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Navigating the Health- Claims Landscape

By Kimberly J. Decker
Contributing Editor

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Health claims have made headlines lately—and not always for the right reasons. First there was last summer's Federal Trade Commission action against the Kellogg Company, resulting in a settlement barring the manufacturer from making cognitive health claims for its Frosted Mini-Wheats cereal. Later, the Center for Science in the Public Interest (CSPI) petitioned FDA to prohibit qualified health and structure/function claims for foods. This March, FDA sent letters to 17 manufacturers, including Dreyer's, Nestlé and POM Wonderful, warning them that

labeling on 22 of their products violated the Federal Food, Drug, and Cosmetic Act. And barely two months later, the Institutes of Medicine (IOM) issued a report calling into question the scientific rigor with which FDA evaluates biomarker evidence in health-claim proposals.



Surely, this isn't the press that FDA, manufacturers or Congress had in mind when the Nutrition Labeling and Education Act of 1990 (NLEA) included provisions for food companies to provide "additional health information" to consumers by way of health claims on packages. But, since the act's passage, health claims have been both a blessing and a curse, giving manufacturers an opportunity to celebrate their products' health-giving potential, and making them a popular target for skeptics. When navigating this regulatory and public-relations minefield, it's best to arm yourself with a clear understanding of the laws, as well as a healthy dose of discretion.

Politics and sausage

"Manufacturers develop products with the intent of fulfilling a need that they believe the public has, and that need covers a lot of things—certainly taste, availability and pricing, but also certainly nutrition," says Allan I. Zackler, Zackler & Associates, Oakland, CA. An attorney with more than three decades' experience in consumer products/food regulatory and marketing law, he's seen nutrition trends and regulatory moods come and go. In his view, the pendulum analogy is an apt fit.

"There really have been swings from a lot of regulation to less," Zackler says. "When problems come up, there'll be more regulation, sometimes related to the administration in office. Other times, manufacturers themselves will seek to come up with something that's acceptable to consumers and fulfills their needs; they'll start pushing the envelope, and it gets pushed back by groups such as CSPI. A regulatory process then comes into play."

The results are thus as much products of politics as of scientific merit. And if there's any truth to the old saw that two things you don't want to see are the making of sausage and the making of laws, then you really don't want to see the making of laws about sausage. As Zackler notes with diplomatic understatement, such laws "do not necessarily comport with the science behind them. In fact, they oftentimes don't comport with the science behind them."

Content providers

Nevertheless, FDA has provided exhaustive language as to the health messages we can deliver on food labels. Responsible manufacturers would do

well to familiarize themselves with the specifications outlined in Title 21 of the *Code of Federal Regulations (CFR)*, Part 101. A handy Q&A lives at fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064908.htm#health.

The most basic are nutrient-content claims, which directly or by implication characterize the level of a specified nutrient in a food. (For a full definition, as well as byzantine requirements for type size, style and placement, see 21 *CFR* 101.13, Subpart D of Part 101, and Parts 105 and 107.) The main purpose of nutrient-content claims is to give consumers a context for judging the relative quantity of a nutrient in a food: Is this a "good" or "excellent" source? Is the nutrient present at "high" or "low" levels vis-à-vis the recommended daily intake? Is this a "free" or "light" food?

The regulations make explicit how much of the nutrient need be present per reference amount commonly consumed (RACC) to qualify for modifiers such as "low," "high," "good," "excellent" and otherwise. For example, to qualify as "low" in sodium, a food must contain 140 or fewer mg of sodium per RACC, or 50 mg if the RACC is small. To earn a "reduced" or "less" claim, a food must have at least 25% less sodium per RACC than a suitable reference food.

But don't get too comfy with these numbers, as in a sign of the continual flux of nutritional guidance, the recommended levels on which sodium nutrient-content claims are based may be in for an overhaul. The current percentage Daily Value is based on a maximum of 2,400 mg of sodium per day. However, the recommended daily intake above which health problems may occur is 2,300 mg. (Recommended adequate intake is a mere 1,500 daily mg, and even lower for those over age 50.) In a report issued April 2010, an IOM committee concluded, "Because using an upper level can lead people to mistakenly think that it is a desirable amount, the committee recommended that the Daily Value for sodium be changed to reflect the adequate intake for adults of 1,500 milligrams per day." FDA has yet to take action, but if and when it does, it will affect how much sodium qualifies as "low," "reduced" or "less."

Staking a claim

Beyond basic nutrient-content claims, FDA authorizes health claims that characterize the relationship of a substance in a food to a disease or health-related condition (see 21 *CFR* 101.14(a)(1)). Health claims have allowed manufacturers to balance the numbers on the NLEA-mandated nutrition facts panel with verbiage that calls attention to nutritional benefits that may not be immediately apparent in the numbers alone.

FDA-authorized health claims encompass not only explicit verbal messages, but implicit claims conveyed via symbols and “vignettes.” Furthermore, the claims can address only disease risk reduction, and not diagnosis, cure, mitigation or treatment. So the statement, “Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the *risk* (author’s emphasis) of heart disease; this cereal has 2 grams per serving,” fits the health claim mold.

Thirteen such statutory health claims—linking everything from calcium and bone health to folate and neural-tube defects—have undergone FDA scrutiny. “Based on the evidence of the science presented to them,” Zackler says, “FDA has determined these claims to be reasonable to make so consumers can be aware of the relationship between this food and the possibility for reducing the risk of one or another of the illnesses.”

Clinching FDA approval requires meeting its significant scientific agreement (SSA) standard, which “is pretty complex,” says Elaine M. Meloan, senior manager, food labeling, AIB International, Manhattan, KS. According to 21 *CFR* 101.14, “FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”

Thus, Steven Young, Ph.D., technical advisor, Matsutani America Inc., Itasca, IL, advises manufacturers to “do your homework. Be sure that you have substantial scientific support for any health claim, and if using one of the FDA health claims, make certain that all the minimum requirements for the consumer product are met.”

FDA may raise the SSA standard even higher in response to the IOM report “Evaluation of Biomarkers

and Surrogate Endpoint in Chronic Disease.” IOM urges FDA to tighten its judgment of biomarker evidence and adopt a “consistent scientific framework for biomarker evaluation” that, among other improvements, applies “the same degree of scientific rigor for evaluating biomarker use across regulatory areas, including drugs, medical devices, biologics, foods and dietary supplements.”

Modern times

While the IOM report may make health-claim approval harder, it was in the interest of loosening regulatory gridlock that provisions within the Food and Drug Administration Modernization Act of 1997 (FDAMA) allowed for yet another class of health claim, the appropriately named FDAMA health claim.

Prior to FDAMA, companies had to wait until FDA published a regulation authorizing a health or nutrient-content claim before using it. FDAMA accelerated that process by permitting distributors and manufacturers to use claims from the get-go, as long as those claims arose from current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences, any of its subdivisions, and organizations like the National Institute of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

How it works, Meloan explains, is that after determining a claim’s merit based on an authoritative statement of a scientific body, companies submit a notification to FDA with their intent to make the claim. “If FDA does not respond to the notification within 120 days,” she says, “companies are free to use the claim stated in the notification.”

Of course, the SSA standard applies to FDAMA claims as well, and FDA reserves the right to prohibit or modify a claim through later regulation. Regardless, the modernization has achieved its goal of expediting the establishment of the claim’s science, as well as its deployment. Four health claims, including for whole grains and reduced risk of heart disease and cancer, and potassium and reduced risk of high blood pressure and stroke, have gone into circulation thanks to FDAMA.

Qualifying round

FDA relaxed the health-claim rules yet again with 2003’s Consumer Health Information for Better Nutrition Initiative—

Call 'Em Like You See 'Em

When deploying descriptive modifiers like “healthy” or “fresh” on product packages, there’s no such thing as a casual deployment of language. That’s one thing that Elaine M. Meloan has learned while serving as senior manager for food labeling at AIB International, Manhattan, KS. Here’s a sampling of what she tells food industry professionals seeking her advice on using words wisely.

Healthy. “‘Healthy’ is already defined as a nutrient-content claim—Title 21 of the *Code of Federal Regulations (CFR)*, Part 101.65—and takes into account the amount of total fat, saturated fat, cholesterol and sodium in a food. The food also has to be a good source of a positive nutrient, such as fiber, calcium or iron, to qualify as ‘healthy.’”

Fresh. “FDA provides guidance on ‘fresh’ in 21 *CFR* 101.95. It has more to do with the physical qualities of the food as opposed to its nutritional value.” According to the USDA Food Safety and Inspection Service, the term “fresh” on a poultry label indicates that the product has never been below 26°F. While raw poultry held at 0°F or below must be labeled “frozen” or “previously frozen,” USDA requires no specific labeling on poultry stored between 0°F and 25°F.

Allergens and gluten-free. “The food allergen amendment to the Food, Drug and Cosmetic Act pretty clearly defines how allergens are disclosed on a label.” This, she notes, has little effect on health claims. As for “gluten-free,” she says, “a proposed regulation for gluten-free labeling was issued in 2007. Although there is not a final regulation yet, FDA does not object to companies following the guidelines provided for in the proposal.”

Natural. “As we know, ‘natural’ is a rather vague term, and FDA has very limited guidance about its use.” USDA, she notes, is the agency that’s “delving in” on its meaning with respect to meat and poultry products, spelling out specific guidelines about “minimal processing” and what that specifically means. She points manufacturers to the USDA’s policy manual for more precise definitions.

albeit after its hand was forced in the matter. In the landmark court case *Pearson v. Shalala*, the U.S. District Court for the District of Columbia ruled that FDA violated the plaintiff’s free-speech rights by prohibiting them from making folic-

acid health claims that FDA deemed “inherently misleading.” While FDA found less-than-significant scientific agreement to support the claim, it was still “directionally consistent with emerging evidence for the relationship” between the nutrient and the condition, Zackler says. “It was something that a consumer should at least be made aware of.”

Thus, Meloan continues, “it was argued that FDA needed to permit claims that do not meet the SSA, if properly qualified to prevent consumers from being misled. The results of this trial led to the qualified-health-claim procedures.” Specifically, companies can petition FDA with emerging evidence of a relationship between a food, food component or dietary supplement and a health condition, and after evaluating and ranking the quality and strength of that evidence, FDA may then issue a “letter of enforcement discretion” detailing the qualified health claim it will allow.

“If a company follows the requirements in the petition or notification for the qualified health claim, FDA will not object to the claim being made,” Meloan says. “However, there may be times when such a statement could be misleading in context with other statements on the package, and FDA retains the right to use enforcement procedures to notify the company of the misleading labeling.”

Here, context boils down to language. FDA makes explicit how strong a qualified health claim can be. The agency has spelled out three levels of qualification, from the strongest support (“Although there is scientific evidence supporting the claim, the evidence is not conclusive”), to moderate (“Some scientific evidence suggests... However, FDA has determined that this evidence is limited and not conclusive”), to weakest (“Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim”).

Because qualified health claims “must follow the exact wording provided for in the notification or letter of enforcement discretion,” Meloan urges manufacturers to read that letter carefully and “make sure your product qualifies for the claim and that you are using the proper wording.” Not surprisingly, she adds, most of the claims manufacturers use are “within the category of ‘approved’ claims, which are unqualified and the strongest of the claims, because they don’t have all that limited wording.”

Structurally sound

It’s precisely their linguistic hedging—and the lack of scientific consensus that it reflects—that leads groups like

CSPI to criticize qualified health claims. “Not everyone agrees that these types of claims should be permitted, due to some of the very limited scientific evidence presented in the petition or notification,” Meloan says. “Although the claims have qualifying language that must be included as part of the claim, some feel that they are still misleading.”

Nevertheless, Meloan says, “once a claim is approved, accepted or not objected to, then any company may use it.” The only case in which a manufacturer would need to provide FDA notification, she points out, “would be for structure/function claims for dietary supplements.” And therein lies an especially tricky patch of the health-claim landscape for manufacturers to negotiate.

A structure/function, or S/F, claim is a statement about a dietary supplement or food nutrient’s ability to maintain a normal bodily structure or function. An S/F claim cannot address a disease state, lest the supplement or food in question creep into drug territory. That’s one reason why S/F claims require special attention from manufacturers.

Another is that FDA oversees S/F claims differently for supplements and foods. “Dietary-supplement manufacturers must notify FDA with the claims they are making within 30 days of marketing the product, and the supplement must contain a disclaimer stating that FDA has not evaluated the claim,” Meloan says. By contrast, “structure/function claims about nutrients in foods require neither FDA notification nor a disclaimer,” she says.

This sets up competing incentives for manufacturers to market a product as either a food or a supplement. And the fact that “there isn’t always a very firm line between what’s a food and what’s a dietary supplement, or what’s a supplement and what’s a drug,” doesn’t make that decision easier, Zackler adds. On one hand, a manufacturer can sidestep FDA approval of an S/F claim on a food. But marketing that product as a supplement, although it requires FDA approval for the S/F claim, exempts the manufacturer from establishing its ingredients’ GRAS status.

“That gives you a little bit more flexibility to put in ingredients that have not necessarily been established as safe by anybody other than you,” Zackler says. By

contrast, food manufacturers must give FDA 75 days advance notice before using a novel ingredient. “In the absence of them saying you can’t use it, then you can,” Zackler says. “If FDA looks at that notice and says, ‘We don’t think that you’ve established the safety of this and therefore you can’t use it,’ then you can’t.”

Even if a manufacturer decides to market a product as a food, avoiding the need to seek S/F claim approval, the claim must still be truthful and not misleading. Should a regulatory agency question the manufacturer’s claim—as FTC did with Kellogg’s Frosted Mini-Wheats—the manufacturer must provide appropriate scientific evidence to defend it. “Then the question becomes, if your evidence is inadequate to convince the regulator, what are the potential consequences?” Zackler says. “And each manufacturer has its own level of risk assessment and tolerance.”

Enforcing credibility


Whether an agency gets around to questioning a claim is no forgone conclusion. “The manufacturers are at least a decade ahead of the regulators, for good or for bad,” Zackler says. “Food manufacturers, as you might expect, have a lot invested in their products, and they have, in many respects, the best R&D facilities in the country. They can come up with a tremendous amount of data through their own research and put it into the hopper along with other groups.” This leads to inevitable push and pull among parties, but ultimately, he says, “what you have is an issue where the government and industry and consumer-activist groups are all trying to make some sense of things.”

Some sense has emerged, along with plenty of legalese. While the claims that FDA has sanctioned have generated their share of controversy, “when you look at the number of claims that are approved and accepted currently by FDA, you’re really kind of limited in the substances that you can actually make a claim about,” says Meloan. “You’re talking about fiber in a lot of cases, fruits and vegetables.” And who could complain about recommending more fruit and fiber?

As for dressing up “junk” food with deceptive appeals to health, FDA has plugged the loopholes by barring health claims on products that don’t meet healthful levels

of total fat, saturated fat, sodium and cholesterol. They've also got the "jelly bean rule," which limits use of the term "healthy" to foods low in total and saturated fat, sodium and cholesterol, and containing at least 10% of the recommended value for certain desirable nutrients like calcium or vitamin A. In any event, says Young, "work with your company's regulatory and legal team when utilizing an FDA health claim on your packaging to be sure that it complies with the FDA labeling requirements."

These rules lend credibility to the sometimes-embattled sphere of health claims. "Increased enforcement by FDA will eventually help with the consumer perception of claims on packages," Meloan says. "However, the enforcement needs to be a steady presence." And manufacturers need to keep expectations in check and act in good faith.

In an area like this, consumer perception and credibility are everything. "Consumers will look for additional information by watching more news and web-based reports for specific health concerns and clinical studies on nutrition," says Young. "They will apply what they find to improving and changing their dietary patterns and habits. Educational programs promoted by the government will also be a valued source of information and influence consumers." In the end, that's just what we want them to do. 

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