



The Organic & Natural Health Association is a unique national trade organization representing the interests of health-minded consumers and the best companies in the dietary supplement supply chain. Our tenets are rooted in consumer demand for access to the safest and highest quality products available -- a demand our industry members strive to meet at every step.

Innovation and modernization must be rooted in consumer safety. Even with an amazing safety record, opportunity still exists for bad actors to sell inferior and dangerous products to unsuspecting buyers.

O&N will advocate for resources to fully fund enforcement against the most egregious players, who sell products online, in gas stations and convenience stores claiming help with weight loss, energy or sexual performance. They represent the majority of adverse event reports. They often contain undisclosed drugs or ingredients. We want FDA to efficiently improve enforcement against these bad actors.

Second, be it through innovation or modernization, there is an intellectual flaw in the definition of health claims vis a vis structure/function claims that must be addressed. Dietary supplements are in fact a category of food, and no change in definitions should blur the boundary between dietary supplements and pharmaceutical drugs. However, it is far too easy to create a new disease. Osteoarthritis, the result of 'wear and tear' on our joints, is a condition that will impact virtually everyone in this room as they naturally age. Yet it is categorized as a disease, and a supplement that may reduce the pain of this malady can only claim to "support bone and joint health". Circuitous label claims achieve technical compliance but keep consumers confused.

With regard to health claims, existing regulation chokes opportunity for science to document how supplementation can reduce the incidence of disease.

For instance, the FDA denied O&N's formal petition to allow a health claim stating that increased vitamin D serum levels reduces the risk of preterm birth (by 60%). The agency's response stated that "as an indicator of vitamin D status, serum levels do not meet the definition of substance. Serum levels are not food or components of food."

Given the strength of the research, undertaken with the Medical University of South Carolina, it leaves one first curious, and then outraged, to contemplate how existing regulations exclude health claims about the correlation of well established nutrient levels with a well defined health status.

Fundamentally, It is not sufficient or accurate to define a supplement simply as a "dietary substance for use by man," -- or pregnant woman -- "to supplement the diet by increasing the total dietary intake" The definition needs to be updated and modernized.

Lastly, dietary ingredients produced using genetic engineering and novel methods of Synthetic Biology should be evaluated as new dietary ingredients even when similar natural ingredients exist. If innovation is defined as the process of creating novel compounds and formulating products with them, then full disclosure for the entirety of the supply chain must be required as part of the regulatory process. Anything less than 100% transparency completely fails consumers desires and expectations. This mistep can potentially instill consumer distrust of whole categories of dietary supplement ingredients, just as we have seen happen in food products. Lesson learned. Any dietary supplement company that is confident in its products and respectful of its customers will not object to full honest disclosure of how its products are made.