OFFICE OF DIETARY SUPPLEMENTS

PUBLIC MEETING

May 20, 2005

Bethesda North Marriott Hotel &
Conference Center

North Bethesda, Maryland

2:30 p.m. to 4:15 p.m.

[PROVIDED TAPE TRANSCRIPTION]

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I N D E X

P R O C E E D I N G S

DR. THOMAS: I'm Paul Thomas, a scientific consultant with the office. I'm sure I can't be more than a nice moderator as Dr. Coates was. I can only hope to be equal to the task but now let's change gears a bit.

We're now going to hear from several of our stakeholders. They're the ones who answered our general call for an opportunity to speak at this meeting and I think we have now four presenters, including several from the supplement industry, as well as academia. Unfortunately, I think we lost our health care provider from New York City.

Well, the order in which they speak is going to be the order in which they actually contacted us to ask to speak with a couple of exceptions to account for the fact that some people need to catch a flight home a little early.

Now here are the rules briefly for this part of the session: Each presenter is going to have five minutes for their remarks. And on our color timer I think it's set up so that the yellow light will come on at four minutes and the red light when the time is up.

And like before, for this part again only ODS staff will be able to ask questions after each

presentation but the rest of you hold on, please, because you'll have an opportunity to give comments and ask questions at the end.

Okay. We are going to start first with Paul Bolar. Mr. Bolar is vice-president of regulatory affairs for the supplement company Pharmavite, LLC, in North Ridge, California.

PAUL BOLAR

MR. BOLAR: Good afternoon. My name is Paul Bolar and I'm vice president of regulatory affairs for Pharmavite. We're in the Los Angeles area and we've been in business for about 34 years. We make a wide range of dietary supplements and vitamins, herbals and botanical products.

We commend the ODS on their progress in furthering research on the benefits of dietary supplements. In recent years the office has made significant progress on this key objective. I'd like to focus my comments today on the office's "IF" major strategic goal, which is to expand and conduct outreach activities that inform and educate the public, health care providers and scientists about the benefits and risks of dietary supplements.

As identified in this goal, the ODS has an important and a unique mandate to serve as an authoritative impartial information resource for

consumers, health care professionals and the media regarding emerging scientific issues related to dietary supplements.

Unfortunately, from our vantage point, as a member of industry, ODS generally maintains a low profile with public audiences at the most critical times when breaking news on dietary supplements is published and media and consumer interest is at its peak.

Now at the risk of sounding like a broken record, I'll again raise the example of vitamin E to illustrate my point. Vitamin E recently received tremendous media attention when its safety was called into question by the release of the Miller Meta-Analysis in November 2004. Much of the media ignored the substantial body of existing evidence, including IOM recommendations which confirmed the safety and efficacy of vitamin E. Despite the highly questionable validity of Miller's findings, many consumers were spooked by the distorted headlines and alarmist articles that appeared in the mainstream media.

The ensuing confusion and concern created by these reports resulted in an almost immediate 40 percent drop in vitamin E sales across all brands and channels and trade, and this remains to this

day. The net result is that millions of consumers who previously received the benefits from vitamin E supplements completely stopped taking these products. This outcome should be viewed in the light of the fact that significant vitamin E deficiencies in the American diet have been well documented in multiple studies, including the most recent NHANES study.

This single questionable study may have had more impact on the American consumer's perception and consumption habits of an essential nutrient than any other study and it has the potential to exacerbate an already serious nutritional situation. It is a perfect example of where ODS could have provided significant insights to health care providers, the media and millions of interested consumers. Unfortunately, the public heard little, if anything, from ODS on this issue.

Even today, six months later, the vitamin E fact sheet on the ODS website does not address the Miller analysis. Many consumers still don't know what to do with this information. The Miller study and the resulting media coverage is a prime example of why ODS needs to weigh in aggressively to educate consumers on the scientific process and consumers need to understand that neither the scientific

community nor the general public should view a single analysis as the definitive answer on a supplement's safety or efficacy.

Consumers need to recognize that more information and analyses are required and better understand how to put this information into perspective.

Unfortunately, the best opportunity for ODS to make a significant impact on the understanding of the media and consumers on this particular issue has passed. However, other opportunities will inevitably occur. When they do, we encourage ODS to take a more active leadership role and be on the front line weighing in with timely accurately information for public audiences who need to hear a balanced, unbiased, authoritative perspective on the latest science.

We, therefore, encourage ODS to embrace its fifth strategic goal by aggressively expanding its outreach and communication activities. ODS can and should inform and educate the public about dietary supplements and promptly provide a balanced perspective for consumers, health care professionals and the media on emerging scientific issues. In other words, establish ODS as a timely go-to source of well balanced unbiased information on current

issues that affect the public's perception of dietary supplements. To this end we would also encourage ODS to reach out to industry leaders and trade associations to develop effective communication approaches.

Thank you for this opportunity to comment.

(Applause.)

DR. THOMAS: Are there any questions from the ODS staff?

Okay. Then we'll move on to our next speaker who is Dr. Susan Moyers. Dr. Moyers is with the Department of Pediatrics at the University of South Florida College of Medicine in Tampa.

Welcome.

SUSAN MOYERS

DR. MOYERS: I do have a powerpoint here so if I could just clarify before I get started. I'm with the University of South Florida. We have a wonderful medical school but no football team to speak of. Our football team is up and coming as they say.

First of all, I wanted to thank Dr. Coates, Dr. Thomas and the Office of Dietary Supplements for allowing me to talk today about databases and also thank them for some wonderful and excellent work that they've done in the very short history of the

Office of Dietary Supplements.

Our organization, the Pediatrics Epidemiology Center, led by my boss, Dr. Jeffrey Cricher, functions primarily as a large data collection management, analysis and informatics center for a number of NIH funded prospective cohort and interventional studies. These studies involve conditions such as Type 1 diabetes, childhood cancers and diseases under the jurisdiction of the NIH Rare Disease Network. It is in this connection that we are here today with a recommendation that we hope will broaden the scope of services offered by ODS and foster collaboration, enhancing opportunities to include dietary supplements in interdisciplinary research.

At the Pediatrics Epidemiology Center we collect large amounts of data gathered by our foot soldiers, that is the study nurses and the clinical dietitians in the field, from food frequency questionnaires, interviews, dietary supplement questionnaires and other kinds of data collection instruments that are largely based on self-reported intakes. And as, I'm sure, no one in this room will be surprised to hear that increasingly our study participants are reporting the use of dietary supplements. In fact, some of our families report

the use of off the shelf dietary supplements in infants as young as two and three months of age.

A large percentage of our study participants, however, seem to be unable to identify the products they're taking clearly beyond the brand name or general product description. In our study we ask them to bring into the clinic their supplement labels, their supplement bottles. Typically they don't remember to do this. As a result, our research staff must often spend hours tracking down the ingredients of these loosely identified products, try to make a determination about how to code them within our data structures.

There is a pressing need for a database system that can rapidly capture, code and categorize dietary supplement products according to brand name and ingredient with perhaps the added capability of including a grading system for authentication of product constituents, uses and doses when that information is available.

The accurate representation of dietary supplement intake in a clinical trial is vitally important even if that clinical trial is not studying dietary supplements per se. As is increasingly clear, dietary supplements are emerging as important variables in our analyses of the

determinants and outcomes of many diseases. At present, as you know, ODS has made some very important advances to create supplement nutrient databases in conjunction with datasets created by the National Center for Health Statistics and plans to merge these datasets with existing food composition databases but thus far the planned efforts don't seem to meet the data collection needs of our large clinical trials.

One reason is that NCHS data is often limited to those dietary supplements that are actually reported by NHANES participants and we estimate that that's probably about 25 percent of the supplement products on the market.

A dietary supplement database can be modeled after databases that currently are used to catalogue medication. What you see on this slide is from a system called RX-NORM which is used by the National Library of Medicine to catalog prescription medications. Each product is given a unique code that is never duplicated even if the product is discontinued. This model captures relationships between brand name ingredient and ingredient strength so that users, our study nurses and clinicians could query from the generic to the specific and vice versa.

Here's another screen at the bottom of this screen-- I don't know if you can see the tiny type-- is that unique coding number that is always tied to that particular product so we can always track that product in this particular system.

Whatever model is adopted for a supplement database for the Office of Dietary Supplements, it is important to ensure that a central data source is made available using good information management practices and is accessible to research throughout all the NIH clinical trials.

Further detail, including data and resource requirements, are being submitted as addenda to this presentation. We believe that a central accessible free of charge up to date data system for capturing product and brand information will enable research communities to better incorporate dietary supplement questions in their research instruments, will enable data sharing across all clinical trials, and will facilitate the understanding of the role dietary supplements play in the determination of disease and health outcomes.

Thank you very much.

DR. THOMAS: Thank you, Dr. Moyers.

Are there any questions from the ODS staff?

Okay. Our third speaker is going to be Dr.

Haidi Zhang. DR. Zhang is a research associate professor in the Department of Pharmaceutical Science at Long Island University in Brooklyn, New York.

HAIDI ZHANG

DR. ZHANG: First I would to thank the organizers for granting me this opportunity to present here and the big issue I would like to discuss today is the research of dietary supplements (inaudible). And dietary supplements can prevent (inaudible) and they can also (inaudible) treatment of (inaudible). My research (inaudible) and also (inaudible) international (inaudible) is the three institutions in China (inaudible) collected effective supplement formula in a clinical case. I would like to share some (inaudible) here.

I visited a hospital (inaudible) in Beijing, China and I was surprised by the effective treatment approach on the patients at this hospital. Over 80 percent of patients (inaudible) and has recovered significantly after six months to one year of supplemental treatment (inaudible).

Since the time limit I'd just quickly show you (inaudible) different--the before and after treatment (inaudible).

Yes, this was (inaudible) after

(inaudible). You can see (inaudible). This is a (inaudible) patient here after seven months. (Inaudible).

DR. : (Inaudible).

DR. ZHANG: No, this was, you know, severe damage of (inaudible) after (inaudible) months. After the more than one year treatment (inaudible).

This patient is 60 years old. (Inaudible). So you can see the (inaudible) of this (inaudible). So we think (inaudible) not only can (inaudible).

So I would ask the question why, you know, (inaudible). What they did? And I was (inaudible) and they treated the patients with the same group of the combination of the (inaudible) and they ground (inaudible) into powder and mix it with the honey so like the patient would take every day during the period of treatment and also (inaudible) the treatment (inaudible).

In the point of view of (inaudible) the principle of the (inaudible) by the supplement is the promoting a lot of the (inaudible) and the (inaudible) but that in a point of view of (inaudible) of the joint (inaudible). The second issue (inaudible) material (inaudible). They needed that (inaudible). And also (inaudible) the function of the (inaudible) and also the

(inaudible). So all of the systems involved (inaudible) those supplements.

(Inaudible) treat a problem in (inaudible) body is the public but it is also people. It's (inaudible) not the material, the (inaudible) the genes. And (inaudible) accountable number of the compounds (inaudible).

So in the tradition of--sorry. So in the tradition of (inaudible) medicine they have the (inaudible) they already (inaudible) the nature of (inaudible) and that they (inaudible) in the human body. So (inaudible) relationship there but since the limitation of the (inaudible) so they (inaudible) of this kind of correlation but I think they show.

(Inaudible) of technology. The highest throughput (inaudible) technology and the computer (inaudible) information technology can provide us the common interface and the language to evaluate the effect of the (inaudible) at the molecular level. So (inaudible) for the correlation between the human and (inaudible) supplements (inaudible).

Thank you.

(Applause.)

DR. THOMAS: Any ODS questions for Dr. Zhang?

Okay. Thank you again.

Now we'll move on to a very familiar face, Dr. John Hathcock, who is the vice president of Scientific and International Affairs for the Council on Responsible Nutrition right here in D.C.

JOHN HATHCOCK

DR. HATHCOCK: I've got some powerpoints even though it's short and sweet. I usually know how to run these myself but this is two screens further back than I'm qualified to work. Of course, a man my age can get by with it. We're not supposed to know which end of the computer is up. My wife always tells me I don't know which end is up. Thank you.

I'm going to make this short and sweet. It's going to be to just one major point as we'll see.

The central point is that ODS's accomplishments are considerable in several primary goal areas but performance is inadequate in my opinion in one and, I believe it or not, I'm going to tell you which one that is. Okay.

(Laughter.)

Five major goals to their strategic plan. Expand evaluation of dietary supplements; doing a pretty good job there and it's certainly

appropriate. Foster research, number one; that's certainly appropriate and doing a pretty good job. Stimulate research at biochemical and cellular level; that's appropriate. Develop methodologies for ingredient identification characterization, ingredient and/or product characterization; that's appropriate. Expand and conduct research outreach to the public health care providers and scientists. This is what you've been hearing most of today. This is an appropriate general charge but there are some components, I think, that are missing in action so I'm going to tell you which ones those are.

Certainly the place to start in finding out what you should be doing is here. The ODS has a mandate under DSHE (ph). I've noticed that speakers this morning have used that word "mandate." It is a law. It is a legal requirement and it not only established the office but it also laid out the duties of the director. Conduct and coordinate research on dietary supplements at NIH. Collect and compile research from foreign sources in conjunction with Office of Alternative Medicine.

Then, number three, serve as the principal advisor--emphasis is mine in red. The original publication law did not have red ink in it--to the Secretary, Assistant Secretary for Health and advise

Directors of NIH, CDC and the FDA Commissioner on issues relating to dietary supplements, including the four below. And those four issues are the usual ones; that's appropriate. And compile a database on dietary supplement research and coordinate funding. All that sounds well and good but I'm going to emphasize what it is that's missing in action in red there.

The actions--advisory role was implicit in some ODS scientific conferences, that is--laid out--I've just chosen the Vitamin E one because I attended that myself very recently--I attended another one recently. And those outcomes--those reports can be seen as advisory.

I think with the law being written the way it is ODS should posture that as advice. Lay it out and call it advice. Call--hold a press conference and call it advice and send it to those five people listed. The Secretary, Assistant Secretary and down the list that you saw a little bit ago and tell them this is our advice to you.

I believe that those people listed in the last point here should also take it as advice. I didn't say they should do exactly what it said but that's the way advisory role works. And certainly with our rule making, notice and comment rule making

by citizens and all interested parties are, in fact, advisory from the citizens to the government about what it ought to be doing. So this is what I think needs to be expanded, enhanced and embellished.

My conclusions then are that most ODS goals are appropriate. The advisory role mandated by DSHE should be clearly incorporated into the strategic plan and the advisory role should be an important component of ODS priorities and actions.

The groups that you should be outreaching that to, I note, are--include those that you've been discussing all day that most speakers have mentioned but certainly I believe that the--if I read the law correctly there is no mention of ODS outreach to the public. It's not mandated by DSHE but the advisory role is but I find a large emphasis on one and no emphasis on the other and, therefore, I'm advising you to change this a little bit.

Thank you.

(Applause.)

OPEN DISCUSSION

DR. THOMAS: Very pointed advice and comments. Thank you, John.

Any questions?

Okay. Well, we started out with him as our first formal guest speaker, we are going to end with

him, Peter Reinecke, who again is the principal of Reinecke Strategic Associates nearby in Arlington, Virginia.

DR. REINECKE: It's not too often I get to play both lead off and clean up batter but I think I'll enjoy it and also argue that I should get paid more.

(Applause.)

I am going to read a statement on behalf of the Utah Natural Products Association with whom I do some advising. Loren Israelson (ph), who is executive director of the association, was unable to be here today and asked me to read the statement.

I will add as one matter that one of the first items I worked with the Alliance on was establishment of a policy that they made just a couple of weeks ago that as a condition of membership of UNPA that none of their companies may sell products containing ephedra at any dosage, including 10 milligrams or less.

Utah Natural Products Alliance very much appreciates the opportunity to provide its views at this meeting. We view the role and work of ODS as vital to the interest of the American public. We have regularly supported expansion of funding for ODS activities and will continue to do so.

Specifically, UNPA commends the excellent work ODS has been supporting to speed up development and dissemination of validated analytical methods and reference materials for botanicals and other dietary supplements. We share the view of ODS that precise, accurate and reliable analytical methods and reference materials are an essential underpinning of the successful implementation of the manufacturing practice standards soon to be promulgated by the Food and Drug Administration.

UNPA believes this activity should continue to be a top priority of ODS and urges substantial funding increases for this effort.

Second, UNPA urges ODS increase its support of research into potential health benefits of several specific categories of dietary supplements. There's great potential in the work being done on the relationship between fish oils and other dietary supplements in combatting anti-inflammatory diseases. This also applies to work being done on potential or selected botanicals to reverse the development of insulin resistance, the key pathophysiologic feature of metabolic syndrome.

Given the obesity epidemic we face, expansion of this area of research is clearly warranted. UNPA strongly supports continuation

and expansion of crucial work being supported by ODS on the health benefits of natural products such as black cohosh and traditional Chinese medicine on the health of women as they age.

Third, UNPA argues that ODS should substantially expand its support for research into herb drug interactions. We had a lot of discussion about that from a number of speakers today. ODS, NCAM and other ICs at NIH are supporting important work in this area and recent reports of this research highlights the need for increased focus and attention to the topic. Improved dissemination of results of this research to the public, health professionals and other interested parties is also needed.

UNPA believes that ODS should continue and expand its outreach to industry stakeholders to share information, gather ideas and assure better coordination of privately and publicly funded research. Today's meeting is an excellent starting point (inaudible) outreach effort.

Finally, and I don't believe this is a matter that should be taken up directly by ODS but maybe (inaudible), UNPA believes that consideration should be given to providing ODS with independent grant making authority. This has proven of great

benefit to the National Center for Complementary and Alternative Medicine and will provide additional capacity, flexibility and autonomy to ODS in carrying out its public mandate.

Again UNPA thanks ODS and its leadership for this opportunity to share its views and look forward to continuing to work with ODS and other stakeholders here today on these issues and others.

(Applause.)

DR. THOMAS: Okay. Let me just make one last call here. is Amy Salerno here or Robert Gregory?

Okay. Then that ends our set of prepared presentations and now we're going to have in the remaining time an open session whereby you have heard for several hours now comments, advice, criticisms about what the office is doing well, how it might be doing some things better, reorganizing some priorities, taking advantage of some emerging opportunities, et cetera. As you've listened to all of this I hope it has caused you to maybe have some questions and comments of your own and, if you do, we'd like to hear them.

And the way we're going to do this is we have two people who are actually, I think, now in hiding but they have--

(Laughter.)

Okay. They will have microphones and all you need to do is to raise your hand and I'll call on you and then they'll put a microphone in front of you. And the reason for this is because we are again recording this whole meeting. We intend to go through every word and every comment that you have so we want to make sure that we are getting it.

Please try and keep your comments/questions sort of with the theme of helping us do our jobs better here and not necessarily to sort of criticize or take issue with one of the speakers that you might have heard unless it's with the intent to sort of go from there and present a somewhat different point of view.

Actually, it turns out that several people had asked about the possibility of being the first questionnaires in the session so I'll ask if they still want to be so.

Etha (ph) Gaye? Is she here? You withdraw.

(Laughter.)

Okay. We do have Ann Fisher and Anna Walker with the microphones.

What about Jag Li?

DR. : We wore him out.

DR. THOMAS: Apparently so. He was actually from the U.S. Nuclear Regulatory Commission. I hope there wasn't any kind of problem or emergency that needed to be attended to that caused him to leave early. If so, I guess we'll know soon enough.

Please raise your hand. Any? Okay. And again even if you've had an opportunity to speak already this is still open session and you'll have another.

I think there's a gentleman in the center.

Also, if you could please tell us who you are and your affiliation.

DR. GUY: Hi. My name is Rolando Guy (ph) and I work for the State of New Jersey, the Department of the Treasury, and I had a question about what I had heard here about methods that people were suggesting about having analytical methods to evaluate the content of the dietary supplements. And one of the things that I had was we analyze all these dietary supplements using analytical methods, is there anybody who does any biological activity of these?

DR. THOMAS: Do we have a response to that? Dr. Staten (ph), do you want to respond to that? You need to get a microphone.

DR. : (Inaudible).

DR. THOMAS: Dr. Staten?

DR. : So now that you've identified me, do you have a question or was that your question?

DR. GUY: That was my question. My question was is there any way to do any sort of biological activity of these supplements to indicate that one preparation is the equivalent of a second preparation?

DR. : Yes, I would say probably by just sitting in on this meeting today you've missed--there's a whole other world of discussion about identification of biomarkers and cells and tissues in animals and humans to evaluate bioactivity of different compounds or different preparations so I think that work is certainly being done, right? I'm not--by many different--many different investigators in many different labs are working on those issues.

DR. THOMAS: And also some of the work at the Botanical Research Center as well on that.

We need to--I know this is a little awkward.

DR. : Thank you. Dr. Farnsworth's group over in Chicago is doing that

right now in regards to their black cohosh extract that is now commercially available. That's the tool they use to pass the product.

The one question I have or concern I have is I really think these biological activity assays are wonderful but we also need to make sure somehow we validate them so they are reproducible from lab to lab and not just unique to one particular lab setting.

DR. : Since I have the microphone in my hand can I raise a question or a comment?

DR. THOMAS: Yes.

DR. : I believe it was John had mentioned that he believed ODS needed a stronger role--advisory role and I fully am in support of that as well or believe that but I also think that when they do give advice it would be nice if it was publicly displayed so there is some accountability in my opinion because they could give advice and then people ignore it and nobody knows that they even gave the advice.

DR. THOMAS: Pay no attention to this red light.

Yes, Dr. Hathcock?

DR. HATHCOCK: This is not a follow up on my presentation. I'm John Hathcock from Council for

Responsible Nutrition. What I'd like to do is ask two questions and they might be directed towards any one of a number of speakers so, Paul, since you were first up and since you're the director, I'll let you field these. You can either do it yourself or have somebody else do it.

I keep hearing repeatedly not only here at an ODS meeting but in other professional circumstances as well the term "evidence-based review". It's widely used by the ODS staff, including today and by other speakers here, and I'd like to know exactly what it is, what that term refers to and how does that differ from other scientific reviews. Let's go there on that one and then I will have another question later.

DR. : I could turn to Anne Thern (ph), who runs the program, but let me make a very strong suggestion to you. There is a--the terminology "evidence-based review" does carry some specific kinds of features to it and the best description that I know of is on the Agency for Health Care Research and Qualities website where their section on evidence-based reviews provides that, in sum, it's systematic review, it's not a single person going through and selecting papers except using a set of very standard up front

identified criteria so it's a systematic review and I strongly recommend that those of you who are interested look at that website for a more detailed description of it rather than spend the time here.

DR. HATHCOCK: I have another question if I may and it's not related to that one. I notice in your list of activities that were handed out here today that ODS has supported comprehensive workshops, including one just recently this month called Nutrient Risk Assessment. It's listed as an ODS activity and when you go to the World Health Organization website it lists that same conference as a Food and Agriculture Organization/WHO activity. And I'd like to know exactly what role ODS plays in that project and how that's managed.

DR. : You just wanted to see that I got exercise. We sponsored through an interagency agreement with the National Institute for Environmental Health Sciences the initial working of an expert panel that met in Geneva earlier in the month. We did this. The NIEHS has an interagency agreement of its own with the World Health Organization to conduct expert panel reviews in areas that are broadly related to toxicology. We viewed this one as being related broadly to the issue of nutritional toxicology and so we in

accounting for it in our system we identified it as a conference that we supported but it was entirely a function of the World Health Organization and their usual planning process.

DR. THOMAS: (Inaudible).

DR. : Hi. I am (inaudible). I am known to change my mind so pardon me.

(Laughter.)

DR. : There are questions about biological activity, chemical markers, the biomarkers, all these issues are part of the supplement issues that we are all constantly grappling with. Now most of the supplements are herbal products and plant related products. Now these plant related products when they are brought about they are grown in various different areas. Most of them come from other parts of the world and, therefore, it creates a problem for quantification and identification and one doesn't even know what active ingredients are in those products to really chemically mark them.

Is there somehow the Office of Dietary Supplements can come up with some kind of a database to clarify that aspect as data is being generated and as knowledge is being generated so we can authenticate some of these herbal products.

DR. : Thank you very much for the comment and I'm glad that it will enter the record as a suggestion to us.

DR. THOMAS: Dr. Marriott?

DR. MARRIOTT: There was a lot--many suggestions about communication today and I wanted to underscore one that was made by Alison Rein. She suggested partnering with major organizations. I know there is some sensitivity to this but there's also precedent. She mentioned working with AARP and I would like to recall how NICHD partnered with the Dairy Council and the Milk Mustache Campaign that has been so successful in our country. So I would just like to underscore Alison's suggestion that this communication plan and effort doesn't really need to be done alone but there are lots of opportunities, I think, for ODS to leverage and partner with other organizations that might take the bulk of that financial responsibility.

DR. : Thank you.

DR. : I was going to address Etha's (ph) question about ID, plant ID. There are a couple of projects currently that ODS is funding to do this but it requires an awful lot of time and plants. I believe they're funding a black cohosh one currently. That's--they're going to survey, you

know, from all over the world and these types of methodologies are long-term and a lot more intense so their big focus right now is on the marker compounds since that's what people are making their label claims on at least from my dealings--I don't mean to speak on their behalf--which is a lot easier project to tackle but ID--plant ID is truly something that is beginning to get funded. It's just still difficult. How do you validate those methods when the plants vary so much? The standardized extracts have been what was used a lot in this industry but not traditionally as you know. So those are whole plants which vary from season to season, region to region. So they are trying to come up and fund some fingerprinting techniques but again validation of that is going to be the difficult thing to tackle.

Hopefully, I didn't speak out of term, Rick.

DR. BENINGER: John Beninger again from Virgo Publishing. I'm just curious. In the Federal Register notice about the meeting it talks about identifying new opportunities and emerging needs and possible additional directions that ODS should consider those types of things, all of which seem to imply new programs or new initiatives or expand it.

All of which seems to imply more resources or more money. And so I'm just wondering if--you know, we could probably come up with dozens, if not hundreds of different ideas and initiatives and really good things to do but there's only so much money and time out there so is--I mean, is there a big pile of money that's unspent so far or are we talking about, you know, in hopes of continually growing budget to implement some of these things or a reallocation of budget as other programs, you know, that are currently operating don't need the funding or, you know, how are we going to do these things.

DR. : I love these multi-part questions. They get me to say--let's see--no, no, maybe. So, no, there isn't an extra pot of money. And, truthfully, in terms of the budget for the office this isn't something that we control. We have to operate under a number of assumptions that include some growth to--if the NIH world is as I'm hearing it going these days there could actually--

(End Tape, Side A.)

DR. : --budget next year so we have to plan for that.

What it would mean is that we'd have to prioritize the ideas that we get from this meeting and from others and then make some tough decisions

most likely about reallocating resources so that's the no, no, maybe.

DR. THOMAS: Is there anyone else? Going once, twice. Are you sure? Okay. Well, one last thing I'll say is that as you're going home, as you're in the Metro, getting caught on the beltway over the next days or weeks, if anything occurs to you in relation to this public meeting and its goals or you would like to give us some information, advice or comments or perhaps even ask some questions, you have an opportunity to do that through June 30th. You just need to go to the ODS website or information in your book to contact us via e-mail regarding the strategic plan.

Wait. A hand is going up here and let's--

DR. : (Inaudible).

DR. : Wait a second. Wait a second.

DR. : (Inaudible). Hi. My question was (inaudible) all these presentations that you had today, are they going to be available on your website? Are you going to make them available so that in case somebody wants to refer to any particular slides or presentations that you-- that they could access those?

DR. : Yes. The answer to that

one is yes. These are the next steps and it includes what Paul Thomas just said that comments will be accepted between now and the end of June, a summary of the meeting and the comments will be available on our--and posted on our website beginning in July.

DR. : Including the presentations made by all the--

DR. : Yes. Yes, summaries of the meeting and the presentations.

DR. : Thank you.

DR. : That is a splendid segue to some closing remarks that I'd like to make and they are given here. There are next steps. This meeting was not in isolation. For those of you who have been with us for the long haul, these things have a life and this will continue. We learned a lot from the public meeting that we held prior to release of the strategic plan. Among the things that we learned from that meeting were we need to keep in contact with the stakeholder communities. This is another example of how we do that.

By the way, I can't help but make a small remark in this respect because as part of our listening we also heard that we needed to do a better job of dealing with our colleagues and

collaborators in the other federal agencies. To that end the ubiquitous Ken Fisher has put together a trans-agency working group on dietary supplements, which includes interested people from a host of NIH institutes. In fact, I think almost all of the NIH institutes. Several other HHS agencies, the Department of Agriculture, the Department of Defense, the National Institute of Standards and Technology and others, all of whom share with us interests in issues related to dietary supplement research. And it's, in part, our way of keeping the advice trail going and keeping it going in both directions or in all of the necessary directions.

So this slide shows you the next steps and this is just a reminder of where the website is. You can visit it at any time. We obviously welcome your comments. Particularly comments about the ODS strategic plan should be e-mailed to the address at the very bottom of the screen.

In closing, I wanted to make a couple of remarks. One is I really thank all of you for coming here and spending time with us and sharing your thoughtful comments with us. We knew they would be and we take them all very seriously.

You've given us and the ODS--all of the ODS staff much to think about and to consider and so in

that spirit, to all of the ODS staff who are here, all weekend leave is cancelled so that we can digest the information and begin work on these on Monday.

Seriously, we have--I have the great fortune to work with an awfully dedicated, highly competent and dedicated--and committed staff, and they can--I think the weekend is a good thing to have, don't you? But probably will be starting on Monday to digest this.

I also wanted to thank our federal partners who--some of whom are here at this meeting and we appreciate their participation. There were some folks from some of the institutes at NIH, from the FDA, from U.S. Department of Agriculture and others, and I think it's a measure of their commitment to the shared interests in dietary supplements that they listened along with us to this.

The last thing I wanted to do was just thank Ken Fisher because Ken is just an extraordinary man. We have profited immensely from having him involved with us in the Office of Dietary Supplements and this public meeting was something that he has spent long hours putting together and I just wanted to thank him on behalf of everybody for his efforts here.

(Applause.)

So to all of you, safe trip home. We'll look forward to keeping in touch with you and see you the next time.

(Whereupon, prerecorded tape transcription was concluded.)

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