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Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Keeping The FDA Honest: Interpreting Label Claims

Law360, New York (April 08, 2009) -- In Lewis Carroll's *Through the Looking Glass*, Humpty Dumpty famously declares that "Words mean what I say they do. No more, and no less."

In a thoughtful opinion for a unanimous three-judge panel of the U.S. Court of Appeals for the Seventh Circuit in *U.S. v. Farinella*, ___ F. 3d ___, Nos. 08-1839, 08-1860 (March 12, 2009), Judge Richard Posner rejected the U.S. Food and Drug Administration's (FDA's) analogous logic as inadequate to establish that labeling is "misleading" and hence in violation of the "misbranding" provisions of the Federal Food, Drug and Cosmetic Act (the Act).

According to the court, the agency cannot rely merely on its naked assertion about the meaning of an ambiguous labeling statement, or even on what an FDA "expert" says the language means, at least when there is no existing statutory or regulatory definition of the term nor even a written interpretive guideline or opinion.

On the contrary, in order to make out a *prima facie* case of misbranding on account of misleading labeling in these circumstances, the FDA is obligated to present "evidence" "concerning consumers' understanding."

This decision, although rendered in a case involving an allegedly misleading statement on the label of a food product, nevertheless has significant potential implications in a variety of other FDA regulatory and enforcement contexts.

In particular, the FDA often relies only on its own expertise in deciding what meaning to ascribe to otherwise ambiguous and undefined representations in prescription drug and medical device advertising and promotion. The decision in *Farinella* suggests that in some circumstances such reliance may well be legally problematic.

Discussion

In *Farinella*, the defendant was convicted after a jury trial of misbranding food. The alleged misbranding involved altering the original manufacturer's "best when purchased by" date on the label of a salad dressing to a date as long as 18 months afterward.

At trial, FDA asserted that the "best when purchased by" date means the food's "expiration date," after which there would be either freshness or possibly safety concerns. But there was no applicable statute or regulation that defined the "best when purchased by" date to mean the "expiration date."

Further, "[n]o consumer evidence was presented, whether as direct testimony or in survey form ... No evidence was presented that 'best when purchased by' has a uniform meaning in the food industry." Slip Opinion at 5.

Moreover, there was no evidence to show that either freshness or safety concerns exist with respect to this shelf-stable salad dressing consumed after either its original or modified "best when purchased by" date.

And, while an FDA employee was permitted to testify at trial as an "expert" about the meaning of the "best when purchased by" date on the label, his testimony lacked empirical support about the meaning of the term nor was it grounded in any specific law, regulation or even in an official interpretation or guidance. *Id.* at 8. It was unsupported "oral testimony of an agency employee." *Id.*

In this respect, it amounted to "some bureaucrat's secret understanding of the law", which, if relied upon to support a conviction, would amount to "a denial of due process of law." *Id.*

On this record, Judge Posner, on behalf of a unanimous three judge appellate panel, had little difficulty in overturning the defendant's conviction.

"[T]o prove a person guilty of having made a fraudulent representation, a jury must be given evidence about the meaning (unless obvious) of the representation claimed to be fraudulent, and that was not done here ... Because the government presented insufficient evidence that the defendant engaged in misbranding, he is entitled to be acquitted." *Id.* at 9-10.

Although *Farinella* involved review of a criminal conviction that requires proof of guilt beyond a reasonable doubt, the substantive standard articulated by the court for determining when a statement is misleading and thus misbrands a product should have equal application in a civil enforcement context.

The Seventh Circuit's insistence that, "unless obvious" (and at least in the absence of any controlling statute, regulation, interpretive guidance or opinion), the FDA must present evidence about the meaning of representations in advertising and labeling is consistent with the FDA's own evolving interpretation of the Act, as well as the requirements of the First Amendment to the U.S. Constitution.

For example, the FDA has acknowledged that the reasonable consumer standard is the appropriate yardstick for interpreting claims, and the agency has explicitly rejected use of the “ignorant, unthinking, and credulous” criterion. See “Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements”, at 6-7; 67 Fed. Reg. 78002, 78004 (Dec. 20, 2002).

The FDA has likewise acknowledged that this reasonable consumer standard is also demanded by the First Amendment. *Id.*

Moreover, the FDA has said that “surveys, copy tests, and other reliable evidence of consumer interpretation can be helpful in assessing the particular message that FDA believes constitutes an implied claim.” 67 Fed. Reg. 78003 n. 1; Qualified Health Claims Guidance at 6 n. 1. Surely, the First Amendment demands at least some reliable extrinsic evidence, such as a consumer survey, before the FDA can simply assert, in the absence of any otherwise controlling authority, that consumers comprehend ambiguous advertising and labeling claims in the way the agency alleges.

See e.g. G. W. Evans and A. I. Friede, “Mixed Results for Free Speech In FDA Health Claims Guidance”, Legal Opinion Letter at 1, Washington Legal Foundation (Jan. 17, 2003) (“ ... the First Amendment demands that FDA adopt transparent and neutral evaluation procedures” that “should include the use, as appropriate, of empirical methodologies (e.g. consumer surveys) for determining what message is communicated by a particular advertising claim.”).

Judge Posner said as much in his opinion in *Farinella*. Indeed, the requirement for extrinsic evidence to support an agency’s “reasonable man” interpretation of ambiguous promotional representations is consistent with the Federal Trade Commission’s longstanding approach to the matter.

See FTC Deception Policy Statement, appended to *Cliffdale Associates Inc.*, 103 FTC 110, 174 (1984) (where representations are ambiguous, “the Commission will require extrinsic evidence that reasonable consumers reach the implied claims”).

This is also consistent with the U.S. Supreme Court’s decision in *Hustler Magazine Inc. v. Falwell*, 485 U.S. 46 (1988). There, the Court found that a “parody” was not legally actionable because it “could not ‘reasonably be understood as describing actual facts’ ...” *Id.* at 57.

While the parody was “offensive” and “doubtless gross and repugnant in the eyes of most” (*id.* at 50), the absence of evidence to show that reasonable people believed it to be true was fatal under the First Amendment to Falwell’s claim.

Implications for Prescription Drug and Medical Device Advertising and Promotion

At first blush, Judge Posner's rejection of FDA's unilateral attribution of a specific meaning to the term "best when purchased by" on the label of a food product in the absence of any pre-existing authoritative interpretation may seem largely inapplicable in the prescription drug and medical device contexts.

After all, prescription drug and medical device advertising and promotion are each heavily regulated with myriad applicable statutory and regulatory definitional requirements, as well as a plethora of written interpretive guidelines and opinions.

Moreover, the approved or cleared applications for prescription drugs and medical devices themselves often establish the specific parameters of permitted promotional representations. In this respect, then, one might credibly ask "why all the fuss about Farinella?"

But as everyone who practices in this area knows from painful personal experience, there are often situations where the FDA simply asserts, ipse dixit and without further ado, that words or images have the meaning it says they do without any authoritative support whatsoever.

This is evident, for example, in any number of Notices of Violation or Warning Letters issued by the Division of Drug Marketing, Advertising and Communication (DDMAC) in FDA's Center for Drug Evaluation and Research in connection with prescription drug advertising and promotion.

In such compliance correspondence, DDMAC regularly asserts that a particular message is being communicated to physicians or consumers without any authoritative definitional support whatsoever.

One can make a compelling argument based on Farinella that, at least in these circumstances, both the Act and the Constitution demand more than an assertion by FDA about what something means.

In the absence of any authoritative definitional support, they require FDA to rely upon empirical evidence to prove that a reasonable physician or consumer who is targeted by the advertising or promotion would necessarily interpret the claims in the way suggested by the agency.

--By Robert B. Nicholas and Arnold I. Friede, McDermott Will & Emery LLP

Robert Nicholas is a partner with McDermott in the firm's Washington, D.C., office. Arnold Friede is counsel with the firm in the Washington office.

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