and learning self care. And we do that with first year students. I have been doing that for all these years with a small group and we are hoping to do that with all first year students as time goes on.

And I think that this part is one that goes along with the knowledge and the experience of the CAM practitioners. They have to learn about and experience themselves.

And my observation that we have not done -- I sort of was -- had a little chagrin because I realize we have not done our follow-up study that we should have done but many of those students are now practicing integrative medicine. I do not know the numbers but a large number are and some of them are running programs as well.

And I think that that may be one of the -- you know, it is not just the students who spent a month with me. It is the students who in the first year had this very powerful and supportive experience that helped them deal with some of the viscidities of residency training a little bit better.

DR. _____: I think as faculty

become more aware and are about to take those teaching moments, if there can be encouragement and a real understanding of what it means to do self-care, if we can be truly modeling it, I think there is some hope.

COMMISSIONER GORDON: Go ahead?

DR. _____: It is not just self-care. I think self-care goes hand in hand with the understanding of how to collaborate, that it is not on your back --

DR. _____: Absolutely.

DR. _____: -- and that is what we are not training and treating, et cetera. So five years out you have forgotten it all because you did not know how to ask for help.

DR. _____: Right. Right.

COMMISSIONER GORDON: Joe?

COMMISSIONER PIZZORNO: I would like to follow up on what Linnea just said and I think your training program is fantastic having the medical doctors to be to actually spend time with practitioners and see what they actually do makes a lot of sense.

One concern I have, and I see a lot of medical schools now doing various forms of kind

of familiarizing the students with the CAM practices, but I have not heard anybody talk about actually developing specific training programs and how to collaborate with CAM practitioners, and I think there is a specific skill group there that is needed and I wonder if you are doing anything along those lines or have any ideas for how that might be accomplished?

DR. MANAHAN: Well, I think the key -- and I maybe did not make that as clear as -- personally I do not think the average MD or DO will be doing much in complementary and alternative medicine. What I see is just the pharmaceutical type of medicine that is now practiced is overwhelming at some level and I think the whole point of my course would be not to teach them how to do these things but to learn what is out there and to be -- and that in itself teaches, I think, and I think Erin could answer that better.

I think they all start thinking a much more collaborative thing. I just think it has to be -- the bulk of medical -- of training of doctors does not happen in medical school. It happens in residency and that is where we need

to do more of the collaborative -- you know, of where -- of sending them out and getting them. Once they have the experience out there then they just automatically, I find, want to start using it more.

MS. O'FALLON: I would agree with what he said. I know a lot of my classmates were eager to refer some of the problems that alternative practitioners told us they were really good at it; when we met the chiropractors they said, "Boy, we love it when we see patients with chronic low back pain or headaches." And we said, "Wow. Great. That is exciting to know." Because what we have seen in Western medicine was not, you know, enthusiasm about treating low back pain, it was apprehension. So we thought, "Wow. We had no idea there were other practitioners that were excited about it and had good responses in these other areas."

So at least in terms of being eager to refer or to collaborate in that sense, even if we were not ready to take on more training in those areas, I think that succeeds in an area.

COMMISSIONER GORDON: Wayne, any questions?

COMMISSIONER JONAS: I think most of the issues around this have been addressed but I did not hear -- and I wanted to ask one thing that I did not hear. I assume it is somewhere in there. And that is, is there any discussion of evidence-based underlying some of these practices or discussion of dangerous practices that may be seen as students are rotating out through these areas? Is that part of the course?

DR. MANAHAN: What I tell them on the first day is that for four years minus three weeks they learn about the dangers of alternative and other practices, and during these three weeks that I think we can afford to trust them to mainly give the positive aspects of it and so I would say, "No, I do not do a lot with that aspect of it."

COMMISSIONER JONAS: I would disagree actually with that. I think what they learn is a lot of propaganda about the dangers but they do not actually learn what the dangers are, which can only come, you know, in looking at what goes on in actual practices.

DR. _____: I would just say,

though, Dr. Jonas, that what Bill has described is one course in the medical school. We actually have identified CAM as one of ten threads that are woven throughout the entire medical school curriculum and so what he has described is one elective in the third and fourth year.

We just had a clinical inquiry session last week where the focus was on low back pain and it was very much looking at the evidence-base for what chiropractic brings, for what massage brings, for what osteopathic medicine brings. So our focus very much is how do we do this in an evidence-based way.

So I think Bill's course offers sort of a wonderful enrichment to students who want to get a more in-depth experience.

COMMISSIONER JONAS: I hope that your expanded course now that you have this grant and expanded program can begin to bring these things closer and closer together. This is not an issue unique to complementary and alternative medicine. I mean, in regular medical school there is -- we learn about evidence-based medicine and have journal clubs and things like

that and then you go out into practice and, you know, a lot of that goes by the wayside but in any case I hope that that occurs.

There is another issue that I did not hear a lot about and then I am -- and it is really related to what you said about the nursing and that is the holistic perspective. Even going around and seeing different practices does not necessarily help you understand that there may be a different underlying perspective, perhaps even a common one about looking at the whole person, which, you know, as you said, has been part of nursing practice for years and I am just wondering if there is any interaction with bringing in the nursing perspective as a Western-based holistic assessment.

DR. _____: I would say that this is probably something we want very much to avoid, is to try to make CAM therapies be the next pill that one could take or the next treatment that one would use, that is more of a how you do what you do than it is what you do. And that kind of philosophy is -- I think, in nursing, is trying to take that idea, that paradigm and work with it in terms of

collaboration because nurses need very much to work with other health care professionals in a collaborative kind of model.

And I think many times they are facilitators of collaboration between patients and doctors and other health professionals so it is the broader perspective.

COMMISSIONER JONAS: There is already not very adequate communication between the physician and the nursing side on these areas and that is already in the Western conventional system.

DR. _____: This is true.

COMMISSIONER JONAS: It would be lovely to bring that in and to bring the holistic perspective in.

DR. _____: You know, if I could just tell you one interesting experience we have. We have a graduate program now in complementary therapies and healing practices, and I taught the research topics class last semester, had ten students and no two students were from the same discipline.

When we began the program we had 37 students a year ago last fall. This spring we

have over 151 students enrolled in courses within the graduate minor. And I would say the strength of it are two things: The interdisciplinary nature and the holistic nature. The fact that it is very much addressing the care of the whole person.

COMMISSIONER JONAS: I think these kind of educational models would be extremely useful for us to see.

Again I want to thank you, Mary Jo, personally for organizing this.

I was hoping I would see some new things coming to the heartland and I have to say I have. There is really some expansion and lateral thinking that is going on here. It is wonderful.

DR. MANAHAN: Dr. Jonas, I gave a little bit of a glib answer on your question of evidence-based. The key thing I also mention on the first day is the whole course is really about critical thinking and so I think that when Erin mentioned about critically starting to look not just at the offices that she and the other students are going out to visit but looking critically at our own biomedicine and what we

are really doing and what science is.

MS. DAHLEM: I would say --

COMMISSIONER GORDON: George?

I am sorry. Go ahead. Go ahead.

MS. DAHLEM: I just want to add one other thing in terms of one of the emphasis in our program at the College of St. Catherine within a holistic philosophy recognizing something that we have learned from some of the cultures. Of communities of color what we have learned is that too often individuals of color have to leave their culture at the door when they see a provider and so I just want to emphasize again that part of the holistic framework has to really emphasize and hold as center of the agenda the concept of culture. And some of us have hardly a beginning knowledge of what that means to not be Euro-centric based and also to embrace and understand and look at different cultural ways of knowing.

So part of that holistic philosophy really has to embrace that, to continue to embrace that.

COMMISSIONER GORDON: George?

Let's give George time and then come

back.

COMMISSIONER JONAS: Okay.

COMMISSIONER DeVRIES: Dr. Manahan, you know, part of the White Commission, our mission is to provide recommendations and one of the specific areas is related to education. And if we were to ask you, you know, given what you have learned in terms of creating really CAM education for medical students in medical and/or residency training, if you had to distill it down to three or four mission critical items that you thought these are the critical issues for creating successful CAM education inside of a medical school or residency program, what would you distill it down to? What would you share with us? What do you feel are those critical points?

DR. MANAHAN: I think the critical point is open-mindedness and attitude. It is not skills and it is not even necessarily knowledge. It would be more attitudinal, and that is why I felt that -- I have learned through this program how attitude changes so tremendously as they are in the offices of the other practitioners.

We started -- I could -- we could

lecture with the best lecturers forever and it would not do what it does with these students and physicians when they are in the offices of the other practitioners.

And one of the more common comments is about they are so holistic, they are so compassionate, they are -- one of my most common comments of students when they are -- is leaving the course is, "Now I have -- I -- now I have the energy to go into residency and the passion that I had when I started as a freshman medical student." And it is their attitude. It is not that they learned a few more techniques or anything. And so I would put it down to one thing. It is somehow about attitudes of -- there is a broad world out there and we need to be more collaborative and the word that Linnea used.

COMMISSIONER GORDON: George, anything else?

Wayne?

COMMISSIONER JONAS: I just wanted to mention one thing that you may or may not be aware of just so -- you may want to contact them.

The American Medical Student Association Humanistic Medicine Group is currently attempting to put together a month-long rotation based on a retreat series that they currently run for medical students around the country in which they bring in and teach and help students experience self-care, learn evidence-based skills and how they might be applied to traditional and complementary practices, cultural sensitivity in terms of how to manage that, patient management issues.

And they are currently looking to do this as a third year type of rotation for a month, and then that would be followed up by, you know, other types of electives that might be taken such as your course or overseas courses or things like that.

You may want to contact with them. There is a number of things missing with that. I mean, it is pretty clear that other disciplines need to be brought in besides medical training or medical students. However, since it is the American Medical Student Association trying to do this, that is what they are focused on.

But that -- just for your own information and I can tell you the individuals who are involved in trying to organize that if you are interested.

DR. MANAHAN: Is that the one Polly Delavid is doing?

COMMISSIONER JONAS: She is, yes. Right.

DR. MANAHAN: We are part of that.

COMMISSIONER JONAS: Okay. Good.

COMMISSIONER GORDON: I had a question for you, Mary Johnson, and that is, is -- do you see -- is your program now currently functioning as the kind of model you have described and, if so, are you gathering some data on stress levels, job satisfaction, et cetera?

DR. JOHNSON: That is a wonderful question.

Nursing curriculum are very, very variable throughout the nation and I think that a holistic framework is probably part of all nursing programs but how much they integrate CAM therapies is pretty individual.

I have been doing a survey on my nursing students. I teach at St. Olaf College and

Gustivas Adolfus College. We have a Minnesota Intercollegiate Consortium. And I have been collecting data for the last five years on students' perceptions of the integration of our holistic framework and they have, as Bill mentioned, have talked a lot about how this has expanded their perspective and helped them see what a benefit it is for clients.

And then we do on a one year and five year, we ask about satisfaction with the program and this has come through as one of the high points of satisfaction from nurses.

As far as employer satisfaction, we have very high ratings. You know, it is hard to know how that compares to others but I think as this movement continues, this should be something that should be very much integrated into our evaluative process.

COMMISSIONER GORDON: I think from our point of view, it will be useful to have any kind of data and obviously from our point of view if there is data that compares people who have been through this program with those who have not that would also be very helpful because, as I think Wayne was saying or perhaps

it was Wayne who was saying earlier, one of us was saying earlier that we -- or George was as well that part of our task is to make recommendations for educational programs and the more data we have about what happens, even if you do not have it now -- I mean, as time goes on if that data can be accumulated it becomes very powerful.

DR. JOHNSON: That is true.

COMMISSIONER GORDON: And I think one of the things I want to say both in appreciation and as a reminder to all of you, it may feel like you are doing just one program but one program that has a really successful outcome and that then becomes a model can become very, very important nationally. So I urge you to collect that kind of data, and from the people who go through your programs, and to do the follow-up data and to --

DR. JOHNSON: And to write up the evidence.

COMMISSIONER GORDON: And to write up the evidence.

DR. JOHNSON: Okay.

COMMISSIONER GORDON: Exactly. Okay.

DR. JOHNSON: I will try to do that.

COMMISSIONER GORDON: All right.

Thank you all very much.

(Applause.)

* * * * *

RESEARCH

COMMISSIONER GORDON: Robert Patterson, please?

ROBERT PATTERSON, PhD

PROFESSOR, PHYSICAL MEDICINE AND REHABILITATION: UNIVERSITY OF MINNESOTA

DR. PATTERSON: I would like to speak on IRB policy.

The belief of the practitioner and the patient may be very important for the success of the healing process. Western medicines standard for scientific research studies, the randomized, placebo-controlled, double-blind study, limits or minimizes the influence of belief. In most cases this requires telling the subject that he or she will be receiving the "real treatment" half the time or they have a 50-50 chance of getting the "real thing." This creates doubt in the mind of the patient, which in turn may affect the healing process.

The recent NIH conference on the placebo presented many studies suggesting the real healing occurs from the placebo. I believe most traditional Western scientific researchers think that the placebo only results in an imagined

healing.

As a result of this, I would like to present an example of the difficulty I encountered in trying to carry out a Qigong study on patients with torticollis treated in our clinic with botulinum toxin every three months to relax the neck muscles.

In our study we wished to have a Qigong master apply a nontouching treatment approximately one week before the patient's scheduled visit for the botulinum toxin injection. We had two very exact measures to measure the head position using electronic tracking system. The second measure was the opportunity for the patient to cancel their scheduled botulinum toxin injection because they would not need it due to the relief given by the Qigong practitioner.

The IRB would not approve this study. They required a sham control group. I responded in a letter describing the need to respect the belief process. I was rejected again after two appeals.

The following is, in part, the written response I received:

"We are, however, concerned about the apparent legitimization of a therapy by an IRB approval of a study of the therapy, especially when the design of the study is flawed. The combining of IRB approval and a likely positive outcome, even if the therapy is without effect..." that is kind of interesting if you think about it "...misleads both the current subject and the general public. The latter through news reports, journal reports and word of mouth." As an aside, there goes my academic freedom. "Being misleading about the efficacy of the therapy is a risk."

In my 21 years as a member myself of the IRB at the University of Minnesota, I have never heard this argument being made before about any other study.

Just two months ago another similarly designed study by somebody else who is in this room was submitted to the IRB with the initial response being similar.

Guidance on this issue for IRB panels is given in the Federal OPRR institutional review board guidebook. Section 4-1 discusses this issue. Suggestions for OPRR policies:

(1) For minimal risk studies the IRB shall not require changes in the study design.

(2) The only risk considered shall be the risk directly affecting the subject.

Thank you.

COMMISSIONER GORDON: Thank you.

Thanks for bringing this to our attention.

Janice Post-White?

JANICE POST-WHITE, RN, PhD, FAAN
ASSOCIATE PROFESSOR, SCHOOL OF NURSING
UNIVERSITY OF MINNESOTA

DR. POST-WHITE: Thank you.

I am going to address the need for rigorous credible research in CAM both as a research professor at the university and the Integrative Medicine Program at Children's Hospital and Clinics so I am going to emphasize pediatric cancer.

There are a few studies documenting the safety and efficacy of CAM therapies, particularly in children. The aim of evidence-based practice is to provide the best care based on the best available research. Research on CAM is needed to determine efficacy, effectiveness

of CAM in comparison to standard of care, the mechanism of action with a physiologic or theoretical model, as well as dosage, provider effectiveness, and cost.

Pediatrics must be included in the integrative medicine research agenda. It is inaccurate to assume that studies in adult patients will be applicable to children.

CAM intervention research, however, has unique characteristics that make standardization of the intervention more challenging, control of a patient's self-practice is difficult, and randomization is sometimes unethical.

CAM interventions are not generalizable. What works for one individual often is not helpful for another.

Despite the scientific strength in randomization, the power of the intervention lies in matching that intervention with the strengths and beliefs of the individual.

We need to be open to new models. However, CAM intervention studies also need to test standardized interventions with consideration for the dose of the intervention, the intensity, frequency and the actual

utilization.

Outcome measures need to be sensitive to that specific intervention and meaningful to cultural and ethnic groups.

New methods of analysis will consider individual outcomes, not just group means.

And qualitative analysis will better determine how CAM affects individuals as a whole.

Funding is desperately needed for large scale powered efficacy and effectiveness studies and trained researchers to conduct them.

Ideally, efficacy studies precede effectiveness. It will not matter if it is cost-effective if it does not make a difference. It is the efficacy studies that I believe will create organizational policy and insurance changes.

Meanwhile, establishing databases that document clinical outcomes and reflect risks and benefits as well as treatments and responses and costs will offer insight into use, trends and outcomes.

I also propose that the integration of CAM intervention research within cooperative

group clinical trials will ensure credibility, access, adequate sample sizes and efficiency in recruitment, data collection, follow-up and analysis.

In the forthcoming grant renewal in Children's Oncology Group funded by the National Institute of Health the CAM subcommittee is designing group-wide protocols to test the effects of specific CAM interventions on outcomes in children with cancer. This is a pioneering collaboration to determine which CAM therapies demonstrate efficacy and are compatible with conventional cancer treatment.

As a cancer CAM researcher and mother of an eight-year old survivor of leukemia, I can assure you it is the clinical trial mechanism that saved my son's life. However, the effects of cancer do not end with the treatment.

Imagine the effect on clinical outcomes if we can identify CAM therapies that could reduce late effects and toxicities as well as improve function and resiliency. We have more than double pediatric cancer survival since the 1970s. Imagine where the science of CAM could be in the year 2030. It is time to critically

test some of our more promising CAM therapies.

COMMISSIONER GORDON: Thank you, Janice.

Chris Hafner?

CHRIS HAFNER, BA, Dipl Ac LAc

CLOUD RIVER TRADITIONAL CHINESE MEDICINE

MR. HAFNER: Thank you.

It is my belief that the greatest benefit that complementary and alternative medicine has to offer us is in the opportunity to see ourselves from other perspectives. In Chinese medicine it is said that nothing brings greater suffering than the stagnancy engendered by the attachment to a single point of view. There is great wisdom in adopting another perspective when it is appropriate to do so and there is great advantage in having a collection of ready perspectives from which to draw.

CAM represents a diverse collection of perspectives on a wide range of human health issues, from the treatment of illness and the prevention of disease to the optimization of health and well-being. This diversity of perspectives is the very definition of CAM and is its greatest value. It is perspective that guides the CAM practitioner in making a

diagnosis and forming an appropriate treatment strategy. It is perspective that directs the safe and effective use of treatment modalities. It is perspective that helps to shape, guide and provide focus for the healing intention. It is perspective that is ultimately responsible for whatever benefits a system of medicine is capable of yielding.

Yet, as important as perspective is in defining a paradigm, it is seldom acknowledged and CAM paradigms often remain unarticulated and poorly understood. If we hope to create policy that will ensure the maximum benefit of CAM in an integrated system of health care, we must recognize where this benefit lies. The benefit is in the perspective. We must do everything we can to clearly define and understand CAM perspectives so we do not lose sight of them in the process of integration. As we develop methods of research to determine safety and efficacy, we must do so in a way that maintains the integrity of CAM perspectives.

This will probably be very difficult to do using standard research models that tend to focus on mechanism. If we are to determine the

validity of any CAM perspective it is my opinion that we must do so not in terms of conventional medicine. The validity of a perspective rests not in how well it agrees with our own, or whether we can even understand it in terms of our own, but whether or not it consistently leads to positive outcomes.

Safety and efficacy of a given therapy are dependent upon its appropriate use. Appropriate use, in turn, is determined by the guiding principles of the perspective. We must encourage and support CAM research within the CAM community itself so that CAM perspectives can first demonstrate the validity of the guiding principles. If guiding principles of a CAM perspective can be demonstrated to be internally consistent then it would be much easier to go on to demonstrate safety and efficacy without having to research the mechanism.

In this way, we may be able to meet the standards set by our society for the safe and competent practice of health care without having to compromise the integrity of CAM perspectives.

Thank you.

COMMISSIONER GORDON: Thank you.

Mary Ellen Kinney?

MARY ELLEN KINNEY, RN

COORDINATOR OF COMPLEMENTARY THERAPIES

RESEARCH: UNITED HOSPITAL (ALLINA)

MS. KINNEY: Thank you very much.

I am working on a research study entitled "The Effects of Therapeutic Massage and Healing Touch on Cancer Patients." Through this study, I have gained a great appreciation for the scientific process, and the subjective comments from scores of our research subjects support its value in their lives.

In fact, one woman could not wait to tell me her story when after receiving healing touch, she rapped on my door and burst into my office saying, "Look at me. Look at me. Today is the day in my chemo cycle when I am always admitted to the hospital but that is not what it is about. It is not about the diarrhea or the nausea or the vomiting or the mouth sores. Can you see it? I a living for the first time since I was diagnosed. It is my spirit, Mary Ellen. My spirit. Look at me." She spread her arms

and twirled in front of me.

In addition to recognizing and appreciating her obvious vitality, my thought was, "What am I witnessing here? And just how do we measure that?" How do we measure the ineffable using the construct of our current scientific methodology?

The goals and philosophy of CAM include wholeness, wellness and healing. These are inherently expansive concepts that lead to questions of consciousness, interconnectedness, transcendence, healing and spirituality.

If we ask the questions that CAM prompts, then a methodology that supports the research to find the answers is required. The current methodology of the randomized double-blind study is serving us well in some arenas but it is based on a reductionist model and reductionism and holism do not resonate.

When we look at the woman in my office, the results we obtain from a randomized controlled trial may be valid but they are certainly incomplete. We can measure her episodes of diarrhea and vomiting, the number of antiemetics and pain medications she uses, and

measure her endorphin, T cell and cortisol levels.

We can measure length of inpatient stay and even quality of life but if we listen carefully to what she told us, we still have missed measurement of what she identifies as the underlying key to her experience, her spirit.

This calls for advancement to another level of reliability and validity in research methodology.

We are already practicing and benefiting from an integrative medicine and our healing practices have moved beyond what can currently be measured in a reductionist manner.

Science must evolve along with medicine to continue answering the questions and assuring safety and effectiveness for the people seeking wholeness.

I have great hope and confidence science will answer the call.

COMMISSIONER GORDON: Thank you.

Milton Seifert? Is it Seifert or Seifert?

DR. SEIFERT: Seifert.

COMMISSIONER GORDON: Seifert.

MILTON SEIFERT, MD

EAGLE MEDICAL

DR. SEIFERT: I am a mainstream family physician in general practice, in the town in which I was raised. My office and high school and ancestral home are within a 50 yard radius. In one sense, I am a domain expert on localness, specifically the localness of Peter Senge.

The town is Excelsior and means "ever upward." It is the title of my testimony and it is an image for a bottom-up system change.

I have two other images on the table before me.

When the work of this White House Commission is completed, I assume it will have created a set of policies that address care, education, outcomes research, organization, systems and governance. These policies will need to be integrated and cohesive and definitely not at cross purposes.

Guidelines for the research and development of each policy will be chosen and I would like to suggest some options, mostly based on a bottom-up approach.

For organizations and systems, the 4C2A

formula means comprehensive and continuing, coordinated and customized, accessible and accountable.

For care and education, the emphasis would be on partnerships where the partners have equal power. Also, there will be a replication of the 4C2A formula.

For outcomes research, a health status assessment that measures and treats both health and disease with equal intensity. Policy would direct that this be a part of daily care and this would produce evidence for the base.

For governance, the intentional logic of Harvey Wheeler where a system of rewards largely replaces regulation and punitive methods while it produces higher performance and greater patient safety. It would give concepts like the 4C2A formula the force of law.

But there need to be some priorities and the main priority would be for a partnership.

A project supported by the NIH, SBIR grant asked patients how they got well and they said, "We got better because you and your staff listened and cared; this allowed us to put in trust and become a partner in the relationship;

this led to willingness to change and we changed our lifestyles in our life."

A recent review of the literature on informed consent showed that both mainstream medicine and complementary medicine are saying the same thing, that you have to have an intimate relationship with the patient before they can choose what you are offering.

I have an image of the top down approach. You can have it that way with the top down but it takes an awful lot of support and eventually the support will not be enough and it will fall down.

(Laughter.)

COMMISSIONER GORDON: Okay. Thank you.

(Applause.)

COMMISSIONER GORDON: Frank Wiewel?

FRANK DENNIS WIEWEL

PEOPLE AGAINST CANCER

MR. WIEWEL: I am Frank Wiewel and the founder of an international nonprofit organization, People Against Cancer, and some would consider me a revolutionary in the war on cancer.

Cancer: You hear about it. You read

about it and you see it on TV but there is one thing you never hear. You never hear the truth about cancer.

You are never told the truth about cancer incidence. In 1960 it was one in four; today it is one in two. This year 1,500,000 American citizens will get cancer.

Despite these horrifying facts, the cancer establishment claims progress against cancer. You are never told the truth about cancer incidence.

You are never told the truth about cancer death rates. Death from caner is on the rise. This year over 750,000 American citizens will die, notwithstanding the best conventional treatment. You are never told the truth about cancer death.

You are never told the truth about cancer diagnosis. The public is told that the earlier the diagnosis the better the chance of a cure. It is a lie. Through the use of scare tactics, many forms of cancer are now being diagnosed at a much earlier stage producing a "statistical cure" but no real survival advantage. Radiation from mammograms and x-rays

is a major cause of cancer. In the Canadian Breast Cancer Study, routine yearly mammograms for those ages 40 to 50, as recommended by our National Cancer Institute, produced a 52 percent increase in the rate of cancer. You are never told the truth about cancer diagnosis.

You are never told the truth about what causes cancer. Recently the FDA found 60 to 80 pesticides in the average American food basket. They did not tell the public and they did not do a thing about it.

You are never told the truth about how you can prevent cancer. We can lower our risk by eliminating carcinogens in the food, the air, the water and the environment. There is also good scientific evidence that we can significantly lower the risk of cancer with exercise, dietary changes, nutritional supplements and stress reduction.

You are never told the truth about conventional cancer therapy. For decades the cancer establishment has relied upon the crude and primitive treatments of surgery, radiotherapy and chemotherapy as their only weapons. These therapies are dangerous, toxic,

ineffective and highly profitable. There is an ongoing and deliberate sophisticated hoax being perpetrated on people with cancer.

You are never told the truth about what innovative cancer therapies can do. There are promising new methods of treating cancer that are safe, effective and cost effective.

Amazing discoveries about the power of nutrients to prevent and treat cancer are made every day. Nutritherapy is the use of nutrients in therapeutic doses to resolve disease.

Nutritherapy is the future of medicine. Chemotherapy and radiotherapy are the past. However, nutritherapy will never be approved under the current FDA medical monopoly scheme.

The White House Council on Alternative Medicine has the opportunity to tell the truth and demand reforms of the current system. The Commission has the opportunity to bring together physicians and researchers and people with cancer to discuss new directions in the war on cancer and research new strategies for cancer prevention through the use of the mind, body, diet, nutrition, detoxification and through the high tech biologicals.

What needs to be done? For people with cancer, we need to tell the truth. We need to conduct good scientific research and tell people there are innovative and alternative therapies which are safe, effective and cost effective. We need to tell people that you can do more for yourself than any doctor.

We need to dismantle the FDA and the National Cancer Institute. They cannot be reformed. We need to reestablish all of the National Cancer Advisory Boards and Citizen Chairman Advisory Boards. These boards should be controlled by people with cancer, not physicians and cancer researchers with a vested interest.

Thank you.

COMMISSIONER GORDON: Thank you.

(Applause.)

DISCUSSION

COMMISSIONER GORDON: Questions? We will begin at this end with George.

COMMISSIONER DeVRIES: Pass.

COMMISSIONER GORDON: Okay. Wayne?

COMMISSIONER JONAS: Let's see. Where do I start?

(Laughter.)

COMMISSIONER JONAS: One of the recurring issues is, in fact, who sets priorities in terms of research and research design. It is frequently mentioned that we need to establish efficacy before effectiveness and there is a whole hierarchy, et cetera, et cetera. And I guess one of the questions I have is how -- and then, you know, when this established -- when this gets established and people begin to say, "Well, I really want to test a theory as opposed to the outcome," which I think Professor Patterson was -- what they were saying, you need to be blind to not just look at what happens. And this is an ongoing debate, which I do not think we have resolved at this point in terms of research.

I am wondering if you have some suggestions as to how to approach this again focusing on research. You mentioned a grounded theory, a multi-modular approach. Now that is not what is currently taken actually at the NIH. In fact, there is an explicit policy to test efficacy first and establish that and then if

that looks promising then to move on to other types of things. And it is not that any particular research design is abandoned, it is just that things are expected to be followed in a certain order.

And I guess I heard this mostly from you, is that this seemed to be a reasonable order and yet there were a lot of caveats in your description there, and I am wondering if you could comment. Should we change this hierarchy in some way? Should there be an alteration of research structures and how would we bring the patients, if that is what is recommended, into more of a control position, if you will, in the area of research prioritization, design and execution?

I mean, is there a way that patients can actually be brought into that, including brought into some of the hierarchical structures that the government has like the NCI and the FDA?

COMMISSIONER GORDON: That is a question.

(Laughter.)

DR. POST-WHITE: When I said that "efficacy should precede effectiveness" from a

scientific model, I believe that but I do not think in any one of them that we should follow Phase I, Phase II, Phase III with exclusion of grounded theory, research, qualitative methodology, capturing the spirit in Mary Ellen's study. Those things, I believe, need to be occurring simultaneously.

It is not that we cannot be collecting outcomes and effectiveness of interventions in comparison to standard care at the same time that we are testing mechanisms of action and actual efficacy of the interventions but I think in order to eventually get funding that we need to be able to prove that long-term these interventions make a difference. We need the efficacy studies. We cannot just ignore the efficacy studies, I guess, is what I was trying to say.

And I do believe that we need to bring consumers into this model because with any research design that you do you have issues of randomization, recruitment, retention. Those issues are magnified in CAM research. They are very unique in complementary and alternative medicine partly because of the commitment we are

asking of the patients and the expectations that we have for them and the change that we are requesting of them. They need to be full participants in that model of care as well as documenting research outcomes so I would support that at any level.

COMMISSIONER JONAS: I guess I am -- go ahead. I am wondering how to do this. I mean, how do you bring -- right now we put consumers on advisory panels. Okay. That does not work. There is some -- I am looking for suggestions as to how consumers can be more integrally -- be more integrally brought into the process and if there are models of how that has occurred successfully.

DR. _____: The grounded theory approach in the real world is a group of consumers talking about the use of Dove soap or Buick automobiles. We have -- I have two examples from our own practice. Our patient council met and they looked at the SF36 and eventually determined that there was no measure of spiritual health. We also asked them to help us develop a language of negotiation so that we could better do the relationship work and when

it was all done we no longer had hypochondriacs or neurotics or schizophrenics or psychopaths.

COMMISSIONER JONAS: So, in other words, the consumer group said this particular measure is not capturing what we are -- what is important to us?

DR. _____: And they re-languaged the medical language in a way that they could help themselves more. So there is no reason why medical practice cannot be a laboratory practice when you bring together care and research and education. The multi-method research of Crabtree and Miller is in a book called Collaborative Care that came out of an NIH conference and at that conference there were a group of patients, a patient advisory council that advised the conference.

COMMISSIONER JONAS: Thank you.

COMMISSIONER GORDON: Frank, did you want to say something?

MR. WIEWEL: Yes. One recent example of this was that we held a conference in the United States Capitol with the head of the National Cancer Institute, the head of the Food and Drug Administration, the head of the National

Institute of Health and the head of the Office of Technology Assessment, and I addressed this group and I said, "We are having a problem here and that is that the people want to know why we are not living longer and feeling better in the treatment of cancer."

Well, the rules were changed somewhere along the line. About 80 percent of the people did not live longer or feel better using the current treatment methods. We changed the standard by which we measured. We are now measuring tumor response so the tumor gets smaller and the patient dies. We claim success but the people want to live longer and feel better and they were left out of that dialogue. And the National Cancer Advisory Board is essentially researchers and doctors who are giving money to each other. The system is corrupt. It cannot be reformed.

You need to put all citizens on who are treating people with cancer, the people with cancer are the ones who will tell you "I want to know if we can live longer. I want to know if I will feel better." Those are the two questions every physician is asked. "Will I live longer?

Will I feel better?"

The size of the tumor is unimportant. It means nothing. It is the standard by which we judge in these advisory boards and the National Cancer Advisory Board by the National Cancer Institute and clinical trials. So I think you have to do the ground-up. You have to do it with the people. What do the people want?

COMMISSIONER GORDON: Okay.

Joe, do you have a question?

COMMISSIONER PIZZORNO: This is for Frank Wiewel.

You made several pretty strong assertions in your presentation today but when I looked at it I did not see any references. Do you have any research to back up the numbers that you are -- you have in the statement?

DR. WIEWEL: Yes, they are all real.

COMMISSIONER PIZZORNO: So where would I find those numbers?

DR. WIEWEL: I will be happy to send them to you.

COMMISSIONER PIZZORNO: Good. I would like to see them.

DR. WIEWEL: They are surprising and I

think that is why people ask for that but they are all sound, solid, scientific assertions.

COMMISSIONER PIZZORNO: Then they should be in the paper because it would be easier for people to follow up on what you are saying.

DR. WIEWEL: I will be happy to send them to you.

COMMISSIONER PIZZORNO: I think those of you involved in cancer research, a lot has gone in terms of quality of life and survival in conventional cancer research in the number of -- in the last several years. In fact, there are often now primary outcomes in studies also so I do not think it has been completely ignored. In fact, it is an integral part. I do not know if you want to comment on that.

DR. POST-WHITE: Except that was top down. Quality of life was added because cooperative groups were mandated to add the quality of life estimate measure to their outcomes and what is wrong with that is that the quality of life instrument does not capture the real quality of life of the patients and the families. We need more sensitive instruments. That is a start. It is a great start but we

need to find out from the consumers or from other people what goes on in your life when you have cancer, what measures do you think would capture this, what should we be looking for. I think we need more than quality of life and we need something more specific if you look at all the quality of life instrumentation in terms of the sensitivity and specificity. It is not there.

COMMISSIONER GORDON: Let me make a request that sort of goes along with some of the questions being asked. If -- Janice, this was occasioned by what you were just saying. If you have suggestions and concrete proposals, for example for better quality of life measures or for better guidelines -- Dr. Patterson, you gave us a couple of suggestions -- but really organized sort of programs for better IRB guidelines, better quality of life measures, those are the kinds of things that we may be able to propose because they are really -- in a sense they may be difficult because there may be resistance.

In another sense they may not be so difficult because I think people are looking --

we are really looking to see a way to have guidelines that are more reflective of what the actual situation is, what the actual needs are, whether they are the needs of patients or the needs of researchers trying to look into this field so we would really appreciate that kind of guidance from you.

Yes?

COMMISSIONER JONAS: Yes, I would just add to that because we have discussed these issues actually in our first research forum. I am sure we will discuss them at the next one also. It would be very nice if we had some examples to go along with those and specifically I do not mean just grounded theory and multi-modal research. I am familiar with the research of Crabtree and Miller and those groups.

But an example of how the public has been brought into the entire process of research from square one to the end, from putting together and thinking about how to design what measurements to occur, the approval process in terms of the IRB, et cetera, as well as the data collection and analysis and the interpretation aspect, which is also an end product of that.

And if there was a way or a model of where this has actually occurred throughout the entire research cycle, this I think would be useful for us to look at because I do not know of any place where that has actually occurred.

COMMISSIONER GORDON: I would just add that even if it has not occurred, it would be great if it has, if it has not occurred, perhaps we are in a position, if not to make it happen, at least to significantly raise the visibility of these kinds of models so we would ask you for that.

DR. POST-WHITE: And that is what I think I was proposing with the Children's Oncology Group Cooperative Model is that what we are proposing is R01 initiated research that would become a clinical trial model. We are working with the CAM subcommittee and the end-of-life subcommittee to determine what those outcome measures from the consumer, from their clinical practice, what would be relevant to them and then how can we as a cooperative group add a spirituality assessment or a qualitative analysis piece or some sort of methodology that expands the quality of life.

COMMISSIONER GORDON: Great. Janice, I would appreciate it if you would send it to us. Also send it to the Cancer Advisory Panel at NIH, CAPCAM and send -- copy me on that as well.

And I want to give Linnea a little chance, Wayne.

COMMISSIONER JONAS: I just want to ask Dr. Patterson -- I am sorry.

COMMISSIONER GORDON: Okay.

COMMISSIONER JONAS: Were any of the patients asked what type of design they wanted in your torticollis study, whether they would prefer to be in a study that looked at standard therapy with additional energy or Qigong or sham? Was that ever brought into the discussion? In other words, the population you were going to do the research with, were they ever surveyed or a focus group done asking what kind of a design would they like? Would they like a sham arm in that in order to get that kind of information or would they like just a standard care arm?

DR. PATTERSON: No.

COMMISSIONER JONAS: I am just wondering what you think they would prefer. Do you have a

hunch?

DR. PATTERSON: It is always, you know, a problem, you know, actually going to people and talking about research that is not approved. That is sort of a touchy area. I mean, you could.

COMMISSIONER JONAS: You can bring individuals in a focus group who may or may not participate in a study just to get an idea of what -- you know, what is the preference in terms of design.

DR. PATTERSON: Yes, that would be good but I might add that the point I was trying to make and I have served on the IRB a long time, this has come up, it has just come up again, is that there is a real bias against this stuff and they want to dictate the design and you saw -- maybe I went quick -- is that most of the stuff does not have any real risk in any reasonable way.

So when I addressed to the committee chairman on my study what the risk was, it is me speaking about the results. You know, I am tenured with academic freedom and now they tell me that they are going to stop me from talking

right at the head and it has happened again. It is not a rare thing and basically they do not want this to go on.

COMMISSIONER GORDON: So where does this sit now, the issue? Is it --

DR. PATTERSON: The study had to be modified after the many appeals and the current one that I referred to that I -- it was ironic on the current study that is under consideration now by the IRB, which I was on the panel and I was actually representing the study, has not been approved yet.

COMMISSIONER GORDON: It has not been approved. Would you keep us posted? Seriously, I think this whole -- it is a very important example for us to take a look at.

DR. PATTERSON: When I said that, there is a potential approval with stipulations but they want to change the design.

COMMISSIONER GORDON: I understand. You mean eliminate the Qigong?

DR. PATTERSON: Oh, no.

(Laughter.)

DR. PATTERSON: In the current study that is open right now.

COMMISSIONER GORDON: Yes?

DR. _____: We have a long running patient advisory council. It goes back to 1972. And as a general practitioner I can understand research design if I am a part of that team designing the research and so can the patients. And it was the inter-study that brought the SF36 to that council meeting and it was there that they said, "So where is your spiritual health?"

The same idea of patient advisory council could serve the work site very well, too, because there are a lot of issues not only about insurance but about health status of the work site that would benefit productivity and the bottom line for industry.

So those are two places where the patients could have a major say so in directing policy and research design and their own care.

COMMISSIONER GORDON: Great.

Linnea, you had -- no?

Any more questions?

COMMISSIONER JONAS: And I think one thing that was implied or actually stated was stratification by risk also was important.

Something that is extremely low risk or

it is being used for something in which if the alternative was not used, it would not create undue risk for the patient is a different situation than something often in oncology where there may be high risk consequences to not going forward with a particular therapy or providing standard of care.

So again those are --

COMMISSIONER GORDON: Wayne, I am wondering if when we do the next research panel if we could not focus on this whole issue.

COMMISSIONER JONAS: I think we should. I mean, you know, the whole issue of efficacy versus effectiveness, theory versus patient involvement in risk is important.

COMMISSIONER GORDON: Yes.

COMMISSIONER JONAS: It can be very sticky. I mean putting back patients to bed, for example, seems like a very low risk strategy but when they actually tested it in a controlled trial it did damage to them. They were worse, the ones who went to bed than the ones who had free rein. So it is not always easy to tell up front what is risky and what is not.

COMMISSIONER GORDON: Thank you. Thank

you very much for a very stimulating discussion.

We are going to take a break for lunch. We will return and begin promptly at 1:30.

(Whereupon, a luncheon break was taken.)

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