-- May I propose something that Dr. Standish and I worked on at the tail end of yesterday.

FW Are we, should we go through the current proposals, or should we finish the proposals within? No one has a problem with any of the other proposals.

-- I have a small editorial question, first page, second line from the bottom.

FW First page, second line from the bottom.

-- The first word efficiency, it should be efficacy. I have another small editorial change. Second page, third paragraph at the top, second line. I think...

FW Quarts?

-- Or quarts or something like that is better...

-- Data

FW Data, alright. Barry?

-- Larry has a third.

-- I have a question, I distinctly remember, unless I remember something from another discussion, but I thought in this committee that we did have wording here that said that something about the importance of educating professionals as well as the general public. I remember that so distinctly and...

-- That was another, I think that was the other group cause we talked a lot.

-- That as the other group, that was the afternoon group because I am the one that who brought it up. Remember about the specific problem we have as professionals.

(several speaking)

-- Frank can I proceed?

FW Okay, you can proceed James.

-- Alright, let me preface my remarks by I hope to be very pragmatic in what I have to offer to afford the alternative research community or treatment community an opportunity to move within the system of regulation in a convenient way. There exists in the F.D.A. a subject called compassionate I&D which allows for two things. For a life threatening disease, one person, one person's physician may make application to the F.D.A. for a special dispensation to proceed under the eyes of the F.D.A. to treat that patient. Okay and there's a whole set of reports and there's follow up and it's all within the system. Okay, and you can bring a drug from outside the country or something that you can copy and if there is justification if you have a physician who will monitor that treatment, than you can proceed. I would like to propose and I'll frame in in the form that we have it, that that concept be expanded to include non-threatening diseases because if you have a splinter in your foot, that's like a life-threatening disease as far as I am

concerned, to include non-life threatening diseases as well as life-threatening diseases. And to include groups larger than one. The group being monitored by one or more physicians throughout the country and the object being that this allows at the present time without any changes in the F.D.A., without any fights or contests, the ability to use a new modality and to show that under complete legal justification for Dr. Brezensky or whoever else who would want to proceed in that direction to the point where you can accumulate data because one of the major things we have not discussed is who in this country can possibly proceed to get data on a modality without some form of protection in the act of getting the data so that if you had a compassionate I&D, you can accumulate data and if you data becomes very persuasive you've got a very good argument for future work through the F.D.A. and through the N.I.H..

FW Joseph?

-- Unfortunately a utility of a compassionate I&D process is one that is going to be seen as being abused.

-- It's under complete supervision at all times.

-- The original intent of the compassionate use I&D was on a case by case basis under emergency situations under the original intent...in deed if you open it up to groups of more than one, okay meaning that we're giving compassionate and compassion has to reflect quite clearly to the emergency aspect of it that you don't have the clinician or the health practitioner doesn't have the time

to wait for...to occur because of the foaming conditions of the disease or the presentation.

-- The amputation of a limb is not a life threatening situation. So you couldn't get a compassionate I&D to try and save that limb. If it was my leg, I would consider it more than life threatening. I wouldn't want it to happen if it could be avoided.

-- It was my understanding, my question is really, does the F.D.A. give a compassionate I&D to a substance that has not received--already received and I&D, I mean..

FW The answer's no.

-- First I have to be a globe of general I&Ds.

-- Usually post phrase three, pre-M.D.A. drugs.

FW That is correct.

-- So in other words, first you must work through the entire--than this would not apply to a substance that has not been gotten the I&D.

-- Through communications Dr. Brezensky had gotten his antioplostoms all the way through post phrase three, but for some reason was stalled between that and M.D.A. and there was an application for an emergency situation that the compassionate I&D may be considered to be granted. So basically you have to rewrite the compassionate use I&D...criteria.

-- Right, I mean drastically rewrite it and in the end you'll wind up with something closer to what...

-- Which is going to be seen--which is going to be visually is going to be basically slaped out and seen as a clear sort of invention and basically there we're not taught...

-- It would destroy it basically.

-- Why would it be circumvention if you are going through the system.

-- If you were to be able to use a compassionate I&D for pre-M.D.A. or pre-M.D.A. pending drugs that's one curriculum convention because of the fact that the reason for that was used I can tell you the...I'm not saying it should be valid or not, is that it was because of the fact because of all the safety and toxicity trial. Whomever the screen process is or the reviewer process is met that criteria, but there is an administrator of bureaucratic unfortunate mess. Even post phase three before M.D.A.. That's point number one. Point number two is that we've gone on a case by case basis so that clinicians who were indebted with pharmaceutical companies couldn't spot soliciting and sequestering patients for the use of a particular drug because there was a kick-back policy that was under the...so that they would not...off all cases. Those are the two major paragraphs underlying compassionate use.

-- I'm stuck here, Peter do you know the rule of compassionate I&D, doesn't that include medications in use in foreign countries. Do you want to bring that

medication in.

-- It includes medication for which we have basic safety data.

-- And that could be from a foreign country?

-- I'm trying to remember a case from a foreign county and I can't draw it to the top of my head.

-- That would be very critical.

-- What about the personal use doctrine.

FW There's two things we're discussing here that's correct, Ralph, one is the compassionate use I&D applies if I am, and you can correct me here if I am wrong Peter, applies to any individual in an individual situation.

-- That's correct, but the question I'm asking whether it has the toxicity where it can be accepted from a foreign country.

-- I can't remember an incidence where that's happened as Frank has pointed out where a number of these things have been brought in for personal use.

FW So a different rule covers that fact, okay.

-- I'm looking for a vehicle to do things very efficiently and make progress to collect data and right now we are...

FW Yeh, but I don't think personal use.

-- Excuse me I don't know that the compassionate I&D is that vehicle because by the degree to which you're suggesting changing it would tend to amount to saying to F.D.A. we want to destroy the current...

-- No, don't use such radical language, its a slight modification.

(several speaking)

-- No wait, you're just a journalist and you want to use invocative language. I'm saying you want to make a move a little bit to the left.

-- He's not just a journalist, he's a author.

-- I have a question, how about orphan drug paradigm is that worth considering for this particular purposes?

-- Well I am in that boat right now. The orphan drug doesn't get you anywhere. Orphan drug is basically two things. It gives you a seven year patent protection for your modality and it gives you a certain tax break which net bottom line works out to about a 10% break from what you'd normally pay in taxes for the research moneys going into the orphan drug. But you still must go through all of the regulatory processes so it doesn't change that process orphan drug.

-- ...we're going through a process now with the F.D.A. on a

substance that we're using over in England. Under the new revised guidelines of fast track or parallel track through the F.D.A., it does specify specific countries from which data you can be accepted into this county by the F.D.A. without being repeated. If that data is significant enough and compelling enough you can expand the existing I&D to a treatment I&D which will allow you to literally open or treat...of patients and I think this can be done in a phase two level of treatment. This is what has been told to me by the F.D.A. when I...two weeks ago. I think that would include a lot of what you're talking about. It is right now specified that it is EDC countries, specific...countries, specifically Japan in which data on the outside will be accepted and will not have to repeated.

FW But I think a point to that and I am familiar with that, the problems is discretional and that's the problem we get with all of us. It is at the discretion of experts in the field. So we have the same problem which is you know, you've got this group who are hostile at what it is we are asking, ruling on whether or not these things can go into treatment on I&D in the same way that as whether or not...

-- But the compassionate I&D...attending physician and that physician then makes a medical judgment and proceeds on that line.

FW Per patient...

-- Per patient, I want to see it expanded to ten patients, but there's a need for us to collect data. If I have

someone in repeated sickle-cell crises, very severe, by employing the compassionate I&D I may have a one case study which doesn't amount to a hill of beans. But if I take ten patients in the United States all of whom have serious sicle-cell crises and we treat them simultaneously, in six months time we have very significant data and if that gives us a step up to then go to the N.I.H. and go to the F.D.A. and saying hey fellas, join the team.

(several speaking)

-- However we want this constructed. I am looking for a means within the existing structure so as not to antagonize the regulatory bodies both state and federal so that doctors can to a significant amount of work to bring it up to the next stage of evaluation which would be your ten case studies. Otherwise you could end up in jail after...

(several speaking)

FW I don't think you were here at the beginning of our meeting this morning.

-- No I wasn't.

FW We passed number seven which will significantly change the face of American medicine if it were so adopted.

-- Wait, wait, but my fear Frank is this...

FW I wanted to remind you of that.

-- Yeh but that is a long shot, point number seven. I would rather come out of this committee with a sure shot because I happen to like the screening process of a compassionate I&D, let me explain. You can get virtually in 48 hours an answer from the F.D.A.. I would like to see that motice expanded to allow more fundamental research to be pursued.

FW My suggestion is then--I in agreement, my suggestion is that you present it as a proposal rather than a recommendation.

-- We have written it.

FW I mean I agree with you totally, completely.

-- I may be wrong in certain mechanics, Joseph, but the intent is surely in the right direction.

-- (gentleman talking--inaudible)

-- Well it's a mechanism, not a loop hole. We have the mechanism, I want to expand the mechanism.

-- ...specifically indicates on a case by case basis.

-- And it also says life-threatening which I deeply resent. You know most of us live a long time before our life is threatened.

-- ...can change the life threatening...

-- I'd like to hear what you've written.

-- Alright let me read it. Excuse me cause I can't read the hand writing too well, but I'll try. Where as current F.D.A. policies may be too restricted for physicians to evaluate innovative material procedures or innovative medical procedures, some of which are established in foreign countries, that the F.D.A. consider enlarging the window of opportunity of the compassionate I&D to include modalities that address life and non-life threatening conditions for groups of larger than one patient.

FW Barry

-- Second

FW Barry, comment before we have...

-- I think we all understand the intent. I think the that the difficulty is that it trying to find more of a structure, it makes the I&D, that particular structure may not be in the way...

-- You may be right, but do we have another right.

-- But I have a suggestion, we have an expert here and I think we should ask him his advise, Peter.

-- I guess again we haven't considered what might be the proper structure and a compromise. Compassionate I&Ds in conventionary are usually one patient at a time. They're usually without compensation to the manufacturer of the products. The treatment of I&D is generally...or life threatening conditions. It is for drug products from

which there is safety data in place. There is a mechanism for the manufacture to seek reimbursement, but the manufactures so doing have to disclose a number of things about the product...

-- Peter is that, is there contradiction between what Joseph said that this was post phase three and you saying that it is safety data some place. I mean isn't there efficacy data involving today's current studies.

-- With compassionate I&D's are frequently given much earlier on.

-- They are?

-- Yeh I mean we can go when we...phase products to...

-- Have you seen a substantial problem with expanding as we recommend from one to a number?

-- Well I mean I think our new drug could probably speak to it better than I.

-- Do you see any problem with the proposal. Any substantial drawback to it?

-- Well I don't off the top of my head, but I am not the right person to. Well I mean I should point out that companies have not historically wanted to give out a number of compassionate I&Ds for a number of reasons. One being they're...reimbursed. Number two, patients in those I&Ds...for getting the necessary clinical results.

(several speaking)

-- But we're speaking of drug tailored by N.I.H.'s own recommendation of the ten best drug case series and it seems to ducktail perfectly with expansion of this particular...

-- I think what has happened is that N.I.H. needs to come out with recommendations based on...that the senior F.D.A. and drug evaluation people have to get together with the office for the study of unconventional medical practices people and work it out.

-- I think this would be a very good means of opening that door.

FW Okay fine, do we have further discussion? Do we have a second, Michael second? All those in favor? All those opposed.

-- Abstained

FW We have--I did not write that down, can you provide that to our writer?

-- Yeh

FW I have two orders of business that I would like to take care of and then it's yours. One we have deleted number two. Does everyone understand that? Was everyone with the committee when we deleted number two? There was one left out from yesterday which either I neglected to give

to Ron or it got lost in the shuffle. It was a vote on a moratorium and it reads as follows and I want everyone to be aware of it so it doesn't scare anybody. In order to protect the innovative in medicine, we formally and respectfully request a moratorium on F.D.A. and state regulatory authority seizures, raids or import alert on physicians, researchers or health care practitioners who have been chosen who study--I'm sorry, who have been chosen by the office for evaluation.

-- We've got that, that's three.

FW Well no, that's MCI. No that doesn't call for a moratorium. No I think that's different. I mean we voted on both of these.

-- This is only on cancer number three, this talking about more broader.

FW Well there--I think they're two different things.

-- Well if you say so, I 'll go along with it. I just thought may you had...

FW Well I think they are.

-- I think they're different.

FW Okay we have a number 1, 2, 4, we have eliminated

-- Number nine.

(several speaking)

FW We have number eight which has been adopted and Jim will or Ron will draft the language about that. Do we have further recommendations?

-- We have made a recommendation about extra mural program that we recommend for the N.I.H.. That is that the office of Unconventional Medical Practices start awarding grants to investigators across the country. But what we haven't discussed is what I think is a great need for an intramural program at N.I.H. and what I would like to propose is that we recommend to the N.I.H. the creation of a center for research in alternative medicine and I don't believe that that's gotten in this document. If I am wrong please correct me.

FW Was this a resolution?

-- Yes

FW Was it, did we vote on it and pass it.

-- Yesterday, it hasn't really come up and we haven't really got a resol...

FW Are you proposing this?

-- I've got something I'd like to read. Alright, I propose the following statement be included in our series of recommendations. The committee sees the need for both intramural and extra mural N.I.H. research programs. In addition to the creation of a new granting program through

the Office of Unconventional Medical Practices, we recommend the creation of an intramural N.I.H. center for research and alternative medicine staffed by scientist selected from the various fields of alternative medicine whos purpose it is to screen and test new developments emerging out of alternative medicine.

FW Okay, if I might just ask the first question. Intramural center, explain for us, explain for the committee.

-- Yes that should get a lot of...on just thinking on the larger scheme of things. Ultimately it might be a case that the N.I.H. would recommend that there be an institute of alternative medicine that would be just one of the, I think there is 16 institutes. I would ask you recommend that that not be how N.I.H. proceed with incorporating alternative medicine in the American health care system. I would rather see that this directive for including alternative medicine come from the highest levels of N.I.H. and that there be a center constructed fairly soon. Not an institute that is autonomously functioning, but a center that is regulated by the directors office at the highest level and that it start to function very quickly and that we not wait for an institute.

FW Are you saying in the interim, is that what you are saying.

-- Yeh a center.

-- I had a question, do you envision this thing to as also having intramural educational functions?

-- Yes and for example this cancell proposal. It would be, apparently what's happened with cancel is that the kind of scientist that are needed to actually take responsibility for conducting both in vitro and invivo studies have not done that and we need a center here in Bethesda, over in Bethesda that does that kind of work.

-- What do you think about the idea of more broadening it a little bit.

-- Yeh research training and research activities.

-- And also something like when we had our meeting at N.I.H. last time. Now maybe I think one person from N.I.H. showed up at the meeting and clearly it wasn't publicized within N.I.H. and there was no educational work done and I would like to maybe broaden it out so that this center would also be able to invite lecturers in to have presentations and ya know somehow relate to the entire campus at N.I.H. as a way of introducing them to the ideas of what's going on. Otherwise you might get terribly isolated as a little pimple on, somebody said on the overall face of N.I.H..

FW But might I suggest also that we as a committee recommend that there be an Institute of Alternative Medicine and that as an interim, we recommend that there be created an Institute of Alternative Medicine as an interim we recommend the center. Richard?

-- Three points, number one I introduced to the concept of

developing strategy...so I am interested in that there is a ...here. Number two... (very difficult to hear)

FW I'm sorry, I don't understand what you just said.

-- I don't understand either.

-- When I asked...sitting up isn't the job of this committee to set up a framework that we can entertain these very concepts and I was about to do that an hour ago...

FW Irrespective of what anyone told you, it is the proper forum because the first rule is there are no rules, so you can propose.

-- Number two I might ask...you envision immediately this particular office and further more if a center were to be developed and further more if an institute were to be developed whether immediately this office would have any rank and ability.

Berk I thought what you say that's in one of our recommendations and I think I was the one responsible and had that amendment passed and I don't find it in our draft, am I missing somthing?

-- Number four was the one that I introduced and I think it covers this.

-- Fourth line.

-- Awarding research grants.

Berk I'm not an expert on this, but I was advised by somebody here that an office does not have authority to make grants and that it needed to be, can anybody here help me?

-- Yes I remember that's when we ewre advised.

Berk Yeh somebody told me that that it needed to be a center or institute, something I don't know.

FW An institute can issue grants, but we don't know.

-- ...for excellence (inaudible)

Berk I think it needed to be a center as Leanna is indicating. I think in order to be able to give grants, but I'm not positive of that, somebody indicated that to me.

FW Harris

-- Sorry to be a thorn in people's sides, but I...being opposed to the idea of any such thing at all. I think a center for investigating alternative medicine strikes me, it fills me with horror. It means within five years, it will be totally corrupted by the ah N.I.H. will have just a bunch of docs who can't get jobs in some other institute sitting there and messing around with our therapies. Who don't know anything about it all and will just publish negative reports that will end up being a millstone around our necks.

FW Harris is this because you feel it will not be under

purview of this office?

-- You cannot possibly avoid when you have a pyramidal structure such you have N.I.H., there's no way in the world that entity can stay autonomous the strength for alternative medicine in this country has been that it's had independent social support in society and economic support in society. A chiropractor started from nothing. They got a long way. The homeopath started from nothing. They got a long way. They went down, now they're coming up again. Other modes of therapy have managed to make their own way because they have the support of the population. I do not want us to end up trying to become independent on people at N.I.H.. They are...hostile to what we are doing and they are going to stay that way. It's not just because if using different medicines. It's because we have a different philosophy and a different method and it's one which they consense is very contrary hostile to theirs and if they don't know it now, then they'll know it very quickly and we're just going to end up putting on, delivering ourselves into the hands of our enemies.

FW Would your suggestion then be to keep this directly under the umbrella of this office?

-- I don't want to have research center at all.

-- Anywhere?

-- Not under the N.I.H.. You want have a research center, let's get it funded by the health food industry or funding

by the chiropractors, funded by the Department of Prescription or whatever you want, but not by the N.I.H..

-- Well I think the unfortunate reality is that the kind of funding, the kind of money that's required for a research center is not existent in any place except the federal government.

-- Well I don't know that we need research...anyway. We have these people practicing medicine perfectly well. Do we have to reinvent the wheel a hundred times over again.

-- I, totally disagree, in AIDS research for example, we need a center for people to do research such as I am doing to have adequate funding. I am really hampered. I have applied five times to the American Foundation for AIDS research and been funded not once by them. Where am I going to get the funds for my research?

-- Well that's another question, but I don't think it should be an institute.

-- Well fundamental side about the rule of government and all this and I have to concur with Harris here. I think we get sucked in to yet another institute, we're going to be headed backwards. There's all kinds of money to fund all kinds of research.

END OF SIDE 2 OF TAPE 2A

BEGINNING OF SIDE 1 OF TAPE 3

-- ...it is not necessarily...it's reaching out to everything that works. Be it outpathic, homeopathic, matropathic,

into a whole and it doesn't carry any emotional advantage.

-- I would second that. Ya know we are really looking to create a medical practice in the future. Where all this integrated into one whole. There shouldn't be alternatives to...yet there is so many choices out there.

-- Can I just--in sitting in for a while on the Natural Panel and they did the same thing, they had a whole list and they came down to complimentary and integrated for the very same reasons and I don't think we're trying to say that we're better than them or we should be doing this. Instead of them instead if everybody gets an awareness that there's other things out there to compliment each other and integrate and you'll have a better outcome. I think that integrated can comply

-- You get the sense it includes it.

-- ...better than anybody.

-- What does the word integrate say in though itself?

FW I don't think the public is going to understand it so I really--I mean I've been around and around about this. My personal opinion is there's a lot better names than alternative, innovative is may be one of them. Integrated may be one of them. The public knows these therapies as alternative medicine. I mean there's an entire section in...about alternative medicine.

-- All I want to say is I would like to get away from the

name alternative because of the lousy connotation it has to the public. Whatever we go for I would like it not to be alternative. Whether it be integrated, innovative, I have to personally like innovative because it's new, it's hoped. I'm a great believer in hope.

(several speaking)

-- In a way we do offend, we will offend N.I.H. by ya know calling this the innovative department as if you know they never innovate which some people believe. But you know it's not if you can--it's not as if you're not going to offend anybody.

-- Do they worry about offending us with unconventional?

(several speaking)

Berk That's not their fault. I have to take a good hunk of the blame. Senator Harkin has to take a good hunk of the blame. That's the way it was written up in the law and it was a mistake I acknowledge. I guess the only think I would plead with you is that on this amendment, I hope you'll leave it to the last amendment because at least my expectation is that these other amendments are probably going to pass without a lot of controversy. I can tell you when you start to decide what the name ought to be. As you can see here your just going to have all kinds of controversy and all kinds of debate and all that sort of thing unless you can get agreement among the groups. Now somebody said complimentary and that's what they want to come with. I don't give a darn what we name it. I would

think maybe we ought to consider seeing if that is agreeable with us and if it is see if is agreeable with other people because unless you have this all set up going to the floor, I think this is the one thing that you're just going to be one mess and I don't think we want that at least until after we try to get some of our amendments that I would expect we could probably get that without a lot controversy.

(several speaking)

-- We also have to decide who we're talking to. Are we talking the pay public or are we talking to professionals. If we are talking to the lay public only then we'll need to put in in their terms. It seems to me we are a bunch of professionals talking to other professionals about how to get professionals working together.

-- Well that's both isn't it. We're really, a big part of what we're about is the impact that this is going to have on the public and so.

FW I'd like to withdraw.

-- He's withdrawing.

FW The resolution at this point.

-- Are we open for other resolutions?

FW Yes

-- I want to address myself to number six. The role of the advisory committee and I would like to propose something like the following resolution. Whereas special N.I.H. programs and pure review systems are required to fully investigate promising unconventional therapy for cancer, AIDS and cardiovascular disease. Be it resolved that the N.I.H. immediately create a fund within the newly created office of unconventional medicine for awarding research grants to qualified investigators working in the various fields of innovative alternative medicine and that adequate pure review committees be established and that members of the current advisory committee be appointed such committees.

-- Put a dollar figure on this. Something with a hundred million dollars.

-- The office of research...started out with a two million dollar budget and I think they're...

-- 250

-- 250, what are they up to now?

-- To 250, it started at two million like a couple of years ago.

(several speaking)

-- ...does anybody know the budget of, the yearly budget of the N.I.H., it's 9 billion, 9 billion a year.

-- And 250 million is what percent of that, anybody.

Berk I'm not sure, I think this, I'm not sure, but I think this would require legislative action because the Legislate-- the Congress has appropriated 2 million dollars for this office and I believe we've got that 2 million dollars supposedly to spend as we see fit which includes this meeting, it includes staff and it includes if we wish to do so, which my understanding is they do not at this time even have authority to do so, some grant money if we wish to do it. I think for us to put in that we are going to give away 5 million dollars or whatever it is. I think probably does not make any sense. I think the amendment as she's got it is a very good one. You may need to add something into it because I was advised by our chairman that at this time since this is just an office they do not have granting authority is what he said. This amendment should be worded so that it also give--we recommend that they should be given granting authority as well.

-- Something very brief. The minute you put the review process in the hands of N.I.H., you are back in that endless circle that Berkley, you and I visited the blood and blood diseases, the people who make the allegations. If we are talked into that, that point of view will never get into the alternative medical...

-- I'm very concerned about the people who have gathered for this meeting over these three days. Disappear in the three days and they never be meeting again and I think it's really important that we stay unified as a group and that we serve as the pure reviewers or some sub-setup.

-- I agree

FW Does you amendment address that?

-- I think ah...

-- You have to define what the pure review committee is here. Just be sensitive to the people that have the grants for us because one of the things we hadn't talked about is the fact that in yesterday's meeting last night, the presentation, I was very disheartened about hearing about the N.C.I. saying that you have come up to our speed. Okay, I think that's a very crucial issue. One of the problems is I think that in many cases of data that these practitioners in alternative medicine have provided is data that could be brought up to their speed if they were availed the proper services on how to simulate, generate and basically document the data. I'm not talking about documenting new data. Take data that they already have. So I think this pure review committee should have some sort of assemblage of individuals so that they can basically like package the data so that its assemable for pure review. I...

-- I'd like to add one...Nobel prizes have been given out in economics for portfolio management and risk in return. Now in medicine, there should be some mention of supporting certain risky modalities. Call them risky for the sake of argument because otherwise they never had a chance to get through the rigid pure review system. But, sometimes in life you have to take a long shot and that's what Xerox was all about and that's what Ross Perot was

all about and so forth. So somehow I think incorporated into your resolution is that there should be a set aside for certain modalities that are considered risky but worth being evaluated. Otherwise you get thrown into the N.I.H. bureaucracy and they can't escape the pure review, they have to. That is the mandate of N.I.H. and this doesn't cover that. You have to have it published in the journals in order to be reviewed.

Berk Can I speak? I think the amendment is a great amendment and let me tell you why I do. The pure review problem is a serious problem as it now exists. I've talked to Moscowich and he's going to, he's even scheduled a meeeting on pure review systems and I think he's receptive towards our suggestion that the pure review system as it considers alternative treatments for disease be made up of a different group of people that now are serving as the pure reviewers under regular N.I.H. and that's a separate issue.

-- I think you have to incorporate that here in that resolution you can vote that if Moscowich gets replaced by Jones then that's going to hold out.

Berk Well I think we need to have such an amendment and you can try to put it in here if you want to, or you can do it separately. I don't care how you do it, but one of the amendments or one of the resolutions we should have and which he's expecting is a resolution in regard to how the pure review system should operate for alternative types of treatments and it seems to me that she does not say the same old type. I think, to me I think she's got a great

amendment.

-- The language is and that members of the current advisory committee to the Office of Unconventional Medicine be appointed to such committee.

FW Okay, I think we going to have to limit some here. We're ten minutes from lunch and we've got some other resolutions.

-- Can we vote on...

FW Do we have seconds?

Berk I have a question. Does this include granting power, your amendment? Because I think it's critical and it should because they don't have that now.

FW All those in favor, opposed.

-- Well I have a very quick one. We call on the Office of Alternative Unconventional Medical Practices to create and fund a journal of conventional medical practices, pure review journal, which will strive to be listed in Index Medicas and will aid and assist people who have therapies to prepare their data in a way that is acceptable to the main stream medical community.

-- I would add a computer network.

-- What do we do with things like the Townsman Newsletter and the public should get our newsletters and journals?

-- Yeh but they get our medical journals.

-- They are all...it may be very hard for alternative practitioners to write the kind of articles that would be demanded if pure review...

-- Well, we're not demanding--that's the point, the point is that there's special is needed, no question. Part of the reason that you don't find too many articles on unconventional medical practices in the main stream journals is because the clinicians and the practitioners have not been specially trained in knowing how to do those articles. That's one of the reasons. I think that this journal would be a little different from most journals in that it would extend a far more editorial help to the people who were applying. To me the closest analogy would be Medical Hypothesis, but I would see it as being, I mean an alternative might be to fund something like ya know to search out journalist to see whether special funding could be applied to a journal like Medical Hypothesis, but more likely I see this as a parallel to the J.N.C.I. type of thing. Barry?

-- I move the question.

-- Are you comfortable the wording pure review without qualifying it at all?

-- Well pure review in the same sense that Leanna is...

-- I would add as a friendly amendment of pure review to include members of this, because if you leave it just pure

review, it's their pure review, you can forget it.

(several speaking)

-- Why don't you say accepted by the...board which is form of people of the same...system?

-- Just leave it out.

-- Okay, we'll leave out the word.

-- Move the question.

FW Anybody have a second?

-- Yeh

FW A show of hands of all those in favor. All those opposed.

-- There's a question.

FW One opposed, we have...

Berk I think there is another amendment, very critical.

FW Okay

Berk And that is my understanding is that they're expecting to appoint this advisory committee, I don't know if they're going call it permanent, you know we're not head hot group, for an advisory committee and it's going to be several months before they do it. It seems to me it's

quite critical if they move forward promptly to appoint their advisory committee. It seems to me we should have a resolution directing them to proceed and that an advisory committee is appointed within, I don't care if you want to say 30 days or...

-- That's very important.

Berk What time do you want to?

-- 30 days.

-- 30 days sounds good.

-- ...committee membership that there be proper representation, okay from those other institutes or regulatory so for an example you were requesting someone from the F.D.A. to be on that committee?

-- No

-- Are you requesting any one from N.I.H. to be on that committee?

-- No

-- From this advisory...

-- People from this committee.

-- Berkley I think it's important that F.D.A. and N.I.H. be integrated into the alternative group.

FW Part of the process, but not part of the panel.

(several speaking)

-- We're advisors too.

-- This panel, it's like the current Adhawk Committee is not made up of people from the institutions, it's made up of people from outside the institutions.

-- I could make a lot of arguments like an old boy system operating Bethesda, Maryland. I could make an argument that if they're part of the group, than they are part of the solution and that you if you integrate them in the beginning, particularly F.D.A. which also gives research grants and so forth as a major role to play. Then you have brought them into the process of conventional approval.

FW I think they should be brought into the process. I don't think that F.D.A. people or N.I.H. people are going to sit on this panel. I don't think that's going to happen.

-- May I speak to that? I think that it's very easy to get scattered to the point where you can do anything and it's hard enough for us to get a consensus and we're all trying to do the same thing. If we try to have an advisory committee that has people that are going to advise everything else but, as far as we can tell, we're going to have trouble. So I wouldn't...

FW Okay, I think that um, how would you word your resolution,

that the N.I.H. choose the...

Berk We direct the office of what do you call it, Unconventional Medical Practices to appoint their advisory committee within 30 days. That's all it would say.

(several speaking)

-- When we say that we choose from existing committees, members from existing committees.

Berk The reality is, and I've had my trouble with N.I.H., but the reality is look at who they sent to this committee, the reality is in my opinion, they have been very objective in trying to appoint people that are supportive of unconventional alternative types of treatment. I think that for us to start to tell them you got to appoint this person or that person is a mistake based upon the history of what they've done. I think the only thing we should worry about is getting a group quickly and I think further than that the minute they load that thing with people that are not supportive of this, I think is going to be quite a fuss in the Congress frankly now.

FW I think we have Congressional oversight and I think Berkley understands that better than we. We have a resolution, do we have...do we have a second?

-- Yes

-- I second that.

FW All those in favor? All those opposed. Unanimous. Do we have any other resolutions?

Berk I've got a question, do we call it a permanent advisory committee or what do we want?

-- Standing

FW Incidentally I should probably say as we're considering here, this other resolution, we're at 12:30. Those guests, I have just some general information here. Those guests who paid the $25 registration fee who were guests and not invited by N.I.H. people, not official participants, that fee covers coffee breaks and lunch only. If the participants would like to attend tonight's dinner, they must pay an additional $46 to cover the costs of dinner. The $46 must be paid at the conference registration desk. In addition I have here a list of people who are going to address our panel, committee tomorrow in this session who will bring us interesting pharmacological and biological treatments. I'm going to ask that you simply take one and ask that you simply move those around. Do we have further resolutions. We're not going to close on resolutions here. We're not closing now. If you have ideas, you have this afternoon, you have this evening. You have time to sit down and draft resolutions. Okay, my feeling is that you should draft these resolutions in as simple and straight forward terms as possible and as general as we have done in these and bring them to the committee tomorrow. We will look at them. We will vote on them. I think that it will be better to have ten important, ya know resolutions than a

hundred. So, let's not bring ten each. But, if we've got other resolutions which we have not covered today than let's bring them. I think that we should probably adjourn. this afternoon we have cross cutting issues panels and as I understand it, people are free to move about those panels. You can attend the one which you are listed in.

-- We're assigned panels.

FW I understand you're assigned panels.

-- Most people are.

FW Well not everyone is assigned to a panel and you can be-- no one is saying you have to be there, except co-chairs of the panels. In other words, there not going to take attendance, if you decide you want to another cross cutting issue panel, you can do that. Are there any questions.

-- I just have one last thing I want to bring up. You know James Caffler's point earlier about the F.D.A., what is the relationship between the N.I.H. and the F.D.A., we didn't really address that and I would just like to say out loud about the notion of F.D.A. creating a third category of substances, foods and drugs and then the third category which might be called natural substances with less rigorous standards of regulation on those substances and I think tomorrow we should consider supporting Senator Hatch's legislation that's currently being discussed. So maybe think about that over the next 24 hours.

-- I would say that my point of view concluding. I think that we're somewhat off course because the major battle is the F.D.A. N.I.H. is the researchers of research science, there not a political group. But, F.D.A. is the watch dog in many faces of the great...but if we don't get into, this meeting should be...F.D.A.

-- But they didn't invite us.

-- ...for that very good, you all have very good intentions, but if those intentions...for the next four years milling around the halls of N.I.H....on the wall, we will have missed an opportunity to put these modalities into science. That's a serious problem. I don't know how many of you have gone through the F.D.A. process.

FW I think it's an important issue. Why don't we do this. Why don't we ask you to draft a resolution that will help us to do that and tonight. We have a writer who will write it up, you just need to write it legible. I want to thank the individuals of this panel today. You've been wonderful, had wonderful ideas.....

END OF RECORDINGS

CERTIFICATE

I, the undersigned, do hereby certify that a recording was made of all of the proceedings had at the said time and place, and that said recording (all audible portions) was reduced to typewriting by me, and that the foregoing typewritten pages are a full and complete transcript for the recording so taken.

DATED at Fort Dodge, Iowa, this 8th day of May, 1993.

Tina M. Hindman

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