WHITE HOUSE COMMISSION
on

COMPLEMENTARY and ALTERNATIVE MEDICINE POLICY

+ + +

CAM In Self-Care and Wellness

+ + +

Volume I
(continued)
+ + +

Tuesday, March 26, 2001
8:15 a.m.

Hyatt Regency Hotel on Capitol Hill
400 New Jersey Avenue, N.W.
Washington, D.C. 20001

I would say if we include those kinds of issues, though, it was probably about 25 percent if we include some of the lifestyle issues.

SISTER KERR: Why didn't you think of exercise under CAM?

MS. SCHILLER: Well, I guess because exercise has been known to be an important element for just good health in general by a physician per se. I do think that we have a somewhat, maybe a little bit more of a line when we think of alternative medicine as those things that, you know, perhaps 10 years ago your doctor wouldn't really discuss. Exercise obviously would be something that if you were trying to maintain your weight heart disease, diabetes, anything, that they would have always included.

So, I was actually reading a survey of something that we reported on from Consumer Reports, and exercise was one of those issues. But I would say strictly if you asked most of the people at the Network News, they wouldn't really view that as complementary or alternative, complementary being more like magnetic therapy, aromatherapy, music therapy, holistic things, as opposed to exercise.

SISTER KERR: Is nutrition complementary?

MS. SCHILLER: We haven't traditionally just looked at that as complementary medicine. We have done a lot of reporting on issues of fiber, fruits and vegetables, the food pyramid, all of that. That is always I

think to some extent been considered mainstream. MS. ALTSHUL: Again, when it comes to us, it definitely depends on what your definition is, and by the definition that would include weight loss and nutrition, we are probably up there in the 75 percent bracket because we regularly feature hard news nutrition stories. We regularly feature weight loss stories.

Of our monthly five features, I would say one every other month is devoted to an alternative or complementary modality, such as herbal medicine or Chinese medicine, or what have you. We have a regular monthly column on nutritional supplements and a regular monthly column on herbal supplements.

So, we skew a little more heavily to the CAM approaches.

DR. GORDON: Thank you.

Tieraona.

DR. LOW DOG: Information as far as news media goes, I think you all are just doing a phenomenal job. I would like to just put a little spin on this.

Many of my patients get a significant amount of their information or ideas to purchase something from marketing, advertisements, and it is shocking sometimes to see on news programs, ads for male sexual products that have yohimbine hydrochloride, other unproven things saying it sounds like it is scientifically researched, "You, too, can have large breasts within six weeks."

I was noticing just even in one of the presentations here, a product with ephedra and guarana, a caffeine substance, "burns fat, raises energy levels, increases metabolism, it works" with a number and everything there.

Is it all comers for advertisement on these shows and in these print journals, or is there some sort of responsibility that needs to come especially in news programs that if you are watching the show, it seems like there should be some sort of level of criteria for advertising, and also in print journals, because this is what actually causes so much of the problems with my patients anyway, is this direct targeting of advertisements that are often quite untruthful or misleading.

MS. SCHILLER: You make a very valid point. It's a two-way street. At CBS News, we have a very strict separation of sales and news. I don't talk to them, they don't call me. While I personally also have observed some of this, if we call them and say you shouldn't be taking this or this is a problem, whatever, it's a two-way street. They are going to put a lot of -- you know, they may feel free to put pressure on us to not do certain things.

What we do right now is we sort of have an informational relationship in that if we are doing any kind of investigative piece on supplements or a drug, anything, we will let them know, so that it doesn't run that day.

It is the same way as if there is a plane crash, we will make sure that we have checked to make sure there isn't an ad for American Airlines in the program, but they are two complete and distinct things, and unless I have specific evidence that something, you know, that I would feel comfortable calling the president of CBS News and saying you are about to put an ad on television tonight that we know killed somebody -- and I would do that -- the real truth is I don't know what ads are coming up on television.

We have nothing, we don't even see it, I don't know it, it is a completely separate function.

I think the issue of making claims on the products is a different issue, it's a governmental issue related to how far should advertisers be allowed to go, and what should they be allowed to say when they advertise products on the air, you know, regardless of what the product is.

DR. GORDON: Please, Sara.

MS. ALTSHUL: We have a similar kind of firewall, but when it comes to supplements that make outrageous claims or that contain ingredients that we consider dangerous or have written about is dangerous, it is incumbent on the advertising department to bring those supplements and the ads up to the appropriate specialist. If it is an herb, it would cross my desk, and I would say no, we cannot advertise a product that claims to cure cancer.

DR. LOW DOG: Can I just say -- I mean with all due respect, you know, and we could argue about ephedra and guarana -- but there have been 17 deaths and 33 disabling adverse effects, and this ad --

MS. ALTSHUL: Was it a Prevention ad?

DR. LOW DOG: -- is in Prevention.

MS. ALTSHUL: Was it a while ago?

DR. LOW DOG: January 2000, so it has been a year. Again, I love your magazine, I think you do incredible work, but I think our things are concerning because in a reputable journal or -- it is one thing to watch an ad like that on Seinfeld, it is never during the Evening News, because there is some realm of authority, I think that comes with it.

MS. ALTSHUL: Right. Well, things can slip through, obviously, but they are not supposed to.

MS. SCHILLER: I do think that a lot of this that you see is in local news, and there are local news spots that might run in the network. You know, I don't want to mislead you and say we never know anything. If there was a question, and Sales had a question, I don't think we would ever put a sales ad on the air that said this will cure cancer in the Dan Rather News without somebody in Sales calling the News Department. I can't foresee that would happen, because the responsibility is just so great.

However, what a station in Iowa runs in the middle of the Dan Rather news, if they have a local spot, we just have no idea.

DR. GORDON: Craig, did you want to say something?

MR. STOLTZ: Yes. Just to provide some background, at least in print media, there is considerable long-standing case law that obligates us to run virtually any ad that comes our way without regard to what we think about it.

We are allowed to make exceptions for the publisher's perception of profanity or vulgarity, but other than that, or if a product explicitly breaks the law or a claim breaks the law, those are the only two legal means we have to reject an advertisement.

In fact, one of the most famous libel cases, Times vs. Sullivan, this was based on an ad rather than an article. So, whether we like it or not, it pretty much has to run in our newspaper, and we don't know a thing about it.

We have gone so far as to actually investigate in subsequent issues, claims that were made in advertisements that appeared in our section when we feel we have to do that. Advertisers don't like that.

DR. GORDON: Joe.

MR. NEEL: I would just say one thing. NPR has often -- well, maybe not often -- but sometimes people raise questions about what role funders may play in our coverage, the same kind of firewall that exists at commercial news organizations between sales departments and the journalists exist at NPR.

I generally only know who our funders are from listening to the shows just like our listeners do. That is not to say -- well, we don't give any consideration to a story as to whether it might hurt our funding or help it.

The story about isoflavone, the ipraflavone is a case in point. It was after it aired, about a day later I heard a funding credit for ADM, maker of some sort of soy isoflavone, and I went oh, my, I didn't even know about that or even think about it, but in terms of day-to-day management, there is a hands-off policy, and I couldn't even tell you what our standards are for accepting funding credits other than to say I know that they don't directly pitch products or make claims, such as the ones that you are concerned about.

DR. GORDON: Christine, please.

MS. GORMAN: We also have a firewall between advertising and editorial, but I just want to digress a little bit and say as long as I have been at TIME, which is 16 years, I have been very aware of the fact that we accept advertising for cigarette companies, and I have tried faithfully in all of my reporting to, whenever possible, bring up the link between smoking and not just lung cancer, but heart disease and many other diseases.

I think that what you bring up is a valid point. In fact, I am often very grateful that there are other media like the television that no longer is allowed to accept advertising for cigarettes, and so you see a lot of very good work there.

This is the real world, and I think it goes back to the point that I was hoping to make before, that so many people think -- I guess it is misconceptions can kill, the idea that natural is safe is one of the biggest. I think the thinking that we, as journalists, are somehow educators and that we are putting out public service announcements, you know, is another one. It is not true, and it won't ever be true.

DR. GORDON: Thank you.

The last question before lunch? Joe.

DR. PIZZORNO: Well, first, Mr. Stoltz, thanks for the great image of the cultural warriors. That was very, very nicely done.

You all play an incredibly important role in helping educate the public. Although you said that is not

your role, the fact is a lot of people get educated by what you folks do, and I have heard several examples where you have looked at difficult issues and actually looked at the research and took it apart.

I would like to actually ask you to address that further. One I have become very concerned about is the inaccuracy of abstracts and how often that what is in the abstract actually does not accurately portray what is in the journal article.

So, I am wondering how much you basically go on abstracts or expert opinion and how much, and what percentage of time do you actually delve into the article and look at it more closely.

A particular egregious example of that is the study on MSG and Chinese Restaurant syndrome, which show a double-blind, placebo-controlled study that it does not cause Chinese Restaurant syndrome. That is what the abstract said, but if you look at the actual journal article, one of the exclusion criteria was when you go to a restaurant, do you get a bad reaction from eating at the restaurant.

So, they basically excluded from their population people who reacted to MSG and then find that it didn't have a reaction.

So, I am concerned about that kind of air coming into the publications based on a study that was funded by the MSG Research Council.

MR. STOLTZ: When we take something head-on, when we are examining a specific report or a specific claim, we always go deep into the research and we talk to the researchers, and we do our best to pick it apart.

I think the real danger is when we are writing about something related to it, and we will make a comment about something being proven in some journal, when it is really at the periphery of our attention, we simply can't afford the man-hours to go deep on every assumption, and that can be dangerous, I am aware of it. We certainly do our best when we are mindfully focused, but I think there is collateral damage at the edges.

DR. GORDON: Other comments? Yes, please.

MS. GORMAN: I think part of it is also -- I can't think of a story I have written where I haven't gotten the paper itself and just relied only on the abstract, but I think part of it is also are you dealing with somebody who is a dedicated health reporter or is this something that is kind of ripped off of the wire services in a local paper. I think that may be some of the difference in quality there.

MR. NEEL: One time that it might be a problem is we scan an enormous number of journals every week, and I don't have time to look beyond the abstract. If it catches my attention, then, I read the article, but if there is something wrong in the abstract that turns me off to an article I should otherwise read, there is a pitfall.

The other time where your particular problem might be relevant is a lot of times I will go to MEDLINE and try to find out either who is doing research in this area who we might contact as an alternative source in a story, or just to get more background.

I wish MEDLINE could possibly provide full access to all articles, but I understand that is a huge undertaking, and that is as close to a recommendation as I will come.

DR. GORDON: Thank you.

MS. SCHILLER: I would just echo Joe. We never would put a corresponding piece on the air based on an abstract, it just would never, never happen. We have on occasion reported based on Associated Press, but even then, even if it is just a reader or something short, we will check it out, we will ask Research to check it out. It doesn't go on the air without being doubly checked, however, in that case, the person may not read the whole article, if it is something very short.

DR. GORDON: Charlotte, go ahead.

SISTER KERR: Dr. Huerta, I just wanted to tell you I heard you, your work is pioneering. It absolutely will be in my considerations, and I thank you very much.

DR. GORDON: We are going to conclude the morning. I want to say on behalf of all of us we really appreciate both your reporting and your interest in the area, and your willingness to come here and be frank with us, and if there are ways that we can help you, either individually or collectively, in the future, we look forward to collaborating with you, to sharing our information with you, and letting you question us about what we are doing, as well.

Thank you very much.

[Applause.]

DR. GORDON: We will come back here at 12:55.

[Lunch recess taken at 12:05 p.m.]

+++

AFTERNOONSESSION

[1:06 p.m.]

Evaluation of CAM Information

MS. CHANG: Good afternoon. Would the following people please come up to the panel: Harrison Lee Rainie, Susan Detwiler, Lucinda Maine, David Schardt, and Christopher Hendel.

DR. GORDON: Srini Srinivasan, because of a family emergency, is unable to be here, but we do have his written testimony, so we will all have that.

Let's begin with Harrison Lee Rainie, please.

MR. RAINIE: Good afternoon. My name is Lee Rainie and I am the director of the Pew Internet & American Life Project, a research organization fully funded by the Pew Charitable Trusts to do nonpartisan analysis of the social impact of the Internet.

One of the major goals of the project is to assess the way Americans are using the Internet to get health

information. Towards that end, the project has done several surveys of Internet users, one of them specifically focused on those who seek health information on the Web.

We released those findings in November in a report entitled "The Online Health Care Revolution: How the Web helps Americans take better care of themselves," and I have submitted a copy of that report for the record, and I hope it is in your notebooks.

Our work on health care pertains to the activities and attitudes of American Internet users, rather than to analyzing online health content, so I will focus my remarks on how users' experiences and expectations are relevant to your work. You will find that my comments add up to an encouragement that you consider Internet users as a distinct contributor on e-health issues.

Almost 60 million American adults, or 57 percent of those with Internet access, have used the Web to get health care information. Most than 6 million adults are getting such information on an average day.

We call them "health seekers," and a majority of them go online at least once a month for health information. We have just come out of the field with a survey of teenagers and found that more than a quarter of the children between ages 12 and 17, who have online access, have consulted Web sources for health, fitness, and dieting information. It is something that girls do more than boys, I might add.

The reason for all this activity is simple: Half of health seekers say access to information on the Web has improved the way they take care of themselves and many report that the material they gather directly affects their decisions about getting care and treatment for their illnesses or the illnesses suffered by someone they love.

In an era when many are not satisfied with the availability of their doctors, they are turning to the Web to provide the information they find hard to get from their caregivers. They are also increasingly interested in participating in shared decision-making.

Perhaps the most important thing to know is that health seekers go online in a very action-oriented frame of mind. They are anxious to get information that will help them make important, even at times life and death decisions. In many cases, they feel they are getting more information about illness, prognosis, and treatment options for Internet sources than they are from medical professionals.

Yet, even as they take this information to heart, 86 percent of health seekers say they worry about getting health information from unreliable source online. This suggests that you would be making a vital contribution by fostering reliable guides to the best information.

Too often, health seekers are stumbling around cyberspace unaided. Fully 81 percent of the health seekers we interviewed told us they found the information they wanted through an Internet search rather than through a search assisted by a knowledgeable helper. They are clicking in keywords to search engines, either general search engines or search engines on health sites and taking the information that pops out.

Sixty-four percent, almost two-thirds, of health seekers say they had never heard about the web sites they ended up consulting in the midst of those searches. Since the majority of health seekers went online for information right before or right after a doctor's visit, there is an opportunity for health care providers or other trusted intermediaries to supply lists of accurate and patient-friendly sites and guidance on sophisticated search strategies.

Under many circumstances now, patients get the exact opposite message from their providers: "You are not helping yourself by getting more information and you are pestering me with these web printouts you want me to look at. I don't want to be bothered." That is the message they get from their providers in too many instances.

Dr. Tom Ferguson, who I know is a friend of some of you on the panel, is the senior fellow for health research at my Pew Internet Project. He argues that the places on the Internet where the most powerful searching and learning occurs, at least some of those places, are not necessarily health sites, but disease-specific online communities and the disease-specific sites run by patients with condition X for other patients or family members of those with condition X.

Within these forums, discussions of alternative and complementary approaches is most common for diseases in which conventional care has the least to offer, or in which cultural mismatches between providers and patients make it harder for patients to get the kind of care they would like to get.

While opinions that many health care professionals would probably label as "inaccurate" or "misinformed" are occasionally posted in those support groups, but not as often as you might think because the support group communities are impressively expert places in their own way, those kind of postings almost never go unchallenged or uncorrected. In other words, bad information gets corrected in most instances in the support group sites. In many cases, differences of opinion boil down not into "right" and "wrong," but rather differing biases for particular types of approaches or treatment.

For instance, some end-users consider themselves anti-drug and pro-natural, and consider most health professionals to be unconsciously pro-drug and anti-natural. Thus, by their lights, they would prefer to begin with "natural" remedies and use "drug" remedies only as a later resort.

This suggests that efforts to encourage users to contribute to the assessment of online information would be a useful addition to the efforts that are being made by providers to establish ethical and quality standards for online health sites.

Dr. Ferguson has done research suggesting that well-mediated and robust disease-support communities can often provide online health seekers more in-depth information, more details about cost effective treatments, more emotional support, and more practical information about coping activities than professional health providers can. Of course, patients continue to say in those studies that doctors are better equipped than support groups at diagnosing illnesses and setting up illness management regimes.

The other Internet sources for information quality assessment are the so-called qualityware search engines like google.com, as well as consumer-oriented sites exemplified by gomez.com and epinions.com. The health site report cards and ratings compiled by the staff and site users are a powerful resource for those asking fundamental questions: What are the best sites to give me answers for my condition?

One of the things that you did not discuss, at least in my hearing in the morning meetings, related to privacy concerns that health seekers have. Most users go to health sites for research and reference purposes and have been able to get the information they need without making any significant trade-offs by giving up personal information.

Only 21 percent have volunteered their e-mail address to a health web site. Anonymity, or at least the

feeling of anonymity, is enormously important to health seekers. Eighty percent say that this is one of the major appeals of getting online health information. A user can hunt for information on a sensitive subject and no one else has to know about it.

That partly explains why Internet users so strongly fear the prospect of such information falling into the wrong hands. A certain amount of shame might be the cause here, but there are practical worries, as well.

Some 85 percent of health seekers say they are concerned about their insurance company finding out such information and maybe changing their insurance status or changing their rates. More than half of health seekers fear their employers might find out what sites an employee has visited and take action related to their employment status.

This concern about privacy also extends to the idea of online medical records. Sixty-three percent of health seekers say that putting medical records online is a bad thing, even if the records are on a secure password-protected site, because they worry about other people seeing their personal information.

As for next steps, I would encourage you to think about three things. The first is a "buy-in" from the medical establishment. Patients are going to hunt for medical information online whether their doctors sanction these searches or not. It would be good of you to encourage them to see themselves as partners in this search.

I would also encourage you to make sure that there is transparency and patient privacy awareness. We find that many patients are not aware of what cookies are, how tracking is done, what kind of activities are done with the information they have provided. You could provide a major service by encouraging disclosure about these technologies, how tracking is done, and what is done with the information.

Finally, I would encourage you to facilitate methods for patients to apply their own expertise to online health matters. Internet-based support groups can play a very constructive role in providing advice to others about what web sites to visit, how to assess the validity of online information, and how to deal with illnesses.

Thank you.

DR. GORDON: Thank you very much.

Susan Detwiler.

MS. DETWILER: Good afternoon, ladies and gentlemen. It is truly an honor to have this opportunity to speak with you.

My name is Susan Detwiler and I am president of the Detwiler Group, an independent information consulting firm, which specializes in the information needed by the health and medical industry.

We not only stay aware of the quality of information that is important to our clients, though, we also evaluate the quality of health information available to the public.

We recently conducted a study of the timeliness of drug data on the Internet, which we released under the title, "The Medium Doesn't Get the Message," and conducted research on medical misinformation on

the Web, published under the title, "Charlatans, Leeches and Old Wives," in Searcher magazine. I believe you have both of those in your binder.

Our specialty is health and medical information, but our emphasis is on the information end of that phrase. No one in The Detwiler Group is a physician, no one in The Detwiler Group is a licensed health professional, however, we are experienced in finding health-related information, as well as in evaluating how well the different sources present the information, and this is where I will direct my remarks.

As Lee's study showed, and he preempted some of my statistics, 70 percent of health seekers search for specific illness-related information, only 13 percent searched for health or wellness related information.

Instead of heading toward sites which had been recommended to them, 81 percent said they do a general search for the information they look for. With all due respect to the information providers we have heard today, with high ethics and quality editorial standards, this commission would be remiss if it ignored the reality of how the public seeks and finds its health information.

We cannot focus on just the quality of top sites or those with brand names. The Commission has to be concerned with the broad spectrum of conflicting information which the public confronts when it searches for health advice.

Therefore in addition to a look at the CAM information presented by popular health sites like WebMD or DrKoop, we also reviewed the results of general searches and sampled message boards. We emerged with three main findings.

First, unlike information about mainstream or Western medicine, information about complementary and alternative medicine is frequently contradictory within the same web site.

Second, many general search engines are more likely to turn up spurious sites than they are to find balanced information. The most popular results are not necessarily the most valid.

Third, much of the information about CAM modalities is spread through chats and message boards, both on mainstream web sites and in person-to-person systems.

Let's take these one at a time. First, conflicting information on the same site. Much of the information on mainstream health sites present balanced perspectives. They do tend to be Western medicine based, but they indicate when there have been clinical studies indicating their effectiveness. However, they offer conflicting information.

For example, on DrKoop, the initial search for acupuncture turned up 50 results. At the top of the list was a news item from Reuters Health, which talked about how useful it is as a treatment for tennis elbow. The following items on the same list calmly and precisely rip apart the science behind acupuncture, stating that, "Researchers have concluded that acupuncture is no more effective than a placebo for weight loss, for smoking cessation, against pain, and against osteoarthritis." The same search, the first two items.

Taking a look at WebMD, the first result for homeopathy is the balanced NIH overview of homeopathic medicine. Meanwhile, on the message boards, we see a diatribe against homeopathic remedies lifted directly from Dr. Stephen Barrett's Quackwatch, followed by a WebMD-sponsored chat with a practicing naturopathic physician and chiropractor who is specialized in homeopathic medicine.

Several messages were commercial in nature, directing individuals to their web sites for more information.

Let's turn to the results of general search engines. Since 70 percent of Americans search for a specific disease, we looked at the results they would get when searching for a cure. Using the words, very simple, just as an average person would do, we put in "cancer" and "cure." We tested three of the most popular search engines.

A Google search turned up first The Cancer Curer Foundation dedicated to the promotion of alternative therapies for cancer, including electrotherapy, hydrogen peroxide therapy, laetrile, herbal extracts and detoxification. The reference to zapper and anti-parasitic herbals led to a site promoting a Mexican-based clinic to cure cancer.

On Alta Vista, the first site listed is a personal page including a listing of alternative therapies ranging from parasite cleansing, to laetrile, to hydrogen peroxide therapy and scores of other alternative therapies.

MSN gives you the opportunity to see the 10 most popular sites that match your words. The first ones were: "Alternative Cancer Cures and AIDS Cover-ups by Lorraine Day, MD." On this site, the health seeker finds sales literature for a video on "Sorting Through the MAZE of Alternative Medicines," as well as treatises on "The Government Cover-up of AIDS", "Why Condoms Don't Work," and similar topics.

According to the counter on that site, I was visitor number 733,332.

Finally, we looked at the information conveyed on person-to-person networks. Since so many people use AOL for its message boards, we tested the forums on its very active Alternative Medicine channel. In four weeks, the Herbal Remedies board picked up 136 subjects, each beginning with a plea from some individual for information about an herb or for herbal help with a disorder or disease. In one case, the respondent who suggested a Western medicine solution to a problem was chastised for posting on the Alternative Medicine board by the moderator.

Many respondents state they are physicians or trained herbalists on these boards, but there is no way to check their credentials. Frequently, the advice of those who identified themselves as experts were contradictory, and in several cases the posted messages descended into arguments.

Based on this study of the Internet as a source for CAM information, I have to reiterate the Commission cannot rely on the mainstream press and mainstream web presences to convey accurate, balance information about complementary and alternative medicine. In effect, what has developed is the Internet as an overgrown version of the village well. Any individual can state any item as fact, and there will be someone around to believe it.

Therefore, I have three recommendations.

First, acknowledge that mainstream health web sites make up a small part of how complementary and alternative medicine information is spread on the Web, and plan accordingly. Turning a blind eye to the invisible networking that occurs among people on the Internet will undercut the effectiveness of any policy you put in place.

Recognize that most people are not aware of the quality health sites. WebMD, the top-ranked health web site with 4.7 million unique visitors in December, still had less than 6 percent of the Web visitors. DrKoop.com with under a million unique visitors, had only 1.2 percent. Meanwhile, AOL Time Warner Network had more than 69 million unique visitors in February.

Second, once you have a policy in place, don't hide it. Create a public education campaign about how to benefit from this policy. Right now, much of the complementary and alternative medicine-using public believes the government is deliberately fighting its use.

As you know, there are whole web sites devoted to conspiracy theories linking the pharmaceutical companies with the FDA in schemes to keep herbal remedies from the public. Create a web site for CAM information that teaches how to evaluate information and how to look for possible harm indications.

Encourage conventional, integrative, and alternative practitioner sites to link to it by using a massive PR campaign.

Third, create an educational campaign for use in the schools, probably at the middle school level, to teach critical thinking. The focus should be on how to evaluate information you get from friends, strangers, people you meet in Internet chat rooms and on message boards, and on various web sites.

Students are taught how to use computers and how to find information on the Internet, but they are often not taught how to evaluate that information, and the lessons don't include how to evaluate the information from the chat rooms. Students should be taught that anyone can claim to be a doctor or a specialist and how to check out the facts they are told.

I appreciate this opportunity to present this information to you, and I hope that it ends up being useful.

DR. GORDON: Thank you very much.

Lucinda Maine.

DR. MAINE: Thanks very much. I apologize to the Commission in advance for not having the forethought to have brought copies of my testimony. I did bring one, and I provided it to a member of the staff, and she has assured me that you will have copies, but after the fact.

I am pleased to represent the American Pharmaceutical Association, which is the national professional society of pharmacists at today's hearing, and to have this opportunity to address several key issues regarding information available to professionals and consumers to guide their selection and use of complementary and alternative medicine products.

Pharmacists largely deal with patient or consumer use of dietary supplements including vitamins and herbal products, and my comments will in large measure relate specifically to these components of CAM products and services.

It is APHA's position that pharmacists have a responsibility to assist consumers with decisions about effectiveness, proper use, indications, safety, and potential interactions between alternative medicines and traditional therapy.

Their ability to carry out this responsibility depends on the availability of credible evidence-based information to supplement their professional education and experience.

I will draw on several sources in framing my remarks including a publication issued as a joint effort between APHA and the American Dietetic Association last year, which I believe has been previously shared with the Commission. In addition, I have gleaned the highlights from focus groups held just one week ago during the APHA annual meeting in San Francisco.

These were convened by staff members of the Office of the Inspector General at HHS, in their Boston office, who had embarked upon a project to evaluate the adequacy of product labeling information and specifically in the context of the elderly patient population.

Finally, research results from colleagues at the University of Minnesota College of Pharmacy, who I believe addressed the Commission at your open hearing in Minneapolis, have been helpful in guiding the development of today's remarks.

For perspective, I believe it is important to note several things about pharmacists and dietary supplements. Pharmacists and especially those practicing in community pharmacy settings are a highly accessible resource for the public for guidance about the selection and use of alternative medicines.

The Minnesota study I referenced indicated that pharmacists are approached on the average of about seven times per week by consumers with questions about herbals and/or other natural products, which was the terminology they used. In sitting here, I just did a little bit of math, and that would suggest, if those results are generalizable to the pharmacy population, that equate to about a million queries a week approximately of pharmacists by consumers.

This is a striking increase when compared to a national survey conducted in just 1996, which found a rate of only about 10 consumer queries a month. In addition, the Minnesota pharmacist survey reported receiving questions from other health care practitioners, as well, about the use of these products.

How comfortable are pharmacists with their knowledge base and their access to scientifically grounded information on these products and their use? By observation and by the focus group results, I would say far less comfortable when compared to other categories of products commonly purchased in pharmacies.

Almost 40 percent of the Minnesota pharmacists responded that available clinical and technical information used in making decisions about herbal and natural products was not adequate, and another 57 percent indicated information was only somewhat adequate for their needs.

For the past several years, standing room crowds of practitioners have attended relevant educational sessions at ours and other association meetings. We feel this reveals an unsatisfied demand for credible information.

In the recent focus group discussions, pharmacists indicated that both they and their patients found dietary supplement labeling confusing and inadequate to guide point of purchase decision-making. Confusion stems from disclaimers that are too small and suggest something about product review by the FDA, but leaves many questions in the minds of both consumers and pharmacists.

Further, while pharmacists find that references on labels to USP is important in judging product quality,

references to other quality reviews that may also appear on labeling is confusing and potentially misleading.

Concerns about product quality and purity, in addition to other concerns about combining these products with traditional therapy, are prevalent in the thinking of pharmacy practitioners.

There are two important points I think about the interface of pharmacists and consumers in the CAM arena. First, while many consumers appear to reach for these products in the context of health seeking and wellness, and we respect that, those who access such products in pharmacies, we believe, are more likely to be individuals who are familiar with the pharmacy setting, because they may also have acute or chronic conditions that prompt prescription or nonprescription use.

Fortunately, when they ask pharmacists for guidance, they may be thinking of their need to assure that whatever self-care activities they engage in won't interact with, or complicate, their other health conditions or therapies.

But there are limits to what is known about such combinations of therapy, and pharmacists do not feel that existing literature, whether primary, secondary, or commercial, meets either their needs as professionals or the needs of consumers for safe use.

The second point about sale and labeling of CAM products in the pharmacy environment is that often herbal natural products are sold very near or actually integrated with traditional, over-the-counter medicines.

Pharmacists are split in their opinions about whether labeling should be modeled more like OTC products or foods. Proponents of OTC-like labeling believe consumers are used to that format and would benefit from similar labeling for CAM products. Others feel that it is inappropriate to infer that CAM products are like OTC medicines.

A third group told the OIG staff that it really didn't matter how products were labeled because they didn't believe that consumers references the product label anyway.

There was a feeling that labels should encourage consumers to share information about their use of dietary supplements with their physicians and pharmacists and other health care practitioners. Further, a warning seeking health care provider input if the symptoms, if any, for which consumers are using the CAM products, don't resolve is highly recommended.

My final point is about surveillance of experience with CAM. Pharmacists are perhaps most uncomfortable with what we don't know about actual consumer experience with CAM products. APHA believes that it is time for a much more robust system of experience reporting by consumers and health care providers.

Ideally, such a system could be voluntary and be embraced by manufacturers of CAM products as a key tool for collecting and analyzing actual use information about their products. A program could be modeled, we believe, after reporting systems used by chemical and related product industries.

APHA would support and cooperate in the development of an accessible reporting system that would meet the needs of manufacturers, regulators, providers, and consumers for information about product quality and consumer experience with dietary supplements and other CAM products.

Thank you for seeking the input of America's pharmacists on these issues before the Commission, and I would be happy to provide additional information if time permits.

DR. GORDON: Thank you very much.

David Schardt.

MR. SCHARDT: Thank you. I am with the Center for Science in the Public Interest in Washington. For those of you who may not be familiar with our organization, we are a nonprofit consumer group specializing in food, nutrition, and dietary supplement issues. We are supported almost entirely by our 800,000-plus members. We accept no money from industry or government.

We have been asked here to comment on the media's coverage of complementary and alternative medicine. We do have a fair amount of experience dealing with the media. One of our functions as it has evolved over the years is to serve as a resource and source of information to the media, and, in fact, a fair amount of our time involves dealing with networks and local TV stations, newspapers, and magazines, et cetera, constantly calling us for information, bouncing ideas off of us, so we have some experience with what the traditional media is looking for and what they use.

I would like to begin by saying that although we have been asked to comment on the traditional media, I think that the most important media is the Internet, and will be so for the rest of our lives, and when I want to find out something about complementary and alternative medicine, I don't reach for the newspaper or magazine, I don't turn on my TV, I don't go down to the library, I go on the computer and I go on the Internet.

That is where I get most of my information and if I can't get something there, then, I will go to the library or seek some other source of information, but it is by far the most important media in terms of complementary and alternative medicine.

Now, most of the traditional media, such as television, radio, newspapers, magazines, and newsletters, like the one we publish, they are valuable for acquainting people with complementary and alternative medicine, and for notifying them of new developments.

They are useful for getting people acquainted, for interesting them, for drawing them into the tent. They are useful for notifying people of something new that they should be paying attention to, for example, when it was discovered St. John's wort interfered with protease inhibitors or oral contraceptives. That type of information can be quickly and efficiently delivered to the public through these traditional media.

But for people who want to seriously consider trying an alternative therapy and who want in-depth, objective, reliable information, these traditional media are not always as valuable. We try to, at our organization -- most of our members are middle-aged and older -- and we try to imagine the typical member, 50 or 60 years old, usually a woman, who is interested in maybe trying something alternative, but doesn't want to hurt herself, doesn't want to create more problems than she can solve, but wants to spend her money wisely.

She can't, none of us can spend our money on everything that people are advocating us to try. You have to be very selective. For those people who want some good, detailed information about what is available, what works, in what dosages, and what to look for if they want to try it, the traditional media, they are

constrained by a number of factors that make it difficult for them to provide this type of information.

Some of those factors are that the traditional media are limited by the amount of air time that they have, the amount of space that they have in their publications.

I don't know if you have ever had this experience, but you will sit down for a TV interview, and you will spend 45 minutes taping an interview, and all they are going to use is 6 seconds. They know that at the start, and you know that at the start, but nobody knows quite which of those 6 seconds they are going to use, and it is probably not the one you want, and it would be a whole lot easier if we could all decide right at the beginning what 6 seconds you want and just get it over with. But that is all that they can afford to use often, and because of the constraints of the medium and, of course, 6 seconds is not an adequate amount of time to deliver any type of good information, so there is that constraint.

Newspapers and magazines also have space constraints, some more than others. We are lucky here in Washington to have the Washington Post with their Health Section, which has a large amount of space to discuss issues in detail, but that is an exception.

Also, the media are constrained by their need for newsiness. They have to have a hook, it has to be something new and exciting, not necessarily what is most important or what is most valuable, but what is going to grab the reader.

There was a good example of this earlier this year when the Institute of Medicine came out with their recommendations on antioxidants. A local reporter here for one of the papers got a copy of the report the day before, I don't know how, but unfairly in a sense, and wrote an article that ran the day the report was supposed to be delivered.

We were dealing with 24-hour news cycles here, and the other media, like the New York Times, found out about it and insisted that night that they also be given the full copy, and so the Institute of Medicine reluctantly released the report the night before.

The other media didn't cover it as much as they might have, because the local paper here, the Washington Post covered it in detail, broke the story and scooped them, so this Institute of Medicine report didn't get the coverage it normally would plus the committee cancelled the press conference that they were hoping would put the report into perspective, and so the public wound up losing because they didn't get as much coverage as they might have or with as much perspective as they might have, and that is all driven by the media's need for newsiness, and if somebody breaks a story, then, they are less interested

Of course, the broadcast media needs visual images, and that is what drives a lot of their stories. If an important story doesn't have some striking visual aspect to it, the media are less likely to run it, and they need human emotion. We are getting calls now asking for human victims of dietary supplements. They want suffering on camera. If there is already a case for that suffering being representative, that is one thing, but if that is what is driving the coverage, not necessarily the significance of the problem, then, the public is being misled.

There is also a need for conflict. Reporters like stories where there is people disagreeing or there is some controversy, and they are less likely to run a story that isn't. I know, although this is not CAM, a popular subject right now is mad cow disease.

We get calls from reporters hoping that we will be controversial on mad cow disease, and it turns out we think the government and industry have done a pretty good job about keeping mad cow disease out of the country, and when we tell that reporter you can hear the disappointment in their voices. They have less of a story now because of that.

Also, the media has a short shelf life. Broadcast programs are gone. They are gone into the ether, which sometimes is a good -- come back to haunt you, but if you are a member of the public, once that program is over, it is difficult to get it back. You can buy videotapes if you wait and you want to spend some money, but if you hear from your friend did you see that program the other night, well, you don't have many options for calling that program back.

It is the same really with newspapers, unless you are willing to save all your newspapers or magazines, or maybe hope that your local library has them, there is a very short shelf life to that information, although the Internet also may have its problems, still, you are more likely to find that information lingering on the Internet than you will from your copies of your local paper.

Also, a serious problem I think is the lack of beat reporters dealing with complementary and alternative medicine, media that have reporters that really focus on this, I don't know if there is any in this country.

The types of reporters we get calling us, generally, there are three types. One are the health reporters who specialize in health, and they usually work for the major newspapers, the Washington Post, the New York Times, and they are usually very good. They know the subject, they know the people to talk to, they have a nose for what makes sense and what doesn't, but they are really a very small handful, there may be a dozen, maybe two dozen at most.

Then, you have the professional reporters who happen to be assigned a health story, and they are very professional, and they will get the story. They won't get it wrong, they may not get it quite right, but they won't get it wrong, they won't make a big mistake, but they are not normally covering this material. There again, they are a minority of the reporters.

Most the reporters you get calling are people that are not necessarily great journalists, and they don't necessarily know very much about the health issue that they are dealing with. So, you wind up spending a lot of time trying to educate them and steering them away from the wrong information, and despite your best effort sometimes, they publish material that is not necessarily accurate.

So, because of that, you don't get the consistent, good coverage of a lot of complementary and alternative medicine issues from the media, simply because there is no one there following it regularly, who knows the sources and knows the information, knows the research that is coming out. I think the public suffers as a result of that.

So, if the CAM community wants to foster better coverage in the press, I think that they should recognize it is very difficult to do these stories. The literature is varied, it is all over, it is not like the traditional conventional medicine stories.

It is difficult to track down and identify the reliable sources, reliable institutions and people to talk to. So, if the CAM community really wants to foster better coverage in the press, I think what they need to do is establish a top-notch press office with people staffed there who are up to date on the material, who can quickly return reporters' calls, referring them to good, reliable background information and identifying the people to talk to on both sides of the issues, so that they can provide a balanced story, so

that reporters know that if they are assigned a CAM story, they know who to call first, and their editors know to say to the reporters did you call that office, did you get what they have to offer.

I think if that were to happen, you would have a lot better coverage in the media of complementary and alternative medicine issues.

Thank you.

DR. GORDON: Thank you very much, and thanks for that specific conclusion to your discussion. It is really very helpful.

Christopher Hendel.

MR. HENDEL: Thank you for inviting us to participate. My name is Chris Hendel and I am the health research manager for Consumers Union. We publish Consumer Reports magazine, Consumer Reports on Health, a monthly newsletter, and we have Consumer Reports Online. The combination of those three reach a little over 5 million readers, and I brought props today.

Dating back to our premier issue of Consumer Reports magazine published in May of 1936, Consumers Union has provided the consumer with unbiased, accurate information about products and services in the marketplace, whether it be a new or used car, a toaster, specific medications, medical treatments, or even a new health plan.

As the largest nonprofit independent testing and information organization in the world, Consumers Union's fundamental mission has always been to test products, inform the public, and protect the consumer. Our income is derived solely from the sale of our publications and services and from non-restrictive, non-commercial contributions, grants, and fees.

We buy all the products we test and accept no free samples. We take no advertising from outside entities and do not let any company use our reports or ratings for any commercial purpose.

In preparing reports for consumers about products and services in areas of medicine and health, in addition to our own tests, exhaustive search, and analysis of the literature, discussions with researchers and clinicians, et cetera, we often have the luxury of turning to our own readers to learn about their specific real life experiences.

In 1999, as part of our annual questionnaire which we send out to subscribers of Consumer Reports in both Canada and the United States, we included a section entitled, "Health Care," inquiring about specific treatments our readers used most often for the two most serious or bothersome medical conditions they encountered during the previous two years.

Since the survey was not presented to the reader as "alternative health care," we are confident our sample is not comprised solely of people with strong predisposed notions regarding the topic. Respondents informed us about their experiences with such conventional treatments as prescription and over-the-counter drugs, physical therapy, surgery, and lifestyle changes, such as diet and exercise, as well as their experiences with CAM treatments.

We received well over 46,000 responses. A separate validation survey was performed by our survey department to demonstrate that the respondents were representative of our universe of readers.

At final analysis, our survey appears to be the largest and most detailed snapshot of alternative medicine use in North America. Before I discuss some of the key points from that survey further, it is very important to note some caveats.

Seventy percent of the respondents were male, and both the men and women in the survey tended to have higher education and income levels than the national norms. Because of this, our findings may not be directly comparable to other studies, however, we feel the findings do provide some very interesting answers to questions about the use of alternative and complementary medicine in our present medical care system.

Without going into every specific detail of our analysis, I would like to share some very intriguing findings about our readers' use of CAM and perceived efficacy of those treatments.

More details can be found in the published results of the survey, which appeared in the May 2000 issue of the Consumer Reports magazine, which I have included in the Commission's briefing book.

When you look back at earlier published surveys by Drs. Eisenberg in '93 and '98, Assin [ph] in '98, and Benjamin Driss [ph] in 1999, we see some similarities, but also several new and interesting developments regarding the use of alternative medicine.

First, 35 percent of the survey respondents tried alternative treatments; 79 percent, who used alternative treatments, also tried conventional treatments, mainly for relief from troublesome symptoms that had not yet yielded to conventional treatments.

Those individuals who said they were in severe pain or stress were more likely to use alternatives. For most medical conditions, the majority who tried alternatives found them very helpful or somewhat helpful, however, some medical conditions including an enlarged prostate scored rather poorly even though the clinical trial evidence published to date suggests that the use of the botanical supplement, saw palmetto, may benefit some men with mild symptoms at least in the short run.

In the early 1990s, we reported that the majority of Americans who were experimenting with alternative medicine were doing so without the knowledge and consent of a health care professional.

Among our readers, this appears now to have changed. When readers felt comfortable enough to tell their doctors about their use of alternative treatments for their condition, and 60 percent did, most doctors expressed approval, 55 percent or at least neutrality, 40 percent. Only 5 percent of the group said that their doctors disapproved.

Nearly 1 in 4 readers who tried alternative treatment did so on the recommendation of a doctor or a nurse. More than half of those recommendations were for botanicals and other supplements, most typically for arthritis and prostate problems. A smaller number of professionals recommended hands-on therapies.

What persuaded our readers to try or not to try complementary and alternative treatments for their medical condition? Although not noted in the final published results, I would like to share some information about that specifically.

Forty-seven percent said they were persuaded to try a specific treatment because of their own reading or

research. Only 9 percent were persuaded by advertisements, and almost all those for botanicals and supplements.

Among those who did not try complementary and alternative treatments, the reasons why they did not were: 40 percent replied they did not know enough about the treatments, 28 percent did not trust treatments not provided by their doctors, and 11 percent specifically replied that they thought complementary and alternative treatments were "too risky."

As noted earlier, the increase in discussion between our readers and the health care professionals they visit is a very welcome sign, because as the medical research community digs deeper into the safety and efficacy of CAM treatments in a broader range of individuals, we are learning more and more concrete information which will benefit everyone, especially in the light of much inadequate and non-scientifically based information circulating in the media, as well as the lack of significant regulation of the dietary supplement industry.

There is still so much we don't know with respect to long-term use and how many dietary supplements work and how those mechanisms may affect other active medications individuals may be taking.

I mentioned the first issue of Consumer Reports magazine here. Along with testing the lead content of toys and the purity of milk, we also tested Alka-Seltzer, which was all the rage in no small part due to the manufacturer's promotion of the simple white tablet's ability to relieve or cure the common cold, headache, neuralgia, muscular pain, rheumatic fever, dissipation, overindulgence, sour stomach, heartburn, fatigue, nervousness, sleeplessness, alcoholic excess, and minor throat irritation.

Consumers Union reported to the public about the truth behind those claims and informed them of the product's ingredients, aspirin, citric acid, and sodium bicarbonate. Some things never change.

Today, we know by virtue of extensive biochemical analysis and the randomized control evidence that aspirin, one-third of an aspirin, standard aspirin tablet has the potent inhibitory impact on prostaglandins, substances in the body that produce a wide range of effects, such as pain and inflammation, as well as clotting of the blood.

We have also learned that aspirin's impact on prostaglandins also affects a protective role of the substance, that of protecting the stomach and duodenum against ulceration. That is why the long-term use of aspirin has been found, not only to reduce the risk of heart attack and stroke, but also to increase the risk of GI bleeding and ulcers.

Aspirin falls under the FDA regulatory rubric as an over-the-counter drug and must meet specific chemistry, compendial and labeling requirements of the FDA. However, you won't find aspirin sprinkled in potato or corn chips, in a pint of ice cream, or a can of soda. I wish we could say the same for a lot of botanical ingredients which do appear to have documented drug-like effects on the body, and unfortunately, no one really knows how much these "functional" snack foods and beverages contain. There is no standard, validated testing method to analyze foods and beverages for the presence and concentration of these botanicals.

We feel the FDA should vigorously enforce existing laws and develop regulations on the evidence needed to document the safety of botanical ingredients in foods and require safety information on food labels.

Regarding dietary supplements, consumers have virtually no protection against inaccurate labeling or substandard preparation because of the lack of meaningful government regulation.

For this reason, since 1995, we have been testing supplement products to evaluate their content and how that content conforms to information on the label. We started with ginseng back then and found substantial brand-to-brand variation in the amount of ginseng in the pills.

Other, more recent analyses have not only found variation in content, but also pesticide residues. Thus far, we have evaluated echinacea, ginkgo biloba, saw palmetto, St. John's wort, cava, and Sam-e, and will continue to evaluate products on the market, working with outside laboratories that specialize in testing of botanical products and focusing on those that have performed well in clinical trials.

Our ingredient testing will follow our usual standards, which include anonymous shopping in a variety of retail outlets, and for many products, the testing of multiple samples of each brand obtained from different parts of the country.

We are learning too much after the fact for a lot of these substances, many of which have very demonstrable effects on the body. We are just now learning how many of these active compounds are metabolized.

For example, we have only recently learned about St. John's wort's effect on enzymes in the liver and how this alters the therapeutic effectiveness of many prescription medications, and just a few weeks ago, both ginkgo biloba and ginseng were found to alter the metabolism of the calcium channel blocker nifedipine.

How do consumers hear about this information? Well, the Internet has created an incredible opportunity for the consumer to obtain information about dietary supplements. Specifically, in complementary and alternative medicine in general, much of that information is of questionable credibility and accuracy.

When we begin to develop our own articles on specific medical treatments or preventive measures to reduce the risk of various medical conditions regardless of whether the option being researched is "conventional or complementary or alternative," we often choose the same approach.

This typically begins with the collection of pertinent clinical trials and/or epidemiological data that exists. While MEDLINE, the database of the National Library of Medicine, is an excellent place to start, not all the information that we need to develop thorough coverage exists there. Actually, an article in this month's American Journal of Clinical Nutrition bears this out, noting that a limited search plan focused on MEDLINE fails to locate nearly --

MS. CHANG: I'm sorry, we are out of time.

DR. GORDON: Thank you, and thank you for the other recommendations that are already in here in your written testimony. The Commission members have a chance to take a look at them, in fact, all the written testimony, and ask questions.

So, let's begin. Yes, David.

Discussion

DR. BRESLER: We have heard a lot of testimony that many consumers are getting a lot of their information about CAM from the media, from the Internet, and from other sources rather than health care professionals.

I remember many years ago there was a computer program called ELIZA, which was a computerized psychotherapy program, and it was very Rogerian in nature. It would sign on and say how can I help you, and you would say I am feeling depressed. ELIZA would say how do you know you are feeling depressed.

What was interesting about this research is when they asked users of this program, a majority of them said they preferred it to their own psychotherapists. They said that ELIZA paid more attention to them, was more responsive, they liked the privacy and the confidentiality of it, and so forth.

The question that I am getting to is as more and more of this information becomes available through these alternative sources, do you, as you analyze this, have concerns that it is degrading the therapeutic relationship which many of us feel is a very critical part of the healing experience, and that more and more people will be estranged and alienated from seeking information from health care providers and will turn to these alternative sources for information, which may or may not be accurate, do you have concerns about this?

MR. RAINIE: Our research shows that at least the current situation is the exact opposite. When people are seeking information, particularly in the online context, they are doing it with the thought that their provider is going to be a partner in this search.

They are not self-medicating, they are not self-diagnosing, they are wanting this information to take it to someone that they then trust, in part just to get another reading on it, or to ask questions that they didn't think to ask in the first time.

A lot of people are doing this on behalf of someone else, so there it sort of -- it takes a village to heal somebody in many respects, so at least for now it is encouraging a different kind of relationship maybe between a provider and a patient.

It is not always top-down, and the patient isn't always in the supplicant mode anymore, and I think that is maybe why doctors resent it, but most people are turning to a trusted source at some crucial point in this information gathering process and decision-making process.

DR. GORDON: Other questions?

MR. SCHARDT: I would just add to that, particularly if it is dealing with a disease, you need somebody to help monitor the progress of it. If you try and lower your cholesterol levels through some alternative therapy, you need to monitor those levels to know if it's effective, so I think a lot of people will work in conjunction with the health professional.

DR. BRESLER: But just to follow up on that, as this technology becomes more interactive and more personalized, again, tracking people as they go through various alternative types of approaches, and so forth, again, is there a concern that any of you have that this is going to tend to alienate the basic therapeutic relationship?

DR. MAINE: Just a couple additional thoughts. I didn't include in my testimony that 25 years ago,

information about pharmacognosy, as we like to call it, was stripped from the pharmacy curriculum. Now, it is making its way back in both elective and required coursework, but I think one of the factors when you see this interplay with a consumer equipped with Internet delivered or whatever kind of information, I think providers feel a little bit ill of ease about their own base of knowledge, and I think that that is an important thing to consider.

I also think that they, quite frankly, don't have as much time as they would like to, to be engaged in a constructive dialogue about therapy alternatives, et cetera.

The last point is that we know that there are people, informed, educated professionals, who don't think alternative therapy is okay, and I am afraid that that does distance them from the consumer who comes in either with questions or bona-fide opinions based on their own personal education and use.

DR. GORDON: In your response, when you say "provider," you are including pharmacists very much in that?

DR. MAINE: I use that very inclusively of all health care, licensed health care practitioners.

DR. GORDON: Could you say a little bit more about what kind of information pharmacists would like to have, and any role that you feel we could play as making either administrative recommendations or legislative recommendations?

DR. MAINE: I think that pharmacists most want to know that (a) that it is evidence based. Randomized, controlled clinical trials is the standard for what we know about pharmacotherapy in general, especially pharmaceuticals, prescription drugs.

But I think probably more than that, they would really like to know a lot about what we don't know which is how does the alternative therapy potentially interact with and interplay traditional modes of treatment, because that is where the pharmacist is grounded, in their database and in their interactions with patients and other health care practitioners.

DR. GORDON: What is the best way to provide that information to pharmacists?

DR. MAINE: Pharmacists are also consumers of information on the Internet, but I think that they have told us, and then they told the OIG staff, that they turn to what they characterize as credible health professional references.

The Pharmacists Letter, for instance, has in the last year or so, published a fairly sizable compendium on natural products, and that seems to be ranking high in pharmacists' access of information. Again, they are turning out for live education programs in record numbers, and have been for the past five years or so.

DR. GORDON: Yes, please.

MS. DETWILER: In response to the first question on whether the professional-patient relationship is degrading because of the Internet, that depends a lot on the professional's response to the patient, when the patient comes up and actually says something about it.

Kaiser Permanente has in place what they call "KP Online," which is moderated discussion boards of

Kaiser Permanente physicians with the patient. The patients can pose questions, they discuss among themselves, but it is moderated by KP physicians.

In some cases, the questions will be, "I tried to look for this information on the Internet and couldn't find it," and the physician answers with how to find it. So, it is a teaching tool on the part of the health network to educate their patient population, and I think that if you can encourage that kind of relationship, instead of having the physicians afraid of a patient-physician interaction online, if there can be some methodology for doing it similar to this, then, it would increase the bonding of the professional-patient relationship.

DR. BRESLER: I very much agree with you because sometimes patients will bring me printouts like this around an issue that they have researched, and I say, "Wow, this is great, can I borrow this, can I take a look at it?"

And what they will say to me is, you know, I showed it to three other doctors and they said I don't have time to look at that.

MS. DETWILER: So, it is a physician or professional, whatever the professional is, education process.

DR. BRESLER: I agree.

DR. GORDON: Thank you.

Joe.

DR. PIZZORNO: First, thank you all for your excellent presentations and particularly your written materials I find really interesting, particularly yours, Ms. Detwiler, very, very fascinating.

Something that seems to be emerging from several conversations, and recommended by David, was this idea of creating a web site in which we would have formal positions on issues by pros and cons and those in between, and allow consumers to look at them, have it all in one place, the pros and cons, make no decision, but also another piece that seems like it might be worthwhile is also to have on that site the consensus of a small group of experts who you might say are open-minded.

It may be a natural medicine practitioner who is science based, a medical doctor who is receptive to alternative medicine, a researcher, maybe a government policy person, and they would see if they could come up with some kind of consensus position.

Do you think something like that would help people get a better understanding of what is going on, allow them to make their own choices, but also give them some guidance?

MS. DETWILER: That depends. How are you going to tell the public it exists? It will all depend on whether they know it is there. MEDLINE is complete revelation to most people still, and it is available on virtually every health web site that is out there.

We can't do anything unless they know it is there.

DR. PIZZORNO: Add a pharmacist to that.

DR. MAINE: Oh, thank you very much. That wasn't what I was going to say, but that is a great idea.

When I was thinking about your question, I thought about the experience that now AHRQ had in attempting to develop evidence-based guidelines and treatment recommendations and whatnot.

While there is I think some real merit to the notion of having panels of experts render consensus opinion with pros and cons or however that gets developed, I think the experience of other agencies would tell you that that is really tough, really hard to do, and I am not sure under whose auspices it would be best and most accessible and credible to have something like that happen.

DR. GORDON: George Bernier, and then Joe.

DR. BERNIER: I have a question for Ms. Detwiler. Earlier this morning, the first panel discussed their use of web sites, indicated they felt very secure that with the system they were using, they were getting that information pretty rapidly into their web site.

Yet, you have given details of experiment that your group did, which would seem to belie that.

MS. DETWILER: George Bernier is referring to the timeliness of data study that I had done, which was when does the breaking news information actually become part of the reference materials on a site, and when the question was asked this morning, I was listening carefully to the answer, George, they all talked about how quickly they jump on news, but the general public, and I, myself, I am professional researcher, and until I did this study, I wasn't doing this.

We don't go and search the news archives when we do a search on a web site for the most part. It is either on the front page where it is news or we are looking in the reference databases, but there is this whole transitional time, and they didn't respond to that part of the equation.

Almost everybody jumps quickly on news items, but they don't necessarily make the transition of taking that news information and putting it into their reference materials on the same web site as quickly. In some cases, it takes up to a year for the data to get into the site.

DR. BERNIER: Would you have a way to correct that?

MS. DETWILER: Sure. There is actually a couple different things that have been tossed around. One is non-restrictive grants to the neutral informational sites, possibly from the pharmaceutical companies, possibly from the government.

A lot of the reasons why this information takes so long to be updated in the database is money. We all know about how the dot-coms are hurting for money, they are laying off people, they are going out of business, and so when they have the option of updating their databases on a monthly basis, a quarterly basis, semiannual, or annual, they are opting to do it on a less frequent basis because they are licensing this data from somebody else, and they have to pay for every reload.

If it cost them money to reload on a quarterly basis, it would cost them less money to reload on a semiannual basis, that is how they do it, whereas, if they had grants that said here is this money, you can only use it to maintain the drug database, we are not going to tell you what has to go into it, because that is mandated by the government. In the particular case, we were talking about my study was on FDA-approved drugs, but this would work for almost anything.

We are not going to say that you have to have this piece of information in there, otherwise, I am not going to give you they money, but if we are going to give you money that you can only use for maintaining the database uniformly, then, the information would be updated more frequently.

I was talking to the Special Libraries Association, Pharmaceutical and Health Technologies Division last week, and tossed that idea, and a couple of people were saying that it might be interesting to bring that up to the pharma companies. Perhaps it would work for the CAM companies.

DR. GORDON: Joe Fins.

DR. FINS: For Mr. Rainie. Do you have any information on the issue of social isolation and the overuse of the Internet as a sort of a therapeutic, and do we know anything specifically about health seekers, CAM seekers versus general users, and sort of the issue of like children not going out to play because they are on the Internet, and they get heavy, and, you know, the issue of just this kind of becoming a virtual life experience as a kind of an alternative to life itself?

MR. RAINIE: There is an enormous controversy raging around this that will not be settled probably in this generation. Our view of it is that in the case of most Internet users, their online activities are connecting activities, not isolating activities.

People love e-mail for the way that it enhances their existing relationships and allows them to extend their social networks. It is particularly true of veteran Internet users. They are the heaviest media consumers of all kinds.

The heavy Internet users are more likely to have read a newspaper than anyone else, more likely to have listened to a TV news program on a given day than anyone else.

So, our view is that there is not a significant amount of isolation going on. One of the new theories in the field that I know is being tested is that the Internet sort of enhances whatever is happening with you. If you are an extrovert, it makes you more extroverted; if you are in introvert, it perhaps makes you more introverted, although there is plenty of contradictory evidence on that, as well.

Children, we actually in this survey that I made reference to, children show what adults show in other contexts, they have a sort of I am okay, the rest of the world probably isn't okay phenomenon. They think that the Internet does good things for them, it enhances the relationships they have with other kids.

They love it for the schoolwork they do, they love it for the entertainment and leisure activities with them, but you ask them about their friends and other children, and they are pretty concerned that they are isolating themselves, they are spending too much time online, they don't go out with their friends, they don't interact with their families as much.

So, the jury is way out on this still, and for the most part, people, if you ask them, they love having these tools, they love having access to the information, as well as the communications piece of it.

DR. FINS: Just to focus on the CAM seekers --

MR. RAINIE: We didn't ask specifically about that, but you guys have inspired me to do that, and the other thing, all of these discussions insist that we do is to look at how users themselves establish the

credibility of information.

There are all sort of ways that we can think about to create credible information. The next piece of research that we are going to do is going to look at how people essentially decide what is true for them.

DR. GORDON: Thank you.

Tieraona.

DR. LOW DOG: That was all fascinating. We have been talking about pharmacists and also physicians and other types of groups and providing information. At least in my own experience, there is a reluctance on the part of many health care professionals to share information or make recommendations for using many of these products because of the lack of data that they consider to be credible, and the whole notion of drug interactions is almost impossible because as a family practice doctor, I mean my patients are taking 8 and 10 drugs and 30 different vitamins and supplements.

I mean at that point, it is so large that you could never predict any kind of drug interaction, and I think because of my midwifery background, I am very interested in teratogenic effects and safety in pregnancy.

I guess my question would be about information. Do you feel that there would be a role or place for recommendation -- and this would be consumer approach, as well -- to some sort of government body, whether it be NCAM or NIH, pooling their resources to take the top 20 herbs, which make up about 80 percent of sales, and to study them extensively for teratogenic effect, mutagenicity, genotoxicity, potential drug interactions, and make that available to health care providers, so that they might be feel more comfortable making that information available to their clients?

DR. MAINE: Unequivocally. I think so. I think that is actually the approach that Dr. Srinivasan would have described to you from a product quality and purity perspective that the USP has embarked upon. They use the same 20 number representing about 80 percent of product sales, and it certainly would be better than sort of the ad-hoc and anecdotal, and pull it together if you can and if you have the time.

So, for a recommendation to come, that there would be that kind of an analysis done by the right credible body with the right expertise, I think is very wise.

MR. HENDEL: I would agree totally. I think if you could bring some funding for the National Toxicology Program to look specifically at those top 20, and do an exhaustive analysis and provide that information as soon as possible, I think everyone would benefit from that.

DR. GORDON: I wanted to follow up on a related question particularly for Consumer Reports and CSPI, although I welcome your other input. What information -- you have particular interest in informing and protecting the public -- and what issues in this field do you feel we ought to be particularly concerned with in terms of providing information that you would see as important to the people with whom you are concerned, the general public?

MR. SCHARDT: Well, I think clearly safety, because these are optional treatments that people are considering. I think they want to make sure they are not going to create more problems than they solve, and so I think safety considerations are particularly important, but first do no harm, the first issue is let's make sure we are not hurting ourselves, and then let's see if it has some benefit.

DR. GORDON: George had a question, and then Tieraona again.

MR. DeVRIES: I am wondering if part of the issue out there is that there is different manufacturing practices on the basis of different manufacturers, and so even if you have research related to a particular product, it really is just as good as your manufacturer is, and that there is a need for the adoption of GMP standards or other good -- you know, standard manufacturing processes, and it is not just what is in the label, but how the process is done, so that we know that there is somewhat of an equivalency of product.

MR. SCHARDT: That is a good point because with herbal supplements, there are a lot of different extracts which have different efficacies, and therefore might have different safety profiles, so you would need to be very extract-specific when you are talking about the safety of a product, as well as how it is manufactured.

DR. GORDON: Tieraona.

DR. LOW DOG: We have encountered these problems -- since Srini is not here -- I would share the dietary supplements and botanicals information with USP, but, you know, it has been interesting because that still is going to be a volunteer program for industry to come in, so they have to buy into it as far as checking for pesticide and meeting label claims, and all of those things, and the FDA, everybody calls this an unregulated industry, it is regulated, but it is just not enforced at all.

So, I think most of us would feel comfortable, because Srini is not here to speak on behalf of this, but I think that is going to hopefully be a step forward to at least assuring that label claims are met, but if you don't want to participate in the program, you don't have to.

DR. GORDON: Ken, you wanted to give a praecipe of the FDA authority at this point?

DR. FISHER: My name is Ken Fisher. I am on the staff of the White House Commission. I am also the former executive director of the White House Commission on Dietary Supplement Labels.

Let me try to put it very briefly. DSHEA requires that the proof of adulteration or misbranding must be the evidence that FDA has to go to court. Therefore, they need the resources to get that evidence before they can go after a manufacturer who may or may not have a product that is not what it says on the label.

FDA does not have those resources because there are so many instances, as you have just heard from the last panel, where products either don't meet what is on the label claim or they do not have a standard for what should be in the product, such as a USP standard or, as Consumer Reports has shown over the last several years, that the active ingredients vary.

You also heard testimony at the last meeting and again at this meeting about products that did not have the appropriate amount of material in them. Unfortunately, they were talking about substances other than the active ingredients, so that really is another dimension to the issue.

So, DSHEA provides some authority, but the authority, it puts the burden of proof on the government, not on the manufacturer, and that was a major part of the law. If FDA had the resources, I am not sure that I would care to comment on how they should use those resources, but that is another issue.

Is that clear, Jim?

That is a particularly difficult question to answer because of the lack of data with drug interactions, it is a mess. You can just basically give people the information that you have so far, but it is very difficult for them to apply it because it is so complex and people are taking so many different medications.

I would point out that the Institute of Medicine is embarking on, as you may know, an analysis of developing a framework for the evaluation of dietary supplements for their safety, as well as efficacy, and they are going to do 7, they are starting with 7 pilot, so, hopefully, we will have some information coming out of that. But it is primarily safety.

DR. GORDON: Primarily, as you think about it, of dietary supplements or herbals or which categories of products or services?

MR. SCHARDT: Well, we deal with food and dietary supplements, so in the area of safety, we are talking principally dietary supplements and herbal supplements. The diets that are advocated are generally safe. So, it is dietary supplements.

DR. GORDON: Other thoughts? Chris Hendel.

MR. HENDEL: I would agree with David. Safety, I think is the primary concern that I know from our surveys of our readership, that is even above efficacy. They want to know, before I even take this, I really would like to know, first of all, what is in this along with the material that I am reading on the label.

As we know, a lot of products even in tests that we have done, if you take a product such as saw palmetto, where there is a modicum of good evidence, people want to buy a product, they want to know that the amount in that product that is stated on the label is going to conform to either the studies or at least what the product is saying it claims.

Some of our testing have shown that some of these products, which claim 320 milligrams or 106 milligrams a tablet, there is nowhere even close to that amount, and then we calculate the cost, it is $18.00 a day if you take all those tablets to get to that level, but safety is the primary concern that we have especially when you see more and more analyses turning up things such as pesticide residues, and a lot of these products are being used in families with young children, and they really need to be concerned about that.

DR. GORDON: Would you agree that the FDA has the authority to make sure that -- it seems to us that the FDA does have the authority now, although perhaps not the resources -- to make sure that what it says on the label is equivalent to what is in the bottle?

MR. HENDEL: I think the FDA deserves that authority. I don't think right now they have that authority.

DR. GORDON: You don't think so?

MR. SCHARDT: They do. That would be misbranding if they had -- but they don't have the resources or the will to do it.

DR. GORDON: That has been our impression, they have the authority, but not the resources.

MR. HENDEL: Yes, exactly.

DR. GORDON: Thank you, Ken.

Other questions or concerns?

[No response.]

DR. GORDON: I just wanted to ask you about good manufacturing practices. We were raising that issue. What are your thoughts about how those standards could be invoked from a federal level, from a private level, both collaboration?

DR. LOW DOG: The FDA is about to publish there for dietary supplements, so those will be what will be used, and they are supposed to be finished anytime.

DR. GORDON: What is the status of possibility of enforcement of that?

DR. LOW DOG: Well, once they are made available, then, dietary supplement manufacturers should be following GMP, and there is a number of groups and organizations right now that are trying to guarantee that people are using GMP, but right now to whose GMP? I mean that is the whole question.

So, we are waiting for FDA to finish their GMP recommendations, and then those will be the ones that USP will use for manufacturers that are trying to get a certification mark from USP for quality of products. USP will grant you a certification mark if you have passed your GMP inspection and your labels are accurate, you meet label claim, they are free of pesticide and heavy metal.

DR. GORDON: Yes, please.

MR. HENDEL: If I could add just one more thing to that, and we welcome GMPs definitely, and it would be nice to see those enforced, but for certification marks, once those start appearing, who is going to check to see if those certification marks are really legit?

We have seen some analyses of the USP certification mark for things like calcium supplements. Not all the products that have USP marks on calcium supplements meet the standard. So, there is a need for funds for somebody to be able to check the certification marks.

DR. GORDON: Who would you suggest that that somebody be?

MR. HENDEL: Oh, gosh, I would suspect that the FDA should have a role in that, or possibly the USP if that could happen. We could do it, but I think it would be such a huge, huge project.

MR. SCHARDT: There is some movement toward third party verification, NSF, which does water and water filters, has started a program, and Schuster Labs is also starting a program, both of them very reputable organizations that would provide independent certification, so there are non-government alternatives. I might also add that GMPs are finished, they are being held up at the Office of Management and Budget right how.

There shouldn't be much opposition or resistance from industry since industry has been begging for this, and it is based largely on the industry's input.

DR. GORDON: Do you have a thought about whether it should be government or private, and if so, which one and why?

MR. SCHARDT: I think FDA has this reputation of being anti-supplement and being slow to act. I think if private third party organizations are capable of doing a credible job, I think you could make a case for them being more accepted by the public and by industry.

DR. GORDON: Any other thoughts about that from any of the other panelists?

DR. MAINE: I think that just from a pharmacist perspective, I think probably in descending order - FDA, USP, and then somebody else, but pharmacists are going to probably have to be convinced. There will be a huge educational curve about the fact that GMPs exist now, and how they are certified, and that they are, in fact, certified, and I think personally I don't think it matters as long as the entity has the resources to do a credible job that back them up. Otherwise, it will be a wasted effort

DR. GORDON: Yes, please.

MS. DETWILER: I just want to echo that. Regardless of what this commission comes up with, regardless of any policies, if you make recommendations, please recommend that there not be any unfunded mandates.

DR. GORDON: Thank you.

Ming.

DR. TIAN: Regarding good manufacturer practice, if I understand, a lot of dietary supplements are not made by that standard. It is not like a pharmaceutical company. By law, it is allowed to do that. In the label, also it is not necessary to put that this is GMP standard.

I think most dietary supplements do not have that name. Do you have a recommendation you think they should have put something over there to make sure the consumer understand this is a high quality?

MR. SCHARDT: GMPs are a part of DSHEA, and it has taken FDA a long time to come up with the regulations. Industry has been waiting for this, and a lot of them want to put that on their label, but it hasn't been available. There have been private efforts to do the same thing, but I think clearly equality is an issue that consumers are very concerned about and want some type of assurance that they are getting what they are paying for.

So, I think within the next couple of years we are going to see a lot of different insignias and logos and things like that, supposedly certifying that these products are in compliance with GMPs or other standards.

DR. TIAN: I have a question. If the consumer wants to find out, see if this product is good or not, or has kind of Medical Watch, where should I send this bottle, to Consumer Reports or to FDA?

MR. HENDEL: You can send it to both. You are probably obliged to send it to FDA first, but --

DR. TIAN: That is called Medical Watch, right? If I have some side effect, I don't feel good if I take it, that is another program. I still want to do quality, does that contain any heavy metals or pesticide?

MR. HENDEL: If you were to send us a single product?

DR. TIAN: Uh-huh.

MR. HENDEL: It is costly to do the analysis.

DR. TIAN: How much do you want to charge for that?

[Laughter.]

DR. TIAN: But still the important thing it has to be available for customers. I think the customer is still in the dark, they don't know.

DR. MAINE: I am glad you brought this up because it really takes me back to my final comment about a workable surveillance model. I think that absent adequate resources for enforcement and then the culture of these products, which I think are very different for the consumer than other traditional medicines and therapies, I think that if we had an epidemiological surveillance system that would allow us to investigate, based on reports by the public and by health care practitioners, the incidence of various kinds of problems that may occur, then, I think that we would all be a lot more comfortable and a lot better served, and it may be, given the prospect of variability from product to product, and batch to batch, because of some of the very peculiar components of the physical nature of these products, I think that that is a direction that we really must insist on.

DR. GORDON: Don.

DR. WARREN: There is a group of manufacturers that are now into comments about the possibility of self-policing and self-funded policing. Would that be a better manner of policing this and then educating the public, would it be perceived as a self-serving commission, their own little group, the industry regulating itself?

DR. MAINE: I think there probably are self-regulating models that can work, and we would certainly support that particularly in the absence of defined legislative or regulatory mandates, but I think it depends upon policing for what and how you construct that system, and I think it is going to require always the participation of some credible third party albeit even if that third party is supported by the voluntary contributions of manufacturers.

DR. WARREN: Of all the manufacturers right now, there are only two that I know of that have volunteered to say yes, we will fund this process, and the rest of them just want to stay out of it.

DR. GORDON: Any other questions?

[No response.]

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

[Applause.[

DR. GORDON: We are going to take a 15-minute break. We will begin again promptly at ten of 3:00.

[Recess.]

DR. GORDON: This will be the final panel of the afternoon. After this panel, Commission workgroups will meet. One Commission workgroup will be in here, and who is going to be in here, is it you, Veronica?

The Plenary Room, George will be here with his group, Veronica will be in Congressional D, which is underneath the escalator. I want to say that all of you are welcome to sit in and observe what we do in those groups, so please feel free to do that, either stay here or go to Congressional D.

After the workgroups, the workgroups will be meeting 4:20 to 5:20, and then we will be back in here at 5:30 for a full Commission discussion.

Let's begin with this final panel. We will begin with Michelle Rusk from the Federal Trade Commission. Welcome.

CAM Marketing and Advertising

MS. RUSK: Thank you, Chairman Gordon and members of the Commission. I am happy to be here and have a chance to talk about the Federal Trade Commission and its role as it relates to marketing of CAM products and services.

The FTC is a law enforcement agency. Our mission is to ensure that consumers get accurate information about the safety and efficacy of CAM products and services, so that they can make informed decisions about their health care alternatives.

The agency does this by bringing actions against false and deceptive claims in the marketplace and also by trying to educate consumers, so that they are better able to spot and avoid fraud.

This afternoon I will outline FTC advertising law and briefly describe our enforcement and consumer education efforts, but before I do that, I would like to acknowledge up front that our efforts alone will never be adequate to make sure that consumers are able to make informed decisions.

There are still many examples of deception in the marketplace and consumers cannot rely with great confidence on advertising as a source of information about CAM products and services.

There are two basic tenets of FTC law. The first is that ads must be truthful, and not misleading. The second, objective claims, both expressed and implied, must be substantiated. The FTC standard for substantiation is intended to be flexible, but also rigorous - flexible to allow advertisers to discuss valid areas of emerging science, rigorous to ensure that the information is accurate and fairly presented.

We require competent and reliable scientific evidence to support any health related advertising claim including those in the CAM area. Our definition of that term is tests, analyses, research studies or other evidence based on the expertise of professionals in the relevant area that have been conducted and evaluated in an objective manner by persons qualified to do so using procedures generally accepted to yield accurate and reliable results.

There is no fixed formula for the number or type of studies that we require or for more specific

parameters like sample size and study duration. We do give great weight to the generally accepted methods of research in the relevant fields, and we attempt to consult with experts in a wide variety of disciplines when we are evaluating substantiation.

We also consider claims in light of all the available evidence including contrary evidence. Obviously, well-controlled human clinical studies are considered the most reliable form of substantiation. The FTC has, however, on occasion considered other forms of research as an acceptable substitute in specific situations.

On the other hand, anecdotal evidence like testimonials of individual consumers are not considered adequate substantiation, and will not be accepted as a substitute for scientific support.

In 1998, the FTC published a guidance piece which provides additional details and examples of our approach to substantiation specifically in the context of dietary supplements, and I have provided copies of that to the Commission.

A few quick examples of how the FTC has applied our standard in the CAM field, and I would like to emphasize that the focus of our cases is advertising. We have traditionally refrained from actions involving communications between providers and their patients about health care decisions. We do not address how health care professionals advise and treat individual patients.

Many of our CAM advertising cases involve Internet promotions. Consumers report turning to the Internet, as you heard earlier, in record numbers for health information and because of the rapid proliferation of deceptive marketing claims in that medium, the FTC has instituted an ongoing enforcement project called OperationCure.all.

In the fall of 1998, the FTC conducted a survey of the web in partnership with 80 organizations from 25 countries including FDA. What we found was an epidemic of health fraud, 400 sites making highly questionable claims about treatments and cures for cancer, arthritis, heart disease, AIDS, diabetes, and multiple sclerosis, often all six, 400 sites, and that was just in one afternoon of surfing.

As an example of our cure-all enforcement, the FTC has challenged two web sites claiming that therapeutic magnet devices would treat or cure cancer, liver disease, arthritis, high blood pressure, and many other conditions.

We have also brought an action against a site promoting essiac tea, a blend of herbal ingredients. The site claimed that essiac tea was scientifically proven to cure cancer, diabetes, AIDS, and feline leukemia among other things.

The FTC has also challenged sites promoting shark cartilage, again as a clinically proven treatment and cure for cancer. Cites to the cases are in my written statement.

Our consent orders in each case prohibit the companies from making claims about the safety and efficacy of these treatments until they have developed competent and reliable scientific evidence to back the claims.

In our essiac tea case, we also required the company to send notices to past purchasers advising them that essiac tea had not been demonstrated to be an effective remedy in fighting cancer or any other disease. In some cases, we have also obtained monetary relief in our case against Lang Labs for its

marketing of benefin shark cartilage as one example. The company was required to pay $1 million for consumer refunds and disgorgement of profits.

In that case, to ensure that the judgment did not interfere with ongoing research, however, the agency took the somewhat unusual step of allowing the company to use up to 450,000 of that judgment toward providing product and placebo for an ongoing study with the National Cancer Institute.

Our enforcement efforts in the CAM area are not limited to the Internet. In a 1999 case involving the American College for Advancement in Medicine, ACAM, the FTC challenged the promotion of chelation therapy as an effective and proven treatment for atherosclerosis.

As you may have seen, new research was reported out last week, again failing to provide evidence that the therapy benefits with those with heart disease, although the same report suggested that millions of dollars are still being spent every year by consumers on this therapy.

As I mentioned, the ACAM case, like our other actions, covered claims made in brochures and other marketing materials distributed to the public. It did not attempt to regulate how doctors use or prescribe any drug or therapy in the course of treating individual patients.

Our continuing monitoring of the Internet and other advertising media reveals that there are still many instances where sick and vulnerable consumers are being misled about the efficacy and safety of alternative health care products and services.

For this reason, the FTC is engaged in a variety of consumer education activities. Our brochures, titled, "Virtual Treatments" and "Fraudulent Health Claims" are two examples. They provide tips on spotting fraudulent promotions. They are available in print and on our web site.

They also set out information and resources relating to specific diseases that are the common subject of health scams, and finally, they direct consumers to objective and reliable sources of health information on the Internet, specifically, the NCAM site, MEDLINE, and several other centers and databases of NIH and other government agencies.

Another effort in the consumer education area, we have also posted teaser sites on the web, and these sites promote fictitious products like Arthriticure and Virility Plus. They mimic commercial web sites using some of the same hype borrowed from our cases except that when a consumer attempts to purchase the product or service, instead of getting ordering information, they are warned that they could have been scammed and then given tips on how to spot suspect claims.

The goal of this technique is to catch consumers when they are at their most vulnerable as they surf the web, and one of our teaser sites has received 12,000 hits so far.

The FTC shares this commission's stated goal, that is, to foster the dissemination of reliable information on complementary and alternative medicine. Better dissemination of balanced information is critically needed.

The Internet, I think can be a valuable tool in helping consumers sift through all the hype, and we have heard some suggestions this afternoon, but some of the ones that occurred to me were third party review of CAM-related web sites, also Internet portals to reliable CAM sites akin to the healthfinder.gov portal, and also quality certification or seal programs, I think are yet another option.

Thank you.

DR. GORDON: Christine Lewis, please.

DR. LEWIS: Thank you, Mr. Chairman. I am Christine Lewis, and I am the director of our Center for Food Safety's Office of Nutritional Products, Labeling, and Dietary Supplements, and it is the dietary supplement component that I believe brings me here to the CAM meeting.

As I did let you know, or at least my staff let you know, I would not be offering written testimony at this time, but would be glad to just provide a quick overview to some of your interests and then take questions as needed. There are always questions for FDA in dietary supplements, so I have allowed a lot of time for that.

The question about our oversight authority and purpose, of course, our intent is to fully implement the 1994 Dietary Supplement Health and Education Act, which has as its starting point that dietary supplements are safe. The provisions under that Act are that prior to 1994, those products used as dietary supplements are assumed to be safe, but there are provisions for new dietary supplements entering the market, and that they are required to give FDA a 75-day notice prior to entering the market, and we have basically a thumbs-up or a thumbs-down chance relative to the safety information provided by the manufacturer.

We have in effect also a provision for health claims, which is separate from the Dietary Supplement Health and Education Act, and if you are interested in that particular component, we can, of course, address questions, but the interesting aspect of the Dietary Supplement Health and Education Act are the so-called structure function claims.

They are required to give us a notice 30 days after marketing such a claim, and to date, most of our interaction with the makers of these claims has focused on whether they are in fact making a structure function claim, that is, affecting the structure of function of the body as opposed to what oftentimes becomes a disease, a treat, prevent, cure, mitigate claim, which, of course, makes them subject to regulation as a drug.

The expectation in the case of substantiating structure function claims is that that is the role of the manufacturer, and the law states that they are expected to have substantiation in their possession for the basis for their claim.

Structure function claims by nature are somewhat broad and therefore substantiation for this remains somewhat unknown, at least as far as the agency providing guidance, and that is often a question we get is our intent and our need to provide guidance for substantiation of these claims.

There are a number of activities we have recently undertaken relative to implementing the Dietary Supplement Health and Education Act, and I will mention several of these briefly, and then again, as I mentioned, stop and at the point at which you are willing to have questions, I will be glad to entertain them.

One is our provisions for adverse events. Again, the Dietary Supplement Health and Education Act makes it clear that it is the agency's role to remove unsafe products from the market. However, the burden of proof is on the agency to prove that the product is unsafe, and one of the tools we have at our

disposal are the so-called adverse event reporting system.

This, however, is a voluntary system. Physicians and manufacturers, neither one are required to report to us, so it is a fairly passive surveillance system, but can be useful in signaling and identifying problems in the dietary supplement area.

This is a system that needs considerable resources and updating, and that is one of our top priorities.

Secondarily, we are about to implement a dietary supplement research plan. Our program priorities for this year are to identify research areas in the dietary supplement world, so that we can go ahead and enter into cooperative agreements and other liaison activities.

Currently, we also have a two-year contract with the National Academy of Sciences, specifically, their Institute of Medicine. It is a two-year contract to develop a regulatory framework for dietary supplements in the safety area, followed by a one-year component of that contract to develop six prototype monographs relative to dietary supplement safety.

Finally, when I entered the room, I was aware of the fact that dietary supplement GMP proposal, good manufacturing proposal, was of interest. I wish I had more specific information as to its procedural events. It is probably the least kept secret that the proposal did leave the agency, but never cleared OMB prior to January 21st.

At this point, as you can well imagine, there are a number of issues in front of the Office of Management and Budget, as well as the Department, and certainly consideration of the procedural steps for the GMP falls into that domain.

At this time, I don't have any information as to how fast or how slow it might wind its way through the system.

I will stop there and take the extra time if you don't mind for answering questions at the end.

DR. GORDON: Great. Thank you very much.

Sarah Taylor.

MS. TAYLOR: Thank you. I am Sarah Taylor and I am a practicing attorney with the law firm of Covington & Burling here in Washington. It is a privilege for me to address this commission today, and I thank you for the opportunity to discuss the key issues which I believe must be considered for our policies on the advertising and marketing of CAM products to serve the public interest as we confront the continuing advances in biomedical science and communications technology which challenge our current regulatory philosophy.

My views are shaped largely by my experience as an attorney in private practice, specializing in food and drug law, advertising law, and First Amendment law for the past 12 years.

A substantial part of my law practice is devoted to advising product manufacturers on the legal requirements governing the marketing of foods and dietary supplements for which health-related claims are a central marketing focus.

While I have worked with a wide range of companies and types of marketing programs, from small startup companies marketing a single product to multifaceted national marketing programs sponsored by industry groups, it goes without saying that my experience has been with those companies who have taken the responsible step of retaining legal counsel, to seek advice to ensure their marketing activities conform with legal requirements.

Much can be said about the complexities of the legal requirements imposed under the Food, Drug, and Cosmetic Act, Federal Trade Commission Act, and the overlapping consumer protection statutes in the 50 states. It is important, however, that we not lose sight of the bottom line.

Current law requires that CAM products be safe under the conditions of use, and all claims must be accurate and fully substantiated based on scientific evidence providing a reasonable basis for the specific claims that are being made.

This "tell the truth" standard is the minimum standard required by current law, and it applies uniformly to advertising and marketing materials for CAM products.

To ensure claims comply with current antideception and substantiation standards, substantial resources and technical sophistication can be required. Smaller companies, in particular, may lack the knowledge and resources necessary to ensure full compliance before entering the market.

It is important to recognize that the presence of unsubstantiated and inaccurate claims in the market is symptomatic of the weakness in our system for enforcing current law and not in the standards applied to the claims themselves.

Responsible companies striving to conform with legal requirements are frustrated when competitors expand their market share through unfounded claims. Expanding our vision on enforcement and compliance policy to more fully engage the industry in self-regulatory activity could substantially enhance consumer protection.

While the government has broad authority to adopt regulations to protect public health and safety, its power to restrict "free speech" to advance its objectives is confined by the First Amendment.

Stated succinctly, while claims that are false or propose an unlawful transaction can be banned outright, the government otherwise cannot regulate the content of commercial speech, unless it can establish from evidence that the restriction would directly alleviate a genuine harm, and the restriction is reasonably tailored to address the harm and does not overlook obvious, less burdensome alternatives.

The First Amendment presumption favoring the free flow of commercial speech encompasses health claims, as recognized in the landmark decision Pearson v. Shalala. Health claims are constitutionally protected even when the scientific validity of the potential benefit identified has not been fully established scientifically. It is sufficient that the claim be stated to communicate accurately the weight of scientific evidence that, in fact, supports the claim.

This reflects a basic constitutional principle of our democracy which protects the freedom of citizens to have access to information to make their own choices, including in matters concerning their health. This founding principle harmonizes with the philosophy embraced in the disciplines of complementary and alternative medicine and consumer "self-care."

As the Supreme Court said, "Our First Amendment assumes that information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. But choice among alternative approaches is not ours to make or the government's. It is precisely this kind of choice, between the dangers of suppressing information and the dangers of its misuse if it is freely available, that the First Amendment makes for us."

Under the Food, Drug, and Cosmetic Act, the regulatory requirements concerning CAM products are dictated by the classification of the product as a food, dietary supplement, or drug. In determining the classification applied, FDA looks to health information disseminated in advertising to determine the intended use of a product.

For example, under the current FDA policy on structure function claims, a dietary supplement product promoted using the advertising claim "helps lower cholesterol levels" would be classified as a drug subject to NDA requirements.

The same dietary supplement product advertised instead with the claim "helps maintain normal cholesterol levels" would be classified as a food. This dramatic change in regulatory treatment could depend on nothing more than the change of the wording "helps lower" to "helps maintain normal cholesterol levels."

For a dietary supplement product, drug status usually presents an impossible barrier to market entry. The policies which have developed around the Food and Drug Act "drug" definition have become the most significant obstacle to manufacturers attempting to include health information in their marketing materials.

As a technical matter, FDA approval of health claims on a case-by-case basis is an alternative to NDA approval in such cases. The significant scientific agreement standard limiting health claim approval was found to violate the First Amendment in the Pearson case, and the approved health claims written by government regulators typically have limited real marketing value, such that claims seem premised on the idea that scientific precision in the statement of a claim is the way to communicate with consumers.

This concept is at odds with the communication principles which drives successful marketing programs.

The severe chilling effect the "drug" definition has on the contents of advertising, Internet, and other promotional matter may be best appreciated by considering basic marketing principles. Fundamentally, for a marketing program to be successful, it must be effective in motivating consumers to purchase the product being promoted.

This means that the content of a promotional message must be compelling to real consumers in the target population groups, and these factors may differ with different population segments even for the same product and the same product benefit.

In all cases, to be effective, marketers must have the flexibility to respond to shifting market dynamics, and to frame and reframe claims to keep them fresh and meaningful to real consumers.

I want to stress here that manufacturers do have a responsibility to ensure that their products are safe and that it is not lawful to go forward in marketing an unsafe product, and in many cases, potential safety concerns do not focus on the formulation, but may concern the conditions of use.

In such cases, potential safety concerns can be resolved through disclosure of information and warnings in promotional material. I would just point out that the kinds of issues that are presented here are not unfamiliar. They are the kinds of issues that come up in the ordinary course when we look at decisions concerning, for example, the switch of a prescription drug to an OTC status. How do we decide which sorts of information needs to be provided to the consumer and whether a product is appropriate for over-the-counter use?

In view of the challenges presented by the advertising and marketing of CAM products, future policy development is merited in the following key areas:

First, expand incentives for industry self-regulation and enforcement of existing antideception and substantiation requirements for promotional claims.

Second, eliminate policies restricting the dissemination of accurate, substantiated health information and claims in conformance with the First Amendment requirements.

Third, ensure that restrictions on the content of promotional messages be established by the government to directly alleviate a genuine harm to consumers, such as to prevent deceptive claims or to disclose information necessary for safe product use.

Thank you very much, and I am pleased to respond to any questions.

DR. GORDON: Thank you.

William Soller.

MR. SOLLER: Thank you, Mr. Chairman, members of the Commission, good afternoon.

I am Dr. Bill Soller, Senior Vice President and Director of Science and Technology for the Consumer Healthcare Products Association, the 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.

I addressed the Commission at its March 16th Minnesota town meeting where I commented on the need for the Commission to support actively the appropriate funding of the Food and Drug Administration to implement its long-range plan for dietary supplements, and I repeat that plea today, nothing that last week at a hearing of the House Committee on Government Reform, Mr. Joe Levitt, director of the FDA Center for Food Safety and Applied Nutrition, indicated CFSAN needs appropriations of $6 million per year, starting with $3 million, scaling up in the second year to about $4.5 million, and reaching full funding in year three.

If CAM practitioners are concerned with quality and labeling issues affecting dietary supplements, then fiscal support to develop reasonable standardization that appropriately implements the statutory provisions of DSHEA is vital to their interests, as well as those of consumers, patients, and, indeed, the industry. I would point out that if you want to have an impact in this particular area for fiscal 2002, you will have to have input to the Administration and Congress, probably by no later than late April for the appropriations process.

I thank you for the invitation to allow me to return to the Commission to address questions that were sent to me in an e-mail prior to this meeting. Before I get into those questions, I would like to just give the backdrop of Congress' intent in enacting DSHEA. Specifically, Congress wanted to facilitate providing consumers with products, information and education that would help promote health and prevent disease through maintenance of healthy aspects of the structure and function of their bodies.

In fact, Congress notes in the "findings" section of the Act, that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." Clearly, adequate truthful information transfer is vital to meeting the intent of DSHEA.

In addition, while my comments focus on dietary supplements, I think they have applicability across other CAM product areas.

The first question: Are current regulations adequate to assure consumer access and assure consumer safety?

The answer is yes, in relation to dietary supplements, both the FDA and the Federal Trade Commission are on record stating they have the tools and the intention to regulate such products.

I placed two quotes in there, both from ex-Commissioner Jane Henney, as well as Jodie Bernstein, Director of the FTC Bureau of Consumer Protection, that basically comment that FDA has the tools and that FTC has the will to maintain enforcement in key areas here.

The Food and Drug Administration and FTC work together under a long-standing agreement governing the division of responsibilities. As applied to dietary supplements, FDA has the primary responsibility on labeling, FTC on advertising, and I list, on page 3 of my comments, the areas of substantial enforcement authority that FDA and FTC have in this area, and I will highlight only several of those.

FDA can stop any company from selling a dietary supplement that is toxic or unsanitary or that poses a significant unreasonable risk of illness or injury, and can stop the sale of a dietary supplement that has false or unsubstantiated claims or make any claim that the product cures or treats a disease.

FTC can enforce laws outlawing unfair or deceptive acts or practices and false advertisements to ensure consumers get accurate information about dietary supplements, so they can make informed decisions about these products, and FTC can challenge and stop advertising that is not adequately substantiated, as well as investigate complaints or questionable trade practices among other authorities.

Given that both FDA and FTC have the tools they need to ensure dietary supplements are safe, effective, high quality, and properly labeled and promoted, it is important for the Commission to consider support of the general position that both agencies should be adequately funded to ensure that DSHEA is appropriately implemented, consistent with Congress' intent in passing the statute.

The second question: What are the barriers to consumers getting the information they need?

I list both barriers as well as facilitators -- I think that is useful in the exercise -- on page 4 of my comments, and I will only highlight four barriers for your consideration.

Rogue manufacturers making unsubstantiated claims, lack of a defined label warning policy within

CFSAN, too many information sources, and no clear/central information authority, and educationally unprepared consumers, patients, and conventional healthcare practitioners.

The next question: What is the company responsibility in providing information to the consumer?

By law, companies must ensure that their labeling and advertising is both truthful and not misleading, and we believe claims made by CAM practitioners about CAM products, especially dietary supplements, should be held to the same standard.

Is the information provided to consumers accurate, adequate, and useful?

Given that consumer- and patient-related labeling, advertising, and promotion must be by law both truthful and not misleading, the question is better re-framed in two parts:

Is enforcement adequate to ensure the information provided to consumers is accurate, adequate, and useful?

Since both FDA and FTC acknowledge that they have the statutory tools needed to implement the labeling and promotional provisions of the Food, Drug, and Cosmetic Act and the Federal Trade Commission Act, do FDA and FTC have the fiscal resources needed for adequately fulfilling their statute-derived enforcement functions, consistent with existing law?

Furthermore, in this regard, CAM practitioners may distribute CAM-related products, including dietary supplements, and it is therefore important that they be cognizant of the regulations and policies promulgated by FDA and FTC. I note some examples of regulations that FDA has elaborated, but I would like to focus on the FTC guideline to industry, "Dietary Supplements: An Advertising Guide for Industry."

FTC notes in this policy guide, for example, that supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles.

The FTC has taken action not just against dietary supplement manufacturers but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions.

Therefore, FTC appropriately cautions that all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.

This particular Advertising Guide has been supported by our Association. Our members, many of whom also market medicinal products under the policies set forth in the guidance, recognize the value of this guide in helping to inform companies of FTC policies.

Companies complying with the law implementing regulations provide consumers with accurate and useful information on dietary supplements. Enforcement by FDA and FTC is intended to create a sufficiently broad environment of truthful and not misleading information on consumer and professional products.

Consequently, the issues, whether FDA and FTC have sufficient resources to fulfill their enforcement

duties in this area, and whether CAM practitioners are sufficiently aware of their responsibilities in the context of promoting, for example, dietary supplements, are both very important.

On recommendations to the Commission:

1. We believe that the Commission should provide a strong recommendation to the Administration to support adequate funding of CFSAN to implement its long-range plan to regulate dietary supplements, consistent with DSHEA.

Funding of reasonable, appropriately-targeted regulatory activities by CFSAN would help address a significant barrier to consumers getting accurate, adequate and useful information, that is, address the practices of rogue manufacturers who ignore the statutory and regulatory framework of DSHEA.

2. The Commission should encourage FTC to develop industry and practitioner guides in the CAM product arena as was developed for dietary supplements. It was important for our segment of the industry.

3. The Commission should support a consistent standard for advertising and promotion of all CAM products, as explained in part herein for dietary supplements.

Thank you.

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

Mark Land.

MR. LAND: Good afternoon, ladies and gentlemen. My name is Mark Land, and I currently hold the position of technical manager at Boiron USA's headquarters in Newtown Square, Pennsylvania.

I would like to thank the Commission and commissioners and the organizers for the invitation and opportunity to address you today. We, at Boiron, have followed your work with interest and look forward to contributing to the goals of the Commission.

I must say that while preparing for this meeting, I had a glimpse of the magnitude and the complexity of the project before you and would like to wish you the best in your work.

It is from the perspective of a homeopathic drug manufacturer that I have prepared my presentation today.

A brief word about Boiron. Our mission is to give every physician and health care professional the world over the opportunity to learn about homeopathic medicines and to use them in their daily practice. Boiron is headquartered in France and here in the United States we have two facilities, one near Philadelphia and one near Los Angeles.

We are present in 61 countries around the world and employ about 2,500 people. Our worldwide annual sales are approximately $250 million. We understand the term CAM as transitional and necessary terminology since we believe in one medicine that incorporates the different therapeutic tools allowing the physician to develop a complete therapeutic strategy considering the diagnosis and prognosis of each patient.

A brief history of homeopathy. Homeopathy was developed more than 200 years ago by Samuel Hahnemann, a German physician. Homeopathy then developed throughout Europe and has been practiced in the United States for over 175 years.

As early as 1834, many states established homeopathic medical societies. The first pharmacopeia was published in 1841. There are currently numerous homeopathic medical boards, state medical societies, professional societies, and medical journals in the United States.

It is estimated that $230 million worth of homeopathic medicines are currently sold in the United States each year and that 10 million Americans use homeopathic medicines. The worldwide scales of homeopathic medicines are about $1.5 billion. This is less than 1 percent of the total worldwide pharmaceutical sales.

Today, in the United States, the majority of retail outlets, including pharmacy, grocery, and mass market stores, stock at least one homeopathic product. Health food stores represent the largest channel of distribution for homeopathic products in the United States.

Homeopathy is unique within the category of complementary and alternative medicine in that manufacturers are required to comply with strict drug labeling and manufacturing regulations. Homeopathic products are officially classified as drugs in the United States as in almost every country around the world. Homeopathic manufacturing is required to comply with drug GMPs or good manufacturing practices.

In 1988, in cooperation with the homeopathic industry, FDA issued a Compliance Policy Guide that set forth the agency's regulatory approach toward homeopathic medicines. The homeopathic Compliance Policy Guide states that the Food, Drug, and Cosmetic Act recognizes as official the drugs and standards in the Homeopathic Pharmacopeia of the United States.

Under the Compliance Policy Guide, homeopathic medicines are subject to a broad array of quality standards, much like other drugs. Homeopathic manufacturers must follow stringent good manufacturing practices and are subject to routine FDA inspections.

Homeopathic medicines are also subject to the same type of extensive labeling and promotional restrictions applicable to all other drug products marketed in the United States. In addition, homeopathic drug manufacturers are subject to the standards imposed by the Homeopathic Pharmacopeia of the United States.

Homeopathic products are required to bear adequate directions for use, as well as indications. They are required to make claims with respect to the condition that a product proposes to treat. All claims must be substantiated with the literature.

As a 200-year-old medical discipline, homeopathy is rich in reported treatment and research. The experience has provided us with a large, extensive bibliography of clinical and empirical information regarding how to optimize the benefits of these medicines. It is important to note that this collection of information is multicultural and there is a history of homeopathy in many countries around the world.

Homeopathic medicines have an overall excellent safety profile owing to their lack of toxicity. They are well suited for treatment of self-limiting conditions amenable to diagnosis by consumers, and because of

their lack of toxicity, they are not contraindicated in patients taking other medications. The majority of these medicines are sold in the United States as in many other countries around the world without prescription.

More than 100 clinical trials have yielded positive results including research centering on effectiveness in treating allergy, asthma, acute diarrhea, and withdrawal from minor tranquilizers. Three meta-analyses have demonstrated homeopathic medicines' efficacy over placebo.

The most recent, published in the September 1997 issue of the journal Lancet, is based on 89 clinical trials. The authors concluded that, "The findings of our meta-analysis are not compatible with the hypothesis that clinical effects of homeopathy are completely due to placebo."

Regarding advertising and marketing information of homeopathic medicines, we recognize six categories of information: product labeling, promotional literature, continuing education programs, drug information centers, Internet, and public relations.

At Boiron, we feel strongly that it is our responsibility as manufacturers and marketers to provide accurate and reliable information regarding the use and administration of our products. Guidelines for labeling, content and format are quite clear.

As a 200-year-old medical discipline, homeopathy is rich in treatment regimens. This information is compiled in text known as materia medicas. It is these documents that are the first step in the development of label indications for homeopathic drugs.

Claims for homeopathic drugs are generally supported by a long history of safe and documented use. Proposed new homeopathic drugs undergo a rigorous review by the Homeopathic Pharmacopeia of the United States prior to marketing.

Internally, Boiron exercises a careful review of label content and format by medical, pharmaceutical, and legal experts prior to distribution.

Promotional literature is designed to visually acquaint the retailer, health care professional, and consumer with product benefits. We are not making claims in advertising other than what is stated on product labels.

Boiron Institute is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education, and articles are developed and written within the guidelines of the ACPE. Professional texts and programs are written to further the knowledge of practitioners in the use of homeopathic medicines, usually delivered in partnership with continuing medical education providers.

Drug information center personnel are instructed to provide information to consumers that is consistent with product labeling. Our web site provides information to consumers, as well as to health care professionals, on many topics relevant to homeopathy and Boiron.

Product information is limited to label claims, warnings, and dosage recommendation. In public relations, Boiron seeks to supply accurate information consistent with product labeling and a fair and balanced interpretation of clinical results.

Barriers to further development to homeopathy in the United States include research. While the 200-year

history of homeopathy is rich in clinical information, we believe that the public could benefit from even a greater insight into the clinical application of mechanisms of action of homeopathic medicines.

The size of the homeopathic industry, particularly in the United States, limits the potential for research. We would like to see more funds allocated towards this research in order to contribute to a better health care system.

Within the environment, despite some positive clinical results, a not so constructive skepticism still prevails within the medical and scientific community. We see this as a barrier to a more open attitude towards research and integration of homeopathic medicines.

Within the regulatory environment, we do not recognize a need at this time for any new regulations regarding homeopathic medicines.

This concludes my prepared remarks for today. Again, I would like to thank the Commission.

DR. GORDON: Thank you very much. Thank you all on the panel.

Questions for the panelists? George, Joe, Ming.

Discussion

MR. DeVRIES: I would like to thank the panel for your testimony this afternoon. Your description of the problems, as well as some of the positive things that are happening, is much appreciated.

In terms of Michelle Rusk, the FTC, you have described some of the enforcement actions that FTC has taken. You have also described some of the unique educational initiatives that FTC has taken for consumers.

In terms of the White House Commission making recommendations to Congress, what would you recommend to this commission beyond what you have described today, what could this commission do to help ensure safety of consumers, as well as better, higher quality information that they have access to?

MS. RUSK: I kind of rushed through the end of my prepared comments, but I do think, despite the problems associated with information that is out there on the Internet, it is really one of your best tools for reaching consumers and getting them reliable information.

I agree with the comment that was made on the last panel, that I think it is a really formidable task to sort through the science on every single product and service that is out there and come up with some kind of definitive answer, but I do think that you can help consumers sort through what is already available on the Internet and give them some direction and some guidance on where the reliable sources of information are.

MR. DeVRIES: And how would you see that happening?

MS. RUSK: Well, I am trying to think of examples. You might want to consider looking at what HHS has done, and I guess to some extent that does provide a portal for CAM information, but their healthfinder.gov site is intended to direct consumers to reliable sources of information.

I think there are other examples. I think Tufts maybe still has a site where they actually rate other web sites that provide nutrition information.

DR. GORDON: Could you explain that?

MS. RUSK: I think it's Tufts University. Maybe somebody else knows more about it than I do, but that they rate other sites that provide nutrition information, so you get a certain number of stars, and they tell you a little bit about who is the sponsor of the site, that kind of thing.

MR. DeVRIES: Thank you.

DR. GORDON: Joe Pizzorno.

DR. PIZZORNO: A question for Christine Lewis and Michelle Rusk. First, Christine Lewis, I think we are hearing today, and I want to make sure that we are clear about this, that the FDA does have adequate authority for regulating dietary supplements or dietary health products, but does not have the resources to do that adequately.

The second question is: What are the triggers that you use to determine when a product is unsafe and needs to be pulled off the market?

DR. LEWIS: We have for quite some time been documenting our resource lack, and we have published not only the dietary supplement strategic plan, but in response to a congressional request, we are completing a report on the cost of implementing the plan.

So, the theme we have sounded is that we could do a great deal more towards implementing DSHEA if we did, in fact, have resources. Again, it is a postmarketing attempt largely, and that does shift the burden of proof considerably to the agency, and resources are needed not only in terms of dollars, I might add parenthetically, in terms of liaisoning and cooperating with others, which is the theme we have also sounded.

DR. GORDON: Liaison with whom?

DR. LEWIS: With other groups. For instance, certainly with the National Institutes of Health and even with industry, contracts with universities for analytical methods. When we take a look at our enforcement options, lots of times analytical methods are entirely critical for being able to establish an enforcement action, and while there are analytical methods for some of these ingredients in their raw and natural state, once you mix them into a dietary supplement product we are facing a number of simply analytical questions, never mind efficacy, simply can we find the ingredient and establish its presence, so that type of effort certainly we need.

In addition, simply to people being able to review claims, review safety, follow up on adverse events, it is a staffing problem primarily.

Your second question was?

DR. PIZZORNO: What are the triggers that you use to determine if a product is unsafe?

DR. LEWIS: Well, at this point in time, we deal with the standard of significant or unreasonable risk,

and I think, as we have implemented it, and we still are evolving it in the sense of what does it mean to have significant or unreasonable risk, there are two kinds of triggers basically.

The adverse event reporting system is one source of signals that there is a problem, however, because it is a passive or a voluntary system, it is not entirely reliable, in fact, it is in some ways likely to miss a number of important events.

We would like to work on getting that to be a much better and responsive system. We therefore rely heavily on scientific literature and scientific reviews, which, as you can imagine, is resource intensive, and quite frankly, we are lacking a lot of research and simply being able to be in a position to foster research in other places that would support scientific reviews.

I might add just parenthetically that with this limited resource issue facing us, we have had to prioritize or triage our efforts, and from our public health perspective, taking a look at safety has been our primary purpose. We understand there are misleading claims, and we resonate with the problems that causes, but if the resource comes down to providing for safety or preventing fraud, given limited resources, we have erred on the side of safety.

DR. PIZZORNO: Let me rephrase the question a little bit because I think you told us how you hear about it, but I would like to know what are the kinds of events with consumers that cause you to take particular notice. I mean does somebody have to die, do you have to end up in an emergency room, what are the kind of things that make you feel something serious is going on.

DR. LEWIS: Well, significant or unreasonable risk would certainly encompass the things you have articulated. A good example might be aristolochic acid for which we have now issued an import alert and we are active in other areas. It causes kidney damage. So, those types of adverse events, certainly when you look at the world of food and dietary supplements, being nauseated is an adverse event, but it is down on one end of the continuum versus stroke, liver damage, heart conditions.

We had a digitalis plantain mix-up a while ago in the dietary supplement industry, and that was a life-threatening - and certainly death. I mean there is no doubt that that is the other end of the continuum.

DR. PIZZORNO: One quick question. You mentioned you found 440, I think, web sites that were presenting fraudulent information, but you only actually prosecuted two of them. How did you decide which ones you are going to go after?

MS. RUSK: Well, the 400 sites that we found, obviously, we made a judgment that the claims were suspect because they were so extreme and often the products claimed to cure or treat 20 or 30 serious diseases, but we didn't actually have the luxury of going and evaluating the science behind every one of those claims, so what we did was we sent out e-mail warnings to all of those sites saying that the government had been to their site and visited, and these are the standards that apply to advertising claims, and we think that the web site operator would be well advised to review their claims in light of the legal requirements.

Going back at some point later, we found that about 20 percent had either taken down their site or dropped the claims that concerned us. That doesn't sound like a great return, but it is a much better response than we can get by going case by case, which is a very, very resource intensive proposition.

I was just giving examples of the cases we brought on the Internet. I think there are probably 10 cases

now that have come out of Cure.all, but obviously, that is a very, very small number.

DR. PIZZORNO: Thank you. That gives more information. So you decide based on how serious the damage could happen to the public?

MS. RUSK: Oh, how do we decide? Our priorities have been pretty much what Chris enumerated, first, safety, is there a safety concern; second, are the promotions about serious diseases, because that obviously is going to increase the risk of consumer injury if the treatments aren't effective; third, I guess would be areas where we know with some confidence that there really is no supporting evidence.

DR. GORDON: Ming.

DR. TIAN: The question for both doctors from FTC and FDA. I understand according to the regulation, the food supplement, you can't claim that it treats any disease. The advertising, the Internet, for instance, like glucosamine and the chondroitin sulfate, they are dietary supplement. According to JAMA, just published a paper, 14 studies evaluated, so between 12 percent to 55 percent are effective.

As a manufacturer, as a company, if they want to sell their product, can they put that as scientific information together, because that is a study already done, and the clinical trial, and to treat arthritis knee. Is that regulation allowed or not?

DR. LEWIS: Under the Food, Drug, and Cosmetic Act, to make a claim about curing, preventing, or mitigating a disease, which I believe is what you are talking about, it does make you a drug, and therefore, you fall under the drug provisions. There is no reason why the manufacturer of such a product, if they believe they have the scientific evidence to support a drug application, is free to do so.

DR. TIAN: So, they can put together at the same time?

DR. LEWIS: Absolutely, uh-huh.

DR. TIAN: What about the patients' report, like a case report?

DR. LEWIS: Again, you are talking about what is necessary for a drug approval, and I am with the different part of FDA.

DR. TIAN: Sorry. I am talking about the food supplement.

DR. LEWIS: For food supplement, you could not claim to cure, prevent, or treat, or mitigate a disease. As far as the substantiation of a claim on a supplement, if it were to be a health claim, which would be reduce the risk of a disease, can come in under the standard provisions of the Nutrition, Labeling, and Education Act for an authorized health claim.

If you are interested in making a structure function claim, the substantiation is under the purview of the manufacturer, and the DSHEA provisions are that the manufacturer must possess that information, but it need not be shown or reviewed by FDA.

DR. TIAN: I see. Thank you.

This morning, there was a question regarding FDA - do you believe you have enough experts to make a

decision or do a study on those food supplements? Do you have any recommendation what should be done by government?

DR. LEWIS: Well, we certainly have experts, and we have good scientists. The issue is that we don't have enough of them. Consequently, our capacity to both review and enforce is limited. This goes back to our request for more congressional funds and the dietary supplement strategic plan.

The plan itself is divided into a number of topic areas, one of which is science, and therefore the need for providing for a better science base.

DR. GORDON: There was also a recommendation this morning for a specific division dealing with natural products. Do you have any feeling about that?

DR. LEWIS: Well, currently, the way the center is organized, and, of course, you are correct in saying that natural products is something that is not within the existing U.S. paradigm as far as where it is regulated.

I would have no comment on creating either a separate unit or a separate office for that, but I certainly acknowledge there are people who have discussed it, and there are countries in the world which do regulate the products that way.

DR. GORDON: Michelle, did you want to say something?

MS. RUSK: Could I respond to the question? I think part of the confusion is that FDA and FTC have overlapping jurisdiction in this area, and our primary authority relates to advertising, claims made not on the label, but in print and other media, and we are not governed by the DSHEA distinction between disease and structure function claims.

So, under FTC law, you can make a claim about arthritis, to use your example, as long as you meet our substantiation standard, which is competent, reliable, scientific evidence, and obviously, we would be consulting with FDA and with other agencies and experts in the area to make that determination, but there is leeway in advertising law to make claims that would be automatically permitted on labeling.

Also, I would like to disclose that I am not, in fact, a doctor, but thank you for giving me that degree. One of the problems we have at the FTC is that we are an agency of lawyers and economists, so when we go out to evaluate an advertising claim in this area, we are relying entirely on expertise outside our agency.

MS. TAYLOR: May I comment on the drug definition just one second, please? I wanted to follow up with your comment about when do you need to file a new drug application because while we talk about there being drug claims and dietary supplement claims, it is important I think here to put this in the context of the history of our Food and Drug Act, and say, you know, what was understood to be a drug effect at the time the Act was adopted in '38. I think our view in medicine has changed quite a lot.

The line between promoting good health and preventing disease doesn't seem to be a reasonable way of dividing on many of the products that would fall in this category, and I think that is the reason I wanted to put before you the issue of the drug definition, which drives so much of the policy in this area, and it is not a very convenient fit for a lot of the products in the CAM category.

DR. GORDON: I just want to clarify something. I think it is clear, but I am not sure.

It would not be possible to put down in spite of controlled studies that glucosamine worked or was useful for osteoarthritis on the label, but it would be possible to advertise it in that way?

MS. TAYLOR: No. The point I was making for is that FDA's determination on intended use, that is, is this product a drug or a food. They look at any kind of claim including in the advertising, and so that is where the chilling effect comes, from the drug definition in the Food and Drug Act, chilling, what can be said.

So, you could have a well substantiated claim. The only reason you can't say it is because your product is a drug, and many of the manufacturers in this category simply don't have the resources to file an NDA. That is just reality.

DR. GORDON: But I thought Michelle Rusk, you were saying it was possible to advertise, but not possible to have it on the label.

MS. RUSK: What Sarah is saying is that because FDA will look beyond the label potentially to see the intent of the manufacturer, that an advertiser may choose not to take that risk.

MS. TAYLOR: She won't enforce this; Christine would.

DR. GORDON: Is that correct?

DR. LEWIS: I think the issue here is intended use, and that oftentimes is a difficult concept for most people to understand. Intended use makes you a drug when you want to prevent, treat, cure, or mitigate a disease.

Part of what you are seeing in the dietary supplement world is people making structure function claims that do talk about effects on the body, but as long as it is not talking about treating, preventing, curing, or mitigating a disease, you are in one regulatory box as opposed to another.

DR. GORDON: Just a practical question. What would it take to move from being a food to being a drug in terms of being able to make those claims?

DR. LEWIS: The interesting thing about the world we live in is that a product can be a food or a drug depending on its intended use, and the claim is what drives oftentimes the intended use. It would be both the scientific data and the fact you filed or not filed for a new drug application.

DR. GORDON: I am curious. Let's say the scientific data existed. How much time, how much would it cost?

DR. LEWIS: There is no doubt that it is expensive and timely to go through a new drug application.

DR. GORDON: Do you have a sense of a range even?

DR. LEWIS: I am not in the Center for Drugs. I couldn't even venture a guess. It is a completely different center.

DR. SOLLER: Yes. You would be going through a user fee application, and it would several hundred thousand dollars or more depending upon the amount of work that you did either internally or you brought in outside consultants, and assuming that you had the data, that is what I am assuming, and you are not paying for the trial, I mean if you now put in the cost of trials, you are substantially higher than that.

MS. TAYLOR: There is one further nuance on that, that I would like to point out. I gave the example of the cholesterol claim in my testimony, maintains normal versus. A lot of times this box problem that we deal with means that it would technically be a better claim, a better substantiated claim to say reduces cholesterol, because maybe that is what your evidence really, in fact, shows, but you are having to wordsmith it to fit it into the structure function category so as to avoid the NDA requirement.

So, we would argue the ironic result here is that it is actually making the information a little bit less accurate, because we are trying to fit into the structure function model, which is "helps maintain."

DR. GORDON: Do you have any suggestions about a way to make this, at least from your point of view, and perhaps ours more rational?

MS. TAYLOR: Well, I think the First Amendment is the way to look at this thing, which is that these boxes do not make sense. We are focused on what is necessary to prevent deception, and so I think the real question is -- we have a category of products that have a recognized place in health, so truthful, non-misleading information of all kinds ought to be permitted, and that the First Amendment really gives us the line drawing principles that we need, and resolves very much of this.

The only additional recommendation that I would like to highlight, which is in the testimony, is the need to be realistic about enforcement. We hear all the time about resources, and I certainly share the view that our regulators could use more resources, but the bottom line is we are talking about a world of the Internet, we are talking about substantiation of truthful claims as opposed to categorical restrictions and bans.

That means that it is a very labor-intensive job to do enforcement, and I think we need to become a little bit out of the box in thinking about how to create positive incentives for good behavior, to get professional groups involved with endorsements, and basically take more of a grass-roots look at how can we create more incentive for compliance.

DR. GORDON: Thank you.

Tieraona.

DR. LOW DOG: Well, somebody hopefully can explain this to me. So, we have homeopathy over here that is actually classified as a drug, those are drugs. Now, that is interesting to me. Even though we have included the Linde meta-analysis here where it clearly states in his conclusion, we found insufficient evidence from these studies that homeopathy is clearly efficacious for any single clinical condition, but you can put on a box for homeopathy, diarrhea, asthma, PMS, colds, flu, and that is what they are sold as on the shelf.

But I am hearing that glucosamine, where there is actually a number of rigorous studies that have found it to be efficacious, or St. John's wort, which we are now up to 32, and the Cochrane's [ph] latest analysis showed that it is clearly superior to placebo for the treatment of mild to moderate depression. You can't

make those claims without applying for an NDA.

I am a little confused how homeopathy got set off in this other box of drugs without clear substantiation of evidence, but there is this very different set of regulations for dietary supplements and botanicals, that it sounds like the bar is extremely high when you compare it to homeopathics.

I may be wrong, but that is just what I understood from listening.

That is not the same as asthma or diarrhea or many of the things that homeopathy can claim.

How did we get there? How come it is different for dietary supplements, botanicals? I don't understand the distinction when actually the evidence -- with all due respect -- the evidence for many of these conditions has not been shown through rigorous science to be effective, and yet my patients go down, buy a bottle, it says asthma on it or colds and flu, but yet my patients do not have the same freedom to enjoy the scientific evidence that is available on dietary supplements on their labels. So, I am just unclear why there is a two-tiered system.

MR. LAND: First of all, if I could just address a point. As far as my company is concerned, you won't find an OTC product marketed by us that is labeled with the claim asthma. It is, as I said in my discussion, we don't disagree. We need to have more research, and when we talk about 100 trials that is available, that can be evaluated, it is a very small collection of information. We would like to supplement that, and we would work every day to improve the collection of information supporting the use of these medicines.

With respect to how did we get to this point, the homeopathic medicines or the Homeopathic Pharmacopeia of the United States was introduced into the Federal Food, Drug, and Cosmetic Act in 1938 at its first writing as an official compendium.

I am not a lawyer, so I am not sure how --

DR. LOW DOG: I was not disparaging homeopathy. It just seemed a very bizarre thing that you could be a drug, and yet we are having all these other problems with glucosamine, St. John's wort, and other things, it is just mind boggling.

DR. SOLLER: If I could make a comment in terms of your frustration about glucosamine, not being able to make a disease-related claim. It is not so much that it is an issue that it costs money and therefore small companies can't go after that, because if this were a particular marketing category that would have a return that would be benefitted by a new drug application, there would be large companies that would be going after this.

However, there is not a system in DSHEA that allows really for research incentives in the context of market exclusivity, and that is really where I think the decision is being made in terms of market entry, what can I say in my product, and I can tell you that there are many companies, at least in our membership, that are doing studies, but not publishing them, because their evidence base is about as much as they can get in terms of exclusivity. So, they keep those studies of and when they need them, and as a basis for making their particular claims.

DR. GORDON: Thank you.

George Bernier, Joe Fins, and then David, and then George.

DR. BERNIER: I have a question for Dr. Lewis. During the half year to a year that this group has been together, we have heard on a number of occasions that a shortage of personnel and of money is keeping a lot of problems from being served.

Would you have any idea, would it be 10 percent of the budget is short or is it a couple of hundred times the budget?

DR. LEWIS: When DSHEA was implemented, no additional resources were given to the agency. Consequently, in answer to your question, it is 10 percent of nothing at this point. So, it is difficult for me to give you a number. We certainly have developed two things that I think would be useful to the commission in the next couple of months.

One is based on the dietary supplement strategic plan. We have developed a buyout cost. In other words, we are calculating based on what we think it would take to fully implement the strategic plan which responds to DSHEA, how many dollars that costs, and as soon as that is cleared by various powers that be, we would make that available to you.

It does document for each of the five topic areas how much and why.

The other is that we do see this as a ramp-up effort. We don't believe that it is possible to get X million dollars tomorrow, so consequently, we are also making available what could be done on a yearly basis dollar by dollar.

DR. BERNIER: And all your scientists and lawyers are in agreement with that, are very eager for you to move forward?

DR. LEWIS: I am not quite sure I understand your question.

DR. BERNIER: Is that something that the agency, as a whole, is very enthusiastic about?

DR. LEWIS: Dr. Henney, who is our previous commissioner, made it quite clear our intent is to fully implement and support DSHEA, so the answer to your question is yes.

DR. BERNIER: Thank you.

DR. GORDON: Joe.

DR. FINS: Dr. Lewis, you mentioned that the adverse event reporting system was voluntary. Would you prefer a system where it was required, and if so, what would be the public health implications of that, what would be the costs, and how would you implement it?

DR. LEWIS: Well, of course, we have what we have at this moment, which is a voluntary system. Certainly, there are adverse event system, reporting systems, as you would see in the Center for Drugs, which are mandatory. I am certainly in no position to talk about it one way or the other in terms of what we prefer.

We have been given through DSHEA the system. I think it is important for everyone to realize the

system could work better, and that is really the theme we want to sound, is that the system could work better. There are ways that we could improve reporting, make it more known to both health professionals and consumers that this is an option for reporting.

DR. FINS: Do you have any specific recommendations or ideas about education of professionals and consumers that would increase voluntary reporting, make them more aware of this set of issues?

DR. LEWIS: Well, certainly, the outreach through MedWatch is something we are exploring. We have also taken a look at the possibility of attending and participating more in professional meetings, so that an awareness is created.

Our web site does tout this quite frequently and we would like to be able to continue to support that effort. It is really a matter of resources and continuing to get the message out there.

DR. GORDON: Bill.

DR. SOLLER: I just had two comments. One, in the drug area, OTC monograph ingredients are not covered under a mandatory AER system, and having been involved in the OTC side, as well as dietary supplement side, but the OTC side for many years, we have addressed many safety issues.

The silium, the choking warning that appears on silium products was developed through the voluntary reporting system, the allergy warning on Neosporin also. I will also tell you, having been involved in this particular safety issue, that no Reyes syndrome case ever appeared in the AER system as it was being developed, but rather, was developed out of the Public Health Service, particularly Ohio and Michigan at that time.

So, the second component that was described earlier in terms of the literature, the case series, and so on, is separate, and we consider part of that overall voluntary system. So, where I have seen a system work in a very sensitive way in a handful of cases, and developed the hypothesis that lends itself to further testing, we look at this in the context of awareness being the most important driver here in terms of having an AER system for dietary supplements that would be viable, work on many of the products which are basically safe.

The other comment I wanted to return to in terms of Dr. Bernier's comments earlier to Dr. Lewis, was just to reiterate my comment that if, as I am hearing today, that you have heard that the agencies have the tools, but the resources are an issue, that if there is to be action to move this forward and move it in the next appropriation cycle, then, I am not sure that what you have here in terms of a schedule, in terms of your report really fits that particular need.

So, I would add in as another recommendation post hoc to my comments, Mr. Chairman, if I could, that you relook at that schedule and perhaps pull out one or two of your recommendations in a way that would perhaps address this issue in this appropriation cycle.

DR. GORDON: Thank you.

David.

DR. BRESLER: At the risk of opening a can of worms, I have two questions for the panel about the placebo effect. There is very good science that the placebo affects just about every disease entity for

which it has been studied. For example, just to give you a simple study, you can take a group of postoperative pain patients and give half of them morphine, half of them saline, and you find, quite reliably, at least 12 studies have shown this, the 70 percent who get morphine get pain relief, 35 percent who get placebo get pain relief, meaning that probably half the effectiveness of morphine is due to the placebo effect.

Well, there was a recent study that showed that the placebo effect works even if people know they are being given placebos. They said to these patients, "There are no active ingredients in these pills, but one in three people who take them get pain relief, would you like to try?" And they found that one in three people still got relief of pain even though they knew that they were placebos.

That question is if a manufacturer or practitioner is making no claims and says there is no evidence whatsoever of any efficacy whatsoever for what I am doing or for this product, but one in three people who do it or who receive it get a benefit, are you going to go after them or can you?

The second question, the second part of this question has to do with the no-cebo, and again there has been very good science on this. There was a classic study by Klopfer on a patient who had extensive metastatic lesions, who was given crabiazin [ph] and had a miraculous response and went into remission.

Then, as the scientists started debunking crabiazin, his symptoms returned. The doctors gave him saline injections and told him it was a double-strength crabiazin, and his response was even more astonishing than before. He went into long-term remission until the AMA released a statement saying that there is no evidence whatsoever supporting crabiazin, at which he was readmitted to the hospital with advanced metastases and succumbed in 48 hours.

So, the question is as we start to debunk some of these indigenous practices with "good science," are we not perhaps reducing the efficacy of some of these indigenous healing practices, and do we need to be concerned about it, or are you concerned about it? Let me ask that question.

MS. RUSK: I am sympathetic to that problem certainly. I think the reason why as a policy matter we don't consider anecdotal evidence to be reliable substantiation because you can have very compelling, convincing, accurate consumer experiences about benefits that people have enjoyed from particular products, and you don't know whether it is placebo or not without the scientific evidence.

I guess in addition to injury to health, we are concerned as an agency about economic injury to consumers, and are they paying $60 a week or, you know, up into hundreds of dollars for therapies based on placebo effect, and is that really fair to consumers.

DR. GORDON: Excuse me. I just wanted to interrupt. I know Dr. Lewis has to leave momentarily. We have another 8 or 9 minutes for questions, and I just wondered if there was anything, a final comment you wanted to make before you had to leave.

DR. LEWIS: No, my role had really been to make sure your questions were answered in the best possible way, so I guess I would put it back on you. Are there some aspects of FDA oversight that you feel are left unaddressed, and I would be glad to try and deal with those?

DR. GORDON: Did you want to respond to David's question?

DR. LEWIS: Well, let me give the bureaucratic answer, which we are very good at. I resonate

completely with Michelle's point. I guess personally I would say I would like to think the placebo effect could be studied scientifically, which in some ways undercuts the thrust of your argument.

Certainly, we have not proceeded down that path with dietary supplements, and it is not to say in my lifetime it wouldn't happen, but I hope it does not.

DR. GORDON: Tieraona had a quick question, and then we will come back to yours, David.

DR. LOW DOG: I am in full support, and I hope you get the budget that you are looking for to be able to enforce DSHEA.

What do you feel about other groups, such as USP, NSF, and other groups attempting to do voluntary programs for pesticides, label, making sure that they have what they claim to have and nothing extra, or is that going to be more under the purview of FDA where there would be a need for those groups, will FDA be able to do all of that themselves? Will you be doing random sampling and testing? I guess I want to know what you are going to do and if there would be a need for some of these other groups to do these voluntary programs with industry.

DR. LEWIS: The principle we have tried to sound is that we certainly do not want to shirk our own responsibilities, and with resources we think we can do a very adequate job. That aside, we have signaled quite clearly that we do think liaison efforts are needed.

The question is how are those structured, how do we interact with them, what is the basis for them, and what is their goal. So, inherently, it is a good idea to be able to expand resources, to liaison, use other groups. The devil is in the details. How exactly that would be implemented would be the interaction between the agency and these groups, I think it is a knotty question and one clearly we are going to have to address.

I think what you are asking is appropriate. I think the answer is down the road somewhere.

DR. GORDON: Thank you. We will let you go and thank you for your graciousness.

DR. LEWIS: Well, I don't want to sneak out, but I do want to make sure that your questions are answered.

DR. GORDON: What we would like to do is just to sort of reserve the option of getting back to you and asking you further questions.

DR. LEWIS: Absolutely. My pleasure.

DR. GORDON: Thank you very much.

David, did you want to continue with the question?

DR. BRESLER: I would just be interested in any concerns that you have or any insights you can give us about how to handle the thorny issue of the placebo effect in both directions, the extent to which it facilitates efficacy of these treatments and the extent to which, as we continue to do science and debunk a lot of approaches that don't have scientific efficacy, are we really doing our citizenship a favor when some of these things are so benign and have no risks. Just your thoughts about it.

MR. LAND: As you can imagine, the placebo effect is quite a sensitive issue for us in homeopathy, and I have been involved in homeopathy for quite a number of years and have seen a dramatic evolution in thinking, or I should say desire in thinking in terms of wanting to be able to do research that is reportable to the scientific community.

There were a number of years where research and homeopathy was considered implausible because of the medical model was not consistent with standard clinical practice, and we have evolved to the point where some thinking has come out where we can actually design studies which unfortunately has not pointed to success in an indication within the classic Western model at this point.

For example, when you say to a homeopathic physician "asthma," we are not exactly sure what that looks like in homeopathy. So, to be able to create a clinical trial to demonstrate efficacy or lack of efficacy for that particular disease entity is difficult. It was considered impossible, say, 15 year ago. At least now we are giving an attempt to thinking about how to define trials and implement them, that might give us some direction as to how to move forward in designing new trials.

So, that is what I have to offer to you today. The effect of the placebo on the patient we know, it is a very powerful one. The diminishing effect when negative expectations, I think is probably at least equally powerful.

How to word that out of the trial setting, I am not an expert in that area, but it is something to be considered.

DR. GORDON: David, I think, too, we can come back to this in the research meetings, as well.

George DeVries is next, and then I have Ming, and then we are going to have to close because we are a little behind time.

MR. DeVRIES: We have talked today about the issue related to enforcement, the need for more resources, the need for more resources and research, the ability to make claims.

Is there a solution out there related to -- I guess I will phrase it as research incentives for private organizations? I am thinking an idea was floated on Capitol Hill was the modeling off of the Orphan Drug Act where private organizations would fund research related to herbal supplements, and if that research was successful in demonstrating St. John's wort was effective in certain cases, that private organization would have the right to basically, for a period of time, to basically advertise that St. John's wort accomplishes a certain result with patients.

I am just curious, in terms of this panel, your thoughts related to maybe research incentives being part of the solution.

DR. SOLLER: We have looked at that, and it is a very difficult issue. For example, if NIH, as it is, finds in its trial on St. John's wort that it is effective for depression, then, a company wishing to go forward and market it for that would likely not be able to get any kind of market exclusivity, and certainly it would have a claim which is not the claim most often used for St. John's wort in the U.S. and certainly not the consumer claim because depression would be classified with an ICD code as a disease.

So, that is one aspect of the issue. If it were a new dietary supplement or one for which a combination of

old supplements perhaps were found to have a unique effect -- well, let me take that one aside -- as a new one, then, we still don't have the same kind of exclusivity that is availed in the drug area.

If it were to be a company that did a study on vitamin C and found that it was effective for the common cold, of all things, and it decided it would go out there, and if market exclusivity were even to be given to them, then, under the current situation, a Safeway brand vitamin C without a claim on it could be on the shelf, and the savvy consumer would be buying on price for the prevention of the common cold.

So, if you thought about one area of DSHEA which was lacking in the context of really driving science, it was that particular area, and we have not come up, and we are not the only association that has looked at this, but no one has really come up with a solution that fits yet, but it is worth having some minds go against that because times change, we rethink things, and it is important.

MR. DeVRIES: Thank you.

DR. GORDON: Thank you.

Ming.

DR. TIAN: If I am not confused, I am trying to figure it out. First of all, the label said you can't treat arthritis, okay, the label is here. Then, you did some study. You are the customer, you buy. Okay. I don't know anything about this, okay. You buy this. The information is here. Is that the practical things they are doing? Don't you think that is a little bit ridiculous?

DR. SOLLER: Arthritis is a disease, so under current law, if you treat, cure, mitigate, diagnose, or prevent except in one category for health claims, you would be classified as a drug.

So, if you did your study for arthritis and you found that, in fact, you had a claim that you put on for arthritis --

DR. TIAN: Not on the label, separately.

DR. SOLLER: All right. So, you don't put it on and now you go out on the air, well, the way FDA usually evaluates labeling is in the context of the overall presentation of the product.

DR. TIAN: Okay. So, FDA does not read any scientific report.

DR. SOLLER: I think if FDA decided to, and FTC decided to, move forward, then, the FTC standard would be are you making your claim in the context as whether it is truthful in the context of the available evidence.

FDA has a regulatory boundary and says are you now using that to treat disease, and if you are, you are marketing it for an intended use as a dietary supplement when, in fact, it appears to be intended for drug use.

MS. TAYLOR: It doesn't gain you anything to put your drug claim or your disease claim in advertising matter because while FDA regulates the product label, with respect to the determination should this be regulated as a drug, they look at intended use including advertising.

Let me just give you one example. About a month ago, FDA sent out a warning letter to a food company, which because the food company posted some research, nutrition research information, which included disease terms, FDA took a position in this warning letter that their entire fruit juice line of products should be subject to NDA.

These are products you are going to buy off the grocery store shelf, you are going to drink it like a fruit juice, nothing in the conditions of usage changed, it is simply because there were some excerpts from some nutrition clinical studies mentioned.

So, I come back to the basic box question. Really, we have gotten stuck with this paradigm for historical reasons, but the real question is what is the proper level of regulatory scrutiny given the safety of the product and then if the product is safe under those conditions, then, the claims under First Amendment standards needed to be truthful, non-misleading, and fully substantiated.

DR. TIAN: So, if the food supplement has got plenty of data or scientific support, wants to apply for a new drug, they have to remove from the shelf, am I correct?

MS. TAYLOR: Right. If you took, say, the First Amendment model, it would say tell me what evidence you have got, and then the question becomes is this a truthful characterization of that weight of evidence, are there material factors that you are not telling us, such as the placebo effect, I mean that is how that would come in, you know, is that a material item that you need to disclose as part of your promotion, so that someone has a fair picture of what the weight of the evidence is, but ultimately, it is not a single watermark that you have to get to with your evidence. It is a floating standard.

In fact, Michelle can probably address this, but there are claims out there that say ancient Chinese folk remedy for X. Now, that kind of claim can meet a substantiation standard as long as the rest of the evidence out there does not convey that that means it is going to work for you. It really has to do what is the overall take-away message, do you put caveats and disclaimers on it.

DR. GORDON: We are going to need to stop. Charlotte, you haven't had a chance, but is it very brief?

SISTER KERR: My question, we were called to the virtue of simplicity sometime today in our work, and this is absolutely the most unsimplistic thing I have ever heard of, and I think of you as the visionaries in this field, and you asked us to think out of the box, and I want to ask you whether it is now or later.

You especially, the trade people, I thought where is the call to what makes sense in all of this, and the reward is for the good guys and gals, things like that, you know, Ms. Taylor called us, too, so that was what I wanted to ask, and if you want to write it down for me, I would be happy to received it. Thanks.

DR. GORDON: Go ahead if it is brief.

DR. SOLLER: Well, I think, you know, you look 1994 post-DSHEA, there was about four and a half, five years in which there was no proposed regulatory structure, and I think what we are seeing now, with Joe Levitt having put forth a series of stakeholder meetings, and then through that, developing what the stakeholders wanted in the construct of DSHEA, and putting forward a long-range plan, and then yearly priorities and a report card on that, that you are seeing the kind of administrative framework that will support a process for appropriations, which was lacking before.

While I think that it is very important that you consider the kinds of comments that Ms. Taylor has mentioned today in terms of the free speech and how that plays into this, and although my remarks may seem very much supportive of FDA, I will tell you we don't always agree with them, but we do understand that it is very much a evolving regulatory environment that is occurring, and I think in two or three years we are in a very different regulatory framework.

Part of the discussion will be wading through some of these issues on First Amendment, which are very, very important issues and things that we shouldn't walk away from, but also other aspects on enforcement. I think what you are seeing is perhaps what might have well taken place in 1995, '96, '97, but be that as it may, whatever didn't happen, didn't happen, at the agency, it is happening now.

DR. GORDON: Thank you.

One of the things that I would suggest, Charlotte, and to everyone, is that we are now begin discussion groups, small discussion groups. There will be one here that George DeVries will be chairing, and another that Veronica will be chairing.

The charge to these discussion groups is to identify some issues and then to make some recommendations, and I think that based on what we have heard, even though everything may not be, as our previous president said, "perfectly clear," at this point, that we need to really think out of the box, and that we don't have to have final recommendations, but we can suggest, for example, that some of these contradictions that seem mystifying, that we can point ourselves toward gathering further information and trying to make recommendations that do perhaps make more sense and are more broadly applicable.

That is the charge for you in the groups is to begin to think of what kinds of issues we need to be addressing. We don't have to have the solutions. The staff has been wonderful in bringing in panelists and bringing us information, but I think we need to have direction for what we need to know over the course of these next months in order to make recommendations.

So, I would like to leave that, thanking you all for coming, I would like to leave the two small groups with that charge, and then we will meet back here as a group of the whole at 5:30.

Does everybody know which small group you are in? Veronica's small group will meet in Congressional D where we had lunch, and George's small group will meet here. Thank you all very much again.

[Recessed to reconvene at 5:30 p.m.]

DR. GORDON: The way we will do this is we will ask, first, Veronica's subcommittee to just present the issues and the recommendations, five or 10 minutes or so, no more than that, and the George's to do the same, and then we will have discussion of all of them together. Does that sound okay? Because the topics are so interrelated, so please begin.

Report by Workgroup No. 1

MS. GUTIERREZ: Our workgroup's mandate was to address issues and recommendations relating to the Internet and the media on information dissemination.

What we recommend is the establishment of a web site, possibly a private and governmental agency

partnership, the site to address both products and services, on the site list pros and cons in the voter's pamphlet model. Link to other reliable sites.

We would like the site to address safety issues, for example, links to state licensing and disciplinary information sites, and we would recommend that states that do not presently have licensing and disciplinary boards do that and that the information then be linked to the site.

We would like to them address under safety issues the drug, the herbal, over-the-counter interaction risks and side effects, the issue of contamination, and use as a resource consumers reports and all of their organizations that evaluate such things.

Under safety, address dosage ranges, safe, dangerous levels. We would like to have pediatric red flags, pregnancy red flags, ethnicity red flags, and a place to check the integrity of the product.

We would like the web site to encourage CAM education and experiences all the way down to the elementary school level.

A suggestion was to check case law to avoid charges and the liability of non-inclusion of groups, and we would do that through creating tight parameters for linkages.

Both in the Internet and the media, disseminate information on an ongoing and regular basis.

Specifically under the media, we would encourage the media to use the web site as a credible resource of information. The concern was then disseminating the information to citizens at as many levels as possible.

Some new ways to disseminate the information would be, for example, to utilize librarians and make sure they are well educated.

We could create a partnership with the American Library Association to aid the patrons, and through their education, they would be able to aid the patrons and access to information and education about health.

We talked about new avenues of educating the populace, those that don't have access to the Internet and maybe not even TV on an ongoing basis. We don't know how to do it yet, but we thought that churches, elementary schools, hairdressers, PTA groups, hospitals, community health resources, and hospices could all be part of that dissemination of information.

We encourage media who address health issues to have and experience the different CAM modalities and services, and through their own personal experience, they would be able to address the subjects more totally.

DR. GORDON: Great. Thank you.

Would anyone else on that committee like to add anything or amplify on it right now?

[No response.]

DR. GORDON: In discussion time, we will come back to it. Thank you very much, Veronica.

George.

Report by Workgroup No. 2

MR. DeVRIES: Our group looked at issues and recommendations related to marketing and advertising of really CAM products, services, and diagnostics.

I think the first issue we really came to recognize is that there is a very broad range of really CAM products, services, and diagnostics, and that really creates much of the challenge that we have with marketing and advertising out there in the sense that there is so much available, and there is so much that needs to be regulated and with oversight, that it creates a very formidable task. Therefore, there is a lot happening in the whole area of marketing and advertising of these products and services that make it a challenge.

So, as we drilled down to further issues related to marketing and advertising, one was really simply enforcement, what is the enforcement of current laws, because we certainly heard today that there are laws on the books that do govern certain products and services, and that those laws are not being enforced.

In particular, we heard of FTC basically finding over 400 web sites that basically were not compliant with the DSHEA statutes, and yet they only sent out a letter, and they really only dealt with enforcement action on 10 of those sites, and that they were happy with enforcement of 10 sites and getting some kind of change on 20 percent of the sites just through a simple letter.

Really, we believe that one issue is a lack of enforcement, and really the recommendation is greater resources to be able to enforce laws that are actually already on the books that are available for appropriate regulatory oversight related to marketing and advertising.

A second issue was really the inconsistent manufacturing standards that are out there in the marketplace and that we heard today multiple times examples of a type of product, and if you look at 20 different manufacturers, you see 20 different products, and yet, we again through the DSHEA regulation already have a solution, which is basically publishing of GMP, good manufacturing processes, and that we are really awaiting that publication. We basically need it to be released and then enforced.

A further issue was really the issue of disclosure and basically felt that there was not enough disclosure that protected patient safety or really disclosed potential efficacy or risk or other issues related to the product or service, so felt like there should be improvement related to disclosure and that basically, the recommendation being there is that there be more specific requirements related to disclosure of safety and risk and potential efficacy and effectiveness of the product.

The next issue we dealt with was really a broad issue, but it was really the concerns specifically as related to nutritional supplements, that part of the challenge in overseeing marketing and advertising is that the classification of nutritional supplements is as food products, and that that really is an inappropriate classification which does not allow for appropriate oversight of marketing and advertising, and just says as products are classified as over-the-counter drug products or nonprescription drug products or prescription drug products, that perhaps there needs to be a classification related to nutritional supplements that would allow the appropriate classification and therefore perhaps more appropriate regulatory oversight of the marketing and advertising of these types of products. So, that was

the recommendation.

Finally, as we dealt with the issue related to just what we saw was so much, shall we say, inappropriate marketing and advertising of products and services, that it was very aggressive, and that we felt that while there is enforcement and disclosure, that these are important recommendations to address these issues.

We came back to the issue of what the amount of resources are that are being allocated for research, because only if there is good, solid research will we, over time, debunk the products and services that are not effective, and support those that are effective, and that ultimately, that will actually have the indirect impact on helping to support appropriate marketing and advertising.

There was also a recommendation just related to with the different agencies that are involved with regulatory oversight, that there really is a need for regulatory coordination.

So, as we look at having an agency or an office or in some capacity within our government overseeing complementary and alternative health care, that there be some responsibility and authority there related to coordinating among regulatory agencies.

I guess I should say last, but not least, we did have a final recommendation from Sister Charlotte related to our changing our current economic systems of pricing and funding of these products, but we saved the recommendation for dinner tonight. We will figure that one out over dinner tonight.

DR. GORDON: Thank you, George.

Anything else from anyone on that committee that you want to add at this point?

[No response.]

Commission Discussion

DR. GORDON: Let's open up to discussion, clarification, amplification of any of the issues or recommendations.

Joe, go ahead.

DR. PIZZORNO: One of the themes that keeps coming up over and over is there is no enough funding for doing the responsible thing whether it is FDA, FTC, education, web sites, et cetera. It was pointed out very well by Susan Detwiler to look at the methodology utilized by the Dairy Council back in the thirties where they required half a cent or a cent on every product sold to go into this fund to educate the public about the importance of dairy products.

I wonder if there would be some way of getting the feds to -- I hate to say it, it is a tax -- put a tax on all the sale of all dietary supplements and utilize that money to take care of these problems.

DR. GORDON: Interesting.

George.

DR. BERNIER: I would point out that there were some of us who wanted to do something a little more radical in terms of the interagency interactions, and had felt that a restructuring of that might be appropriate. We got talked out of it, but I think that is something we ought to keep on our back burner, and I don't know how easy it is to move something like that, probably absolutely impossible.

DR. GORDON: Restructuring not just the coordinating office, but some actual restructuring of agencies.

DR. BERNIER: Right. You share the same cynicism.

[Laughter.]

DR. GORDON: I wouldn't call myself cynical, perhaps experienced. I think we should be open to thoughts and processes and ways of streamlining things, that we shouldn't shy away from that as certainly for discussion and perhaps a recommendation, because even if my own experience is that sometimes even if you don't get what you want, you may get what you need, and we may be able to make a difference.

So, I think that all of this is open for discussion.

Yes, Joe.

DR. FINS: I just want to say for the record because I think one of our audience members had an important point that didn't really get brought up during our formal meetings here, that we were talking about supplementals and stuff, but there are all kinds of things that are advertised out there on the Internet and TV and on the radio, that should at least not escape our consideration - clinical services, diagnostics, new technologies that have not been approved for certain indications, and I just think that we were cautioned, and I think it is an important point not to get too narrowly focused simply on the supplementals.

DR. GORDON: That is a good point. Thank you.

Don.

DR. WARREN: On the regulatory cooperation, the EPA and OSHA both recognize mercury as a poison, but yet the FDA classifies amalgam filling, which is 52 percent mercury, as a medical device, and it is not regulated. There is no cooperation there between the agencies.

We are going to have the same problem with this, and we are going to have real problems trying to get the regulatory commissions to act responsibly.

DR. GORDON: I think it is a beginning to start raising these issues, though, and saying that we want more collaboration, at least a common perspective that could be shared.

DR. WARREN: If we asked for documentation of the effectiveness of each one of these things, every agency should accept that documentation, but if we have something that is utilized and has been utilized for 20, 30, 40, 50, 100 years, and it suddenly is grandfathered in, if we are going to have it and be accepted, and I want them to have the same requirements for acceptance that anything new would have.

DR. GORDON: I had a couple of specific questions of the first group. There was a recommendation that

was made by the first panel this morning that people agreed on, seemed to agree on pretty much across the board, and I wonder if you were addressing this - an association, some kind of encouragement of an association of Internet providers of information, and whether your panel thought that would be a good idea or how you dealt with that.

DR. BERNIER: Are you talking about our panel?

DR. GORDON: Yes.

DR. BERNIER: We didn't discuss it as such, but I think clearly this morning that there was some pretty strong agreement that that is the way to go.

MS. GUTIERREZ: That was one of the last items that I mentioned, that we were advised to check case law to avoid charges and liability of non-inclusion, and we would do that through creating tight parameters for the linkages to the web site.

DR. GORDON: The other was a somewhat different recommendation, that that group of people get together or be encouraged to get together and set certain standards, consortium with some kind of minimum standards of reliability of information.

Effie, and then Joe.

DR. CHOW: I think it sort of got lost here. I mentioned an association of both government and private institutions, and cross-representation. I called it a council. It is not just a web site of cooperation, but it is a whole group of people, association of people, whether you call it council or association or whatever.

DR. FINS: The model that I was thinking of this morning when I mentioned the consortium idea of getting all the web sites is what the medical journal writers have a consortium where they set standards for peer review, they meet regularly, and that sort of thing might be something that, you know, if we gave a grant or something or recommended that Congress appropriate funds to the National Library of Medicine, which would bring the government into it, to host a consortium of web collaboration might make a lot of sense.

Again, I think it is very important that we do not in any way engage in a kind of censorship of ideas, but just that these are standards, and if somebody wanted to have on their portal that they were NCAM-approved or whatever the designation is, that would be something that would help them gain market share, there would be economic reasons to do that.

I think the other half of it is public information, which is something that we didn't really talk a lot about, but public service announcements could play a very big role. The FCC is another agency that really hasn't even come on the map today.

We can have public service announcements saying when you go to your web portal, you want to look for this particular designation, that is an accredited portal, and that could not only be for CAM, but for any kind of medical information, that it is National Library of Medicine approved or whatever it is.

DR. GORDON: I had a question related to that. Were there thoughts about encouraging NCAM to provide sort of more FAQ sheets, more information to the public? Was that taken up by your group?

MS. SCOTT: We didn't have the time to go through all of the entities that might be involved in this information dissemination. We just made the point that the information needs to be disseminated to the various populations.

I think a concern that I have, always have and especially today, as I heard all of the references to the Internet and the Internet uses, are all of the many people who do not have access to Internet. So, I think access issues we dealt with under the rubric of media in general, and we talked about the places within the community where this information could be disseminated and the influential people in the community that could bring the information to the community.

We didn't identify NCAM, but we just said that that information needed to be brought to the community in addition to the Internet and other kinds of media vehicles.

DR. GORDON: Effie, please.

DR. CHOW: Another strong factor was that the adults may not have access to computers or television, but the children all now deal with computers, so it is just like the alcohol, you use the children to educate the parent, and smoking, you know, so we use the children to help educate the parents, too, and this can reach out to mass.

DR. GORDON: Thank you. I wanted to ask just for a little more clarification. There was a strong emphasis on licensing and safety issues in that first group. Can you say a little bit more about the kind of information that you are thinking that should be there about licensing, about safety?

MS. GUTIERREZ: It is just another resource of information. I know both the medical and the chiropractic professions have -- well, chiropractics called Sinbad, but you can now access all the disciplinary action taken against, in this instance, a chiropractor.

So, if you are looking for a provider, whatever the provider group might be, suggesting there be a place that you could go and get the information and make sure they are duly licensed or certified, and have not been involved in any disciplinary activity, and that whole aspect of information.

DR. GORDON: Were you also talking about just having general information about who is licensed and what professions are licensed, in what state, what the qualifications are?

MS. GUTIERREZ: Right, and in our different state laws, it would give you the consumer public the opportunity to go and find out what is allowed under their state law.

DR. GORDON: I am curious, thinking of both groups, the safety issues, what are the different views, are you talking about safety of product, safety of services, and what are some of the thoughts?

Maybe we could just spend a couple minutes talking about how to get out that information, what kind of form it would take, what some of the ideas were that either came up during your meetings or they come to you now.

DR. LOW DOG: We had again just explored that perhaps somebody, NCAM, NIH, somebody, ODS, look at the top 20 dietary supplements, the top 20 botanicals from a safety point of view, and that could extend to devices, medical devices, but I mean we have limited resources, but if we could get those, that would probably take care of about 80 percent of the sales, and have them studied for effects on

cytochrome p450, teratogenicity, safety in pregnancy, safety in lactation, dosage forms, those kinds of things, and that those be available then at the point of purchase.

Isn't that what we were talking about? Sort of like is a package insert almost for patients to be able to have safety information available because part of what we discussed is that it is very difficult to get that kind of proprietary information that companies have available, they don't want to share because if they put it out, even if they paid for all the whole animal studies, they don't want him to go over and use your product insert where he never paid for any of the stuff and just used it on his product.

So, it is going to be hard to get that without somebody else doing the studies.

DR. GORDON: How did your group deal with safety issues, what were your thoughts?

MS. GUTIERREZ: We didn't resolve them, but we did list them, which I listed earlier, the drug, herbal, over-the-counter interactions, the contamination, the dosage ranges, the red flags for pediatrics, pregnancy, ethnicity, and so forth.

DR. GORDON: So, it would be very similar except one would be in a web site format, the other would be on-site at package insert, so you would basically agree with each other about the kind of information.

MS. GUTIERREZ: Yes.

DR. GORDON: Go ahead, Joe.

DR. FINS: One of the things that we talked about in our group was that the presence of an insert would not be construed as an endorsement. You know, it is a kind of DSHEA-like prohibition on putting certain things in there because it looks like you are endorsing, and it looks like a package insert in a drug, but a supplement could have an insert and still not be a drug, and still be just a supplement.

DR. GORDON: Right. Other thoughts?

DR. WARREN: Maybe it's off the subject, but what about funding for determining what analysis or what diagnostic procedures are valid and what their accuracy is, what lab tests are valid, is hair analysis good, is parasite analysis good, what percentage accuracy do we obtain from those tests, and put those out?

DR. GORDON: I think the putting out is part of this committee. I think the whole issue of diagnostic tests is one we have to look at on the research, when it comes to the research panel, but I hear you, I think that is an issue we have not really dealt with on either side, either on developing research on the diagnostic tests or on putting out information.

I think we have to develop some research, as well as put out the information. Thank you.

Other issues that have come up, that came up in the discussion? Yes, go ahead, Effie.

DR. CHOW: I just want to expand a bit on what David expressed and what Charlotte expressed and what has been in my mind is that I would just caution us not to emphasize too much of the negative. I know we need to have rigor, I know we have to be cautious, and I would be cautious as to being too negative on our practices.

Do you know what I am talking about? David, you expressed, well, in that essence, your attitude affects the effectiveness of the complementary alternative medicine, the mind-body concept, the energetics, it affects it, and I think I would like to put that out in front and be aware.

It is the enthusiasm oftentimes and the enthusiasm and the hope that the person gets, and the exposure to something new and looking at it as a quote -- a lot of people don't like to use this word -- but "miracle-like happenings." I don't want to lose that embodiment in this whole philosophy.

DR. GORDON: How do you see, in this context, providing information? How do you see keeping that perspective there?

DR. CHOW: I think we need to put out the positives even if it is not rigorous scientifically oriented, and I think that is where we need to look at -- what do you call it -- evidence base, whatever it is, and that time Wayne Jonas said evidence base because that meeting we kept saying evidence base, we have to have evidence base, and then he finally established, he said what is evidence base, he said even acknowledging that, it is what I think works, what my experience worked, and what the person's experience worked, and then as long as it is acknowledged, where the information came from.

DR. GORDON: Part of the answer -- and I wonder, David, Dean, what you would think about this -- part of the answer is putting out much more, much more complete, and a kind of humanistic, as well, in scientific information about mind-body approaches.

DR. CHOW: Exactly, exactly.

DR. GORDON: And the whole notion of not only of placebo, but of taking control of one's own destiny and doing things that one believes in and the positive effect that can have.

DR. CHOW: And then also we generally talk about placebo as being very negative. If it does work, we need to take a look at placebo from a positive standpoint rather than from a negative standpoint.

DR. BRESLER: Again, I was reluctant to bring up this issue because it is a can of worms, but I know that there is something most powerful in the therapeutic relationship that is above and beyond the information part of it, and I know that -- it is interesting, a patient said this to me the other day.

They had a little bump on their body, I call them "nebulomas," little nothings that show up on your skin, but they went to their dermatologist. They were very concerned because they had a history of melanoma.

He went into the dermatologist. The dermatologist took a quick look and said, "Oh, it's nothing, don't worry about it." And that was so healing, so therapeutic. They could search the Internet up and down, one side or another, and never get that kind of therapeutic benefit.

It is above the information that we have to preserve something.

DR. GORDON: The question in this context is how do we bring that in, or any recommendations we may have about information.

DR. BRESLER: I think we have to think about this a little more.

DR. GORDON: Go ahead, Joe.

DR. FINS: One way to bring it in is to appreciate the anxiety that often motivates all these Internet searches, in other words, we have presumed a rational model. You have got a problem, you are looking for information, and you are somewhat disembodied from your own self, but the reality is, is that people are psychologically very, very troubled when they are going on the Internet looking up nebuloma, because Dr. Bresler had said you have got a nebuloma, and they are scared out of their mind about it.

I think when we approach this, I think we have to be aware of the fact that the Internet is not a health care delivery system and when people do this, it is a cry for access, it is a cry for compassion, it is a cry for touch. So I think we don't want to get overly rationalistic about it because people still need their doctors, they need to be well informed, they need to have information to make good health care choices, but we need to remember that a lot of this behavior is a reflection of the fact that 40-plus million people in our country do not have primary health care.

DR. GORDON: Conchita.

DR. PAZ: Sometimes I have people come into my office with a big sheet of paper saying, "Doc, this is what I got, I know it. All my symptoms fit this thing." And it is something that we have probably looked at in the past, but it doesn't come close to being what is truly there. So, you are right. A lot of that has to do with actually having them come in and letting us talk with them, examine them, and go from there.

DR. GORDON: Other thoughts?

[No response.]

DR. GORDON: I know it is still early in our meeting.

This is great. These recommendations, it is pretty clear, it is pretty straightforward, the kinds of recommendations, the kinds of issues that we are dealing with.

The process will be, at least this is what I think the process will be, is that we will take, the staff will take these recommendations and some of the other issues that have come up, and over the next couple of months, we will be getting back to everybody with what we put together, and then there will be another time and another go-around to take a look at some of these issues.

One of the things I just want to remind us of is that we don't have to have everything settled by the Interim Report, so it is good to think about, there are going to be a number of issues that we are going to think about more.

Our goal for the Interim Report is to find a small, significant, and not too large number of issues and recommendations that we want to make, that there is basically a consensus about, that we all feel can be moved forward.

So, this is a very good day. Did you want to say something, Effie?

DR. CHOW: I have a question. Is Wayne coming in?

DR. GORDON: I'm sorry, I just got a message telepathically -- I just got a message from my office. There was a kind of minor family emergency, and that is why Wayne hasn't been able to be here, I'm

sorry. He will be here tomorrow.

DR. CHOW: Oh, okay.

DR. GORDON: Thank you for reminding me. He is fine. He is well. He apologizes and he will be here tomorrow.

Thank you all very much. It has been a really good day. Everybody has worked very hard.

George, did you want to say something?

DR. BERNIER: I wanted to say I thought this was probably the best meeting we have had, and if you try and dissect it, I think we got much more out of our panelists, much more interaction among the panelists than we had in previous ones, and would like to congratulate the staff on doing a really great job.

DR. GORDON: Great, yes.

[Applause.]

DR. GORDON: So, let's adjourn to dinner. We will be back here 8:15 tomorrow morning.

[Meeting recessed at 6:10 p.m., to reconvene 8:15 a.m., Friday, March 27, 2001.]

+ + +