United States v. Bayer: Preventing or Treating Disease Claims

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In recent years, the FTC and the Center for Science in the Public Interest ("CSPI") seem to have seen disease claims everywhere, regardless of whether the FDA has deemed the same claims appropriate, non-disease structure/function claims. In the *United States v. Bayer Corp.*, for the second time in recent months, a court called them on it. We discussed before a similar ruling in a class action case brought by CSPI.

In this latest case, the FTC alleged that Bayer violated a 2007 order by disseminating unsubstantiated disease claims for the probiotic supplement, Phillips Colon Health. The 2007 order against Bayer required "competent and reliable scientific evidence" for any future claims for dietary supplements. In promoting Phillips Colon Health, Bayer used claims, such as, "Helps defend against occasional constipation, diarrhea, gas and bloating." Under FDA guidance, these claims are clear structure/function claims, rather than claims to treat or prevent a disease. Claims to treat or prevent disease generally require FDA pre-approval through the drug approval process or another route. In support of its case, the FTC offered "an expert in gastroenterology and clinical research." This expert was, self-admittedly, not expert in probiotics, was "not paying attention to the law or regulations about the difference between dietary supplements and drugs" in forming his opinion, and had not reviewed the FTC's guidance specifically on substantiation for dietary supplement claims. He opined that "competent and reliable scientific evidence," as specified in the 2007 order, required a "human clinical study" that is randomized, double-blind, placebo-controlled, "done in the target population," using "the specific product at issue," "designed with the desired outcome as the primary endpoint," and "using appropriate statistical methods."

Two experts who testified for Bayer were both experienced physicians and researchers with expertise in probiotics and the conduct of clinical studies. According to the court, in forming their opinions, each expert had "understood and relied upon the FTC [g]uidance and the distinction it draws between supplements and drugs." Contrary to the FTC's expert, these experts "presented evidence . . . showing that experts in the relevant fields do not require [studies of the nature described by the FTC expert] to substantiate probiotic supplement claims." The court ultimately found that Bayer's scientific evidence was adequate and that by offering "one expert who seems to require a higher-level RCT," the FTC "had not met its burden [to show] that Bayer is in contempt of the 2007 Order." The FTC's guidance on dietary supplement advertising correctly advises that in assessing claims "a number of factors determine the appropriate amount and type of substantiation [required]." These factors include "the type of product" at issue, "the type of claim" at issue, and "the amount of substantiation that experts in the field believe is reasonable." The court, in effect, found that neither the FTC nor its expert, in this case, appropriately heeded the type of product, the type of claims, or general consensus among experts.

It is important to bear in mind that where clear disease claims are at issue, courts have credited and

relied upon scientific experts, offered by the FTC, who have opined that randomized, controlled clinical trials are necessary. In *FTC v. POM Wonderful*, the D.C. Circuit found POM Wonderful liable where it did not possess at least one randomized, controlled trial for claims for prostate cancer, erectile dysfunction, and heart disease. Likewise, in *FTC v. Wellness Support Network, Inc.*, a court found the advertisers liable where they did not possess at least one randomized, controlled trial for diabetes claims. There is no doubt room to debate whether this level of evidence is too high for disease prevention claims, but for treatment claims for serious diseases, an advertiser would likely face an uphill battle in defending a lesser level of evidence at this point.