

## FTC v. Bayer: The Good News

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The Department of Justice recently filed a motion in federal court against Bayer Corporation over advertising for its probiotic supplement, Phillips' Colon Health. The DOJ alleges that Bayer lacks the "competent and reliable scientific evidence" that a prior 2007 order requires the company to possess for any efficacy or benefit claim for a dietary supplement. According to the government's medical expert - a gastroenterologist and professor at Yale medical school - appropriate science for constipation, diarrhea, gas, and bloating claims for Phillips' Colon Health should consist of randomized, double-blind, placebo-controlled studies on the product or "a product comprised of the same combination of the same strains of bacteria." Without such evidence, the government alleges that Bayer's claims are not properly supported. The FTC is assisting DOJ with the case.

The recent action against Bayer has caused a stir in the dietary supplement industry with trade groups and others questioning whether the FTC is requiring a drug-type level of evidence. The government's position in the Bayer case, however, is considerably more measured than in many past cases - to name a few, *FTC v. Direct Marketing*, *Daniel Chapter One*, and *FTC v. Nat'l Urological Group*. In those cases, the FTC actually argued that, as a matter of law, "competent and reliable scientific evidence" requires controlled clinical testing for *all* health-related advertising claims. One court was entirely persuaded and even observed as follows: "[T]he FTC cites numerous [cases] that 'have consistently found or upheld that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of health-related efficacy claims.' [I]t seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims . . ." This type of sweeping statement is a clear misapplication of the law. In the Bayer case, however, the FTC appears to have dropped this type of broad, legal position and instead looked solely to the opinion of experts in the field to inform what might constitute competent and reliable scientific evidence *for the particular advertising claims at issue*. This is very good news and may be the result of the FTC's changes to its enforcement strategies for health-related advertising in the past few years - and the discussion among stakeholders that those changes prompted. If Bayer hopes to win its case, it will need to counter the FTC's experts with its own experts defending its science as adequately reliable and relevant to its product.

The 2007 order against Bayer resulted from a settlement with the FTC over advertising for One-A-Day Weight Smart multivitamins. The FTC alleged that claims for One-A-Day Weight Smart violated a prior, 1991 order against Bayer's predecessor, Miles, Inc. The 1991 order required claims for all One-A-Day multivitamins to be supported with "competent and reliable scientific evidence."