

# FTC Sends Notice of Potential Penalties to Approximately 670 Companies Regarding Substantiation of Advertising Claims

April 13, 2023 | Blog | By [Bruce D. Sokler](#), [Joanne S. Hawana](#), [Robert G. Kidwell](#), [Benjamin M. Zegarelli](#)

---

## VIEWPOINT TOPICS

- Antitrust
- Health Care

---

## RELATED PRACTICES

- Antitrust
- Health Care Enforcement & Investigations
- IP Advertising & Marketing
- Health Care Compliance, Fraud & Abuse, and Regulatory Counseling

---

## RELATED INDUSTRIES

- Consumer Products
- Cosmetics & Personal Care Products

On April 13, 2023, the Federal Trade Commission put approximately 670 advertisers on notice that they should avoid deceiving consumers with advertisements that make product claims that cannot be backed up or substantiated. In its [press release](#), the FTC expressly noted that a recipient's inclusion on the list does not suggest that it has engaged in deceptive or unfair conduct. It does suggest that the Companies' claims are potentially candidates to be put under the FTC's substantiation microscope.

In the notices, the FTC delineates specific unlawful acts and practices, including failing to have 1) a reasonable basis consisting of competent and reliable evidence for objective product claims; 2) competent and reliable scientific evidence to support health or safety claims; 3) and at least one well-controlled human clinical trial to support claims that a product is effective in curing, mitigating, or treating a serious disease. The unlawful acts or practices also include 1) misrepresenting the level or type of substantiation for a claim, and 2) misrepresenting that a product claim has been scientifically or clinically proven.

Notice of penalty offenses allows the FTC to seek civil penalties—up to \$50,120 per violation—against a company that engages in conduct that it knows has been found unlawful previously.

The [list of companies](#) are nearly 700 entities involved in the marketing of OTC drugs, homeopathic products, dietary supplements, or functional foods. However, the FTC expressly noted that this action is not limited to health claims and applies to any marketer making claims about the efficacy or performance of its products.

The motivation for this Notice is principally prompted by the Supreme Court's 2021 decision in *AMG Capital Mgmt. LLC v. FTC*, 141 S.Ct. 1341 (2021), which eliminated the FTC's use of Section 13(b) of the FTC Act to seek equitable monetary relief for consumers. The [Commission's majority believes](#) that the Notice of civil penalties is a "work around" that limitation. The Commission's vote here was 3-1, with outgoing Republican Commissioner Wilson, [dissenting](#) because she believed that ad substantiation cases were too complex for this process (all the Commissioners, including ex-Commissioner Wilson, have asked Congress to restore their authority to obtain equitable monetary relief.

**At a minimum, the message here is that on top of the FTC staff's recently issued "[Health Products Compliance Guidance](#)", the staff has clearly been empowered to increase enforcement. For the 670 companies---and others---a review of products claims and their substantiation is certainly timely and in order.**

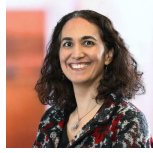
If you have questions about the FTC's actions, or if we can help in any way, please contact any of us.

## Authors



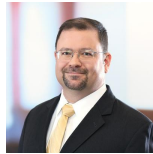
**Bruce D. Sokler**, Member / Co-chair, Antitrust Practice

Bruce D. Sokler is a Mintz antitrust attorney. His antitrust experience includes litigation, class actions, government merger reviews and investigations, and cartel-related issues. Bruce focuses on the health care, communications, and retail industries, from start-ups to Fortune 100 companies.



**Joanne S. Hawana**, Member

Joanne counsels global clients on the regulatory and distribution-related implications when bringing a new FDA-regulated product to market and how to ensure continued compliance after a product is commercialized.



**Robert G. Kidwell**, Member

Robert G. Kidwell is a Mintz attorney who counsels clients on business strategies, regulatory matters, policymaking and lobbying, compliance issues, privacy, and litigation. He defends clients in class action and competitor litigation, and guides transactions through merger reviews.



**Benjamin M. Zegarelli**, Of Counsel

Benjamin advises pharmaceutical, medical device and biotech companies on the FDA regulatory process to identify the correct regulatory pathway, assisting with FDA communications and strategy.