Remarks of Peter Reinecke Reinecke Strategic Solutions Office of Dietary Supplements, National Institutes of Health 2004-2009 Strategic **Plan Public** Meeting May 20, 2005

Good morning. It is an honor to be here with such a distinguished group of presenters and attendees. Today's gathering really is a "Who's Who" in the world of nutrition and dietary supplement research. If this group can't figure it out, nobody can!

I want to thank Dr. Paul Coates, Dr. Ken Fischer, Dr. Rebecca Costello and the rest of the staff of the Office of Dietary Supplements (ODS) for calling this important meeting and inviting me to participate. It is a tribute to ODS as an organization that you are constantly seeking input and staying on the cutting edge of trends. I think many organizations, government and in the private sector, could take a few lessons from today's meeting. ODS has a solid 5 year strategic plan that it adopted after quite a bit of work just last year. But this is a rapidly advancing field, like so much of biomedical research, with lightening quick changes brought on by new technologies and new discoveries. So it is quite appropriate that ODS seek input now and on a regular basis on new directions and new approaches to carrying out its critical public health mandate.

Dr. Coates and Dr. Fischer asked me to spend a couple of minutes reviewing the history, from a Congressional perspective, of ODS before turning to the future. Well, for me this is all quite remarkable. I guess the best way to sum it up is this. We have come a long, long way. We have much, much more to do. But this field of the study of dietary supplements and natural products has taken exponential steps forward in a relatively short period of time. And everyone in this room should take some pride in their role in that achievement.

For it was just about 15 years ago that as health care staffer for Senator Tom Harkin, who had recently taken over as Chairman of the Senate panel that funds health, education and social services, I was asked to look into what the federal government was doing to look into the ability of what were then called "unconventional" therapies to help make and keep people healthy. At the time we were hearing anecdotal information about how use of these therapies was rapidly rising and helping some people. After some exploration, I reported back to my boss that there was some work being done through the Agriculture Department on vitamins and minerals and some limited research supported by NIH on individual therapies, but the volume and intensity of work was not commensurate with the level of use among Americans. In effect, in this area, the government had not caught up to the people.

In response, Senator Harkin wrote a provision into the next appropriations bill for NIH directing $2 million to create the Office of Alternative Medicine. The purpose of this new office was to investigate and validate alternative therapies being used by many Americans. As Senator Harkin said the purpose was simply this -- to let people know

what works and what doesn't. Americans were using these products and the government had a role to make sure they had reliable information to make informed choices.

In 1994, Congress was debating the role of the government in regulating access to dietary supplements. In a rare display of bipartisan unity, it passed the Dietary Supplement Health and Education Act (DSHEA) by unanimous vote in both the House and Senate. DSHEA set forth a new regulatory structure for supplements that was intended to preserve access to supplements while protecting the public from unsafe products. Another critical part of the Act was the establishment of the Office of Dietary Supplements. The overarching purpose of this new entity was similar to the Office of Alternative Medicine -- to make sure consumers and health professionals (and in this case government regulators as well) had access to the latest and highest quality scientific information about the health effects of dietary supplement consumption. In establishing ODS, Congress said research and education are essential and need more attention.

Well, a lot has certainly happened as a result of those two actions by Congress. What started as a $2 million investment in the OAM has risen to about $130 million NCCAM budget. ODS now has a budget of about $20 million and NIH is supporting well over $200 million a year in research into dietary supplements.

Over the years I continued to be Senator Harkin's principal advisor on these issues. As such I've had the opportunity to work closely with the leadership of ODS on a range of issues. I always found them knowledgeable, interested in the views of Congress, and cooperative in fulfilling Congressional directives.

But I have to say, in reading the materials prepared for this meeting, I was really taken aback by the breadth and depth of the activities that have been supported, are being supported and are being plarmed by ODS. It is truly impressive. And I think the actions are very much in keeping with what Congress had in mind in establishing the office. In my opinion, the new Strategic Plan got it right. A strong foundation has been built. The guiding principles are the right ones. Now the stage is set for even more substantial progress and achievement.

I see really three major interconnected roles for the ODS as it moves forward. All are vital to the public health - and I might add to a more cost-effective health care system in this country.

First, the office must continue to be the driving force behind an expansion of quality scientific research on supplements. This means giving direction, setting priorities, coordinating, leveraging and filling gaps in basic and applied research. It also means fostering the infrastructure and capacity of scientists and institutions to support the volume of quality research needed. Congress gave ODS the mandate of being this driver. That ODS has been able to drive the car while only paying for the steering wheel is a testament to a very skillful and talented staff.

Within this role, I would argue for an expansion of research into the most commonly used supplements and in the role of supplements in assisting with the major long-term challenge to our health care system - chronic disease and disability. When resources are limited, they should be focused on what supplements are being used the most and on where supplements can potentially have the greatest public benefit.

Also within this first role, I would argue for expanding ODS support for university-based botanical research centers and research training grants. We need to give our nation's top academic medical centers and our best and brightest students the incentives to commit themselves to dietary supplement research. And these two specific established mechanisms have proven effective warranting expanded support.

Of equal important to its first role, is the ODS responsibility to educate and inform - to make sure the public and the health professionals who care for them have access to stateof-the-art of knowledge about dietary supplements and their role in health promotion and disease prevention. ODS should be the "gold standard" of information on supplements
in terms of breadth, depth, timeliness, reliability and usability.

Again, a solid foundation has been built and I am very pleased that ODS has contracted out to get advice on how it can improve in this area. I look forward to learning the results of this effort. In terms of on-line resources, I would argue that there should be one website that combines the information currently contained in a number sites funded by ODS, NCCAM, NLM, other NIH ICs and USDA. I like the format of the fact sheets that ODS and NCCAM have co-funded and believe --at least for consumers -- that is the type of information that should first to "pop-up" when an on-line query is made on specific supplement or health condition.

Equally crucial is to make sure that consumers and health professionals know about the resources both on-line and not that ODS is making available. ODS needs to invest (in cooperation with others) in developing a marketing plan for its public information. How do we make sure the woman in Dubuque, Iowa knows there is a reliable place she can go to learn the latest and best information about whether she should consider black cohosh as an alternative to hormone replacement therapy? How do we make the family doctor in EI Paso, Texas who wants to answer questions about the health effects of herbal remedies used by his Hispanic patients a regular user of ODS information? This has to be a higher priority in the coming years.

A third vital function for ODS it to continue and expand its efforts to assure that government regulatory decisions are based on sound science and the most up-to-date and reliable information and methods. In this regard, I again recommend an expansion of existing ODS efforts.

First, ODS should at least double its support for the development and dissemination of reliable analytical methods and reference materials. A great start has been made, but this is an expensive and time consuming effort and we are really just scratching the surface. Given the impending release by the FDA of Good Manufacturing Practice standards for

dietary supplements, the timing is even more urgent for ratcheting up this process. This expanded role would enjoy widespread support in Congress and among the varied dietary supplement stakeholder groups.

Also within this third role, ODS should expand its efforts to maintain a database of dietary supplement labels. Congress directed ODS to take greater advantage of existing databases in the private sector and the office should move forward to carry out this directive. Such an action would be cost effective and greatly assist in government and private sector research and response to safety concerns. .

Finally, the use of evidence-based reviews such as those co-funded by ODS should be continued, expanded and refined. The evidence-based reviews are particularly useful in areas where difficult regulatory decisions are needed and where substantial bodies of research have been developed and major investments **in** large-scale trials are under consideration.

Obviously, I have touched on just a few of the many activities crucial to ODS successfully carrying out its mandate. I know others who will follow me today are much more knowledgeable and will add significantly to my presentation. At least I hoped to help what I am certain will be an informative and informed discussion of some very important public health issues today.

Again, thank you for inviting me to speak today and I look forward to listening and learning the rest of the day.