

Food Chemical News



This week's On the Front Burner contributors:

Paul Hyman & Ricardo Carvajal



Weekly in-depth coverage of food regulations, additives, microbiology, contaminants and feed

ON THE FRONT BURNER

There's a reason the Food and Drug Law Institute's recent webinar on FTC's enforcement actions against POM Wonderful drew as many as 180 listeners (see related article, Page 7). The FTC's recent attack on health claims represents a new regulatory threat for food companies, or at least a bigger threat than previously experienced. Fortunately, for this edition of On the Front Burner, Food Chemical News was somehow able to recruit two top attorneys following the FTC to offer some insight.

The Cost of Inadequate Substantiation

By Paul Hyman and Ricardo Carvajal

It is evident that both the Food & Drug Administration and Federal Trade Commission are ratcheting up enforcement activity against false or misleading food labeling and advertising.

For FDA, the change in attitude is especially notable, given the extent to which enforcement activity in the labeling arena had fallen victim to tight budgets. However, when it comes to requiring that claims made in labeling be adequately substantiated, FDA continues to tread lightly. Although funding for FDA has improved, the agency still must contend with many competing priorities that are readily perceived as having a stronger link to public health protection. In addition, the agency recognizes that it would be neither easy nor cheap to overcome a First Amendment challenge to restrictions on potentially misleading speech.

FDA Associate Commissioner for Foods Michael Taylor gave a nod to both of these constraints in a recent blog posting that called on industry to exercise restraint, while at the same time inviting continued scrutiny of questionable claims by consumer groups and the media.

FDA's reluctance to take a more aggressive stance with respect to claim substantiation does not mean that the pressure is off, however. Where FDA has chosen to hold back, FTC has forged ahead with a number of investigations of allegedly false or misleading advertising that have resulted in restrictive settlements.

By way of background, FTC requires that advertisers have substantiation, or a reasonable basis, for objective claims before those claims are disseminated.

The level of substantiation must at least be commensurate with any express or implied claims. Claims for consumer health products are subject to the relatively higher standard of "competent and reliable scientific evidence," defined as "tests, analyses, research, or studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results."

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When asked, FTC officials will state that the "competent and reliable scientific evidence standard" does not imply a fixed formula for substantiation, and that claims must be evaluated in light of the totality of available evidence. However, it is clear that FTC expects claims made for health products to be supported by at least one "gold standard" clinical study, meaning a study that is randomized, double-blind, and placebo controlled, and that is conducted by qualified persons – preferably independent from the sponsoring company.

In recent speeches and consent orders, FTC has revised the "competent and reliable scientific evidence" standard described above to require scientific evidence that is "sufficient in quality and

quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true."

More importantly, to avoid subsequent court challenges to its consent orders, FTC has begun inserting very specific language regarding substantiation in those orders. For example, a recent consent order for Nestle Healthcare Nutrition Inc. requires "at least two adequate and well-controlled human clinical studies. . . conducted by different researchers, independently of each other," to support claims related to specific health-related benefits such as reduction of the duration of acute diarrhea or absences from daycare or school.

POM Wonderful cites First Amendment

These more stringent terms in consent orders are cited by POM Wonderful LLC in its recently filed lawsuit against FTC, in which POM alleges that FTC has changed its substantiation standard without engaging in notice and comment rulemaking, in violation of the Administrative Procedure Act (see related article, Page 7).

Undeterred, the FTC struck back with a complaint alleging that POM's advertising is not supported by "competent and reliable scientific evidence" (although the proposed order in that case does not seek to impose the requirement of two clinical studies).

Early indications are that POM intends to mount a spirited defense of

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its advertising, grounded in part on its contention that the First Amendment affords POM the right to communicate truthful and non-misleading scientific information about the potential benefits of its products. FTC thus might find itself waging a protracted battle over constitutional limitations on its authority to restrict commercial speech – a battle much like the one that continues to plague FDA's administration of health claims.

In the interim, it is clear that the plaintiffs' bar – which need not concern itself with First Amendment constraints – regards inadequately substantiated claims to be fertile ground.

Residents of two states recently filed a putative class action against Basic Research LLC et al alleging that defendants made false and deceptive claims about dietary supplements advertised to help “prevent stress-related abdominal fat” (among other claims). The plaintiffs allege that the claims lack scientific validation, and ask for damages for alleged violations of the Racketeer Influenced and Corrupt Organizations Act (better known as RICO), Florida's Deceptive and Unfair Trade Practices Act and New Jersey's Consumer Fraud Act. Actions such as these have become commonplace and can be costly to defend even when their merit is open to question.

Even in ordinary times, the flexibility inherent in the substantiation standard has made it difficult to ascertain when the standard is met. In these less ordinary times, prudence calls for consultation with qualified, independent scientific experts as a means of ensuring that marketing claims do not race ahead of the supporting evidence. Even then, one should expect a challenge from a regulator or plaintiff's attorney. However, a properly substantiated claim provides a viable defense to such challenges, and can help minimize their considerable costs.

ABOUT OUR AUTHORS



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in the Chief Counsel's Office of the FDA, entered private practice in 1968. He chaired the Federal Bar Association's Food and Drug Law Committee from 1972 to 1974. He was a member of the Board of Directors of the American Council on Science and Health from 1987 to 1989, and a member of the editorial advisory board of the *Food and Drug Law Journal* from 1995 to 1997. He received a special recognition award from the Regulatory Affairs Professional Society in 1999, and the FDLI Distinguished Service and Leadership Award in 2003.



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(including dietary supplements and medical foods). He has substantial experience with all food and dietary supplement issues, including recalls, Reportable Food Registry issues, and GMP and HACCP compliance issues. He also has substantial experience with labeling and advertising issues, including those that arise from the use of health, nutrient content, structure/function, and disease claims. He has particular expertise in the regulation of products derived through biotechnology and nanotechnology.

From 2002 to 2007, he served as associate chief counsel in FDA's Office of Chief Counsel, where his work was recognized with several individual and team awards. He currently serves on the Editorial Advisory Board for the Food and Drug Law Institute Monographs, and served as Chair of the Public Policy Outreach and Implementation Task Force of the Institute of Food Technologists.

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