When Supplement Product Advertising Goes Too Far

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Where is the line on what the Federal Trade Commission (FTC) can require of supplement companies to support their advertising claims? It's a tough question with still no clear answer. However, there are some new lessons learned from a recent federal court decision out of New York.

Across the marketing spectrum of websites, TV infomercials, social media, newspapers and magazines, Quincy Bioscience advertised its Prevagen supplements as improving cognitive function. Quincy Bioscience advertised Prevagen as a supplement that was "clinically shown" to improve memory problems related to aging. Despite the use of a double-blind and placebo controlled study, two Federal Trade commissioners initiated the filing of a lawsuit with the New York attorney general against Quincy Bioscience related entities and officers alleging false advertising and unfair or deceptive acts and practices under the FTC Act and New York state law.

After the lawsuit was filed in January 2017, Quincy Bioscience released the following statement: "We vehemently disagree with these allegations made by only two FTC commissioners. This case is another example of government overreach and regulators extinguishing innovation by imposing arbitrary new rules on small businesses like ours." This fall, the Federal Court dismissed the government's claims. Why?

Quincy Bioscience based its advertising claims on a study called the Madison Memory Study. This study was designed to determine whether Prevagen improved cognitive function in older adults. It employed what is often considered the "gold standard" of scientific inquiry, a randomized, double-blind, placebo-controlled study and used objective outcome measures of human cognitive function. The study's overall design was left unscathed through this lawsuit.

The FTC's allegations, however, were based on the fact that there was no statistically significant result across the entire 218-person study population on the measured cognitive tasks. Yet, certain subgroups showed statistically significant improvements over those who received placebos in cognitive tasks, including measuring memory, psychomotor function, visual learning, among others. The study also showed trends toward significance in a couple of other tasks such

as measuring verbal learning and executive function. The study's researchers concluded that Prevagen demonstrated the ability to improve aspects of cognitive function in older participants in the sub-grounds of those who had normal cognitive function or very mild impairment. Here is where the FTC tried to draw the line on how supplement companies could use subgroup results.

The two FTC commissioners pushing the lawsuit reviewed Prevagen's advertising and concluded that the claims were false or misleading based on the assertions that Prevagen "clinically shown to improve memory," "helps with memory problems associated with aging," can support "healthier brain function, a sharper mind and clearer thinking," and similar claims. The FTC asserted that there were no statistically significant results observed for the study population as a whole on any of the measured cognitive tasks, and that Quincy Bioscience's reliance on results obtained for various subgroups was improper. The FTC further asserted that Quincy Bioscience conducted numerous "post hoc" analyses of the data broken down by variations of subgroups looking for statistically significant results and that these "post hoc" analyses greatly increased the risk that the positive subgroup results were merely the result of chance, and not Prevagen. The FTC asserted that the Madison Memory Study's few positive findings on specific cognitive tasks for small subgroups of participants was insufficient scientific evidence to substantiate a reliable treatment effect.

The Federal Court disagreed. In fact, the judge concluded that the FTC and New York attorney general's "challenge never proceeds beyond the theoretical." The FTC did not assert that there were in fact any false positives in the subgroup results. It challenged the use of "post hoc" identification of subgroups that benefitted, but failed to explain the nature of any risks associated with use of post hoc analysis or demonstrate that the use of such after the fact analysis of study results affected the subgroups' performance in any way or caused any false positive conclusions. The court observed that there were statistically significant results in the subgroups for certain cognitive tests and those results supported the claims in Prevagen's advertising, none of which appeared to go beyond what the results in the specific subgroup tasks reflected. Since the subgroup concept is widely used in analyzing information from dietary supplement studies, FTC's broad claim that it is a risky practice to use subgroup analysis without any specific basis for demonstrating its use was improper in the Madison Memory Study was insufficient as a matter of law to conclude the advertising was false or misleading. Thus, the court dismissed the claims. However, the FTC and State of New York have both appealed this decision.

For now, FTC should draw a lesson from this decision about how far it may rely on its own interpretation and analysis of data after the fact. Mere theoretical or speculative risks about possible issues with subgroup data are not enough to overshadow researchers' proper conclusions of measured test results. The subgroup concept remains a reasonable and reliable method of analyzing data obtained in properly designed supplement studies. Assuming statistically significant results in specific areas are obtained, a supplement company should be able to use that information as substantiation for well-tailored product claims.

Indeed, it is critical that advertisers ensure that their claims reflect the support available from any study or other information relied on. Ad copy must distinguish between results shown across an entire study population versus any results applicable to only a subgroup. So, when a supplement company advertises its product's great traits, it should be particularly mindful of not making statements suggesting that the entire clinical study group showed improved results if those results arise only in certain subgroups. Supplement companies must continue to pay close attention to this difference, as the FTC will continue to vigorously pursue cases where proper substantiation is lacking. **NIE**


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