exactly. There are different implications and consequences of even the findings in the practice of medicine than there are in the use of herbal supplements.

So it seems to me, what we really need is, probably, look at the whole field and decide what are the main types of issues and what are the appropriate methodologies, and to move away from the idea that there is one, and only one, scientific methodology which is all-purpose, valid for any and all purposes.

DR. TEMPLETON: Just on the question of spirituality or religion, that sort of thing, I think there are new openings, such as in the training of medical students, and perhaps residents, to understand that it is appropriate to take a spiritual or religious history. You can do that fairly quickly, in two or 3 minutes, which may or may not open doors that will be very meaningful to that patient as they face their illness or their health problem.

So I think that there are some new approaches that can bring these spiritual or religious-based sensitivities into the mainstream.

DR. GORDON: Thank you.

Joe.

DR. FINS: I just want to endorse the notion of really looking at methodology as an important issue. I think Wayne is absolutely right, we can have new therapies and new methodologies coexisting. We have to foster the development of new methodologies, but this is an old question about -- viability. This was a question for psychoanalysis. Freud had the same problem. So this is an old, ancient question that we will have to address as well.

I want to also add to the issues, and I think Dan mentioned this, the issue that this is really a public phenomenon, and resonate with what Dean said about the difficulty of saying no. I would also expand to the psychodynamic aspects of being an investigator in CAM, being marginalized, perhaps, by your traditional peers and finding a tremendous resonance with your patients, and whether that phenomenon is different than a conventional investigator who is handling chemotherapy and can't enroll another patient because the funding has run out or they have accrued the number of patients necessary. So the sociology of the investigator as well

as the phenomenon.

I have a really concrete question, just to add to this session, for Ms. Hayes and Dr. Templeton.

We heard yesterday that some of the investigators, because of the marginalization, are not affiliated with institutions or with not-for-profits. There are for-profit practitioners who may not qualify for the 501(c)(3) issue.

I am just wondering how a not-for-profit foundation could support people who don't have their own infrastructure, and what kind of suggestions both of you might make to foster that as an outreach.

MS. HAYES: It is not illegal for a foundation to make a grant to an individual. It just requires that the foundation bear the responsibility. We call it expenditure responsibility. It demands more staff time and a willingness on the foundation to do that, because many times we fund organization that aren't U.S.-based. We have to be willing to take that grant. It just requires some additional due diligence up front and so forth.

Unfortunately, the Hilton Foundation rarely

will fund an individual. I can't think of an instance that we have in our history, but we do fund organizations that are not 501(c)(3).

DR. TEMPLETON: I agree exactly with What Dyanne said. As a new foundation and in pushing some frontiers that are not generally picked up by a lot of other foundations, we are more flexible in resorting to expenditure responsibilities when we think someone's undertaking is really worth supporting. We don't do it commonly, but we are much more open to it.

DR. FINS: But if we want to generalize it, and have foundations that are, perhaps, less enamored with this new evolving area of funding.

Are there recommendations that you might perhaps mention now or send to us, changes in the law, in the not-for-profit law, that might help to encourage greater outreach on the part of foundations that, maybe, do not want to take this additional set of responsibilities on?

Maybe you can supply that to the Commission, because we could make those recommendations downstream.

DR. GORDON: Anyone else want to respond? Tom.

MR. CHAPPELL: Dr. Templeton, thank you for your presentation. I was curious, as you were speaking about spirituality as a complement to traditional medicine, whether you have explored 12-step therapy, recovery therapy, in any one of the addictions as an efficacious complement for health.

DR. TEMPLETON: We haven't done it. We try, because our funding is to some extent limited, to find cutting-edge research that has not been done before. There are a fair number of studies that have addressed the 12-step approach, and they do seem to support the efficaciousness of it.

The study that I mentioned about the 200-some men who were addicted to opiates was not our study, but that is an example of the impact of a spirituality-based therapeutic approach for those people who were addicted.

MR. CHAPPELL: Thank you.

DR. GORDON: Any other questions from any of the commissioners?

[No response.]

DR. GORDON: I have one. If you could push us in the direction of doing something, recommending

something as a commission to move the whole field ahead, I am just curious, what would each of you suggest to us? One recommendation that we might make that would push or bring with us the whole field of CAM, that would make sense from your perspective.

DR. CALLAHAN: I guess I would simply stress the point I made. I would like to have a better understanding of what there is about CAM that attracts so many people when there is this alternative system that purports to be dealing well with people.

To me, there is a mystery here and it is worth really trying to explore; what gap is it filling, and how is it filling it.

DR. GORDON: Thank you.

MS. ADES: I would like to see the working group to study the research methodology.

DR. GORDON: The study the research methodology, okay.

MS. HAYES: I think it is about communication and openness.

DR. GORDON: Any specific kind of proposal for that?

MS. HAYES: Well, I am coming from a funding perspective. I think foundations have to be inspired to look at this, but they need help. The two of us here, we are among only a handful of foundations that are willing to look at this. It is a very small fraction of our budgets.

We have to be willing to share our experiences, but at the same time, I think the government bears some responsibility in this, too, and as I mentioned, to facilitate those conversations.

DR. GORDON: So to facilitate a conversation among foundations as well.

MS. HAYES: Yes, and communicate that it can be done. As I said earlier, it is not going to be messy and it is not going to hurt, and we can all benefit from it.

DR. GORDON: Thank you.

DR. TEMPLETON: I would like to urge that, because all of us are in this learning process, that if one looks to a consensus conference or something, that it not be a CAM consensus conference but pick two or three components of CAM that has more coherence to it, herbal therapy or something like that, and then work with a

meeting that would involve the foundations as well as the research experts to be able to come up with better models for studies. It becomes too diffuse if you try to just do it all at once.

DR. GORDON: Thank you all very much. We really appreciate it.

Let's take a 10-minute break now, okay, and then we will come back.

[Recess.]

DR. GORDON: We are going to begin Session X. This is Private Sector Support for CAM Research.

Again, thank you all for coming, and thank you for coming and clearing your schedules on short notice.

We are going to have five speakers, and we will listen to all five, and then we will have a chance for questions and dialogue.

First, is Mr. Randy Burkholder from Advanced Medical Technology Association.

Session X: Private Sector Support for CAM Research

MR. BURKHOLDER: Good morning, Dr. Gordon and Commission Members. Thank you for having me speak here this morning. Forgive me if I don't directly answer all

your questions, I have been listening to the debates this week.

[Laughter.]

MR. BURKHOLDER: I am here on behalf of Advanced Medical Technology Association. We represent the producers and innovators in the field of medicine thank you, and our members produce over 90 percent of the medicine equipment and supplies that are consumed in the United States.

Today, I hope to offer to you some insight into private-sector research, and complementary and alternative medicine from the vantage point of the medical technology field.

First of all, a little context on the health trends shaping CAM research that I am sure you are familiar with. Consumers, as we all know from personal experience, are spending more and more on health care. In fact, that figure has quadrupled over the past 20 years. It now tops $500 billion a year.

One thing we still have money for, certainly, is complementary and alternative medicines. I am sure most of you are familiar with the figure reported by Dr.

Eisenberg, that Americans spend an impressive $12.2 billion of their own money on complementary and alternative medicines in 1997.

Five Mountain Medicine Center in Hawaii is one place that some of that is being spent. This center seeks a new model for health in the 21st century by bringing together leading-edge technology and complementary and alternative techniques. Dr. Earl Bakken [ph] is president of the board of that facility. He also invented the first wearable external pacemaker in 1957, and cofounded Metronic, Incorporated.

Dr. Bakken foresees 10 important health trends in the coming decades. Some of them are particularly relevant for our discussion today. One of those is rising demand for quality versus cost-cutting; the rise of the individual as his or her own health manager; the rise of the Internet, of course; and the integration of complementary care.

Several of these trends can be described together as the shift toward a patient- or consumer-centered health care delivery system. The dramatic growth in CAM over the past 10 years, of course, has been

an important and early indicator of this trend.

But who exactly are these empowered health care consumers that we keep hearing so much about? Well, for one, they are spending almost three times as much on diet products, $33 billion a year, as they are on CAM. The outcome, or at least one way of looking at it, was reported this week in the Journal of the American Medicine Association, a 60 percent rise in obesity since 1991, and obesity, of course, is second only to smoking as a cause of premature deaths in the United States.

It might make you wonder what exactly the health care consumer is going to do in the coming years with all his or her new-found power. I think that is what brings us to this table today, is to answer that question, what will health care consumers do with their new clout. With reliable information, I believe they will do good things. In fact, the longevity of a patient-centered health care system depends on reliable information. CAM, as a vibrant, integrated component of that system, depends on reliable information as well.

From the private sector perspective, then, how do you foster development of good information on CAM? As

we consider that issue, I think it is instructive to look back at Dr. Bakken's pacemaker. It was, as I mentioned, a rather bulky, wearable, external device. Today, if you can see it, the little one I put on the table in front of me would be on the larger side. Today, they are often implanted on an outpatient basis in the pectoris with non-thoracotomy leads inserted transvenously. They are packed with therapeutic capabilities that even Dr. Bakken probably wouldn't have dreamed of 30 years ago.

So medical technology certainly has come a long way since the early days of the pacemaker. There are three fundamental characteristics of medical technology innovation that I think are important to consider. One, it is very diverse. It encompasses, of course, everything from laparoscopes to molecular diagnostics and image-guided surgery systems.

Second, it is dynamic. It draws on many different areas of science. It is a non-linear process and it involves close dialogue between the innovator and the clinicians, and it is very rapid. The average life cycle of a new medical technology is a mere 18 to 24 months, and in some segments such as cardiology, it is

even less than that.

It is important to note that the incredible technological advances of the past three decades have occurred in concert with the development of a rigorous pre- and post-market regulatory system in the field of medical technology.

In the Medical Device Amendments of 1976, Congress set some basic scientific principles to guide the marketing of medical devices and diagnostics. To the extent to which Joe Levitt or David Feigal went over those in detail yesterday, I will keep my comments brief, but some of the important things that Congress said in that law were, they said if you want to sell a new medical device or diagnostic test, you need to prove that it is safe and effective. They said if you want to make a new labeling claim, you need to back that up with reliable data.

They said if there is an adverse event with your product that causes patient harm, or could have caused patient harm, that you need to report that to the Food and Drug Administration, and they said that FDA will inspect manufacturer's facilities to ensure the quality

of the products being produced.

This regulation, as I said, has been an important component of the dramatic boom in innovation over the past 30 years. It has helped inspire and maintain consumer confidence in medical technology. It has helped the industry weather the rare safety problems that inevitably arise, and it has formed an important part of the foundation for innovation over the past three decades.

In spite of the breakthroughs that have been made and are still being made, there are some barriers to continued research that we face in the medical technology field. One of those is a lack of research funding. There is less venture capital funding today as a percentage of overall financing than there was seven s ago. It has been in decline over that time, in part, due to the great interest in the Internet dot-coms.

Sources of private research funding also are diminishing. The Whittaker Foundation, as you may know, is the largest private sponsor of bioengineering education and research at universities and medical schools in the United States and Canada. That foundation

has decided to spend down its principle and to cease operation in 2006.

Finally, there is comparatively little funding at the National Institutes of Health for bioengineering. Currently, only 5 percent of NIH research spending, about $500 million goes for bioengineering research. Despite the importance of the NIH to funding bioengineering research, it is not explicitly recognized at the NIH.

Regulation can, of course, be another important barrier to research. For complementary and alternative medicine, I think this could take the form either inadequate or excessive regulation. In the field of medical technology, we haven't faced the problem of inadequate regulation over the past 25 years, but what I am meaning by that is that regulations must be sufficient to govern or direct research and foster development of reliable data.

Further, the lack of adequate regulations in a field like medical technology or CAM, can leave the field more vulnerable to erosion of consumer confidence when serious health problems or safety problems arise. This in turn can weaken the field overall and discourage

further research.

That being said, excessive regulation can, of course, also have an equally detrimental effect. It is interesting to hear the debate over randomized, controlled trials over the past few days. There has certainly parallel debate in the field of medical technology over the past 10 years, or at least comparable in some ways.

When regulators start asking for excessive data up front on comparative clinical or cost effectiveness outcomes in defined patient populations, they likely will drive away good products and freeze further research.

CAM, like medical technology, is a diverse field, and it is important for the regulations to recognize this diversity and to be commensurate with the type of technology that is under consideration.

Despite these potential barriers, I think there are some encouraging trends in private CAM research. One is the ongoing debate over regulation. I think this is healthy. It brings the key stakeholders together, and hopefully enters into a process of defining an appropriate regulatory system that encourages further

research.

The increasing number of medical students interested in CAM and the increasing attention being given to CAM at medical schools in providing instruction also is encouraging. Those students, of course, are tomorrow's champions and researchers in the field.

Third, I would point to the increasing integration of CAM and traditional medical technologies and technology companies. I think that will be an important factor in the growth of research in this field. You can see this in the growing number of pharmaceutical companies taking an interest in CAM as well as the activities of companies like Metronic, which through their foundation, are funding research into areas that link cutting edge cardiovascular technologies with alternative treatment techniques.

To the extent that CAM becomes linked to these endeavors and to these companies driven by scientific research, research on CAM itself will increase.

I think that leaves us with three basic points, or it leaves me with three basic points, anyway. One is reliable information, a patient-centered health care

system, and I think the role of CAM in that system depends on reliable information and the provision of that information to the consumer.

Second, is adequate regulation. Companies need to be up front, involved in a system of appropriate regulation. Third, is continued integration. As I mentioned, as CAM increasingly is linked with medical technology and technology companies, research in CAM will increase.

I think that would move us toward the goal that we are seeking, which is a field based on sound science that enjoys strong consumer confidence and continued growth in the 21st century. Thank you.

DR. GORDON: Thank you very much.

Next is Dr. Raymond Ruddon from Johnson and Johnson.

DR. RUDDON: Thank you. Someone mentioned this morning, I am not used to talking without slides, or as an old professor, at least a piece of chalk in my hand. So I hope this will be clear.

I also want to thank the White House Commission on Complementary and Alternative Medicine for this

opportunity to present, from Johnson and Johnson's point of view, our thoughts about this very important area of public health concern.

Meetings such as this will help focus public policy initiates to assure that this important approach to the prevention and treatment of human disease reaches its full potential. We want to address the Commission concerning the issues involved in facilitating research in this area, and particularly how private industry may help facilitate that.

Johnson and Johnson has addressed this expanding need for research and product development in complementary and alternative medicine in a number of ways, and I will list a few of these. We believe that complementary and alternative medical products do provide a new approach to disease prevention that is different from the traditional medicines that are aimed primarily at treatment rather than prevention. As more and more people become better informed about their own health and wellness, we believe that the so-called complementary and alternative medical products will come to represent an important range of new choices for consumers.

At J&J, we have undertaken a number of initiatives to address this focus. In 1997, we established a Disease Prevention/Health Promotion Task Force, which I chaired, consisting of members from a number of our operating companies that have interest in this area that do provide products for a wide range of health care products.

This task force had the following specific aims: first, in order to broaden our understanding of the disease prevention and health promotion strategies, the task force undertook an extensive review of current literature in the field. We also sought to identify some of the key individuals, research groups, and organizations who are leaders in these fields and to make arrangements to consult with them about the status of research and potential opportunities.

The task force then acted to identify and prioritize the best leads that provide an opportunity for Johnson and Johnson, based on the quality of supporting data, consumer self-selection, proprietary protection, market size, and fit within the Johnson and Johnson operating companies' existing business competencies and

platforms.

The need for further research and the best way to accomplish that research was carefully assessed at J&J. We have established a number of ways to help support projects and bring potential products into development in this area.

I will mention, for example, two granting mechanisms that the Corporate Office of Science and Technology has, of which I am the director. One is a focused giving grant, which is a basic grant, no strings attached, primarily to fund academic investigators in a wide variety of biomedical research, but this could include CAM research. We also have a seed grant program, which is more focused. There are some strings attached, in the sense of right of first refusal for data that comes out of that.

Finally, our task force was charged with the responsibility of developing ways to monitor the progress of research in the field of disease prevention and health promotion, and to anticipate future product opportunities. The task force interviewed, either on-site or at J&J, a number of key investigators in

alternative medicine, and these included groups from Harvard Medical School. We met, in fact, with David Eisenberg twice from Harvard. We also met with investigators from Johns Hopkins University, the University Illinois-Chicago, Rutgers, the National Cancer Institute, and a number of others.

J&J has used its seed grant program to sponsor academic industry research collaborations. We have one ongoing right now at the University of California-Berkeley, for example, on developing methods to screen bioactive materials in complex mixtures and to do development mechanism of action studies.

J&J companies have also been active in the development of products for disease prevention such as Benecol to reduce cholesterol levels, and Splenda, an artificial sweetener that diabetics can use.

Our company has also pioneered in the field of health and wellness programs, and we have a wealth of knowledge and proprietary intervention programs which have been introduced to American workers through job site programs. Indeed, we have a whole company in our family of companies called Health Care System that is focused on

this important issue.

Against this backdrop of activity experience, I would like to approach the questions that were posed by the Commission. First: What can be done to expand the current research environment, and can the private sector stimulate CAM research?

It is clear, I think, from the number of speakers both today and yesterday, that we do need solid, basic research to be carried out to provide the fundamental knowledge of the mechanism of action of complementary and alternative medicine agents and practices, on ways to identify active components in complex mixtures, to carry out bioviability studies, basic pharmacology and toxicology studies. We also need robust clinical protocols to verify that complementary and alternative medicine agents and procedures truly produce the claimed clinical benefits.

Now, private industry can help these efforts through research collaborations with academic and other research groups, and NIH, and foundations, as mentioned this morning. A number of such collaborations could be cited as precedent, including the Human Genome Project,

the SNP Consortium, and a recently funded Alliance for Cellular Signaling.

I think, also, we should keep in mind that there are a couple of mechanisms available using, for example, the Small Business Innovation Research, or SBIR, grants. In the Technology Transfer, such as the Cooperative Research and Development Agreements, or CRDA agreements.

The second question posed is: What types of incentives are needed to stimulate research on complementary and alternative medicine practices, and what are the obstacles and solutions?

In order to provide the incentives to private industry, intellectual property issues must be resolved. Even assuming significant consumer demand for a product or device a reasonable business plan cannot be constructed to enter that market unless some marketing protection is available in return for substantiating the public health benefits of a product.

Additional approaches, such as legislative exclusivity remedies, for example, something akin to the Ortho-Drug program, may be necessary in order to provide

incentives to establish that these products are safe, effective, and have desirable public health benefits.

Finally, without established and transparent regulatory pathways, well established and well-meaning corporations, like J&J and others, cannot fulfill the public health need for these medicines, complementary and alternative medicines.

The third question: How can complementary and alternative medicine and conventional research communities be more effectively integrated to stimulate and coordinate research?

A number of speakers have addressed that, so I will just be brief in added some of these. First of all, I think we do need to expand communication between traditional and conventional medical experts, and many speakers have addressed that. I think we do need to stimulate review and acceptance of high-quality complementary and alternative medical research in publication for top journals, scientific and medical journals.

Third, cooperative effort between private and federal funding needs to be stimulated in this area.

Fourth, a rigorous review process involving both academic and industry scientists should be put in place to evaluate scientific-merited proposals. I think that would stimulate and foster some of these collaborations that we are looking for if that is carried out.

Then finally, as I mentioned, protected marketing rights that will allow for substantial, meaningful, and costly programs must be put in place.

In conclusion, acknowledging that intellectual property rights must be respected, we wholeheartedly endorse of coordinated research programs between private and federally funded, and between traditional and conventional medical investigators in order to transform medical science into the health care products and services that American consumers want and need.

We also see a need for discovery research in this field, using, for example, the modern things that we know about, using gene expression arrays, or proteolytics to identify new bioactive substances in natural products.

Also, to use the emerging field of pharmacogenomics to individualize therapies. I think I disagree with a previous speaker who mentioned that these

data are always going to be probablistic. We are learning more and more ways now, using pharmacogenomic analyses to individualize a therapy.

Finally, we would welcome the opportunity to share our learning and experience in order to advance both medical science and the public policies surrounding this opportunity. Thank you.

DR. GORDON: Thank you very much, Dr. Ruddon.

The next speaker will be Dr. Frank Sciavolino from Pfizer.

DR. SCIAVOLINO: Thank you, Chairman Gordon, Commissioners, Dr. Groft. Thank you for the invitation to present comments from the private sector to the White House Commission on complementary and alternative medicine policy.

The focus of my comments this morning will be on one aspect of CAM, drugs from botanical or herbal sources. I will also comment on what we think is needed to stimulate CAM research as well.

Several years ago, we established a research and development initiative at Pfizer to assess whether botanical remedies represent a viable source of new

prescription medications. We instituted this program because nature has traditionally been a fruitful harbinger of new medicines.

By some accounts, nearly 60 percent of all pharmaceuticals have their origins in natural products. Morphine, cortisone, penicillin, paclitaxil, luvistatin [ph], are but a few examples of prototypical molecules occurring in nature that have led to medicines which are safe, effective, and quality-assured.

The largely empirical screening methods of so many of these useful natural product-derived drug discoveries during the middle of the last century have now fallen into disfavor, largely because they are highly labor intensive initiatives and they are becoming increasingly unproductive.

More recently, R&D in the pharmaceutical industry has toward molecular design and the use of automated chemical technology to synthesize huge libraries of compounds that can be screened by Ultra-I throughput methods against novel biological targets.

The revolutionary advances in molecular biology, genetics, robotics, in information technology,

have propelled drug research in this new direction. However, the link between pharmacological activity against newly discovered molecular targets and clinical effectiveness in specific disease indications is not always clearly understood, nor fully charted, despite the best efforts of our brightest minds.

Consequently, clinically validated mechanisms and clinically effective new chemical entities remain highly prized milestones in drug research and development. The road from a new idea to a new medicine is long, it is treacherous, and it is expensive. This journey from a newly observed biological concept in the laboratory to a medically available registered drug typically takes 10 to 15 years at a cost which has been estimated by the Tufts University Center for the Study of Drug Development to be in the range of $400- to $500 million.

A key factor contributing to the time and expense metrics associated with drug development is attrition. Most drug candidates nominated by sponsors for clinical development fail to become registered pharmaceuticals. For every five to six drug candidates

which reach the investigational new drug stage, the INDIVIDUAL status, industry experience indicates that only one becomes a product.

The majority fail for a variety of technical reasons, most of which involve safety, efficacy, and the benefit-to-risk judgement, but other less prominent parameters such bioavailability and stability may contribute to the decision to halt development. This is the reality of pharmaceutical R&D today.

With the passage of the Dietary Supplement Health and Education Act, DSHEA, in 1994, a resurgence of interest in herbal medicines is beginning to take hold, and natural products are again attracting attention as a potential source of new drugs. The seminal change that is kindling fresh interest in nature as a reservoir of useful medicines is the increasing recognition of herbal medicine by regulatory agencies.

Enabling policy changes dealing with botanical drug regulation are beginning to be addressed. The draft guidance for industry on botanical drug products, which the FDA published for comment in August of this year, appears to be a meaningful first step toward opening the

door for sponsors to conduct randomized, controlled clinical trials to confirm the efficacy of botanical mixtures in patients.

This impending change could shift the focus of natural products research from what was largely a laboratory effort seeking lead structures for chemical modification to a clinically driven initiative with product orientation. Final guidance from the FDA on the registration of botanical drugs would be a landmark event that could stimulate investment in this area by interested sponsors.

In our Natural Medicines Initiative at Pfizer, we coined the term "naturceuticals" to designate prescription drugs of plant or natural origin that have been rigorously characterized for safety, efficacy, and quality.

The development paradigm for a naturceutical differs from established pharmaceutical strategy, in that, it seeks to rapidly address clinical efficacy up front with candidates having anecdotal or folklore histories of use in man. Opportunities with proven clinical efficacy then become the subjects of more costly

investments for full-scale registration of a safe and effective product.

If botanical medicines are to be developed as true pharmaceuticals, that is, naturceuticals, their development must be conducted to the highest standards of safety, efficacy, and quality. There can be no compromise on the science or medicine of naturceuticals. We see the level of investment that would be required for the NDA registration of a naturceutical to be comparable to that of a pharmaceutical.

Therefore, a key issue in developing botanical medicines is the need for an incentive mechanism to provide for a return on investment. One possibility is a Waxman-Hatch type data or marketing exclusivity period that would allow the sponsoring investor to fully develop the medical and commercial potential of natural medicines.

Nature has been an unparalleled source of unique chemical structures with extraordinarily potent pharmacological activity. We urge the Commission to recommend enabling policy that will provide incentive for the private sector to invest more substantially in

research and development of natural medicines. Thank you.

DR. GORDON: Thank you very much.

The next speaker will be Mark Blumenthal from the American Botanical Council.

MR. BLUMENTHAL: Good morning, everybody. Howdy, and thank you for inviting me to be with you all this morning. I want to also congratulate for being appointed to this important group.

To optimize time, I have provided some written overview of the mission, publications, and projects of my non-profit organization, the American Botanical Council, but just to let you know that since 1988, we have been dedicated to educating on scientific research on herbs and phyto medicines, and stimulating such research in the United States. Since 1983, our publication, "Herbalgram," has reported on results of foreign research on herbs when information on herbs is almost non-existent in the medical and scientific literature in this country.

The federal government obviously has made excellent progress in funding clinical research and the other botanicals. I will speak only on the issue of

trying to provide some private sector initiatives, of course, and incentives. That is my primary issue today, and not coordination but the incentives.

Basically, the White House Commission on Dietary Supplements in 1997, in its report, dealt with this issue by saying, "A manufacturer lacks incentive to expend resources for research that might benefit competitors as well as itself. In other words, there is no proprietary interest here.

We dealt with this issue back in 1986 in an article by Jim Duke in Herbalgram when he talked about the high cost of pharmaceutical drug registrations and approvals basically requires federally funded natural product research because at that time it was not going to come from the private sector.

The CDSL, the Commission on Dietary Supplements, also wrote that, "The FDA might consider a mechanism for review of research conducted to validate a statement of nutritional support so the label disclaimer mandated by DSHEA could be modified or removed."

In other words, there was guidance for the possibility that the FDA has not evaluated the claim, and

the product is not intended to treat or mitigate a disease might be considered for removal if a product met certain requirements for research, although that has never been followed up on, to my knowledge.

Now, in the area of research, there is a clear correlation between what is research, especially in Germany and the rest of western Europe, and what products are the top-selling products in the United States. If you look at all the top-selling products in the United States in the mass market, except for the inclusion of Golden Seal in the top 10 or 20, which has no research in it for the last 60 years, almost every one of these herbs are the most well researched ones from western Europe, ginkgo, garlic, ginseng, palmetto, et cetera.

So there is a clear correlation between funding of research, even though it is coming from out of the country mostly right now, and the success of these products in the market, success, at least, generically speaking, and I will provide documentation of that in my written comments.

Centers for manufacturers ought to be able to publish clinical studies that deal with their specific

product and get that information into current medical journals and in the news, especially when that publicity is tied to the brand that is studied. One of the primary obstacles that we are dealing with right now is regulatory, the lack of government recognition of the benefits of herbs.

Because most of published clinical research comes from Germany, it is instructive to look at their regulatory system there, where they have a so-called Commission E, which is a federally empaneled group of experts, of physicians and pharmacists, that evaluate all the published literature out of the 300 herbs that are sold in pharmacies as non-prescription drugs to determine whether these herbs are safe and effective for their non-prescription drug uses. Then they publish their results in these monographs which are intended as package inserts for therapeutic guidance for clinicians as well as for patients.

There in Germany, you have a recognition that these herbal products have benefits, and the government recognizes that in the product itself. Therefore, the research that is being generated in Germany today is not

being done for regulatory approval because they are already approved. It is done for market considerations.

The companies' research is published in the journals, and then the detail going to the doctors and saying, here is our study on R-ginkgo or R-garlic, whatever, and doctors recommend them. Half of the herbs sold non-prescription in Germany are basically semi-ethical, doctor-recommended or doctor-prescribed. So there is a very strong impulse in the German marketplace where physicians are recommending certain brands of phyto medicines.

Sadly, in the United States, excepting for a few herbs approved as OTC and drug ingredients and silvium for an NLEA health claim, our government does not recognize health benefits for herbal preparations. This results in exaggerated public health concerns when adverse event reports appear in the media against a backdrop of no recognized benefit, having a negative effect on the public's view of herbs, as well as professional view, contributing to a loss of public and professional confidence in this category, often unwarranted.

So if promoting information on herb research presents a unique set of challenges dealing with phytoequivalence, science, and generitization. Let me explain. Much of the European research is done on the proprietary commercial phyto medicines, often chemically defined and standardized. The question arises then, when can results of the trial on a specific commercial product be transferred to a purportedly similar and/or different product? When is the science transferrable? It is a big issue, not often discussed in the open market, but it is there.

In some cases, clinical research might be transferred to products that can prove phytoequivalence or bioequivalence through bio assay and/or chemistry, but his depends on formulations involved, designs of studies, et cetera, and these questions play the open market agenda in the United States right now.

Further, the expropriate of European research in the United States has caused some European phyto medicine companies to become concerned over the borrowing and generitization of their research efforts over here. Similar concerns face many U.S. companies that are doing

clinical trials on products, unless they can assure that the results of their research is not unfairly used by their competitors.

It is important to note that DSHEA has been an agent for promoting herbal research in the United States. A DSHEA has supported the research. New private research has been funded in herbs here in the United States with the passage of DSHEA since most of this has been tied to INDs and most of it has yet to be published it is often difficult to determine how privately funded studies are in process or are pending publication, if at all.

The estimates are rumored to be within 50 to 100, or possibly more. In the area of private sector funding by members of the herb industry, there are numerous examples that I could tell you about specific products, but time does not allow this elaboration. They are in my written comments.

And there are numerous incentives we can discuss. One obvious incentive is exclusive claims, usually for a drug, usually requiring an MDA, very expensive, as we have just heard. Many of these herb products are OTC-type products, often sold as OTCs

overseas, but there is no market protection for OTC product claims unless the company files for an FDA. OTC-monographed claims are not protected by market exclusivity.

The recently published FDA guidance document on botanical drug products allows a five-year market exclusive if a company has fulfilled NDA requirements. Right now, in Congress, the Nutriceutical Research and Education Act, NREA, bill proposes exclusivity for nutriceutical for 10 years. At least one acceptable clinical study is required, according to the bill, and borrowing of research is not allowed, unless the research supports the present study, the new study.

Small manufacture exemptions would be allowed to pool resources and share claims with small companies from their combined research efforts. Claims under NREA would deal with disease prevention, reduction and disease management, but yet, public support for this bill is not clear.

Is there a reason to conduct clinical research on herbs sold as dietary supplements, not as drugs? Yes. People want benefit-related research, not just an

explanation of mechanism of action or identification of active compounds.

Do we want all companies to have to conduct studies on every product, like every garlic and every ginseng product? Are there sufficient financial resources among the industry to do this? Are there enough contract research organizations and other centers to conduct these studies?

I would like to suggest some government-sanctioned incentives that could help promote research. First is, structure/function claims might be approvable by FDA. FDA approval of structure/function claims might promote research. This is under DSHEA. However, this may lead to other problems, like long delays and additional cost, and whether this conforms with Congress' original intent for DSHEA.

Further, the CDSL suggestion that modification of the Dietary Supplement disclaimer, when its removal from a product that has undergone some clinical study review, I believe is worth your consideration.

There is the issue of patents. Herbs cannot qualify for composition of matter patents, like

pharmaceutical drugs. However, since DSHEA, the U.S. Patent and Trademark Office has been very active in granting process patents and use patents for botanicals. These represent potential incentives. However, some use patents may not be able to withstand possible future challenges based on their claims, possibly coming from the public domain and traditional use.

The case of the recent reversal of the tumeric patent is a glaring example when India protested against the U.S. Patent Office's allowance of that patent, because tumeric has been used in Vedic medicine for so long.

There are also potential tax incentives, maybe some tax credits to companies for funding research might be considered. Also, important, I think, is the creation of an expert review panel. Consistent with recommendations of the CDSL, the government should establish an expert review panel similar to Commission E to evaluate the safety and appropriateness for claims for herbal products, both the structure/function claims under DSHEA and as OTC drugs.

Trademark value is a very important commercial

commodity, and developing consumer recognition and confidence in a trademark is a strong motivator for research investments. With the herb market filled with such a wide variety of products, many of them looking very generic, companies are trying to establish a clear identity and differentiation. The recent example of Smith-Kline Beecham introduction of Laluna, I believe, is a very useful example.

Finally, we must find a viable balance among free market and competitive issues, science, regulation, and the need to respect cultural heritage, and traditional use. It is likely that some of the highest quality herbal products produced in the United States are made by some of the smallest companies. Allowing larger companies who are able to invest in research to satisfy exclusivity requirements may discriminate against small businesses, posing serious economic and social problems.

The problems we are dealing with here require legislative solutions, administrative attention, industry time and attention, and commitment and cooperation. Responsible elements in the herbal community are looking for solutions and assistance on these issues from both

within and outside the industry.

I thank you for your time and attention in allowing us to be here today.

DR. GORDON: Thank you very much.

Dr. Annette Dickenson from the Council for Responsible Nutrition.

DR. DICKENSON: Thank you for the opportunity to be with you here today and to share some ideas on private sector involvement in stimulating research on CAM.

The Council for Responsible Nutrition, which I represent, is a trade association representing more than 110 companies in the dietary supplement industry. Our membership includes companies that supply the bulk ingredients used in dietary supplements, as well as the national brands and store brands of finished products that are available to consumers through all types of retail outlets, including supermarkets, drug stores, discount chains, health food stores, direct sales, mail order, and the Internet.

Our member companies provide all types of dietary supplements that are covered by the Dietary

Supplement Health and Education Act, including vitamins, minerals, amino acids, botanical products, and specialty supplements. CRN was established in 1973, and prides itself on developing policies and programs for dietary supplements based on sound science. CRN science staff currently includes four individuals with expertise in nutrition, toxicology, natural products chemistry, and genetics.

We are in the process of creating a new executive position charged with the specific responsibility to identify opportunities for research partnerships with government and with academia, and to help industry members take advantage of such opportunities to maximize their own contributions to current scientific evidence.

As part of this effort, we will also seek to be actively involved in the development of agency research agendas and the establishment of priorities based on optimizing impacts on public health. Dr. Cathy Frohmus [ph] of our staff will be taking on these responsibilities, and I believe she is known to many of you.

We are pleased to be able to offer some suggestions on the role of the private sector in stimulating research into CAM from the perspective of the dietary supplement industry. Regarding ways in which the private sector can stimulate CAM research, we believe industry should be encouraged to submit its studies to peer review journals for publication. Industry should also provide data from its unpublished studies to assist in selection of therapies for further study and to contribute to study design.

For example, these data may help narrow dosage ranges for Phase I studies and alert investigators to potential side effects. Industry could provide the vitamins, minerals, botanicals, and other dietary supplement ingredients for clinical studies, and also assist in the preparation of appropriate placebos, not an insignificant task.

Industry could cosponsor symposia or conferences to provide networking opportunities between researchers and clinicians. For example, CRN is currently planning one such conference in November of 2001 in cooperation with the American Society for

Pharmacognosy. Regarding some of the obstacles and solutions that exist in industry cooperation in this effort, we would suggest that it would be useful to convene meetings with journal editorial boards to solicit recommendations which would increase the acceptance of papers submitted by industry, which face some barriers to that acceptance.

We believe it would be useful for industry, especially for smaller companies in the industry, to generate a clinical trials guidance document outlining the standard components and proper design of study protocols. CRN's Dr. John Cartelina [ph] is currently working on this type of document and will be seeking partners to contribute to its content and enhance its value. Resources that will be used in preparing the guidance document include existing NIH guidelines and information being compiled by the International Conference on Harmonization.

A mechanism is also needed for industry to share study results that may involve proprietary information. The soon-to-be-launched ODS CARDS database, which I think was discussed to some extent yesterday,

might serve as a repository for a listing of unpublished studies identifying the lead investigator or contact person in order to facilitate communication.

We believe that standardized products that are commercially available should ideally be used in clinical trials when possible. If special formulations are used that the consumer cannot buy off the shelf, the study results don't have the immediate translation to the direct population.

Industry needs to form partnerships with clinicians or academia, depending on the type of study. Various mechanisms are needed to bring together these disparate communities, as has been emphasized earlier today. CRN is in the process of establishing a dietary supplement information center in cooperation with a major academic institution. We believe this center, once established, could also play a role in this regard. Also, a special web site could be established to facilitate communications regarding ongoing research needs and opportunities.

In response to the question regarding how CAM research can be better coordinated with federally

supported CAM research, we believe industry representatives need to participate on advisory panels, particularly at NIH. A visible representative can address the concerns of clinicians and of government officials, and serve as a bridge between the public and private sectors.

A primer on funding mechanisms for research and conferences within government agencies that apply to industry should also be compiled to explain, for example, cooperative research and development agreements, small business grants, investor-initiated grants, and contracts.

We believe ongoing research and potential funding opportunities need to be more visible, and private studies need to be added to government databases. For example, CRISP is an excellent tool to seek information on federally funded studies, however it needs to be updated more expeditiously and expanded to include clinical trials that are not federally funded.

The ODS CARDS database will target dietary supplement research. The project should receive sufficient funding to include non-governmental funded

research, also, and be updated expeditiously. NCAM serves as an excellent model for its open and visible process in determining priorities and future research projects.

Concept ideas are discussed at its advisory council meetings. Approved concepts are posted on the web site, and within a few months, a request for applications is issued and also posted on the web site. A document explaining, for industry use, how each research agency determines its research agenda would also be extremely helpful.

We believe consensus conferences would also be a useful tool to highlight CAM therapies and remaining research gaps. For example, a conference on the safety and value of ephedra for weight loss could make a valuable contribution in this highly controversial area. A conference on St. John's wort should be held, we believe, soon after completion of the NCAM NIMH-funded study which is now centered at Duke University.

We appreciate the opportunity to share some of these ideas and to continue to work with you in the future. Thank you.

DR. GORDON: Thank you very much, and thank you for the very specific suggestions. It is extremely helpful. Thank you, all of you. You are opening up whole other perspectives for us, which are really very important.

Are there questions from Commission members? Yes. Tom, and then George.

MR. CHAPPELL: Thank you all very much. It was really very helpful, very clear.

I guess I would like to pursue the question, Dr. Ruddon, if I may, of the proprietary interests that need to be part of the total picture. If we imagine the marketplace that consumer is driving currently, consisting of, let's say, single herbs, some OTCs that can be formulated, a decongestant, for instance, and then pharmaceuticals.

Do I understand that your suggestion is that we have private industry find a way to protect the marketing long-term exclusivity on all three categories? Just the last? Could you help me understand these gradations and where you see private industry expecting to be protected for the high, up-front investments.

DR. RUDDON: I think, to some extent, it is all three categories. It is certainly in the area of pharmaceuticals. OTCs probably somewhat less so, but certainly still included.

I think even in the area of nutriceuticals and natural products, there needs to be some kind of competitive advantage or proprietary protection that would allow the investment and the research that has to go into these agents to prove clinical efficacy.

So that, even in the case of those agents, I think the view is that there would need to be some kind of proprietary protection, most likely, or frequently, not around the chemical entity itself but around process, extraction, production, and use of unique mixtures or combinations of agents. I think there would need to be some exclusivity around all three of these categories.

MR. CHAPPELL: Especially if an NDA is required.

DR. RUDDON: Especially if an NDA is required.

MR. CHAPPELL: Thank you.

DR. GORDON: Mark, is your light on because you wanted to respond to that?

MR. BLUMENTHAL: Well, obviously, the NDA process if very extensive, and it is going to be a barrier to anybody except the larger companies.

The issue of exclusivity for dietary supplements is something that is being discussed as part of this bill that is NREA, allowing 10 years of exclusivity if you came up with one clinical study that was acceptable.

I am not sure that is going to get a lot of industry support because, obviously, everybody is going to be like a land rush to grab one claim for one particular product, and then try to tie it up. Then you run into the issue of, how does that deal with the fact that herbs have been part of our heritage. We all own the right to use herbs for various things. Does that translate to the commercial sector? And to what extent does allowing people exclusivity in the area of dietary supplements for herbs tread on our public heritage and our traditional culture.

Those are issues that have been dealt with, from the patent point of view, by the example of tumeric, and then also iawasca [ph], where native shamans from

South America have petitioned the Trademark Office for allowing a healing patent for iawasca, a traditional vine of South America. The Indian Government protested the Patent Office for allowing, I think, an inflammatory patent for tumeric, which is part of medicine.

So we run into a lot of issues of intellectual property and otherwise when we talk about allowing for exclusivity for herbs as drugs and as dietary supplements both.

DR. RUDDON: I would like to just respond to that. I think we ought to be clear that we are talking primarily about development of new products, not about trying to gain exclusivity around things that people have been taking for 1,000 years. I think we are talking about new product development here, where there needs to be exclusivity. A lot of investment goes into the research, both basic and clinical to do that.

I don't think we are trying to gain exclusivity around things that have clearly been in the public domain for a long time.

DR. GORDON: Could you give an example of -- I think this is a very helpful discussion between the two

of you -- an example of what you would consider a new product as opposed to a traditionally used product.

DR. RUDDON: Well, I think, for example, many of the agents that have been talked about already, St. John's wort, ginseng, ginkgo, and so on. I don't think one could foresee trying to have exclusivity around those.

If, however, there were, let's say, some new components of green tea that were identified and had previously been known that might, either by itself or in combination with other agents, provide a new approach, a new therapeutic approach, yes, then I think one might expect some kind of exclusivity around that.

DR. GORDON: You mean components extracted from green tea.

DR. RUDDON: Yes, right.

MR. BLUMENTHAL: Pure compounds, however, are usually excluded from the definition of herb or phytomedicinal. So when you start getting into pure compounds that have been extracted from a plant, that no longer is the domain of herbal medicine. That becomes pharmaceutical drug, and that is a distinction.

To give you an example of a common ingredient that exclusivity might become a controversial in, let's take something as common as peppermint. Peppermint, right now, is not included in the over-the-counter drug monograph for digestive aids. So it is basically just a dietary supplement, and now FDA has allowed supplements to be able to make heretofore unallowed claims in the area of over-the-counter drugs if it is not a disease claim.

So digestive aids, not being a disease has now allowed for peppermint. Somebody, theoretically, under some schemes that might be proposed, could make a land rush for peppermint for a digestive aid and try to tie that up. Of course, that would make it a real problem for after-dinner mints. It is part of our culture.

I am just trying to raise these issues. Hopefully, that is not an extreme example.

DR. GORDON: It is helpful.

Dr. Scaviavolino.

DR. SCAVIAVOLINO: Maybe I can contribute in an example from Pfizer that may put some perspective on this for you. We are pursuing at this time an opportunity

that we found through a botanical company in England called Phytopharm, who in turn found an opportunity from South Africa. This was a material which has been publicly designated as P-57, which was used by Hottentots and bushmen in South Africa who were going into the bush, going into the jungles and realized that they may not have access to food for some periods of time.]

In the folklore associated with this, if they ingested this particular extract, or sucked on the juice from this particular plant, that their hunger pains, their appetite requests, were suppressed. We have studied this fairly carefully. There are very interesting materials. We are pursuing it as a mixture of materials, but not as single chemical entities.

DR. GORDON: You said you are pursuing it as a mixture?

DR. SCIAVOLINO: We are pursuing it as a mixture just as it has been used by the natives in South Africa.

To make the point that what we are attempting to do is very different from the ginsengs and the garlic extracts, and that sort of thing. We are really pursuing

this from the point of view of looking for medicines that could be potentially useful, that are not commonly in the common use right now.

MR. BLUMENTHAL: Something like that could be possibly subject to a use patent and process patents, but probably not a composition-of-matter patent. So you have several lines of protection there. Then you have the problem that the Hottentots might come back, and that you are giving them some intellectual property, and say, hey, wait a minute; you are patenting our intellectual property here.

DR. SCIAVOLINO: If you are going to deal with this sort of thing, you really have to incentivize all parties involved. So Phytopharm is involved, South Africa is involved.

DR. GORDON: That is very helpful.

Tom, is your question finished yet?

MR. CHAPPELL: Thank you.

DR. GORDON: George is next, then Tieraona, Wayne, Bill, and Effie.

DR. BERNIER: I have a question for Dr. Ruddon.

You have talked about expanding research

collaborations. Could you let us know with whom you have developed these collaborations? Particularly in the areas of SNPs or genomics.

DR. RUDDON: Actually, the study that I mentioned at UC-Berkeley, part of that study is to use the gene expression arrays to identify signatures that indicate a particular pharmacologic activity.

So that is one example. There are a couple of others that I could mention, but that is one idea of using the emerging new molecular biologic techniques to identify bioactive agents. So that is one example.

DR. BERNIER: Do you collaborate with people who are interested in CAM?

DR. RUDDON: Well, this particular laboratory, that is what they do.

DR. BERNIER: That is all.

DR. RUDDON: That is what they do. They are focused on natural products, as antioxidants. So the answer is yes, and there are other examples where we have collaborated with an investigator. Rutgers looking at green tea as a chemopreventive agent, and other tea components. So yes, we do collaborate with investigators

working on CAM.

DR. BERNIER: Thank you.

DR. GORDON: Tieraona.

DR. LOW DOG: Thank you. Those were wonderful presentations from all of you.

We have been focusing a lot, yesterday and today, on larger concepts, conceptual ideas around complementary and alternative medicine. This is an area that is fairly specific. Dietary supplements and botanicals, for the most part, can be subjected to double-blinded, randomized, controlled trials, except for individuation of therapy the way a lot of traditional herbalists practice, but in the large sense that the public uses.

My question, and since we are here to develop policy and come up with ideas on how that helps the public, I think many physicians' concerns about botanicals and dietary supplements is, whose responsibility is it ultimately to determine, less so the efficacy at this point but safety, safety in children, safety in a five-month old, safety in a 90-year old, somebody with hepatic or renal insufficiency. Is it safe

during pregnancy? Can a lactating woman use it?

Sam-E, MSM, glucosamine, huperizia [ph]. It just keeps coming out more and more all the time. While we haven't had significant adverse effects, you can just sort of see the writing on the wall. At some point, we are going to have to be addressing this.

If we don't make incentives for companies to pay for this sort of research, do we need to put the government more involved in this? What are some of your suggestions as far as this?

Because this is an area that I think is going to hold back many conventional medical practitioners, because they see this as an area that has been under-investigated. We are still debating, whose responsibility is that?

DR. DICKENSON: I think from the point of view of the dietary supplement industry, we would view that the company has the ultimate responsibility for the safety of its product, regardless of what the target population is, even in the case where there may be questions about exactly what the regulatory responsibility is on the company. Certainly, from a

liability point of view, the company has complete responsibility for the safety of that product.

However, there are many questions such as you mentioned, especially regarding use in pregnancy, which came up in January through March when FDA had tentatively proposed to allow the industry to use statements about use of various products for morning sickness, and quickly reversed that position when questions were raised about what would be necessary to confirm the safety of the product for those uses, not simply in terms of lack of any knowledge of un-safety, but in terms of proactive, positive demonstration of lack of teratogenicity and for safety during pregnancy.

This clearly raises very broad questions in which I think it is clear that the industry is going to need partnerships with government in order to do those kinds of studies if indeed it has concluded that the positive demonstration needs to be made for each and every one of these ingredients.

MR. BLUMENTHAL: One area of safety but one that is not well known, the herbal industry, through its trade association, the American Herbal Products

Association, put together a book in 1997 called "Botanical Safety Handbook" in which they reviewed the availability literature on over 550 herbs commonly sold in the U.S. market, literature from monographs, clinical studies, case reports, et cetera, and triaged the herbs based on four levels of safety to try to establish a uniform pattern of labeling under DSHEA for some of the risks, contraindications, or drug interactions that was now allowed by DSHEA for the first time for these products.

So you have at least an industry-based baseline of some 550 herbs that is, frankly, unfortunately, not well known but could be helpful for people to look at.

DR. GORDON: Thank you.

Did any of others of you want to respond?

DR. SCIAVOLINO: I might just input a little bit to that. At various meetings that we have sponsored, and some focus panels, we agree that it has become very clear that general practitioners, in particular and other physicians as well, are reluctant, concerned, about putting patients onto supplements for particular indications without knowing particularly what drug

interactions are going to look like. There is very little data that is available to them, and that is certainly an area that needs to be looked into carefully.

From the guidance that the FDA put out last month, or two months ago now, it is very clear that companies seeking to go either the OTC or NDA route will be able to get to early Phase II trials quickly, but to obtain the full NDA package where physicians, then, could be fully educated on the kinetics of the material, the stability of the material, its interaction with other medications, particularly seniors who will be on multiple medications.

To have that full technical package available, they are suggesting in the guidelines that a full, typical NDA package for a pharmaceutical is what will likely be required, with perhaps some concessions in the CMC package, the chemical manufacturing, the controls package.

So that is leaning toward generating this kind of information for those who would do it through the NDA route. So it would be a mechanism for generating that kind of information.

DR. GORDON: Thank you.

Wayne.

DR. JONAS: This is a very informative discussion, and thank you very much for your organized and succinct remarks.

I had a question. Well, a number of questions. The attrition rate. I was kind of puzzled by your estimate that the costs for developing a naturceutical. I love that term, another one we can add to our potpourri.

If development of a naturceutical would be in the same range of costs as developing a pharmaceutical, and if the bulk is due to attrition, have you done some estimates that in fact you think this would occur, at least under current regulatory processes?

If those were changed, it seems to me, that it would be possible to significantly reduce the likelihood of the attrition rate, and therefore the cost, of developing these products.

DR. SCIAVOLINO: One of the benefits that is being suggested here is that being able to get early Phase II data and establish efficacy and reasonable

safety in limited populations would certainly contribute to the outcome, would potentially. I mean, this hasn't been tested yet.

Data would have to be generated, but one would assume that by generating that early data and showing that you do have efficacy and you do have safety, then the attrition might be reduced, which then would leave you with developing just one material instead of having to take five or six shots on goal to get to the final product.

DR. JONAS: A lot of that would depend on whether the guidance that is provided really helped to shift this toward that kind of --

DR. SCIAVOLINO: Yes. Allowing early access to Phase II trials could help.

DR. JONAS: Right. Process patents, how valuable are those in terms of actually producing incentivization? Mark, you mentioned there is the question of challenging those types of things. The idea of incentivization, to me, seems to be a very complex task that involves both patenting as well as FDA regulations, as well as a variety of other things, such

as copyright and getting one's name on it, and this type of thing.

I am just wondering, is there a mainstream in which incentivization could occur? Use in patent, would that be the main focus, use in process patent? Or, does that not exist?

MR. BLUMENTHAL: One thing about the process patent, it is sometimes easy to get around that if you develop a similar but different process, and the difference in your process is significant enough to allow the Patent Office to let you around or not, depending on if you get into a contest with the person you are competing with.

So process patent just deals with extraction or development of the actual material. It is more of an industrial issue, and the uses, of course, are obvious. With herbs, of course, you can't get a composition-of-matter patent, usually, because the herb is already there. It is public domain.

Patents are obviously are a good way to go. It has been very high on people's agenda in the last five years since DSHEA came out, so obviously it is a great

incentive for a lot of people. I think, trademark is ultimately your best asset because Coca-Cola and Band-Aid says it all.

PARTICIPANT: Tylenol.

[Laughter.]

DR. RUDDON: I think I would agree with Mark. I think that, depending on the size of the market, the process or use patent would certainly be an incentive. As we just mentioned a couple of products, certainly branding, but yet, in order to gain that, you really need solid evidence behind it.

DR. JONAS: I get the sense that that would have a relatively small impact if that was all that happened, that there would need to be some other exclusivity protection, like you have mentioned, that would require a lot more than that, and primarily around the definition of, what is a new product that would allow you to get this kind of information.

For example, the gene arrays of ginkgo, for example, a well established product, we are now finding under gene array screening that it was useful for certain cancers. This potentially could be thought of as a new

use or a new product, perhaps.

DR. RUDDON: Yes.

DR. JONAS: I had one question for Dr. Burkholder.

It appears to me, and I have been to a number of biotech meetings where there has been a fair amount of interest in CAM, but it appears to me that it has been more curiosity than anything else. I get the sense that the tech industry itself still is not quite sure. There is not a lot going on in these areas, other than that there is curiosity.

DR. BURKHOLDER: I can speak more directly to the medical device and diagnostics makers and biotech, but if it is any indication, Metronic certainly is probably on the leading edge of that interest in CAM. A lot of other companies, it is more curiosity, or they are not, maybe, even at the curiosity stage yet.

DR. JONAS: My sense is there is practically nothing. Even though what Metronic is doing on the leading edge, it is still extremely small, from what I can tell compared to the industry, certainly.

DR. BURKHOLDER: That is true.

DR. JONAS: Just one other thing. It would be very useful, and this is in the whole area, to try to think about some ways, and perhaps later on we can get focused specifically about tech areas as well as the devices industries as to, are there ways in which that area can be incentivized, because I think that area is dealing with a lot of the cutting edge technology in these areas. So an interface with that, I think, would be extremely useful.

DR. BURKHOLDER: Yes. I think for some products it might be easier to apply existing regulatory incentives in some ways. Acupuncture needles, I guess, would be one example where they now do go through a limited premarket process, just to at least establish safety.

Another intriguing concept might be a use of private or public reimbursement mechanisms as a means to incentivize products. I guess the reason I find it intriguing is that it already is essentially a non-exclusive endeavor. At least in Medicare, if Johnson and Johnson comes in and asks for Medicare of an intracoronary stint, they can get the coverage, but

everybody else who makes stints gets the coverage as well.

As much as that might spur development of data to justify coverage, it might be an incentive.

DR. GORDON: Bill, and then Effie.

DR. FAIR: I have two questions, the first to Dr. Dickenson.

Would you tell the panel, what is the purpose of this Dietary Supplement Information Center? What gap does it fill, and who will be served by it?

DR. DICKENSON: It would fill the gap that both health professionals and consumers would actually prefer to get information about health and safety of dietary supplements from another third party group rather from an industry group. We do provide some information, both to health professionals and consumers.

Of course, I remember companies do directly, but there is a demand for access to a third party academic institution, other health professionals that are knowledgeable about these products, that would not have the commercial motivation.

So the purpose of the Institute would be to

make available to health professionals, perhaps through an 800 number or perhaps through other avenues, production of background materials and information. For example, authoritative information on what is the current state of the science on either safety or efficacy of some of these ingredients.

DR. FAIR: Would that be a web site, also?

DR. DICKENSON: Ideally, there would be a web site, an 800 number, a generation of printed and other kinds of materials, the availability of these people to present at professional meetings, for example, and other areas where health professionals will be discussing these issues.

DR. FAIR: And that doesn't exist now.

DR. DICKENSON: It doesn't exist in terms of a group that is specifically focused on dietary supplement type products. Obviously, there are numerous research institutions that have special interest in specific kinds of products.

For example, earlier it was mentioned that numerous researchers at Berkeley have a particular interest in antioxidant products. Numerous researchers,

at Creighton [ph] and elsewhere, have interest in calcium type products, but there is not a center that covers that whole range of dietary supplement ingredients.

DR. FAIR: Thank you.

The second question is addressed, I guess, to the panel in general. I think probably some of you know one of the leading ethnobotanist at the New York Botanical Garden, Mike Ballick [ph], has spoken and written that fewer than half of 1 percent of all the plants on the planet have been identified for medicinal uses. I assume that is a valid source.

Now, if that is the case, which seems surprising to me, but if that is the case, it clearly must be something more than disincentive to look at plants. Other countries don't have the same regulatory problems that we have. I hear a lot of talk about the regulations and the lack of incentive, and so forth.

Is it the molecular design that has taken over? What is the reason for that low percentage?

MR. BLUMENTHAL: First of all, I want to say that Michael Ballick, Dr. Ballick, is on the Board of Trustees of the American Botanical Council. So I know

him quite well, which might disqualify him as an authority here now.

I believe the figures that Frederick Farnsworth throws out is that 5- to 10,000 plants around the world, out of a quarter to half a million vascular plants, depending on if you are a lumper or a splitter, botanically, how many plants there are. Five- to 10,000 plants have been fairly extensively studied for their chemistry and/or pharmacology, toxicology, for compounds in them, or whatever, and/or have been used in traditional systems of medicine, basically.

Regarding incentives, from the pharmaceutical perspective, I will let some of these gentlemen here answer that, but a lot more than that have been screened probably, especially with some of the high-throughput screening processes like Phytopharm does in England for compounds. But from a total medicinal point of view, maybe 5- or 10,000, and many of them reflect those that have been used in traditional medical systems.

DR. FAIR: But even that out of, what, a quarter million plants, that is a small percentage. What is the big problem? Are they deemed not worthy of

looking at?

MR. BLUMENTHAL: Well, first of all, those are the plants that reflect what in ethnobotany comes down to us historically as the plants that people have been using. So there is a self-selection, or there is a historical selection process over the last 60,000 years that that 5- or 10,000 represents. It doesn't mean that people have caught everything, but we do have give some credence to the selection process of trial and error and empiricism.

From a pharmaceutical perspective, I am sure these gentlemen can give better answers, from a drug discovery point of view.

DR. SCIAVOLINO: I think what has happened in practical terms in the industry is, yes, there are multitudes of plants that are out there and available for people to look at.

As I pointed out in my comments, this was an approach to discovering drugs some decades back. What this has lead to, basically, is people making extracts of materials and testing these extracts of materials through standard screening methods. What that leads to is, by

and large, some activity against a number of enzymes or a number of receptors. Then people go and they scale up those materials, and go fish out individual components, and then find that they followed some line of activity. They may come up with a structure, but that has only got 10 percent of the activity that they were looking for, and 90 percent is still remaining in the plant.

So it becomes a very labor-intensive and a very unproductive way to proceed. So those things can be done, but with the economics of drug research where it is now, it really isn't a way to proceed.

What we are advocating, and what the FDA guidelines are suggesting, is to be able to move some of these materials with a minimal preclinical package directly into Phase II studies. There you have, particularly, for example, in chronic disease areas where you may have multiple events going on, pharmacologically, that could have an impact, instead of taking an individual component out of those plants, determining the structure, scaling it up, bringing a pilot plant into play, having to do regulatory toxicology. You build up an enormous bill just to get that single component looked

at.

On the other side of the coin, you can get the whole extract of the plant, or some preparation of the plant, into Phase II trials to see if the whole thing is working, where you have got multiple components at play.

DR. FAIR: So what you are saying is, if I interpret it correctly, that the regulatory problems in the United States, or obstructions in the United States notwithstanding, the reason that pharma companies in other areas, Germany, Europe, China, whatever, are not pursuing this more intently is that the molecular techniques are easier and less expensive.

DR. SCIAVOLINO: They can move more expediently in those areas now.

DR. GORDON: Effie.

DR. CHOW: I want to thank the panel for the enlightening material.

I was especially glad you mentioned, Dr. Sciavolino, concern about the reactive factor about herbs to drugs, and herbs to herbs. Also, your last comment brings me to what some of the concerns are. You talk about the isolating factor of an herb, and then 90

percent is gone. This is what I think, in the cultures that are practicing herbs, like, let's use China, as some of the herbs are found, that if they isolate factors, it just doesn't work.

Now, the thing is, also, there is a cultural, social behavior, a psychosocial behavior, that goes along with that. I am coming to a question. Medicine is known for a lot of a side effects. I will give an example. Chicone [ph] has reduced the side effects of medication and, for example, chemotherapy has reduced most all of the side effects, if used properly. It is really amazing. There is a sense that herbs may fall into that factor.

In research, is there thought about considering researching the herbs, not as an isolated entity, even if it is in the whole, but along with lifestyles, along with behavior and attitudes, and all that? There are concerns that it may fall into an isolated, let's use this herb and it may work. I think it effects research, too, if herbs are researched in isolation.

DR. SCIAVOLINO: I will input from a pharmaceutical company point of view. My colleagues can

contribute as well.

We have not looked at this from a psychological point of view, a quality of life perspective, at least in the work that we are doing. We think that that component might well reside in the physician's corner a little bit more as the materials come about. Things certainly aren't here yet. We would tend to look more at looking at these arrays of extracts, not from an isolation point of view, but now that gene research has advanced so exquisitely well, such that, in a period of time not too far down the road we will be able to see various sequences, perhaps the entire sequence of the genome on some type of an electronic computer chip, and that looking at these extracts in this fashion might be able to then get some mechanistic input, what is going on, not from one receptor, or not from one enzyme system, but a various cascade of things that are taking place in the chronic disease states.

So you really could begin to generate some insights along these lines. From a basic science point of view, we are more interested in applying some of that to the genetic side of things.

DR. CHOW: I guess your company, Dr. Ruddon, is noted for its wellness component. So I hope that there is some thought in that area.

I just want to make a comment. In supplements Vitamin A, C, and E are known to become free radicals in this isolated usage, and there is a push now for whole vitamins, whole food vitamins.

If you have some comments on that, please.

DR. RUDDON: Yes, you are right. In fact, our health care systems company isn't looking at, again, the whole concept of health and wellness as a unified field, not just as one component, or taking one sort of remedy. So, yes, that is a focus that we have.

I think, though, that the cultural aspects of that, I agree with Frank on that. That is something that probably the health care provider needs to take into consideration. I don't think certainly in the area of product development, it is hard to do that when you are thinking about the things that go on in product development, per se. We need to identify if something is active and safe, and so on.

I guess I would just comment that the whole

idea of an herbal product or an herbal remedy is important. Frequently, as you mentioned, when you start isolating individual components, you find out they don't work, or the activity is lost. So there clearly are interactions that we need to keep in mind.

Having said that, I think we still need to try and identify what are the bioactive materials within a mixture. There may be more than one. Then perhaps we can even optimize what is in those mixtures to put together, not necessarily a single pure component, but the most efficacious mixtures of those components.

So we are aware of the fact. I tried to find a single bioactive --

[Interruption.]

DR. GORDON: I think you said something important.

[Laughter.]

DR. GORDON: Mark, go ahead.

MR. BLUMENTHAL: One of the things that characterizes herbal medicines and herbal products, even individual herbs, is often the combination of synergy of multibly-acting, diluted active ingredients. Volarian

has never been able to be isolated for its one active compound. When they are fractionated out, the central nervous system depressant activity is less than when the whole extract is given. So there is definitely synergy there.

In the case of the Chinese medicine and other forms of traditional medicine system like Ihrveda [ph] from India where multiple herbs are used more often than not, compared to European model where there is often just single herbs being done, monopreparations, you have the compounding the issue of how many active compounds are actually in that chemical soup or that chemical cocktail that you are taking of the herb, or the soup, or the tea, or whatever is going on, the extract.

An interesting study design that is worth looking at in trying to assess some Chinese herbs for irritable bowel syndrome was published in November in JAMA in '98 by an Australian herbalist named Alan Ben Soussan [ph]. I think he is an acupuncturist.

The thing about Chinese traditional medicine is that they do individualized treatment, so different people will present with the same symptoms but they will

get different treatment based on their pulse and characteristics. It is called differential diagnosis, as most of you know.

In this study, it was a three-armed study, they did a placebo, they had a standard formula of Chinese herbs for the irritable bowel syndrome, and then each patient in the third arm got individualized treatment ala the traditional Chinese method. After a certain amount of time, the standard formula of herbs was rated better, in the mid term, than the placebo or the individualized treatment, but at the end of term the individualized treatment group had the best result.

So it was interesting that both the herb groups had good results, but they were randomized differently, and that is a very interesting way to test the individualized treatment and a standard in a very different model, or a paradigm for a clinical study.

DR. GORDON: Joe, I want to say to everybody that we are running over time, and there are people wanting to question again. If we are going to run over time, we are going to go later this afternoon, and I want to make sure that everybody is going be here to be with

the preventers.

DR. FINS: With that in mind, I will just ask very quick questions. First, Dr. Ruddon, in any future editions or current editions, which I may not be familiar with, of Goodman and Gelman, will there be anything about CAM?

I will just ask them all, and everybody can respond.

Is the NDA a good, bright-line distinction about when you want exclusivity, or do we need a middle category as far as timeline to satisfy the competing interests that we heard at the table?

Then finally, moving straight to a Phase II clinical trial, presumed safety. Of course, Phase I trials are for LD-50s and toxicity. At what point would you say we would need to still have a Phase I trial, and what kind of dosage escalations and things like that beyond the conventional use?

DR. RUDDON: Yes. Your point about Goodman and Gelman's Textbook of Pharmacology is a good one. Unfortunately, there is a bias there. I got kicked off the editorial board because I am now a part of industry.

So I really don't have any input to that anymore, but I will suggest it to the editors. I think it is a very good point. Whether it is scheduled for future editions, I don't know, but I think it should be. I agree.

I think it would be acceptable to have a sliding scale in the sense that an NDA route is certainly going to have to have more proprietary exclusivity to it, and I think it would be acceptable to have something less than that for a nutriceutical. That is my opinion, not necessarily my company's opinion, but I think that would be true.

DR. SCIAVOLINO: On the safety question, we actually have examples going on right now on those categories. Where a substance has reasonably documented evidence of administration to humans, for example they may be open-label trials that were done somewhere in the world where there is documentation available, the agency is willing to accept that documentation for safety and allow immediate progression to Phase II.

In other cases, where the documentation is more in terms of folklore and really not much is written down, we have actually done the regulatory toxicology to move

to Phase I. So we are probing it both ways.

DR. FINS: Was that at your discretion?

DR. SCIAVOLINO: Yes.

DR. FINS: Do you think we need regulations to flesh that out a little more clearly, so that for safety reasons we can defer to industry.

DR. SCIAVOLINO: From our own reasoning as an organization, as a company, we would not be willing to progress directly into Phase II trial without having assured ourselves that we have got adequate safety.

DR. GORDON: I have just one question, which may or not be quick. I hope, in a way, it is, but I think it will lead us, perhaps, to further discussions.

The most critical point that I hear from patients as I go around the country talking with groups of physicians as well as patients, is very simple, how do we know that what they say is in the bottle is really there. I am wondering, particularly from your, Dr. Dickenson, but others as well, what is the industry doing to make sure that we know the answer to that question?

DR. DICKENSON: Let me say first that the legal requirement under DSHEA is that the product deliver 100

percent of what it claims to deliver. So any product that isn't delivering that is an illegally formulated product and we would fully support and have told FDA in many settings that we would fully support enforcement against products that don't deliver that, because obviously they give everybody a bad name.

In addition, though, since there doesn't appear to be resources for that amount of enforcement at this time, the industry is about to undertake a third-party testing program in which we would contract with an organization called the Institute for Nutriceutical Advancement, which has been working for the last two and a half years with industry support on developing methods of analysis for many of the botanical ingredients.

We will be moving forward with them to extend that to an actual individual product testing system in which the companies would, up front, pay a licensing fee for third-party testing, and then periodic retesting over a period of time, potentially, in return for having some kind of seal, although the seal aspect of that has not been resolved, but certainly we do recognize that consumers and health professionals are very concerned by

the number of products that fail these quantitative tests.

We are trying to take expeditious action on a self-regulatory system at the same time that we would support strict enforcement on this as well.

DR. GORDON: That is the follow-up question I wanted to ask. Are both necessary? Do you want a different role for the FDA?

As you know, our charge is to make recommendations for legislation. I am wondering what you think we should recommend.

DR. DICKENSON: I think both parts of it are necessary. I think, first of all, industry has to take full responsibility and do whatever it can to assure that products are what they are supposed to be, but I think, unfortunately, there are always going to be those who don't fully meet their responsibilities in this area. For those companies, I think FDA does need to have and exercise that enforcement authority.

Our perception is that one of the things that is needed now is more enforcement resources for FDA on the food side. Apparently, most of the funding that they

currently have for enforcement is in other centers on the drug side, and they are under funded on the food side for enforcement activity.

DR. GORDON: Thank you very much.

Yes, Mark.

MR. BLUMENTHAL: I fully agree with Dr. Dickenson on this matter. Our organization has an open seat on the INA Methods Validation Program Board. We have been involved with this since the very beginning to develop analytical methods for the raw materials and the herbal products.

I was also one of the founding consultants for the group called Consumer Lab.com, which I am no longer associated with, but which has been doing a private for-profit evaluation of herbal and other dietary supplement products, and posting the passing products on their web site, generating a lot of publicity and some degree of controversy.

My own organization, ABC, has been involved for six years in a $1.2 million study of over 500 commercial ginseng products that we have tested in two university laboratories by analysis methods that we developed, which

are now becoming accepted by the AOAC, the Association of Official Analytical Chemists, which will be a worldwide acceptance as a regulatory method for determining ginsengicides in Asian ginseng.

So we really have a lot of investment in this. One of the things that is really interesting in our study on ginseng is, we did a baseline study from 1994 to '95 -- some products were purchased before -- and after DSHEA was passed, tested those products. After blind-testing in two laboratories to determine if they passed or failed, we then contacted the manufacturers and informed them about our results before publication.

We went out and bought new products in '97, '98 from the companies, not directly, but from the marketplace of the companies who failed our initial ginseng studies, and then compared the products from '95 and the products from '97, '98, and we found a significant increase in the quality of these products.

So one of the news reports that will come out of our Ginseng Evaluation Program when we publish it in "Herbalgram-51" in the early spring will be that there has been significant improvement in the quality control

in the dietary supplement industry as seen through our tests on the ginseng products.

That is the good news. The bad news is, you still don't always know which products when you buy them because there is not a universally accepted seal that is trusted.

DR. DICKENSON: If I could add just one point. Mark did mention the AOAC, which is the official method, the body of official methods that is available for food ingredients, including dietary supplements. USP has also been undertaking an initiative for the last five years to develop standards in the botanical area.

This INA program that we are going to be working with will be coordinating both with AOAC and USP to increase cooperation among all of these groups. Ultimately, on the food side, FDA considers AOAC to be the preferred method. So we will be feeding these methods through their peer verified process.

DR. GORDON: Thank you. Thank you all very much. I hope that we will be able to consult with you as we develop other panels on public information and other issues. So thank you very much for your help now.

We are going to adjourn for lunch. We will come back here. We have to give people time to digest their food, very important, so we will come back at 1:50, 1,5,0, to begin with public comment. That will give us close to an hour. Public comment people can sign up outside at the table.

[Lunch recess taken at 1:05 p.m.]

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A F T E R N O O N S E S S I O N

[2:05 p.m.]

DR. GORDON: We will begin. Public comment will work the same way it did yesterday, which is where each of you 3 minutes, and then there will be a time to interact with the Commission after each talk.

The reason we do this, as I explained yesterday, is because unlike other panels, each of you is speaking on a topic that may or may not have much relation to the others. We want to have an opportunity to interact with each of you in turn.

So let's begin with Rick Levy.

Public Comment (Open Session)

DR. LEVY: I am Rick Levy, a clinical psychologist in private practice. Since 1966, I have been involved in psychospiritual healing approaches as well as mind-body treatment. During the last 20 years, I guess, much of my work is focused on developing the use deep hypnotic states, plus energy-healing methods in treatment of catastrophic and chronic illness.

While being supportive of the wide range of CAM interventions, I wish, today, to argue especially for a

focused inclusion of mind-body-spirit practices in the Commission's thinking. There is tremendous in various CAM approaches, however I must argue that the role of mind and spirit in the healing process probably still is being vastly underestimated.

In the near future, I will submit a relevant research literature review to the Commission which focuses on the mind-body-spirit interventions, but please let us properly value and promote the scientifically based role of mind and spirit in healing physical as well as psychological illness.

Now, I am talking about such interventions, innovative methodologies like energy healing, oracle meditation, regression, psychotherapy, relaxation procedures, a wide range of alternative hypnotic procedures, but also these mind-body-spirit procedures can include more traditional mental health treatments which are applied to new areas.

Examples include using traditional hypnosis, behavior modification, cognitive therapy, reprogramming techniques, and psychodynamic psychotherapy to impact on catastrophic illness such as cancer, and not simply to

assist in patient adjustment to coping with such illness.

Currently, there are far too few properly trained and credentialed CAM practitioners using such methodologies. I propose that this commission contact the relevant professional societies to begin ongoing formal dialogue to develop recommendations on how to operationalize the entrance of CAM interventions into the traditional health care communities.

This is a most important recommendation and lies at the heart of my testimony. I represent, as an individual, the scientifically informed practitioner community, rather than the research community. Of course, I strongly support ongoing research, however now is the time to directly bring to the public scientifically based CAM interventions.

People are suffering and even dying every day due to being denied access to CAM. In my clinical practice I witness their plight each and every day, and it is heartbreaking. We must do a better job of making available CAM procedures here and now to those people who need our skills.

This is why I strongly encourage this

commission to not only emphasize research but to also emphasize development activities which promote CAM to those in need. Here, I am only reinforcing what is part of the stated mission of this commission.

Specifically, I request that this commission begin formal discussion to develop recommendations to this end with the professional societies representing the relevant traditional and alternative practitioners. I, for one, intend to be taking an active role in bringing a focus on CAM interventions within the American Psychological Association. Thank you.

DR. GORDON: Thank you very much, Rick.

Any questions? Joe.

DR. FINS: Could you help me understand better the boundary lines between conventional psychotherapy counseling issues that a psychologist or psychiatrist might do, and when does it veer into CAM, definitionally?

DR. LEVY: Sure, at least as I see it. First of all, I think that there are innovative methodologies that simply are gradually coming into the mainstream, and that is really what I was specialized in during my career, helping promote them in. But then you have got

other methodologies which are well established. I use a lot of cognitive therapy reprogramming methods in subconscious mind work, treating people with cancer, for example. I am getting a lot of people going into remission with these combined with deep hypnotic states and the energy-healing work.

Now, when you have got cognitive therapy or some of the behavior modification -- I will use systematic desensitization work as part of a traditional hypnotherapy, for example -- those aspects of it really are traditional methodologies, but they have usually not been used to directly impact on the disease process itself. Yet, combined with other methodologies, what I have observed is, they are very helpful. That is, I think, the boundary.

DR. GORDON: Any other questions?

[No response.]

DR. GORDON: Thank you very much, Rick. I particularly appreciate your drawing our attention to working with the professional societies. I think that is a really, really important aspect.

DR. LEVY: I come from a research background.

I am the son of a famous cancer research scientist. I grew up in the NIH research community. So I have all my sympathies in that direction, but I am a clinician and I would like to see this stuff get operationalized. I am tired of being one of the few people out there in my community.

DR. GORDON: Great. Hopefully, you won't continue to be.

DR. LEVY: Yes. I do want to say this is the first time I am addressing a body like this. I used to do a lot of legislative work in past years, and I hope to be doing more of this. I hope I am someone that you will see around a little bit.

DR. GORDON: Thank you very much.

Ingrid Lucis [ph].

MS. LUCIS: Good afternoon. My name is Ingrid Lucis, and I am the director of Government Relations for the American Chiropractic Association. Due to a scheduling conflict, Dr. Bruce Nordstrom who was scheduled to be here today couldn't make it, so I will be expressing the Association's views.

There is no question that as the public demand

for complementary and alternative care increases, research must continue to ensure that safe and effective CAM services are made available. Therefore, the Commission, in its formal recommendations, must encourage Congress to continue and increase funding for the National Institutes of Health Center for Complementary and Alternative Medicine.

While investigating the best approach to expand and integrate and coordinate research, the Commission is reminded not to reinvent the wheel. As you have heard, currently there are many successful research programs being conducted throughout the United States. The Commission should continue to query these programs as to what works and what type of incentives they need to continue and facilitate additional research into CAM practices.

In gaining insight into the types of research currently being conducted, the Commission may also wish to contact professional organizations representing complementary and alternative providers. These organizations are able to provide the Commission with research organizations that are actively engaged in

research in CAM practices.

On the chiropractic research issues, the ACA urges the Commission to remain in contact with two of your panelists, Dr. Rossner from the Foundation of Chiropractic Education and Research, and Dr. Meeker from the Palmer Center of Chiropractic Research. As you heard yesterday, both of these doctors are excellent resources in chiropractic research.

In encouraging research, the Commission should also make formal recommendations to Congress to change regulatory guidelines that restrict and deny reimbursement for complementary and alternative health care in all federally funded programs. For example, the Health Care Financing Administration announced a proposed national coverage decision regarding Medicare coverage of clinical trials and coverage of routine costs.

The Commission should encourage Congress to instruct HCFA to also provide reimbursement for complementary and alternative practices in these clinical trials. However, in providing for clinical trials with CAM procedures, HCFA as well as other researchers should recognize the need for balance between clinical trials,