PERSPECTIVES ON THE STRATEGIC PLAN FOR THE OFFICE OF DIETARY SUPPLEMENTS

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I am pleased to participate in this public meeting to offer my perspective on the new opportunities and emerging needs for the National Institutes of Health/Office of Dietary Supplements (NIH/ODS) to consider incorporating into its Strategic Plan. I have reviewed the plan, the impressive binder of materials on the status and progress of specific ODS programs and activities, the ODS website and information resources.

More than ten years after DSHEA mandated the creation of an office of dietary supplements at the National Institutes of Health, it is apparent that NIB/ODS has been successful in capturing the Congressional intent of this landmark legislation. ODS has established itself as a respected and credible institution to strengthen knowledge and understanding of dietary supplements by implementing a significant number of diverse programs, activities, and events that focus on evaluating scientific information, stimulating and supporting research, and disseminating research results. ODS appears poised to expand communications initiatives to inform and educate the public about supplements.

With these supporting thoughts in mind, my overall theme is to suggest that ODS make more effective use of the fruits of its labor to benefit consumers, industry, and malnourished people in developing countries. My suggestions could be achieved by fine tuning the Strategic Plan with mechanisms and initiatives that weave together the threads of ODS' numerous activities and tap into the ODS reservoir of scientific and technical data and research results.

The NIH/ODS information and research results should provide scientific support to help supplement companies enhance product safety, manufacturing quality, product formulations and substantiate product claims. Likewise, ODS should make timely, useful, and accurate information available for consumers to choose and use supplements.

Finally, ODS should take a leadership role in encouraging the inclusion of supplements to help improve nutrition by eliminating vitamin and mineral deficiencies in developing countries.

I recommend consideration of three additions to the ODS Strategic Plan:

- Convene a Global Summit on Supplement Use for Improved Nutrition and monitor follow through
- Become the ultimate information resource and answer place on dietary supplements
- Stimulate consensus on key dietary supplement regulatory initiatives.

Convene a Global Summit on Supplement Use for Improved Nutrition and monitor follow through

Millions of people in developing countries, many of whom are children, are hungry and malnourished and the number is increasing. Malnutrition is recognized as the second most serious global health problem. Only HIV/AIDS is considered more serious. Indeed, both the House and Senate of the US Congress are establishing Caucuses to address global hunger.

A strong rationale exists for ODS to demonstrate that supplements can help eliminate vitamin and mineral deficiencies around the world. ODS has begun an international outreach with support to FAO and WHO in providing scientific advice and is participating in developing a framework for a globally-relevant nutrient risk assessment. ODS can expand its leadership role by encouraging the use of appropriate dietary supplements in nutrition intervention programs. The following points support the need for dietary supplements as a part of the nutrition package in developing countries.

- Hunger and malnutrition are recognized as major global problems affecting the health and well being of over 2 billion people, leaving populations vulnerable to infections, diseases, premature deaths, impaired learning, lower economic productivity, and providing a breeding ground for political instability and potential terrorism supporters.
- Micronutrient deficiencies of vitamin A, folic acid, iron, and iodine, among others, persist. The CDC website notes that:
  - Consuming adequate amounts of Vitamin A would prevent up to 2.5 million deaths annually among children under 5 years, and prevent over 500,000 cases of blindness a year.
  - 4-5 billion people in the world may be iron deficient which impairs intellectual development in young children.
  - Iodine deficiency is the most important preventable cause of brain damage in developing countries and iodine deficiency is causing as many as 20 million babies a year to be born mentally impaired.
  - Folic acid helps prevent spina bifida and may help reduce the risk of heart disease.
  - And, WHO notes that other micronutrient deficiencies of public health concern in developing countries include the B vitamins, vitamin C, and vitamin D, and calcium, selenium, and zinc.
- National governments and scores of international agencies and NGO/CSO organizations are working to eliminate hunger and malnutrition in developing countries around the world.

ODS should consider convening a Global Summit and monitoring its follow through, in cooperation with USAID, CDC and other US agencies that are supporting efforts to eliminate malnutrition. Partnering with WHO and F AO should provide an opportunity to involve a broad and diverse base of participants. The Summit should explore how to promote a greater awareness of the value of supplements and how effective use can be

made of supplements in nutrition programs for eliminating micronutrient deficiencies. All supplement product forms should be considered, including pills, tablets, and capsules as well as conventional and nutraceutical food product forms such as beverages and food bars that are acceptable to and meet local and national needs.

The Summit should invite influential decision makers from the **donor sector** (bilateral and multilateral aid agencies, foundations, and philanthropic groups), **doer sector** (agencies and NGO/CSOs who implement programs) and **thinkers** (politicians, scholars, writers, and researchers who help define, rationalize, and monitor the progress and direction of nutrition and food programs). The goal of the Summit would be to develop a road map that defines the specific actions needed to infuse dietary supplements into programs in developing countries, identify potential implementers, the timeline for initiatives, and estimate resource requirements. The quality of advance preparation and planning will determine the success of the elements of the desired outcomes of the Summit and the likeiihood of a viable road map for:

1. Forging relationships among all sectors engaged in attempting to eliminate vitamin and mineral micronutrient deficiencies;
2. Increasing the role of supplements;
3. Establishing a basis for partnerships to help implement program activities in specific countries;
4. Promoting good corporate citizenship and responsible production and marketing of innovative delivery forms of supplements for malnourished people in developing countries; and
5. Generating potential donor support.

The expectation is that with the improvement of individual diets with needed nutrients, vitamin and mineral deficiencies will be eliminated, health status will improve, mental functions will be stimulated and productivity will increase. The overall health and well being of consumers in developing countries will improve as more individuals become more productive and national development will occur more rapidly allowing for a more robust economy.

DSHEA allows US consumers continued access to dietary supplements. Now an opportunity exists to extend dietary supplements access to people in developing countries plagued by vitamin and mineral deficiencies and provide **Freedom from Malnutrition.** Hopefully successful programs will change the grim fact that approximately 25,000 people die each day from malnutrition.

Become the ultimate information resource and answer place on dietary supplements

The recent controversy surrounding the safety of vitamin E again highlighted the damaging impact that unexpected information can have upon a dietary supplement. Consumer confidence in vitamin E supplements was shaken by a study from credible scientists at a highly respected university showing that high doses of vitamin E may increase the risk of dying among older, high-risk users. The dietary supplement industry responded by assembling supportive, similarly respected scientists from credible institutions challenging these results. Industry spokespeople and full page ads were also visible in the media. Consumers were caught in the crossfire of dueling experts, not certain whom to believe and what to do regarding their use of vitamin E.

The vitamin E issue exemplifies an information credibility vacuum that exists and for which ODS should explore whether, and if so how, it can help fill this void. The ODS strategic plan recognizes its role to "inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements." One goal of its communications plan is to "establish ODS as a source of accurate, credible information on dietary supplements." The current plan assigns top priority to communicating with the public, including industry, consumer and public interests groups, and individual consumers.

ODS has commissioned a comprehensive needs analysis of its communications program to be completed in July, 2005. Not knowing the scope of this effort and the likely recommendations, I will do what any seasoned Washingtonian would do. . . .offer my insights on the subject anyway... ...with the qualification that I reserve the right to modify my comments after I read the final report.

One telling observation in the ODS budget is that there appears to be a significant imbalance between funds earmarked for research and scientific support and those for communications support. In a related and quite impressive vein, it is worth noting that there has been a rapid increase in the NIB funding for dietary supplement research from $98 million dollars in 1999 to $260 million dollars in 2003, representing a total commitment to supplement research of$ 774 million for this five year period.

I offer these additional observations:

- First, I have a different perspective on the ODS materials presented on their web site in my consumer role today than I did earlier as the head of a trade association. As a trade association head, I found the material extremely useful, especially the links that were established. But as a consumer, I am uncertain if my needs are being met. For example, I was recently questioned by friends on vitamin E and black cohosh and found I had to draw from other resources to provide answers. My personal unscientific view is just what it is.
- Second, ODS needs to determine if the interests of the consumer and the industry are being adequately served by its current communication outreach in general and the web site in particular. Indeed, the threshold facts needed are the level of penetration among consumers and industry and the use/value patterns. For example: are the web site fact sheets and other information pieces timely (was the vitamin E information useful during the controversy?), user friendly (too technical or detailed?), and does the information provide adequate guidance?
- Third, a comprehensive and cohesive communications and education program focused on the eleven ODS constituencies will require significant financial support and present program development challenges to break through the clutter of the numerous other societal education campaigns.
- Fourth, ODS might begin with an information and education campaign built around the supplements for which FDA has approved health and qualified claims and any special matters, such as the safety/benefit issues with vitamin E.
- Fifth, ODS' longer term goal should be to develop mechanisms that will allow it to provide science based commentary and information in layman's language in

real time when issues such as the safety of vitamin E arise, or when new benefit information on supplements becomes available. Such an ongoing information management response mechanism would demonstrate the value of the research that ODS supports and the scientific data it collects. ODS views will carry inherent credibility.

- Sixth, ODS should expand its existing Interagency Agreements with federal agencies and other third party resources to establish relations in advance that can be called upon to assist with communications efforts and/or to provide quick access to develop new or updated scientific information. In this regard, ODS could:
  (a) Assess the 1FT and ADA spokespeople programs, and see whether and how a similar ODS program can be established;
  (b) Draw upon the NIH Office of Consensus Conferences for filling information gaps on the benefit/value of supplements by fast tracking needed consensus conferences;
  (c) Negotiate advance basic agreements to use IOM/NRC, LSRO, and other organizations to conduct safety assessments on suspect or questioned supplements;
  (d) Expect ODS funded Botanical Research Centers to play prominent roles and contribute information and analysis and work closely with NCCAM on herbal matters;
  (e) Have rapid access to commercial third party information being generated on GMPs, quality control, and claims especially from the NSF International, United States Pharmacopoeia (USP), ConsumerLab.com, and the National Advertising Review Council (NARC) and scientific organizations and consumer advocacy groups; and
  (f) Explore supplementing the ODS Gift Fund with a free standing 501(c)(3) Foundation as CDC and USDA have done to open up fundraising opportunities, especially to generate resources for communication programs.

Now, let's return to the earlier mentioned vitamin E crisis. In the short run, an instant ODS comment and information release at the outset may have helped put the journal article report into proper context for the media, consumers, and others. In the longer run, if additional science data were needed, ODS could have considered stimulating new scientific information and elevating the dialogue. Some possible examples:

- First, the Life Sciences Research Office (LSRO), a respected, authoritative and globally accepted resource for state-of-the-science safety reviews, could have been asked to assess the safety of the different chemical forms of vitamin E at different dose levels.
- Second, the National Institutes of Health, Consensus Development Program could have been asked to plan a Vitamin E Conference to assess the current state of the scientific evidence on the value of vitamin E supplements and the amounts needed for such expected benefit and to produce a consensus statement.
- Third, ODS could have worked to more broadly place its web site information into the mainstream media channels.

Implementing this package would have been unique. The information from such a credible source could have helped consumers make more informed decisions about whether and how much vitamin E supplements to use, provided support for science based claims for the benefits of this essential nutrient, and allowed manufacturers guidance to produce rationally formulated and safe products.

ODS should consider establishing a goal and taking appropriate implementing actions to become the ultimate information resource and answer place on dietary supplements. ODS can use the vast storehouse of scientific findings at its disposal and provide information that is useful, timely, and credible about the need, benefit, and safety of dietary supplements.

To achieve this goal, ODS must build a platform of visibility to the outside world so that potential users, especially consumers, are aware that these resources are available. In addition, ODS must generate the significant funding resources needed to establish, sustain, monitor, and adapt communications program initiatives.

Stimulate consensus on key dietary supplement regulatory initiatives

Eleven years after the passage of DSHEA, consumers and industry are still waiting for FDA to develop a comprehensive regulatory framework that addresses dietary supplement safety, quality, and health claims issues. During this "decade plus one," there have been numerous FDA proposals, public meetings, Congressional hearings, a Presidential Commission, FDA sponsored studies, speeches, reports, a ten year plan, and most recently a new FDA three part plan.

During this same time, commercial initiatives have sprung up in the GMP area, and trade associations' self-regulatory initiatives and responsible actions by individual companies have tried to fill the regulatory void. The net impact has been to support a perception of uncertainty about whether and, if so how, supplements are regulated. Indeed, it would not be surprising to me, if a consumer who reads the FDA website "Overview of Dietary Supplements," expressed concern about the manner in which FDA portrays what appears to be a lack of their regulatory oversight on these products.

In November 2004, the acting Commissioner of FDA announced that FDA would pursue three major initiatives to further implement DSHEA through a regulatory strategy "to improve the evidentiary base FDA uses to make safety and enforcement decisions about dietary ingredients and dietary supplements." This follows an FDA sponsored study by the IOM/NRC of the National Academies released in April 2004 which provides a detailed framework for evaluating the safety of dietary supplements. FDA has indicated that they "will work collaboratively with its Federal and other partners [including] the National Institutes of Health Office of Dietary Supplements and the National Center for Complimentary and Alternative Medicine..."

Now is the time for ODS to seize the opportunity and serve as the **"Ombudsman for Regulatory Closure."** ODS should consider stimulating representatives from industry,

consumers and third party organizations to work together to reach consensus on regulating ingredient safety, manufacturing quality, science based claims, and rational product formulations for dietary supplements. Closure is needed as soon as possible for interested parties to craft new systems and processes tailored to the unique character of dietary supplements. These results should be made a part of the FDA process that ODS has been asked to participate in. This consensus building process would be an essential part of the due diligence that ODS should provide for its input and, while it cannot substitute for the regulatory role of FDA, it can provide an essential adjunct.

It seems appropriate for the ODS to consider how to build on progress to date, shape and use the fruits of its efforts to stimulate partnerships between the industry, regulators, third party expert groups, and consumer advocates to work to reach a more certain regulatory path. Responsible efforts along this line would address the safety challenges, restore consumer confidence, and stimulate the elements of credible and transparent regulatory and business models.

Safety is the most mature area for priority action. The framework for evaluating the safety of dietary supplement ingredients that 10M developed for FDA provides a comprehensive and useful tool to stimulate an open and transparent dialogue. This dialogue could forge a broad based consensus among the affected parties to categorize dietary supplement ingredients based on safety issues, agree on a methodology to review scientific data and peer reviewed literature and consider how other expert bodies have dealt with these safety and efficacy issues. The outcome of this effort should be submitted to FDA as the basis for regulations to better ensure the safety and wholesomeness of ingredients used in dietary supplements.

Given the 10M report and other well established safety assessment approaches, such a consensus project could be done quickly. Indeed, the dietary supplement experience at the Transatlantic Business Dialogue, which achieved consensus on safety, GMPs, and claims in a short period of time, suggests this can be done. Based on existing resources, one can obtain a good understanding of the options and opportunities to assess existing Food, Drug & Cosmetic Act regulatory provisions, such as Generally Recognized as Safe (GRAS), and self-regulating models of other regulated industries to adapt a safety system appropriate to the special category and needs of dietary supplements.

After ingredient and product safety, I would urge ODS to develop consensus next on GMP and quality, then evidence requirements for product efficacy and claims substantiation, and finally to develop guidance on product rationale.

Conclusions

In summary, I respectfully suggest that consideration be given to strengthening the ODS strategic plan in the three areas I have described.

ODS should expand its international program activities to get dietary supplements included in the strategic planning and implementation of programs designed to eliminate micronutrient deficiencies in developing countries. Millions of people, mostly children, will benefit as mortality declines and morbidity is reduced. Freedom from malnutrition will be achieved and new markets will unfold as we seek to reduce the grotesque figure of25,000 people a day dying from malnutrition.

ODS should assert itself as the primary information resource for its broad constituencies to obtain needed answers to scientific, technical, and consumer concerns about dietary supplements. ODS will need to ramp up its financial and staff commitment to communications programs and tailor the messages into useful formats to the different audiences, while maintaining its reputation of accuracy and science based credibility.

ODS should accept the opportunity to be the ombudsman to push for closure on the numerous pending regulatory initiatives at FDA. ODS should establish a priority schematic with product and ingredient safety first, next GMPs and quality standards, followed by product efficacy and substantiation requirements for claims and finally product formulations

To achieve these additions, ODS will need to maintain its current high level of openness and transparency, expand its current partnerships, and seek innovative and creative ways to fund key initiatives such as communications.

Thank you.

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