others.

(2) Make it easy to report adverse reactions/interactions such as a telephone hotline when that involves no paperwork for the person reporting.

(3) Utilize a critical review process to distinguish between significant reactions and minor ones.

(4) Provide the information to manufacturers so that they will, in turn, provide the information to consumers by way of labeling.

(5) Provide the information to health care providers so that they can: (1) assist their patients when labels state "seek advice from your doctor or pharmacist before using" and (2) eventually develop enough confidence in these products to recommend them.

The collection and distribution of adverse reaction/interaction information needs to be a priority so that people can safely reap the benefits of dietary supplements.

Thank you.

COMMISSIONER GORDON: Thank you.

Rick Kingston?

RICK KINGSTON, PharmD

PROSAR INTERNATIONAL POISON CENTER

MR. KINGSTON: As a University of Minnesota professor in the College of Pharmacy serving as course director for one of the few CAM courses in the Academic Health Center that specifically focuses on the clinical application of herbal and other dietary supplements, I personally believe in the incredible potential of CAM practices as they pertain to improving and maintaining the health of Americans.

Unfortunately, my views are not shared by many of my colleagues. CAM certainly includes a variety of approaches and practices but often times the most visible link with patients and their health care provider regards patient use of commercially available dietary supplements, more broadly defined as nutriceuticals. Although these substances are regulated by the FDA through DSHEA, pharmacists and other mainstream medical practitioners continually cite inadequate regulation as a barrier to full acceptance.

It is apparent that GMPs, which are in large part supported by industry, are on the

way. What will remain an issue with many is how we can monitor both for the successful implementation of these GMPs as well as the overall patient experience regarding safety, including interactions with pharmaceuticals and adverse incidents.

Along with many of my colleagues and others interested in the safe and efficacious use of these valuable health care related products, I believe there are a few specific things that can be done to address this area.

First, the Commission needs to embrace strategies that encourage and support the development of product stewardship programs that address these concerns on the part of product manufacturers and/or their professional trade associations. Effective post-market surveillance cannot be accomplished solely by regulatory bodies. It will only be accomplished with effective partnerships with responsible manufacturers.

As regards dietary supplements, the partnership is even more important as the consumer routinely turns to the manufacturer as the product expert. Thus, the manufacturer is

in the best position to monitor the patient experience and share necessary information that they learned with regulators, patients and the practitioners that recommend or advise on product use. Changes in DSHEA, which could require manufacturers to report adverse events involving their products may be one way to move the process forward.

Another option would be for the Commission to encourage conscientious manufacturers to implement voluntary systems of their own that collect, analyze and report information related to the patient experience.

Second, the Commission should also support the development of multi-disciplinary education programs that teach clinical application of dietary supplements in a broader sense across the multiple health care disciplines that typically recommend or advise on their use.

And, third, the Commission should also support the development of a recognized -- of recognized certification programs by professional bodies that assess the competency of those professionals that request the public

trust when recommending or advising on the use of these products for a variety of medical or health related needs.

Thank you very much for the opportunity to comment.

COMMISSIONER GORDON: Thank you.

John Mastel?

JOHN MASTEL

NUTRITIONAL CONSULTANT AND OWNER:

NATURAL FOODS STORE

MR. MASTEL: Thank you and welcome to the heartland.

I am dealing with dietary supplements as far as the freedom to buy them and sell them. It seems that the AMA, the FDA and pharmaceutical companies are involved in a silent conspiracy to prevent the average consumer from getting proper access to nutritional supplements and information regarding supplements' role in bettering our health. This may not be a full-fledged conspiracy but the results are certainly the same.

One example is the B vitamin, folic acid. Until 1974 regulations for a

nonprescription supplement only allowed one-fourth of the daily requirement of folic acid. Studies on folic acid showed a decrease in instances of spina bifida when you increased the folic acid intake. It has been shown that folic acid helps to lower homocysteine levels. Homocysteine is involved in heart problems, stroke and various other diseases, including terminal death.

We cannot make claims for folic acid as a supplement even though they have proven these things. The food industry is now adding it into white flour but we also know that white flour is what a lot of people are avoiding nowadays in nutritional diets.

There is also studies on vitamin C like, let's say, the orange juice study and they make the claims on it. You cannot sell vitamin C tablets with the same claims.

Putting the benefits and the possible interactions with drugs on a label would be -- make a pretty big bottle if you had to write it on there.

There should be a central source for this information like maybe even on the bottle

an 800 number where you could get both the positives and the negatives because we are not allowed to list the positives and the negatives are -- every time a new drug comes on the market you wonder is this going to interfere or is this going to complement that drug?

It seems that the guidelines and laws seem to please the regulators more than the average citizen.

The FDA through the Federal Register tried to make a law that vitamin supplementation beyond the RDA could only be dispensed by prescription. It took many years to get that through the Proxmire -- what they call the Proxmire Vitamin Bill.

It seems that in this country medical doctors seldom recognize nutritional problems and our health system depends on them to do it.

Research and regulatory bodies need to be established, possibly that German Commission E monograph would be a good one, which gives the whole, the dark and the light side of everything.

COMMISSIONER GORDON: Thank you very much.

William Soller?

R. WILLIAM SOLLER, PhD

VICE PRESIDENT AND DIRECTOR OF SCIENCE AND TECHNOLOGY: CONSUMER HEALTH CARE PRODUCTS ASSOCIATION

DR. SOLLER: Thank you, Mr. Chairman, members of the Commission. My name is Dr. Bill Soller. I am senior vice president and director of science and technology for the Consumer Health Care Products Association, a 120 year old trade organization representing the manufacturers and distributors of dietary supplements and nonprescription medicines. We have over 200 members across the manufacturing distribution, supply, research and advertising sectors of the self-care industry.

We have been intimately involved in the regulatory development of the industry, commenting and facilitating dialogue and activities relating to safety, labeling, quality and other matters affecting the production and distribution of dietary supplements.

Just last week our association adopted eight voluntary programs on dietary supplements relating to manufacturing, labeling and

formulation of safe and high quality products, adding to our programs already in place on St. John's wort, ephedra and use of dietary supplements during pregnancy.

My remarks address two aspects of the questions that were set forth.

First, health professional and consumer access to safe and effective dietary supplements and, second, educational issues relating to complementary and alternative medical practitioner use of dietary supplements.

First, on safe, effective, high quality dietary supplements. Our call is to the White House Commission as well as health professionals to support the Congressional appropriations process soon to be initiated by the Center for Food Safety and Applied Nutrition, CFSAN. Consumers, health professionals and industry need an FDA that is adequately funded to appropriately and reasonably implement the spirit and intent of the Dietary Supplement Health Education Act or DSHEA.

Along these lines, let me share that the FDA and the Federal Trade Commission have the tools they need to adequately regulate dietary

supplements.

FDA has put in place the strategic management tools to justify allocations of increased funding, including the development of its long range plan, annual proprieties, all through extensive stakeholder input, as well as the use of a year-end report card process to define the extent it met its priorities the previous year.

This spring, FDA will provide Congress with two important fiscal reports. One pertaining to how much it spent last year and one on what it needs to implement its long-range plan.

This is the start of the appropriations process and our message is this:

The White House Commission should report to the new administration the clear need to push for the level of appropriations necessary for CFSAN to fairly and reasonably implement DSHEA, thereby allowing FDA to use its existing substantial enforcement tools to regulate dietary supplements, all in order to ensure safe, effective, high quality dietary supplements for consumer and health care

professional use.

And just an added point, I have added the long-range plan as well as the priority list, and we would suggest the Commission task one of its members to review those full documents, which can be obtained on the web page, to look for other areas that the Commission can support.

Very importantly, good manufacturing practices without which FDA would not be -- will not be able to have an effective field presence through the enforcement program.

Thank you.

DISCUSSION

COMMISSIONER GORDON: Thank you and thank you for clear recommendations as well.

Questions? Linnea, do you want to begin?

Joe?

COMMISSIONER PIZZORNO: Yes. Well, botanical medicines and dietary supplements, I think, have a high level of safety. I am becoming more concerned and I think others are about the drug-herb-nutrient interactions and, since these nature medicines are physiologically

active, one must assume they are going to interact with drugs as well.

I would like to hear a specific recommendation from you folks here about how we can establish a mechanism for detecting or recording potential interactions, assess the validity of why the interaction actually occurred or not, and establish methodology by which consumers and practitioners can have easy access to this information so they can avoid these interactions. We need to establish a mechanism.

DR. SOLLER: I do not know that I am going to have very specific recommendations for you today except to return to what I mentioned in terms of the long-range plan and what CFSAN wants to do this year in relation to adverse experience reporting, and that will be a process that they will engage through wide stakeholder input.

I can tell you that there -- the way ephedra was handled was done extremely poorly in terms of scientifically how it was looked at and that is recognized within CFSAN and that is something that will change.

There is a tremendous resource crunch right now and many people leaving that part of the agency, and so there is need for encouragement.

Now I would ask you to reflect and we were the first association to immediately attend to the St. John's Wort-protease inhibitor interaction and, in fact, petition the agency after we adopted a voluntary program to have a general prescription drug warning on that particular herbal.

And my interaction here, and I do not want to take the microphone, I will just make a brief comment, in the AR field goes back about 20-25 years and, in fact, helped to work through this same issue in the nonprescription drug industry in the late '80s. I reflect on this, there is not a mandatory program for monographed OTCs.

What we found is that actually the system that is there when it is up and running and working and has the right government infrastructure through MEDWATCH in place is a sensitive issue, a sensitive program. The psyllium choking warning was placed on the

product as a result of a handful of reports. We petitioned the agency on neosporin for an allergic reaction based on a few cases of anaphylactic shock associated with that particular product some years ago actually in a different -- not even in a self-care setting; a professional setting.

So our experience has been is that the system is very sensitive. Yes, there are drug-herbal interactions that will occur. There is a mechanism at FDA to be able to review this. They need the right people in place and they need the resources to get it done. They do not have to build something new.

And remember as we have looked at this over the years, this issue of drug-drug/drug-herb interaction is not just applied to dietary supplements. We have new prescription drug products that are being every day approved and we do not know all the drug-drug interactions on those until they get into more widespread distribution.

So you will see the same issues applied on the Rx side. They also apply on the OTC side, the drug side, and they apply on the

dietary supplement. So much of the concern is very well placed. There needs to be a high level of awareness. In fact, the actual number of interactions that occur are really relatively low. That does not mean that you do not have a high level of awareness and you do not have the infrastructure in place.

So, finally, support early and I think before July a comment from the Commission to the Administration to tell them about the spring report and the importance of that full funding will address this as well as other issues.

MR. KINGSTON: I would like to just add a couple of comments to that. I think that everything that Dr. Soller mentioned is very important. There is one additional aspect that we have to keep in mind and that is the fact that there are limits to what the FDA can accomplish here, especially when you take a look at some of the Institute of Medicine reports on the MEDWATCH program and the ability to communicate with not only practitioners but also the public.

I know when we had the issue with the ephedra come up there was a lot of concern about

the type of incidents that were actually reported to the MEDWATCH system and the quality and the validity of that information. It was of very poor quality in many circumstances and so I think what we found out was that it was more of an indictment of the collection process rather than a complete vindication of the problem.

So one thing that the Commission can do is help manufacturers understand and need to know what is expected of them. I think Firestone will give you a good history of what you need to do in that regard.

So from a broader sense, manufacturers really do have the opportunity to be very, very proactive in this regard but again you have responsible manufacturers out there and you have other manufacturers that may not be as responsible and so you have to find ways to raise the bar and have organizations like the Consumer Health Care Products Association be able to take a message back to their membership and tell them what is expected of them so that they can collect information in a responsible manner, review that in a responsible manner and share that information with those that need it.

COMMISSIONER GORDON: John?

MR. MASTEL: I might add that there is a lot of food interaction like the green foods and even grapefruit juice so protecting the consumer you have got to take supplements and there is a graying of the line between food and food supplements also. You do not know really where that line is anymore. Is it a green powder or is that a food or is it a supplement. So there has been a lot of food interactions, too, like with coumadin.

COMMISSIONER GORDON: Given all this, though, what would you suggest? You a couple of times cited the ephedra situation. What was bad about that? What have we learned from that? What was better about the St. John's wort situation and how can we best -- you begin and then we will go with her.

MR. MASTEL: Okay. In China they had to use that for at least 4,000 years and the big problem started when people were trying to get more buzz and bomb into a supplement so they were concentrating more and more and one capsule would equal maybe ten of them when they would concentrate that factor and that is where the

problems, I think, really started with it.

COMMISSIONER GORDON: Okay. That was the problem from the manufacturing side but what about from public -- what would you do as a public policy response -- what did happen -- I mean, I think I know. I am not sure everybody here does. What did happen and then what would be a better way to handle it.

DR. SOLLER: Well, just at the outset, ephedra is on a separate track this year. You know, CFSAN has given a million dollars to NAS/IOM, Institute of Medicine, to initiate a review of a select cast of dietary supplements and we are in the process with FDA, NIH and others to determine what that small cast would be. Ephedra is on a separate track.

And I think, as I reflect on this, if you look at the Federal Trade Commission, they are very, very active on the truthful and not misleading side of this. It took them a while to understand how to approach the rogue manufacturers and then effectively go after them and have a particular litigation stick. And I reflect on that because I think CFSAN in some respects over the last several years has engaged

that growing pain process through ephedra.

And the sorts of things that I think were not well handled had to do with the basic administration of AERs and how they were not available on a timely basis through FOI, through, you know, manufacturer's request, just a note dealing with the products.

COMMISSIONER GORDON: Do you want to explain what the acronyms are?

DR. SOLLER: I am sorry. The Freedom of Information Act.

COMMISSIONER GORDON: Okay.

DR. SOLLER: The inability --

COMMISSIONER GORDON: And the ADR?

DR. SOLLER: Well, AER, adverse experience reports.

COMMISSIONER GORDON: Adverse experience report, okay.

DR. SOLLER: Yes. And the types of scientific reviews that were applied were applied in a way where CFSAN was saying we simply are put in a position where we have to prove it is unsafe. And I can tell you from an industry standpoint we have very little sympathy with that because we have to prove -- you know,

I do not mean that in a -- in sort of a wisecracking way but we are in the position and have been as our history to prove that a product is safe or address that it is unsafe.

And so there was a time at FDA where that played out and I think under Joe Levitt, brought to us by Jane Haney and her commitment to dietary supplements, we are in an era where this will very dramatically change over the next year or two. And I have confidence that there is a very serious program to engage the best science against the safety of dietary supplements if they can get funding.

And, in fact, what I recently told our members was that this particular long-range plan, if implemented, will probably be the most dramatic thing that will be occurring to dietary supplements quite possibly in the last ten years, and that would include DSHEA.

COMMISSIONER GORDON: Wayne?

COMMISSIONER JONAS: Yes. I appreciate your clear recommendations. I would be interested to hear -- it seems to me that there is a number of things that need to be done, one of which is to try to support the continued

development of the authority and the plan that the FDA currently has in dietary supplements. I think that is clear.

It is also clear that certain of our monitoring and reporting areas are inadequate and we need to buff those up, like MEDWATCH, and it may be also that the Commission could begin to make sure that complementary medicine, especially supplements, are involved in some of the new activities that are going on not only in the government but in other health care centers just to better improve drug-drug, herb-drug, drug-food interaction reporting and that -- provide that information to those that are using it.

Now that brings me to the question of who is using it and I was recently consulted by a quite high level federal public servant about his/her dietary supplements and when I finally figured out where he was getting his advice, it turned out it was from his massage therapist. And so we went over and the massage therapist was extremely happy to have someone else involved in the process and, you know, looking at recommendations.

It makes me wonder about is there a process currently going on for regulating this because obviously people can go out and purchase whatever they want but if someone is now giving them advice, is there a way of assuring that they have some adequate training and making recommendations about supplements and this type of thing.

I know, for example, in herbalism as far as I know there is no standards for credentialing, licensing, minimum amount of training, either on the licensed professional side or the currently unlicensed professional side. I was wondering if you could comment perhaps.

MR. WOOD: Well, we do have the American Herbalist Guild and we do peer review because there are so many different ways to practice herbalism.

We just tried -- we have a board of -- a panel of maybe six or seven people who -- people turn in questions, essays, and these people are practitioners that are on the board and, therefore, they respond by - you know, they can kind of tell whether the people are, you know,

basically competent on some level.

We are trying to do a certification test which is not very popular with a lot of people. A lot of people prefer the peer review and I think that you have to do something like that in order to have a -- to kind of have flexibility in the field and I think it is very easy to say, "Oh, let's regulate everything." But there are so many different traditions and even if we only had one tradition, say one national ethnic group in America, there would be so many different herbs and different possible uses that we really need flexibility so we have been working on that ourselves. It has been -- and it has been difficult. A lot of different opposition from different people.

DR. SOLLER: You know, maybe just to add a couple of comments on that as well. I really do think that we need to take a look at more broad-based certification programs across multiple disciplines, especially as it pertains to the use of dietary supplements and nutriceuticals because you find that different disciplines use, you know, different types of substances but there is a basic science that

really spreads across all these disciplines. And finding out information about the St. John's Wort with the protease-1 inhibitors, you know, is that being taught across all the disciplines. I mean, you need to have some base level there and I know that there is some organizations like the American Nutriceutical Association that is looking at a multi-disciplinary certification process.

One other thing that I thought I would mention just in terms of a comment that was raised earlier about the St. John's Wort and identifying those types of events, remember that was not identified in clinical application. That was identified in an NIH study where they actually anticipated, they thought this was a potential interaction and then tested it in healthy patients and they confirmed it. We did not find that out from adverse incident reports of patients having unsuccessful therapies for their AIDS.

So again it gets back to the situation where we have to have methods and systems in place so that you can identify those sentinel events, look at them in a proper context, and

then take them to the next level so that we are not doing that study now instead of, you know, having that information ten years ago.

So that is just a couple of comments to add to that.

DR. SOLLER: Just in brief support, we understand the American Nutriceutical Association and the University of Minnesota are exploring a certification program. We support those kinds of collaborative educational efforts. I think a recommendation that might come from the commission is to look at the many millions of dollars that are given to NIH each year and think about a percentage that would be used to help develop those. There are -- you know, look on these certification programs as a business, in effect.

They have to ultimately be self-sustaining but they do need start up funds and although -- and I cannot speak for our members because we have not exactly debated this within our membership but I think having industry supporting a certification program has the potential for a conflict of interest.

I think when NIH is involved and people

are able to compete and have peer review for their suggested certification programs and the start-up that that would be an interesting way to really gain important credibility.

The last comment on the St. John's wort and I think Rick and I agree on the importance of AERs and how to look at it. We would have -- and we did look at that published report, even a case series, in the context of adverse event reporting. So that is all -- yes, there is the case report but we encompass clinical trial and other theoretical constructs in terms of how we think about AERs.

MS. CHAFFIN: I just have a comment on what is needed for the consumer, patient. These people are self-medicating and that might be the number one priority is to get them the information by way of labeling. If there was some type of policy or group that had recommendations to manufacturers to get these cautions on their labels then we would reach those people self-medicating much sooner than trying to go through the health care provider or the herbalist or other alternative practitioner.

DR. SOLLER: Could I offer a brief

comment here. Terminology is extremely important. You know, I was involved in the approval of aspirin for heart attack and that is professional use of aspirin but there is also the consumer use. And we think about self-medication in terms of a consumer taking an aspirin for a headache. We think about an individual who would be self-caring for health promotion and health maintenance by way of taking St. John's wort or echinacea or a botanical.

So we do not put that into a self-medication context and I think it is important as in the OTC drug arena to just remind ourselves as we go through these different policy modes that we have professional use of these products. We also have consumer use. And where I see that most divergent is when you look at some of the NIH funding where they are looking at botanicals for frank disease states, and that is in many cases only a small subset of how that botanical is actually used in the United States for very different structure/function type of health promotion and health maintenance claim.

COMMISSIONER GORDON: Matt was going to say something and then Joe.

MR. WOOD: Yes. Also on the question you had, was it Wayne Jones -- yes. I think it is important to allow that massage therapist to have opinions and express them. I think there is a difference between having a certification for people giving that type of advice and saying nobody else can give that advice because people will just learn things on their own that are very valuable and they should be allowed to be able to express that but these professions can also be encouraged to develop and become something and people within them will then be able to give advice.

COMMISSIONER GORDON: Joe?

COMMISSIONER PIZZORNO: A question for Jodi Chaffin. I am concerned about the practicality of putting warnings on labels mainly because this is such an emerging field right now and products tend to stay on shelves for varying lengths of time so I just want to ask you kind of a practical consumer question. If we were to simply put on the labels a website to go to and recommend everybody look at that

website when using this product, would something like that work or is that -- would that not do the job?

MS. CHAFFIN: You are asking would something like a third party information work. It is a real dilemma what you would put on the label. I do not know if that would work. We have so many resources now. I do not know how you would get out to the -- unless it was on the label, "Go to this website or call this --"

COMMISSIONER PIZZORNO: That is what I am suggesting.

MS. CHAFFIN: Yes, if it was on the label that they could go -- yes.

MR. WOOD: Could I make --

MS. CHAFFIN: And if manufacturers could support that and if manufacturers -- I would like to see some of this burden go back to the manufacturer where they were required maybe to have their own number on there for reporting adverse reactions. You know, you cannot help but wonder. We require this for pharmaceuticals. We require it for cleaning products. We require all these safety for everything but why not dietary supplements. We

need to respect these supplements. If we respect them then we will also know that there is a safety issue.

COMMISSIONER GORDON: Thank you.

Matt, and then Bill?

MR. WOOD: Yes. I think we have to think creatively about packaging because I have seen in homeopathy where they can do recommendations. I mean, if you have a box and then you have a bottle inside and then you have something wrapped around it that has all the indicate -- those things, then you could do it. You have enough space so to speak. So with just creative packaging I think you could have a lot.

COMMISSIONER JONAS: Bill, and then John?

DR. SOLLER: Just a quick comment in terms of an earlier comment by Dr. Chaffin about is -- would there be a group available. The group is actually FDA. In the law there is 201N, which is failure to reveal a material fact, that is being worked on by CFSAN now in terms of how it takes actions to implement labeling. We have a number of citizen's petitions requesting specific labeling to trip

that process forward and make that happen, and I am confident that the agency can, with the adequate funding, will be able to have in place over the next three years something that is very, very different than where we are today.

COMMISSIONER GORDON: John?

MR. MASTEL: Real quick. I would say like aspirin you would probably have to have a package like a five gallon can to put all the side effects on there so it would not be practical and giving advice by phone if these people call in, they are not going to remember everything that somebody is saying to them. It should be in writing and the label on the bottle is not really the best place for that.

MR. WOOD: Not everybody has a computer. Everybody has to pick up the product to use it. That is where the information needs to be.

MR. KINGSTON: This can get quite complex.

COMMISSIONER GORDON: Rick, Wayne and then John.

MR. KINGSTON: This can get quite complex. The individual I was -- supplements I was referring to, by the time I got the list of

what they were on, many of them were complex supplements that had multiple things in them and as it turned out three of them had ginkgo biloba in them and he was taking ginkgo biloba separately. The total dose was around 300 milligrams a day. Totally unaware. Now probably there was not that much actually in those because we know that they often do not put that in there but several of the green supplements that were put in there included St. John's wort and a number of very active herbal products as part of the complex. This person is a very intelligent individual and had no idea about these. He was also on aspirin.

DR. SOLLER: I would just make one last comment. There is -- in terms of a post-market surveillance system if you look at a model for that, take a look at what the EPA has in terms of the 6A2 reporting system for adverse events involving FIFR regulated products. It is probably one of the best systems in the entire marketplace and it is essentially run by the manufacturers who collect the information. They analyze it and then they share it with the EPA but it is incredibly effective.

COMMISSIONER GORDON: Thank you. I have a question and you seem like a very good panel to ask it of. We are talking about certification and I am wondering whether since employees in health food stores particularly but also in pharmacies and also in grocery stores are the ones who are giving out, I think, probably the most advice about supplements, whether there should not be some kind of certification program for them because everybody is asking them -- and I have noticed that some are knowledgeable and some do not have a clue. So I am curious. What do you all think about that?

DR. SOLLER: As far as the certification program I talked about with the American Nutriceutical Association, I think what they are starting with is licensed practitioners and those individuals that are in that circumstance so that they can have an educational program and certification in that regard.

COMMISSIONER GORDON: Right.

DR. SOLLER: But as far as other folks, we have talked about the possibility of having education and certification programs for those

individuals to accommodate the delivery of basic information that is really -- that would be very valuable at least helping them understand maybe even limits of recommendations that they might be making so I think that is a good point.

COMMISSIONER GORDON: John?

MR. MASTEL: Yes. A lot of times the proof is in the pudding like if you are giving bad advice there is a lot of intelligent consumers who will write you off. You will be -- you will not be selling a product to them if you give them bad advice. I have maintained if you put a gas station across the street that duplicates everything I have, they are not going to sell, little or none and people do not trust a gas station guy giving you advice on supplements. So that is one way of telling -- if they are giving good advice, they are going to get more people coming in. If they are bad advice they are going to be out of it pretty fast or corrected quickly.

COMMISSIONER GORDON: You feel that market forces will take care of it?

MR. MASTEL: Very much. It is just like you build a Yugo automobile. It is not going to

be on the market very long.

COMMISSIONER GORDON: It has actually not been my experience. My experience has been that those -- there is a -- we have a place called the Apothecary in Washington where the advice is very good and they do very well. I have near me health food stores where sometimes the advice is very bad, they are still doing quite well, and I know that because my patients come back to me telling me what has been said to them.

MR. MASTEL: They need more competitors then.

COMMISSIONER GORDON: That may be.

(Laughter.)

COMMISSIONER GORDON: Matt, did you have any thoughts about this?

Anyone else with any thoughts about this?

Okay. Thank you all very much.

* * * * *

EDUCATION OF CAM PROVIDERS

MS. CHANG: -- Rose Haywood and Michael Green. Thank you.

COMMISSIONER GORDON: We will begin with Margery Wells.

MARGERY WELLS, DIPL

ORIENTAL MEDICINE: AMERICAN ASSOCIATION OF ORIENTAL MEDICINE

MS. WELLS: My name is Margery Wells and I am here representing --

COMMISSIONER GORDON: You need to speak into the microphone.

MS. WELLS: Sorry. I am here representing the American Association of Oriental Medicine.

COMMISSIONER GORDON: Closer.

MS. WELLS: I am licensed by the Minnesota Board of Medical Practice and a Diplomate of Traditional Oriental Medicine by the National Certification Commissions of Acupuncture.

COMMISSIONER GORDON: I am sorry. You are really going to have to bring it a little closer because your voice -- you fade in and out as you turn your head away.

MS. WELLS: I am sorry. I am just catching my breath.

COMMISSIONER GORDON: Okay.

MS. WELLS: I just got a parking place. Okay.

I am licensed by the Minnesota Board of Medical Practice and a Diplomate of Traditional Oriental Medicine by the National Certification Commission of Acupuncture and Oriental Medicine. I have been practicing and integrating medicine since 1982.

In our paper "Integrative Medicine: Merging Traditional Oriental and Western Medical Practices," Dr. Gonzalez-Campoy, MD, PhD, and I define Oriental medicine, compare it to Western medical practices, and address the potential for creating collaborative research and clinical work.

Traditional Oriental Medicine or TOM is a system much different than Western medicine with its own views of pathogenesis, its own methods of diagnosis and its own methods of treatment. There are numerous modalities of treatment which this system as a whole, which in general are meant to be used together to provide

the best possible benefit to the patient.

Just as individuals have the right to responsibly choose how they care for themselves and the right to choose their health care practitioners, people also have the right to expect that the licensed acupuncturist they select is fully trained in traditional Oriental medicine.

Nationally, graduates from colleges of TOM have, on average, between 2,700 and 3,300 classroom clinical hours over a two to three year period.

These hours are often over and above the health science prerequisites of a two to four year undergraduate degree. Then the focus of training is on pathogenesis, methods of diagnosis and methods of treatment in TOM, which includes acupuncture, herbal pharmacopoeia, nutritional therapies and various exercise recommendations.

The health care consumer has the right to know if a practitioner has abbreviated or partial system training of anything less than the above mentioned educational hours.

And since there are new immigrants who

wish to practice acupuncture, people also have the right to expect that their licensed practitioners speak fluent and articulate English, and that they are capable of communicating with patients and their physicians.

It is the recommendation of the AAOM and myself that only those with full TOM training be allowed to advertise and practice the treatment modalities of traditional Oriental medicine.

Also, utilizing any of the TOM modalities without proper TOM diagnostic training, as in a "cookbook" approach has resulted in a great deal of variability in the type and quality of care among current practitioners.

For the future development of our profession, for the benefit of our patients, and for the opportunities to collaborate on research projects with the Western medical community, which ultimately benefits all, I respectfully submit these recommendations.

COMMISSIONER GORDON: Thank you.

Lynn Lammer will be reading a statement for Val Ohanian.

VAL OHANIAN, RS, Hom (NA)

ASSISTANT DEAN:

NORTHWESTERN ACADEMY OF HOMEOPATHY

AS PRESENTED BY LYNN LAMMER

MS. LAMMER: I have two letters that Val sent last night. She is out because of illness.

"The Northwestern Academy of Homeopathy was founded in 1995 as a training institution of classical homeopathic practitioners. Our four-year program offers a total of 1,440 hours, including 610 hours of extensive clinical training. Our standards meet and in some areas exceed the 1993 guidelines for training published by the International Council on Classical Homeopathy.

"We wanted to let you know we are strong advocates of the Minnesota model. We acknowledge that government regulation is important to protect the safety of citizens but that the health care consumer's right to choose is equally important.

In our experience, government officials do not have the necessary expertise to set appropriate standards in the areas and hours of training for the numerous safe and effective

complementary healing modalities that exist in today's health care marketplace.

We have seen that in an open market with full support for the consumer to make an informed choice, the most effective and competent practitioners will be found and will flourish. We applaud the Minnesota legislature for following a fundamentally sound principle that no regulations shall be imposed on any occupation unless required for the safety and well-being of the citizens of the state.

"The Minnesota model ably follows this principle and protects the consumer's right to choose appropriate individual health care while at the same time protecting the consumer from fraud or harm."

And that is signed by Eric Somerman, R.S. Hom, PhD, Dean of the Northwestern School.

From Val Ohanian, registered homeopath and certified classical homeopath:

"The Minnesota Homeopathic Association was founded as a state-wide professional organization for homeopathic practitioners with the following mission:

"To promote homeopathy as a safe and

effective health care choice for Minnesotans;

"To protect the public interest by upholding high standards of care by its member practitioners;

"To serve and support the community of Minnesota's professional homeopaths.

"We would like to share with you our dedication to the idea that health care consumers should have access to the modalities they feel are most appropriate to their individual needs. While government should protect citizens from harm, we believe it is also the government's important role to protect the citizen's right to individual choice and autonomy as regards the way in which they decide to protect and enhance their own health and well-being.

"We enthusiastically support the Minnesota model.

"We believe that the Minnesota model was carefully crafted after much thought and deliberation."

And I will end with that.

COMMISSIONER GORDON: Okay. Thank you.

Jackson Petersburg?

JACKSON PETERSBURG

DIRECTOR: CENTER POINT

MR. PETERSBURG: Thank you.

My name is Jackson Petersburg. I am co-director of Center Point, formerly Northern Lights School of Massage Therapy, and the Minnesota Center for Shiatsu Study, and I have been in private practice for the past 22 years.

Mr. Chair, members of the Commission, let me begin by saying what a privilege it is for me to be participating in a process that I am convinced will impact on the very nature of the health care delivery system in this country.

I originally intended to start by giving a brief history of my own profession, citing some of the major factors that may have influenced how massage therapists were and are educated in this country. Unfortunately, that would have taken up all of my allotted time. I will instead give you a very condensed version of the salient points of this history. In a nutshell, war, drugs, sex and a defining moment in time.

After World War II, the development of analgesic drugs started to replace manual

methods of pain control. There also seemed to be a proliferation of massage parlor activity, which slowly eroded the reputation of legitimate therapists. This tainted reputation lasted well into the end of the Twentieth Century and heavily influenced the development of municipal massage parlor ordinances that are still in effect in many cities and towns across the country that do not have some form of statewide regulation that supersedes municipal jurisdiction.

Technically, I am still practicing illegally in the State of Minneapolis.

To my knowledge, we are the only emerging health care profession regulated by municipal law and this is still a problem in Minnesota.

In addition to drugs and sex, the other primary factor that influenced massage therapy education after World War II was the conscious decision by massage therapy organizations not to align themselves too closely with the conventional medical model. In hindsight, this proved to be a defining moment for the profession. I think that it severely slowed

down the development of educational standards for the profession, while at the same time, allowing the profession to develop in a much more organic way.

The most balanced educators who emerged out of this process managed to create a system that established boundaries and ethics while at the same time retained the experiential energy and heart of the profession.

In my experience, I do not think that this history is decidedly different from that of many complementary and alternative professions.

Finally, what national trends do I see in massage therapy education that may also apply to other CAM professions? The first trend that is especially evident across the country is that cutting -- the cutting edge education will never be contained by either state or municipal laws. This is evidenced by the fact that training institutions across the country are developing degree granting programs varying from an AA degree to PhD programs that far exceed the requirements of existing laws.

Another trend that is closely related to this is that free-standing training programs are

establishing some form of articulation agreements with colleges and universities to streamline this process and also allow them to participate in research that otherwise would be too complicated and costly to do on their own.

And the third trend is the rapid growth of programs across the country being developed by trade and technical schools who are scrambling to create curriculum and find qualified faculty to teach their program.

COMMISSIONER GORDON: Thank you.

Barbara York?

BARBARA YORK, PRESIDENT:

MINNESOTA TOUCH MOVEMENT NETWORK

MS. YORK: Thank you.

I believe that the best practitioners of complementary and alternative medicine are those who realize that this work is best met with experience, personal study and the time to know their client. Because of the variety of practices, I do not believe that uniform standards can be applied in this field. It has been said that you cannot put your foot into the same river twice. By the same token, every session with a client is a new experience for

both parties, no matter how exacting the technique may be. We must remember that this is a uniquely subjective work.

Though I have practiced for over 18 years and I personally chose to pursue 1,000 hour accreditation course and passed the national certification exam for massage therapist, I still believe the best lessons come in hands-on experience, whether as an apprentice or a seasoned practitioner for over 30 years. Essentially learning is never finished regardless of certificates and testing. The true lesson is with the client. Without respect for that, any education is worthless.

As a Jin Jin Jitsu practitioner, I participate in an ancient art that was passed down from generation to generation by word of mouth as many of our practices have been. Jin Jin Jitsu is a Japanese phrase which means "the art of the Creator through compassionate man." The study of Jin Jin Jitsu is a way to expand awareness and understanding. The practice is considered a demonstration of the art. The responsibility for usage of knowledge received is within each practitioner. I believe each

person in this room is equally wonderful at Jin Jin Jitsu, the only difference between us is in awareness. n similar fashion, I have a book called Primitive Remedies which was collected by John Wesley, the founder of the Methodist Church. It was a record of parishioners remedies, which he collected and shared as he traveled his church circuit. He did not present himself as a trained healer. Many of these remedies are practical and based on principles recognized by contemporary healers.

I would like to quote from the introduction to Primitive Remedies. "Wesley's concern was for the common people and it was his purpose to give them a plain and easy way of curing most diseases; to set down cheap, safe and easy medicines; easy to be known, easy to be procured, and easy to be applied by plain, unlettered men."

The field of complementary and alternative medicine remains this simple. It is safe. It is accessible to the consumer. It is uncomplicated, despite the sometimes confusing emphasis on technique. The Minnesota Complementary and Alternative Health Care

Freedom of Access Act of 2000 provides a legal environment in which CAM practitioners can practice regardless of their education and training as long as they practice within reasonable conduct guidelines.

I encourage the Commission to consider this simple, profound approach of honoring both the consumer and the practitioner.

Thank you.

COMMISSIONER GORDON: Thank you.

(Applause.)

COMMISSIONER GORDON: Rose Haywood?

ROSE HAYWOOD, ACADEMIC DEAN:
MINNESOTA COLLEGE OF ACUPUNCTURE
AND ORIENTAL MEDICINE OF NORTHWESTERN
HEALTH SCIENCES UNIVERSITY

MS. HAYWOOD: Thank you.

Good morning. My name is Rose Haywood. I am academic dean, Minnesota College of Acupuncture and Oriental Medicine of Northwestern Health Sciences University. I am going to start with my recommendations for the commission regarding Oriental medicine.

Members of the public need to be informed about educational standards for the

practice of Oriental medicine across different provider categories so that they can make better informed choices.

COMMISSIONER GORDON: Rose, could you come a little closer?

MS. HAYWOOD: Yes. Is that better?

COMMISSIONER GORDON: Yes.

MS. HAYWOOD: So they can make better informed choices of practitioner.

Members of the public should be able to consult an Oriental medicine practitioner without the need for medical doctor referral.

Oriental medicine is safe, effective and inexpensive and should be reimbursable by insurance companies when practiced by Oriental medicine board certified professionals.

The educational standards for the practice of Oriental medicine that have been established by the Accreditation Commission for Acupuncture and Oriental Medicine should be adopted as the standards for all categories of providers wishing to practice this medicine.

Some discussion of my recommendations:

Patients have the right to safe and effective health care. The key to safe and

effective health care is education. Oriental medicine is a comprehensive system of health care including the treatment modalities of acupuncture, herbology and Oriental body work.

Its theory and practice grew from Oriental traditions that evolved over 2,000 years. Its modalities cannot be practiced effectively without understanding the complete paradigm. This requires rigorous professional education. Fortunately, we have this.

Our accreditation commission has established minimum hours for programs of study. 1,725 for the master of acupuncture, 2,175 for the master of Oriental medicine. These are minimums. Most programs are much longer than this. Our school's, for example, is typical at 2,800 for Oriental medicine and 2,350 for acupuncture. And only graduates from accredited schools may take our national board exams.

Why so many hours? Accredited programs provide comprehensive training in Oriental medicine, theory, diagnosis and clinical practice. They provide sufficient hours of Western biomedical sciences for graduates to recognize conditions that require referral to

Western medical providers. These hours are recognized minimums to ensure safe and effective practice.

Oriental medicine is a very safe system when practiced by properly trained practitioners certified by our national boards. Please see my safety record of acupuncture appended information.

When Oriental medicine modalities are practiced by other providers, sufficient training is essential. Without knowledge of Oriental medicine theory and proper training, acupuncture becomes a mechanical procedure, less effective and maybe harmful.

Practicing Oriental herbology without proper training can have serious consequences. Practicing without enough education compromises safety and efficacy. It also damages our profession. Patients may not benefit from treatment and blame the medicine rather than the practitioner's training.

Practitioners of Oriental medicine and Western biomedicine should work together in a spirit of mutual respect and cooperation. We welcome other practitioners who wish to practice

Oriental medicine provided it is respected as a comprehensive system and provided they meet educational requirements as established by our accreditation commission.

Thank you.

DISCUSSION

COMMISSIONER GORDON: Thank you.

Is Michael Green here?

Okay.

Wayne, do you want to begin with questions?

COMMISSIONER JONAS: Is there an attempt in Minnesota to license homeopaths?

MS. _____: No. The decision was not to license homeopaths, rather to work with the national professional organizations in terms of a registry and certification exam.

COMMISSIONER JONAS: They would fall under the Minnesota law as nonlicensed practitioners then?

MS. _____: That is correct. Although there are also some that are physicians who then are accused of practicing outside the scope of the license and we still need to address that in this state.

COMMISSIONER JONAS: Okay. So at this point if you are licensed then you are at risk for using homeopathy in your practice more so than you would be under the current Minnesota law if you were not licensed and practicing full-time homeopathy; is that correct?

MS. _____: That is correct.

(Laughter.)

COMMISSIONER JONAS: Okay.

COMMISSIONER GORDON: Just a quick follow-up on that. Why did you decide to not go for licensure?

MS. _____: The reason is there are different training models that are still being worked out both nationally and internationally for homeopathy and within homeopathy there are a number of different types of homeopathy and there has not yet been concurrence on the best education process for that. The best result was to develop national certification recognition of specific types of training to ensure that there was minimum training in the biomedical sciences in homeopathic philosophy and in the use of the naturimedicas and remedies.

COMMISSIONER GORDON: So what you are

saying is that the national certification includes knowledge of biomedical sciences?

MS. _____: That is correct. The schools that exist currently require basically the same biomedical training that you would have for a premed program.

COMMISSIONER GORDON: And you were saying there are different schools of homeopathy. How does the certification take that into account?

MS. _____: The International Council along with the Homeopathic Association under NACH, the National Association of Certified Homeopaths or Society of Homeopaths, the National Councils for Homeopathy and the American Institute of Homeopathy, which deals with the medical portion of practitioners, decided that there were basic educational requirements they could agree on but because currently there are different situations state by state, some states -- for example, Arizona, only license medical practitioners. It was decided that it was best to start with basic educational kinds of requirements and recognize that at the national registry so we currently

have a registry for unlicensed practitioners and for medical practitioners.

COMMISSIONER GORDON: I think this is Michael Green.

Do you want to follow up on that?

COMMISSIONER JONAS: Yes, I just want to follow up briefly and yet make sure I understand this correctly. Acupuncturists now have gone the other route, however. They are licensed, certified and do not really fall under the jurisdiction of the new Minnesota law. They have their own licensing regulations. Is that correct?

MS. HAYWOOD: Yes. Our licenses -- the Minnesota license, we are under the Board of Medical Practice in Minnesota.

COMMISSIONER JONAS: And are there acupuncturists who could practice underneath the Minnesota law without a license and still be covered by this?

MS. HAYWOOD: No.

COMMISSIONER JONAS: Or once you are licensed you do not fall under -- you cannot, therefore, be a nonlicensed practitioner and so it is divided in that way.

MS. _____: I would like to respond to that. There are a couple of groups of people who are practicing acupuncture without the level of education we are recommending. There are certain groups of chiropractors that are practicing with from two to 500 hours of training and MDs.

COMMISSIONER JONAS: And MDs, right.

MS. _____: Yes.

COMMISSIONER JONAS: So this -- is the law then -- is it perhaps a disincentive for some of the emerging practices that no longer -- that do not yet have licensing status to obtain that?

MS. _____: It is not my feeling that is true. I think there is actually a higher bar that we are establishing professionally for people that are unlicensed because we want to be able to give education and full disclosure to the consumers of our practices as to what they can expect from them.

COMMISSIONER JONAS: I see. So in the disclosure area especially it is a higher standard in the unlicensed area.

MS. _____: Yes, that is correct.

COMMISSIONER JONAS: But any sense of a disincentive that is going on for licensing?

MS. _____: The disincentive as -- one of the things we looked at with the Minnesota model was that by licensing all of these different areas, including homeopathy, they were actually increasing the cost to the consumer of delivery of the services and that by trying to put it under medical practices board where the philosophies are substantially different in a number of the areas with the alternatives then we are really working at odds in terms of providing options for the consumer.

COMMISSIONER GORDON: I do not understand why it would increase the cost to consumers.

MS. _____: Because in order to have a board exist at the state level there are costs that are passed back to the practitioner for maintaining the cost of that board.

COMMISSIONER GORDON: I see.

MS. _____: Which are several thousand dollars a year. You start running into professional reliability issues in terms of insurance costs. You start running into

difficulties with reimbursement issues.

COMMISSIONER JONAS: You do not see any licensed acupuncturists then saying, "Gee, I am going to give up my license and just become a lay practitioner," or something like that?

MS. _____: Well, acupuncture has been recognized as a reimbursable medical expense by many existing insurance plans. They have received funding and they have a long history in terms of some of their clinical data than some of the other practices have.

COMMISSIONER JONAS: I can see as a physician, though, if I wanted to be a full-time classical homeopath, I might say, "Gee, I am going to take my shingle down and no longer make any diagnosis," if I preferred that.

MS. _____: That is currently going on.

COMMISSIONER JONAS: Is it?

COMMISSIONER GORDON: Okay. Michael Green is here so please talk to us.

MICHAEL GREEN, MD

DR. GREEN: Thank you.

Although I am listed under education, the main thing I wanted to talk about was

reimbursement, although the other is covered in the handout.

In addition to the general problem of lack of reimbursement for CAM evaluation and treatment, existing coverage is complicated by the use of coding systems poorly suited for describing conditions treated and treatments given by nearly all CAM systems. Although many patient presentations can be described by ICD-9 codes, its emphasis is on physician-centric diagnoses, Western diagnoses rather than patient-centric symptoms and signs found in most CAM systems.

Even though, for example, the CPT system lists two codes for acupuncture, it does not reflect other modalities used as part of acupuncture treatment, let alone treatments from other CAM systems other than perhaps chiropractic and osteopathy.

Similarly, the current standards for documentation for the evaluation and management codes are poorly suited to most CAM systems where there is a heavy focus on patient's history and review of symptoms and often the physical exam and decision making process is

fairly limited by Western medical standards and because of the way the E&M code is determined, CAM E&M is usually heavily under valued.

I hope that the commission can recommend that the coding systems used for medical reimbursement and review be revised to better reflect the very different paradigms of the CAM systems.

On education, vis-a-vis what was just brought up, there is a lot of organizations that have come into existence to define and control what is legitimate complementary and alternative medical care and training and this may obscure what are significant differences in philosophy and therapies among what appear to be very similar groups of practitioners and the one of physician acupuncturist, chiropractic acupuncturist, and licensed acupuncturist is an example.

In my own area, my own training includes a number of techniques that are not really considered Oriental medicine. They look like acupuncture and they use the same needles. They use the same equipment but they are based strictly on Western medical principles.

How to work this into trying to compartmentalize different paradigms under labels is something that I would really ask the commission to be careful about because of the risk of mislabeling certain practices and thereby making them difficult from a licensure or a reimbursement or other basis.

DISCUSSION

COMMISSIONER GORDON: Thank you.

Joe?

COMMISSIONER PIZZORNO: First, I would like to ask Lynn Lammer --

MS. LAMMER: Lammer.

COMMISSIONER PIZZORNO: Lammer. Okay. The -- after Val Ohanian's name it is RS, Hom (NA). What does that all mean?

MS. LAMMER: It stands for registered homeopath, North America. The first registry of the Society of Homeopaths existed in England and still does to this day. We started the North American one to recognize the unlicensed professional homeopath in this country.

COMMISSIONER PIZZORNO: And then from Michael Green, we heard testimony at the last -- two weeks ago that the international standard

for acupuncture for medical doctors was 300 hours but also in talking to some of the acupuncture accrediting people I was told that the World Health Organization actually has two standards, that 300 hours was the minimum standard for acupuncture medical doctors and 1,500 was the recommended standard for full practice of acupuncture.

Could you comment on those different standards and what they mean?

DR. GREEN: Yes. There is a fundamental difference in philosophy and training, I think, implied by that. For someone to sit for the national board exam, the NCCOM exam for acupuncture in the U.S., the assumption is that when you finish your education you are ready to begin full practice as a fully qualified -- fully experienced -- you know, you are done effectively. Although clearly there is continuing education involved.

The philosophy in the sort of medical acupuncture community has been a minimum educational standard for safe and effective practice with the assumption being that you will accumulate additional information, additional

experience, additional education in the process of honing your skills. So there is a very different philosophy involved and I think that accounts somewhat for the difference in hours.

COMMISSIONER GORDON: Go ahead.

MS. HAYWOOD: If I could respond to that briefly.

COMMISSIONER GORDON: Please.

MS. HAYWOOD: The American Association of Oriental Medicine also adheres to pretty strict continuing education practices for Oriental medicine practitioners over and above just your graduation. So I think that is pretty normal for all professionals. And we would still be recommending 2,700 to 3,300 hours as a -- you know, in terms of professional development, and that is what we are looking at for the future.

COMMISSIONER GORDON: Okay.

Linnea?

COMMISSIONER LARSON: This is to Margery Wells.

In your testimony you said that you -- and I want to clarify this. Would you recommend that those trained in medical acupuncture not be

permitted by law to practice the "modality" of acupuncture due to -- you said those who do not have traditional Oriental medicine training should not be allowed.

MS. WELLS: Sure. I think I understand the question. It is delicate because what I am advocating essentially is that patients, the health care consumer has a right to know what is the level and extent of education and training, and that there is a distinct difference between a different licensed health professional who is practicing acupuncture and someone who has actually trained extensively in Oriental medicine practicing acupuncture simply because the methods of diagnosis are so different. The clinical experience is so different. They are two totally different paradigms from which to function and from which to view the patient.

DR. GREEN: Can I address -- I am sorry.

COMMISSIONER GORDON: Do you want to ask a question?

COMMISSIONER LARSON: Yes, I just want to follow it up. So basically you are making a statement about a philosophical basis for treatments and can I then extend it to,

therefore, a reimbursement rate, you know, basis? Would you receive less reimbursement than someone who is trained as a physician in acupuncture?

MS. WELLS: Would a licensed acupuncturist receive less?

COMMISSIONER LARSON: Yes.

MS. WELLS: Absolutely not. A licensed acupuncturist potentially should receive more. I mean, there -- and it is kind of the reverse of that right now. I know -- I personally have physician friends who are being reimbursed. Well, this was several years ago, 125 bucks for a five-minute acupuncture session with no differential diagnosis in the TOM paradigm.

COMMISSIONER GORDON: I would love you to give me the name of those insurers.

(Laughter.)

MS. WELLS: I can tell you the name of the physicians.

COMMISSIONER GORDON: As somebody who has --

MS. WELLS: I can tell you the name of the physician.

COMMISSIONER GORDON: As somebody who

has been practicing acupuncture for 25 years I have never been reimbursed --

MS. WELLS: What state are you in?

COMMISSIONER GORDON: In Washington, D.C.

Go ahead, Michael.

DR. GREEN: I would like to caution that, as I mentioned, there are systems of acupuncture that are not Oriental medicine. They use the same needles and the same equipment. It is not sticking the needles in people that is necessarily the defining piece. It is the philosophy and I could give examples but I think it is important to make the distinctions about what system one is using to treat, not necessarily the implements that one uses to make -- to do the treatment.

COMMISSIONER GORDON: I had a quick question and then George and Wayne.

We have had this discussion at town halls. We have had this at meetings in Washington. Very similar kinds of discussion. And the point I would like to ask for your opinions about is -- and I raised this also once in Washington. In medicine I am licensed to

practice medicine and surgery. I am unlikely to do much major surgery. I think it would be a disaster for my patients as well as for me. But that is based -- I have the license and I use my judgment about what I can do and what I cannot do.

And I am wondering if there might not be a way to think through this, that there are some people who are clearly more qualified in Oriental medicine than others. Some people who are -- for example, I know something about Chinese herbal prescribing but when there is a life-threatening illness I have a colleague who spent 40 years in China doing Chinese herbal prescribing who is also an oncologist and I definitely refer people to him.

So I am trying to think what you think about this and I also work a lot with addicts and ear acupuncture of HIV positive addicts is very helpful and a licensed acupuncturist will not do it because the reimbursement is very low and the need is so great.

So I am wondering if there is not room in this house for many mansions of people knowing -- at different levels of skills doing

different kinds of work. That is both an opinion and a question.

MS. HAYWOOD: I would like to address that if I may. May I address part of what I understand is the question there?

COMMISSIONER GORDON: Sure.

MS. HAYWOOD: What practitioners of Oriental medicine would wish -- I mean, we do not all agree on this by any means but, however, addressing the previous question a little bit as to whether medical providers should be entitled to practice Oriental medicine is a question of definition of terms as Michael correctly points out.

And it is also a question of level of education and what the Oriental medicine profession would like to see is that if one is going to practice the full paradigm of Oriental medicine that the practitioner receive the full education that an Oriental medicine provider has, which is 705 -- the minimums of 705 hours of theory and diagnosis, 660 hours of clinical training, and if you are going to use Oriental herbs, 450 hours in just herbology in addition to the Western clinical sciences.

So medical doctors would already have the Western biomedical sciences, therefore they would need all of those hours on top of that to practice the complete paradigm.

If the type of practice that Michael is describing is going to be practiced by Western medical providers or whoever then it needs to be spelled out exactly what that is so that members of the public do not run away with the impression that this is Oriental medicine.

COMMISSIONER GORDON: So you are saying as long as people spell out what their training is and the scope of their practice is appropriate to the training --

MS. HAYWOOD: Exactly. And also there needs to be a review of the training of all providers who attempt to practice Oriental medicine as a whole or any of the modalities of Oriental medicine to ensure that the number of -- the requisite number of hours matches what they are claiming to be able to do.

COMMISSIONER GORDON: Thank you.

MS. HAYWOOD: We would rather see all people -- all practitioners practicing any of the modalities of Oriental medicine receiving

the full training, which we have to have.

COMMISSIONER GORDON: Okay. Michael and then Jackson?

DR. GREEN: Yes. I would like to bring up the example of family practice, which is my training. In the training for that I spent a little time working with all kinds of specialists, surgeons, ear, nose and throat specialists and so on. I learned about the kinds of conditions that are easy to treat and difficult to treat, much like your comment about surgery.

I would not begin to try and represent myself as a surgeon and yet I am competent and trained in doing minor office surgery. The same thing for ears. The same thing for prenatal care for very simple obstetrics. And yet I would not handle anything very complicated in those areas.

I think the same thing can be applied. I mean, I would love to see licensed acupuncturists treated as if they were medical specialists, which I believe they are, but that does not mean that all of what fits into that specialty is practiced only by those

specialists.

There may be some differentiation in complexity and it is usually the board of the individual who is practicing it who sets those standards so that the family practice board defines what ought to be roughly the range of training of a family practitioner in areas like surgery or obstetrics.

I mean, obviously there is a collaboration.

COMMISSIONER GORDON: Thank you.

Jackson?

MR. PETERSBURG: I want to just expand the conversation kind of back into my realm and maybe some of the other modalities that we have not mentioned so much but one of my major concerns and I think one of the reasons why I certainly was attracted to the education field is that I am not convinced that people who are exclusively eclectically trained have a basis in, you know, things like contraindications, when to refer under appropriate ethical boundaries and so on and so forth.

COMMISSIONER GORDON: When you say "eclectically trained" you mean?

MR. PETERSBURG: Well, let's just say that there was no formal education process that may have looked at all the various aspects of the profession and I think also that there is a real difficulty in helping define their own scope of practice and what the limitations are in the scope of practice and when to refer inappropriately.

And I am not an advocate of a tiered system within my world. I think there is a baseline of education that anybody should have when they are practicing and touching people professionally.

There is a lot of other concerns in addition to physical harm that are involved in that that I think a lot of people do not think about but I think there is going to be another level that will emerge here in advance studies that will start to concentrate above and beyond the basics, whether it be energetic models or structural issues or whatever it is within the professions.

This, to me, I think is where we are heading but we have a real dichotomy certainly in this state, if not in the country, between

people who, I think, are much more libertarian minded in terms of any kind of regulation and/or training and people maybe go way in the other direction than somebody who is going to kind of sift out in between. This to me is a great issue.

COMMISSIONER GORDON: Wayne and then, George, if you have questions.

COMMISSIONER JONAS: Well, again I am interested in the impressions of both the licensed and the unlicensed groups about the current status of the Minnesota -- what the Minnesota model is going to do. I mean, it is almost like, well, if you got in quick before the law occurred then let's keep our licensing but everybody else did not quite get in and it is okay, homeopaths or energy practitioners and this type of thing.

I am just concerned about what kind of precedent that sets and what will be the direction of that. Will groups continue to want to obtain licensed status?

What I may do is open up my rehab practice in the morning and have my license up there and do rehabilitation medicine and then in

the afternoon go to my next door office, take all those things down, have to have higher standards of disclosure and documentation but practice massage therapy and then refer to myself back and forth.

(Laughter.)

I am just very confused about what the licensed practitioners feel about the current particular law.

COMMISSIONER GORDON: Please.

MS. WELLS: I think that as John Mastel said earlier, it is a certain factor of competition.

If you are coming into a massage therapist that is ineffective even though trained but could care less about dealing with you, you are going to know very quickly that you do not want to go back and that in many of these fields it is so much about the rapport between the practitioner and the consumer, and that it is not something you can just dispense.

I have pharmacy friends who know that even though they are handing a package over the counter that there is a big difference if they have a rapport with the client, you know, even

though they have high levels of education.

So I think that sensitivity to -- even if a person has disclosed they read a really great book this weekend and they would like to practice on you and would you please pay them for the time that if that person was willing to go back to them for their time, not what they do, but to spend the time with each other in that sense of there is a healing presence.

COMMISSIONER GORDON: Other comments on that? Yes, Jackson.

MR. PETERSBURG: If I could just comment and make one more statement which I was not able to do in my comments about this existing law.

Because of our profession being managed on a municipal level, what it does not afford for us because it does not develop educational requirements and it does not require scope of practice, is that the municipalities are still not convinced that that will protect the public and so we still are governed by municipal laws even though this exists and has some other things that we have to abide by.

And I think it is -- it clearly is one of the weaknesses of the structure and does not

do the job for us to allow our practitioners to move from one municipality to the next municipality without having to fulfill the licensure requirements of each municipality so in that respect I think it falls very short.

COMMISSIONER GORDON: Lynn?

MS. LAMMER: I think it is important to point out that licensure does not necessarily mean that there is competency to practice.

(Applause.)

MS. LAMMER: I think the Minnesota model goes farther than licensure in terms of protecting consumer interest because of the very detailed types of disclosure that are required.

It will also force practitioners to become more educated in order to keep their clientele and be effective. If you do not produce results, even with a good relationship, people are not going to come back.

COMMISSIONER GORDON: Thank you.

Okay. Thank you all very much. We are on time, which is nice.

(Applause.)

COMMISSIONER GORDON: We will take a break and we will come back at ten after 11:00

in 15 minutes.

(Whereupon, a break was taken.)

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EDUCATION OF HEALTH PROFESSIONALS

COMMISSIONER GORDON: Okay. We are going to begin the next panel now and we will begin with Mary Jo Kreitzer.

MARY JO KREITZER, PhD

DIRECTOR: CENTER FOR SPIRITUALITY AND HEALING

DR. KREITZER: Honorable Commissioners, welcome to Minnesota.

Over the past several months as the Commission has held hearings, I suspect that you have often heard quoted statistics from the Eisenberg study on the high utilization of complementary and alternative medicine. Today I want to highlight a different study that will provide a context for my remarks and policy recommendations. Dr. Jon Astin in this study that looked at the profiles of people who use CAM therapies found that fewer than five percent of the population uses these therapies strictly as an alternative. The remaining 95 percent are seeking care that draws from the best of healing traditions, both complementary and conventional. This has very significant implications for how we educate health professionals as well as CAM providers.

The University of Minnesota is strongly committed to preparing health professionals who are knowledgeable about CAM and who can help patients evaluate options.

Additionally, there are biomedical providers, physicians, nurses and others who are returning to school to acquire new skills in CAM because they want to expand their knowledge base and repertoire of skills. Many of these health professionals are keenly aware of the risk of reducing these healing traditions to tools that are provided in a reductionistic way. They also recognize that many of these complementary and alternative systems of care are based on world views that are entirely different than the biomedical model in which they were educated. There is a need to educate healers who are capable of being bicultural, to practicing in a way that embraces multiple world views.

From a policy perspective, there are four recommendations that I urge you to consider.

To date, schools that are developing programs to educate health professionals in CAM are doing so as a result of demands from

students, consumers and at times faculty. Curriculum is optional and often elective. Accreditation requirements and board exams need to be changed so that CAM becomes an integral part of required education.

Academic health centers need funding to develop curriculum for both the basic training of health care providers as well as funding to develop specialized programs to educate health professionals who want to acquire additional skills in CAM.

There are only a handful of graduate and fellowship programs in the country. I serve on the policy board of a foundation that provides fellowships to physicians who are seeking mid-career change and over the past three years 25 to 30 percent of all applicants who are seeking training in CAM areas are seeking training in those areas and there are not enough training programs to prepare physicians.

To create a team that is truly interdisciplinary we need to address a need to also train CAM providers. Present CAM education programs do not include information on working with biomedical providers or working with an

interdisciplinary team.

Federal funding to date has been limited to conventional health professional training programs.

And, lastly, there are a few clinical sites where students from different healing traditions can learn together. We need to create and fund models where students can observe, learn and work in tandem.

Thank you very much.

COMMISSIONER GORDON: Thank you and thank you, also, for all your work on pulling together these wonderful sessions.

(Applause.)

COMMISSIONER GORDON: Bill Manahan?

BILL MANAHAN, MD

ASSISTANT PROFESSOR

DEPARTMENT OF FAMILY PRACTICE:

UNIVERSITY OF MINNESOTA

DR. MANAHAN: The purpose of my presentation is to tell about what I believe is a successful model of how to educate physicians and physicians in training regarding complementary and alternative medicine.

The core idea of the training is to

expose students and physicians to the office practices of multiple CAM practitioners so the physicians can experience what is really going on in the world about which they know very little.

Here are some typical comments from medical students and physicians who have taken the course over these past couple of years:

"This course was wonderful. Every medical student and every physician should take this same thing."

Another one, "I think that I broadened my mind to the level of confusion but I trust. I trust things will sort themselves out some day in my psyche."

Another student, "I am awed by what is out there. The practitioners we visited have so much training, have such good credentials, and they really want to help people optimize their health."

Specifically speaking to a recent student and the psychiatric talk that we just had, this student stated -- she gave her final presentation at the end of the three weeks on mental health problems and exercise and she --

her starting statement and her ending statement was, "How could I be starting a residency in psychiatry in four months, gone through four years of medical school, taken two extra electives in psychiatry, and never heard the word 'exercise and fitness' with any psychiatric thing, and goes into the web and picks up thousands of scientific articles on exercise and mental health."

This is another student just this last time, the same thing with otitis media. She is going into pediatrics and presented the same -- presented her final paper on otitis media and CAM and says, "How could I go through four years of medical school, starting a residency in four months, and never heard the word 'food allergy' related to serious otitis media?"

(Applause.)

The reason I believe this course is so powerful, and this is the key to my presentation, is because the primary faculty are the CAM providers in the community. They teach the students as they are taking care of their own patients. The students get a chance to talk to the patients and discover from them strengths

and weaknesses of our own present medical system. The course also acts as a bridge bringing together CAM providers and physicians or physicians in training.

The students also act as ambassadors for allopathy bringing to the experience some humility, compassion and a desire for learning from the CAM practitioners that has frequently been absent in our previous relationships.

The course is primarily for medical students but is also taken by residents and by practicing physicians and it consists of 30 half days over three weeks, 15 of those half days spent in the office of other practitioners. Much of our work is done by e-mailing each other about our thoughts and feelings about the rotations.

With all due modesty, as my recommendation, I believe this course is one of the best ways I have ever experienced to educate physicians about CAM and educate CAM providers about physicians. I suspect that the health delivery system would be markedly changed if we had every senior medical student, every third-year resident and every physician in training do

a similar three week course.

COMMISSIONER GORDON: Thank you, Bill.

(Applause.)

COMMISSIONER GORDON: Erin O'Fallon?

ERIN O'FALLON, BA, (MD in May 2001):
UNIVERSITY OF MINNESOTA MEDICAL SCHOOL

MS. O'FALLON: Thank you for letting me participate today. I think I will echo Dr. Manahan a bit because I just had the chance to take his course and as a fourth year medical student I must say until then I had had very limited experience with alternative and complementary medicine until I took the "Introduction to Alternative and Complementary Medicine" course this spring. And, as he said, it lasted three weeks and I got the chance to visit approximately 15 different alternative practitioners, meeting their patients, observing their practice and/or training.

I took this class with seven other medical students and I believe I speak for all of us when I say it was one of the most powerful and thought provoking courses during our medical training.

We feel that every medical student would

benefit from this exposure and training. We agree the course is valuable for a variety of reasons. Although focused on complementary and alternative medicine, it definitely enhanced our perspective on allopathic medicine. By glimpsing the world of allopathic --

COMMISSIONER GORDON: Do you want to come a little closer to the mic?

MS. O'FALLON: Yes.

By glimpsing the world of allopathic medicine from the outside, we more clearly understand the strengths and weaknesses of our chosen field. By considering the alternatives we developed critical thinking skills that applied not only to new and novel ideas but developed our ability to look more critically at our own practices.

Secondly, we felt that our visits with different practitioners allowed us to begin to build a meaningful understanding, rapport and level of collegiality.

Last, the course increased our interest and confidence in discussing alternative therapies with our patients. Since we know that many Americans now use a wide variety of healing

practices, we know that our ability to discuss them candidly and knowledgeably is vitally important.

Our brief exposure to the vast field of complementary and alternative medicine served well to show us how much more there is to learn. We felt that continued courses during residency training, and as part of continuing medical education would be invaluable. Continuing education is required because the scope of complementary and alternative medicine is huge. We also recognize that at different times during our careers we would comprehend and integrate our knowledge of CAM in different ways.

Of course, as with the field of medicine as a whole, the continued expansion and evolution of knowledge and treatments demands keeping your information refreshed and up-to-date.

I personally plan to continue to educate myself about CAM and its relationship to allopathic medicine and I sincerely hope that my colleagues at all levels of their training would benefit from opportunities similar to the course that I took.

I also hope the future of medical education holds an increase in understanding of CAM by allopathic practitioners and I hope that collaborative training, dialogue and respect between our many fields and practitioners will enhance the medical care that we can offer in the future.

Thank you.

COMMISSIONER GORDON: Thank you.

Patricia Cole?

PATRICIA COLE, MD

DIRECTOR OF FAMILY PRACTICE RESIDENCY:

HENNEPIN COUNTY MEDICAL CENTER

DR. COLE: Thank you very much.

As a family physician and an educator, I am proud to be involved in graduate medical education but I am deeply aware that our current system is not serving patients, nor is it serving the medical students who come to us for training.

Many, many patients deeply know that issues of spirituality and relationship are essential to their healing and we do not teach that much.

Our physicians are burning out. I

recently encountered a colleague of mine who trained with me 25 years ago and he has had a quadruple bypass. He listens to patients. He values taking time but he has not ever learned how to care for himself. I think it is essential that we do our education differently.

Now in residency training that is the opportunity where students, doctors in training, not only are exposed to fascinating new ideas like Bill Manahan's course but really need to acquire the skills and ideally begin a path towards integration of those skills into their final practice and the challenge for those of us trying to create programs is how can we bring change into sometimes stodgy old systems that prefer to do it the old way.

There needs to be total system change really. Our nurses need to be empowered to be doing more healing. We have to have our environments be healing ones. We need to be relating to the community so that we can de-medicalize so many conditions that are offered to physicians as if we had answers to domestic violence and chemical dependency and so on.

In my prepared recommendations you have a list of ways that I think this Commission can be helpful. I want you to strongly say that to the medical community and then let us figure out how it is we are going to teach it. Please demand that it be part of our evaluation and board certification exams. Money for CAM demonstration clinics, we have heard about them earlier, these are essential practice sites if residents are really going to learn how to acquire and integrate the skills that I believe they need to care for our population.

Thank you.

COMMISSIONER GORDON: Thank you.

Mary Johnson?

MARY JOHNSON, PhD, RN

DEPARTMENT OF NURSING: ST. OLAF COLLEGE

DR. JOHNSON: I would like to thank all of you for coming to this rather chilly state in the middle of the heartland and I speak on the benefit and on the behalf of nurses.

Nurses have a very unique position and a high trust level in the minds and hearts of patients. They are present at very pivotal times in the lives of people who are in the

process of a healing journey and, therefore, in the basic nursing education I believe that information and evidence, legal and ethical issues, and cultural differences concerning CAM practices needs to be incorporated into the nursing curriculum.

Prelicensure, students need to understand the premises that support healing practices and develop skills in assessing and evaluating their clients' use of complementary and alternative therapies.

Nursing theory and practice has embraced the philosophy of providing holistic care to the whole person ever since its beginnings with Flossie Nightingale.

CAM therapies provide a means of operationalizing and of demonstrating this kind of care. Students who learn the therapeutic use of touch and massage, relaxation techniques, and guided imagery as part of their nursing skills set become more comfortable and competent in nonjudgmentally obtaining and recording information about other healing practices that their clients might be using.

Nurses need to have the ability to

assess and evaluate their client's use of complementary therapies and to develop comprehensive and individualized care plans. Knowledge concerning the information about CAM therapies, research programs and cultural differences needs to be included.

You all know that there is a nursing shortage going on now and it will be probably lasting for many years. I have found that by incorporating the use of CAM therapies into nursing practice, many advantages come from that for the nurse themselves in terms of job satisfaction, meaningful work and centered living. At a time of these increasing shortages, nurses need to provide opportunities and need support from other nurses and from their organizations to continue this kind of practice.

So I would recommend that you speak to nursing national organizations for the inclusion of this kind of information in their educational curriculums and to encourage the Board of Nursing in many nurse -- in many states to expand nursing scope of practice to include some of these complementary therapies.

COMMISSIONER GORDON: Thank you very much.

Janet Dahlem?

JANET DAHLEM, MA

DIRECTOR: HOLISTIC HEALTH STUDIES PROGRAM, COLLEGE OF ST. CATHERINE

MS. DAHLEM: Thank you very much and I, too, extend a welcome to all of you to Minnesota.

I am the program director and assistant professor at the College of St. Catherine in Minneapolis of the Holistic Health Studies program and I have been in that position for 11 of its last 17 years in existence. So that particular program, academic program, while serving a lot of professionals, our primary audience has been historically the health care professions so that is to which I want to speak.

I collaborated on a study in 1999 aimed at our health professions division faculty and 78 percent of that faculty, some, of course we know very, very conservative faculty, have stated that they felt like students coming out of their disciplines would not be adequately prepared if they did not have education in this

particular area.

So to really deal with the demand for education of professionals in this field, the College of St. Catherine is in its final stages of launching and looking at the development of a master's program in this field in addition to the current certificate program.

So my -- the recommendations that I want to speak to are both in policy and action and I want to read those to be able to get through all of those.

My first action recommendation follows my colleague of Mary Johnson, which is to really ask of you from the federal level to enact federal policy and legislation that will make recommendations and mandates to the states at that level which would require the licensing boards of the different health professions to examine, expand their professional practice acts to allow individuals within their professional scope of practice to legally practice and receive reimbursement for using complementary and alternative therapies.

Secondly, my second action recommendation is to establish a national

financial incentive program to encourage academic institutions offering education to health professionals to develop programming and curriculum in this field of holistic, complementary and alternative health care to really continue to meet the growing demand from the educational standpoint.

Our academic institutions that offer health professions degrees need financial incentives, much as the NIH has historically done with research.

And, also, in terms of one of my other policy recommendations that I want to speak to, because the philosophies and theories of some of the holistic health practices are so different from those of conventional medicine, academic institutions need to root curriculum in the historical and cultural traditions from which many of the practice evolved. So this may mean to include partnerships between academic institutions and centers that work to promote the health of cultural communities to guarantee that the voice of cultural ways of knowing are central on our agenda, and I cannot say this enough.

I really, in closing, want to say that I do not want us to recreate a Euro-centric model of health care but -- and I know that that statement reinforces what you all are attempting to do as well.

So thank you very much.

DISCUSSION

COMMISSIONER GORDON: Thank you.

Questions? Linnea?

COMMISSIONER LARSON: I thank all of you for your testimony. This is directed to Dr. Manahan and to Dr. Cole specifically.

I have been involved and actually wrote a curriculum in alternative and complementary medicine for family practice a long time ago and I am very well aware of what you have been doing and then also your commentary, your opening commentary about how many of your colleagues are in grave distress.

So my comment or my question actually has to do with having both trained medical students and residents and having been -- my having seen their eyes opened to "Oh, my goodness, why didn't I learn this before" and then seeing the grave distress of the practicing

physicians, what happens? Is there any follow-up that you do in the training of these medical students and residents? Follow-up after it? How do they really integrate these practices in their own lives and in learning how to collaborate with the alternative practitioners?

DR. COLE: This is a tough one.

DR. MANAHAN: We both would like the other one to answer that because there is probably not a very good answer and I probably could sum it up. Just last week when I was precepting, I had one of the second year residents who was -- just loved the course two years ago. And I said, "How is it going?" And he said, "That is but a distant memory in my mind." And that is why it needs to be -- and Pat and I have talked about that, at third year level of residency and probably out at five years of practice. It is almost like three times it needs to be offered because the residency training overwhelmed them with biomedicine and, no, it was pretty distant.

DR. COLE: I am fortunate to have some extraordinarily motivated first year residents in my program that want to do CAM as their

career and last night speaking to one of them, she was totally exhausted. There is nothing like working 80 to 100 hours a week and being up working all night, 36 hours in a row, four days every other -- every fourth night, to take away any sense of wholeness.

She said, "You know, I have done the Helm's course. I can put the needles in." She said, "I am not sure it would be a good idea for me in this state to be putting needles into anybody. Drawing blood, yes. Doing medical things, okay. But not healing."

And that is a tragedy really. We not only do not model it but we haze them to the extent that we sap even what they know what to do before they come in because exercise goes, relationship goes, spiritual life goes. It is an enormous problem.

DR. _____: If I could add just a couple of comments to what Dr. Cole said. We did recently receive at the university one of the R25 grants from NCAM, a $1.6 million grant, to do a better job of integrating CAM into pharmacy, nursing, dentistry, as well as expand our graduate program. So I think there is hope

and I know I serve on curriculum committees with both Bill and Pat and we really are making an effort to do this not only in the undergraduate but also in the residency programs.

We are developing a survey that I think will be quite interesting that we intend to do at the baseline of this grant period at three years and five years to look at how do attitudes and practices and beliefs change.

We also are in the process of developing an inner-life of healers program that will be addressing many of the kinds of issues that Pat so eloquently spoke of that we hope will be available to not only students but also practicing health professionals.

COMMISSIONER GORDON: One thing I just want to follow up on, which is kind of information for you, Linnea, is that I have seen the -- I have taught medical students at Georgetown complementary medicine for 20 years and one of the things that is important, I feel, is to be with students in the first year and to give them not only the kind of rich experience that you are describing but our experience is really focused on students becoming self-aware