

Written Testimony of Nutrition 21, Inc.
Before the NIH Office of Dietary Supplements
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N21 is grateful for the efforts of the Office of Dietary Supplements (ODS), in addressing many of the interests and needs of its stakeholders. The ODS has helped advance recognition of the need for and conduct of quality scientific research on dietary supplements.

ODS' future contributions to advancement of dietary supplement recognition will be enhanced by focusing on:

- Studies to demonstrate improved health outcomes and the health care cost savings provided by the use of dietary supplements;
- Education and communication of the scientifically documented health and cost benefits of these products to improve integration of these products into standard health care practices;
- Advocating and facilitating interagency study with the goal of inclusion of dietary supplements into mainstream medicine.

The Dietary Supplement Health and Education Act (DSHEA) mandates an exploration of the role of dietary supplements as a significant part of the United States' efforts to improve healthcare ; and the promotion of scientific study of the health benefits of dietary supplements in disease prevention and risk reduction.

Nutrition 21 would like to see ODS take a leadership role in fulfilling the mandates of the DSHEA. Consumers use dietary supplements to improve their quality of life, enhance performance and prevent chronic disease. Yet, little emphasis has been placed on integrating their use to improve healthcare at any level of government. ODS has the opportunity and responsibility to advocate for and promote adoption of dietary

supplements as a part of standard care. Increased government support of cross disciplinary studies and translational research will be needed to provide the necessary information required by medical practitioners and third party payers to justify the use of dietary supplements and accelerate their adoption into mainstream medicine.

Healthy People 2010's has a goal of preventing and reducing the risk of diabetes within the U.S. population, reducing the economic burden of the disease and improving the quality of life for people with and at risk for diabetes. Diabetes is a disease that poses an increased clinical and public health challenge among certain ethnic groups who suffer significantly more risk. The increased risk of diabetes among lower socio-economic groups and the elderly place an even greater burden on the public health costs and social issues associated with caring for at risk populations. There is an urgent need for improvements in care to lessen the economic and social burden of this disease. It is well established that improvement in diet and lifestyle can have a measurable, positive impact on diabetes care, greatly reduce unnecessary illness, disability, death, and expense.

There is evidence to support the potential role that micro-nutrients can play in enhancing diet and lifestyle benefits, yet additional research is needed to conclusively demonstrate improved health outcomes and decreased costs when dietary supplements are used for disease prevention and risk reduction. Improved communication of the health and cost benefits associated with dietary supplementation will ultimately facilitate integration of supplementation as a standard of improved healthcare.

The ODS Strategic Plan lists three goals that are particularly relevant to our work at Nutrition 21:

1. Expand the evaluation of the role of dietary supplements in disease prevention and reduction of risk factors associated with disease;
2. Foster research that evaluates the role of dietary supplements in maintaining and improving optimal physical and mental health and performance;

3. Expand and conduct outreach activities that inform and educate the public, healthcare providers and scientists about the benefits and risks of dietary supplements.

1. To expand the evaluation of the role of dietary supplements in disease prevention and reduction of risk factors associated with disease

We recognize the accomplishments and contributions of the ODS in improving appreciation of the health benefits of dietary supplements. Yet, this alone will not facilitate acceptance by the health care community or improve healthcare. Focus must be directed at demonstrating that supplementation can improve health outcomes in a cost effective manner.

It is essential when evaluating the benefits of dietary supplements for risk reduction and prevention purposes, to study health outcomes and cost effectiveness in the context of broad based healthcare programs and populations, as opposed to looking simply at individual consumer use.

As mandated by DSHEA, we must fully explore dietary supplements as a significant part of efforts to improve healthcare, not just health maintenance.

Outcome and cost-benefit analyses will facilitate expansion of the role that dietary supplements may play in disease prevention and risk reduction. . This will also benefit the dietary supplement marketplace by identifying those dietary supplements that do in fact offer a health benefit in disease prevention and risk reduction and eliminate or minimize the attention paid to those products that do not live up to that promise. This approach will also provide an incentive for and reward companies that make an investment in scientific research to establish the health and cost benefits of their products.

Scientific substantiation of health benefits is important. Nutrition 21, Inc. has spent millions of dollars to demonstrate the health benefits of chromium picolinate in insulin

resistance, diabetes and heart disease. Government funding is crucial to future health outcomes research and communication of the health and cost benefits discovered. ODS is uniquely situated to advocate for, promote and facilitate these analyses and advocate for communicating this information. The ODS should aggressively begin investigating improved health outcomes with products like chromium picolinate and other supplements which do not fit into the classic drug model.

Despite the remarkable potential that chromium picolinate offers in helping to prevent and reduce the risks of diabetes and heart disease, it continues to be extremely difficult to gain the acceptance of healthcare professionals without proof of improved health outcomes and cost savings. This is an area where government and the private sector could work together.

Randomized, controlled clinical trials have shown that chromium picolinate supplementation can help lower elevated blood sugar levels in people with diabetes and prediabetes, reverse insulin resistance, reduce body fat in combination with diet and exercise, and reduce the risk factors for cardiovascular disease. Studies also have shown that chromium picolinate is the most effective and well absorbed form of supplemental chromium.

Since 2000 The National Center for Complementary and Alternative Medicine (NCCAM) has advocated for transitional research on chromium and type 2 diabetes in minority populations to address health disparities. In 2005 Labor Health and Human Services Appropriations, Congress expressed the desire for NCCAM to conduct research on chromium supplementation to prevent and reduce the risks of diabetes in Native American populations and in children. Yet, no NCCAM sponsored research has been funded on the use of chromium in type 2 diabetes to address health disparities in minority populations.

ODS should engage NCCAM to facilitate, conduct and or sponsor a cross disciplinary study to demonstrate improved health outcomes and cost savings from the use of

chromium picolinate for the prevention and reduction of risk of diabetes and heart disease in minority populations. We believe this would document the validity of incorporating of chromium picolinate in the prevention and treatment of diabetes and heart disease, and thereby reduce the social and economic costs of these diseases.

2. To foster research that evaluates the role of dietary supplements in maintaining and improving optimal physical and mental health and performance.

Central to the mission of ODS, is establishing the role of dietary supplements in improving the public health. The public health would be greatly benefited from a low cost, safe, effective nutritional supplementation to help address the diabetes epidemic. Government recognition of these public health benefits will foster adoption of dietary supplements into mainstream medicine.

The toll of diabetes on the health status of people in the United States is expected to worsen before it improves, especially in vulnerable, high-risk populations—African Americans, Hispanics, American Indians or Alaska Natives, Asians or other Pacific Islanders, elderly persons, and economically disadvantaged persons.

Nutrition 21 has taken on the public health challenge in the Native American community by partnering with the National Congress of American Indians. We have created pilot projects offering physician education and nutritional support with chromium picolinate and biotin for people with and at risk for diabetes. The results thus far are encouraging. Physicians are excited and patients are improving.

A substantial amount of diabetes care is self-care, so educating patients, providers and payers about the benefits of dietary supplements to improve health and healthcare is vital to positive outcomes. Primary care providers are the gatekeepers. Yet surveys report that people frequently do not receive advice from their clinicians about lifestyle interventions and nutritional support therapies.

Chromium picolinate dietary supplementation can contribute to prevention, reduce the risks, offer relief from complications of the disease and improve the quality of life for people with and at risk for diabetes. Helping government, healthcare providers and payers keep pace with the emerging body of evidence supporting the usefulness of chromium picolinate remains a challenge.

Nutrition 21, Inc. believes that ODS has a unique opportunity to take a more active role in the public health policy debate, to reinforce the importance of the role of dietary supplement use in quality healthcare; and to promote translation of research results into practice. Continued support for research of mutual interest to other federal agencies through co-funding and cooperative agreements is necessary. Chromium picolinate is a perfect example. The advancement of chromium picolinate research has attracted significant interest from both NIDDK and NHLBI. We appreciate the efforts of ODS in building these alliances. However, many of the NIH Institutes do not have accurate and current information with regard to recent advancements in chromium research.. Interest, support and advocacy from ODS could facilitate a more timely review of the science and health benefits of chromium picolinate and advance the integration of chromium therapy into standard medical practice to the benefit of the public health.

In addition, we suggest that ODS establish a process by which all stakeholders can partner with ODS to facilitate the examination of dietary ingredients that offer the promise of improving the health status of Americans and assist the industry in building relationships with other ODS stakeholders. An established process or designated ODS staff contact would assist companies that desire to work with ODS on a regular basis as opposed to an ad hoc basis. This would help coordinate efforts on a proactive basis, rather than on a reactive basis, as was done with Ephedra.

ODS should continue to advocate for and help create partnerships with other federal agencies to conduct translational research to speed adoption of these products into the mainstream. It is of vital importance to the dietary supplement industry that public private partnerships be nurtured and supported by ODS. ODS should assume a leadership role in

developing collaborative relationships aimed at improving public health among all stakeholders, including industry, government, public health agencies, consumer advocacy groups and medical trade organizations.

3. To expand and conduct outreach activities that informs and educates the public, healthcare providers and scientists about the benefits and risks of dietary supplements.

This goal is an essential element of the Dietary Supplement Health and Education Act (DSHEA) and should accomplish the objective of providing reliable, unbiased information to healthcare consumers, providers and payers, to make informed choices about dietary supplement use and the role of dietary supplements in healthcare and disease management. Essential to the validity of any ODS supported information, is that it be updated frequently to incorporate new scientific information as it becomes available.

Nutrition 21, Inc. believes the ODS, more than any other government agency, can help to fulfill the objectives of DSHEA to improve the health status of Americans and reduce healthcare spending. As part of this effort, ODS is in a unique position to demonstrate the validity of incorporating dietary supplements as a significant part of improved healthcare in the United States.

In addition, Government educational efforts will help to insure the credibility and reliability of the reference materials available to consumers, payers and providers to make informed healthcare choices.

In DSHEA, Congress expressed its intent to facilitate truthful and not misleading information about a dietary supplement by an individual affiliated with an accredited educational institution who has no financial interest. Unfortunately, dietary supplement research funded in whole or part by a supplement company is dismissed as marketing, even when researchers are not influenced by the financial interests. In order to assure that unbiased research results are available to stakeholders, ODS must continue to advocate for and oversee government conducted dietary supplement health outcomes research and

facilitate cooperative research agreements with other federal agencies. These efforts will assist FDA in advancing its standard of “significant scientific agreement” for health claims. Health claims are essential to communicating the benefits of dietary supplements for disease prevention and risk reduction. Structure function claims fail to offer a vehicle to communicate prevention and risk reduction benefits. If the promise of DSHEA is to be fulfilled, communication of the disease prevention and risk reduction benefits of dietary supplements must be improved by government sponsored health outcomes research guided by ODS, the only agency dedicated to fulfilling the promise of DSHEA.

Section 13 of DSHEA established the Office of Dietary Supplements with the specific purpose of making this Office an advocate within NIH and HHS for dietary supplements and to advise the Secretary of HHS on related public health issues impacted by dietary supplementation. When ODS champions these issues, we believe general acceptance of dietary supplements among health professionals will improve and along with it, the health of the American people.

We trust that ODS will embrace an advocacy role to advance the integration of dietary supplements based on health outcomes and cost benefit research, and expand dissemination of information to policy makers and payers in the interest of the public health. Nutrition 21 strongly believes that its products can make a significant contribution to the health of the American public; products which can play a role in preventing and treating people with and at risk for diabetes and its complications. Nutrition 21 plans to maintain its commitment to invest in research to demonstrate the improved health outcomes associated with its products in clinical practice. Our Company is eager and willing to continue to partner with ODS to communicate and build on these findings in order to help make the goals established in Health People 2010 a reality.

Thank you.

