

## Obesity Policy Promises A Functional Food Feast

by Nancy Childs, Ph.D.

A confluence of public events on a global scale have placed obesity front and center of food policy and corporate strategy. While it has generated innumerable conferences and an entire low carb food frenzy in the short run, its real promise is in long-term proven product development of foods that are demonstrated to functionally impact obesity—or functional foods for obesity.

Such documented products may have a double reward—eligibility for qualified health claims and possible reimbursement under Medicare as a disease treatment. They also offer laudable product franchises which provide a “healthy” balance to food company product portfolios, thereby limiting corporate liability on both legal and stock valuation fronts. Opportunities abound for ingredients and well formulated products—those providing both taste and convenience with their functionality—that carefully document and demonstrate their ability to aid weight loss and prevent weight gain.

### Emergence of Obesity as Major Public Health Issue

Surgeon General David Satcher issued the formal Call to Action to Prevent and Decrease Obesity in 2001. Lawsuits against McDonalds followed in 2002, generating tremendous media attention if not legal respect. The World Health Organization declared obesity a global epidemic in March 2003 and followed it up with bold recommendations in 2004. April 2003 witnessed the JPMorgan equities report which ranked public food company product portfolios based on their exposure to obesity. This tied corporate stock valuation to anticipated liability risk and profit erosion from over reliance on high caloric foods. Later in Summer 2003 Department of Health and Human Services Secretary Tommy Thompson announced his Obesity Roundtables which began a well publicized and high level stake-

holder dialogue. He also instructed the Surgeon General, Center for Disease Control, NIH and the FDA to address the obesity epidemic with high priority. In 2003 and 2004 numerous state legislatures took up the obesity charge with a variety of bills to tax high caloric foods and beverages or restrict sales venues for such products. In summer 2004 Medicare formally declared obesity an illness with eligibility for reimbursement of medically documented products and treatments for seniors.

The FDA has proposed label changes that rationalize portion size to package size and alter the Nutrition Facts Panel to emphasize calories as percent of daily total. They are giving early consideration to the possible addition of symbols on the label translating calories to physical energy expenditure. Also they are implementing a qualified health claim policy that allows a reference to the health value of foods or ingredients provided the label carries a qualified health claim denoting the level of science and certainty behind the claim as rated by the FDA. The figure on page 15 details the standardized qualified language for the proposed levels of qualified health claims for use on the food label. These are the operating models until FDA sponsored consumer research is evaluated on the claims’ differing language and their receptivity and viability with consumers. This consumer data will explore communication issues and impact decisions regarding the final qualified health claim format for implementation.

While qualified health claims provide potential communication opportunities for many functional bio-actives, they likewise are available for use with obesity-related products. The high priority given weight loss efforts assures the FDA would give such products timely and thorough scrutiny with a hope of seeing genuine weight loss products entering the market.

### Ingredients With Functional Potential to Mitigate Obesity

Product development approaches are three-fold to address obesity:

**1.) Less is more** meaning a straightforward reduction of undesirable ingredients associated with weight gain such as sugars, fats and

most recently carbohydrates. The latter has peaked rapidly with enormous product reformulation to create low carbohydrate products and brands overwhelming the consumer with lower carbohydrate product alternatives. By mid year 2004 interest in these products and in a serious low carbohydrate diet is waning.

**2.) More is less** as a plethora of new ingredients are being developed and touted to bulk up foods to achieve a low caloric density. These can be as simple as adding more water, air, or fruits and vegetables to formulations. Whipped versions of yogurts and desserts permit lower caloric density of favorite products with all the taste and mouthfeel. New novel oils and fats such as diacylglycerol (*Enova* by ADM Kao LLC) and structured triglycerides (*Benefat* by Danisco), sugar substitutes, flours and fibers (*Raftiline* inulin by Orafit and *Oliggo-Fiber* from Cargill) can be formulated into products to achieve a lower calorie product. Additional ingredients which extend products without adding excessive calories include starch blockers, flaxseed, and soy (*Solae* from DuPont-Bunge and USDA’s *Soytrim*) among other possibilities.

**3.) Functional Ingredients** show real potential for actively assisting weight management. Several of these products are pursuing both GRAS status and qualified health claim approval. All such products would need an ongoing research program demonstrating efficacy for FDA review. Potential runs the spectrum from familiar ingredients with new weight management evidence such as calcium, to more tentative and novel products under review. Functional food candidates in this group, as highlighted by the Institute of Food Technologists’ *Food Technology* journal in March 2003, include leptin, chromium, soy and whey proteins, L-carnitine, conjugated linoleic acid and other products. Fibers such as barley or oat derived beta-glucan (*Maltrim* and *Nutrim* by VanDrunen Farms; *OatVantage* by Nurture, Inc.) may aid satiety and maintain blood glucose levels for weight management. Specialty corn-derived starches (*Novelose* by National Starch and Chemical Co.) may lower glycemic responses. Extensive work with flax lignans suggests health functionality with many co-factors with obesity as licensed by

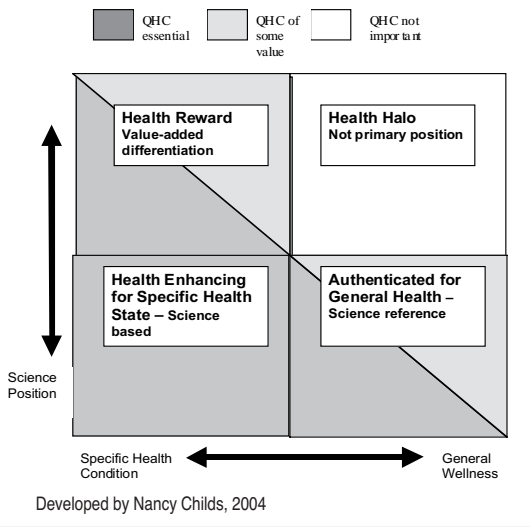
ADM. Whey proteins (such as *Grande Ultra* by Grande Custom Ingredients Group) may suppress appetite, and dairy is showing a multifaceted functionality for weight loss (including *TruCal* by Glanbia and efforts by Dairy Management Inc). Conjugated linoleic acid (*Xenadrine* by Cytodyne Technologies or *Clarinol* by Loders Croklaan Lipid Nutrition) may accelerate fat breakdown and increase lean body mass. New functional fibers which manage sugar levels to assist weight loss include fenugreek (*FenuLife* by Acatris and *Fenupure* by Adumin Food Ingredients), and polydextrose (*Litesse* by Danisco). Chitosan polysaccharide fibers inhibit fat digestion (*ChitoClear* from Primex BioChemicals). Chromium and chromium picolinate are long associated with weight management potential (*ChroMax* by Nutrition 21 and *CarnoChrome* by FutureCeuticals). L-Carnitine is another ingredient associated with weight control through energy. Other novel products include cocoa extract (*Chocamine* from NatTrop) and hydroxycitric acid to suppress appetite, betaine, a component of sugar beets, improving fat metabolism, 4-hydroxyisoleucine (*Promilin* from Technical Sourcing International), DHEA (*7 Keto* by Humanetics Corp.) and forskolin root extract.

While these ingredients are identified for their promise in assisting weight loss and weight management they need adequate science and GRAS status for consideration for FDA qualified health claim approval. Additionally they would need medical substantiation such as clinical trials for Medicare reimbursement. This list, by no means complete, indicates the impressive potential for functional food opportunities to address obesity. Most encouraging is the number of trademarked and branded ingredients which suggest an ingredient supplier may be interested in sharing the scientific effort to document the functional value of the bio-active.

### Strategies for Qualified Health Claims Depend on Product Positioning

Qualified health claims remain generic in their application. Unless the ingredient sup-

### Advantage of Qualified Health Claims by Type of Functional Food Positioning



plier demonstrates a purported health value from a proprietarily derived ingredient, the qualified claim would have application to all similar products. Even if an ingredient is proprietary and is permitted a qualified health claim, the claim would be generically available to all food products which used the ingredient. This situation creates a dicotomized set of opportunities in the market place.

The value and appropriateness of qualified health claim use becomes dependent on the product's positioning in the marketplace and whether the claim is fundamental to authenticating the position or is a value-added enhancement to a position that is not primarily based on health benefit. In this case it provides a "health halo" to the product via its presence in the formulation, and actual use of the qualified health claim is not central to the positioning. For science-based positions for health specific states, the qualified health claim is essential and meets the needs of consumers seeking information for specific product needs. Also, past research shows that the less familiar the bio-active the larger the role for the qualified health claim. For Health Reward and Authenticated product positionings the claim can be useful but not to the same degree as a science based health specific position. The figure above presents the positioning continuums in a matrix format to demonstrate the type of product best served by the qualified health claim (QHC).

### Obesity Creates Opportunity for Functional Ingredients

Attention to obesity creates market opportunity to identify and develop promising functional ingredients to help reduce and manage weight. Documented science leading to a qualified health claim lends the necessary credence to the new ingredients. The functional food category expects 6-7% annual growth through the decade. This category appears as a sustainable and appropriate long term market category and important source for functional food growth. Genuine functional foods for weight loss and maintenance should be rewarded with an enormous market response. Consumer interest in obesity-fighting products will not wane, and consumer patterns of faddish over-response should remain the norm. Demographics for the consumers targeted for obesity functional foods should increase in size as the American baby boom generation avalanches into middle age, typically with spreading waistlines.

The obesity foods category will continue to evolve from the deliberate *less is more* approach, to the more technically driven *more is less* capability to substitute new products for former fattier or sweeter components. Lastly the novelty and technical accomplishments of the *functional food ingredients* category offers the larger opportunity—for possible proprietary positions and for helping consumers to pursue a healthier diet and lifestyle. The category should remain lucrative and sensitive to products that provide scientific documentation rather than reliance on anecdotal endorsements too often associated with economic fraud. The abundance of branded functional ingredient products already in the market bodes well for developing a successful obesity targeted functional food category based on scientific documentation.

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