

Comprehensive Cancer Care: Integrating Complementary & Alternative Therapies  
Freedom of Choice: Are There Limits?

Moderator: James S. Gordon, MD

Panelists: Robert Atkins, MD; Berkeley Bedell; Barrie Cassileth, PhD; Michael Evers, JD;  
William Fair, MD; Robert Temple, MD

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Dr. Gordon: First is Barrie Cassileth. We serve together on the Advisory Council to the Office of Alternative Medicine at NIH, and she was an extremely helpful voice on that council. She has worked in medical sociology for many years. She's written some of the earliest papers on who uses complementary and alternative therapies and why they use them. She has been a very important force in helping the American Cancer Society think through its positions on complementary and alternative therapies. She is recently the author of *The Alternative Medicine Handbook: A Complete Reference Guide to Alternative and Complementary Therapies*.

On my left is Michael Evers, who is a lawyer. For more than 15 years Mike has been a frequent visitor to the Office of Alternative Medicine Advisory Council and an eloquent speaker, particularly on issues related to freedom of choice. He has been working both legislatively and legally to help move the examination of alternative therapies ahead and to help ensure wider access to them. Since 1987 he has served as executive director of Project Cure, a 19-year-old public advocacy group. They are forging a dynamic and ever-expanding network of groups and individuals who are interested in creating a more integrative and holistic medicine.

On the far right is Robert Atkins, who is a physician, the founder and medical director of the Atkins Center for Complementary Medicine, and the editor of a number of best-selling books. One of his books is just about at the top of the best seller list – *The New Diet Revolution*. He has a radio show in New York. He is not only a practitioner who sees many patients, but he is somebody who grapples with these issues every day in a public forum.

On Bob Atkins' left is Berkley Bedell. He was the major driving force behind the legislation that created the Office of Alternative Medicine. Working with Tom Harkin, Berkley, who served in the House of Representatives for many years, helped create and move that bill forward. He came to complementary and alternative therapies through his own sieges with prostate cancer and Lyme Disease. He is an outspoken and powerful spokesman on behalf of people's right to have access to whatever medical treatment makes sense to them and their physicians as long as it does no harm.

Berk is the founder of a new foundation, The National Foundation for Alternative Medicine, dedicated to doing the field trials that he has championed so long. It will go out into the field, looking at some of the work that we have seen here these last couple of days. They will look at other people worldwide who are doing interesting and hopeful work studying, practicing, and researching complementary and alternative therapies. Berk has been tireless in his efforts, going all over the world, and meeting with clinicians and researchers.

On my far left is Robert Temple, who has served with us as an ex officio member of the Office of Alternative Medicine Advisory Council. He has a significant commitment to looking at these alternative therapies. He is Director of the Office of Drug Evaluation, and Associate Director for Medical Policy, at the Center for Drug Evaluation and Research of the FDA. He's going to give us some sense of the approval processes, some of what goes on at the FDA as well as to comment and to answer questions.

In the middle is Dr. William Fair, whom you've seen up here before, who is formerly Chief of Urologic Surgery and Chair of Urologic Oncology at Memorial Sloan-Kettering. As you know from his morning presentation, Dr. Fair is very interested in how one appropriately

integrates conventional and complementary/alternative therapies in a comprehensive cancer treatment.

I will be acting as moderator, so let's begin. We're going to have a brief statement from each person. We'll see what kind of discussion ensues and then we'll very quickly include everybody. This panel will go for a total of an hour and a half. There will be plenty of time to talk. When the time for audience participation comes, please line up behind the mics.

Dr. Cassileth: Jim, thank you very much. It's a pleasure to be here. I'm trying to figure out Jim's thinking in asking me to go first. I'm not quite sure what it is. We'll see what happens. I'm not used to reading my presentations, but I wanted to stay very carefully within the five minute limit, so I'm going to try to do that.

We face some difficulties in discussing freedom of choice, in large part because of problems of terminology and definition. The term "alternative therapies" includes an enormous range of disparate programs. They can be divided roughly into three categories from my perspective: 1) self-help and lifestyle activities; 2) complementary therapies; and 3) literal alternative therapies.

Self-help and lifestyle activities include keeping fit, by eating well, dieting, perhaps with the help of a commercial program, going to a spa and getting massage, attending support groups, joining a gym, going to church, soothing a sore throat by drinking tea with raspberry jelly (my father's favorite remedy) – all the things we do to take care of ourselves in sickness and in health. All the things that we do to maintain a healthful lifestyle. From my perspective, these are not alternative or complementary therapies. Some may be therapeutic, but they're not

medical treatments. They don't belong in the category of alternative medicine. We have the freedom to select these lifestyle approaches and access to them requires no set of regulations.

I define complementary therapies as treatments aimed at controlling symptoms and enhancing quality of life, particularly during illness. In cancer medicine they include herbs to relieve nausea, acupuncture for pain, relaxation therapy to reduce stress, and many others. Complementary therapies are minimally if at all invasive. They cost very little. They effectively enhance well-being. Should they require regulation? Many of us who use botanicals and other food supplements want information that we do not now have about products. Which ones are better than others? Which ones are uncontaminated? Which ones contain the actual ingredients mentioned on the label? There are a lot of difficulties with the products that are offered over-the-counter these days. Food supplements aside, complementary therapies generally are safe and effective, and in my view require no limits to their access.

The third and final category is alternative therapies. These differ profoundly from lifestyle choices and complementary therapies. They are promoted for use as treatments not for symptoms, but to treat serious illnesses such as cancer. They are generally expensive and invasive. By definition they are unproven. I believe they require assessment and regulation. Only proper evaluation provides the information that is necessary to informed freedom of choice.

This is where we need limits on that freedom. Limits are placed by government on all of our freedoms. Freedom of speech is constrained by libel and slander laws. Freedom of religion can be restricted when its practice threatens the life of a child, as when parents deny a child needed medical care because of their religious beliefs. Freedom of choice in medicine and medical services historically have been regulated by law. These restrictions protect us from the harm that might result from unscrupulous or careless manufacturers, promoters, or practitioners.

In the past few days you've heard speakers at this conference talk about the dangers that some alternative practices and practitioners present. Ralph Moss gave us examples of death that occurred as a result of unproven and unfounded medical practices. Blanket freedom to choose any alternative therapy, especially one to be used in place of treatments that have undergone rigorous scientific investigation, could be harmful to both body and pocketbook. If we eliminate the information and protection offered by FDA and USDA review and standards, we may gain a freedom that comes at tremendous cost.

Suppose we applied unlimited freedom of choice to the responsibilities, not of the FDA, but of the Federal Aviation Administration. Relaxing regulations that protect us from dangerous flying practices would increase our opportunity for choice, but certainly would not be in our best interests. Engineers point out that engineering is much more objective than medicine. We all know that medicine tends to be quite subjective. When weight is added to it, the bridge either falls down, or it doesn't. Engineers know this on the basis of tested knowledge and scientific principles. Randomized, double-blind studies are not needed to determine the load capacity of a bridge or to compare the thrust of one airplane engine to another.

Why would we accept in medicine what we would dismiss in engineering? Would you fly in an airplane designed according to alternative, unproven concepts of gravity and aerodynamics? I favor evaluation based on proven scientific principles before a therapy is made available to the public. Just as we accept the principles and data used to construct safe bridges and airplanes, we should require scientific documentation that a therapy works before it is made available to treat cancer. Neither Medicare nor our health can survive opening all "cancer cures" to public choice. I'm one of those who will willingly give up a little bit of freedom for a whole lot of information and protection. Thank you.

Dr. Gordon: We'll go in order. Each panelist will make his or her own statement. Afterwards we'll have any thoughts or responses that anybody here on the panel has and then we'll go to the audience. Mike Evers.

Mr. Evers: Freedom of choice is a concept that is really as old as mankind. If you think about it, from the very earliest beginnings, there was no government. Man, woman, were free to do what they want. God's law came in somewhere along the way, so they had to obey that law if they chose. Otherwise it was quite some time before government got into the act. As government begins to intrude in man's affairs, we lose our freedom. I don't want the government to tell me what kind of refrigerator to buy. I don't want them to tell me what kind of car to drive. I don't want them to tell me where I can go on a vacation. These are my choices.

When it comes to medical care, the government feels that it really needs to step in and make many of these decisions for us. They feel we're not smart enough, we're not equipped with the intelligence, we don't have the information, the training, the experience, the awareness, to make these decisions for ourselves. I don't buy that. Sure I want a government to regulate food and make sure that it's safe. I don't want to go to a hamburger stand and eat something that's going to kill me. I don't want to take a product off the shelf in a drug store, an over-the-counter product when taken as directed – take two of these for your headache – and keel over dead from that. I want to be protected from some things. But when it comes to really deciding what kind of health care you want – do you want to go to this medical doctor or this naturopath or this acupuncturist – if we have the information and the knowledge necessary to know how to discriminate among those, fine.

I know what some critics are going to say. Mike, you can't possibly be expecting people to make these decisions for themselves. These are serious life and death decisions. It requires the intervention of an intelligent, caring, kind, loving person in a white lab coat with a stethoscope around their neck. I don't buy that. That community has its own faults. What did they say – 300,000 people died last year from drug-induced deaths in hospitals around the country from prescription drugs? Not a good track record. For a lot of this stuff. The malpractice that's going on in this country is soaring. There are a lot of problems.

If you really want to give up your sovereignty as an individual and turn it over to people in white lab coats with stethoscopes around their neck, that's your choice. I choose not to do that. I choose to study, to read, to talk to colleagues. I choose to get on the phone, get on the Internet, arm myself with the knowledge, consult some more. Finally I have to put it all on the table and say, "I've got to make a choice here." Sometimes I go with the conventional choice. I take the allopathic approach. I take the shot, the drug, the surgery. Because that's my choice. That's really what freedom of choice comes down to for me. It's making sure that we watch out and protect our ability to have choices. If we don't, the government will assume that responsibility for us, plain and simple.

I don't think anybody in this room really wants to see the day when we go to the doctor, and the doctor has to tell us, "Well, this is what you have. Unfortunately, I can't give you what I think you need because the government regulation, code section 306-57, says that for your condition you only get this and that's all. If I go outside those regulations, I'll lose my license. I'm not going to do that, so there's your choice." If you think that's not going to happen, you just let things keep going the way they are.

The Clinton administration started to show us what they thought health care ought to look like. It ought to look like something run by Yale lawyers. They didn't bring any doctors into the room to talk with them about how to change the face of health care. They brought in all their own friends, their policy wonks. They were going to decide what kind of health care we were going to get. Fortunately that was stopped, but it will come back. It hasn't gone anywhere. It has just backed off a little bit because, you know, we don't want to crush too many sensibilities here.

I want to leave you with a quote from a very famous case, *Evers vs. US*. My father was a fighter. My father never quit. One time the FDA went after him for using a therapy in an unconventional way. They persecuted him. They hounded him. They prosecuted him. He finally won. The judge said, commenting on the FDA's position, "To require the doctor to use only orthodox, state-sanctioned methods of treatment under threat of criminal penalty is to invite a repetition in California of the Soviet experience with Lysenkoism." (Remember what Lysenkoism was? In Russia, everybody that went into the mental hospital got the drug therapy from Dr. Lysenko.) The judge said, "The mention of a requirement that licensed doctors must prescribe and treat within state-sanctioned alternatives raises the specter of medical stagnation at best, and statism, paternalistic big brotherism at worst. For it is by the alternatives to orthodoxy that medical progress is made. A free progressive society has an enormous stake in recognizing and protecting this right of the physician."

Dr. Gordon: Bob Atkins.

Dr. Atkins: Thank you. I have to tell you how much I've enjoyed every minute that I've been here, and how appreciative I am. When you said we were going to talk about freedom of choice, I said I've been thinking about that for a long time. I realized what I had done. Back in 1984 and 1985 I wrote a book called *Dr. Atkins' Health Revolution*. The subtitle was *How Complementary Medicine Can Extend Your Life*. I remember what the thesis was. I wanted to tell people that in order to have freedom of choice they had to know that they had a choice. That was the whole thesis.

I said there are two kinds of medicine being practiced by physicians. Some are orthodox, mainstream, consensus, doing exactly what mainstream consensus leaders are telling them it's okay to do. There's another group who couldn't buy that, who felt that there were other healing arts. It was clear that there were basically three therapeutic modalities that were being used – pharmaceuticals, surgery, and other high tech interventions. It was apparent to many doctors that there were things in nature. It was apparent that things like nutritional medicine were not part of mainstream medicine. These doctors began to practice a little differently.

In the 80's I began to say, "This is a different medicine. I wish everybody knew about it. I am getting better patient results than I was getting before." I had the luxury of practicing mainstream medicine for about 16 years before I did anything that was not consensus or mainstream. I did cardiology and internal medicine. I knew what kind of results to expect. When a heart patient came in and I asked how they were doing, if they said, "Oh, no change," I said, "Wonderful." As a mainstream physician, I was happy that they didn't get worse. Now if they say the same thing to me I am very distressed. That's not what I expect and that's not why I am practicing my kind of medicine.

I thought it was important to give a name to that kind of medicine. I noticed that in the UK they called it complementary medicine, so I brought that term to the United States. Now here's what's happening. Right here at this conference, complementary medicine is being defined in a way which I had not heard in the 13 years that I've been practicing complementary medicine.

To me complementary medicine is being aware of, conversant with and able to use all of the healing arts. We use all of this knowledge and this wealth of information and experience to create a strategy for patient care that is optimum, that would give better results. Mainstream medicine is one of the options. Complementary medicine is not – and no complementary physician I have ever met would agree to this – it's not something which complements mainstream consensus medicine.

It is a different system, a different strategy, with different rules. One of the rules is maybe the consensus could be wrong. Maybe the consensus is done by people whose departments – most of them are department heads – are being endowed by the great sources of endowments, the pharmaceutical industry. In the case of nutrition departments, endowed by the food industry. I found it absolutely necessary to reject this kind of medicine in order to get the patient outcomes that I tried to get. I learned patients would get better when I treated them nutritionally, when I changed their diet, and changed it away from what mainstream was saying is the diet that everyone should be on.

Mainstream says one diet fits all. It denies individuality. Jack Sprat and his wife should be eating the same thing. They also say that one vitamin program fits all. It's the minimum daily requirement of their RDA. They even went so far as to say that the diet they're

recommending contains the RDA. In point of fact it's based on white flour. Why white flour? Why not eggs, cheese, butter and meat?

Look at the endowment of the nutrition department. The food industry cannot make anything more than the usual profit from selling meat or butter or eggs. The markup is standard. But should they sell junk food, margarine, white flour, cornstarch, high fructose corn syrup, then they can make a profit. I believe that that's all part of what we now believe about nutrition.

In other words, our ability to make choices has been co-opted by a belief that mainstream is offering the right advice. People have talked about proven scientific principles as the basis. Only if you are comfortable within mainstream can you say that. It becomes apparent to somebody whose life is involved in helping people get well using complementary medicine, that there is no funding to achieve that proof. This conference can go a long way to beginning not only the dialogue but the actuality of doing something which would change all that.

Perhaps we can come to a recognition that there are ways of evaluating complementary medicine. It's not by using the same modalities which are appropriate in mainstream medicine. By using a different system of evaluation, people can see the two systems of medicine compared one against the other. They can make a decision, an informed choice. They will see the differences between one system of medicine and the other system. It's not about individual piecemeal additions. It's not about complementary therapies. It's about an entire system of practicing without being encumbered by the restrictions placed upon physicians by consensus doctrinism. I thank you.

Dr. Gordon: Berkley Bedell.

Mr. Bedell: I'm probably going to go home in the morning. I want to echo what's already been said about how great it is for all of us to get together and talk. How about a great hand for Jim Gordon and this tremendous job he has done here. (Applause) I appreciate the nice things that you said about me, Jim. One of them that was really accurate is that I'm outspoken.

I came about this as he said because I had both Lyme Disease and prostate cancer. Both were successfully treated by alternative treatments after conventional treatments proved not to be effective. It is very sad for me to have to tell you that the treatment that cured my Lyme Disease – a special whey from cow's milk – is illegal to be dispensed in the United States because of our laws and regulations. It's hard to believe that whey from cow's milk should be sufficiently dangerous that we should tell people that they can't have it in order to cure their Lyme Disease. Because of my interest in all this, I've been heavily involved in efforts to try to get legislation changed.

I was involved in the introduction of the Access to Medical Treatment Act. This is my opportunity to tell you a little bit about that since we're talking about freedom of choice. That act says that any person will have the right to be treated by whatever treatment they desire, so long as 1) it's administered by a properly licensed practitioner under the limits of their license, who has examined the patient, 2) there's no evidence to indicate that the treatment will be of danger to the patient, 3) the patient has been completely informed of the contents of the treatment and any possible side effects, including 4) a written statement that says this treatment has not been certified safe and effective by the federal government and anyone who uses it does so at their own risk, and 5) there have not been advertising claims made for the treatment.

We can have disagreements in our society, and the people on the panel don't have to all agree. I would argue that your health care is very different from building a bridge or building an

airplane. (Applause) It's different because when you build a bridge you might adversely affect a great many people if that bridge collapses, or if that airplane crashes. That's true. But for me to take colostrum from cow's milk to try to cure my Lyme Disease sure isn't going to do any damage to anybody else.

Health freedom is the same as what Mike Evers talked about, which is the freedom to decide what kind of a refrigerator you're going to buy. I would argue further that in our current system it costs so terribly much to go through the FDA approval process, to get permission to market whey from cow's milk, that nobody is going to go through that for anything that they can't patent. Unfortunately many of these alternative treatments are treatments which cannot very well be patented. People are going to have to go to Europe, or Mexico, or Japan, or the Bahamas, or wherever, to get many of these treatments that we can't get here because of our current laws, rules and regulations. (Applause)

I can go into the store and buy rat poison. It will kill anybody. But I can't have whey to drink to cure my Lyme Disease. That's our society. I'm not exactly in love with everything that the FDA does. But don't put the primary blame there. The primary blame is right here in this room. Congress passed laws that said the FDA is supposed to make sure that all treatments are "safe and effective." Let me tell you, when you tell a bureaucracy to be sure things are safe and effective, they're going to take that seriously. Until we get the laws changed, we've got this same problem.

The only way we're going to get the laws changed is if the words come from the people that we want that freedom. With all the work I've done so far, that message has not come through loud enough for us to make that change. Everybody I talk to says that law makes good sense. In the Senate it's introduced by Sen. Daschle, the minority leader, and one of the

cosponsors is Sen. Lott, the majority leader. You'd think it would be just like that. But we've got to have the message. They're only going to do those things for which they get the message – they must feel it is sufficiently important.

My plea to you right here is that you go back and contact not just your congressmen and senators, but for God's sake, contact the White House. That's part of our problem. The FDA has convinced many of those members that the administration is against it because they're against it. I don't know if that's true or not, but it doesn't matter as long as they can do that. It's a terrible deterrent to getting this passed. If you believe that we should have freedom in our health care as we do in almost every other personal area of our society, if you think it's important, I plead with you to let your congressmen, your senators and the White House know that you care.

I want to tell you a little bit about what I'm trying to do to help with this problem. My wife and I have just formed the National Foundation for Alternative Medicine. We're going to go around the world and investigate various clinics to see where we can document effectiveness. My plea is keep up your great work.

Thanks for this great conference. I'm glad to be a part of it. Please, please contact your congressman, senators and the White House. Thank you.

Dr. Gordon: Next is Bob Temple.

Dr. Temple: I can't talk without visual aids, so I have a few. There's no question that issues of access and choice evoke very strong views. There's no question that plausible

arguments can be made for a range of views. We're in an area of competing good. The present situation represents a compromise that not everybody will find perfect.

I wanted to talk about what the limits of freedom of choice are and then turn to the question of whether there need to be any. Worry was expressed about this earlier, but there are essentially no limits on the use of substances that are legally marketed. Freedom of choice for patients and physicians is essentially complete. Things are marketed in this country under fairly different standards. Drugs, devices, veterinary products are marketed either according to some prior approval standard or requirement, or because they meet some specified standard.

Foods are evaluated for safety to a degree – at least certain additives to them are. Dietary supplements, a very broadly defined category, are marketed basically on the belief of the seller that it has some value in affecting the structure and function of the body. As long as there's no claim that it treats a disease, there's really no limit. These are now widely marketed. They're all available and anybody can basically do whatever they want.

Not everybody can say whatever they want about how to use one of these products. That's where the limitations in this country are. Anyone who isn't a manufacturer of a product can say essentially anything about how to use these substances. But the manufacturer may be limited. For drugs, only claims that are in the labeling and that are consistent with the approved package insert can be made. Actually there's a recent change that will allow drug manufacturers to hand out reprints that are scientifically sound describing other uses.

Health claims for foods can only be made under standards set by the NLEA, the Nutrition Labeling and Education Act. Disease claims for dietary supplements are not allowed under DSHEA, the Dietary Supplement Health and Education Act. We've recently put out a document

that tries to describe what we think a disease claim is. I'm sure there will be considerable discussion of the definition.

For drugs, as an example, that aren't yet approved, there is access only under the limitations associated with what's called the IND. There is considerable ability to gain wider access for drugs that are under investigation that look particularly promising, but there's no question that a drug that's under investigations is not necessarily available to everybody. It could be limited by the manufacturer. It could be limited by our concerns about its safety.

I personally agree with most of the current law. That's what the law is, whether I agree with it or not. The question is, should there be a different standard? Why couldn't anyone market anything they want and claim anything and allow tort law to handle the problems? That's how many products are marketed. I don't believe that would be in the community's interest. The reasons are scientific, economic, and moral. I should emphasize that I'm expressing my own personal view, not an FDA position. We don't really have a position except that we're supposed to follow the law.

Standards for marketing and promotion (standards imposed on manufacturers) are critical to medical progress. They're the basis for evidence-based medicine. Standards are supported by the rise in understanding that controlled studies are the way to learn things. They can be the basis for enthusiastic public support and widespread promotion of certain interventions. These include lowering blood pressure, controlling cholesterol, adding folic acid to the diet to prevent spinal abnormalities, use of aspirin, a variety of drugs after people have had a heart attack, mammography, adjuvant use of certain drugs to prevent cancer. Many of those things could be equally well applied to what are sometimes called alternative or dietary interventions. They are

subject to the same kinds of study. The only way to know whether something works, to weigh risk and benefit, is to have appropriate studies of it.

It's also important to realize that standards are critical to safety. Lack of safety can come in funny places. To illustrate that skepticism should attach to conventional medicine as well as other medicine, look at the last group of post-1962 enthusiasms. For many years anti-arrhythmics were given to people after they had a heart attack to keep them from dying suddenly. This was conventional wisdom. It was an established practice, although no one had ever shown that it was useful. A Heart and Lung Institute study called the CAST (Cardiac Arrhythmia Suppression Trial) proved that the people subjected to this benefit were actually being killed at a rate of about 2 ½ times what it otherwise would have been. That was a conventional wisdom that was unquestionably wrong.

Problems can arise from other areas too. Beta carotene was included in three studies in people at high risk of lung cancer to see if their cancers could be prevented, and incidentally to see if their cardiac status could be improved. In both studies, for reasons that remain somewhat mysterious, the rate of lung cancer actually increased. This finding has not aroused as much enthusiasm as the opposite finding would have. Both studies showed highly significant results showing an increase in lung cancer. If the results had gone the other way they would have been the basis for a claim. It's also critical to know that if you don't know the truth, you can use ineffective therapy where there is effective therapy.

Nothing I've said has anything to do with the theory of the product, the theory of the treatment – whether it's allopathic, naturopathic, homeopathic, or anything else. It applies equally to conventional or alternative treatments, eastern or western philosophies. Dr. Atkins

suggested that somehow you can't test all these things in the same way. I disagree very strongly with that.

You can design well-controlled studies to test almost any intervention, whether it's a single intervention, a way of life intervention or anything like that. It can be done. It's sometimes easier than others. It's important, because most human diseases don't have a completely predictable course. Some do. Where they do, you don't need a control. But most don't. Nobody can make a sensible choice without data. They can make a choice, but not a sensible one.

There are economic reasons for asking people to show what it is they want to claim. The Kefauver hearings led to the change in the Food, Drug and Cosmetic Act in 1962 to require evidence of effectiveness. They spent a long time showing how inflated and wholly false claims were bilking people out of untold billions of dollars. That's a serious matter.

Finally, there are moral reasons for insisting that people prove what they're claiming. It's immoral and irresponsible to claim benefits that are not properly demonstrated. It's wrong and cruel to propagate false hope. It's especially wrong and cruel to gain financially from doing that. Having said that, people can disagree on what constitutes proper demonstration. That is inevitable.

However, the basic principles are well established. I'll be glad to talk about this more. They are not hard to fulfill for a dramatically effective treatment. The idea that it takes 400 million dollars to show that a drug works when it's really terrific is just a fantasy. It's not true. Those figures involve the entire cost of the development enterprise for the entire drug industry, all the dry holes, all the other stuff. If you have a drug in hand and want to test it, it's not very hard. It's well within the kind of resources that people could make available.

There is even a federal agency that is supposed to help pay for the study of alternative therapies. I can tell you that we at FDA would be glad to sit down with people and help design trials. I will personally, and I'll find other people who'll do it too. We will help design trials even in areas we don't regulate at all, if anybody wants to call on us. We like trials. I see very little excuse for failing to get reasonable data on conventional or alternative methods of treatment. People who get an unestablished treatment can be harmed or at least not helped and defrauded. Perhaps more important, people who could benefit from these innovations won't because the scientific credibility will be lacking.

If people would pay more attention to getting the kind of evidence we need, we wouldn't have this conflict. There's no particular reason why, early in the development or assessment of a program, people shouldn't be put into reasonable trials right off the bat.

A famous clinical trials person, Tom Chalmers, who died a couple of years ago, used to advocate that people randomize the first patients to a new treatment. Before enthusiasm became great, before people got a view of what they wanted, we'd have an answer. There was a lot of wisdom in that. Thanks.

Dr. Gordon: Bill Fair.

Dr. Fair: Thank you. Like Dr. Cassileth, I don't like to read from a prepared script, but Jim said he'd give us the gong if we exceeded the time limit, so here I am.

By definition, complementary and alternative therapies imply the use of modalities not currently accepted as part of standard cancer therapy. The reasons these approaches are not being extensively utilized as part of allopathic medicine are many. A major factor is that most

practicing physicians, especially of my generation, have gone through medical schools without any formal educational experience or clinical exposure to the role of complementary or alternative therapies.

Are there limits to the use of these therapies? If so, who should determine these limits? Ideally, the use of any treatment, alternative or conventional, should be based on clinical observations or laboratory research and documented evidence that it has value in cancer therapy – either in halting or reversing disease progression or in improving the quality of life. The limits for the use of alternative or complementary therapy in cancer treatments should only be demonstrated evidence that a particular modality is ineffective or devoid of rationale for use.

We need more testing in the area of alternative therapies, in a fashion very similar to that used for standard therapy. Ideally, these studies should be conducted as prospective randomized controlled studies. Sometimes the data are not there. In my own case, I rejected experimental chemotherapy for alternative therapy. I may have made the wrong decision. Time will tell. But the data were simply not there. However, I don't believe that the definition of complementary medicine includes opposition to appropriate, scientifically valid clinical investigation.

In judging the results of these investigations, the quality of life or freedom from toxicity must also be considered. If a given alternative method is just as effective as standard therapy but less toxic or less costly, it may represent a major advance in therapy, even if there is no evidence that it will extend life in a given individual.

The role of government in the process should be limited to providing funding and assessments of the results of these studies. Government should protect the safety of those participating, and not mandate or restrict treatment. In the last analysis, the limits of choice must be left to the individual patient. The complementary medicine community should undertake

studies to provide evidence to enable physicians to guide and encourage cancer patients in making their own decisions – decisions relative to the appropriateness of a given complementary modality. Thank you.

Dr. Gordon: Thank you, Bill. No gong for you. I'd like to open it initially to the panel. Are there other thoughts that are evoked by any of these comments, other issues that you think need to be brought up, or specific issues that are on your minds that you would like all of us to address? Please use the mics there and I'll stay here and moderate. Anyone? Okay, we'll hear from the audience. Yes.

Participant: My name is Robert Burdick. I'm a medical oncologist, a physician from Seattle. I've noticed that the panel has picked up on the theme that they'd like to have data when they're making a decision as a patient. It's important for everybody in this room to understand that what you want is quality data. What you also need to know is that my fellow medical oncologists believe in a lot of things, but are unable to have the data to show you that it actually works. The same is true of radiation oncologists and surgical oncologists. (Applause)

You need to ask, for instance, when your medical oncologist recommends a bone marrow transplant for your breast cancer, "Is this your belief, doctor, or do you actually have data that shows that this prolongs life?"

This is difficult for lay people to ask. But you must ask that question so that you'll get the answer – breast cancer and autologous bone marrow transplants don't have any data that shows they prolong life. Similarly, one of the panelists has had an experience with prostate cancer. When you go to your urologist, you need to ask him, "What's the data that shows that

radiation, chemotherapy, or surgery cures prostate cancer?" You need to pin him down, because the answer is – there isn't any convincing data that any of those modalities help. (Applause)

It's going to be difficult for anybody to do that. However, you've got to do that to get to the data so that you can use the data to make informed choices.

Dr. Gordon: Thank you very much, Dr. Burdick. If anyone wants to make a comment, people are raising hands, that's not the modality here. The modality is to go to the back of the line and speak at the microphone.

I have one comment I'd like to make. One function that I have for myself, and that I encourage other clinicians to assume, is to go over the data with patients. When someone comes for a consultation and they have questions about what to do, I say, "Let's take a look at the studies on the modalities that your conventional physician is suggesting. Let's take a look at the studies that a complementary physician is suggesting. Let's take a look at the data for what I'm suggesting. Let's sit down and put our heads together and see what makes sense."

This is a very important function and one of the issues about freedom of choice that I want to encourage. We're very interested in teaching people how to perform this function, particularly teaching physicians how to perform this function. It's really crucial that one be both open-minded and critical at the same time. Bill, you had a comment, and Bob had a comment.

Dr. Fair: Dr. Burdick's comments were very appropriate. Regarding the issue of prostate cancer, you're absolutely right. We're not here all beating our breasts and saying mea culpa because the fault's all with the complementary medicine community. There are lots of things in standard medicine that also need the same kind of testing. The difficulty with something like

prostate is that it's a rare individual who will allow the decision as to whether he goes into the operating room for a major operation or not to be left to a computer, as opposed to the intuition of his doctor. I don't think we'll ever see a randomized trial in a situation like that. There are some things that just can't be done. You have to go on the trust and the intuition of the individual who is giving you advice.

Dr. Temple: Sometimes things can be studied that people once thought were settled. I'd like to remind everybody of a study reported in the *New England Journal* about two years ago of whether you should transfuse people who had had a stab wound. Now that's pretty obvious. You transfuse them, right? They have lost blood. They're shocky.

It turns out that shock is something of a protective mechanism. The study found that if you transfuse them, they bleed more, and they don't do so well. That's just a reminder, as Dr. Burdick said, that there are all kinds of things that people do both in conventional medicine and in complementary medicine that have never been properly evaluated. Everybody should bring skepticism to all of those – not just to some of them, but to all of them.

On the whole, unless some regulation requires it, people don't bother to do well-controlled studies most of the time. You have lots of well-controlled studies of drugs because you can't get into the marketplace without doing that. You don't always have well-controlled studies of surgery. You rarely have well-controlled studies of interventions in mental health because you can do them without it. The whole world needs to know more about these interventions. People who care about these things should be advocating more trials. Fran Vesco, a breast cancer advocate, points out that less than 3% of all people with breast cancer are in

clinical trials for a disease where the treatment, for metastatic cancer anyway, is really not very satisfactory. She thinks that's terrible, and I do too.

Dr. Gordon. Thank you. Over here please.

Participant: My concerns have to do with freedom of choice and access to information. As has been demonstrated here, there's so much false information,. One of our problems is that the standards for testing drugs are woefully inadequate. The standards for drugs used for cancer have not much to do with actual success in extending survival. That measurement is not required. A false standard has been designed. Everybody accepted it until we came along with the patient advocacy movement. We say, why measure tumor response when it doesn't correlate to survival? It has no meaning for a person like myself, Ann Fonfa, a woman living with breast cancer. I'm still living, but this is a major concern.

Another concern is that FDA apparently does have statistics on survival. These things are tested on metastatic people, and they're subject to death a relatively short time after the test is concluded. That information should be made public. (Applause) I understand that people have sued to find out. I don't want to sue. I want you to tell us.

Another thing is animal studies. Very often I hear manufacturers of drugs tell me that doesn't matter, it was only in animals. That side effect doesn't count. If animal studies do not count, why do we do them? Why do we use them as standards of trust? There's something wrong here. I'm a breast cancer patient so I know a lot about breast cancer treatments. We're talking about possible tamoxifen, possible Raloxifene as being so wonderful. Yet the side effects in animals are pretty bad. I'm wondering what the correlation is. Ovarian cancer, not

uterine cancer, for Raloxifene so the manufacturer can say we're not worried about uterine cancer. Well they're not, because uterine cancer isn't the side effect. It's possible ovarian cancer, which is quite a serious cancer.

Another consideration is access to direct information. Protocol B6 indicated a comparison between mammography, lumpectomy, and lumpectomy with radiation, yet a woman comes in to get treated with lumpectomy and she's told lumpectomy with radiation is acceptable. The overall success of the clinical trial demonstrated that survival is exactly the same in all three arms of the study. Why do they give us radiation when it does not impact survival? We're not told that that's the actuality. Thank you.

Dr. Temple: I'm not sure I can put my finger on the question, but let me address one or two matters. Cancer drugs are approved for a variety of possible effects. What you would like the therapy to do is extend survival. It's increasingly difficult to study effects on survival because people who progress are always crossed over to the other drug, so we tend to look at improving time to progression.

We have as a policy, at considerable urging of the cancer community, agreed that for refractory disease (disease unresponsive to other therapy) we will reach a preliminary judgment about effectiveness on the basis of response rate. This is subject to a requirement that people carry out further studies after approval to look for effects on survival and more important outcomes. There's a considerable debate about that.

The statement that partial responses don't necessarily correspond to improved survival is perfectly true. We're waiting to see what the outcome of this policy is. The companies that have promised to carry out further studies so far are doing them. They are in fact finding benefits in

the studies to the extent that they've been carried out so far. I'm not sure how to answer the rest of it so I'll duck.

Participant: Mr. Bedell, I'm confused. You were involved in setting up the Office of Alternative Medicine at NIH, or were a supporter of that?

Mr. Bedell: That's correct.

Participant: And now you've set up a foundation which is separate from it in order to study alternative therapies. Why? Do you feel that that office is not doing something right? I'm also curious how do you intend to go about evaluating those therapies yourself?

Mr. Bedell: There are two parts to the question. First of all, I've been on the advisory committee to the Office of Alternative Medicine since it was formed. It was formed with a mandate to "investigate and validate these alternative treatments." I might just as well say it out in public. In my opinion, the mistake was it was put at NIH. I think our director, Wayne Jonas, is a tremendous guy. He's been here. I have great admiration for him. He happens to work at NIH. We have not done a single investigation in six years with all the money they've put into it. That's why I have set up a foundation. We're going to try to do it ourselves. (Applause)

Participant: I have a brief comment on the issue of choice, and then a question for Dr. Temple. It's a very complicated subject. I am also a breast cancer patient and I know the issue of choice is difficult. There are many cancer patients who probably don't want to choose, and

that's something we don't talk about very often. It's a very difficult thing to look at information. The more you see, it affects your hope for your disease in some cases, so it's a difficult issue. But the first choice is whether or not you want to choose.

I wanted to ask the FDA, since you're interested in some clinical trials, and since there are some substances that the private sector is not interested in pursuing for reasons that everyone I think here knows, for example, DHEA and melatonin, would FDA be willing to undertake trials of these substances?

Dr. Temple: For the most part, we don't do trials. There's a fairly obvious reason. We're supposed to review the results of them and that's at least a potential conflict. We also don't have that kind of budget. We work with people to help design trials. We work with NIH and other groups to do that, but we don't on the whole do them. We're not set up to. We don't have a clinical facility.

The slight exception is that under the Orphan Drug Program, which has a fair amount of money, we can support trials of promising therapies. They have supported some trials of alternative medicine, but I can't cite chapter and verse. If there were things that were promising, seeking a grant to study them in that way is perfectly possible. The two substances you named are alternative, but they're sort of druggy kinds of things too, so that's not that big a stretch.

Participant: So it could be done?

Dr. Temple: It's a competitive grant thing. They have a certain amount of money, and they have a competitive granting process.

Participant: This is the FDA?

Dr. Temple: The Office of Orphan Drugs, which is outside of the review part. They're separate enough from the rest of us that we think there's no conflict. Could I just mention something? Many of these potential therapies are things that could be studied along with conventional therapies in studies that are generally under the heading of cooperative group studies. There's no particular reason why, while studying one intervention, you can't add, for example, a nutritional support program in a randomized way to both groups and see whether that contributes. It shouldn't interfere with the rest of it. It adds very little to the cost. These kinds of things are done in the area of cardiovascular medicine all the time. I've never understood why that hasn't been done. Maybe there's resistance. Maybe they don't want to do it. But you all have ways of getting your way. Why don't you find out?

Dr. Gordon: I want to respond to Berkley, because I've been thinking about it since you spoke, and also to respond to your implied question, Bob. I was the Chair of the Advisory Council for the Office of Alternative Medicine for three years. Some small studies have been done. There were \$30,000 grants. Some 42 of them were given out to people to do studies on massage, on healing, different vitamin therapies, acupuncture, a number of therapies. The results are all available on the OAM web site. Some are very interesting, including use of tai chi for frail elderly to prevent fractures.

At the same time there are significant limitations. I think this is what Berkley has felt all along. For example, the Office of Alternative Medicine is now involved in a clinical trial

comparing St. John's wort to a selective serotonin reuptake inhibitor. That clinical trial is probably going to cost five million dollars, even with all the support of NIMH. That's going to take a long time. That's one herbal substance versus one pharmacological substance. It's a good clinical trial. It's five million dollars over three years. The OAM budget was just this year increased to 20 million dollars. There are significant budgetary limitations.

The second issue addresses some of the things that Bob was saying. There has been a kind of inertia within NIH. We saw this with Dr. Bob Wittes coming here the first day. The answer to your question, why aren't there arms of clinical studies with a Qi Gong intervention or with melatonin, with tamoxifen, or whatever, is that it is a very small office in the office of the director. It has very little power in a very large institution with established ways of doing what Thomas Kuhn called normal science. What is needed is a great deal more money and a great deal more independence, as Sen. Harkin said. What is needed is not only a greater openness to investigating particular therapies, looking for particular substances that will work. That is going to happen little by little, and it may be too little by too little. We also need an investigation of comprehensive integrative therapies and the approaches that actual people are using in real life.

For that to happen, repeating the theme that Berkley raised, will require significant popular demand. It's going to require political pressure. There are many scientists at NIH who are interested in this. Every time I have spoken there, after I finish speaking I've had half a dozen or a dozen scientists come up to me and say, "That's really interesting. Those are interesting issues, both basic science and clinical science. We'd like to look at them." It takes money and it takes more authority to look at these issues. I'm hoping that that will happen.

What Berkley is doing is wonderful. I see that as hopefully a catalyst to the OAM. What any of us are going to do outside is very important. We also need to move the institution along,

to present the information, to present the data, to work together as we're working here. Dr. Wittes indicated his willingness and his interest in studies of these approaches. We need to take him at his word and move the agenda ahead. Thank you. Barrie.

Dr. Cassileth: Just a brief comment. I've been working in oncology and cancer medicine for almost 20 years. During that time I have conducted many research studies. I consider myself a patient advocate as well as a scientist. One of the most important things we have to do is develop information, good solid data that people can use so that they can make decisions. One of the many problems has to do with the cost and logistics of trying to study a variety of techniques.

Dr. Temple suggested it would be a good idea to attach studies of alternative practices or complementary therapies to arms of existing clinical trial. I pushed for this many years ago to look at quality of life in patients. It took a long time for that to come about. But I am now working with one of the major national cooperative groups to do exactly that – to add to cancer trials, to each arm, randomly assigned patients to receive one kind of complementary therapy or another. I hope we will get some solid data from that.

Participant: I'm Ted Wadman. I'm with the Burzynski Patient Organization. My experience in cancer is with trying to find a cure for my child's brain tumor. What I found in this quest is that it seems like a lot of them – I have a scientific background. When we start dealing with treating brain tumors, the trials get so small that the statistical significance seems irrelevant.

I have a question for Dr. Temple about any attempts or uses of things like correlation, ways that can actually acknowledge the individual cases. Some of the science seems no better than case-based analysis. If I look at a child very similar to my child, who has a brain tumor exactly the same as my child, in the exact same spot, has the exact same personality, has the exact same skin color, isn't that as valid as looking at a trial that has 40 participants and gets a 10% response?

Dr. Temple: Individual cases can be very impressive if the natural history – that is, what would have happened without treatment – is well known. You don't necessarily need a control group to know that you have a dramatic difference. The reason you pay attention to randomized trials in the treatment of say solid tumors is that you don't expect very much. The results are going to be different. If you're lucky you'll see a difference of eight or ten weeks in survival. To tease that sort of difference out, you really do need a control group. In the kinds of situations you're talking about, where there's dramatic improvement such as disappearance of tumor, things like that are often interpretable by themselves.

At the previous session I pointed out that all of the treatments for testicular cancer that are approved in this country are based on single arm studies – there wasn't a control group – and individual persuasive responses. It was very clear that within a year people with metastatic testicular cancer were going to be dead, almost all of them. The first treatment was with cisplatin. It showed, I don't remember the numbers any more, but a 70 or 80% response rate. A fair number of people were cured. That was persuasive by itself. For people who failed that therapy, a drug called etoposide had a similar response in a small fraction of people. For people who failed that, a drug called ifosfamide had similar responses.

In the end, the approval of ifosfamide for that disease was based on five patients, maybe case-based, I don't remember, who had long-term responses after failing two previous therapies, and were free of disease at the end of a year. So individual results can be extremely persuasive. Responses of that kind are not seen very often. Where they are, it's pretty easy to know what to do, as long as it's well documented, as long as you know what other therapy they had. You have to take slight account of the fact that in some diseases, like kidney cancer and stuff, there are spontaneous remissions, but in many others that's extremely rare. A modest number can be persuasive, and has been, in the approval of cancer drugs.

Participant: Can I make one more comment? Do you see a problem with the fact that some of these drugs – for example, carboplatin was approved based on ovarian cancer. Yet it was one of the chemotherapies recommended for use with a brain tumor. There's the division between what's statistically known and what's common medical practice. Common medical practice is what the insurance companies pay for.

Dr. Temple: Right. This is part of the choice that in fact everybody has. We approve drugs for a particular purpose and appropriate practitioners can use them for anything they want. They sometimes do that in advance of the data, usually because the situation is desperate and they don't have any choice. Or in the case of carboplatin, because they think it's going to be like cisplatin, and they think it's less toxic. It's hard to know what to say about that. You'd like to have data on all these questions, but you don't get data on everything. Under present circumstances, people can use marketed drugs any way they want.

Dr. Gordon: Mike.

Mr. Evers: One of the problems that we're going to keep confronting is that you've got to have one foot in the grave and have exhausted all other therapies before you can take these experimental clinical trials. (Applause)

In Dr. Burzynski's case, you've got to be Stage IV, literally with one foot in the grave. You've exhausted all your other remedies, and we'll give it a shot. Guess what? If it doesn't work, well, it doesn't work. You know I might like the choice when I'm at State A or Stage I. I might like that as an option. And we live in a system where that is simply not available.

Now I understand the need to do clinical trials. I know we've got to get some answers here. But we're going to have to begin balancing that with the patient's right to have access to the kind of treatment that they want. If my child had a brain tumor I might be really interested in what Dr. Burzynski has to offer. (Applause) But if I go down there and they say, "I'm sorry. You don't fit the protocol. You haven't exhausted your remedies," (that's one lawyers love to hear) then I'm just flat out of luck. I don't like that.

Dr. Gordon: Bob, and then Berk.

Dr. Temple: It's hard to comment on that without knowing the particular protocol and the particular case. Where there is no reasonable therapy, no one would insist that unreasonable therapies be exhausted. You won't see requirements – well, I don't know what you'd do in pancreatic cancer. Nobody thinks any of the therapies are very good, or there might be one that has a little bit of an effect, so there isn't the same requirement. It is true that where there are

considered therapies that are useful, we have generally required that before moving on to a therapy that isn't yet known to be useful (remember, in our terms that's the state of these therapies) people must exhaust their other therapy.

Those things are to some extent negotiable. You'd really have to get to the particular case. If therapies are only of marginal effectiveness, I'm not sure we'd be prepared to insist. Those are all things that can be discussed. There are no rules about these things. It's case by case and study by study. But as a general matter, if there is a good therapy like in ovarian cancer or something like that, or certainly Hodgkin's disease, we would certainly expect that people use the therapy known to improve survival first. You could argue that point, but we don't believe it's responsible not to. That is a limitation of choice, but there aren't very many with such limitations.

Mr. Bedell: The fact is that what Mike Evers said is right. For Burzynski's patients, they would not let them go on that treatment unless they had exhausted chemotherapy and radiation as the case may be or surgery. For most of us, and I'm one of those, chemotherapy, radiation or surgery are not my first choice. I don't think we ought to pass that by as not amounting to very much. It's tremendously important that if I want to try Burzynski's treatment, I ought to be able to try his treatment for myself or my children. I shouldn't have to put them through chemotherapy and radiation and this sort of thing first. (Applause)

We had testimony before one of the Senate committees about a young red-headed lad who had been treated. They had given him up for brain cancer. He had gone to Burzynski and he had been cured. The sad thing about it was they had given him so much radiation that he was somewhat retarded. Who could think it's okay to do that to a young man who could have been

treated earlier and not had that problem? We sit here and talk about it as if this is something that's off on the side somewhere. These are people. These are young folks who either are going to live a normal life or they're going to be retarded.

I'm sorry I get so emotional about it, but it just tears me apart to have our government and our bureaucracies talking about this as if we're in a courtroom. We're not in a courtroom. We're here for people who want to be treated. What scientists want in terms of trials and what people want in terms of trials are completely different. (Applause)

You clapped because you thought I'm through, but I don't get through that easy. It also was said that we're going to spend three million dollars for a study at NIH on St. John's wort. That's great. Wonderful. But I told you what we ought to do is do the trials that people want. I formed this new foundation. We're going to depend upon contributions in order to fund it. If we can get three million dollars, we're going to do a heck of a lot more than one study on St. John's wort. (Applause)

Dr. Temple: It's important not to confuse issues of effectiveness and choice. I realize there could be differences of opinion about both of these. If there were evidence presented to us, which it is certainly within the capacity of someone to do, that a treatment is active in say brain cancer, there would no longer be a requirement that people exhaust other therapy before that. But we haven't, at least not yet, been presented with that kind of information. That's not to say it doesn't exist. Maybe some of the stuff we saw earlier today is that evidence.

The requirement that people exhaust available, not very satisfactory but nonetheless somewhat effective therapies, is meant to reflect the need to use the therapies that are known to exist. Remember, the things that are being studied are not known to work. To the extent that

changes, and they become more promising, the kinds of studies that get carried out would appropriately change.

It's necessary to bring forward data. There are people who would say, "It doesn't really matter whether there are any data. Just let me have whatever I want." There is some disagreement about that. But part of what Mr. Bedell said was because he believes strongly that these therapies really work in brain cancer. Well, to the extent I believe that, I'd agree with him. So it's partly a data question.

Dr. Gordon: I have one other response to what Berk said. First of all, we need see if we can do some of these studies in somewhat different ways. I know that's one of the concerns that you have very strongly. There are other methodologies. We've had at least two major conferences at the Office of Alternative Medicine on other research methodologies. It's very important on the one hand that we have significantly more money to study these therapies. We also should make use of a variety of research methodologies, not simply the randomized controlled double-blind study, which is only one methodology.

I'm delighted that Berkley is doing what he's doing. It's our government's responsibility to undertake these studies. (Applause) It's wonderful that we do studies privately, Bill does studies privately, Berk does studies, probably Barrie does studies. We're all doing studies on our own and trying to find a little bit of funding where we can. But this is our government's responsibility.

A very interesting issue was raised in an earlier panel. Maybe there should be a focus and some kind of position paper about the government undertaking exactly those kinds of studies that the pharmaceutical houses will not undertake on these nonpatentable substances.

(Applause) We'll talk more about that tomorrow. We have time for one more right now and then we really have to break.

Participant: My name is Steve Austin. I'm a naturopathic physician from Portland, Oregon. The FDA official has put his position out as though it were scientific. From the outside looking at the positions of the FDA, however, they seem to be remarkably antiscientific and ideological. For example, when the issue came up with folic acid and the protection against neural tube defects, I can't off the top of my head think of a health agency around the world – the Centers for Disease Control in Atlanta acknowledged long before the FDA that folic acid was necessary.

The FDA knew that babies were getting damaged as they were trying to withhold acknowledgment that a vitamin was useful in protection against disease. Right now, folic acid, according to FDA, should be put into the food supply to an extent that is widely acknowledged to be insignificant. In fact the *Journal of the American Medical Association* editorial from the CDC recently chastised the FDA publicly for withholding a level of supplementation that was necessary to optimally protect people.

What are we to do when we see therapies that you find acceptable like chemotherapy for pancreatic cancer that are absolutely proven to fail? You accept them. Simultaneously look at substances like glucosamine sulfate for arthritis. There have been 24 double-blind placebo-controlled studies, some of them randomized, some of them in peer-reviewed journals. Every single one has proven that the substance works. You say, "No, the supplement company cannot provide that information on the label." How are we to see you as scientific rather than as an ideologue? (Extended applause)

Dr. Temple: I'm sure that was very exciting for everyone. Let's get at some of the questions. The effect of gemcitabine is small, but it's described accurately on the labeling. It does what it does. It doesn't do what it doesn't do. The effect is modest. Nobody is really thrilled with it. That was sufficient to make it available. There isn't anything else, so that's the treatment for pancreatic cancer.

I can't speak with any knowledge about folic acid. I know that we believed that folic acid supplements are effective in preventing neural tube defects for a long time. There was a debate about how best to deliver it to people. Since I'm not part of it, I can't speak to that. I don't know what to say. But there was no doubt about the value of folic acid supplementation in the people who were handling this.

To my best knowledge no one has come forward with an application to market glucosamine for the treatment of osteoarthritis or any other kind; so, I can't speak to whether we would accept the data or find it persuasive. What we do believe is that people who are making disease claims for dietary supplements have to have those things treated as drugs. This is what our proposal said, and it's what DSHEA says also. You don't know what our response to the data would be. We haven't seen it, as far as I know.

Participant: It's published. It's readily available.

Dr. Temple. No, no. Sorry. Someone has to make an application to market something. They need to pull the data together, answer questions if there are any. We need to look at the studies, and see what there is.

Participant: What does that cost, to do that?

Dr. Temple: To pull the data together without doing new studies? Not very much.

Participant: No, to go through the whole process.

Dr. Temple: There's a user fee, but it can be waived in certain circumstances. The user fee is probably about \$200,000 now. Pulling data together from the literature is not expensive. The question that arises, and I can't answer this for you, is whether the reports of those studies are detailed enough to be credible, whether it would be necessary in some cases to go look at the case reports and reconstruct it. But compared to the cost of actually doing a study, this is not that high.

Also I should tell you, even though many of these substances are not patentable, they are subject to five years of exclusivity under a law called the Waxman Hatch Law. It allows no one else to market that drug on the basis of the same data. The problem here, as people in the audience will recognize, is that the same substance would be available as a dietary supplement without a claim. Someone who wanted it could probably use that. So whether a dietary supplement that actually gains approval as a drug can be successfully marketed isn't really yet known. I don't know the answer to that, and nobody has thought up a good mechanism for doing that. But if the data that exist are good and no new data are needed, it's not a terribly expensive proposition to put together. I can't speak to the quality of the trials. I haven't seen them.

Dr. Gordon: There are still a lot of people standing up. We'll stay for a little bit more. Most of the people up here have been on panels all day, and they really need a bit of a break. If it's quick we'll have two questions.

Participant: First I'd like to comment about terminology, about complementary and alternative. I was interviewing a doctor who worked with Dr. Emanuel Revici about three years ago. She said, "It's not alternative medicine, it's real medicine." I think that applies to all of these treatments, whether it be Dr. Burzynski or vitamin C or herbs or what have you. It's real medicine. I invite everyone to consider from this day forward, to look at all of these things as real medicine. I also prefer to call mainstream medicine common medicine. That's my personal choice.

I have a question for Congressman Bedell. Will the Access to Medical Treatment Act prevent drug companies from using the FDA approval process for any drug it wishes to market?

Mr. Bedell: No. It will not in any way adversely affect the way you go through approval process for a pharmaceutical drug.

Dr. Gordon: Yes, Candace.

Participant: We all want more data. We'd all like to see more research. We all think clinical trials are terrific, but it all boils down to who gets to set the rules, who gets to make the

standards. Right now it's the FDA. I think Berkley was right in saying we really got the FDA that we asked for, which maybe wasn't such a smart move.

My question to you is, since you've all been in this field for a while, why are we banging our heads against the wall and insisting that an agency that is a round hole accept a square peg? Why don't we change the rules? Do you see another place, or another way, in which we could gather enough information and not have the FDA be put in the same position of measuring nonpatentable substances by the same yardstick as a pharmaceutical drug? Is it possible, and how do we do it?

Mr. Bedell: The Access to Medical Treatment Act does that, Candace. It says that people will be able to use those treatments without having to go through the FDA approval process. However, if you wanted to mass market a medication or this sort of thing you would still have to go through that process. It would give us the chance for those nonpatentable medicines to be tried by those doctors who wish to try them, and solve our problem. Maybe I'm prejudiced, because I've been so much involved in it, but if anybody else has got a better idea, anybody would welcome it.

Dr. Gordon: Bob.

Dr. Temple: I don't have a better idea, but I have a question to put back. Which are the particular standards that you don't think are applicable?

If you have the idea that any treatment has to have the same effect, or that no difference is made for something that's essentially harmless, or you think it's harmless anyway, and

something that's very toxic, you're just incorrect. I'm curious about what part of the idea of a well-controlled trial you think is not applicable to other interventions. I'm very sympathetic with the argument that terminology is plaguing us. I don't see any reason to call something alternative, conventional or anything else.

These are interventions, and the question is whether they work. There are very well-established ways of finding out whether things work. They do not all cost a lot of money, especially if the thing works very well. Which are the things that you don't think you need, and why don't you want to get the right answer?

Participant: I do want the right answer, but I don't want to be held to a standard that takes ten years and costs 300 million dollars, when I couldn't recoup that because it's not a patentable subject.

Dr. Temple: Those numbers are fictitious. Let me be sure you understand that. When people calculate the cost of developing a drug, they ask drug companies for their entire cost of research and development, including all the screening of compounds that they do in test tubes, all of the animal studies they do beforehand, all of the drugs they start to bring to market that fail along the way, and then they divide that by the number of drugs that are approved. That's how you get 300 million. Also a lot of that is actually not dollars but is the cost of waiting around for the ship to come in. It's the cost of money.

Audience: They're real numbers.

Dr. Temple: Well fine. They're real numbers. But what does that have to do with an intervention that you don't have to be searching for, that you already know you want to study? You don't have to do mountains of animal studies to find out what might work. You don't have to do searches of molecules. You just have to do the trial.

It is true that it probably cost a lot of money to do the depression trial. That's because that trial is going to have 500 people in it, because the effects of antidepressants are so small you need huge studies to discover them. But if you have something that makes an important difference, that's dramatically effective, it is not very long or hard to study it.

Even for substances about which nothing is known at all, the average time of development under an IND is only six years. It's much shorter than that for others. That's to enroll several thousand people and go from the beginning to assure that you're not going to harm people, go through an orderly sequence of studies. For many of the things you're talking about, you wouldn't have to do all those steps, because there is experience already. Those numbers are grossly inflated.

Dr. Gordon: Any last comments from here and then we're going to close for today. There will be a session on where we go from here tomorrow. We'll have some time for discussion then. So any last comment?

Participant: I'd like to ask Mr. Temple how many applications he has in at this time for INDs or NDAs for nonpatentable medications.

Dr. Temple: I don't know the answer to that, but I know there are a number of things under the heading of alternative medicines that are under active study. These include saw palmetto, feverfew, a variety of Ayurvedic medications, and I believe we also have one for St. John's wort. Some people are willing to do that. We'd like to see more.

Dr. Gordon: Thank you all very much. I really appreciate that. We'll keep the dialogue going.