Claim Substantiation and the Bayer Case

Kevin M. Bell and Richard J. Oparil
Porzio, Bromberg & Newman P.C.

It is a bedrock principle in the dietary supplement industry that any product claim must be substantiated with scientific evidence. The difficult question is what type and scope of evidence is sufficient for a structure/function claim. Certainly, multiple randomized, controlled, double blind clinical trials (RCTs) – the "gold standard" of evidence, which the Food and Drug Administration (FDA) requires for new drugs – would suffice. However, the Dietary Supplement Health and Education Act of 1994 (DSHEA) made clear that supplements are not held to the same substantiation requirements as drugs. But despite DSHEA and two decades of guidance from the FDA and the Federal Trade Commission (FTC), the federal government has resorted to the use of costly litigation as a means of forcing the industry to obtain "gold standard" evidence.

The Natural Products Association (NPA) believes that the government's litigation-driven strategy is contrary to both law and consumer welfare. We represented NPA in filing "friend of the court" amicus briefs in the government's latest case against Bayer's probiotic product, asking the Court to reject a broad requirement that structure/function claims for human dietary supplements may only be substantiated using expensive and burdensome RCTs. A contrary result would financially devastate the dietary supplement industry and cause consumers to lose access to supplements that they find beneficial and want to use.

DSHEA struck a balance between the need for consumers to have access to and information about safe and effective dietary supplements, while also preserving the government's interest in protecting the public from unsafe products and false and misleading claims. DSHEA requires that a statement of nutritional support (i.e., a structure/function claim) must have "substantiation that such statement is truthful and not misleading" and contain a disclaimer that the "statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." As Senator Hatch, a sponsor of the legislation said at the time, DSHEA was intended to counteract "unnecessarily stringent" federal intervention and that supplement producers should be free from intervention as long as "the labelling and advertising are truthful, non-misleading, and there exists a reasonable scientific basis for products claims."

For years, federal regulators recognized that dietary supplements were not subject to drug-like substantiation requirements. In 2000, the FDA said that "DSHEA's purpose [is] to broaden the scope of labeling claims that may be made for dietary supplements without subjecting them to regulation as drugs." It issued guidance that substantiation of structure/function claims requires only that manufacturers have "competent and reliable scientific evidence," which was defined to include "tests, analyses, research, studies, or other evidence . . . ."

The FTC similarly advised the industry in 2001 that the competent and reliable scientific evidence standard is lower and more flexible than the standard applicable to drugs. In fact, the FTC explained that, unlike with drugs, "[t]here is no fixed formula for the number or type of studies required" to measure "the adequacy of the scientific support for a specific advertising claim" for a dietary supplement.

Thus, for 15 years, the industry has relied on the administrative guidance that the evidence needed to support a dietary supplement claim depends on many factors, including the type of product, the type of claim, the benefits of a truthful claim, the cost of developing substantiation, the consequences of a false claim, and the amount of substantiation that experts in the field believe is reasonable. While gold standard RCTs may be the most reliable form of evidence, they are not necessarily required; animal studies, in vitro studies, and epidemiological evidence will often suffice.

Given this history, it is disturbing that the federal government is trying to "reform" the industry by imposing drug-like requirements on dietary supplements without issuing new rules or guidance documents after providing notice and receiving public comments from those knowledgeable in the industry, but by going after companies one-by-one in litigation.

Certainly, the government is using this strategy in its case against Bayer for its Phillips' Colon Health probiotic supplement. In 2007, Bayer entered into a consent order that required Bayer to possess "competent and reliable scientific evidence" for all dietary supplement claims. Bayer's product packaging and advertising states that PCH "Helps Defend Against Occasional Constipation, Diarrhea, Gas

and Bloating." When the government began investigating the claims, Bayer submitted 100 scientific papers as evidence of substantiation. Bayer did not, however, have "gold standard" RCTs. Based on that fact, in September 2014, the government asked a federal judge in New Jersey to hold Bayer in contempt of court, alleging violation of the 2007 consent order.

The government based its case not on DSHEA or regulatory guidance documents, but on the opinion of one doctor, who opined that the only way for Bayer to substantiate its PCH claims –or any structure/function claim – would be by conducting one or more drug-like RCTs on the product. Shockingly, the expert testified that the balance Congress struck in enacting the dietary supplement regulatory regime is irrelevant and should simply be ignored. He said that the "only way" to substantiate claims for drugs and human dietary supplements is to conduct drug-level RCTs, and that scientific evidence from animal, in vitro, or genetic studies could never be used to substantiate supplement claims. He also revealed that his analysis did not consider the significant cost of doing RCTs to meet his testing criteria.

Concerned about the government's attempt to force drug-like standards on the industry by attacking one company at a time through litigation and administrative proceedings, NPA asked the judge in the Bayer case to reject a broad requirement that structure/function claims for human dietary supplements may only be substantiated using the expensive and burdensome RCTs as designed by the Government's expert. A contrary result would devastate the dietary supplement industry and cause consumers to lose access to supplements that they want to use. NPA argued that if the government wants to try to change the evidentiary requirements for substantiation of structure/function claims, it should at least follow the Administrative Procedure Act and engage in notice and comment rulemaking.

NPA's second brief directed the Court's attention to the January 2015 decision of the U.S. Court of Appeals for the District of Columbia in POM Wonderful, LLC v. FTC. There, in an administrative proceeding, the FTC found POM violated the FTC Act by advertising that its pomegranate-based products could treat or prevent heart disease, prostate cancer and erectile dysfunction. The advertising allegedly mischaracterized the scientific evidence concerning the benefits of POM's products. The FTC found that one or more randomized and controlled human clinical trials were necessary to establish a causal relationship between those products and the treatment, prevention, or reduction of risk of heart disease, prostate cancer, or erectile dysfunction. However, in reaching that conclusion, the FTC itself emphasized the distinction between "generalized nutritional and health benefit claims" and "the specific disease treatment and prevention claims at issue in this case," i.e., "that the Challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, and ED, and that such claims are scientifically established." The FTC did not require randomized, controlled, human clinical trials to support non-disease claims. Thus, the FTC itself recognized the distinction between the level of substantiation between structure/function and disease claims – a distinction that the government is attempting to blur in the Bayer case. NPA also pointed out that the POM Wonderful decision held that requiring two RCTs for disease claims was not required by law.

After holding a trial with both sides presenting evidence, the government's motion to hold Bayer in contempt is now in the hands of the New Jersey Court to decide. The decision could have a far reaching impact on the dietary supplement industry. And while it is safe to say that whichever side loses will appeal, an important lesson is that supplement companies cannot ignore the substantiation requirement. Until there is new regulatory guidance that clarifies what "competent and reliable scientific evidence" really means, supplement companies will continue to be at risk.