The Functional Foods Paradox

By Peter Leighton

Diet and lifestyle are critical components in overall health & wellness. As such, functional foods are valuable in the maintenance of health. As more and better science is applied to food's bioactive constituents and their relationship to health, it does not imply that the foods we eat are drugs (and should be regulated as such) rather, it helps identify those foods which provide specific functional health benefits. This is science that should be encouraged and communicated to all consumers.

Yet here we find ourselves in a great paradox. The more science we apply towards greater understanding of the benefits of the foods we eat, the more criticism and regulatory scrutiny we must endure. Speaking on behalf of IOM's Committee on Qualification of Biomarkers and Surrogate Endpoints in Chronic Disease, committee chair John Ball said, "Many people naturally assume that the claims made for foods and nutritional supplements have the same degree of scientific grounding as those for medications, and this committee thinks that should in fact be the case". What's missing here is the fact that foods and nutritional supplements don't make anywhere near the health and disease claims made by medications.

Daniel Fabricant, Ph.D., vice president of scientific and regulatory affairs, Natural Products Association makes a key point: "Trying to see foods through the same lens as isolated pharmaceuticals is impractical from a policy standpoint." You see, pharmaceuticals are usually single small molecules which are created synthetically so as to be laser focused on its structures, actions, mechanistic responses, etc., and carefully studied because they are in fact, by nature of their concentrated potency, dangerous. Yet each year more than 2 million people in the United States are hospitalized or injured, including more than 100,000 fatalities from FDA approved medications. In fact, according to the Journal of American Medical Association, adverse drug reactions are one of the leading causes of death in the United States.

Foods are not drugs. Plant based phytonutrients present so much variability, whether by species, genus, crop geography, seasonality, harvesting methods, processing methods, etc. And that's just the plant. When you start to consider that in a particular plant extract there may be hundreds of molecules, representing millions of variable interactions, you can see why traditional medicine favors a new chemical entity that they can create and manipulate. As we have had greater capacity to understand and characterize the functional health benefits of the various compounds in foods, functional foods have emerged as excellent options for consumers wellness concerns and as a better option than "traditional" processed food options. I doubt the supermarket will be mistaken for a pharmacy but deterring the consumption of better food choices and stifling the communication of scientific research related to these foods is irresponsible.

Senator Herb Kohl, chairman of the Select Committee on Aging, echoed what many government officials have said, "Consumers should have access to comprehensive, accurate information about these products so that they are empowered to make the best decisions about their health". Yet the paradox maintains that nutraceutical products regulated under DSHEA are prohibited from comparisons with or relationships to any pharmaceutical medication, disease state or treatment. So whereas there is sufficient evidentiary data that garlic, for instance, may decrease the progression of cardiovascular disease, it cannot be marketed based upon that (accurate) information. Garlic seems to help decrease LDL and total cholesterol levels while raising good cholesterol (HDL), decreasing platelet aggregation (helps the blood flow more easily), and decreasing blood pressure. Recently, garlic was also found to decrease two other markers of cardiovascular disease, homocysteine and C-reactive protein.

You would think that consumer access to advancing scientific information about the functional benefits of certain foods would be encouraged and appreciated. God knows, there is little question about the poor quality of the "Western Diet" and the chronic disease epidemics that are directly linked to it. In offering food options that have scientific research supporting their functional health benefits would allow consumers to make choices. These choices likely will have a long term and profound impact on our healthcare system, our quality of life and our mortality. There is only one reason I can suggest as to why there would be a resistance to these functional products: Their success threatens the economic interests of too many powerful parties.

What is currently threatening the nutrition industry is a combination of regulatory roadblocks, poor communication and self inflicted wounds. From the regulatory standpoint, functional foods are bound to meet ongoing resistance from FDA and FTC based upon not just "claim" issues but a host of technical and procedural issues.

For instance, the FDA recently announced new guidance (see 21 CFR 10.115(g)(5)) related to the difference between liquid dietary supplements and beverages bearing novel ingredients. According to the FDA, “We have seen an increase in the marketing of beverages as dietary supplements, in spite of the fact that the packaging and labeling of many liquid products represent the products as conventional foods. Products that are represented as conventional foods do not meet the statutory definition of a dietary supplement…” The FDA further explains, “Liquid products that suggest through their serving size, packaging, or recommended daily intake that they are intended to be consumed in amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the US, are represented as beverages.” Such products, the FDA said, “may not be marketed as a dietary supplement.”

The nutrition industry has done a poor job marketing and communicating. Considering that over half of households are using food or beverages to treat or manage specific health issues, it is important to recognize the burden that must be carried by companies marketing these products. If consumers are eating medicine like its food, they will get too much of a good thing. And the consumption of additional calories simply feeds a real health pandemic: obesity. Science tells and emotion sells, meaning successful functional foods are based in science but purchased for taste and convenience; they are not medicines.

Consumer interest in functional foods is related to their “health halo”— their scientific support or experiential effect in maximizing health, performance and perceived wellness. These products fail miserably when marketed or consumed as therapeutic products. The largest functional food categories are ones that are not considered therapeutic, but rather preventative/wellness. 69% of Americans are pursuing a preventative lifestyle vs. 27% who are trying to treat a health concern. Consumers are looking for tasty, convenient and “healthful” options to “traditional” foods and beverages. They will not sacrifice taste, but prefer products that will enhance their wellbeing. Functional food success is defined by *wellness*, not disease treatment.

The nutrition industry has a history of self-inflicted wounds. Quality and standardization issues aside, like many industries there is a perpetual parade of violators driving the hyperbole highway. Companies that market any food, “functional” or otherwise, and make unsubstantiated claims are doing a huge disservice to the entire industry for their own short term self interests.

Functional Foods are not a panacea and are certainly a product category bound to be “abused” just as dietary supplements have been. What do I mean by abused? In controlled dosing, such as pills, one can specify the amount of certain bioactive compounds. But when these compounds are in a food product, it is a bit

more difficult to manage the dosing, especially when a good tasting snack product is involved.

The nutrition industry has been undergoing significant regulatory changes recently, particularly with respect to health and dietary claims. This trend seems to be accelerating and will require better consumer communication and a modified (or at least better articulated) regulatory framework. This year Senators Hatch and Harkin introduced the Dietary Supplement Full Implementation and Enforcement Act of 2010, which appropriates FDA funding for DSHEA enforcement, requires annual accountability report to Congress and mandates FDA guidance on NDI's. And while there is increasing chatter about functional foods in Washington, it will likely require a legal challenge from FDA before the core issues threatening these products will be truly dealt with; and like so many issues before, the outcome may not be what it should.