

**FDA Public Meeting on Qualified Health Claims**  
**November 17, 2005**  
**5100 Paint Branch Parkway, Room 3B-035**  
**College Park, MD 20740-3835**

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The California Walnut Commission received a preliminary approval and language for a health claim on heart disease from the Food and Drug Administration in July 2003. More than 8 months later on March 31, 2004 the final letter was received by the Commission. Between these two dates, the discussion on qualified health claims reached what we thought was its peak. The irony is in light of the subject of this meeting that the claim language became more complex and confusing in the 8 months between July of 2003 and March of 2004.

The California Walnut Commission conducted four separate pieces of research to evaluate the language being used in the health claim. It did not seek to significantly alter the language which FDA deemed necessary. Rather, we chose to take the path that would provide us with the clearest message to consumers without overstating what we frankly believed the FDA would accept. In hindsight, that was not a good judgment. In our own quantitative research, conducted in September 2003, 74% of consumers said the proposed FDA authored claim for walnuts was vague, not clear and/or confusing. I would hasten to point out that in our study we had only two iterations of the claim to assure reliable results.

In addition, we learned that just a slight modification of the claim language resulted in three fold increase in the number of consumers saying the claim was "easier to understand". The better approach would have been to begin this analysis at ground zero. If we had assumed we knew nothing about the consumers' reaction to claim language the research could have been directed toward the right choices in communication. Instead we only determined whether what we thought was a good message truly was making the point.

Unfortunately, the other worthy efforts conducted by the FDA, IFIC and others only prove that what we chose was unacceptable and did not communicate the intent of the efforts to create the desired levels of claim "value". We still do not have data to **prove** what will work. My choice of the word "prove" is intended to provoke a debate over what does constitute "proof" in any form of research be it scientific or marketing.

Definitive proof may not be practical especially in the environment in which we all must function.

The difficulty of this task is that we are trying to communicate a very complex message. This is confounded by the fact that there are other messages consumers are receiving on a daily basis. There are existing tools such as the nutrition facts and unfortunately, there are emotional and rational beliefs on the part of consumers about what constitutes health.

In trying to define what constitutes a health claim, the Federal Trade Commission has done an outstanding piece of work in looking at print ads dating back to 1978. Their definition of a "health claim" is far more in keeping with reality. That is, it is not simply what the FDA may decide is a health claim but rather, what communicators present to consumers that for whatever reason has merit in the minds of the consumers. Further, we must deal with the clutter of messaging from a variety of sources and a variety of industries. Low fat, no fat, reduced fat, lower calories, only 2 grams of carbohydrates are more meaningful, "claims" the consumer responds to because they are simple. Make no mistake about it; to the consumer these are health claims. This makes achieving simplicity in a message FDA designates as a health claim that much harder.

The Food and Drug Administration is doing its utmost to provide us with the best possible message however, the FDA must acknowledge that it can only do the best it can. It will not be perfect. The FDA must use its influence however to awaken the consumers consciousness of what good food is.

#### Suggestions for the Development of Claims

We must use the existing tools that have been given to us. The Nutrition Facts Panel is a valuable tool and it can be revised from time-to-time to reflect current policy on what we wish to communicate to the consumers. Dietary guidance is another wonderful tool. It too is complex. If we simplify it we'll take away its meaning

Other programs, educational programs and health educators such as registered dieticians, should seek to reach those who cannot interpret what is already available in the system. Without that kind of education, these efforts are relatively meaningless.

It will be impossible to achieve a perfect balance of specificity and simplicity. We are talking about science after all. We must accept the standard of satisfactory scientific agreement in this regard. I have never come in contact with a researcher who did not want to know more. By definition their inquisitive minds are never satisfied. We must reference the nutrition facts panel, dietary guidance in conjunction with a claim. There is no need to duplicate language and make information intimidating to the consumer.

It is important to find the right communications tools for the claim itself. The right word sets will be critical. Word sets such as excellent/good/some or gold/silver/bronze, good/better/best, and visual images such as 4-stars and measuring devices such as gauges all have their place in communication. However, we are not looking for gimmicks. We are looking for the simplest most straight forward way to communicate to people what foods are good and healthful and whether or not a food claim is supported by adequate science. This however raises another debate.

The Food and Drug Administration must consider separate protocols which will acknowledge the higher burdens of proof for the products they govern. Perhaps more importantly, the FDA must consider how the consumers view the relative strengths and weaknesses of language as it is influenced by those categories of products on which they are used. The same statement on a processed food may carry different connotations on a naturally occurring whole food. The more complex the product choice (the recent lycopene claim for tomato based products) the more specific language must be and this leads to confusion. Let us consider why this might be so.

Drugs or combinations of compounds not found in nature. Therefore, there is no historical consumption data available. This would require a very high burden of proof in order to acknowledge not only the efficacy but the safety of the new compound. Consumers are very sensitive to this fact especially since the Vioxx issue.

Supplements are derived from things found in nature but do not exist as they are presented to consumers in their natural form in most cases. The interaction of supplements with other compounds and foods consumed in the diet are uncertain and therefore, it would seem as though the burden of proof would be second only to drugs.

Processed foods may be and are altered at will and have indeed been altered over the last several years as we've identified key health issues and the compounds that help control, eliminate or reduce those conditions. A very important issue is whether or not a processed food contains a compound that is deemed desirable and whether or not that compound is bio-available. In fact, as we all know, processing can harm certain components of their ingredients (i.e. bran) and thereby reduce the value of foods that are inherently good. Therefore, it would seem as though processed foods would require less of a burden of proof than supplements and drugs but still must be looked at with care.

Finally, naturally occurring whole foods are found unaltered in nature. In most cases, these foods have a very long history of consumption and depending upon which archeologist you believe, walnuts have been consumed for somewhere between 8,000 and one million years. Naturally occurring whole foods should not have the same burden of proof as other categories already mentioned. In fact,

research protocols on foods are much more difficult to conduct in large numbers over long periods of time than drugs or supplements. This is acknowledged by leading researchers across the country. It is viewed as impractical to believe that a large cohort would remain compliant over a long period of time. It is not the way people eat.

Is it about the food or the compound? You have to look no farther than the humble walnut to know it is about the food which contains many important elements which work in synergy.

Therefore, we would suggest that satisfactory scientific agreement or some new interpretation of what is adequate science be considered on four different levels.

It will also be necessary to evaluate any words or graphics to be used in conjunction with a health claim. Good, better, best; Excellent, good, fair; Gold, silver, bronze are familiar word sets but what will they mean to consumers in this context. Most consumers understand the limits of the qualifier "may". In combination with other qualifiers, they become confused. This is not acceptable for the petitioner or the FDA.

Four stars; three puffs which by the way has nothing to do with smoking; A speedometer needle (left is fair, right is excellent); there are a host of well know graphics from which we may choose. Others will claim these images for their own programs creating confusion and conflict. Who is the authority on these matters? Often it is whoever acts first.

If we put communication ahead of the regulatory "cookie cutter" environment, we can succeed. However, we must start anew. This system must be built from the ground up and if nothing else the research conducted to date **proves** that fact.

The effort is already in grave danger. The "danger" is that consumers have already voiced their concern through their actions in regard to the validity of any information about food and health. In large part this reaction is due to the efforts to inform them with "claims" that are too long, too complex and too confusing. We must start at the beginning. Often less is more.

Thank you.