Claims Substantiation and the Bayer Case

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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. Porzio principals Kevin M. Bell and Richard J. Oparil 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.

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