Advertising Law

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In This Issue

SPECIAL FOCUS: Avoiding Potential Pitfalls Associated with Functional Food Claims

Functional foods – or foods often fortified with nutrients that offer functional benefits – are among the fastest-growing categories of foods, but as their popularity increases, so too does scrutiny over whether these foods truly provide all of their claimed health benefits. The U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have increased their enforcement efforts against these products, and it seems that nearly every week another food company is challenging its competitors’ claims in court or before the National Advertising Division (NAD).

Amid this flurry of activity over functional foods, our newsletter editors caught up with Ivan Wasserman, a partner in Manatt’s Advertising, Marketing & Media practice, who counsels national and international food, dietary supplement and cosmetics companies on the legal and regulatory aspects of marketing, and who has successfully challenged and defended numerous clients in proceedings before the NAD. Ivan provided much-needed clarity on the types of claims that are allowed when marketing functional foods and highlighted the key issues companies should consider before embarking on a new campaign.

Editors: Now more than ever, the FDA and FTC are cracking down on the marketing and advertising of drugs, foods and functional foods. To kick off our discussion today, could you bring us up to speed on the definitions of these three closely related products?

Wasserman: The short answer is that the FDA looks at a product’s intended use. If a company claims its product is a food, or its label says so, or oral statements used by a salesperson suggest the product is a food, then it is. However, if a company claims that the product is intended to diagnose, cure, mitigate, treat or prevent disease, then it is a drug. Similarly, medical foods are formulated to be consumed or administered under the supervision of a physician and are intended for the specific dietary management of a disease or condition. Functional foods do not actually have a legal definition different than regular food; however, the conventional definition is any food that claims to have an additional “functional” benefit beyond simply supplying nutrition.

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Practice Area Links

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Upcoming Events

October 26-27, 2011
ACI Social Media, Business Technology and the Law Conference
Topic: "You Better Disclose That: Ensuring that Your Company is Closely Adhering to the FTC's Endorsement and Testimonial Guidelines"
Speaker: Marc Roth
New York, NY
For more information

November 14-16, 2011
PMA Marketing Law Conference
Topic: "What's New in the Game Today - New Twists on Traditional Sweeps, Contests and Promotions," Linda Goldstein; "The Perils of Partners - Affiliate/Advanced Consent Marketing," Marc Roth; "Courting Disaster - Mock Trial of Promotional Mishaps," Chris Cole
Chicago, IL
For more information

November 15, 2011
ABA Private Advertising Litigation and Consumer Protection Teleseminar
Topic: "The Television Network Advertising Clearance Process: Soup to Nuts"
Speaker: Jeff Edelstein
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Editors: Given the slight variation between these definitions, it almost seems that there could be overlap between how these foods are characterized and marketed. Can companies sell functional foods as medical foods?

Wasserman: Despite how similar these may seem, the definition of "medical foods" is extremely narrowly construed by the FDA. Historically, claims about medical foods flew under the radar, but the new FDA leadership under the Obama Administration is now taking enforcement very seriously. For example, Bioenergy was marketing a food product called Corvalen as a "medical food" to treat conditions including fibromyalgia, chronic fatigue syndrome and cardiovascular disease. In November 2010 the FDA said the company could not make medical claims about this product because a recognized food regime to treat these specific illnesses does not exist. This action again demonstrates that "medical foods" are construed as a very narrow category.

Editors: If you work at a company and are preparing to launch a new functional food product – say, probiotic yogurt or eggs fortified with Omega-3 – what types of information must you place on your product's label, and what information should you omit?

Wasserman: The FDA requires certain mandatory label information – such as the net quantity of contents, ingredient lists, nutrition labeling, allergen labeling, name/address of the manufacturer – and additionally, there are certain types of claims that you may voluntarily include on your label under very specific requirements. Certain health claims – or those that talk about disease risk reduction – are allowed for specific foods. However, the claims must either use the exact language the FDA has permitted for specific foods by regulation (known as "authorized health claims"), or the company must petition the FDA to make a health claim, after which the FDA may decide to issue an "enforcement discretion" letter laying out the specific conditions for making this claim (called "qualified health claims").

Additionally, the FDA permits foods to use what are known as "structure/function claims." These are claims about the effect of a food on the structure or function of the body. Such claims are allowed so long as the statement does not claim to diagnose, cure, mitigate, treat or prevent a disease, which would bring it under the classification of a drug. Companies must be careful, however, about implied "drug/disease" claims. For example, pictures of organs could be construed as beyond a structure/function claim and therefore fall outside of the scope of a functional food.

Editors: It seems that manufacturers and marketers of functional foods are on the defensive as of late. What changed with respect to regulatory enforcement efforts?

Wasserman: You're correct. The FDA previously hadn't been that active in going after functional foods. This changed dramatically under the new FDA leadership in the Obama Administration, starting in mid-2009 and continuing through the present time. For example, in

February 2010 the FDA sent out 17 Warning Letters regarding label violations for unauthorized drug claims and nutrient content claims. Simultaneously, the agency sent an open letter to the industry stating that it was scrutinizing conventional foods that were making these types of claims.

Editors: Now that we've covered food labeling, could you elaborate on how advertising claims involving functional foods are regulated?

Wasserman: The FDA and FTC have joint jurisdiction over claims for food products. The FDA regulates from the labeling perspective, whereas the FTC evaluates advertising claims. These lines are getting blurred, however, particularly as companies increasingly make certain health claims on their Web sites. Both agencies assert jurisdiction over the Internet, and if you are making a claim on your Web site, you should worry about both. Further complicating the regulatory landscape impacting functional foods are the FTC's settlement agreements with Iovate and Nestlé, which were entered into on July 14, 2011. Previously, when advertisers settled with the FTC, they would sign a document agreeing not to make the claims at issue again unless they have competent, reliable scientific evidence; however, exactly what that required was not expressly stated. Per the July 14 Orders, if Iovate and Nestlé wish to make certain claims again, they must have competent, reliable scientific evidence consisting of at least two clinical studies on the same or an equivalent product completed by independent researchers.

Editors: Did this settlement effectively change the level of support required for making advertising claims about functional foods moving forward?

Wasserman: No one knows for sure whether the FTC meant to create a new standard that every company must comply with, or whether the standards articulated in the Orders are applicable just to certain claims made by the companies subject to the Orders. The FTC is on record stating that it has not changed its standard going forward. On the other hand, it would behoove any advertiser to meet this heightened standard, as clearly it is one that the FTC considers to constitute competent, reliable scientific evidence for claims for a functional food.

Editors: Could you leave us with a final few words of wisdom and takeaways for advertisers and marketers of functional food products?

Wasserman: The No. 1 takeaway is to know the rules. They are complicated and long, but you should be very familiar with them before selling a product as a functional food. Secondly – and this is key – have good science and don't oversell. Make sure express and implied claims are consistent with what your science shows, and if your studies are limited to populations (for example, age), make sure your claims are so limited. Lastly, extra care and caution should be put into marketing any functional foods specifically targeted to children. Functional foods for kids are in the highest-risk category and are at the top of the enforcement agenda. You must ensure your science is buttoned down.

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Lather Up: FDA Issues New Sunscreen Rules

For the first time in 30 years, the Food and Drug Administration has issued new rules tightening standards on how the manufacturers of sunscreen can label their products and make claims about whether or not they are waterproof.

The FDA said the new rules, which go into effect June 2012, bring existing regulations up to date with the latest scientific data and safety standards.

“FDA has evaluated the data and developed testing and labeling requirements for sunscreen products, so that manufacturers can modernize their product information and consumers can be well-informed on which products offer the greatest benefit,” Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research, said in a press release.

Under the new regulations, a sunscreen that passes FDA testing may call itself “broad spectrum” if it can protect consumers from both UVB (ultraviolet B) and UVA (ultraviolet A) light. If a product meets the standards for broad spectrum and is at least SPF 15, it may also claim to reduce the risks of skin cancer and early skin aging. Products that do not meet the broad spectrum standards, or are broad spectrum with an SPF between 2 and 14, must carry a warning that the product has not been shown to help prevent skin cancer or early skin aging, the FDA said.

In addition, manufacturers can no longer advertise sunscreen as “waterproof,” “sweatproof,” or “sun block.” Instead, labels can claim that products are “water-resistant” and work for a period of 40 minutes or 80 minutes, depending on test results. Products that are not water-resistant must now carry a warning to consumers to use a water-resistant product if they will be exposed to sweat or water.

And all sunscreens must now include a standard “Drug Facts” information box on the back or side of the container.

The agency also released a proposed rule that would limit the maximum SPF value on sunscreen labels to “50+,” as the FDA said that insufficient evidence currently exists to show that products with higher than 50 SPF provide greater protection. The agency said that manufacturers could submit data to support higher SPF values, however.

Still remaining on the agency’s radar: sunscreen sprays. The FDA released an advance notice of proposed rulemaking and requested information about the safety and effectiveness of sunscreen sprays, as well as comments on possible warnings for sprays.

To read the new rule, click here.

To read draft guidance for the industry, prepared by the FDA, click here.

Why it matters: While the new rules don’t take effect until next summer (with an exception for manufacturers with annual sales of less than $25,000, who have two years to comply), companies should begin to work toward compliance to be ready for the deadline.

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Facebook “Likes” Two Legal Victories

Facebook won two legal victories recently, with a California federal judge dismissing a class action suit against the company and an Illinois judge denying a motion to dismiss a trademark suit brought by Facebook against site Teachbook.

In the California case, parents alleged that the social networking site used the names and images of minors for advertisements without first getting parental permission in violation of state law. The Complaint alleges that while the site encourages children to participate on the site and to “like” products and services, it then markets their names and likenesses, generating significant revenue for Facebook.

But California state judge Debre K. Weintraub dismissed the suit, leaving the plaintiffs 20 days to amend their complaint.

“Plaintiffs’ claims based on state law for Facebook’s alleged failure to obtain the parental consent of users aged 13 to 17 to the commercial use of their name and likeness is preempted by the Children’s Online Privacy Protection Act,” she wrote.

Facebook also had success in Illinois federal court, where it filed a lawsuit against Teachbook, a social networking site specifically targeted at teachers. Facebook alleged that the site is “trading on the fame” of the Facebook mark and touting itself as a substitute for Facebook, as many schools prohibit teachers from joining Facebook so as to avoid interaction with students.

Teachbook contended that the only similarity between the sites was the suffix “–BOOK,” which is a generic mark, not sufficiently distinctive to merit trademark protection.

U.S. District Court Judge Marvin E. Aspen agreed with Facebook that its rights were based on more than just the “-BOOK” suffix, and found that the aggregate effect of the term “Facebook” gave the mark its distinctiveness.

“And given the ubiquity Facebook claims its mark has achieved, one could reasonably infer that the choice of the Teachbook mark – which, like the Facebook mark, is a curt, two-syllable conjunction of otherwise unremarkable words – to offer a similar service in the same medium was not accident,” Judge Aspen wrote.

The court also found it likely that consumers – particularly teachers – could be confused by the Teachbook site. Given “textual and aural similarities between the marks . . . it is reasonable to infer that someone browsing the internet might understand Teachbook to be ‘in some way related to, or connected or affiliated with, or sponsored by’ Facebook.”

Although Teachbook pointed to language on its site that it argued distinguished the site from Facebook – by referencing the fact that some schools forbid teachers to use Facebook – Judge Aspen said that teachers might think Teachbook is Facebook’s response to such actions.

“In light of such policies, a reasonable consumer might assume that Facebook was offering social networking services targeted specifically at teachers and addressing the privacy concerns at which the schools’

policies are apparently aimed. The same consumer might further assume that Facebook, in order to draw on its famous name, decided to call that service Teachbook," he wrote, refusing to dismiss the suit.

To read the court's order dismissing the *Cohen* suit, click here.

To read the court's opinion in *Facebook v. Teachbook*, click here.

Why it matters: With suits similar to the California case filed across the country, the dismissal of the class action bodes well for Facebook. And the court's decision in the Teachbook case shores up Facebook's argument that its trademark is distinctive and will survive legal challenges.

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NAD: Claims Should Be Based on Product Testing, Not Testing of Individual Ingredients

The National Advertising Division recently recommended that BioLogic Solutions discontinue several claims made in Internet and broadcast ads for its "Stem Cell Therapy" skin cream, finding that testing used as the basis of support for the claims was performed on individual ingredients and not on the product as a whole.

The NAD requested substantiation for several performance claims made by BioLogic, including "Look and feel years younger with Smooth, New Skin in Just Days!" and "Look up to 15 years younger starting the very first day."

In response, BioLogic provided the NAD with studies consisting of each of the three principal plant-based ingredients of its Stem Cell Therapy skin cream, but not any testing of the product itself. BioLogic argued that because the dosage amount of the ingredients tested was comparable to the amount in the product, it was acceptable to rely on the tests and studies to support its claims.

But the NAD said that BioLogic's product performance claims – including before and after pictures – required stronger substantiation than the studies and tests provided. "Accordingly, when there is substantiation only for the efficacy of ingredients in a product, but not for the product itself, the claims must be clearly expressed as ingredient claims," the NAD said, recommending that use of the photographs be discontinued. Remaining claims should be "significantly modified to identify only the ingredients tested and to make clear that *emerging evidence* indicates that these ingredients *may help* reduce some signs of aging," the NAD said.

In addition, the NAD recommended that a "dermatologist recommended claim" be discontinued, as it was based merely on the testimonial of one dermatologist.

To read the NAD's press release about the case, click here.

Why it matters: The NAD reminded advertisers of the value of substantiating claims based on testing of the product itself, not its component parts. "As a general rule, product performance claims should be supported by reliable testing on the actual product," the NAD said. "The nature and extent of performance claims dictates [the] level

of substantiation required to support them." BioLogic disagreed, noting in its advertiser's statement that the NAD "misinterpreted, misunderstood or overlooked certain tests and studies," reaching "unwarranted and unsupported conclusions." The company appealed the decision to the National Advertising Review Board.

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Lawmakers Contact FTC Over "Supercookies" and OnStar

Lawmakers are keeping the Federal Trade Commission busy, requesting that the agency investigate potential privacy issues.

Reps. Ed Markey (D-Mass.) and Joe Barton (R-Tex.) sent a letter asking that the agency investigate the use of "supercookies" by Web sites, which they contend constitutes an unfair and deceptive practice. "Supercookies" are different from regular cookies, which consumers can delete if they do not want to be tracked online. Instead, new technologies allow companies to track consumers online by hiding files in Web browsers that cannot be deleted and can be re-created even after the deletion of regular cookies.

"As Co-Chairs of the Congressional Bi-Partisan Privacy Caucus, we believe this new business practice raises serious privacy concerns and is unacceptable. We are also very concerned about the extent of this practice by websites as well as the impact supercookies have on consumers. Furthermore, we believe the usage of supercookies takes away consumer control over their own personal information, presents a greater opportunity for the misuse of personal information, and provides another way for consumers to be tracked online," the legislators wrote.

The letter noted that sites such as MSN.com and Hulu.com have used supercookies to track consumers, according to a report in *The Wall Street Journal*.

In a separate letter to the agency, Sen. Charles Schumer (D-N.Y.) asked the FTC to investigate a new policy announced by OnStar, the GPS tracking company.

In September, OnStar said it planned to continue to track drivers and sell their data to third parties even after they cancelled the service. The company said maintaining a connection would make it easier for consumers to reenroll and would enable the company to provide customers with information about recalls affecting their vehicles and natural disasters. Although OnStar said consumers could specifically request not to be tracked, the request would need to be explicit and in addition to a request to terminate service.

Calling the policy change a "brazen invasion" of consumer privacy, Sen. Schumer said it "put consumers at risk for having sensitive personal data collected and shared without their knowledge."

An estimated six million Americans currently have OnStar installed in their vehicles, according to the letter, and most new General Motors vehicles come standard with the device, potentially impacting millions more consumers.

But just days after Sen. Schumer sent his letter requesting an

investigation into whether the practice constituted an unfair and deceptive practice, OnStar reversed its position.

In a press release, the company said it no longer planned to keep a data connection to customers' vehicles after OnStar service is cancelled.

"We realize that our proposed amendments did not satisfy our subscribers," said OnStar president Linda Marshall in the statement. "This is why we are leaving the decision in our customers' hands. We listened, we responded and we hope to maintain the trust of our more than 6 million customers."

If the company ever offers the option of a data connection after cancellation, it said it would only be in situations where consumers affirmatively opt in, and would "honor customers' preferences about how data from that connection is treated."

"We regret any confusion or concern we may have caused," Marshall said.

To read the letter from Reps. Markey and Barton, click here.

To read Sen. Schumer's letter, click here.

Why it matters: Under current law, both the use of supercookies and OnStar's policy change are legal. But the negative public reaction, coupled with possible privacy legislation and regulation on the horizon, could add to support for measures such as a Do-Not-Track mechanism.

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