind of...in 20 years and writing grants and kind of going in bird of prey approach is going to be afforded any lawfudable or sizable competition to someone who's gone through...

-- We spent hours with material, how do I grant and that sort of thing yesterday and came up with the idea that's exactly what we need is training. It may not be one week, but incorporating people who know how to do this in the N.I.H. or whoever who don't know what the heck we're doing. So what I am saying is I don't think this is place to do this. I think there is another area and I think we're running short of time so that to try and get an added statement at this point I think is pushing it.

-- I have a question about something on page one on my mind, paragraph two. The way it reads to me it seems it's

terribly limited. Cancer, cardiovascular disease and AIDS. I think we went far well beyond that. Perhaps not in this exact sequence. I wish that we could add...

-- We debated that at great length yesterday and to rehash it now ya know.

-- I am afraid that...

-- Not that I don't agree with you, but the point is at the 11th hour, if you have to change everything you resolved the day before, then you'll go on forever. I think the reasoning for it was that these are major causes of death in the United States and that these have the greatest priority. Not to the exclusion of other problems.

-- I think we had agreed though that...

FW I'm sorry, someone is going to have to fill me in.

(several speaking)

FW Okay, page one, paragraph two, okay.

-- Sounds too exclusive to me, although the sequence of discussion may not have been indicated so later on we began to talk more about serious mental illness as a major. I would like to add that.

-- Sir we went over all this yesterday though and we all have our feelings and our opinions and as Mr. Capland or Dr. Capland said that we decided that this was the way to go

to make the best impact to not exclude everything, but to focus on those three issues that are known to be responsible for 80% of the...

FW That's correct. I think what you're asking is should there have been language in there regarding with exclusion to any other disease or illness.

-- Something like that.

FW I think you're right and I think it just wasn't included.

-- So moved.

FW Do we have a second?

-- Yup, I second it.

FW All in favor? All opposed? Okay we could phrase it the consensus of the group was that without exclusion, without the exclusion of any other therapy, without the exclusion of others. Without exclusion, cancer, cardiovascular disease, inquired immune deficiency disease which combined total 80% of the death. I think it should be preventable deaths in the United States would benefit from alternative treatments.

(several speaking)

FW Ron, can you monitor the tape just to make sure that we have enough tape and that we don't cut off in the middle.