Federal Trade Commission (FTC) Overreach

Action Requested

Request a Government Accountability Office (GAO) report examining FTC's waste of taxpayer dollars related to *Bayer vs FTC*.

Background

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the FTC regulates the advertising of dietary supplements and foods to determine that they are truthful and not misleading, and that they are substantiated by competent and reliable scientific evidence.

The Food and Drug Administration (FDA), on the other hand, regulates proper structure/function and disallowed disease claims.

Issue

While the FTC has increased action against dietary supplement companies making claims on product labels, they continue to overstep its regulatory authority.

NPA is concerned that the FTC is taking regulatory action against companies making drug claims, requiring a company to have two randomized controlled trials (RCT), and then attempting to make this a standard for all claims made by supplement companies contrary to the section of the FFDCA which regulates dietary supplement claims. Such a requirement is not in food law but is part of the law that regulates pharmaceutical products, and is possibly a violation of the Administrative Procedure Act.

The law states that foods/dietary supplements are held to scientifically different standards than prescription drugs. Drugs are approved on a risk/benefit standard, and, unlike foods, safety and efficacy has to be proven before going to market. However, the FTC continues to push for this burdensome and extremely expensive standard to be applied to dietary supplements.

Example

A 2015 decision by the US District Court of New Jersey (*Bayer vs. FTC*) to not hold Bayer in contempt for claims made by the supplement company in support of one of its products proved a victory for supplement manufacturers across the country.

The decision maintained the integrity of existing law that RCTs for dietary supplements is not the standard. That standard is used in the approval process of pharmaceutical drugs which are approved on a risk benefit basis.

Adding specificity to FTC law, which would require FTC to judge

supplement claims under current FFDCA laws and not drug-like FTC standards, would be beneficial to FDA, FTC and the industry. A product should not be judged on two different sets of regulations.

Had the court ruled in favor of the FTC, thereby requiring two RCT studies, the impact for dietary supplement consumers and manufacturers would have be devastating. Consumer choice would have been curtailed, as manufacturers would have devoted less time and resources to product innovation.

Currently, it costs more than $1 billion and takes 10 to 15 years to bring a new drug to the marketplace. These costs and time frames would destroy all supplement innovation. Additionally, under these requirements, companies bringing novel dietary ingredients found in nature to the marketplace would have to pay the same costs for claims but would receive no intellectual property protection to recoup their investment costs.

The fact is, with a long history of safe use by millions of consumers, there is no need for two RCTs to tell us the health benefits of dietary supplements. It is well-known that calcium builds strong bones, and the requirements already in place are more than ample to back up this claim.

NPA Position

NPA welcomes regulatory action from the FTC when appropriate, within the agency's boundaries that do not violate the Dietary Supplement Health and Education Act (DSHEA) or the FFDCA.

NPA will continue to strongly oppose any FTC requirement of two RCTs, as there is no legal or safety basis to mandate this requirement as a rule of general applicability.