some linkages to sort of tie in with them, looking at ways to help people make these choices.

They looked at how people comply with generic medications, not CAM modalities, and it was really problematic, the level of understanding people had, which is just another issue that I want to just harken back to.

On Recommendation 1(b), you say conduct a public education campaign. It teaches people how to evaluate CAM information. It brings up the issue of scientific literacy. We should be focusing on education. This again may be an area where this administration, focused on education, might be consonant with that, because people need the basic skills to make these determinations, especially if it is about self-treatment and about wellness, and doesn't involve the intermediary of a professional practitioner. So, I think that might be another linkage area.

DR. BRESLER: Other comments? Tom.

MR. CHAPPELL: I am trying to imagine how this information delivery occurs to some of these special groups that we are talking about, and I don't think we want more literature piling up in government offices or government buildings.

These populations don't necessarily use the Internet, so my question, I am thinking how does CAM become real to them. I am thinking about people who go out and just promote and educate about CAM in rural communities.

These are ombudsmen or advocates or they are teachers, but they are promoters of this, and on any of these issues, whether it is 7 or 8 or 6, you know, it would be great to have countywide people whose job it was to go into the school systems or wherever they might go and educate.

DR. BRESLER: Again, we do this on certain public health issues like HIV, don't we? When we have certain public health concerns, we do have public health educators who go into the rural communities, into school systems, other kinds of places.

MR. CHAPPELL: Great, perfect model. I think it needs something like this, because it has to be made real, and too few of us can read something and get it. I mean it needs to be engaged.

DR. BRESLER: Other comments? Joe.

DR. FINS: Thinking about Tom's desire to do stuff with the marketplace, I mean pharmacists are probably very close to where a lot of this information would be really relevant. Maybe we could have some -- maybe Steve could comment on this -- but some sort of educational program for pharmacists, with the Pharmacy Association, so that they also become educators, especially about drug interactions and the like.

DR. GROFT: I know the pharmacists are definitely interested, and they have initiated some programs to start to educate the practitioners more and more I think. Tyrone has been a very avid supporter of doing this for botanicals, and I expect to see this increasing more and more as we go on.

DR. BRESLER: We have about 20 minutes to finish our discussion this afternoon. We still have a lot to cover.

Effie, and then Jim.

DR. CHOW: I was looking up there for indication of grocery stores, you know, like for populations, specific racial, ethnic, cultural populations, limited literacy skills.

The schools, what about the schools, dissemination of information through the schools, and the churches, the grocery stores, public areas?

DR. BRESLER: A lot of that will be covered in the wellness discussion tomorrow about getting to the schools, and so forth.

DR. CHOW: Oh, I see. Okay.

DR. BRESLER: Jim.

DR. GORDON: I just wanted to say that I think this is really a very important area, and again this is one of those areas that we should be focusing on with specific recommendations in October when we come back to it, if we can enunciate a few general principles here.

The other thing I just wanted to share with people, and I will be happy to talk more about it later, in Kosovo, where sometimes it seems easier to spread information about CAM and self-care, we are doing this, we are working with all the mental health professionals in the country to teach people skills of self-care.

So, it is possible to do, and it is a very interesting process, and I would be happy to talk more about it in October or any other time.

DR. BRESLER: Charlotte.

SISTER KERR: This really follows up on what Jim is saying, but I had put in a comment to someone that I still think we need to hear more from CDC, and this is maybe October, but I think it is all fitting in with this and still a part of the public health piece.

DR. GORDON: Charlotte, can you just say just in a moment what you would like to hear from CDC on this issue?

SISTER KERR: Well, I would like to hear -- I have not heard, and I don't know if I missed it in the thousand speakers, but I did not hear clear claiming by the public health community of how they were relating to CAM, and the language for my opinion from the public health, treating the body politic, and the historical framework of what public health is, is in my opinion CAM, the original CAM.

CDC is exciting, a lot is going on and the world has changed about what that is, and we need to hear from them. I think they have got some good new ideas.

DR. BRESLER: Other comments? Wayne.

DR. JONAS: I find myself wondering how all these other recommendations would be implemented other than to say, gee, you all ought to do this, and if there is going to be a central source for providing this information.

Perhaps it should be more than just a clearinghouse of information, but should be something that is actively developing with these various groups information and communication efforts through these various modalities, which would be much different than what our current models of clearinghouse in the federal government are like.

DR. BRESLER: But are there other precedents like the way that the HIV campaign was coordinated between various agencies and the private sector?

DR. JONAS: Yes, I think there are some models that are, in fact, more than what your standard clearinghouse is like, and that is actually one of them that we could look at as examples for developing this.

DR. BRESLER: Good. Other comments?

DR. GROFT: I think one thing to remember with information centers or clearinghouses, it depends on what you define as their role and their task, and you put that in the contract, and that is what has to get done.

I look at what a number of the institutes have done as far as producing fact sheets, and they are very, very good fact sheets on various disorders. I think it is a matter of just extending that out into what you want and what an office wants who is going to support that activity. Then, you get what you want.

DR. JONAS: I agree. Again, NCI is another example where they provide much more dynamic interaction and public information than simply a clearinghouse.

DR. GORDON: One of the things I would ask, Steve, is if you and the staff, with help from Wayne and others, can pull together some examples of the best practices that can help us see where we need to be headed with this.

DR. BRESLER: I would like to make sort of a global suggestion. Would it not be appropriate as this particular office is being designed, that that office not be empowered to do all these 10 things right here on this list, to bite off the question, do we want to set up a standards panel to evaluate Internet sites? What about the accuracy of information?

Maybe this is the charge of such an office, to be able to handle these particular kinds of issues.

Comments? Tieraona, Tom.

DR. LOW DOG: Yes, if they could handle it, I think that is a great idea, and I would just like to go back to the Issue No. 1.

There is a typographical error there that basically said no site will not be required to have a rating.

DR. BRESLER: That is a typographical error.

DR. LOW DOG: Right, but that changed a lot of things for me. No site will be required to have a rating is a totally different thing, and I actually support that. What you are saying there is it is voluntary, the site can put it on if they meet the criteria, and I just wanted to say that earlier, that was a big problem for me was because it seemed like you were saying every site had to have this rating, and I was concerned about that.

So, if you are saying it is voluntary, you meet the criteria, and you want to put that rating on your site, because you are making a higher standard of information, I am in full support of that.

DR. BRESLER: That was the intention.

DR. LOW DOG: I just wanted to go on record with that. Thank you.

DR. BRESLER: Quickly, Tom.

MR. CHAPPELL: I would rewrite all of these starting with No. 3, the creation of the center, and then I would subsume all of these as acts and roles of that center.

What that does, again, it reduces the number of recommendations we are trying to make here, which I think is also a goal.

DR. BRESLER: Can we look for consensus here? How do people feel about this as a position for us? Let me just ask. Any objections to it? Wayne.

DR. JONAS: Let them try.

DR. BRESLER: Comment, Joe?

DR. FINS: We are not talking about the Central Office and the Office of the Secretary, we are just talking about a central office.

DR. BRESLER: In the government.

DR. FINS: Okay.

DR. BRESLER: Comments about this, Wayne?

DR. JONAS: Just one other item on page 9, at the top, again, looking at land mines and red flags, verify CAM information in a timely manner and facilitate balance report, and often by providing referrals to experts in different areas of CAM.

I am on page 9 of the report.

DR. BRESLER: No, we are not looking at that one.

DR. JONAS: So, I will save that until tomorrow.

DR. BRESLER: Yes.

DR. JONAS: Okay.

DR. BRESLER: Can we move on in the little bit of time we have left to discuss the second issue, which is concerns about information that comes through advertising, marketing, and labeling, and we have bitten off four issues here

Did I skip 9 and 10? I thought those could be subsumed under the office. Was that the general intention?

DR. GORDON: I think the general intention is to subsume under the office and that we may well have more discussion in October of some of these issues, but we have a kind of structure that you have established at this point.

DR. BRESLER: So, let me just open. I hope everybody has read these recommendations from your briefing book about our concerns about information that comes through - advertising, marketing, and labeling. Again, we have already discussed DSHEA, so let's stick with these other issues.

Comments from the Commissioners about this issue? Tom.

MR. CHAPPELL: I think the recommendation is well justified here, and the FDA has responsibility for the claim substantiating in the file with DSHEA, but the FTC has the responsibility of compliance.

DR. BRESLER: With marketing and advertising.

MR. CHAPPELL: Yes, with advertising. I think anything we can do to beef this up is great.

DR. BRESLER: Good. Other comments? Joe.

DR. FINS: While I totally endorse Issue No. 2, about the Spanish-speaking population, I think it needs to be also made more generic for other vulnerable populations. It is said there, but it really has a real focus on the hispanic media because we heard from Dr. Huerta back in March, so there are other populations that are equally vulnerable.

DR. GORDON: I have a question, and it is really just that. Are we content with the way the FTC is monitoring the fraudulent claims? I am not saying we have to answer this question now, but do we not want to take a look at what is actually going on and seeing if the monitoring is in line with our sense of how CAM claims or other unconventional claims ought to be monitored?

MR. CHAPPELL: It is woefully insufficient.

DR. GORDON: In what sense, Tom?

MR. CHAPPELL: The products and the claims that are going on out there, and I am not even talking about the Internet. The watchdog is just not sufficient. Actually, competitors bring claims against another brand, and then the issue is sort of negotiated and resolved lawyer to lawyer, and I am not really clear on what the FTC does to intervene and to seek compliance, but I do know that the amount of inappropriate claims that are going on out there is huge, and the best way to do something about it is for a competitor to complain, and even at that, it is tough, it's a long process.

We need teeth in the system.

DR. BRESLER: Bill.

DR. FAIR: But it would seem to me that as far as, if I understand this correctly, the clearinghouse, you know, if it is a false claim, we just don't even include it in the access to the clearinghouse.

My concern is not so much the false claims from the herbal products, but it is from some of the ethical pharmaceutical houses. I mean George and I were talking about this earlier. If you read the reports in the lay press during the meeting of ASCO, the American Society of Clinical Oncology, you would think that cancer was being cured next week, I mean the way these were coming out.

Gleevec, you know, it is the greatest thing since night baseball, well, the response is three months, for instance, things like that. I think that medicine has become such a business anymore, that the false claims are just not limited to people making false claims for herbs.

My thinking would be is include the good sites as links to this clearinghouse thing, and the other sites, unless you are prepared to go and do battle with them, just forget about them, they are not in the link.

DR. GORDON: What we are addressing here is the issue of the FTC, Bill. Do you not think the FTC should be prosecuting or disciplining people for fraudulent claims?

DR. FAIR: Yes, I do. Maybe I misunderstood. That is different from what we were talking about.

DR. GORDON: That is a separate issue from the clearinghouse and links.

DR. FAIR: Right.

DR. BRESLER: Tieraona.

DR. LOW DOG: I agree. I think that the FTC needs to be more aggressive in its review of many of these sites, or it is not even just the Internet, it's anything where there is false claims being made, but that is because it is illegal, and they should just be encouraged to step up their job, and then I think the clearinghouse provides good information, and I think they are just two separate things.

One is just saying that the FTC has done, in the Commission's opinion, a poor job for whatever reason, and in all fairness, this is a huge, huge, huge area. I mean I don't know how that one group could possibly keep up with it. Internet sites come and go just by the day, and it seems very hard to me. I don't have a good answer.

DR. BRESLER: Tom.

MR. CHAPPELL: We don't want to limit the recommendation to the Internet. I would be the Internet, mail order, and retail stores.

DR. BRESLER: Radio, the media.

MR. CHAPPELL: I'm sorry, I was thinking about the product, but you are right, all media.

DR. BRESLER: Other comments around this issue?

[No response.]

DR. BRESLER: The staff has asked me to express to you their interest in really being open to a lot of creative ideas about this information dissemination notion, and I think we can look elsewhere in our culture to get some good ideas. Think about the voter ballots, for example, and proposition issues where you have constituencies that have very vested interests in the outcome. Each present their positions in a very clear, supposedly unambiguous way to voters, and provide the voters with information on both sides.

Maybe on some of these controversial issues where the jury is still out, there is the opportunity to do a similar kind of thing, but I guess what we would ask is just open your eyes and look around, and see what other precedents might exist, and let's see if we can find a way to get really good, clear information out to the public, and also identify the information that is misleading or fraudulent.

Joe.

DR. FINS: I am just wondering if there is a role for the FCC and the FTC collaboratively and whether or not there is a way that we could sort of suggest that they have public service announcements related to CAM kinds of issues, the benefits, as well as the interactions.

DR. LOW DOG: The good, bad, and the ugly.

DR. FINS: The good, bad, and the ugly, but, you know, sort of if you are going to carry advertising, for example, that relates to drug supplements or something on the radio, then, you also have to carry a requisite amount of PSAs.

DR. BRESLER: Other comments on this issue?

DR. FAIR: Being from Florida, I will take the CAM chads.

[Laughter.]

DR. GORDON: I do have one question. Do we feel the FTC has the sort of appropriate guidance to be a good arbiter of what is fraudulent and not fraudulent on CAM sites or indeed conventional sites? That is a question.

MR. CHAPPELL: David, I didn't know if you were going to cover Issue 3.

DR. BRESLER: Yes, there were two other issues that I think we ought to look at.

MR. CHAPPELL: I don't agree. This is kind of a bleeding heart issue. I don't think there is an action here that we can do anything about, so I don't agree with the recommendation.

DR. BRESLER: We are talking about the way the deceptive practices can affect legitimate companies.

DR. GORDON: Could I just ask again that question about whether the FTC needs guidance? This is one of those areas where CAM expertise, just the way we have suggested for the FDA, that CAM expertise might be helpful in deciding on fraudulent claims.

DR. BRESLER: Joe.

DR. PIZZORNO: Speaking from experience, actually, the FTC does search out appropriate experts. I have been an expert witness twice for the FTC on fraudulent claims. The one that was mentioned, I took part in one of those. My concern is not that they don't access proper expertise, but looking at what it costs them to prosecute that one web site. They don't have the resources to do all this.

I think they are able to do it, and they are asking the right questions, but they don't have the resources.

DR. BRESLER: Effie.

DR. CHOW: How about the associations working, the associations and all the different CAM practices, and so forth, working with the FTC, et cetera, for aiding in the quality of information?

DR. BRESLER: In the hopes of generating a consensus for now, it seems to me and to Corinne that we could include No. 3 under No. 1, just subsume it under No. 1 and however those fraudulent claims are handled, by whatever regulator agency, if there is an impact on other providers, let them deal with it.

Since we don't seem to have a consensus on it at the moment, can we just subsume it under 1 and drop it off the list? Does anybody have any concerns about that? Tom?

MR. CHAPPELL: My concern is that I don't think the government should be providing funds for damage in the marketplace. This is just life, you know.

DR. BRESLER: I don't think it says that, Tom.

MR. CHAPPELL: You don't think it says that?

DR. BRESLER: No.

MR. CHAPPELL: Okay. I thought that is what it said. It says to provide adequate funding --

DR. BRESLER: To explore the impact.

MR. CHAPPELL: -- to enforce current requirements.

DR. BRESLER: It seems to me it could be

subsumed under 1.

MR. CHAPPELL: Okay.

DR. BRESLER: And we don't have to waste our time on it.

Does anybody have any concerns about doing that?

DR. JONAS: I have a slightly different issue.

DR. BRESLER: Is it related to the deceptive advertising issue?

DR. JONAS: Well, it is in a sense. It was more of a general comment. Michele pointed out that one of the things that I had requested earlier in general, but also this is a good example, is for us to get more information about which agencies would be responsible for these different activities. For example, advertising, marketing, labeling, et cetera, those are all dealt by different agencies, and they have specific mandates in those agencies, and to know how to go about doing that, and then facilitate that process, I think would perhaps be useful.

Again I am not exactly sure how this would perhaps be any different than what a coordinating office that was responsible for these types of things in the area of information might do. I mean the process would be I think similar in the sense of working with agencies in various groups that are doing this already to facilitate their addressing of CAM.

DR. BRESLER: Maybe the staff can help us get that additional information, so we can target our recommendations a little bit more specifically.

DR. JONAS: Did you want to elaborate on that, Michele?

MS. CHANG: No, that is pretty much what I was suggesting that we look at, but we are also out of time on this discussion.

DR. BRESLER: What do you suggest we do with this last issue about consumer information on CAM practitioners' level and scope of training?

DR. GORDON: I suggest we give it five minutes anyway, and then I will sum up very quickly, because this is a relatively easy session.

DR. BRESLER: Comments on No. 4?

MR. CHAPPELL: It's a good idea.

DR. GORDON: Yes.

DR. BRESLER: Is that the general consensus?

DR. GORDON: I see this potentially as a function of that central information source in the government. This is just the basic kind of information that everybody wants and needs.

DR. BRESLER: Comments on the part of Commissioners on this one?

[No response.]

DR. BRESLER: Well, thank you all very much.

DR. GORDON: Thank you, David, for moving us on. I think that in looking over these two large areas, which we moved through -- Tieraona, do you have something to say?

DR. LOW DOG: Encourage states and local governments to make information on state guidelines, requirements, and licensure of CAM providers readily available. Should there be, when you are looking at information because of what we were saying earlier about licensure and not licensure, should there be information available that if -- my patient has asked me before if you are unhappy with your massage therapist or if you are unhappy with something that happened, who are you supposed to contact.

They don't know who they are supposed to contact. If they have a grievance, who do you contact? Don't you think that is relevant information that somebody should know? If you are asking for all the rest of this, don't you think as a public service that they should just know who they are supposed to contact?

DR. BRESLER: A can of worms. Comments?

DR. PIZZORNO: I concur, because the states do have people for them to contact, and that should be a part of that list. It makes a lot of sense.

DR. BRESLER: Other comments?

[No response.]

DR. BRESLER: Jim.

Session Summary

DR. GORDON: In dealing with the issues of providing information, there was a general agreement that No. 3, having a central federal location for providing information of a variety of different kinds about CAM practices, products, practitioners, research, et cetera, is something that we developed a consensus on, and that that office or entity or clearinghouse will deal with virtually all of the other issues related to information as time goes on.

There was some I think as yet unresolved disagreements about the advisability, although a generally favorable sense I felt, once the grammar was cleared up, of having some kind of public/private venture that would issue or create certain kinds of standards to which Internet sites and other sources of information could voluntarily ascribe.

Is everybody with me on that, that syntax? That there is a sense that that would be a very useful thing for us to do, and we may want to talk more about this tomorrow, as well, when we come to the recommendations, because that is one of the recommendations, so I would urge everyone to look at that one.

It is also clear that there is a significant need for the provision of information to the public beyond any kind of centralized web site and beyond any kind of code of ethics and standards for Internet sites and other media sources, that there needs to be a significant activity and outreach to the public, and a variety of different means are suggested including the use of libraries as a way to reach people, perhaps public service announcements, that there be an emphasis on both encouraging working somehow -- and this is kind of vague at this point -- dealing with the issues of both literacy and scientific literacy, and helping people to think through the kinds of decisions that they are making at various points of contact.

Schools were mentioned, pharmacists were mentioned, grocery stores, as well as libraries, and we made a commitment, and the staff made a commitment to help us identify some of the ways that information has been provided to the public about other kinds of public health issues, in particular the way the NCI provides additional information, the way information has been provided to the public about HIV and other health concerns.

I just want to emphasize this again, that this is an area in which we can use our imagination and that we really may be able to make a significant contribution to improving public health, particularly through techniques of self-awareness and self-care, but not just limited to those approaches.

When it came to issues of advertising, marketing, and labeling, there was a strong consensus that we both concur with the FTC, with the location of responsibility for assessing claims, that that be in the FTC, that we support the FTC in its efforts, that there is a sense from those of us who have been involved in those efforts that they are responsible, that they do make use of information and insights provided by CAM professionals, and that the main difficulty is taking a look at the vast number of sites that are providing fraudulent information or may be providing fraudulent information.

As Bill pointed out, this issue is not just limited to CAM, but this goes across the board in the provision of health information. Again, I think this may be an area that, as time goes on, we may want to make a statement about it, a general statement, and then we may want to make some more specific statements about the kinds of standards that we would recommend as an independent body to the FTC.

Also, there is a sense of the need for

interaction between the federal source of information and sources of information at the state and local level, and that this may be a very good area of coordination, not only in terms of providing information about practices, but also about providing information about the recourse that consumers can have, both to find out who is available, what kinds of practitioners are available to help them, and also should there be, if you will, adverse events with these practitioners, ways to report these events to a responsible body.

Anything else? Are we okay?

[No response.]

DR. GORDON: Wonderful. Thank you, thank all of our facilitators, as well as the staff.

[Applause.]

DR. GORDON: We have some changes in tomorrow's schedule. The main one is, we will be beginning at 4:30 a.m. instead of 8:00

[Laughter.]

DR. GORDON: We will be beginning at 8:00 tomorrow. What we have done, in order to allow more time for discussion of the Interim Report, is to make a few changes, taking off a few minutes here and a few minutes there in some of the other discussions.

This is the schedule. We will be starting at 8:00. Again, I really appreciate the attention that everyone has paid to the material that has been handed out. Tomorrow, again we will be going over just the way we did today with the facilitators, going through the material, and looking toward the big picture and looking toward issues where we have consensus, as well as those we need to address further.

Then, we will have over two hours to take a look and to talk about and to address both the style and the recommendations of the Interim Report. So, please take a close look at that, so we will all be ready to discuss that one tomorrow afternoon. At the end of the day tomorrow, we will have time for public comment.

Thank you, everybody. See you tomorrow morning.

[Whereupon, at 6:30 p.m, the meeting was recessed to reconvene the following day, Tuesday July 3, at 8:00 a.m.]

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CERTIFICATION

This is to certify that the attached proceedings

BEFORE THE: White House Commission on Complementary and Alternative Medicine

HELD: July 2-3, 2001

were convened as herein appears, and that this is the official transcript thereof for the file of the Department or Commission.

DEBORAH TALLMAN, Court Reporter