I have met this eccentric, controversial, crazy dentist, who thinks he can cancer with pancreatic enzymes. He has been universally vilified in the press. He has been arrested. There is absolutely no reason why I should believe that what he does works, except he does seem very sincere about wanting to have his work tested.

This was before the Best Case Series concept. Dr. Goode was always willing to support controversial areas of research and that eventually led to his demise at Sloan Kettering and he suggested I begin this as a student project. What began as a simple summer's project eventually developed into a five year research project, which I completed while doing my immunology fellowship under Dr. Goode, who by that time had already left Sloan Kettering.

This was a very exhaustive investigation. It wasn't done in a cursory fashion. I think in many respects represents the first academic, Best Case Series or best case evaluation of an alternative therapist, who is doing things outside the academic mainstream.

I went through 10,000 of Kelly's records, evaluated over 500 of his cancer patients in detail, got

full medical records and put my findings together in a 500 page monograph. One of those patients, whom I mentioned earlier today, was a lady with biopsy-proven pancreatic adenocarcinoma with metastases into the liver. The liver nets were biopsy-proven at the Mayo Clinic.

She was told she had six weeks to eight weeks to live in 1982. She is still alive. Two weeks ago, as I said earlier, referred a patient to me, 18 years later. I know of no such patient in the orthodox medical literature. If you can find some, please let me know because I have been unable to do so.

I thought that having done this five year expedition under Dr. Goode's direction, he was at the time the most published author in the history of medicine, I would have no trouble getting it published. Boy, was I foolish. I spent two years trying to get this study published. I was universally attacked. Robert Goode at the time was up for the Nobel Prize. He w as sent letters from editors saying that his involvement with this kind of garbage would jeopardize his chance of winning the Nobel Prize, that he should dissociate himself completely.

When I finished my fellowship training, I left his group because I could see the writing was on the wall. I came back to New York. Dr. Kelly gave up, closed his practice, figured his work would never see the light of day and I very cautiously or perhaps insanely began to treat patients with enzyme therapy myself in New York.

My 1993, the National Cancer Institute had begun to investigate alternative therapies and I was one of the first people invited down there to present a series of cases as part of their initial attempts to evaluate non-traditional therapies. On July 7th, 1993, I came prepared to present 25 cases, which I did. It was a three to four hour session.

Wayne Jonas was there. It was kind of an interesting panel. There were at least 20 people there. One of the cases I presented, and I can use his name because he is going to be actually on the Discovery Channel, they are doing a piece on him, Mort Schneider, who had metastatic pancreatic cancer with four tumors in his liver, two tumors in his adrenals, metastases into his lung, all biopsy-proven, diagnosed in September 1991.

Now, at the time I presented at the NCI, his tumors had not regressed. They had stayed the same. At that time, the definition of a response was a 50 percent reduction in tumor size that lasted four weeks. I argued that the NCI had to start considering quality of life as well as survival, in addition to this arbitrary designation of a 50 percent reduction that lasted four weeks.

Mort Schneider is still alive nine years later. In 1997, we repeated his scans and all his tumors were gone. As a result of that presentation, the NCI suggested I do a pilot study with pancreatic adenocarcinoma, the thinking being pancreatic cancer is the worst cancer there is. If I could show any response at all, people would take it seriously and the NCI would take it to another level.

Michael Freidman, who at the time was associate director and suggested the pilot study, said if I could get three patients out of ten to live one year, he would be impressed. We were fortunate at the time that the Nestle Corporation became interested in funding some research of my work. Their medical appeared yesterday,

the former director of the Pasteur Institute, had done a case review in my office. He spent two days in my office and went through hundreds of cases.

There is a reason I mention that specifically. He invited me to Switzerland. I presented to his senior scientific staff just about the same time the NCI suggested I do a pilot study. On the basis of that presentation, Nestle agreed to come up with the money to fund the pilot study, which we began in 1994.

Eventually we had 11 patients in the study. Eight out of 11 were biopsy-proven in Stage 4. The other three were biopsy-proven in Stage 2, but inoperable. They were all very sick patients. Of the 11, 9 lived one year; 5 lived two years, 4 lived three years, 2 surpassed four years. One died at five years from a heart attack. To put this in perspective, in the clinical trial of Jim Seidebene of 126 patients, not a single patient lived longer than 19 months and only 18 percent lived one year.

We published that in Nutrition and Cancer in June of 1999. As a result of that publication and that study, the NCI suggested that we do a large scale randomized trial. Now, Wayne and I were talking about

randomized trials before. I was against the idea of a randomized trial for the simple reason I wasn't sure it was going to work. There was already so much interest in my work, I figured patients who are interested in my study would want to be in my arm. That is exactly what happened.

After trying to get the clinical trial to work for years in randomized study, of course, for the non-scientists in the audience, a randomized study simply means patients who agree to go into the clinical trial, have no choice of treatment. In this case, it was a two-armed treatment. It was my therapy versus Jim Seidebene and the latest chemotherapy approved for the treatment of adenocarcinoma of the pancreas.

Since no one lived 19 years and my preliminary pilot study had shown good results, out of 260 patients who expressed in the study, only three agreed to be randomized, two when they were assigned to chemotherapy dropped out of the study and the other one who was assigned to me, decided she didn't want to do anything and quit the study. So, it was really not working.

Eventually, working with the NCI and the NIH

and the National Center for Complementary and Alternative Medicine, who actually put up the money, we agreed to make it a case control study. So, this is an example of some of the difficulties you face when trying to do rigorous scientific study.

The reason I mention the fact that I was flown to Switzerland to present to Nestle, the very day I was in Switzerland presenting to Pierre Gastri's [ph] group was the very day the medical board served my office with a subpoena announcing they were going to try and close my office down because to sum it up in non-legalese terms, I basically represented a subhuman pond scum that was, you know, taking money from unsuspecting cancer patients.

All the time while I was trying to present my work and getting funding and doing clinical trials, the medical board relentlessly tried to basically close my office down. We eventually prevailed. It is an interesting situation to be an alternative practitioner, particularly since I come out of an orthodox research group.

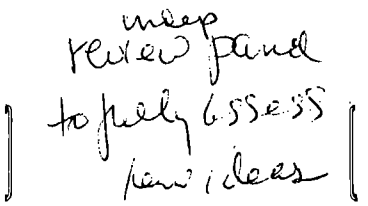
It is a very dangerous world out there. In the State of California, it is a felony to treat a cancer

patient with anything other than surgery, chemo and radiation. Interestingly enough, they left off immunotherapy. I have not heard of anyone getting arrested for using Interleukin and Interferon. Had I treated Mort Schneider, that pancreatic cancer patients who was night years out, in California, I would have been guilty of a felony and we could be in jail right now.

The reason I bring all that up is Jim said what can we do. You have an extraordinary opportunity, an extraordinary mandate, to help develop and protect new ideas.

The essence of the democratic society, of course, is the protection of new ideas. One of the characteristics that you commonly find in all tyrannies is they legislate scientific truth. The California law is an attempt to legislate scientific truth. I think it is extremely dangerous.

What can you do practically? I think you should serve as an forum, that if an alternative practitioner or any scientist thinks that he is being harassed unfairly because he has a new idea, he should be able to come to you as an independent group. What power


review panel
to help assess
new ideas

do you have? There isn't a state in this union that could survive if the federal government shut down Medicare or Medicaid funding to that state. The economies of these states would collapse.

Yes, I understand the separate of state and federal government, but you have enormous power in the state. Certainly you should use that power to help protect new ideas. I don't think there is a more noble effort than that that any of you could do.

Thank you.

DR. GORDON: Thank you very much.

Next will be Dr. Ann McCombs and Dr. Devi Nambudripad. They will share the time, as they share their work.

DR. McCOMBS: Thanks for staying so late to hear what we have to say. I know you are exhausted and we are happy to be able to talk to you today.

You want to know some of the obstacles. I think Nick summarized them extraordinarily well. The first time I have actually gotten to meet him was in June of this year, although we have talked on the phone several times when I have consulted him about other

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DR. McCOMBS: Thanks for staying so late to hear what we have to say. I know you are exhausted and we are happy to be able to talk to you today.

You want to know some of the obstacles. I think Nick summarized them extraordinarily well. The first time I have actually gotten to meet him was in June of this year, although we have talked on the phone several times when I have consulted him about other

patients over the years.

I was involved in the American Holistic Medical Association meeting in Seattle in 1994 and putting that on and he couldn't even come then because the medical board said you either be here on this day or you won't have your license. So, we didn't get the benefit of hearing him at our conference, right on the spur of the moment, two days before, we were supposed to hear him.

That is a very real outcome of what we face as practitioners in this day and age. I mean, exactly what he is talking about is the fear elements that all of us face. Dr. Mildred Paz [ph] from California, she is exactly in the milieu that he described in Washington. I am not in much better milieu myself there.

When I treat cancer patients or I use these kinds of CAM therapies, I do them very quietly. I do them behind closed doors and I do them only with patients that I trust, who, hopefully, it won't be a problem for. I let them know right up front there is no research information that I can actually show them, but that I have had good clinical outcomes and on the basis of my relationship with them as their physician, they come.

They get treated and they get well and I tell them to be very quiet about it and don't tell anyone because I can't afford that. I don't want to lose my license.

At least in one case in our state, we were all reminded that having a medical license was a privilege not a right and that the medical board could take away our license just because they want to because it is not our right just because we have been through medical school. It is only a privilege.

So, money, time and fear. Those are our obstacles in a nutshell without going into a lot more data. Insurance reimbursement is a huge, huge factor right now. It doesn't matter what we do. We can code using the CPT codes. We can do all the things that we have been trained to do. It doesn't make one bit of difference. If they want your chart notes, they see what you are doing, they will cut the reimbursement to the client off without anything else. Your name goes on a list. My name is on a list certainly in my state and all over the country because I treat patients all over the country. As soon as they see that my name is on the list as the physician, my patients won't get reimbursement.

So, that limits what I can do to the people who can afford my care. That is not why I went into medicine, at all why I went into medicine. You know, I didn't go to Cornell. I didn't do the research track that Nick did. You know, would have loved to. Now I am interested in practice-based research. I know that we can do it. I know that with some help we can present a research paradigm that will work and with Dr. Nambudripad, it is a very simple technique, non-invasive and we have, you know, a practitioner network of 4,000 practitioners and growing, but she trains practitioners every other month to do this very, very simple technique that works across many diseases, all the way from any kind of allergy component, all the way to cancer. I will let her speak about that.

So, our needs really are for people to be open minded about the approach that we use, to be able to think outside the box and to really look at the methodology that we have come to in a way that diagnoses and treats, that is different from what we were all trained to in school. I have had to get a whole new practically degree in complementary and alternative

medicine since I got my degree in 1988, but you know why? Because for the 15 or 20 percent who never get well, under the way I was trained. I don't want to practice medicine like that.

Medicine, I can't do it in seven minutes. The managed care issue is a very big real issue in practice-based medicine and I am not interested. I would rather not be a doctor than to do managed care. That is blatantly how I feel about it.

I don't like the fact that I can't treat Medicare patients because it doesn't come under Medicare guidelines. I don't like the fact that I can't work in the low cost clinics in which I was trained, in which the medicine I did with my hands as an osteopath and maybe that was all I could do for them that really did help. I a restrained in that way and I feel constrained.

We need sort of that kind of open mindedness. We feel that we would be protected as practice-based physicians if we had the blessing of the federal government, of the state government. I don't care where we get the blessing from, as long as somebody comes out and says you can do this. It is okay. Nobody can take

your license away. Now have at it.

We would like to put it through our 4,000 practitioner network and we would like to ensure them that if they participate with us and do this, that their licenses won't be in jeopardy either. I don't have time. I am not going to be able to mastermind this research, except between 2:00 and 4:00 a.m. in the morning. I am too busy treating patients, who fail therapies all over the country and who come to me through my back door and that I have to treat quietly and I would like to be more open about what we are able to do.

So, that is what I have to say and I want to turn the rest of the time over to Dr. Nambudripad.

DR. NAMBUDRIPAD: Thank you for inviting me here. This is a surprise. Life is full of surprises for me lately.

For the past few years, 17 years, I have been treating patients for allergies. I am a chiropractor from California and I am an acupuncturist. My license is in California. I am not supposed to treat cancer and I don't treat cancer. Patients come to me with allergies and I happen to treat them and this is a technique I

learned 17 years ago and you can eliminate the allergies and they don't come back. They don't cause anymore problems. I look at everything with my eyes, with a narrow tunnel vision for allergies.

So, when I treated these patients with a cancer with allergies, their cancer went into remission and they started getting better and then the word started spreading and I do train a lot of doctors. It is not only me. Everybody else can reproduce the same kind of results. So, that is where the word got into. They asked me to come and present Best Case Series in last June.

Since I don't treat cancer, I cannot have a Best Case Series. If I treat cancer as everybody else mentioned, I will get into trouble. I don't want to step beyond my scope of practice in California. So, that is one of the biggest obstacles I have there because I cannot treat anyone for cancer.

If the side effects of allergy treatment will be getting better on the cancer, that is the only way I can present a case here. So, that is one of the problems I am having about treating cancer. There are so many

patients who would like to come and get treated if I had a chance, if I had another station to do that.

We work very hard, of course, and you have to come up with a lot of money to hire someone to do all this work for us, the writing up and publishing and et cetera. I did do some studies on my own, just to prove it to myself how this will -- am I imagining this or is it really working. So, I did a study, a milk study and an egg study and a cholesterol study and a few other studies. I know that they work. I haven't published. So, I don't have any published to present.

Anything else Ann wants to add, she can add.

DR. McCOMBS: We have provided you with some information that is very similar to exactly the kind of information that Dr. Beard, you know, was suppressed after 1923. I just happen to have had a mentor from Germany. So, the information I gave you was from Reckeweg, from Germany. Reckeweg's research was known there. It wasn't known here very much. This book just got translated from German into English. So, you wouldn't have even had a opportunity to learn about that.

I happen to have a German mentor and I took

German in college. So, I learned a little bit about it myself. But this kind of thing is just not readily available to practice-based people until, you know, the Internet, for example, the advent of the Internet. You have patients come in and they say, you know, Dr. McCombs, what do you know about this? For the most part I don't know.

You know, if I happen to have time to be on the Internet, I might know and I certainly try to take the time I can, but then it stimulates me to find out more. As I said, the people that lead you by the nose are the ones that don't get well. That is that 15 to 20 percent that you always want to help because they are outside of that bell curve. It is the people that we are treating, you know, we can certainly treat within the bell curve, but it is those people on the fringes, you know, who are on either side of the bell curve that we end up seeing day in and day out in chronic pain and chronic illness.

DR. GORDON: Thank you.

Dr. White, would you like to say a few words?

DR. WHITE: Well, thank you. I actually didn't prepare any specific comments, but I could react to some

of the things that I have heard.

I actually did wonder why I was asked to speak in this session about the interface between CAM research and regulatory agencies. I thought, well, it sounds like an FDA type issue. I think it is becoming much more clear to me why you asked me to come to this panel. It perhaps may not be of as much value for you as it perhaps is for me to hear some of these issues.

But I would still like to offer some ideas about things. I am certainly more aware of Nick's situation since we are directly involved in research together. But the other issues that are raised, it is important for me to become more aware of them. The Best Case Series program is what we have been partly talking about and what Nick did allude to, one of the programs that he did get involved in. The program is very dependent upon practitioners feeling comfortable presenting documentation of their practices to us, to the federal government.

We do go through great efforts to try to keep this information confidential. When it is reviewed, it is reviewed in closed forum so that we can talk about

patient identifiers and not have all that information aired to the general public. But many elements of the Best Case Series are open to the public.

I have been somewhat unclear about the degree to which these kinds of concerns that Dr. Nambudripad is raising and other issues that Nick has expressed, the degree to which these have affected the flow of submissions to the Best Case Series program.

Basically, our approach has been to try to have it become better known among CAM practitioners. It has really been an unadvertised program until about the past year. So, we are trying to get it better known. But I think that will certainly not affect these other issues that were discussed. So, I would be happy to explore with you ideas about how issues about regulation could help the Best Case Series program become more productive.

The second thing we didn't quite mention it here, but it is about INDs, I wanted to at least mention that. I have recently become more aware of the problems with getting INDs for certain herbal products and the degree to which that has inhibited some cancer research.

Well, it is an issue that we are planning to

have a meeting with the FDA to explore more fully and with the guidelines I think it is certainly the right time to be discussing this. But I do have concerns that I would like to learn more about what these problems are.

Some very high quality cancer researchers have had some difficulties getting INDs for products and I think it is just an issue that we need to explore more. The third thing was about expanding safety and efficacy of CAM products, one of the issues that you asked us to address. I think basically we are providing funding through certain mechanisms to try to improve at least that side of the equation. We have an RFA, request for applications, out to the comprehensive cancer centers to support developmental research. So, this is research that doesn't really require a lot of previous data.

So, it would be amenable to bring along projects that deal with products with very little in vitro or previous human data. These are just some general ideas. I will leave the rest of the time to respond to questions.

DR. GORDON: Great. Thank you very much for coming. We appreciate it.

So, questions that anyone would like to raise? Yes, Joe.

DR. FINS: Dr. Gonzalez, I just want to ask you one question. These are enzymes that are taken orally? Yes.

DR. FINS: As proteins, why aren't they --

DR. GONZALEZ: Why aren't they destroyed in the gut?

DR. FINS: Right.

DR. GONZALEZ: The first paper proving that orally ingested pancreatic enzymes are not destroyed in the gut but are absorbed intact goes back to 1976 in a Science article. We have a whole pile of papers. In fact, there was a conference in 1994 in Germany on the oral absorption of pancreatic enzymes, an entire conference devoted to that.

There was a very basic study done in Leningrad in 1980, where they took trypsin and put it hydrochloric acid and boiled it for an hour and there was no loss of activity whatsoever. It isn't destroyed by acid. It is absorbed -- they are both active transport mechanisms and passive diffusion mechanisms for the absorption of

proteolytic enzymes, even though they are big molecules. That has been documented carefully.

DR. FINS: Okay. The second question is your story here is really as a personal narrative very compelling and am just wondering if you had to do it all over again, looking forward to, you know, future Dr. Gonzalez's, who are going to have similar kinds of problems and are looking for the kind of confirmation that you are hopefully going to achieve with this collaborative effort, what would be the role of a basic science model, animal models, more preliminary studies? Would you have done it differently and not done it in a clinical trial mechanism but more to try to prove it in a different, less threatening way, in a more incremental way?

DR. GONZALEZ: Oh, I would have voted 100 percent to do it in a nicer, simpler, easy, less threatening way. Unfortunately, as Dr. Straus said quite eloquently, a lot of these developed out there in the fringe, away from the academic centers on patients without any documentation of animal studies, but in terms of pancreatic enzymes specifically, there are animal

studies that go back 100 years. There was an animal model for cancer, the Jansen sarcoma model, at the turn of the last century, that Dr. Beard used very effectively and published his results.

There are studies from 1965 showing that orally ingested pancreatic enzymes in the CH-3 mouse model do protect against carcinogens. There is a lot of animal research. It has just been ignored. One of the reasons it has been ignored is pancreatic enzymes cannot be patented. No drug company ever took up the cause. I think if it had been a patentable substance, pancreatic enzymes would be used in every major cancer center in the world today.

DR. FINS: So, you are saying its market forces not solely disbelief of the science?

DR. GONZALEZ: Animal studies have been done.

Oh, I think along with the market force goes a disbelief in the science. Because it has been marginalized, along with that goes, well, it can't be true. If it were any good it would be used. The fact of the matter is when I got interested in this and started looking through the medical literature, I found animal

studies eloquently done, properly done studies in the major literature confirming that pancreatic enzymes have an anti-cancer effect, proving that they are absorbed, all of these issues that you have raised, completely ignored.

That is why you folks have such an extraordinary opportunity to help nurture new -- forget my idea, but there are other new ideas out there that need nurturing that didn't exist when I started doing this. I worked under the former head of Sloan Kettering. It didn't make a darn bit of difference. In fact, it was even used against him. It was going to jeopardize his chance for getting the Nobel Prize.

DR. McCOMBS: I would like to add to that. The first time I heard about pancreatic enzymes was in 1994. I was at a conference in Mexico. I spoke to the researcher, who was from Germany, who was at that conference as well. The conference was held outside of the United States so that we could talk, so that we could actually talk freely.

The woman from Sweden, who had done the original research at Karolinska Institute was there,

people from NIH were there. There were people from all over the world who were there. We could not hold this conference in the United States because of the fear of what would happen. Pancreatic enzymes at that time from Germany, which were the only ones we could get a hold of then were being sold on the black market for an exorbitant price.

I had a pancreatic cancer patient, who could not afford that. There wasn't anything I could do. I knew about the research. Nothing I could do about it because we couldn't get it in through the FDA.

DR. BERNIER: I would be very curious, what other kinds of tumors has it had activity against, other than pancreatic?

DR. GONZALEZ: In the Best Case Series we did of Dr. Taylor, we looked at 26 different types of cancer. That includes some subdivisions of the various lymphomas, but we looked at both epithelial and bone marrow tumors, such as myeloma and leukemias. It seemed to work across the board. In my own practice, I have treated everything from glioblastoma to acute leukemias with effect.

We are using it in pancreatic cancer for the

clinical trials, only because pancreatic cancer is considered to be the worst cancer; maybe acute myelocytic leukemia is a little bit more aggressive. But that is why we are using pancreatic cancer, but they seem to work for just about any cancer.

DR. BERNIER: It has been as efficacious?

DR. GONZALEZ: Yes. Admittedly, with something with like acute myelocytic leukemia, there is such a narrow window of opportunity to get them started on the program. You have to move real fast. I probably have 250 patients with breast cancer in my practice, ovarian cancer, colon cancer, metastatic colon cancer, lung cancer.

DR. BERNIER: Myeloma?

DR. GONZALEZ: Myeloma, yes. In fact, I presented a myeloma case to Jeff just last week in my office. He was in New York and I presented a six year survivor of myeloma. They want to do a bone marrow transplant. Never had any chemo or radiation or anything like that.

DR. BERNIER: That is great.

DR. GONZALEZ: Thank you.

DR. GORDON: Effie and then Bill and then Wayne.

DR. CHOW: I am also touched by what you have reported.

One simple question, is Dr. Kelly alive?

DR. GONZALEZ: He is alive and he is on the Internet ranting and raving that I am part of an international scheme for the CIA to steal his work. In 1987, after all the stresses, he really went off the deep end. He is clinically paranoid. I mean, he was arrested at gun point in front of his four adopted kids at midnight. I mean, the authorities when they want to harass you, they know how to do it really well. They would do everything they could to humiliate him. They would drag him in handcuffs in front of his neighbors.

Thirty years of that finally got to him. Those were the days, again, where if you mentioned nutrition and cancer in the same sentence, you were in serious trouble. It just got to him. I have nothing but -- it is a very sad story.

DR. CHOW: It is a sad story. Is he pleased now?

DR. GONZALEZ: Oh, no. He is beyond being able to be pleased or to be happy. He is beyond that. That is why I said when I began this talk, this is a story of trying to keep a good idea alive without giving myself credit because I didn't invent the idea. I am just trying to keep it alive.

DR. CHOW: I have just one more question.

I don't recall you saying whether this is being used now, I mean, still being researched, but it seems a shame that so many people are dying of pancreatic cancer. Is it available to be utilized?

DR. GONZALEZ: This is not a gratuitous offer. You are all serious invited to come to my office and spend a day and watch my staff deal with the hundred calls we get sometimes a day from desperately ill cancer patients all over the world that I could not possibly see because there is only me and my colleague, Dr. Linda Isaacs and we don't run an assembly line. We will spend four hours with a new patient. We can see maybe two or three new patients a day.

We will get 50 calls a day. Just this week we turned down a 32 year old woman with three kids, who had

a bone marrow transplant for breast cancer and ended up with cancer everywhere. We just can't see her because we are booked and I have to come to a conference like this. So, we are turning her down. She is hysterical because it is like her last chance.

So what we need out there, Jim, and all of you is we need help. There are people like myself and Ann, who are trying to do really serious work and we need help. It is a tragedy.

DR. CHOW: You need to develop a training program.

DR. GONZALEZ: That is right.

To answer the second part of your question, it is only available in our office and the reason we are doing it is because I was trained in research. I believe in research. I don't want this to be out there until we prove it works by the strictest standards of orthodox medicine. What I have wanted from the day I began researching this under Dr. Goode at Cornell in 1981, was to do appropriate clinical trials. That is the way I was trained. I expected to spend my entire life in basic sciences.

I believe in the scientific method. It has taken 19 years. That is okay. But the tragedy is when you sit in my office and sometimes I can't sleep with the patients calling, begging for this therapy. The enzymes we use are not commercially available. If we did that, you know, you are inviting trouble, but I also believe we have to prove it works first, but it is a terrible dilemma.

DR. CHOW: But there must be a balance, though, you know, because the traditional method is accepted, but they are having side effects and everything. With things like this working, there must be a balance where you can continue research and then be able to utilize it.

DR. GONZALEZ: Well, we are treating patients in a private practice situation. It is just we are just limited by how many patients we can see. Yet, we don't want to start training doctors because it is like putting the cart before the horse. First, you want to prove a therapy works before you start training doctors.

You know, I think that is appropriate. We could have training seminars. I am not criticizing my colleagues for doing that. We have decided not to do

that. We want to prove it works. When we prove it works, we are begging for the NCI and the NIH to help us to get it out there. I mean, if it works, it should be and we will need help because, you know, we are just two doctors in my office. We don't have the capabilities or the resources to do that.

DR. FAIR: Nick, I am sort of curious as to why this was not picked up, say, in Germany or some other countries. We heard about all the herbal research being done in other parts of the world. I know pharmaceutical firms are often farming out their clinical trials to other countries, where it may be easier to get it done.

Why hasn't this been picked up in some of the German clinics using chelation and --

DR. GONZALEZ: They do use pancreatic enzymes in German clinics. There is a German formulation called wobenzime [ph], which you might have heard of. Without getting into the criticism of their enzyme preparations, what I think is Kelly really perfected the therapy and he really perfected it as an oral therapy. Beard only used injectable enzymes, believing that they would be destroyed in the gut. One-hundred years ago, that is

what they believed.

Kelly perfected it as an oral therapy and really helped develop an oral preparation of enzymes that just isn't available anywhere else and he became an expert in enzymes. I have had to become an expert in the manufacturing of enzymes. We have actually spent the last ten years perfecting the way to manufacture enzymes to protect their anti-cancer effect. Most pancreatic enzymes available in health food stores or drug stores are there to help digestion.

No one even things of them as an anti-cancer element and the way they are made, the processing technique that is used destroys a lot of the co-factors necessary for a major anti-cancer effect. We have had to figure that out without any resources.

So, there are enzyme preparations available in Germany. They don't know how to use them right. It is not as sophisticated a therapy as Kelly's. It is a very complicated issue. Like any good therapy, it is a complicated issue.

DR. LOW DOG: [Comment off microphone.]

DR. GONZALEZ: Oh, was that the question? I am

sorry. I answered the wrong question. That is okay. Maybe you learned something from the wrong question.

DR. FAIR: That was my question. Why not use your enzymes in Germany?

DR. GONZALEZ: Oh, I see. No one has asked me.

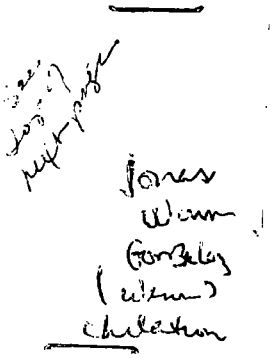
DR. GORDON: I think the other thing that is important to point out is that yours is a comprehensive therapy. It is not just the enzymes. It is individualized diets. It is detoxification.

DR. GONZALEZ: Oh, yes, it is a complicated therapy. It is not just using enzymes. Yes, the enzymes have an anti-cancer effect. The animal studies deal only with enzymes. Beard used only pancreatic enzymes. Kelly enlarged it to diet, accessory nutrients, specific diets for each patient. It is a very complicated therapy. I think that only increased its efficacy. I don't think they are just window dressing it. I think it really makes a difference in using pure enzymes.

But the simple answer is no one from Germany has approached me to do that.

DR. GORDON: Wayne and then Charlotte.

DR. JONAS: We started with a book on



scientific opportunities and public need and talked about setting research priorities and how do we do that. We talked a lot about the public and praised the importance of making sure NIH is involved in the process. What I hear, and I am very saddened actually by the diminishing energy at the end of the day, when we hear this in retrospect and everything is better in retrospect. Perhaps this should have been first and I think we even had discussed that, because the individuals who are setting the priorities in these areas are not sitting here to hear this.

DR. GORDON: That is right.

DR. JONAS: I would suggest that one of the things that we might, except for one individual -- I think it would be very useful for us to hear not only the importance of public input into the prioritization process, but practitioner input into the prioritization process. How can we do that?

In an ironic twist, this is also the suggestion that I made to Dr. Winn, who doesn't feel like they have had much input into getting chelation tested, for example. So, if there were some suggestions that we

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could have, again, it is going to have to come from multiple, but at least from you all and also from others that we talk to about how to do that and about the type of research that would be important and the issues that go into setting priorities.

I think this would be key. Related to this -- you want to respond to that and then --

DR. McCOMBS: I do want to respond to that. I think that is an excellent point that you are making and one of the things, for example, that we are looking at is looking at the United States public health departments list of the top 35 public health problems and addressing those particular issues and, you know, aiming our therapies to that, you know, that group of top 35 ailments, shall we say, that are problematic for every United States citizen, much less any person in the world, but in our country in particular.

That is one way that I think that we as practitioners can look at that. A second way, I believe, is that we have to be able to, as I said earlier, think outside the box. When I couldn't get these enzymes in 1994, I just started thinking of other possibilities.

When I can take an ovarian cancer patient and see her one time, treat her using the therapy that I learned from Dr. Nambudripad in 1994 and on Monday she goes to surgery and they don't find the cancer, it gets my attention.

I have to say what happened and why. These are the kind of things we need to be researching because if it is working, we need to be doing more of it.

DR. JONAS: Thank you very much for that. I think we are going to hear probably tomorrow a bit about attempts to do this, attempts to actually bring these things together. But my suggestion would be that if the practitioners can help us in terms of saying what types of methodologies provide the information they think is important, again, since we are focused on research methodology.

Nick, I don't know if you talked about the fact that NCI attempted to do this as a randomized controlled trial.

DR. GONZALEZ: I did, yes. You were out when I discussed that.

DR. JONAS: And why they did that when that is -- it is kind of one of the premiere examples as to a

situation in which you don't do a randomized controlled trial. Therefore, what has evolved in that and what has facilitated the ability of you to move to a radically different research design, hopefully in a way that will be acceptable and will move these areas forward.

Do we need gold standards or what we mean by gold standards? Do we need gold standards in the sense that there is a methodology to which everything is held up to. Or are there appropriate methodologies that then become the gold standards for the information they are going to provide for the audiences who are going to be using them? I think these are issues that we need to hear from practitioners, as well as the public.

DR. GONZALEZ: Well, as you know, coming out of the government, that gold standards can be waived whenever we want them to be waived. For example, Interleukin-2 got approved by the FDA in 1990 as a treatment for metastatic renal cell carcinoma, based on a pilot study. When the randomized trial was finally done and published in 1998, lo and behold, Interleukin-2 for renal cell carcinoma worked as well as placebo. Six percent of patients on Interleukin responded, 6 percent

of patients with placebo responded. Interesting study, that even with nothing, 6 percent of patients will respond.

I think it is an interesting finding, but certainly Interleukin-2 proved to be less than what we had hoped initially, but there is a case where there was so much enthusiasm about it, in fact, Dr. Rosenberg, who developed the original trials, ended up on the cover of Time magazine in 1986 over Interleukin-2. Based on the enthusiasm, it got approved. Based on simply a pilot study. So, even within the orthodox medical world, as you know, ,methodologies can often be waived.

DR. JONAS: Oh, they are. We have the methodologies actually. As Bill mentioned, surgery really is an example of an entire field that has been developed based on observational research, where there is a will to do it, where there is a rational to do it.

So, the question is how can that be developed in these areas, how can that also be -- and we will hear from them, I am sure. So, that would be useful for us.

DR. GORDON: Charlotte.

MS. KERR: I have sort of a comment and a

request for feedback now or later and maybe something for us as a panel to think about. It has to do with the area of ethics. What really prompted me to think about it -- I mean, there are so many things that have been said that have prompted the thought of ethics, but one certainly is the actual issue of the lady with the three children who wants treatment and how long -- and I know there are protocols and this and that for ethics for how long something has to be examined before it can then become practice.

I think we may need to look at that in another way or a new way, but there may be a new ethics. We have new committees now in hospitals for people dying and all this, but, you know, it seems to me there needs to be some kind of new ethics in the complementary and alternative medicine. I only put it as a seed because I don't know quite what all I mean by it yet. But there is something about even the medical doctor, who said if we are continuing -- I thought it was incredibly wonderful what he said about if we know -- if chelation could be helping these people and we are insisting on whatever we are insisting on, angioplasty, bypass, then this is

wrong.

It is the same here, applied to this. So, how responsible are we to address the 25 list of public health problems and not look at these new therapies. I would like to have the brains and ethics, which we have here -- Joe, of course, is a major brain -- but this is exciting to me. You know, how is this to be applied and be thought through in a new way in this field and just future for healing.

Thank you. I won't comment, but --

DR. GONZALEZ: One comment to your comment. I think the history of science when you look at it is basically orthodoxy is right even when it is wrong and unorthodoxy is wrong even when it is right. I think it would be nice the first time in the history of Western civilization to change that model, that something may be right even if it is not orthodox.

DR. McCOMBS: It is not only in cancer. I mean, we get these same kind of phone calls everyday. She just fielded them yesterday. I field them everyday. I have a staff who fields them, you know, and it is ALS, it is heart disease, it is every malady that you can

think of or, you know, mothers who can't afford the treatment but who have, you know, asthmatic children, who can't afford to keep going to the emergency room, for example, just for example.

To turn these patients down, I can't tell you what this is like,, those of you who are practice-based physicians will know what I am talking about. This is heart rending. This is the stuff that keeps me up at night and I worry. I worry. You know, you talk about ethics. I think it is a perfect example and I know what you mean about getting phone calls in the middle of the night.

Those of us who are out there doing it want to keep doing it, but we need help. We need tremendous help and we need help in a way that our licenses aren't jeopardized. We can get you the proof that you need and want and that we need and want. I think sometimes people think practice-based physicians don't want this because we are not academicians and we didn't decide on research as our career. That is not true.

We want efficacy. We want safety just as much as you do and when we find therapies that do work and

drive us to those places because our patients, 51 percent of the population is paying out of pocket for these kind of therapies and they come to you and they say help me. You know, as physicians, I think -- as practitioners, let's just take it out of the physician realm here, we all have an obligation to do something about that.

We have a 4,000-practitioner network that we can plug this kind of stuff into, but we need help. We can get you the data, but we need help and we can't do it alone.

DR. GORDON: I want to come back to that, but first, Effie, and Joe, and Bill.

DR. CHOW: Sorry. This is late in the day, but this panel, the discussion has brought up, I think, an extremely important area that we need to deal with as part of the Commission, as part of the practitioners, and I am a practitioner myself, that -- and also former Congressman Berkely Battle [ph], who was very instrumental in this whole movement, he was also distressed.

Maybe we can explore it and you folks may be a good input in this is that how can we continue to

research? I want to really pose this as a question. How can we carry on research and where there is some indication that it is valid, but the validity was before the research was carried out in that there were some evidence-base, I mean, evidence in clinical work that it is successful.

So, if there is a research that is done and maybe not accepted totally yet, the people are dying. So, how can we balance the two, continue research, good research, but perhaps we need to recommend as part of our duty is to can we use that for the people because they are dying. They are dying the next week. They are dying the next day. Hundreds of people are dying. So, can we balance that? I just want to throw that out as a very important issue.

I think that faces a lot of practitioners out in the field.

DR. GORDON: Joe.

DR. FINS: I think this is perhaps the most fascinating part of the day and it is compelling again to hear this. Charlotte's question about the new ethic -- I just want to observe a paradox and if you don't mind, Dr.

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Gonzalez, I just want to use you as sort of the poster child for this issue, because I think it is really so compelling.

You know, you were sort of a victim, as it were, of the pathology of science, but you stayed true to the science and that is really a mark of professionalism. I think it is really is what is the professional ethic of all practitioners? It should be efficacy, sort of the next -- that has been a big part of your career, but still not deviating from the scientific norms that you have maintained and embraced even when it didn't embrace you.

So, I think that is the paradox and I think that the things we heard about this morning, that tried to bring people who have novel ideas back into a mechanism where they can access the science, which ultimately is going to validate this is really, I think, tremendous progress and I think we can learn from your own narrative about, you know, what kind of ethic and methods and procedures we should try to recommend that promote and not inhibit.

I want to just ask one quick question for Dr.

McCombs because if we are going to bring people who are complementary practitioners in and ask them to share their insights and their innovations and their practices, some of which might be sanctionable in certain state situations, do you think that there should be a safe haven or immunity legislation for these practitioners so they can share their best practices without fear of sanction and that should be, you know, kind of a special relationship? I don't know who we would do that. We would need a lawyer to help us with that, but is that something that you think is necessary to engender trust?

DR. McCOMBS: I think it is mandatory. I think you won't get what you are after -- this commission will not get what it is after from practice-based clinicians if you don't guarantee them some kind of protection. We will do the research for you if we can just get -- we can't be clinicians and researchers, but if we can get grants to do it, help to do it, help to collect it, help to write it up, we will do -- we have got the data. It is not like we are not sitting out there with the data. We have got it.

But we don't want to come out of our closets,

if you will, and give it to you for fear of what is going to happen to us. This is a prime example. I feel like Aaron with Moses here. I mean, I truly do.

It was truly out of -- having no access to the kinds of things that Dr. Gonzalez was talking about, and I just think it is funny that we are finally sitting here, six years later, on a panel together. You know, I couldn't get those enzymes that he was researching. I didn't know he was sitting over there researching them. I live in William Kelly's state. I only know about Kelly's view of things over here. I know what problems he had. So, I go to an alternative, you know, way of doing it, discover this woman, who is a true pioneer, just like Beard was in his day, just like Kelly was in his day. Find something that works, but I have to be so quiet about it. I can't tell anybody because I am afraid I will lose my license.

Now, I have got full practice rights in this country. Nobody can fault my degree. Okay? She doesn't. Okay? But she is over here writing books like this. God knows when she has time to do it. She writes more books and has more cases, 4,000 plus cases, 4,000

practitioners she has trained.

You know, I want to help her. I want to help her because when I can do this kind of work with an -- it moved me beyond tears. I am telling you, to treat this woman on a Friday night, have her got to surgery on a Monday and that cancer was gone. I can't tell anybody about it for fear of what might happen to me, to her, to anyone else and then tell the patient don't tell anybody. Don't tell anybody.

DR. FINS: Your analogy to Moses might be apt because Moses did not make it to the Promised Land.

DR. McCOMBS: That is right. Moses did not make it to the Promised Land, but we can.

DR. GORDON: We are getting late.

Bill and then Tom.

DR. FAIR: I would just like to revisit the issue of the ethics and how heart rendering the stories you tell are. Of course, every practitioner has -- I used to hear that when I was an active surgeon. Why can't you operate on me instead of going to somebody else.

But, you know, I have heard Steve Rosenberg and

Marsha Lenihan say that at the time when IL-2 looked like it would work. We are all familiar with suits brought against HMOs and insurance companies for not authorizing autologous bone marrow transplant, when we thought that worked. So, I don't think we can excuse or bring things into practice just on the basis of the fact that some people feel that if they have access to them, that they will be cured. In other words, nothing is 100 percent.

But I am curious, Dr. McCombs, why can't you do a Best Case Series, and show Jeff White what you are dealing with there? In one of his meetings, he had a couple homeopaths from Calcutta and I think the NIH is now helping them to collect data. Is that right?

DR. McCOMBS: We will do it. You know what? Some of us have to stand up and we will do it. That isn't the issue. We will do it. You know, if my license goes on the line, I am going to writing you, calling you, saying "help." Okay? But I am going to do it. In my lifetime this will happen because I am just tired of fielding these kind of phone calls and dealing with these heart rending kinds of situations.

I now use a paradigm, for example, that will

require you, for me to explain it to you, for you to think outside the box, but I can individualize it now, treat people. It won't matter where they go but if you stand ten people up against that wall with the exact same diagnosis, their treatment course will not be the same. It is the same thing that was talked about earlier. Yes, we have got a protocol, but as a practitioner you have got to say I have got to up those level of enzymes or I have got to take those down or take those out of the treatment protocol because it is not working for this patient.

So, it is a way to individualize that kind of care and have that kind of a paradigm for both diagnosis and treatment acceptable. The research on that, on the paradigm itself, has been done. It is being ignored. It was done in Israel. I have sat here and listened to other people talk about it, but, you know, Valerie Hunt did at UCLA in unified field theory. Nobody is listening to her either.

I am just saying the research that you are talking about is out there. You have just got to allow us to use it and build on the research that has already

been done. So, we don't have to reinvent the wheel again. Nick over here had to reinvent the wheel because nobody would listen.

We don't have interest in reinventing the wheel and I don't think you are interested in having us reinvent the wheel. We would like to build on what others have done and then be able to easily stand up and say we are going forward.

DR. FAIR: But, again, an individual, a standardized therapy is not -- that is not a sine quo non of good science. You can evaluate traditional Chinese medicine, the little bit I know about Effie, and there is no cookbook approach to traditional Chinese medicine. You may get ten patients with the same symptoms and be treated differently.

Is that correct? So, you evaluate the system not the approach. So, I am still --

DR. McCOMBS: The approach has been criticized significantly. I won't go into this --

DR. GONZALEZ: I agree with you, Bill. I think you have to do research. That is why we haven't commercialized what we are doing. I absolutely believe

in the scientific method. If it takes 100 years, if it takes my grandkid -- if it takes them to finish doing it, tough on me, but that is the way it has to be done.

Jeff is sitting here very quietly. I really want to say the NCI has been wonderful through all this. I mean, they are really helping us to do good science and that hasn't been said yet. He is remarkable and he has taken a lot of gaff for what he is doing, too, as you can imagine. But the NCI is determined in the most objective proper scientific way to test any therapy, be it, you know, moon dust from Pluto, pancreatic enzymes or chemotherapy and I think they really mean that and they are helping.

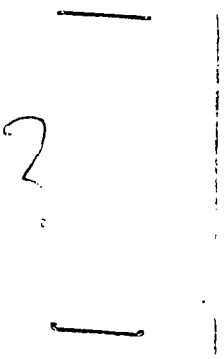
So I think Bill is right. You should be able to do a Best Case Series.

DR. GORDON: We are going to be informally having dinner. If there is something you want on the record, Tom, that is fine. Otherwise, there will be plenty of time to talk with them.

MR. CHAPPELL: I would like it on the record.

DR. GORDON: Sure. Then go ahead.

MR. CHAPPELL: I think for me the understanding



the discovery process is as important an issue as the one we identify three months ago and that was the need to talk about a world view. Discovery process is a very unique beast. As I said earlier today for the other people, it is sponsored by the highest authority that gives that process extraordinary permission to occur.

It is championed by belief and passion and intimacy, the intimacy of the subject, the trust of those very close to that understanding and the passion. They are the ones that create the model and the prototype.

Third and only then do you expand it into collaborative integration with the rest of the system. It is kept out of the system until it is ready to be believed and I really think we have to lift this out as -- it is bigger than how it works at Harvard or how it works at the University of Pennsylvania. It is as big as this whole question. So, I would like to recommend that we have evidence again that we need to raise up the fact that discovery has to be given permission, nurtured in a close intimacy of small working groups, not large, that come to the larger only when they need to be refined, understood better and institutionalized.

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I just think that is important.

DR. GORDON: I just want to conclude with one comment. The reason that we asked this particular group to come is precisely because of the issue of how we can help to midwife this kind of discovery. I think that Ann may have said it and one of the things that we saw at our conference in June so clearly is that Dr. Nambudripad was forced to talk in a way that was at best paradoxical if not incomprehensible at times because of the difficulty that she is being put through by the fear of retaliation.

So, I know this panel comes late in the day, but it is really meant to set a new path for us and help us to understand this issue among the many other issues, which is precisely how we provide some kind of protection for people who are sincerely committed to doing research on their work, which at present lies outside the box.

The issue here is, what I am hearing is an energy of people's responses, is that we need to come back both with some of the suggestions that you made and if you have a couple of suggestions, more suggestions for ways that would be helpful, and then perhaps we need to proceed and we have talked about, Jeff White and I have

talked about this at NCI as well, what can we do as a commission, what kind of recommendations can we make to foster and nourish this kind of research and how can we reach out to the medical boards and provide some kind of protection so that people can move ahead and what are the criteria and what are the conditions and what are the needs to take that next step.

So if you have any final words, great. If not, please, we are going to continue the dialogue and we understand that this is an issue we need to deal with.

Thank you very much.

[The meeting was recessed at 7:22 p.m. to reconvene the following day, Friday, October 6, 2000, at 8:30 a.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.

DEBORAH TALLMAN, Court Reporter