# **Nutraceuticals World**

## **Fat Chance**

'Weighing' the risks and opportunities in the weight management market.

## By Rebecca Wright

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Overweight/obesity is a health issue that doesn't discriminate—all types of consumers battle it every day. For most, it is the gateway to heart disease, cancer and diabetes.

"Obesity and its associated diseases are fast becoming a huge problem worldwide," said R.V. Venkatesh, managing director, Gencor Nutrients, Anaheim, CA. "What little drug options there are have been unsuccessful. Not enough is being done in the U.S. and the world to tackle this issue." Interestingly, FDA has not approved an obesity drug in a decade.

Weight management for many industries (e.g., food, supplements, gyms, exercise equipment, pharmaceuticals) is the Holy Grail of product opportunities. Yet for all of the billions spent on the current "solutions" available in the market, the overweight/obesity problem is not getting any better. In fact, a recent *USA Today* article called obesity this "century's greatest public health threat."

To make matters worse, the negative effects of the Western diet are spreading across the globe to developing parts of the world, where consumers are working more, moving less and eating calorie-rich, nutrient poor foods.

For dietary supplements in particular, the weight loss market has been a lightening rod, simply because it is one of a handful of categories that opens itself up to abuse by rogue ingredient suppliers and product marketers. Add a shaky economy and a vulnerable consumer set to the mix and you have a perfect storm of controversy.

"The issues [for this market] continue to include negative media coverage of weight loss ingredients stimulated by a few marketers who utilize unsubstantiated claims," said Mitch Skop, senior director of new product development, Pharmachem Laboratories Inc., Kearny, NJ. "Overcoming this obstacle will require consistent efforts to focus the industry on research and public education."

For these and other reasons, Caroline Brons, senior marketing manager, DSM Nutritional Products, Inc., Parsippany, NJ, believes weight management is a category that is currently in transition. "Weight loss supplement sales were negatively impacted by

product recalls and FDA warnings in 2009, and the category is down by about 5% in FDM (food drug mass), according to SPINS."

But things may be looking up. According to a recent report from Packaged Facts, "Weight Management Trends in the U.S.," the shift toward weight management and healthy habits as priorities at the forefront of consumer consciousness are expected to gain momentum as the nation slips further into a semblance of economic relief from the recession.

"Industry experts and Packaged Facts agree that healthy eating is a solid measure of consumer confidence," said Don Montuori, publisher of Packaged Facts. "As the economy improves, consumers will once again focus on health and wellness priorities."

Packaged Facts estimates the global weight loss and diet management market—including diet food and drinks, weight loss programs and services, weight loss drugs and natural therapies, and surgical interventions—reached \$26 billion in 2009. Diet food and drinks—consisting of weight loss bars and snacks, drinks, frozen meals and diet desserts—was the largest category, with \$18 billion, or 73% of total worldwide sales.

Developing foods and beverages that provide satiety, or hunger satisfaction, is projected to be one of the hottest trends in weight management, Packaged Facts says. And though "minus" formulations of foods and beverages—i.e., low-, no- or reduced-calorie/fat/carbohydrates/sugar formulations—continue to dominate weight management products, there currently is a subtle shift toward tinkering with formulations to add functional ingredients that can help people lose and maintain weight. "Many of these same functional ingredients are being used in dietary supplements and over-the-counter weight management drugs," the market research firm said.

#### **Legislating a Solution**

Beyond the toll obesity takes on an individual's health, it also places a financial burden on the nation's healthcare system—costing the U.S. nearly \$150 billion a year. As a result, obesity has emerged as a political problem that federal, state and local governments are attempting to legislate away, Packaged Facts claims. "Perhaps the most ostentatious effort to date has been the Obama Administration's 'Let's Move!' program, which targets the troubling trend of childhood obesity by bringing together several federal agencies to focus on improving nutrition and encouraging exercise," it said.

Speaking of kids, the number of those who are overweight/obese is staggering, says Joseph O'Neill, executive vice president, Sales and Marketing, Beneo Inc., West Morris Plains, NJ. "About one in six children and youths (ages 2-19) in the U.S. are already overweight or obese," he said. "Since overweight kids are more likely to become overweight adults, some experts believe that if obesity among kids continues to increase at this rate, our current generation could become the first in American history to live shorter lives than their parents." After First Lady Michelle Obama kicked off the Let's Move! program, explained Shaheen Majeed, marketing director, Sabinsa Corp., East Windsor, NJ, the administration awarded more funds to fight obesity than tobacco through two big new money sources for preventive health. "The funds, totaling \$1.15 billion, came from economic stimulus and healthcare reform. While one person in five still smokes, one in three is obese," he said.

The First Lady is also lobbying Congress to pass The Child Nutrition Bill, said Mr. Majeed, which would allocate \$4.5 billion over 10 years to support school cafeterias and introduce new standards for food sold in schools, including in vending machines. "The legislation, if passed, would effectively allow the [USDA] to ban junk food in schools," he said. "Childhood obesity has become Michelle Obama's signature issue as she spearheads a national campaign with a 70-point plan, challenging Americans to defeat the problem in a generation."

Bob Green, president, Nutratech, West Caldwell, NJ, also supports the First Lady's initiative. "I'm a fan of First Lady Michelle Obama's Let's Move! campaign. The program helps kids develop healthy eating habits and implement daily exercise regimens, so children born today will reach adulthood at a healthy weight," he said. "That's still an extremely ambitious goal. But it's a comprehensive program that provides simple tools to families, schools and communities that will help kids be more active, eat better and ultimately enjoy better health."

Corey Jansen, associate product manager, Kemin Health, Des Moines, IA, also believes in the long-term potential of government programs focused on obesity, but that ultimately consumers need to be responsible for themselves. "Education is a good thing and government assistance is a good thing. I think those are great programs and it is important that people are aware of those. But the challenge now is getting people to change their lifestyles," he said. "I think we have a long way to go in changing behavior."

#### **People Are the Problem**

Most Americans (more than 75%) are trying to lose or maintain their weight at any given time, according to DSM's Ms. Brons. "With such a large part of the population being overweight, imagine the huge implications for quality of life, healthcare costs and productivity," she said.

For some experts, while the overweight/obesity issue is complicated, the solution is simple. "I think consumers need to be more educated about their bodies," said Dr. Virender Sodhi, MD, ND, CEO, Ayush Herbs, Redmond, WA. "Our genetics and bodies are the same. Now we just have more colorful packaging and addictive foods."

He said in most cases solving the problem comes down to exercise and portion control. As an example, he said, "Mice live an average of two years. Double their diet and they live one year; cut their diet in half and they live three to four years." When the body is so overwhelmed with fat, Dr. Sodhi said, it starts to store it throughout the body. "Consumers wonder why they are protruding and it is because the body is depositing the fat under the skin, which is a protective mechanism. When I did surgeries in India we would find so much fat around every organ in obese patients."

According to the latest U.S. National Health and Nutrition Examination (NHANES) survey data (2007/2008), one in three adults is obese; and as many as two in three are either overweight or obese.

Looking more globally, Scott Steil, president, NutraBridge, Shoreview, MN, pointed out, "As a population, overweight/obesity is a really serious issue for humans. Exercise in a certain subset is growing but on the whole it is declining. Eating healthy is not a priority for everyone and for some it is a luxury."

Dr. Anne Birkett, nutrition science manager, Corn Products International, Westchester, IL, shared some other startling statistics. "The World Health Organization projects that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese. As for the U.S., according to the Centers for Disease Control, 32 U.S. states have an obesity prevalence equal to or greater than 25%."

Experts like Rhonda Witwer, senior business development manager, Nutrition, National Starch Food Innovation, Bridgewater, NJ, believe the current problem is related to denial. "Consumers are in a state of denial about their weight and the obesity epidemic," she said.

According to HealthFocus International, Ms. Witwer added, 59% of adult grocery shoppers are overweight or obese (based on their reports of height and weight), but only 42% report being concerned about it and only 32% report that they are personally overweight or obese. "Sadly, only 26% report being concerned about obesity for their children," she said.

#### The New Dietary Guidelines

The 2010 Dietary Guidelines for Americans, to be released by the end of this year, heavily emphasize calorie reduction, a plant-based diet and increasing physical activity. But most pundits believe they need to go further in stemming the rising tide of overweight/obesity.

"Although the Dietary Guidelines are a step in the right direction—that being improved awareness, early education and public information—they still need to be improved," Beneo's Mr. O'Neill said. "And after all, they are not the real culprits in the obesity epidemic. The larger concerns are poverty, inadequate exercise and lack of portion control in an environment that promotes overeating and a largely sedentary lifestyle."

Dr. Michael McBurney, head of scientific affairs, DSM Nutritional Products, Inc. presented some other reasons why the Dietary Guidelines won't solve the U.S.'s

overweight/obesity issues. "The prevalence of overweight and obesity worldwide is a result of many factors. It will take more than new dietary guidelines to reduce the incidence of overweight and obesity; it will require both individual and community action."

"One of the most important aspects of the 2010 DGAC Report is that it is used to establish federal and state policies," he continued. "These can transform our communities and our lives. However, the pillars of health are a healthy diet and regular exercise. For those who do not consume a variety of foods as recommended in the Food Guide Pyramid and Dietary Guidelines, dietary supplements may help ensure that you get adequate amounts of essential nutrients to promote optimal health and performance."

Taking issue with the new dietary guidelines and the absence of information on supplements was Paul Dijkstra, CEO, InterHealth Nutraceuticals, Benicia, CA, who said, "The conundrum of the 2010 Dietary Guidelines is that they recommend cutting calories without recognizing how vitamin and mineral supplements can help fill specific nutrient gaps that often occur on a restricted calorie diet."

Ms. Witwer from National Starch was also critical. "I predict that the 2010 Dietary Guidelines will have little impact on the rising tide of obesity in the U.S. The recommendations of the Advisory Committee were not substantially different than dietary recommendations issued over past years," she said, adding "They have not been successful in convincing people to eat healthier foods in the past, and there is no evidence to suggest they will suddenly become more effective with consumers now."

Ms. Witwer was particularly disappointed in the dietary fiber conclusions. "Instead of utilizing an evidence-based analysis of individual dietary fibers, they chose to continue to evaluate dietary fibers as a generic category. The scientific community has long known that different dietary fibers behave differently—the major mechanisms are bulking, viscosity and fermentation," she said.

"Only when different types of fibers are evaluated for their individual impacts on the human body will we be able to make more substantial recommendations on which fibers offer benefits for which conditions," she added. "In the absence of a thorough review of the evidence, the Advisory Committee resorted to more generic recommendations focusing on consuming more whole grains and less refined foods. This is not helpful advice for consumers trying to manage their weight."

#### **New Approaches**

The obvious approaches to weight loss in the context of nutraceuticals include dietary supplements and functional foods. Some industry executives believe the weight loss market, particularly in the U.S., is more suitable for supplements, since it is a predominantly pill-popping society—and overweight/obesity is looked at as any other health issue, as one that needs to be treated with a pill. Others, however, believe solving weight issues comes down to providing food solutions, since managing weight is a matter

of changing lifestyle, not treating a disease.

Kemin's Mr. Jansen commented on both philosophies. "The last bit of market research I saw said consumers are more used to using supplements for weight management but that they are increasingly turning toward food because it represents a more natural incorporation into a lifestyle change."

While he believes these markets are complementary, he says it really depends on the consumers and how they choose to address their weight management issues. "Some will be more interested in supplements and others will be more interested in food," he said, adding, "In the end, consumers are looking for all the help they can get."

Believing consumers should have their pick of several different types of products, Sharrann Simmons, North American marketing director, Cognis Nutrition & Health, La Grange, IL, said, "I think they (foods and supplements) can be and should be complementary. People who see one category cannibalizing the other are shortsighted. The smarter and savvier the consumer, the more accepting they are of all the choices in this area."

Research from Mintel International, Chicago, IL, indicates that while the list of functional ingredients well understood by consumers is short, the list of benefits highly desired in functional foods is long, suggesting significant and diverse opportunities for marketers looking to expand the market. Healthy body weight and a few other desired benefits have widespread appeal, with 60% or more of functional food-using respondents expressing interest.

Commercial ingredients for weight management are targeted at three key areas, according to Lorraine Niba, PhD, marketing manager—Americas, FrieslandCampina Domo, Paramus, NJ. These include ingredients that reduce caloric intake such as zero calorie replacers and digestion blockers; satiety inducing (appetite suppressing) ingredients; and ingredients for boosting and enhancing metabolism.

DSM's Ms. Brons discussed the satiety angle. "We see that consumers nowadays are looking for weight management tools that are more easily incorporated into their daily lifestyles. Ingredients that help them eat less throughout the day are therefore gaining popularity as weight management solutions."

She added that fibers, proteins and lipids are becoming increasingly popular because they have a clear and understandable message.

National Starch's Ms. Witwer agreed. "Shoppers are looking for help in reducing their intake and see it as a major strategy for weight management. Proprietary National Starch research found that 65% of shoppers 'strongly agree' or 'agree' that 'Foods that help me feel fuller for longer are important for managing my weight.""

In terms of demographics, she said individuals between the ages of 30 and 49 are more interested in this claim compared to older individuals. Further, individuals with higher incomes also find this claim more appealing than individuals with less income.

Ms. Witwer went on to say that interest in the labeling claim "helps you feel fuller longer" is "extremely" or "very interesting" to nearly half of all 18- to 29-year-old individuals (48%), compared to one-third of individuals over the age of 65 (35%). "Eighty-four percent of dieters are extremely or very interested in dietary fiber for weight management," she added. "They look for fiber on product labels significantly more than the total population."

Ms. Brons also touched on the increasing amount of emphasis being placed on "energy balance"—managing calories in and calories out. "While 66% of Americans are overweight, we spend \$19 billion on gym memberships and more than 45 million Americans belong to a health club," she said. "The problem lies in closing the energy gap, suggesting it is not only how hard you work it off, but what you eat that matters when losing weight. Therefore, weight management tools that address satiety, hunger and portion control fit perfectly into today's consumer needs."

Matthew Pikosky, PhD, RD, FACN, vice president, Scientific Affairs, Dairy Research Institute, Rosemont, IL, shared his thoughts on protein and satiety. "Research shows whey protein provides a satiety benefit that may help individuals with weight management goals," he said. "Calorie for calorie, whey protein can help people feel fuller longer than carbohydrates or fats."

Mr. Pikosky said opportunities exist for functional food and beverage manufacturers to leverage consumer interest in satiety benefits and weight management by using whey protein in product formulations. "Significant scientific evidence—more than 40 nutrition studies—tell the benefits of higher protein diets and their effects on satiety or a feeling of fullness," he said.

Dr. Vladimir Badmaev, director of medical and scientific affairs, Polifenoles Naturales and PL Thomas, Morristown, NJ, believes consumers are failing at weight management because they are not treating the liver. "We are losing the battle of the bulge because we're not looking deeper into the mechanism," he commented. "The moment we realized it was bacteria that was causing infectious disease, we figured out how to save millions of lives. Today's situation with overweight/obesity is not much different."

Non-alcoholic fatty liver disease, discovered in the 1980s, is a result of fat accumulation in the liver. The liver, Dr. Badmaev explained, is a metabolic organ that works to transform dietary fat. If it is too fatty, however, it functions more like a clogged vacuum. "The only way to get rid of the fat is to make the liver functional again. When you lost weight you actually lose weight in the liver too," he said. "You can exercise all you want but if you don't treat the liver weight loss will not happen."

#### The 'Weight'ing Game

There is a definite element of volatility and unpredictability to the weight management category that makes it difficult to anticipate where it will go in the next decade, says Beneo's Mr. O'Neill. But as far as the general directions it might take, he believes these should include: lower sugar; lower calories; thermogenic combinations of ingredients, that is, ingredients that will promote fat oxidation and catabolism; blood sugar control; hormonal regulation of satiety; and perhaps control of other biological components of fat and sugar metabolism.

Offering some words of caution in navigating the market, Jeff Wuagneux, CEO, RFI Ingredients, Blauvelt, NY, said, "Several years ago, the weight loss market was dominated by ephedra-based products. When FDA banned ephedra's use in supplements, the market responded with new research and new ingredients that used different mechanisms to support many of the biochemical pathways that aid in weight loss.

"Now that the market is under tighter regulatory control," he added, "it must also respond similarly, with new ingredients, new combinations and real science to support less grandiose claims—no more 'lose 20 lbs in 20 days.""

InterHealth's Mr. Dijkstra said the focus needs to be on education, particularly in a segment filled with hundreds of products, many of which are ineffective and some of which are adulterated with pharmaceuticals.

"Hyperbole consisting of wild claims (e.g., lose weight while you sleep, etc.) and before/after tall tales are the marketing hallmark of many of these products. This hype, combined with negative media coverage has made many consumers wary," he said. "Weight loss supplements continue to represent important sales drivers, but many in the industry are waiting to see how negative attention will affect long-term category growth."

And perhaps taking a more long-term view is the way to break the quick-fix cycle that is so prominent among dietary supplement consumers, particularly in the weight loss category. "We need to stick to things that have solid science. We have a 10-year perspective on Capsimax, our flagship weight management product," said Hiren Doshi, president, OmniActive Health Technologies, Inc., Short Hills, NJ. "The moment it becomes a weight loss product, the regulatory authorities will get involved—[this category] is currently a favorite obsession of FTC."

Regardless of market hurdles, Scott Steil of NutraBridge says he thinks weight management remains one of the top markets that this industry needs to focus on and deliver solutions for. "Obesity and diabetes will be here for a long time. Going forward consumers will be more responsible for their own healthcare—the government can't do it and health insurance can't do it. So using a supplement to help manage weight and the glycemic impact of the foods we eat will become a good investment in our health in the future."

### **Researchers Claim Weight Loss Supplements Don't Work**

At a recent obesity conference two studies found no evidence of efficacy for some slimming supplements.

Two studies presented at the International Congress on Obesity in Stockholm, Sweden in July found that some popular slimming supplements were no more effective than placebo.

"There are scores of slimming supplements out there claiming weight-loss effects through all sorts of mechanisms of action. We have so-called fat magnets, mobilizers and dissolvers, as well as appetite tamers, metabolism boosters, carb blockers and so on. The market for these is huge, but unlike for regulated drugs, effectiveness does not have to be proven for these to be sold," said Dr. Thomas Ellrott, head of the Institute for Nutrition and Psychology at the University of Göttingen Medical School, Germany, who led one of the studies. "Few of these supplements have been submitted to clinical trials and the landscape of products is always changing, so we need to put them through rigorous scientific evaluation to determine whether they have any benefit."

Dr. Ellrott's group tested nine popular supplements against placebo pills in a randomized controlled trial. The supplements tested included L-carnitine, polyglucosamine, cabbage powder, guarana seed powder, bean extract, konjac extract, fiber pills, sodium alginate formulations and selected plant extracts.

The researchers bought the supplements from German pharmacies, changed the packaging and product names to make them look neutral and rewrote the information leaflet inserts to eliminate the product name from the text. They then gave 189 obese or overweight middle-aged consumers packages of either fake pills or of one of the nine supplements, each week for 8 weeks, in doses recommended by the manufacturers. Some of the products came with dietary advice, while others didn't, so the researchers provided exactly the same advice as that written in the relevant product leaflets.

Average weight loss was between 1 kg and 2 kg across seven of the products, depending on the supplement, and was 1.2 kg in the group getting the placebo pills. No statistically significant difference in weight loss was found for any of those products when compared with the placebo.

"Most previous studies have examined only one product. This is the first to include nine supplements with different proposed mechanisms of action and we found that not a single product was any more effective than placebo pills in producing weight loss over the two months of the study, regardless of how it claims to work," Dr. Ellrott said, adding that if there is an indication for the use of weight-loss drugs, consumers should opt for regulated obesity drugs with proven effects (prescription or over-the-counter) instead.

In a second study presented at the congress, Dr. Igho Onakpoya of Peninsula Medical School at the Universities of Exeter and Plymouth, U.K., conducted the first systematic review of all existing systematic reviews of clinical trials on weight loss supplements. His analysis summarized the state of evidence from reviews of studies involving nine popular slimming supplements, including chromium picolinate, ephedra, bitter orange, conjugated linoleic acid (CLA), calcium, guar gum, glucomannan, chitosan and green tea.

"We found no evidence that any of these food supplements studied is an adequate treatment for reducing body weight," Dr. Onakpoya said. "Annual global sales of dietary supplements are well over \$13 billion. In Western Europe, sales of weight-loss products, excluding prescription medications, topped \$1.4 billion in 2009. The weight-loss industry in North America is worth over \$50 billion and Americans spend over \$1.6 billion a year on weight-loss supplements. People think these supplements are a shortcut to weight loss and may spend huge sums of money on them, but they may end up disappointed, frustrated and depressed if their weight expectations are not met in the long term."

Dr. Onakpoya went on to say that some of the supplements included in the study were reported to cause some adverse effects. However, more rigorous research is needed, he said, as only very few trials have been of long duration and the number of patients in most of the trials has been small—factors which together limit the conclusions that can be drawn about the effectiveness and safety of such supplements.

According to Mitch Skop, senior director of new product development, Pharmachem Laboratories, Inc., Kearny, NJ, researchers supporting weight loss drugs, or critics of the weight loss supplement industry, often point to a lack of properly constructed, published studies. "Thus the negative analysis of weight loss supplements coming from two recently presented, unpublished, non-peer-reviewed studies at an international obesity conference in Sweden seems quite ironic," he said. "Additionally the recommendation of a drug, orlistat, by one of the researchers, whose position is funded by the maker of the drug is also suspect."

Further, Mr. Skop explained, "The researchers in the German study seem to skip over the positive results, which showed up to a 4-lb. weight loss for some of the supplements compared to an average 2.5 lbs. for placebo. The major flaw here is that the researchers may have been looking for the 'magic bullet' approach, that is, significant weight loss attributed to each of the dietary supplements used. Responsible and ethical manufacturers and suppliers in the industry do not make claims for such dramatic results in a short time. We also acknowledge that healthy weight loss and subsequent weight management is a lifetime commitment. Dietary supplements are part and parcel of the overall goal of developing and maintaining healthy lifestyle habits for the long term."

Disclosure: Dr. Ellrott's study was funded by a German consumer issues magazine, while the study by Dr. Onakpoya and colleagues had no particular funding. However, Dr. Onakpoya's position is funded by an unrestricted grant from GlaxoSmithKline, which makes the obesity drug orlistat.