PUBLIC COMMENTS SUBMITTED
TO THE NIH OFFICE OF DIETARY SUPPLEMENTS (ODS)
ON THE ODS DRAFT STRATEGIC PLAN 2022-2026

Comment 1

Dear Sir, Madam,

Thank You for requesting input on your draft planning.

My main comment is what you are addressing strategically. All your efforts are directed towards the professional reservoir. Consumers are more and more seeking their own roads towards better health and food. The supplements often have to be taken " in the dark" as no personal measured data are available.

What is my status on iron, zinc and many others?

It would be better if on a number of variables, of course starting with the easy ones, the interested consumer himself, could acquire the needed information.
This would eliminate/decrease incorrect food additions.

In general, I would appreciate if you would help the consumer more self helping, without professional involvement, as much as possible.

Organising the development of simple, cheap, but good measurement devices, eg a sensor with an app.

Comment 2

Dear ODS,

I have been using GNC supplements for over 20 years since I know GNC produces quality products and the main point - harmless supplements and vitamins so far. There are many other vitamins and supplement companies (the number has tripled in the last ten years) offering "experimental" supplements particularly in longevity area without full responsibility. I tried a couple of their "products" and barely survived in result. This has to be changed. At least the companies producing supplements should have license extended each year depending on public response. ODS might want to offer website where customers could post their commentary and feedback or complain. Briefly, you need to be more involved before these new "companies" poison majority of supplemental and vitamins lovers))
Thank you for your concern.

Comment 3

Dear ODS,

While I understand government concerns with the use/misuse/abuse of dietary supplements, I do not fathom the government's belief that adults are incapable of taking care of their own needs. Intrusion by agencies and authorities bespeaks the government's belief that Americans are idiots. Truth be said, some are.

There are instances where dietary supplements are overzealously used, leading a person to suffer the consequences of uneducated behaviors. This is where dietary professionals enter the picture, especially those trained in integrative and functional modalities. All that is needed is labeling that describes the intricacies of using supplements. We who are well-trained know how supplements interact with drugs, with foods. and with each other. Even physicians cannot address this issue because they are not educated in nutrition, and they lack the time to discover the nuances of nutraceuticals and their salubrious applications. PubMed is filled with research papers that support supplementation.

The FDA recalled more than twenty "approved" drugs a few years ago. Some were on the market for more than two decades, some for less time. It is unfair to label supplements as dangerous if "approved" pharmaceuticals also might render misery and death.

Please be deliberate in your decisions.

Comment 4

I think its a bad idea for 1 but for 2 they have no right to take away our right to choose also herbs and supplements were put here by God and people use them with in their religion.... trying to strongarm supplements and try to regulate them is only gunna lead to more black market and more problems

Comment 5

The regulation of supplements will obviously lead to a black market supply of likely dangerous products that aren't lab tested. It's a tale as old as time really. When something is controlled, there will always be criminals looking to capitalize on the opportunity to make money with supply and demand.

I, and countless others, urge any parties involved to reconsider this proposed regulation and consider the very real potential for harm to the public.

Thank you for your time.

Comment 6

The constant advertising on my cell phone that if you chew one gummie or one pill you can looses so much weight. Too good to be true. I guess that is expecting too much. We just have to use our brains.

Comment 7

In response to your email. Thank you for this opportunity.
I really worry about some supplements that look like and may say they are certified safe or have the correct medication and amount. I try to buy big name brands that have the USP symbol...but actually i was just looking, and not seeing it this time on any of my bottles! Scary! I was sure they used to.

I have had liver and allergic and other reactions to different "natural supplements." Also, a friend gave me dried nettles and comfrey for my arthritis...i really got sick, i am sure from them. The comfry was yummy and i chowed down. He was older and an Indian. I thought he was so wise! I was new to supplements. Last year, i accidentally drank a tea with valarian. It made me hallucinate! I bought a popular box of herbal teas, and got totally weird after drinking that. This wasn't a "natural foods" store, it was a grocery store and popular brand of mixed teas! Who would expect drugs in herbal tea? Why is it allowed in grocery store teas? Years ago St John's Wort nearly killed me as my tongue swelled.

So, i do not get remedies any more unless the docs refuse to help and want to throw anti-depressants around though i have no signs of depression. Those are the new oxys for them. But they cause me SEVERE depression. Why take them? Very, very scary weird reality from those. I was given one for ADHD! Never ever again, very bad trip! It was half a dose.

I now start any new med at half a dose. And every 6 months i try to cut back on some to see if i can reduce them. My doc was prescribing metropolol 2 twice a day! I kept complaining, but no one changed it. I was only taking 1/2 twice a day! I would have died if I took that much.

They refuse to help with severe pain, just say take tylenol and antidepressants! Tylenol messes up my liver since they overdosed me in the hospital. You trust them, but never again. I did try a few cannabinoid ointments one of which truly helps, but i have no idea how or if that is messing up my liver or could cause other issues. I don't think so, but no one is minding the store. The pain is so severe without that and celebrex, i would not be able to walk at all, go to church, grocery, or do crafts. But no one cares. Why? Why aren't they finding safe pain meds and not putting out surgeons that know what they are doing? Why force people to find their own remedies that often are poisoning them?

I understand you get flack from the whackadoos, i get it, but that is no reason to shirk your duties to the rest of us. Buck up..,you are the government! There will always be complainers. Monitor supplements and OTC meds, anyhow. Do you want YOUR Mom and Dad killed? You

often must protect us from ourselves. It is hard, but it is your job. We want to find a reason to trust you. Please.

I saw an older lady drained of her money because of TV programs and 700 Club saying to get these supplements. She finally died so thin and of heart failure due to leukemia, because the frauds also said not to eat many foods so that she was down to weak soup, so afraid she would get leukemia again...she did anyhow, the hospital said. But her doc was treating her for pneumonia. Finally she was so sick her daughter took her to the hospital. They said it was not pneumonia, but the last stages of heart failure. She died 3 days later. Great docs! Tv said to just take these supplements! No one could talk her out of it.

She had friends doing the same thing. One of them just died of leukemia. She, too, followed the weak soup and many supplements routine.They were older so no one really cared, but i do. They were precious, but ignorant people. This should not be allowed. Greedy, lying people are killing innocent beautiful people. Please stop them as though they were your precious people. Please!

Comment 8

So I've consumed a small variety of Suppliments over the time period beginning from 2017 until maybe a month prior of today. I believe there are effective in what the label specifies usually. I can recall seeing a certain supplement label stating it supported health for one aspect and then seeing the same supplement, possibly a different make, bust specifying a different use for the supplement. I believe false advertising is an concerning issue if not in the United States solely, should be world wide as well. I'm aware a lot of makes/brands even for medications are manufactured off the United States of America Soil, in foreign countries, but the United States is one of the highest percentages recorded, if not the highest, of consumption of Prescriptions, Medicines, Health Enhancers and supportive health Suppliments. This should be an alarm of concern. A vast majority of doctors I have encountered one way or another are also foreign. Insurance companies cover most expenses but, the theory I have been theorizing for a substantial amount of time and have 94% solidified, is that the medical practice has been solely about monetary gain for quite some time because of the influence of a certain force of greed, not the focus that had been intended from the beginning, which I believe to be seeking knowledge of the way VESSELS operate and how. Today, at the amount of information, experience and documentation of experience acquired over centuries. I believe it is time for all nations across the globe to turn diligence and intense focus to HEALING beings' Mind; brain, Neuro activity, neuro connections, strength of an important muscle, mind state, specified functions, faith, sub-conscience etc., Body and Spirit. Only three basic words with so many terms/ tangent/aspects of knowledge to apply in the most profound way; with all perspectives, perceptions, information/knowledge obtained/absorbed along with the input of the most Wise and Philosophical Comprehensions world-wide.

Comment 9

Recommend adding the information from the PDR for Herbal Medicine and from the PDR for Nutritional Supplements to the information sheets

available to the public and healthcare professionals from the NIH.

Comment 10

Do not interfere with our right of access to nutritional supplements!! Nutritional supplements should not be placed on prescription because medical.

Comment 11

I would like to see much more control over the contents of each Dietary Supplements .
Description of each ingredient must be exactly what is shown on level

1. Quality.
2. Quantity as dietary supplements specified.
3. Possible use of products based on study.

Comment 12

your main question:
Q. are the supplement rec that ODS govt should make now?
A: Yes,

1. zinc to help discourage viruses like covid or colds or flu.
2. K2 for calcium absorption
3. cinnamon and chromium to lower blood sugar (diabetes type 2 is epidemic, in 1980, the prevalence of all diabetes was.. 3% !!!)

4. REishi or gandaderma lucidium mushrooms for immunity
5. Turmeric for cancer prevention.

your other items:

- Are there additional emerging public health issues that ODS can help address?

The rise of contagious bacteria due to warmer climates.
HUman-non human virus transfer due to markets in the far east. and certain parts of USA.

- Are there existing knowledge gaps that ODS can help address (not included in the current plan)?

taking Calcium does NOT help bones. weight bering exercise and unfortunately hormones post menopause. do more research on bone regeneration/ degeneration and knowledge transfer

- Is there anything that ODS can do differently to meet the needs of its stakeholders

YES__incorporate more NUTRITION courses in MD and PA and NP training. reimburse patients for nutrition education.
also offer more public education about the gut health microbiome importance and "you are what you eat" and the colon as second Brain.....

Comment 13

the public who takes zinc did better in the pandemic that you couldn't figure out. they had less covid. shows how much science emanates from this mercenary fedearl agency. i dont think you provide either sound scientific research or leadership at all at the nih. i think this agency gets billions of dollars and wants to take more money from big pharma so that you dont pay attention to natural products at all.natural products have been serving mankind for millennial, but all of a sudden endless drugs and fake vaccines have been plunged into our throats. i think money talks at this agency and you ar enot balanced at all. i am in favor of totally defunding this crooked agency. i think the work of this agency is worth a grade of f minus. the results of this agencys works is more chaos for america and this agency is certainly of zero benefit. this comment is for the public record.

Comment 14

Require that all products sold as medicine, whatever the source, be FDA or NIH certified as safe, effective, content certified, and all claims verified by clinical evidence.

To do less ensures that your mandate is ineffective and possibly detrimental to the general health and welfare of the people.

Comment 15

It could be a service to healthy care providers and researchers to provide a white paper on the status of new delivery forms for dietary ingredients with marginal bioavailability— ie lysosome, phytosome, nanoparticle delivery—safety? Need? Effectiveness? Or to support research into this area.

Perhaps this would fit under Goal 3, though it may be too specific.

Comment 16

I am a physician and I am currently taking a course on medicinal plants through Cornell. I have used your data base as a resource for my courses. Your database does not include most of the supplements consumed in the US and the information you provide is often simplistic and there is always a warning that this supplement has no scientific evidence proving validity for anything .. which is most likely because they have never been properly studied. It also often conflicts with information in the Sloan Kettering database for herbal treatments. This database contains information for patients and a separate area for providers, with more detailed information

about safety and efficacy.

Linking your database to a Cochran database and NIH currently funded studies on herbal treatments and the Sloan Kettering information on alternative medicine would be very helpful for consumers and providers. Also having a database for providers with more detailed information would be helpful.

Comment 17

Thank you for the opportunity to provide comments on the draft ODS strategic plan. I've taught on topics related to dietary supplements and integrative medicine to student pharmacists, medical residents and other healthcare professionals for over 20 years. One area of my scholarship has also been in dietary supplement use.

My primary comments are related to Goal 4, Strategy 4.1 and 4.3. At the beginning of the covid-19 pandemic, significant misinformation on the value of DS was spreading across the internet. Some of the information was simply extrapolating from in vitro studies and applying it to the clinical setting as a "proven" therapy for consumers to use. There were "protocols" of DS promoted for nursing home residents for prevention and treatment. Other misinformation was simply quackery. My comment is....Should ODS have a more active role in responding / addressing these public health issues? I've already started seeing some diets promoted for treating monkeypox. Perhaps this is more in the realm of NCCIH, but during the pandemic I saw little response from either organization.

I also wanted to ask with respect to: *ODS provides an array of information on dietary supplements and their ingredients that the public views as reliable and up to date. Dietary supplement users will continue to benefit from free access to this objective information.* Is there actual published data on consumer use of this website?

Comment 18

I am a lay person who has spent many hours researching the voluminous number of current studies being published on the positive impact that proper diet and the judicious use of nutraceuticals can have on our health, individually and nationally. I congratulate the NIH ODS for providing significant leadership in publishing authoritative reference documents on foods and nutraceuticals.

My input is short and to the point. It can be summed up with a brief review of my visit three years ago to see my primary care doctor regarding a shoulder injury. After assuring me that I did not have a separated rotator cuff, I asked several questions regarding a few of the nutraceuticals I was taking. He politely indicated that he was there to take care of injury or illness but not "that kind of thing."

Our entire health care system from physicians to health insurance companies (including Medicare) is built around the principle of treating illnesses after the fact, and not addressing the causation of most illnesses which overwhelmingly are the result of lifestyle choices such as diet, alcohol, inadequate RDA consumption of vitamins/minerals, etc. CVD is the most significant example of a long list that our healthcare system, as currently constituted, is ill equipped to reasonably address.

I hope that NIH has a plan to put forth the basis for structural change to our country's health care system. Specifically I hope that the NIH OSD can be a powerful and meaningful proponent of requiring health insurance companies and medicare to support a billing process for physicians to counsel patients on the significant healthspan extending benefits of what the research is currently reflecting, proper diet and where necessary appropriate supplements / nutraceuticals.

Comment 19

I'm a senior female, healthy without taking any prescription meds. I have been relatively strict with myself practically all my life regarding what I eat and do not eat. I also research and take vitamins and herbs. I sincerely hope this agency does not take away my ability to buy vitamins and herbs of my choosing after extensive research from a health food store or Amazon.

Thank you for your considering my request.

Comment 20

It is my right as a human born to Earth that I may use the herbs found within my home planet. Please don't infringe upon my right to consume medicinal herbs.

Comment 21

Thank you for drafting the strategic plan and asking, "Is there anything that ODS can do differently to
meet the needs of its stakeholders?"[i]

To meet the needs of its stakeholders, the draft strategic plan has two strategies that can be updated:

- Strategy 1-3: Identify knowledge gaps and research needs. Topics will include the efficacy and safety of supplement use in health maintenance and its potential role in reducing disease risk.
- Strategy 1-1: ODS will evaluate the health effects of dietary supplements—primarily for promoting health and reducing the risk of disease.

COVID-19 continues to be a disease risk. The 28-day COVID death count for the United States[ii] is: 12,572. For COVID-19, you have the following dietary supplement fact sheets:

- **Dietary Supplements in the Time of COVID-19 - Consumer**

- **Dietary Supplements in the Time of COVID-19 - Health Professional**

The fact sheets have numerous research results. To easily understand research results, you can add the following, according to the NIH plain language guidelines: [iii]

- Visual aids. "Visual aids can help you connect with your readers and better communicate your message."
- Tables. "Tables can make complex information easier to understand. They're useful for making comparisons and showing relationships without using a lot of text."

With minimal text, a table compares COVID-19 dietary supplements shown in www.c19early.com. (c19early.com was created by PhD researchers and scientists who were published in journals like Science and Nature.)[iv]

The [cited] table lists dietary supplements and non-dietary supplements. The Office of Dietary Supplements can create a similar table for dietary supplements for COVID-19 fact sheets. Tables can help ODS fulfill its responsibility to "compile the results of scientific research relating to dietary supplements."[ix]

[i] https://ods.od.nih.gov/About/StrategicPlan.aspx
[ii] https://gisanddata.maps.arcgis.com/apps/dashboards/bda7594740fd40299423467b48e9ecf6, last updated 8/6/2022 at 10:20 AM
[iii] https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/plain-language/formatting-visual-clarity
[iv] https://c19early.com/faq.html
[v] https://c19quercetin.com/
[vi] https://c19melatonin.com/
[vii] https://c19vitamind.com/
[viii] https://c19zinc.com/
[ix] https://ods.od.nih.gov/pubs/ODSDraftStrategicPlan2022-26.pdf

Comment 22

Below is a longer narrative providing some background and a rationale for the suggestions.

Currently there are ***No data***, I repeat "***No Data***" from Clinical Case Series, Rickets Surveillance Series - Australia, Canada or Great Britain - Case-Control studies that contain a clinically accepted definition of Nutritional Rickets, ***and*** VDSP standardized measurements of key metabolites in the pathophysiological pathway for Nutritional Rickets, i.e., 25(OH)D; 24,25(OH)2D; 1,25(OH)2D; and Parathyroid Hormone (PTH) and FGF23. (I am currently a Consultant to an FAO-WHO Expert Committee setting vitamin D requirements for children 0-3 years of age. The lack of data is really frightening) (Wise SA, et al. Vitamin D Standardization Program (VDSP) Intralaboratory Study for the Assessment of 25-Hydroxyvitamin D Assay Variability and Bias. J Steroid Biochem Mol Biol. 2021 May 16:105917. doi: 10.1016/j.jsbmb.2021.105917 and Thacher TD, et al. Reading JC. Radiographic scoring method for the assessment of the severity of nutritional rickets. J Trop Pediatr 2000;46(3):132–9.)

This lack of standardized measurements for those metabolites in NIH research has resulted in vitamin D Guidelines paralysis. Currently, the IOM guidelines 25(OH)D concentration to define vitamin D deficiency (12 ng/mL) was taken from the British definition of 10 ng/mL. Moreover, those British guidelines are based on ***single 1976 study*** with only "***9***" nutritional rickets cases (Arnaud SB, et al. "Serum 25(OH)D in Infantile Rickets" Pediatrics 1976;57(2):221-225.) Furthermore, the IOM 25(OHD cut points - "Insufficient", "Sufficient", and "No Added Benefit" ***are based entirely*** on research opinion and without data to support them. Therefore, ODS/NIH must work to promote research in nutritional rickets in human studies, appropriate animal models and in Vitro models. Without new data meeting the two criteria given in the first paragraph the paralysis will continue. It *is impossible to conduct mesa-analyses without VDSP standardized vitamin D data.*

Again, I emphasize that it is the association among 25(OH)D, Calcium Intake, and nutritional rickets that is the ***fulcrum*** upon which vitamin D guidelines are based. Moreover, based on the recent analysis published AJCXN paper, a ***significant interaction*** between 25(OH)D and Dietary Calcium intake was found. Those results, therefore, suggest that vitamin D and calcium guidelines are ***not static***, i.e., that is as the level of one ***decreases*** the amount of the other to prevent Nutritional Rickets ***increases***. As Prof. Bouillon wrote in his accompanying editorial that, if replicated, these results will have important ramifications for nutritional guidelines and clinical medicine. Sempos CT, et al.Am J Clin Nutr. 2021 Jul 1;114(1):231-237 and Bouillon R AJCN 2021 Jul 1;114(1):

In order to develop an ***appropriate*** vitamin D research database for developing vitamin D guidelines requires the following actions by ODS/NIH.

1a. Re-generate the Vitamin D Standardization Program (VDSP) and develop instructions for researchers on the VDSP methods needed to prospectively and retrospectively standardize serum vitamin D measurements;
1b. Work with experts to develop a suitable clinical case definition for nutritional rickets and post the information for both points on the NIH PhenxToolKit website.

2. CDC currently provides 24,25(OH)2D target values for DEQAS using their non-RMP assay. It is has to be established if the CDC values are traceable to the NIST RMP. If not a calibration correction equation needs to be developed to convert those CDC values to NIST RMP values.

3. Complete the standardizations of 1,25(OH)2D and then work to provide target values for DEQAS samples;

4. Fund NIST to work on the development of a PTH assay. The IFCC has been ***supposedly*** working on a PTH RMP for about 15-20 years. Task was given to CDC about 5-7 years ago. I put funding for this effort in the last VDSP budget, about 2015. The purpose was to ***generate competition***. Unless CDC has made progress unknown to me the same problem exists ---***Competition is essential***!

5. Request and support funding of rigorously constructed: Clinical Case Series; Nutritional Rickets Surveillance Studies; Case-Control Studies and animal and in vitro research based on standardized vitamin D measurements and an accepted clinical case definitions (Sempos CT, Br J Cl Pharm 2018;84(10):2194-2207. Sempos CT, Binkley N.Public Health Nutrition Public Health Nutr. 2020 May;23(7):1153-1164.) – all based on the criteria in paragraph 1.

6. Provide support for NIST to develop SRMs, i.e. Trueness Controls, for 25(OH)D Dried Blood Spot assays.

Comment 23

Importance of intake of Omega 3s is well known. But Most People are not finding its importance. I request this is to be highlighted to the society. For vegetarians, Flax seed, Chia seeds daily intake in a limited quantity is must.

Comment 24

To: Office of Dietary Supplements
RE: Comments on the ODS Strategic Plan 2022-2026

I commend the ODS's work on the Strategic Plan 2022-2026. Many aspects of natural products/dietary supplement research have been addressed. However, it does not appear that ODS has fully explored the relationship between cultural and scientific diversity in researching nutritional supplements/natural products**.** As part of the ODS Strategic Plan it mentions that different stakeholders were identified. However, I believe a group of stakeholders has either not been identified or is not reflected in the ODS Strategic Plan 2022-2026. This missing group of stakeholder opinions appear to be from people that use natural products based on traditional knowledge. The ODS has a responsibility to this group of individuals.

This responsibility is not only when the research project is actively exploring questions about natural products with traditional use but also when the research is investigating natural products that have a history as having been used in traditional medicine and may still be. These groups of people using these natural products are also stakeholders as the research being conducted may have impacts not only on their physical health but may also have cultural impacts involving the substantiation or non-substantiation of traditional knowledge. **Incorporating a cultural and scientific diversity framework in the ODS Strategic Plan is important and should be multifaceted and involve an oversight plan even after the research project/funding is complete.**

Just as the government supports the work of different types of modern scholars, e.g., engineers, anthropologists, analytical chemists, biologists, MDs, agronomists, etc. and that each have different perspectives to add to questions about the world around us, so too should the government support the fact that there **is a wide range of specializations within healthcare and that there is cultural diversity in healthcare.** Some of these healthcare

specialists include practitioners of different sorts of "traditional" medicine. These are not ill-prepared charlatans but rather represent cultural traditions of healing that predate modern science and have had, and continue to have valuable contributions to our understandings of the human condition and our interactions with the matrix of the biological, physical, cultural, and psychological world in which we are each enmeshed.

Funding agencies need to leave the door cracked open a bit to allow for scholars with different perspectives to compete with those who have narrow, modern perspectives. If good science may be presented within a proposal and that science involves different sorts of practitioners, then the proposals should be evaluated based on the quality of the proposed scientific methods for data collection, analysis, and evaluation rather than on whether or not the proposed work fits within a particular model of health care. Health care as we know it has evolved over time, and there is every reason to believe that it will continue to change. **We need as much diversity of data and understandings of our world as we can possibly bring to bear if we expect to continue to have the quality of our knowledge improve and provide the basis for future health care.**

As a naturopathic doctor and researcher, I have acquired a diverse skillset from volunteering in herbariums, researching natural products both in basic laboratory and clinical settings. I have worked in cell culture, animal and human studies investigating natural products. Since entering this field in 2001, I have encountered numerous hurdles and commend ODS on addressing some of these issues in their Strategic Plan. Unfortunately, the timing is too late for my career which is also why I am writing this letter. I was fortunate enough to be selected with other collaborators to further conduct research on a botanical plant that I have been researching for over 10 years. This particular plant is very important to the people that use it, so much so that it is not discussed outside of ceremonial practices. As I learned more about this plant through my research, I became more aware of its importance and have not published my findings as I wanted to collaborate with the people using this plant. As a White woman researching a culturally significant plant, I have tried to make connections with the groups of people using this plant.

As part of my clinical training, I worked as a clinician in clinics where people were using this plant traditionally. As part of the collaborative grant funding that was awarded, one of the aims centered around continuing to build relationships with individuals using this plant; which was hampered by the pandemic. The horrific details of the abuse and murder of Native American children at the Government run/supported Indian Boarding Schools has also been an understandable barrier to building relationships at this time.

One of the exciting aims of the research project has been to chemically characterize the plant by research groups that are funded through ODS and NIH. I had hoped to build upon this research in future projects that centered around the people using this plant and what research would further benefit them.

Unfortunately, my institution is no longer committed to supporting its research program and I am unable to compete for career training awards or other grants without my institution's support. This has been a terminal blow to not just my career but many other researchers who have received NIH funding and training over the years. However, the most worrisome concern for me is that now plant material that I collected and extracted that is extremely important to the groups of people that use it will now be housed in a library of botanical extracts (with already collected data) that will **not be overseen by individuals that either have a cultural relationship to this specific plant or by a panel of individuals with knowledge in traditional medicine, ethnobotany, intellectual property rights as they exist outside of the United States.** I fear that discoveries could be made where the people that use this plant will **not benefit** from the knowledge gained and **could potentially be harmed** as has happened in past research studies lacking cultural and ethical oversight.

I am also concerned that these botanical extract libraries, although fantastic in theory, may also without proper cultural and ethical oversight lead to potential harms. The incredible advancements in "omics" technologies (ie proteomics, genomics, metabolomics and lipidomics) make studying botanicals and their effects in human tissues much more complex and exciting. People and plants have evolved together and the increased knowledge of human genetics and genetic biobanks make studying specific botanicals in specific human populations with genetic knowledge very feasible and may prove to be quite fruitful in better understanding plants and people. **However, these studies have the potential to create harm and lead to uneven benefits of research findings without cultural and ethical oversight.**

In conclusion, I implore ODS to further address how the Strategic Plan 2022-2026 can incorporate more cultural and scientific diversity from the initiation of the research idea to the dissemination of information to a diverse group of stakeholders.

Comment 25

The Institute for Natural Medicine is pleased to provide comments on the NIH ODS 2022-2026 Draft Strategic Plan. We applaud your approach set forth in this draft plan, in particular the five goals that synergistically address all aspects of research from expanding research collaboratively and enhancing the research workforce to disseminating results to professionals and the public. Leading scientific stewardship by addressing health disparities and enhancing health equity is also to be applauded.

As you are aware, NCCIH has established a focus on Whole Person - Whole Health research initiatives, recently issuing an RFI for Identification of a set of Determinants for Whole Person Health that the Institute for Natural Medicine responded to. The ODS can contribute significantly and in measurably important ways to these Whole Person - Whole Health research initiatives.

To explicitly bring in Whole Person research into your strategic goal 1, the Institute for Natural Medicine recommends that ODS spearhead the launch of a multivariate efficacy treatment trial

through co-sponsors. Specific nutrients studied by ODS in context with all other nutrients required to address a disease state will yield rich, new efficacy results and fill existing knowledge gaps, since supplements do not work in isolation, they work in a system that includes internal and external determinants of health. This may be accomplished by ODS offering administrative supplements to study additional nutrients for trials of nutrients primarily funded by ODS collaborators. This is the most significant thing ODS can do differently as it moves forward strategically in the next four years.

Understanding the activity of a nutrient within a complex field of co-factors and recognizing the interconnectedness of multiple disciplines is essential. One or more multivariate supplement trials for 2022-2026 designed in the context of this whole person perspective will greatly further NCCIH's Whole Person - Whole Health research initiatives and also support the VHA Whole Health System of Care efforts.

Thank you for the opportunity to provide the Office of Dietary Supplements with our recommendations.

Comment 26

The Council for Responsible Nutrition (CRN)[1] is pleased to submit these comments in response to the Office of Dietary Supplements (ODS) Five-Year Strategic Plan for 2022-2026.
Are there emerging public health issues that ODS can help address?

- We recognize ODS's efforts to create the "Dietary Supplements in the Time of COVID-19" fact sheets and update these sheets as new research emerges. We encourage ODS to continue regularly updating the fact sheets when new information becomes available. For vitamin D in particular, we are aware of numerous studies that have been conducted since the beginning of the pandemic, or are currently in progress, that demonstrate a relationship between higher vitamin D levels and a lower incidence or severity of COVID-19. CRN has been closely monitoring this research on vitamin D and COVID-19 for the CRN Foundation's educational campaign, Vitamin D & Me**!**. We strongly encourage ODS to include these new research findings in its education.

Are there existing knowledge gaps that ODS can help address (not included in the current plan)?

- Although mentioned briefly in the draft strategic plan, dietary supplement use and its contribution to meeting the unique nutrient needs in lactating women is under-researched. ODS could conduct or support research in this area and educate consumers and healthcare providers on the different nutritional requirements during the post-partum period compared to during pregnancy. The recent Dietary Guidelines for Americans 2020-2025, issued jointly by the U.S. Department of Agriculture and U.S. Department of Health and Human Services, identifies some of these differences. Consumers and healthcare providers could be guided to look for appropriate supplements to address these requirements.
- ODS mentions health promotion in the draft strategic plan; however, health promotion is not defined, nor are the outcome measures that would be indicative of health promotion.

We recommend that through interagency efforts, ODS contribute to establishing a definition of health promotion and the measurable outcomes used to demonstrate it.

- We applaud ODS for establishing the Trans-NIH Resilience Working Group to look beyond reducing illness and focus on how to enhance health and lengthen life. The benefits of nutrients and bioactives have traditionally been assessed through the lens of correcting deficiencies or preventing disease, but research shows that they can play important roles in health promotion, healthy aging, and active lifestyle throughout the age spans. However, scientific consensus on a research paradigm on how to assess optimal health is lacking. We encourage ODS and the Working Group to support the development of such a research paradigm.

Is there anything that ODS can do differently to meet the needs of its stakeholders?

- ODS provides educational materials to health professionals through fact sheets and other materials on their website. Additionally, ODS offers a dietary supplement research practicum to academics, doctoral students, and postdoctoral fellows; healthcare practitioners; and other professionals with advanced biomedical degrees. While the information is useful, it may not reach the healthcare provider community broadly unless these professionals proactively seek it out. We recommend that ODS target educational outreach to healthcare providers, including doctors, physician assistants, nurse practitioners, pharmacists, and others who regularly counsel their patients about nutrition, diet, and supplement usage, who generally do not receive adequate education on nutrition and dietary supplements.
- We commend ODS for providing fact sheets as a resource for health professionals and consumers. These fact sheets, and other information on the ODS website, should be regularly updated to reflect the evolving science on various dietary supplement categories. For example, there is a growing body of research on the effects of probiotics on different health endpoints beyond the few that are listed on the Probiotics Fact Sheet. Probiotics are a popular category of dietary supplements, and it is important for consumers and health professionals to have access to accurate, up-to-date information that reflects the full range of potential health benefits.
- As industry is an important stakeholder in the dietary supplement space, we recommend that specific language is developed in the strategic plan on how to develop and maintain two-way communication and potential partnerships with industry members. Much of the language is one-way, coming from ODS to industry, but does not appear to be encouraged from industry to ODS, beyond commenting on the strategic plan. Having an industry advisory council with members from both smaller and larger companies, as well as trade organizations, could support continuous two-way communication. It would also be helpful to have industry partners involved in consumer education campaigns, which could be bolstered by academic-industry partnered research on various supplements.

- ODS is the only government-funded office (likely in the world) that supports and funds research, tools, and education focused on dietary supplements. While we recognize that the stakeholders of ODS are in the United States, we recommend that ODS, to the extent

possible, extend its efforts globally to help other governments establish similar entities in other countries.

Thank you for this opportunity to provide our feedback.

1 The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

Comment 27

We are writing to express our views on the Office of Dietary Supplements(ODS) proposed draft of their Strategic Plan for next five years (2022-2026) regarding research and innovation.

The National Center for Health Research (NCHR) is a nonprofit think tank that conducts, analyzes, and scrutinizes research on a range of health issues, with particular focus on which prevention strategies and treatments are most effective for which patients and consumers. We do not accept funding from companies that make products that are the subject of our work, so we have no conflicts of interest.

NCHR supports the efforts to improve research in the ODS proposed strategic plan. Research on dietary supplements is needed so that patients are able to make informed decisions about their safety and effectiveness. We especially support the proposed research and initiatives to reduce disparities and to disseminate information about the research results. Partnering with minority-serving organizations and institutions throughout the research process is vital.

While we support the plan in general, we strongly recommend several major revisions, primarily focusing on the "Addressing Health Disparities and Advancing Health Equity'' section. While there are overarching goals in place, the proposed plan lacks specific, measurable milestones and a defined timeframe for each of these goals and subgoals. For example, ODS should explicitly explain how it plans to achieve continuing "to offer opportunities for academic faculty members to work at ODS during their sabbaticals," with clear targets showing whether that goal is achieved. The research goals and achievements need to be explicit and made available to the public. In addition, given the increase in the sale of dietary supplements during the pandemic, we agree with the December 2021 recommendation of the Center for Science in the Public Interest (CSPI) that there should be more emphasis on examining how the promotion

of these dietary supplements and their sales affect COVID-19 (1) and the health of the public during the pandemic.

In the "Addressing Health Disparities and Advancing Health Equity'' section, ODS states the need for "training, career development, or funding junior and mid-level scientists…", which we support, but we also recommend that ODS provides these opportunities for senior-level scientists. In addition, ODS should require that researchers and manufacturers perform studies in an ethical manner that includes and respects minority communities, possibly incorporating community consultants in their process. As is well-documented, there is sometimes mistrust and reluctance to participate in research in some communities (3). These concerns must be addressed in order to collect accurate data that appropriately represents members of these groups.

We would welcome the opportunity to address any questions about our recommendations, by contacting Ashley Hystad at info@center4research.org or (202) 223-4000.

References:

1. Lurie P & Jose J. Comments of Center for Science in the Public Interest on Office of Dietary Supplements' Strategic Plan. 2021
2. Crawford C et al. Analysis of Select Dietary Supplement Products Marketed to Support or Boost the Immune System. *JAMA Network Open.* 2022; 5(8):e2226040. doi:10.1001/jamanetworkopen.2022.26040
3. Scharff DP, et al. More than Tuskegee: Understanding Mistrust about Research Participation. *Journal of Health Care for the Poor and Underserved*. 2015; 21(3): 879-897. doi: 10.1353/hpu.0.0323

Comment 28

Thank you for this opportunity to submit public comments on the ODS Strategic Plan Draft. As a member of the ChromaDex Science Team, we would like to offer the following recommendation to the question, "Are there existing knowledge gaps that ODS can help address (not included in the current plan)?"

Biomarker(s) of NAD status and population assessment of NAD in health and disease

- Background
  - Interest in the role of nicotinamide adenine dinucleotide (NAD) in health and disease has grown substantially over the past decade, including a workshop from the NIH's National Institute of Aging in December 2021, "Exploring Opportunities and Feasibility of Trials on Effects of Increasing NAD+ Levels in Older Adults."
  - NAD is an essential cellular co-factor required for cellular energy and contributes to over 300 cellular processes including DNA repair, cellular senescence, cellular respiration, circadian rhythm, and innate immunity.

- To generate NAD, cells use NAD^+ precursors including members of the vitamin B3 family (niacin, nicotinamide, nicotinamide riboside and nicotinamide mononucleotide) and tryptophan through various pathways.
- Metabolic stressors including a poor diet, environmental exposures, infection, and certain diseases are linked to a reduction in the cellular NAD pool resulting from an increase in NAD-consuming enzymes such as PARPs and sirtuins to combat these insults, suggesting a role for optimal NAD status in health.
- Studies have associated declines in NAD+ with age, which may be the result of the accumulation of cellular insults that deplete NAD.
- NAD is being touted as an anti-aging molecule and disruption in NAD metabolism has been implicated in certain chronic conditions, such as inflammaging, heart failure, fatty liver and neurodegenerative diseases.
- Current dietary recommendations for NAD are based on niacin and avoidance of pellagra, and the tolerable upper intake level (UL) is based on skin flushing, both outdated endpoints. Pellagra as the only indicator of NAD deficiency is not likely sufficient based upon recent discoveries of the role of NAD in health and disease.

- We would like to recommend that ODS address the following knowledge and public health gaps:
  - Develop a validated biomarker of NAD status (that goes beyond pellagra) to determine the role of NAD in health optimization at various stages of life and its role in chronic health outcomes, such as heart failure, sarcopenia, obesity, Alzheimer's, and Parkinson's diseases.
  - Population-based assessments of NAD status and health outcomes.
  - Evaluation of the impact of higher intakes of vitamin B3 (well above the current RDA of 16 mg/day) and potential health promoting effects, including the reduction in the risk of certain chronic diseases in the population (similar to what was done for vitamin D).

Please feel free to reach out if you have any questions.

On behalf of the ChromaDex Science Team, thank you for your consideration,

Comment 29

The Consumer Healthcare Products Association (CHPA)1 appreciates the opportunity to provide additional comments on the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) Strategic Plan 2022-2026. Many of our member companies manufacture and/or market dietary supplement products and are impacted by efforts undertaken by ODS to conduct and support scientific research to enhance the evidence base for dietary supplements and their ingredients.

CHPA applauds ODS for undertaking a comprehensive effort to examine the benefits and safety of dietary supplements and dietary ingredients and for prioritizing the dissemination of useful information to consumers and other stakeholders. CHPA underscores our previous comments that support ODS's research regarding how supplementation can help fill nutrient gaps that the

Dietary Guidelines for Americans have identified as a public health concern. In addition, CHPA encourages ODS to involve experts from the dietary supplement industry into important dietary supplement stakeholder conversations. For example, CHPA welcomes being part of NIH workshops, meetings, and conferences that help to identify research gaps and priorities. CHPA also recommends that the Federal Working Group on Dietary Supplements include industry stakeholders.

CHPA members promote transparency and are long-time supporters of NIH's Dietary Supplement Label Database (DSLD). The DSLD contains 143,369 current and historical dietary supplement labels, which makes it the most comprehensive database of dietary supplement products, brands, and ingredients. CHPA is encouraged by ODS's continued progress on the DSLD through Work Strategy 3-3 ("Develop and provide publicly accessible databases for use in clinical, epidemiological, and other population research on dietary supplements"). The DSLD has become more important as the topic of a dietary supplement label database has become a timely priority for more than just dietary supplement researchers and consumers.

The Food and Drug Administration (FDA) and Congress are seeking to amend the Federal Food, Drug, and Cosmetic Act to require dietary supplement product listing with FDA for all marketed supplement products. The proposal, known as Mandatory Product Listing (MPL), would have significant overlap in design with the current DSLD. One noteworthy difference is MPL would be mandatory, while DSLD is voluntary. CHPA feels that now is the opportune time for ODS to educate Congress and FDA about the important technical work done over the past 10+ years on building and improving the DSLD which could serve as a successful model for the MPL system.

CHPA acknowledges that regulatory and legislative purviews are outside the scope of ODS work. However, given the significant effort and expense that ODS has invested in building, improving, and maintaining the DSLD2 we believe that ODS could best speak to the diverse stakeholder population that would be impacted by implementation of MPL were it to become a requirement through legislation.
Should FDA require that manufacturers/distributors submit listing information including labeling for all marketed dietary supplement products, the need for a database to store and maintain accurate and up-to-date labels of dietary supplements would become apparent.3 Were FDA tasked to build this database from scratch, it would be a missed opportunity if FDA did not lean on the technical knowledge gained by the development and improvement of the DSLD.

CHPA believes ODS should seek an opportunity to provide Congress and FDA an overview of the DSLD and discuss the significant efforts undertaken, along with the Therapeutic Research Center (TRC), to improve this database. While there would be challenges to overcome in making the DSLD the official FDA mandated repository for all dietary supplement labels, we believe these would not be significant and that ODS and TRC could leverage the experience gained over the past several years to facilitate inclusion of all on-market labels in the DSLD.

Many members of the dietary supplement industry have already embraced the DSLD and are accustomed to submitting and maintaining up to date labels in the DSLD. Should MPL become an FDA requirement and provided there are no significant changes to the label submission process, we believe that all stakeholders in this process, including the entire dietary supplement industry, the FDA, and consumers would benefit from the DSLD serving as the model that informs the official FDA repository for dietary supplement labels.

We appreciate all the efforts undertaken by ODS staff to enhance the knowledge base and understanding of dietary supplements for both consumers and professionals. Should you have any questions about this proposal we would be happy to discuss.

Respectfully submitted,

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over the counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self- care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[2] Saldanha LG, Dwyer JT, Bailen RA. Modernization of the National Institutes of Health Dietary Supplement Label Database. J Food Compost Anal. 2021 Sep;102:104058.

[3] The FDA Fiscal Year 2023 Budget Proposal includes an effort to "Modernize dietary supplement regulation, seeking to require annual listing with the FDA of individual dietary supplement products, including basic information about each unique product."

Comment 30

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

In 1998, the U.S. National Institutes of Health Office of Dietary Supplements (ODS) established the practice of developing five-year strategic plans. ODS has continued to use the goals-oriented five-year framework established in 1998 during subsequent strategic planning activities over the following 24 years.

On October 25, 2021, AHPA received an advance draft of the 2022-2026 strategic plan from ODS to serve as an external expert reviewer. AHPA provided feedback on this version of the plan on November 18. On July 28, 2022, ODS issued a request for information in the Federal Register announcing the public availability of the draft 2022- 2026 strategic plan and requesting public feedback on its contents.

Greater external stakeholder engagement will improve outcomes AHPA identifies several points in the draft strategic plan at which proposed ODS and broader NIH activities would be enhanced by the inclusion of greater external stakeholder input.

Strategy 1-3 states in part that "ODS will continue to conduct internal and NIH-wide portfolio analyses with NIH ICOs [Institutes, Centers, and Offices] and other federal partners, leading to priority setting for funding decisions and identification of emerging research opportunities." Opportunities and knowledge gaps may exist that are not visible from a purely governmental perspective. AHPA therefore encourages the inclusion of external stakeholders from industry and academia in these portfolio analyses.

Strategy 3-2 describes ODS's ongoing commitment to the development of new analytical methods and reference materials for dietary supplement evaluation, including through interagency collaboration activities. AHPA encourages the inclusion of industry stakeholders with experience in application of analytical methods and reference materials in the identification and prioritization of projects on this subject.

Strategy 4-1 states that ODS will publish new dietary supplement fact sheets and revise existing fact sheets as necessary to keep them current. AHPA lauds the efforts of ODS to encourage the dissemination of information on supplements of interest.
However, the fact sheet preparation and revisions process does not provide an opportunity for a review and comment period by affected stakeholders (consumers, academia, supplement industry, trade associations, etc.). The inclusion of an open comment and review period could help reduce the possibility of potential data gaps and could improve the overall impact and relevance of the fact sheets to stakeholders.

Strategy 5-2 and a separate "new initiatives" section later in the draft plan discuss the proposed creation of the NIH Dietary Supplement Research Coordinating Committee (NIH DSRCC), to "identify emerging and cross-cutting research areas and to develop platforms for encouraging collaborative initiatives across NIH and within the federal government". AHPA notes that the stated purpose of the DSRCC envisions "collaborative initiatives" that include government actors beyond the NIH, but further notes that the DSRCC as proposed consists exclusively of participants from within NIH. AHPA encourages the direct involvement of government stakeholders from outside of NIH in the DSRCC, as well as representatives of academia and the dietary supplement industry.

Enhance dissemination activity through trade organization outreach Goal 3 of the strategic plan includes the dissemination of research resources and tools to enhance the quality of dietary supplement research. AHPA agrees that such communication activity should be part of the standard dissemination strategy for the Office. Furthermore, AHPA encourages the direct communication of new or updated ODS tools, educational activities, and research outcomes to industry associations as a part of all strategies addressing Goal 3. Trade associations can serve to expand the reach of ODS communications in these areas, drawing new academic, industry

and consumer audiences to ODS activities. This was demonstrated by recent AHPA outreach promoting major updates to the Dietary Supplement Label Database[1].

Broader collaboration is needed to address research gaps
Goal 5 of the strategic plan is to "Coordinate and support the development of collaborative initiatives to address gaps in dietary supplement research." AHPA notes that while the stated purpose of this goal is to address gaps in existing research, the strategic plan does not clearly identify how new coordination activity by ODS will identify or address research gaps. The strategies addressing Goal 5 refer exclusively to activities among NIH ICOs, and the Goal 5 description itself refers to collaboration with only the FDA, U.S. Public Health Service, and USDA.

AHPA suggests the inclusion of a broader set of governmental entities in the set of "sister agencies" with which ODS collaborates under Goal 5 strategies, especially in the identification of research and resource gaps. For example, EPA uses NHANES data in intersection with other sources (including recipe and intake databases) in the determination of commodity dose exposures for the purpose of establishing pesticide tolerances. This activity has a direct impact on public health and numerous areas of research, and utilizes a set of database frameworks which could benefit from the collaboration and gap analysis framework described in Goal 5.

Conclusion
AHPA greatly appreciates the opportunity to present comments on the draft strategic plan. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. If ODS requires clarification or additional discussion on any of the items raised in these comments, please feel free to contact us.

Respectfully submitted,

[1] AHPA Update 2/1/2022, "Dietary Supplement Label Database adds thousands of labels".

Comment 31

On behalf of Haleon and the millions of consumers who use our vitamins, minerals, and supplements to support a healthy lifestyle, we appreciate the opportunity to submit comments on the National Institutes of Health's (NIH) Office of Dietary Supplements (ODS) draft ODS Strategic Plan for Fiscal Years (FY) 2022-2026. Our feedback focuses on the need to create a new definition for "nutrition insecurity" to better address current issues instead of the term "nutrition status."

About Haleon

Haleon is one of the world's leading over-the-counter (OTC) healthcare companies with number one positions in several markets, including the United States. We combine science and

consumer insights to create innovative everyday healthcare brands that consumers trust and experts recommend for oral health, pain relief, cold, flu and allergy, tobacco cessation, digestive health, vitamins, minerals, and supplements. In addition, we invest in scientific and technical excellence to develop and launch a pipeline of new products that meet the needs of patients, payers, and consumers.

Americans Continue to Struggle in Meeting Nutritional Goals

While the proposed Strategic Plan provides tools and appropriate strategies to examine diet and dietary patterns, we believe that emphasis should be added to the relationship between food intake and nutrition insecurity. As you know, recent USDA nutrition surveys and databases revealed that many Americans are unable to meet their nutritional goals through food and beverage consumption alone.[1] Ninety percent of Americans fail to consume the daily recommended intake of vegetables designed to supply the needed daily nutrient intake, and 40% of Americans fail to consume the daily recommended intake for five or more key vitamins and minerals, including Vitamins A, C, D, E, Magnesium, and calcium.[2]

The Need to Define and Identify Nutrition Insecurity

Given the aforementioned statistics, we encourage the Draft Strategic Plan's 1-2 strategy to include a definition for nutritional insecurity and its subsequent adoption in the Plan. While the draft plan includes the term "nutrition status," such phraseology does not fully encompass everyday Americans' difficulties in meeting their nutritional needs with food and beverage consumption alone. In adopting a nutrition insecurity lens, NIH ODS would take a significant step in addressing current knowledge gaps while helping Americans better understand their daily dietary needs. Such definition should incorporate elements of food insecurity but be distinguishable to tackle nutritional deficiencies in population subgroups. We believe that adopting this lens will provide the NIH with new tools to address current nutrient-based health disparities. In addition, the agency would better concentrate collaborative efforts with interagency, public, and private stakeholders to understand better the relationships between dietary supplements, over-the-counter products, and prescribed medications. We believe that this approach could yield valuable data to inform the Strategic Plan, create avenues for public-private partnerships, and ultimately achieve the Plan's objectives on addressing knowledge gaps and meeting the needs of stakeholders.

We applaud the ODS' commitment to include our industry alongside NIH ICO leadership, representatives of the scientific community, other federal agencies, and the public in the strategic planning process. As a company focused on providing better everyday health with humanity, we thank your agency for providing an opportunity for public comment and consideration of our views.

Conclusion

With 80% of Americans using dietary supplements, we hope that the NIH will consider the broader benefits of these supplements and the crucial role they play in improving the health and wellness of all Americans.[3] As your agency moves forward with implementing the ODS Strategic Plan, please know that Haleon continues to support your efforts and looks forward to collaborating with your agency on nutritional issues where possible.

[1] U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Dietary Guidelines for Americans, 2020-2025." Washington, DC, December 2020, https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf
[2] U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Dietary Guidelines for Americans, 2015-2020." Washington, DC, January 2016, https://www.dietaryguidelines.gov/sites/default/files/2019-05/2015-2020_Dietary_Guidelines.pdf

[3] 2021 Council for Responsible Nutrition Consumer Survey on Dietary Supplements

Comment 32

First, my congratulations on the achievements of the ODS which are outlined in the strategic plan document. I also appreciate the goals and robust strategic plan to achieve them in the next 5 year period.

In relation to the questions posed, I do have a few suggestions:

Are there additional emerging public health issues that ODS can help address?

- While the need to assess safety is described, there could be stronger emphasis on the need to evaluate interactions between dietary supplements and conventional drugs. The establishment of NAPDI is a great advance; as dietary supplement use increases, so will the risk of interactions and the need for such research.

Are there existing knowledge gaps that ODS can help address (not included in the current plan)?

- There is excellent support from ODS for the validation of analytical methods. However, the current wording suggests that this is mostly applicable to methods of evaluating the composition of the supplements themselves. It would be useful to have a declared extension of this support to bioanalytical methods to evaluate bioavailability of the components of a dietary supplement, particularly botanicals. Indeed little is currently known about the bioavailability and metabolic modifications of phytochemicals found in the majority of botanical supplements. Encouragement of such studies would move the field forward.

Is there anything that ODS can do differently to meet the needs of its stakeholders?

- The ODS could play an important educational role for reporting of associations between a dietary supplement and observed toxicity among users. It would be helpful to develop some guidelines to assist healthcare workers/coroners on (a) what details to note about

dietary supplements and their intake if suspected to be involved in cases of toxicity and (b) how to evaluate and describe the strength of the evidence linking the observed toxicity to a particular dietary supplement. Without this, even weak or nuanced associations can get magnified and create an erroneous picture. This is unfair to the public, the dietary supplements industry and the field of complementary healthcare. A case in point is the recent publicity surrounding the stated role of white mulberry leaf ingestion in the unfortunate December 2021 death of Lori McClintock, wife of a congressman. The American Botanical Council recently issued a statement outlining major weaknesses in the available evidence on which white mulberry leaf was identified as the cause of death in the coroner's report. While media response is more difficult to control, it would be helpful to have a way of educating those making the initial assessment and reporting of associations and also perhaps a way of standardizing the description of those associations.