medicine, what I hear from many of my patients who go where they have more time than a seven- or 10-minute HMO visit, when they have more time, is that they have a deeper sense of partnership or relationship with the practitioner that they are going to, that they spend 45 minutes or an hour, that they really listen to them, they are exploring emotion, they are exploring why do you think you are sick, all these kinds of things.

I think that when we are studying, you know, does ginkgo affect dementia, well, that is kind of an easy thing, but when we are talking about modalities, when we are talking about acupuncture or naturopathy, I guess what I am trying to ask is shouldn't we, if we really want to understand the impact of many of these systems, shouldn't we also be looking at what makes certain practitioners perhaps very effective at what they do, so that we could take that, that they do well, and try to teach that.

I mean it is like if acupuncture works for migraine, great, then, we could use that information to perhaps even perfect better techniques with acupuncture in migraines, but if we found that it was no better than

placebo, but placebo was 28 percent, perhaps we could still study what was the psychological impact of why 28 percent of both groups got that, what happened.

So, I guess my question is, in all this randomized, double-blind trial -- I am primarily into botany and plants, so my model works pretty well for the double-blinded RCTs -- but what I am hearing a lot or what I hear a lot from complementary practitioners is that it is an artificial trial, it is more than individuation is what I have heard. It is more than just individualizing therapy.

There is a relationship. Physicians used to have this very much, like the home visits that you went on. I don't know how you measure that, but it seems that we need to come up with instruments. Leanna, I think that you should be doing this up at Bastyr, studying the relationship of the patients and the practitioner as a part of the modality.

DR. STANDISH: You know, that is such an important issue, the practitioner effects, and I guess my response is this. Let's go back to this question does comprehensive naturopathic medicine really help women

with breast cancer as an example of the question.

See, for me, I just want to know whether what I do makes a difference first. Now, it could really be, as many detractors have said, it is just because you are spending more time, it is the relationship, it has nothing to do with the therapies or the actual modalities that are being applied.

That is a secondary question. First, I want to find out if what we do as a practice makes a difference or not. If it does, then, the next place to go is, well, what is making a difference inside of the practice. There is now a whole field of research in this area, and it is a tremendous amount of work, but once again it is solvable.

DR. LOW DOG: I don't think it has to be a detractor. I am confused by that whole thing, that if it was the amount of time or the handling, if that was what actually did affect that, that is good information to know.

DR. GORDON: I am going to interrupt just for a minute. I want to let everybody know we can go on, and it is now almost 4:30. We are going to take a five-

minute break, and then we are going to come back and we have one more panel. It is not that anything anyone is saying is not valuable, it is just a question of time.

With that in mind, that is fine.

Tom.

MR. CHAPPELL: Tieraona, I think Dr. Templeton would be very interested in that question because that really is a spiritual, the partnership or the relationship.

DR. GORDON: I have one very brief question, which is NCAM currently funds a number of centers. Leanna, you were director of an OAM-funded center. I am wondering how you think the centers that are funded might provide some of the assistance that Dr. Segal was talking about and that seems to be so necessary to so many people.

DR. STANDISH: Oh, I think the centers could play a very important role in Best Case Series in providing methodological support, such as Dr. Cramer could do, yes. But, you know, it is funny, it really hasn't happened to the extent that we had hoped, and I think we need to put our heads together to really answer

why has that connection between the CAM practitioner community and the centers not really jelled together, and I don't have an easy answer.

DR. GORDON: Thank you.

Joe.

DR. FINS: I just want to make the observation that this problem is not unique to CAM research and that there is a universal problem even in major academic medical centers that have departments of public health, the need to set up a kind of biostatistical infrastructure through a CRC.

So, I think that we are focusing on the nuances of CAM research, but the epidemiologic challenges are out there, and all of the challenges that you mention are time and energy and motivation is more of a generic than a specific problem.

DR. GORDON: Effie.

DR. CHOW: I think that is true. The only thing that makes a difference in this case, paradigm number 6 perhaps, medicine, is the energetics that is new now -- not new -- bringing ancient into the new and the adaptation of the old ancient theory of chi or ki, or

VA

prano or mano, that makes the difference. We have to look at it with different eyes.

DR. SEGAL: I agree.

DR. GORDON: Thank you. Thank you very much, I appreciate it. We may come back for further suggestions about moving this field ahead.

We will take a five-minute break and then we will come back for the final panel.

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DR. GORDON: This is going to be another panel on Federal Agency Support for CAM Research. One of t things that we feel is very important is to look at although the bulk of funding, as you have heard, fede funding comes through NIH, it is important for us to at the opportunities that are arising and that are be made by other federal agencies, as well.

So, we have asked three people to speak about the issues, two in person and one hopefully by phone.

We will begin with Dr. John Demakis from Veterans Affairs.

Thank you both for your patience with us.

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DR. DEMAKIS: Thank you, Mr. Chairman. It is an honor for me to be here representing the VA. I am sorry Dr. Burris, who should have been here, had a last-minute emergency and asked me to fill in.

First, I will tell you a little bit about the VA. The VA, as many people may not know, is not simply a large health care delivery system, which it is, of course, it also is a research granting agency. It has a line item from Congress to perform research in the Veteran Affairs hospitals.

This gives us a very unique opportunity, not only to deliver care, but also to do research with the patients we give care to.

As far as health care delivery, the VA has over 170 hospitals, over 200 nursing homes nationally, and many hundreds of clinics, both hospital based and community based. We have almost every type of long-term care service available including hospice, respite care, and many others.

We care for approximately 4 million unique veterans every year. We also, as I said, are a research granting agency. We have a line item in the federal

budget. This last year it was $320 million was granted to the VA by Congress to do research as an intramural program.

In addition, our investigators and our clinicians in the VA successfully competed for another $370 million in other federal grants from NIH and about another 200 million in non-federal grants.

The VA also has a very large cooperative trial program. You heard from the lady who was sitting in this seat a few minutes ago how difficult it is to do cooperative trials. The VA, in fact, has several centers dedicated to doing cooperative trials. Traditionally, we will have a minimum of 10 or 15 hospitals, and our largest cooperative trials to date, we have 120 hospitals enrolled.

These centers have their own IRBs, have their own data monitoring boards, have their own specialists in knowing how to do randomization, methodologic studies, statisticians, et cetera. We have done quite a few cooperative trials, and interestingly enough, we have quite a few ongoing in CAM right now.

Let me tell you a little bit about what the VA

is doing as far as CAM goes. For a little over 10 years, the VA, out of that federally-appropriated budget, has funded $60 million worth of research into CAM, 9 million alone in 1999, 6 million in 1998, et cetera, but a total of 60 million in the last 10 years.

Likewise, VA investigators -- by the way, that was 475 individual projects -- in addition, the VA investigators have competed successfully for another 970 projects over these last 10 years from other agencies, for a total of $92 million. The two of those figures together comes out to $152 million spent on CAM research in the VA. About a third of that the VA funded, and two thirds funded by other agencies. That was 1,300 or 1,400 projects.

In addition, the VA researchers did another 2,000 projects which are listed as CAM projects without funding. This was done locally, on their own, through different mechanisms that only they know and we don't bother to find out.

The types of studies we are either doing or have done in the last 10 years including studies on acupuncture, antioxidants, aversive therapy, behavior

therapy, biofeedback therapy, counseling, various types of interventions, electromagnetic fields, and I think as you can see, it sort of covers the spectrum of CAM.

I have more details, by the way, if anybody would like them.

In addition to the research that the VA is doing in CAM, the VA recently awarded a contract to survey alternative practices as they might apply to our system of health care, elements of the report which would include the current state of use and familiarity with CAM practice within our system, a review of the VA's patient database, and a literature-based assessment of the applicability of CAM practice to VA patients, an evaluation of the state of alternative practice in the private sector, and an appraisal of the cost effectiveness of CAM practices.

Unfortunately, the report has not yet been completed. We do, however, have some survey data regarding the state of alternative practice in the VA facilities. While knowledge and even awareness of CAM practices varies widely among providers and facilities, most facilities in our system provide some such

treatments.

These have generally included modalities, such as acupuncture, diet therapy, yoga, biofeedback, relaxation, music therapy, and Native American therapy, such as sweat lodges.

These practices usually reflect the presence of practitioner advocates and managerial willingness to accept the implementation of these programs. Most facility management teams were reported as pragmatically oriented and described as having no biases for or against CAM treatments.

The main concerns expressed related to the highly variable training and credentialing of practitioners, the lack of sound scientific evidence supporting the use of many of the CAM therapies, and uneasiness about budgetary impact of alternative practice in an environment of constrained resources, such as the VA presently finds itself in.

I will stop there. Those are the few remarks I had planned and will be happy to take any questions at the end of the session.

DR. GORDON: Thank you very much. We

appreciate it. I am sure we will be coming back to you with some questions. It seems to be an impressive amount of activity at the VA.

Our phone caller perhaps will come later. For now, Dr. Craig Vanderwagen representing the Indian Health Service.

DR. VANDERWAGEN: Thank you, sir. My name is Craig Vanderwagen and I am the director of Clinical and Preventive Services for Indian Health Service. I am happy to be here. I am from Zuni, New Mexico.

The other thing to be said is that again in the world that I live in, the complementary and alternative practices are very well funded, 16 billion to NIH to research, allopathic interventions, which in the world that I come from are the alternative or complementary practices. I sort of joke about that, but I think that that is true for many societies.

Let me say that Indian Health Service is the federal partner for an Indian health delivery system. The other partners in this, of course, clearly are the tribal governments and the tribal programs, and a very small amount of funding, unfortunately, is provided to

urban Indian programs to try and address the health needs of Indian people.

As my colleague in the VA indicated, certainly we are never happy with our funding which right now amounts to about $1,400 per capita compared to Medicaid at about 3,000 per capita, and the VA at about 5,000 per capita. Obviously, we don't have much squeeze room for activities other than the provision of basic patient services. We are not authorized or funded to provide research. We are authorized and funded to provide health services to Indian people, and our mission is to elevate the health status as best we can to the highest possible level.

Now, we have had some success in that the life span for Indian people since I was a child has increased about 40 years. Infant mortality now is essentially at the U.S. average in most places. The exception to that is the Dakotas where, in fact, infant mortality is about twice what the national average is.

But we have had some success, and that success has come because we have empowered the Indian people to control and operate their own programs. That is, those

of us that are public health providers know that changes in health status emanate from the community itself, not from somebody externally applying some process to how health practices occur and the behaviors that people choose.

I personally have been the agent for the federal government in transferring about $500 million to tribal control to operate their own programs and design them in the ways they want to as the law provides for them.

The role of traditional healing practices in those communities is variable. There are 558 federally recognized tribes. They are each a sovereign and independent entity, and we deal with them on that basis.

Their cultural practices are not homogenous, they are very heterogeneous, and consequently, any attempt on our part to direct and legislate through standardization, certification, credentialing, et cetera, for traditional healers is ludicrous on the face of it.

More importantly, the moral basis on which we operate would prohibit us from expropriating what is the patrimony of these people in some large measure. Because

their traditional healing practices emanate commonly from religious and spiritual values, it is not appropriate for us, as a federal entity, to attempt to bureaucratize those processes and expropriate them into a federal system.

Now, that presents us with some dilemmas at times. On the other hand, it is very positive, and we have found great support for this notion in the World Health Organization and particularly the regional entity OPS/PAHO in its initiative for indigenous people in that a major element of that is the respect, the support for the use of, and appreciation and respect for, those traditional healing practices.

We work very closely with Los Pueblos Indigenas, the American Centrel, the America del Sur, with indigenous people in Central and South America. We have a collaborating center for Indian health or indigenous health, not traditional practices per se, but indigenous health on a more broad basis in the works with PAHO at the moment.

So, where are we with research on traditional practices? We do not fund or support traditional

practices research at this time. We believe that there may be interest on the part of some Indian communities in this.

Some Indian communities are very well organized in the way they practice and work with traditional practices. Navajo, for instance, has a Medicine Man Society that is pretty big. They may have interest, but our recommendation to you would be that if you are interested in exploring research in traditional practices as utilized by American Indians and Alaska Natives, you need to work with tribal governments to establish those research priorities.

They are not unfamiliar with research. In fact, they will tell you they have been researched to death in some way. They understand the technical jargon that we practice in that they understand what IRBs are. They have IRBs, and they have a mechanism for controlling research in their environments.

NIH has helped greatly in the last year by announcing funding for Native American Centers for Health Research. This can be a platform for focused research whether it is in the area of traditional healing

practices or other research practices, and an absolute requirement for funding of those centers is that they are governed by tribal entities. It may be the University of Arizona, it may be Hopkins, it may be these places, but priorities and policy will be set by Indian people, not by researchers.

Those platforms, however, provide a great opportunity for exploring with tribal people how they might want to explore the impact, the efficacy, the outcomes of traditional healing.

We have actively supported this practice. We have constructed our facilities in such a way that we may have specialized healing rooms. If you go to Navajo, our facilities are constructed with a healing room that is centered and placed in a proper and appropriate manner.

Many of the tribes have a whole program of traditional healing services that they provide in conjunction with the allopathic programs. So, it is an important part of healing in Indian communities, and I resonate very much to the notion that the healer has a ton to do with this, and I think Indian people would see it in some large measure in that way, as well, and there

are opportunities in exploring priorities and how they would like to proceed.

I apologize for our director, he is not here today. He is actually out in Indian Country, which is where he is probably 50 percent of the time, which drives some of our colleagues in this building crazy, but that is where our people are. That is who we serve. That is what we exist for. So, you are stuck with me today and I apologize.

DR. GORDON: Thank you. Thank you for coming.

Thank you both. I think we are not going to wait for the phone call.

You both represent very interesting and very special groups of people. I would like to ask Dr. Demakis, how do you choose what kind of research you are going to do on CAM therapies, and are the priorities set specifically by the specific needs that veterans have?

DR. DEMAKIS: We do in certainly different ways. We can indeed put out a solicitation as we have done on many of these when we perceive there is a need and there is a gap in the knowledge we have or on the research we are doing.

We have oversight committees that look at our research portfolio and where there are gaps, they recommend that we put out solicitations to that effect to fill a gap. So, that is one way we can do it.

Another way, most of our research is done from our investigators in the field, our practicing clinicians. I should tell you also the VA research is intramural, only VA clinicians can apply for VA research funds, so the doctors, nurses, social workers that take care of our patients are the only ones that can apply for our research grants.

I have rattled off to you the numbers of how much CAM research we are doing. For the most part, this came from our practitioners themselves. They perceive the need, they perceive the idea, and they came to us. Much of our resource starts with a concept paper, a letter of intent that, once approved, they then go on to a full proposal that has to meet a rigorous merit review.

DR. GORDON: Thank you.

Joe.

DR. FINS: Dr. Demakis, I just want to thank you for your service to those who serve the Nation. It

is vitally important and, having lots of friends who are academics in the VA system, I know the good research that is being done and how collaborative it is.

I just wanted to ask you about the structure of the organization of the CAM research, is there any kind of infrastructure, because unlike the national center at NIH, you are dispersed throughout the entire country, which raises the possibility of having expertise of the sort that you describe available, so is there any kind of organization of the people who are doing this that could be tapped into from outside sources and foster the kinds of synergies that we have been talking about for the last two days?

DR. DEMAKIS: Did you say you were a veteran?

DR. FINS: No, I am not, my father is.

DR. DEMAKIS: Because, you know, we don't like to take thanks from a veteran, we say thank you to them, because they are the ones that have made the sacrifices. We never forget that, we try to instill in our younger colleagues.

No, the answer to your question is we do not have an organized approach to doing CAM therapy. It has

come to us from the field for the most part. So, I can tell you how many projects we have in any of these areas. We have got them all categorized out. We have not sat down and said we need more of this and more of that. These are what has come and is passed through merit review.

DR. FINS: So, just to make this a question, would the VA be interested in funding our resources to sort of organize that in an organized way?

DR. DEMAKIS: How do you mean fund the resources?

DR. FINS: Well, in other words, one of the things that we have the ability to recommend is funding for an office for complementary, alternative medicine research activities within the VA health care system. It seems to me that for very little cost, you know, you have a budget here which rivals what is going on at the NIH, but it is extramural in a sense, it is outside, it is around the country.

So, for a small incremental investment, we could organize that conceivably and leverage that expertise, so I am wondering if that would be something

that you and your colleagues would be responsive to.

DR. DEMAKIS: I don't know if our director would be responsive there, that is an interesting point you bring up. The research in the VA is organized among four major types - basic medical research, which is usually your wet lay-up, your bench research, and that sort of stuff, rehabilitation research, health services research, that happens to be what I do in outcomes research, and finally, cooperative trials.

So, we have not listed them by that sort of special category, and I would be a little bit concerned about that, because there could be many other special interests that would want their special interests carved out, as well.

So, within the four areas, we think we do pretty well. Now, I understand where you are coming from. There is not an organized way of looking at CAM research, and that is something I think we could take a look at and explore better, and I think we would certainly welcome ideas and thoughts to do that.

We could put out new solicitations, you know, very focused ones.

DR. GORDON: I just want to say that Bill Fair, Charlotte Kerr, and Tom Chappell have to leave in a few minutes. I am wondering if any of you who has to leave for a plane has a question that you want to ask before you go, and then we will come to the other people.

Bill.

DR. FAIR: Dr. Vanderwagen, I had a question. You mentioned, and Tieraona mentioned that earlier, about the impact of the healer, and, of course, this is true of any medicine, it is true of science. Durkie [ph] said, "Scientific observation is the interaction between the observed and the observer."

So, I think that this is a factor that is true in any healing tradition. You mentioned the Society of Medicine Men, was it?

DR. VANDERWAGEN: Yes.

DR. FAIR: I didn't get from your presentation where we would go if we really wanted to find out what are the CAM areas that might be worthy of investigation. Would it be the Society of Medicine Men?

DR. VANDERWAGEN: Again, we are missing my good friend and colleague, Buford Rolin, here, and I think

Buford will be an ongoing source for you of counsel and guidance in that direction. I was happy to hear that his coronaries are slick as can be, and I will see him in Nashville next week.

There are a couple or three ways to go. I mean there is the National Indian Health Board, which Buford was the former chairman of. The National Indian Health Board reflects the health interests of the tribal governments nationwide. It is representative, they are elected representation, and that group is a policy entity that has some merit as a policy entity to look to for counsel and advice on these matters.

That becomes then an entree point for specific medicine groups, whether we are talking about the Navajo Medicine Men Society in Alaska. There are collections of healers. A sidebar comment here. I mean the power of an individual healer, as an individual, is memorialized in many ways in many Indian societies.

In Zuni, where I grew up, there is the Nawayquay [ph] and the Nawayquay is the Medicine Society whose healing power is conferred on them by the fact that they survived whatever that illness was, and therefore,

their healing power in that environment is totally through that individual because of the power.

That is a sidebar note about the impact of an individual healer and how that could be even institutionalized in some societies, but, yes, I think the National Indian Health Board is a nice policy tribal-directed entity that offers an entree into a variety of tribal environments that reflects those tribal governments. That is who we think the entree point would be.

Now, there is also a National Council of Urban Indian Health here in this country, and they represent or speak to a set of different interests, and that is Indian people who either by the government's intent or by economics moved into urban environments and do not have the kind of tribal ties perhaps that folks in the reservation environments would have.

That is significant. That is 45 percent of the Indian people in this country. So, that is a significant entity, as well, and I think they have a point of view and operating realities that are somewhat different than if you were just focused on reservation-based Indian

people.

DR. GORDON: Thank you.

Wayne and George and then Effie.

DR. JONAS: I have two questions, two and a half questions. Dr. Demakis first.

I didn't see in the materials, and perhaps I just missed it, what is the research budget of the VA? What is the annual research budget of the VA?

DR. DEMAKIS: The VA is appropriated $321 million last fiscal year, however, that is sort of misleading because since the entire program is intramural, we do not pay salaries nor indirect costs out of that. Every hospital is expected to be both medical care, research, and education.

So, if you were to take the costs of the salaries and indirect costs, that would more than double that amount. So, a much more honest figure than 321, it would be more like 700 million.

In addition, our investigators and clinicians get about that much more from other federal and non-federal agencies. So, there is about a $1.2 or 1.3 billion of research going on in the VA, of which 321

million is funded directly by Congress.

DR. JONAS: Amazing. Actually, I didn't realize the scope of that.

It has always seemed to me that the VA would be an ideal place to do demonstration projects, and I am wondering if there would be some way in which, in the area of complementary medicine, a demonstration project or two or three, or now that I hear the budget, four or five, could perhaps be facilitated.

DR. DEMAKIS: I think so. I think that is quite appropriate. As I rattled off the figures, again, it is not as if we are doing a small amount, we are doing quite a bit already, but we do expect the investigators to come forward with the ideas.

They are all looked at carefully and they all take their place among many other research that is going on.

DR. JONAS: So, all of this is within VA investigator-initiated stuff.

DR. DEMAKIS: Yes.

DR. JONAS: So, there are no specific RFAs or types of things within the --

DR. DEMAKIS: We put out a lot of RFAs, as well. We certainly could put out an RFA specifically for CAM. If I were to look at all of our RFAs, I would probably tell you CAM is covered in it, maybe not as -- maybe we could be more specific, but certainly we welcome research and proposals in innovative new therapies. With the amount of funding we have, I think you can see we do not discriminate against CAM.

DR. JONAS: Right. I think it would be very useful to look at what is already going on.

DR. DEMAKIS: I think what you see is the interest of our clinicians, and we probably don't have a lot of clinicians who have special interest in certain types of CAM. Most of our researchers are physicians, and that probably limits again the type of research that is being done, CAM especially, but any type of research.

DR. JONAS: It is also an advantage in many cases now.

DR. DEMAKIS: Oh, yes. We have a terrible gap in rehabilitation research. Although we have a large rehabilitation research group, when you look at the VA and the type of people we care for, we should be doing

much more in rehabilitation research, but unfortunately, the clinicians doing rehabilitation are often not well trained in research methods, have a hard time getting projects funded.

That gets back to a question that was asked of the previous panel, that I think a lady was alluding to. Most clinicians are not trained to do research, and those that are trained, they are usually not the ones that would be interested in this type of research, but that is a problem.

DR. GORDON: Do you want to yield for a moment to Dean, because he has to go.

DR. ORNISH: I am really sorry I have to go. I thought we were going to end earlier, and I have got to fly to the West Coast, so I apologize.

I wanted just to say in many of the kind of CAM interventions I can think of would really fall into three, if not all four, of your areas of expertise, I mean your rehabilitation, your health services research, cooperative trials, even basic looking at mechanisms.

So, what percentage of your studies are RFA directed and how many are investigator directed, just

ballpark, half, two-thirds, one-third, something?

DR. DEMAKIS: I am not trying to evade the question, I really don't know. For each of the four sections it probably is different. For cooperative trials, I think it is almost all investigator initiated. That is maybe less than a quarter of our total budget.

I would say half the research budget is biomedical research, and that is almost all investigator initiated. For health services research, I would say probably our stuff, probably at least half of it is RFA initiated, the other half is IIR.

We put a huge push on quality improvement. I could tell you all of our research is quality improvement, but we have a new endeavor called "QuERI," Quality Enhancement Research Initiative, in which we have made a concerted effort to get the clinicians, the managers, the policymakers together to look at what are the key areas they need to do to improve quality, taking available research findings and applying it to the patient.

What we find is there are a lot of good research findings out there that are not being used and

have not been translated into either policies, practices, attitudes to improve patient outcomes.

So, we have made a concerted effort in eight fields. They are clinical areas - diabetes, heart disease, spinal cord injury, HIV/AIDS, mental illness, stroke, and I probably forgot one or two -- substance abuse. These are the highest number of cases we care for in the VA.

We have taken those, and we have made a concerted effort to improve quality outcomes in those areas, and translating our known findings. That is a very difficult thing to do, to take a research finding and to get it into the practice.

DR. GORDON: Thank you.

DR. JONAS: Dr. Vanderwagen, I have really two questions for you. It sounds like you have really decentralized your health care delivery, and I am extremely curious about whether you have looked at the effect. You have said it has been highly successful.

Now, I assume that by decentralizing it, you were not in the process of regulating, licensing the practitioners in their particular practice to practice

medicine or this type of thing, so I assume that many of these deregulated practices have practitioners in them that would not necessarily fit into a category outside of the Indian Services as a medical doctor or something like that.

So, I am just wondering how that aspect of it has gone. It sounds like you said it has gone very well, but the thing I am mostly curious about is have there been any increase in adverse effects due to that, have there been problems with quality in terms of health care delivery, have people gotten inappropriate practices, for example, and not gotten appropriate practices because of perhaps less well trained practitioners from a conventional point of view, or vice versa.

I mean you could say have not gotten appropriate Native American practices because of inappropriate training on the medical side.

DR. VANDERWAGEN: Well, the second arm is harder to know anything about than the first arm, but has the transfer of the programs to tribes led to any change in the quality of services provided, and the answer to that is no.

What is the evidence to support that assertion? The quality of care is measured by the usual industry standards, and that is JCAHO, AAAHC. Every one of our facilities is accredited. In fact, the tribes have demonstrated higher scores on accreditation site visitation than the federal hospitals is the reality.

Now, there are a couple of reasons for that. One is the tribes have a lot more latitude to bring in other revenue streams. Certainly, we capture about a half a billion a year in revenue from Medicare and Medicaid, and we have the authority to do that, but the tribes are able to tap other revenue streams, whether it is gaming money or whether it is other funds, tribes are investing in the program beyond what the federal government gives them.

As I have suggested, the federal government is failing to meet its obligations is the reality.

Now, as to providers per se, we have hired providers and called them mental health technicians when, in fact, they were traditional healers. You have to put them into some kind of GS place to cover them. So, we would hire them as "mental health technicians," in

quotes, but, in fact, there really was traditional healing practices.

Now, that varies from location to location in how the tribe use -- how actively they want to be involved in that clinical environment.

The other piece of evidence that I would offer you is that tribes are covered under the Federal Tort Claims Act when they take over, just like federal facilities are. We have seen an increase in tort claims in Indian Country over the last 10 years, but that rise reflects the same kind of rise in the balance of the society vis-a-vis litigation activity, and it is not focused in any way on traditional practices as opposed to allopathic practices at all. In fact, it is all exclusively allopathic practices.

DR. JONAS: So, it is actually less proportionately in traditional practices.

DR. VANDERWAGEN: True, because I mean the fact of the matter is, and, of course, I was raised in a pueblo environment, so I have a slightly different view than some, but traditional practices have to do, the worth of those practices is measured, not by how much

money the federal government would pay them as addenda under a contract arrangement, it has to do with how much the family and the patient themselves put into that process.

So, it is difficult to monitor the utilization in some ways, because we aren't running a cash register when those transactions occur, and that is how we generally monitor utilization, rates of failure, and so on, in the society is when the cash register rings.

DR. JONAS: So, there is some data that you can't capture really in terms of that.

DR. VANDERWAGEN: Right. It is more anecdotal. Now, how those centers that I described to you, and how CAM might reach out to tribal communities and offer them tools and techniques for examining internally the effectiveness of their providers, that is a good question, and it is one that I think some people have an interest in.

DR. JONAS: I think it is very interesting, and you have been able to put them in mental health categories and somehow gotten away from federal perhaps issues about their qualifications because they are not

required to have state qualifications if they are on the reservations, is that correct?

DR. VANDERWAGEN: Sure.

DR. JONAS: Can I ask just one other question, and this really has to do with research methodology, the other one was practice.

The folks that are working in it, have been involved in these Native American research centers that you have talked about, you have mentioned and I believe you completely, understand data, they understand research.

My sense is or my perspective is there is perhaps some value differences here in terms of what kind of data is useful and should be collected, and I am wondering if you could mention how that is managed in an NIH-funded set of centers, how has that occurred.

DR. VANDERWAGEN: Well, they just started the funding process, so we don't have an experience base to really rely on, but I will give you reflections from the Association of American Indian Physicians, many of whom have been researchers.

Walt Haller runs a program to train Indian

research fellows up at the University of Washington, and I think that the experience has been that they are willing to sort of push the limit, and not be constrained by what has been traditional qualitative or quantitative measures, even though I think for some people, that has led to some personal difficulty because their professional colleagues have a tendency to sort of say, well, now, isn't that just like what you would expect. I mean it is sort of a banana republic attitude, which is the way we have been treated as a federal agency, too.

I mean I am speaking now from the perspective of living inside an Indian world, and so that problem is there for people, how much are they willing to risk scientific credential, going with their heart and their society telling them is appropriate versus what the dominant mainstream, whatever you want to call it, society says is appropriate. So, it is a challenge for those researchers.

DR. JONAS: I guess it is something we should look at in great detail.

Thank you very much.

DR. GORDON: George, Effie, and Joe.

DR. BERNIER: Dr. Demakis, I want to thank you for testifying today.

Over the last three or four decades, the VA really achieved a place of enormous prominence in terms of its research. The classic studies on coronary artery disease, bypass versus angioplasty, really became the world standard.

With all that success behind the program, you, as an institution, have made the decision to pursue in a much greater way CAM. We have been hearing the last couple of days how hard it is to do something like that.

Do you have feelings about, one, how easy was it to accomplish, and two, what is it about the VA system that lends itself to such rapid change?

DR. DEMAKIS: Rapid change, I don't know.

DR. BERNIER: Quasi-rapid change.

DR. DEMAKIS: Most of the studies that we have here, that we have funded, as I said, have come from the investigators themselves, and I think all that showed you we have not been prejudiced against CAM, rather, we have taken every proposal and every grant on its worth, and it has to be rigorous.

Our cooperative trials are done in a very interesting way in the VA. You have to first bring up about a five- or seven-page concept paper, which has some of the background, why is this a compelling question you want answered, and if it is decided this is worthwhile looking at -- and many of the CAMs have been that way -- the VA, in their Cooperative Studies program, will then allow you to set up a committee of 10 to 15 experts from around the country, and they will pay for them to come together twice, face-to-face meetings, to put together a proposal that could pass merit review.

It is not surprising when you bring in 10 to 15 of the experts, there is about an 80 percent funding rate of those that get to that point, so that many of our cooperative trials that we have ongoing or have completed, have had the benefit of having this type of, shall I say, executive committee that put together the proposal, and they are very successful in getting done.

I think more basically, they have taken pretty much every proposal and every concept paper at its worth, and I think have been very good in not showing bias against any form of treatment.

I don't know if that answers your question.

DR. BERNIER: So, was it easy to do?

DR. DEMAKIS: Well, I have been here two years. The previous 27 years in the VA, I have been running after VA monies, okay? I have been on the other end of it in Chicago. No, it is not easy to do, but, you know, from some of the horror stories I hear other places, the VA is probably as good as can be and gives it a good-faith effort. It is rigorous, and it should be rigorous, it should be rigorous.

DR. BERNIER: And I am a veteran.

DR. DEMAKIS: I salute you, sir. I won't ask you which war.

DR. BERNIER: It was Vietnam.

DR. GORDON: One of the things I think I heard you say is in some ways it is easier to do research in the VA than most anywhere else.

DR. DEMAKIS: Oh, I think so. As I told you, first of all, we have a health care delivery system. We have one database, national database for all our hospitals, all our nursing homes, all our outpatient clinics, so it is very easy -- and these are all rolled

up in one place, Austin, Texas -- so it is fairly easy for us to do large studies, and not having to develop new databases each time.

DR. GORDON: And you are willing to bring together a committee of experts to help people develop their projects.

DR. DEMAKIS: These are for cooperative trials. These are traditional, you know, randomized, controlled trials that you heard so much about just before from the young lady from -- Cramer, right. We are experts in doing that. We have several centers doing nothing but that, and it is hard to do, but because of the way the VA is structured, we are in an ideal situation to do that, and we do quite a few of them.

We have five centers nationally, one in New Mexico, by the way, that do nothing but that, and they have data monitoring boards, they know how to do the randomization, they know how to do all that sort of stuff. It is a lot of work. You don't just dismember those things and start again when you want to do new studies. These are standing committees that do this.

DR. GORDON: Effie.

George, are you finished? I am sorry, I didn't mean to cut you off.

DR. BERNIER: I will wait.

DR. CHOW: Please go ahead and finish.

DR. BERNIER: I also worked in some of the VA studies, and I must say there was a time that the VA was extremely concerned that it was going to be dismembered, that it would be shut down.

It seemed to me that that was right at the time that the VA was approaching the crest of its outstanding clinical research programs, and I think it was the presence of those programs that deterred that action from happening, that is, to consign the VA medical system into ashes.

Is that from your perspective?

DR. DEMAKIS: I would like to think so. The VA has been a marvelous institution. I think where the troubles began with the VA, it was always a sacred cow, I am sure you have heard that before, but there were always a large number of veterans serving in Congress, both in the House and the Senate.

I think there came a time probably in the early

to mid-eighties where a lot of the veterans, congressmen retired, and so a whole new set of congressmen came in who didn't have the same allegiance to the VA.

Also, at that time, the eighties were more difficult, I think, the health care costs were rising and people asked why support a VA medical care program, why not just, you know, for a while the private hospitals were having trouble, why not just let them go to private hospitals and let Medicare take care of them.

But I think the research and the educational mission of the VA is what really saved it at the end, because there was no longer that hard-core veteran serving in the Congress, where we do have a very deep and very well respected research program.

Many of the breakthroughs that you mentioned, you mentioned coronary bypass, the treatment of hypertension, treatment of depression, I can go on and on.

DR. BERNIER: Nobel prizes.

DR. DEMAKIS: Nobel prizes. Unfortunately, a lot of people don't realize how deep and how impressive and how meaningful, what impact the VA budget, the VA

research has had on the care of not just veterans, but on setting the standard of care for the country.

DR. BERNIER: Yes.

DR. DEMAKIS: So, I think more and more people came to realize that and, of course, the medical schools were adamant, they wanted the VA because close to half of all medical students and residents are trained in VA hospitals, that the VA pays for, as a matter of fact.

So, I think a lot of our friends finally came out of the woodwork, and I think we have turned the corner. The bigger problem, of course, is there is fewer and fewer veterans, thankfully I guess, that means there are fewer and fewer wars, but we now have 26 million veterans.

That is a big drop from where it was about 10 or 15 years ago, and by 2025, if there is no new war, and hopefully, there will not be, the question is will there be enough veterans to sustain having a VA, and that is real question. Hopefully, I won't be around to worry about that problem.

DR. GORDON: Thank you.

DR. DEMAKIS: Thank you for those nice words.

DR. GORDON: Effie.

DR. CHOW: Some of the comments that I have had or questions have been sort of answered, but I really appreciate the two major sort of, I call it monolithic systems, that is outside of the main system, and the power that you have.

I had the pleasure in mid-seventies to explore the VA, guiding, you know, the potential national health systems that was coming out with the seven laws, John Kennedy's law, and all that, so I had the chance to kind of explore into the system. Also, I had the chance to deliver Chinese medicine to the Indians, teaching them through the system. So, I had great contact with them.

I am impressed, perhaps you can reconfirm, that if we had a study with the VA or the Indian system that proved to be valuable, that you can still move it to your different centers for multiple research.

That is what I was impressed with, that once you have one research carried out and it was proven well, good potential, that you have the power to move it and do multiple studies, and this is where I think the Commission here would benefit from having the alliance

with the system.

Now, is that so? You are nodding your head, but is this so? My question is would that be so with the Indian health care system, too?

DR. VANDERWAGEN: To the degree that Indian people themselves felt like they owned what went into the process up-front, then, dissemination or diffusion or replication is clearly -- I mean Indian people, as you recognize, are fairly pragmatic. If something seems to work, they are going to pick up on it and use it where it fits their needs.

So, I think the fact that we have decentralized in the way that Wayne talked about, and we are not a federal monolith, I mean the initial swing is, you know, give us the money and get the hell out of the way, I mean that is sort of one response that went on five or six years ago, but now the pendulum has swung back because people recognize the power of shared energy, shared resource, and shared emphasis, so that even though we don't have the top-down hierarchy, we now have the sort of lateral or horizontal diffusional mechanisms strengthened in ways they never were before.

DR. DEMAKIS: I would just say, too, in our case, we are able to diffuse research findings out to the field fairly quickly, either to make changes in our practices or, if we do a developmental trial or a demonstration project, and it looks very promising, we can then move it along to a large cooperative trial.

We had one of the first trials, in fact, in my hospital, one of my colleagues was the PI, that showed that hospital-based home care was indeed cost effective. From that, we made that into a large cooperative trial involving 15 large hospitals to take a look at that.

Unfortunately, we found out that that was not the case once you enlarged it and got a larger power, and that is the other reason why you do these randomized controlled trials.

At our hospital, one doctor was able to probably make the difference. It was a well-published study to show that hospital-based home care was quite cost effective, had good outcomes, et cetera.

Once you spread that into 15, 20 hospitals, however, we were unable to replicate that, and it probably was the fact that this one person was so

powerful -- probably the wrong word -- but so charismatic, was able to do it, and one person was able to show that, in her hands, hospital-based home care was cost effective, was better outcomes, the patients loved it better, but when you put it throughout the system, in large numbers, we found that wasn't true, and that is the importance of having randomized, controlled trials, and not simply taking, you know, one guy did a few cases and found this, and that's good.

The other thing I feel what we can do is we had a large study comparing two drugs for treatment of benign prostatic hypertrophy, obviously very common in the VA since 90-plus percent of our patients are men, a very expensive drug finasteride and a very cheap drug terazosin.

We put them head to head, and we did a large cooperative trial nationally and found that the cheaper drug terazosin was about 10 times cheaper than finasteride and much better.

What we did, we took finasteride out of the formularies of all the VA hospitals. The VA can do something like that. As a result, finasteride use went

down. Of course, Merck, which had finasteride, was not a very happy camper, and they helped fund the study, and they were quite angry, as a matter of fact, but that obviously was something the VA, we were research agency, found the finding, and were able to put it into our practice immediately.

DR. CHOW: Thank you.

DR. GORDON: Joe.

DR. FINS: Dr. Vanderwagen had a lovely phrase, I believe I got it right. He was talking about the moral imperative of not expatriating patrimony. It raises a question that I don't think we have ever thought of before, and I would like your comment on this, but it is sort of the protection of religious freedom, and whether, you know, regulating some practitioners in the context of the practice of a religious belief raises constitutional questions, you know, much bigger than whether a state medical board could regulate, and sort of like the Jehovah's Witnesses refusing blood.

I just wondered if you would like to comment on that speculation.

DR. VANDERWAGEN: Well, there is a law that

protects Indian people and their religious practices, Indian Religious Freedom Act. So, I mean there is a statement out there. As an agency, we fully comply. But there is a moral leadership principle that is involved there, as well, and when I alluded to the relationships with OPS and folks in Central and South America, I mean the globalization effect for Indian people oftentimes means expropriation of traditional practices, so a pharmaceutical company can create a profit engine.

That expropriation of patrimony becomes a killing blow. I mean genocide is still being practiced directly in many parts of the world on indigenous people. We stopped killing Indian people in this country 100 years ago or so, and there were 100,000 Indians left. Now there is 2 1/2 million. The new census may show us more.

We have achieved a large measure of self-determination as the principle that we operate within on a federal perspective with those people, but that is not true elsewhere in the world, so that that whole principle, the moral leadership is an important issue, whether it is a legal prohibition as there is in this

country or not.

DR. FINS: Can I just ask a follow-up question that your comment sparks? We heard earlier during the day -- at this point I can't tell you if it was in the morning or in the afternoon because we have been here all day -- but we were hearing that pharmaceutical firms looking for products that come out of indigenous communities, and I am just wondering if you have any thoughts about the appropriate recompense that comes from the hundreds or thousands of years of activity that have demonstrated that bark of willow could have some promise, and, of course, it became aspirin.

So, how can we think about the proper compensation, in what kind of ways, and who should we talk to, to make sure that these communities are rewarded for the inheritance, as it were, of all that hard work that had been going on?

DR. VANDERWAGEN: One of the problems is that you are talking apples and oranges because recompense to indigenous people often has nothing to do with material wealth. It has to do with freedom. It has to do with self-determination. It has to do with the ability to

control their own life and world.

I don't think we always attend to that, and that, to me, I mean it is a wellness of that society that becomes the challenge there. I mean we talk about complementary medicine vis-a-vis individual patient care, and that is important and appropriate, particularly in a society that values individuals as the core and the center, but we are a traveled society is the more important issue than individual care.

Wellness involves the notion of that population as a whole. Now, we call that public health in this country in some ways, and that is not a real popular way of viewing health in this country in general. I mean we are struggling to build back public health infrastructure that has been decimated over the last 20 years.

I mean it is a way of viewing what is wellness and what is our concern about the wellness of people, and while we may want to research the efficacy and utility of individual patient therapies, be they looking at the provider and their impact, be it looking at a particular modality and its impact, and so on, and my colleague from CDC articulated those questions very nicely, but what is

the wellness of people and what is our obligation to think about that. I mean that is an alternative way of looking at health, too.

Sorry for the sermon.

DR. FINS: No, I think that they are incredibly thoughtful comments that we have to really take into consideration and realize that the recommendations can have kind of downstream effects that could be unintended, and I think that we would probably need to dialogue with Buford and yourself to make sure that it is culturally appropriate and it is sensitive to all the important points that you raise. So, thank you very much.

DR. VANDERWAGEN: I think you have attended well in the distribution of people that you have in this group in some measure at least to reflecting that the tradition that gave us allopathic medicine is not the tradition that affects the majority of the world, so reflecting that in the makeup of this body is an important piece.

DR. GORDON: Wayne has a question and I have a brief question. Are there any others around the table?

My question that I will ask briefly is, has

there been any research done on Native American church and the use of peyote?

DR. VANDERWAGEN: I am not aware of any specific studies done other than maybe Don Jinero [ph].

DR. GORDON: This is an issue that we may take up in a future panel, but since these plant medicines are used as sacraments and as healing, they have a tremendous potential it would seem for healing particularly in conditions we might call psychological or spiritual, and I am wondering if you have thought about it and what obstacles you have run into if you have thought about it or if the leaders of the Native American church have thought about it.

DR. VANDERWAGEN: Let me feed back a thought. Again, there are people that Buford and I could recommend to you to talk to in the Native American church directly, and I think you need to talk to them directly because I can't speak for them.

But it would be like asking Catholics to assess the efficacy of participating in communion.

DR. GORDON: That is happening.

DR. VANDERWAGEN: Well, I mean that is fine,

but I think you have to market it in a very different way than talking about it as scientific research per se.

DR. GORDON: Actually, there is very interesting research going on in South America of indigenous communities using Iowaska, and using Iowaska for healing a variety of different conditions. So, that is why I am asking in that context.

I would like to know the names of people whom we should get in touch with.

DR. VANDERWAGEN: That is part of the popular initiative I think, too, and there is a partnership for you with those folks because part of that indigenous initiative has to do with --

DR. GORDON: I am sorry?

DR. VANDERWAGEN: -- part of that support that they provide for the indigenous initiative is to try and support those very kinds of issues, convincing the allopathic practitioners in Central and South America that their Indian neighbors may have useful practices.

DR. GORDON: Thank you.

Wayne.

DR. JONAS: I think that getting at the

cultural perspective in terms of research is extremely important because we clearly have a very dominant paradigm and an important one, that there are particular substances that produce effects, and we want to know what those are, and that type of thing.

I will never forget, however, the comment of someone, and I do not remember his name right now, but he was a traditional practitioner, a Native American practitioner who was sitting on one of the first ad-hoc OAM advisory groups. This was before they had officially established an advisory group, and we had this large discussion about placebo and placebo-controlled trials, specific agents, et cetera -- and he sat there for a long time listening to this elaborate set of comments, and then somebody said, well, how is this dealt with in the Native American community, and he said, well, let me tell you about how we deliver medicine.

So, then he described that he had a patient in which they had very serious acute, a blast crisis, with acute myelogenous leukemia. They went through a ceremony and put together a concoction, et cetera, et cetera, et cetera, and delivered it to the patient, and they got

well.

People around the table then -- he kind of paused -- people around the table looked and said what was in it, and he said it was Kool Aid. He said all of our pills have eyes and ears, and I will never forget that phrase.

DR. VANDERWAGEN: It was either Paul Ortega or Edmund Attachi [ph], and that sounds like Paul more than Ed.

DR. JONAS: Thank you. I couldn't remember who it was.

DR. VANDERWAGEN: Again, that goes to the great belief in the power of the healer and the attention beyond physiology. I mean when we look at allopathic remedies, we are inevitably dealing with molecular biology and physiology.

That is a biological phenomenon. But in an Indian environment, [Indian language], the way it is in Zuni, there is the holistic concept that I have heard people talk here, and the question that Effie asked Dr. Segal, I think, from Kaiser, what about mental health interventions, counseling, and that sort of thing, well,

I mean there is the mind, the body, the spirit, and you have to get all that really, and that is what Paul is speaking to.

DR. GORDON: Yes.

DR. DEMAKIS: Unless somebody has any direct questions to ask me, I would like to enter into the spirit of this a little bit. At the beginning of the Christian era, there was a large body of people who felt that Christians should not go to doctors, the belief that Jesus Christ not only saved souls, but saved the body, as well.

In the West especially, in the Catholic West, this was very, very common. In the Christian East, however, they sought to look to how to bring the science of medicine and the belief in God, the spirituality together.

In a very beautiful book by Timothy Miller called "The Birth of the Hospital, the Byzantine Empire" sort of chronicles the development of this attitude of how science and medicine and spirituality can go together. I would suggest you might want to take a look at that. Many of these things we are arguing over, or

maybe not, arguing is the wrong word, but discoursing together really is not new.

It is a very old, old thing, and you might want to take a look at how the Eastern Christians of that time solved the problem of trying to wed science, at that time, which was the cutting edge what they had, whatever they had, with spirituality and belief in a higher being.

I think it is done in a very beautiful way. Of course, that empire was destroyed in 1453, but up until that time, all their hospitals had chapels, many of their first doctors were monks who indeed practiced spirituality, as well as giving medical care.

DR. GORDON: By Timothy Miller, "The Birth of the Hospital"?

DR. DEMAKIS: It is called "The Birth of the Hospital; Byzantine Empire" by Timothy Miller. The second printing has just been out about three or four years, they reprinted it.

DR. GORDON: Thank you.

DR. DEMAKIS: I think it you might find it sort of covers medical care from ancient Greece to the incubation, that sort of stuff, up to modern times. It

gives you a different insight.

DR. GORDON: Those are our questions. Thank you very much for sharing your experience. I would very much like it, Dr. Demakis, if there is a list of research, could you give that to us, that is being done in the CAM area at the VA? I think that would be very helpful.

Also, Dr. Vanderwagen, if you have any other suggestions about ways that we might -- I mean I think this was a very interesting discussion -- any other suggestions about ways that we might think about approaching Native communities and talking about research issues.

DR. DEMAKIS: All of our research, by the way, is up on our web site, VA.gov/restev. All of it is in there, I don't think it is categorized the way you want it.

DR. GORDON: Thank you very much, and I want to thank the Commission members, all of you who are here and all of you who have stayed through to the very fruitful end.

We will see you in the beginning of December,

if not before.

[The meeting was concluded at 5:45 p.m.]

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CERTIFICATION

This is to certify that the attached proceedings

BEFORE: White House Commission on Complementary and Alternative Medicine

HELD: October 5-6, 2000

were held as herein appears and that this is the official transcript thereof for the file of the Department or Commission.

SONIA GONZALEZ, Court Reporter