Reining In The FTC's Crusade Against Dietary Supplements

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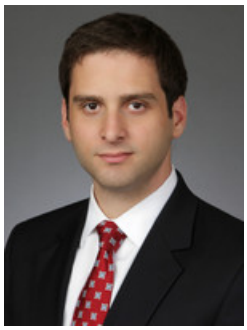

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In United States v. Bayer, the Federal Trade Commission found out the hard way that it cannot invent novel legal standards in a contempt action.[1]

The Department of Justice, litigating on behalf of the FTC, brought a civil contempt action alleging that Bayer had marketed a probiotic dietary supplement, Phillips' Colon Health, in violation of a 2007 consent decree between the company and the government. The government sought hundreds of millions of dollars in contempt damages and $25,000 a day in fines. After a two-and-a-half week bench trial, Judge Jose Linares of the United States District Court for the District of New Jersey denied the government's contempt motion in its entirety. The court's decision will help clarify the law for industry and could help rein in the FTC's overly aggressive enforcement practices.

Regulatory Background

Recognizing the many health benefits of dietary supplements, Congress enacted the Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, sec. 8, §

413(c) (codified at 21 U.S.C. § 350(b)), to ensure that supplements can be marketed and sold without following the stringent requirements imposed on prescription drugs. Whereas new drugs must be preapproved by the Food and Drug Administration,[2] and traditionally must be supported by randomized, placebo-controlled, double-blind clinical trials, Congress relaxed the standard for dietary supplements.[3] Dietary supplement claims, such as structure-function claims, need only be "truthful and not misleading."[4]

DSHEA does not specify what substantiation is necessary to render a claim "truthful and not misleading." Accordingly, in April 2001, the Federal Trade Commission promulgated guidance stating that the relevant standard is "competent and reliable scientific evidence."[5] The FTC guidance defines "'competent and reliable scientific evidence'" to mean: "tests, analyses, research, 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 persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[6]

Elaborating on this standard, the guidance makes clear that drug-level randomized clinical trials are *not* required. Instead, "competent and reliable scientific evidence" is a "flexible" standard and "[t]here is no fixed formula for the number or type of studies required."[7] Although "well-controlled human clinical studies are the most reliable form of evidence[,]" they are not necessary and "[r]esults obtained in animal and in vitro studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible."[8] "[R]esearch explaining the biological mechanism underlying the claimed effect" will also be considered.[9] "[E]pidemiologic evidence may be an acceptable substitute for clinical data" in some circumstances.[10] And studies need not be conducted on the precise formula used in the advertised product; it can be "appropriate to extrapolate from the research to the claimed effect," even if there "are significant discrepancies between the research conditions and the real life use being promoted."[11]

FTC's Attempt to Raise the Standard

After promulgating this guidance, the FTC entered into consent decrees with Bayer and numerous other companies. Parroting the language of the guidance, these decrees used the same standard, "competent and reliable scientific evidence," and the exact same definition.[12] Because the language was identical, the companies under decree believed they did not need to substantiate their claims with drug-level randomized clinical trials. Instead, they relied on other forms of substantiation and for several years, the FTC made no objection to this practice.

But, starting in 2009, the FTC decided it wanted to raise the standard. The agency had lost a number of enforcement and contempt actions and, according to the then-director of the FTC Bureau of Consumer Protection David Vladeck, the FTC "need[ed] to take steps to make our standard injunctive language ... more exact."[13] But, rather than following proper procedure — such as revoking its guidance or lobbying Congress to change the law — the FTC attempted to impose a novel drug-level standard through threats of litigation. The agency began investigations into a number of companies and, with threats of exorbitant damages, coerced them into agreeing to the higher standard, embodied in new consent decrees.[14]

Following a similar path, the FTC began an investigation into Bayer and sought to strong-arm the company into revising its consent decree. But, unlike other companies, Bayer did not capitulate. As a result, the FTC was forced to litigate and to defend its position that

dietary supplement claims must be supported by drug-level randomized clinical trials.

FTC's Evidence at Trial

The government's only support for this novel standard was a single gastroenterologist, Dr. Loren Laine, who unveiled his opinion in a declaration attached to the government's contempt motion. Dr. Laine was not the FTC's ideal witness. He conceded in his deposition and at trial that he was not an expert on probiotics, he had never done any clinical study on probiotics, he was completely unfamiliar with the regulatory regime for dietary supplements and he could not point to any probiotic or other supplement on the market that met the drug-level standard.

At trial, Bayer presented two experts of its own: Dr. Daniel Merenstein, a lead investigator on eight probiotic trials who is widely considered one of the country's foremost experts on probiotics and Dr. M. Brian Fennerty, a world-renown gastroenterologist who has studied probiotics and regularly uses them in his clinical practice. Both of Bayer's experts testified that there was overwhelming scientific evidence that Phillips Colon Health was effective. This evidence included *hundreds* of clinical studies, as well as other types of scientific evidence. Bayer's experts also testified that while randomized controlled clinical trials are required for drugs, they are not required for a supplement making structure-function claims. Finally, Bayer presented evidence regarding its extensive claim-review process that it follows to ensure that all of its supplement claims are medically and scientifically accurate.

The Court Rejected The FTC's Novel and Unlawful Standard

Following trial, the court denied the government's contempt motion in its entirety, rejecting the government's novel and unlawful standard, and finding that Bayer did not violate the consent decree. The court made five significant holdings that could impact industry and the FTC's future enforcement efforts:

First, the court concluded that the government's demand for drug-level randomized controlled trials was "inconsistent" with DSHEA and the FTC's own guidance.[15] The court required the FTC to follow the law and the guidance it promulgated.

Second, the court required the FTC to abide by the terms of its agreement with Bayer. The court held that Bayer cannot be held in contempt because the drug-level requirement was "found nowhere within the four corners of the consent decree."[16] Rather, it was found "only within the expert report that was filed with the government's motion for contempt."[17] "The government cannot seek contempt on the basis of a lone expert who proposes a standard that was not disclosed to industry until the day the government filed its contempt motion."[18]

Third, the court rejected the government's attempt to elide the distinction between structure-function claims and disease claims. The court noted that Bayer's PCH claims "are ubiquitous in the industry" and the government "has not pointed to any instance when it has asserted that these clams are disease claims."[19] If they were disease claims, the court explained, "then many of the most popular probiotic supplements on the market would be in violation of the law and subject to seizure by the FDA."[20]

Fourth, the court rejected the government's attempt to use an unqualified and uniformed expert to impose a novel standard on the entire industry. The court explained that "Dr. Laine lacks the expertise necessary to prove" that randomized controlled trials are required because he is "not an expert in probiotics."[21] Nor can he provide the standard because,

he was not familiar with the regulatory framework (including DSHEA and structure-function claims). Indeed, the government did not even provide him with the statute or FTC guidance before he rendered his opinion.

Fifth, the court rejected the government's argument that Bayer was required to print out each individual study it relied on, in order to "possess" that information. The court explained that the consent decree "does not require Bayer to make records or copy studies."[22] In the electronic era, "Bayer need not copy [each study] from an electronic database that Bayer already possesses and put it in a filing cabinet." It was therefore sufficient that Bayer's scientist, Dr. Pana Beke testified that she and her medical team "reviewed data in the public domain on an ongoing basis to evaluate substantiation."[23]

Implication for the Dietary Supplement Industry

The court's decision should have serious implications for the dietary supplement industry. To start, companies need not possess drug-level evidence for dietary supplements. If the government's novel and unlawful standard had become the law, entire shelves of dietary supplements would have been cleared from stores, because few, if any, supplements meet this standard.

The court's decision, moreover, provides a roadmap to help dietary supplement companies stay on the right side of the substantiation line. Industry will take notice that the court strongly endorsed "Bayer's review process," whereby a member of its legal, medical and regulatory teams reviewed "every single piece of promotional material" to ensure that it was medically and scientifically substantiated.[24] This process "starts at idea generation" and requires unanimous consent of the committee for every advertisement. Bayer's medical team also created a medical point of view file to document the scientific support for its claims and regularly reviewed the published scientific literature to stay up to date with the evolving scientific data.

Finally, strong, credible and appropriate experts were key to Bayer's success. The court relied heavily on Bayer's experts and made clear that, unlike the government's expert, Bayer's had the relevant expertise and were familiar with the legal and regulatory standard for supplements.

The court's decision is welcome news to an industry that too often has been subject to the FTC's overly aggressive enforcement efforts. Companies should remain vigilant in ensuring that all of their claims — like Bayer's — are fully substantiated. At the same time, though, companies should be ready to take issues like these to trial against the FTC when the agency oversteps its bounds.

—By Jonathan F. Cohn and Benjamin M. Mundel, Sidley Austin LLP

Disclaimer: Jonathan Cohn and Benjamin Mundel were members of the Sidley Austin LLP trial team that represented Bayer Corp. in this litigation.

Jonathan Cohn is a partner and Benjamin Mundel is an associate in Sidley Austin's Washington, D.C., office.

[1] See United States v. Bayer, 07-001 (D. N.J. Sept. 24, 2015).

[2] See 21 U.S.C. § 331(d); id. § 355(a).

[3] See 21 C.F.R. 5, § 314.126,2.

[4] 21 U.S.C. § 343(r)(6)(B); see also id. § 321(ff) (defining "dietary supplement" as any nontobacco product "intended to supplement the diet"); id. § 343(r)(6)(A) (identifying types of dietary supplement claims, including structure-function claims); id. § 343(r)(6)(A) (defining a structure-function claim as a claim that "describe[s] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans [or] characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.")

[5] Dietary Supplements: An Advertising Guide for Industry at 3.

[6] Id. at 9.

[7] Id. at 8-9.

[8] Id. at 10.

[9] Id.

[10] Id.

[11] Id. at 16.

[12] See United States v. Bayer, 07-001 Dkt. No. 2.

[13] "Priorities for Dietary Supplement Advertising Enforcement" Remarks by David C. Vladeck, Director FTC Bureau of Consumer Protection Oct. 22, 2009.

[14] See e.g., FTC v. Iovate Health Sci USA, Consent Decree at 7, No. 10-CV-587 (W.D.N.Y. July 29, 2010); United States v. Jason Pharm. Inc., Consent Decree at 3, 6, No. 12-CV-01476 (D.D.C. Sept. 17, 2012).

[15] Opinion at 28.

[16] Opinion at 27.

[17] Opinion at 27.

[18] Opinion at 28.

[19] Opinion at 24.

[20] Opinion at 24.

[21] Opinion at 30.

[22] Opinion at 35.

[23] Opinion 35, 37.

[24] Opinion at 13.