



Ingredient Testing for Food and Supplement Advertising Claims: Keeping Up with an Evolving Standard

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Must an advertiser substantiate claims for multi-ingredient products by testing the full-product formulation or can claims be supported by testing only certain individual ingredients? This question has caused a good deal of confusion among food and dietary supplement manufacturers, advertisers, and legal practitioners alike. This confusion, however, is being alleviated somewhat with a push by the Federal Trade Commission (FTC) to provide more specific substantiation standards for health-related advertising.

This article, as an introduction, provides a brief overview of the basic substantiation requirements for advertising claims for foods and dietary supplements. It, then, includes summaries of the FTC's current guidance, on full-product versus ingredient testing, and recent FTC consent orders that set forth a new standard for using ingredient testing. Finally, the article addresses the practical implications of the FTC's current guidance and the new standard.

Substantiating Claims for Foods and Dietary Supplements

As with any other advertising claim, the FTC Act requires objective claims for dietary supplements and foods to be truthful and non-misleading.² Further, if a claim specifies the

level of substantiation relied upon (e.g., "a clinical study showed . . ."), then that level of substantiation is required to support the claim.³ If a claim does not specify the level of substantiation relied upon, then an advertiser must have a "reasonable basis" for making the claim.⁴ What constitutes a reasonable basis depends upon several factors, including (1) the type of claim, (2) the type of product, (3) the consequences if the claim is false, (4) the benefits of a truthful claim, (5) the ease and cost of developing substantiation, and (6) the level of

commerce." 15 U.S.C. § 45(a)(1). An advertiser violates Section 5(a)'s prohibition on deceptive acts or practices if its advertisement contains a material representation or omission that is likely to mislead consumers acting reasonably under the circumstances. *See* Cliffdale Assocs., 103 F.T.C. 110, 164-65 (1984). Section 12 of the FTC Act also applies to dietary supplement and food advertising. That section prohibits the dissemination of "any false advertisement" for the purpose of inducing "the purchase of food [including dietary supplements], drugs, devices, services, or cosmetics." 15 U.S.C. § 52(a). Section 12 also provides that any such false advertisement constitutes "an unfair or deceptive act or practice in or affecting commerce" in violation of Section 5. 15 U.S.C. § 52(b).

³ *See, e.g.,* Thompson Med. Co., 791 F.2d 189, 194 (D.C. Cir. 1986) (internal citation omitted).

⁴ *See, e.g.,* Fed. Trade Comm'n, FTC Policy Statement Regarding Advertising Substantiation, appended to Thompson Med. Co., 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987) [hereinafter "FTC Policy Statement"], available at <http://www.ftc.gov/bcp/guides/ad3subst.htm>; Pfizer Inc., 81 F.T.C. 23, 65 (1972).

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² In relevant part, Section 5(a) of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting



substantiation experts in the field would agree is reasonable.⁵

Based on the foregoing factors, a showing of “competent and reliable scientific evidence” has been required as a reasonable basis for health-related efficacy and safety claims.⁶

Traditionally, the FTC has defined competent and reliable scientific evidence as “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”⁷

Current FTC Guidance on Ingredient Testing

The FTC released *Dietary Supplements: An Advertising Guide for Industry* (Guide) in 1998, following a year of meetings between FTC staff and industry groups, government offices, and consumer organizations.⁸ The Guide does not

create new, legally binding rules, but “describes the basic principles of [advertising] law and uses examples from the supplement industry to illustrate how those principles apply in practice.”⁹ Although the Guide specifically focuses on dietary supplements, the same law and concepts are equally applicable to advertising claims for foods.

The Guide states at the outset, “When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.”¹⁰ Although the Guide does not directly address the issue of ingredient testing, it provides a basic formula for assessing the substantiation value of any type of scientific evidence. In short, any scientific testing, including ingredient testing, may provide adequate substantiation, as long as it is (1) “internally valid,” (2) consistent with the totality of available evidence, and (3) relevant to the product and claims at issue.¹¹ Each of these three requirements is discussed in turn below, with relevancy proving to be the biggest hurdle for ingredient testing:

- **Internally valid.** According to the Guide, “[t]here is no set protocol” for what makes a study internally valid.¹² Studies, however, should reflect “principles generally accepted in the scientific community to enhance . . . validity.”¹³ The FTC will consider a variety of factors for determining validity, such as whether testing was “carefully controlled, with blinding of subjects and researchers” and whether testing yielded statistically

⁵ See FTC Policy Statement, *supra* note 4; Pfizer Inc., 81 F.T.C. at 65.

⁶ See, e.g., *FTC v. Direct Mktg. Concepts*, 2009 WL 2707554, slip op. at 299 (D. Mass. 2009) (stating that “[f]or health-related efficacy and safety claims, the FTC has commonly insisted on ‘competent and reliable scientific evidence’” (citing *Removatron Int’l Corp. v. Fed. Trade Comm’n*, 884 F.2d 1489, 1498 (1st Cir. 1989)); *Sterling Drug v. Fed. Trade Comm’n*, 741 F.2d 1146, 1156-57 (9th Cir. 1984).

⁷ FED. TRADE COMM’N, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 9 (1998), [hereinafter *FTC Dietary Supplements Advertising Guide*], available at

<http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf>.

See also *U.S. v. Bayer Corp.*, Civ. Action No. 01-01 (HAA), at 2 (D.N.J. Jan. 3, 2007) (consent decree following investigation of Bayer’s One-A-Day Weight Smart multi-vitamins).

⁸ Press Release, Fed. Trade Comm’n, Business Guide for Dietary Supplement Industry Released by FTC Staff (Nov. 18, 1998), available at

<http://www.ftc.gov/opa/1998/11/dietary.shtm>.

⁹ *Id.*

¹⁰ *FTC Dietary Supplements Advertising Guide*, *supra* note 7, at 3.

¹¹ *Id.* at 8-18.

¹² *Id.* at 12.

¹³ *Id.*



significant results, as compared to a placebo.¹⁴

- **Consistent with the Totality of Available Evidence.** The Guide provides that “[a]dvertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not.”¹⁵ Further, according to the Guide, the advertiser’s testing or other evidence should be largely consistent with the surrounding body of relevant research. If other research conflicts with or calls into question the advertiser’s research, and there is no plausible explanation for the inconsistencies, the advertiser’s research will not be considered consistent with the totality of available evidence.
- **Relevant to the Product and Claims at Issue.** The Guide provides that scientific evidence must be “relevant to the specific product being promoted and to the specific benefit being advertised.”¹⁶ Accordingly, “[c]laims that do not match the science, no matter how sound th[e] science is, are likely to be unsubstantiated.”¹⁷ The Guide provides several examples of questions that advertisers should ask in assessing relevancy of scientific testing to the product and claims at issue:

How does the dosage and formulation of the advertised product compare to what was used in the study? Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study? Is the advertised product

administered in the same manner as the ingredient used in the study? Does the study population reflect the characteristics and lifestyle of the population targeted by the ad?¹⁸

The second question posed by the FTC is obviously the most important for purposes of deciding if ingredient testing is sufficiently relevant. The Guide does not provide a black and white answer for how to proceed once this question is asked, but provides an example suggesting that ingredient testing will be *inadequate* when “there is reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the [tested] ingredients”:

An advertiser wants to make claims that its combination herbal product helps increase alertness and energy safely and naturally. The product contains two herbs known to have a central nervous system stimulant effect. The advertiser compiles competent and reliable scientific research demonstrating that each of the herbs, individually, is safe and causes no significant side effects in the recommended dose. This evidence may be inadequate to substantiate an unqualified safety claim. *Where there is reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the individual ingredients, studies showing the effect of the individual ingredients may be insufficient to substantiate the safety of the multiple ingredient product.* In this example, the combination of two herbs with similar stimulant properties could produce a stronger cumulative stimulant effect that might present safety hazards. A better approach would be to investigate the safety

¹⁴ *Id.*

¹⁵ *Id.* at 14.

¹⁶ *Id.* at 16.

¹⁷ *Id.*

¹⁸ *Id.* (emphasis added).



of the specific combination of ingredients contained in the product.¹⁹

Recent Developments and New FTC Consent Orders

For at least the past decade, the vast majority of FTC cases on health-related advertising have resulted in similar relief with regard to the substantiation required for future claims. Specifically, most of these orders simply have re-stated applicable law and required that companies possess “competent and reliable scientific evidence,” meaning “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”²⁰

¹⁹ *Id.* at 17 (emphasis added).

²⁰ See, e.g., *FTC v. Direct Mktg. Concepts*, Civ. Action No. 04-11136-GAO, at 5-6 (D. Mass. Aug. 13, 2009) (final order) (requiring competent and reliable scientific evidence for all health-related claims for foods, dietary supplements, and drugs), available at <http://www.ftc.gov/os/caselist/0233138/0233138.shtm>; Daniel Chapter One, FTC File No. 082-3085 (initial decision of Chief Administrative Law Judge D. Michael Chappell filed Aug 5, 2009) (requiring competent and reliable scientific evidence for all food, dietary supplement, and drug health-related claims, including several cancer prevention and treatment claims specifically identified in the order), available at <http://www.ftc.gov/os/adipro/d9329/090811dcoinitialdecision.pdf>; Kellogg Co., FTC File No. 082-3145, at 3 (decision and order issued July 27, 2009) (requiring competent and reliable scientific evidence for cognitive-benefit claims for morning foods and snack foods), available at <http://www.ftc.gov/os/caselist/0823145/090731kelloggdo.pdf>; *FTC v. CVS Pharm.*, Civ. Action No. 09-00420-DLM, at 4-5 (D.R.I. Sept. 18, 2009) (stipulated final judgment and order) (requiring competent and reliable scientific evidence for cold and flu treatment and prevention claims and immune “boosting” claims), available at

However, last year, in *FTC v. Lane Labs-USA* a New Jersey federal district court dealt a blow to the FTC and held that a dietary supplement company was not liable for violating a previous order that contained the traditional, broad competent and reliable scientific evidence standard.²¹ This loss—a rarity for the FTC—triggered a swift and decisive response. Soon thereafter, at conferences and in interviews, FTC staff announced that, in response to *Lane Labs*, the Commission intended to revise its standard order language to be more specific.²² The FTC remained true to its word, announcing in July of this year two consent orders containing more specific substantiation requirements.²³ Embedded within these substantiation provisions is a new standard for determining when ingredient testing may be considered adequate substantiation.

The two new consent orders—*Nestlé HealthCare Nutrition, Inc.* and *Iovate Health Sciences U.S.A.*—provide that weight loss claims (at issue in *Iovate*) and claims to treat diarrhea in children or prevent absences from school (at issue in *Nestlé*), must be substantiated

<http://www.ftc.gov/os/caselist/0723237>

[/090908cvsstiporder.pdf](http://www.ftc.gov/os/caselist/0723237/090908cvsstiporder.pdf). But see, e.g., *Schering Corp.*, 118 F.T.C. 1030 (1994) (consent order) (requiring two well-designed clinical trials for appetite suppression and weight loss claims); *FTC v. Thompson Med. Co.*, 104 F.T.C. 648 (1984) (requiring two well-designed clinical trials for claims for OTC analgesic drugs).

²¹ Civ. Action No. 00-cv-3174, slip op. at *19-29 (D.N.J. Aug. 11, 2009).

²² See, e.g., Dan Schiff, *FTC Sharpens Consent Order Language in the Wake of Lane Labs*, THE TAN SHEET, Nov. 16, 2009, at 18.

²³ Press Release, Fed. Trade Comm’n, Nestlé Subsidiary to Settle FTC False Advertising Charges; Will Drop Deceptive Health Claims for BOOST Kid Essentials (July 14, 2010), available at <http://www.ftc.gov/opa/2010/07/nestle.shtm>; Press Release, Fed. Trade Comm’n, Dietary Supplement Maker to Pay \$5.5 Million to Settle FTC False Advertising Charges (July 14, 2010), available at <http://www.ftc.gov/opa/2010/07/iovate.shtm>.



by “competent and reliable scientific evidence” in the form of at least two randomized, double-blind, placebo-controlled clinical trials that have been conducted by “different researchers, independently of each other” and are consistent with the totality of available evidence.²⁴ These highly prescriptive requirements for certain types of claims, in and of themselves, have no effect on using ingredient testing as substantiation. However, an additional part of the provisions relates directly to ingredient testing. The new consent orders explicitly provide that the testing may be on either the advertised product or only certain ingredients. If only certain ingredients are tested, however, the following requirements must be met:

- The advertised product must contain “the identical ingredients” as were tested, except that “inactive ingredients (e.g., binders, colors, fillers, excipients)” may differ between the advertised product and the tested ingredients;²⁵
- These “identical ingredients” in the advertised product must be in “the same form and dosage [as was tested], and with the same route of administration (e.g., orally, sublingually) [as was tested]”;²⁶

²⁴ Nestlé HealthCare Nutrition, Inc., FTC File No. 092-3087, at 2-4 (May 18, 2010) (agreement containing consent order), available at <http://www.ftc.gov/opa/2010/07/nestle.shtm>; FTC v. Iovate Health Sciences USA, Inc., Civ. Action No. 10-0587, at 4, 6-7 (W.D.N.Y. July 29, 2010) (stipulated final judgment and order), available at <http://www.ftc.gov/os/caselist/0723187/100729iovatetip.pdf>.

²⁵ Iovate, Civ. Action No. 10-0587, at 4 (defining an “Essentially Equivalent Product”); Nestlé, FTC File No. 092-3087, at 3 (defining an “Essentially Equivalent Product” in the same manner, except listing slightly different examples of inactive ingredients).

²⁶ *Id.*

- For ingredients (other than inactive ingredients) that are added to the advertised product, “reliable scientific evidence generally accepted by experts in the field [must] demonstrate[] that the amount and combination of add[ed] ingredients is unlikely to impede or inhibit the effectiveness of the [tested ingredients].”²⁷ Both orders place the burden of proving that ingredient testing is appropriate on the advertisers.²⁸

Practical Implications of the Evolving Standard on Ingredient Testing

The new consent orders represent a shift in the FTC’s approach on ingredient testing. As discussed in Section II above, current FTC guidance allows ingredient testing as long as it is (1) internally valid, (2) consistent with the totality of available evidence, and (3) relevant to the advertised product. “Relevant,” in short, appears to mean that the advertised product includes the same form and amount of the tested ingredients and there is no reason to suspect, based on available evidence, that any added ingredients will interfere with the safety or efficacy of the tested ingredients. As discussed in Section III above, under the new consent orders, testing still must be internally valid, with certain design requirements prescribed for weight loss and disease treatment claims that were at issue in the cases. The testing also must still be consistent with the totality of available evidence, and the advertised product must contain the same form and amount of the tested

²⁷ *Id.*

²⁸ Nestlé, FTC File No. 092-3087, at 4 (stating that “[r]espondent shall have the burden of proving that a product satisfies the definition of essentially equivalent product.”); Iovate, Civ. Action No. 10-0587, at 7 (noting that “[d]efendants shall have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.”).



ingredients. However, the new consent orders depart from the current FTC guidance in requiring that the advertiser possess “reliable” scientific evidence demonstrating, affirmatively, that additional ingredients are “unlikely to impede or inhibit the effectiveness of the [tested ingredients].”²⁹ Thus, while a *lack of evidence* pointing to negative ingredient interaction appears to be sufficient under the guidance, the consent orders require *affirmative, reliable evidence* showing that negative interaction is unlikely.

Enforcement of the New Ingredient Testing Standard

The new consent orders bind only the named parties; other advertisers are not obligated to comply. Nevertheless, similar to interpretive guidance, the new consent orders reveal the FTC’s latest thinking on how Section 5(a) applies to ingredient testing for food and supplement advertising claims. FTC staff, moreover, have indicated repeatedly that the Commission plans to seek additional orders with similar standards to those in the *Nestlé* and *Iovate* matters.³⁰ Staff also have mentioned, at least once, that the Commission intends to

reform its guidance to conform to the new standards.³¹

Against this background, and given the attention paid specifically to ingredient testing in the recent orders, companies are well advised to ensure that if they are disseminating any claims based on ingredient testing, those claims are, at a minimum, in compliance with the FTC’s current guidance. Risk of FTC enforcement likely could be reduced even further if companies come into compliance with the new ingredient testing standard provided in the *Nestlé* and *Iovate* consent orders.

Complying with the New Standard

Specifics on how to comply with the new standard from the *Nestlé* and *Iovate* orders, and what evidence will be necessary, will depend on the product and claims at issue. In general, however, advertisers should consult with at least one well-qualified scientific expert. That expert should fully understand the new standard and consider the available evidence on both the ingredients that have been tested and those that will be added to the product. If, based on the evidence, the expert concludes that negative interaction is unlikely, the advertiser should obtain a written report. An expert report is likely to be more persuasive if it expressly ties conclusions to specific research, such as mechanism or site of action studies.³²

²⁹ *Iovate*, Civ. Action No. 10-0587, at 4 (defining an “Essentially Equivalent Product”); *Nestlé*, FTC File No. 092-3087, at 3 (defining an “Essentially Equivalent Product” in the same manner, except listing slightly different examples of inactive ingredients).

³⁰ Elizabeth Crawford, *FTC Raises Substantiation Bar for Dietary Supplements in Settlements*, THE TAN SHEET, July 19, 2010, at 5-6 (reporting that Mary Engle, Associate Director of the FTC’s Division of Advertising Practices, indicated in an interview that the FTC will seek similar consent orders with more specific substantiation provisions); David Vladeck, Dir., FTC Bureau of Consumer Prot., Remarks at National Advertising Division Annual Conference (Oct. 5, 2009), available at www.ftc.gov/speeches/vladeck/091005vladecknationaladvertising.pdf.

³¹ Dan Schiff, *FTC’s Pending Claim Substantiation Changes Will Weigh on Small Firms*, THE TAN SHEET, Mar. 1, 2010, at 9 (“FTC plans to promulgate the revised [substantiation] standard initially through consent orders and eventually revise its advertising guide for the supplement industry,” said [Richard] Cleland, assistant director of the FTC’s Division of Advertising Practices.”).

³² The line is somewhat difficult to draw between what is expert opinion versus affirmative evidence. In *Pfizer*, the FTC rejected the argument that competent and reliable scientific evidence “could [never] be found in medical literature, clinical experience, or general medical knowledge.” *Pfizer Inc.*, 81 F.T.C. at 65. Thus, expert



Will the New Ingredient Testing Standard Stick?

The FTC, in its communications to industry, has emphasized that controlled trials on the full product are the best substantiation for food and supplement claims.³³ The ingredient testing standard in the new consent orders, nevertheless, is a clear acknowledgment by the FTC that full product testing is not a legal requirement, despite what might be the best possible type of testing available. Relevant precedent, likewise, suggests that a stronger *per se* rule for full product testing would be difficult to defend.

The FTC has argued, fairly consistently, in court that all health-related advertising claims require controlled clinical trials *per se*.³⁴ Moreover, in one 1999 case, *FTC v. SlimAmerica*, the FTC apparently argued not only that clinical trials were required for the defendant's dietary supplement claims, but also that the trials must be on the full product, rather than single ingredients. The FTC won on both accounts, and the court stated explicitly that, because

individual ingredients may interact negatively, the entire formulation of the multi-ingredient product at issue must be tested:

Scientific validation of the defendants' product claims requires a double blind study of the combination of ingredients used in Super-Formula. This is so because ingredients taken in combination may interact in ways which negate the benefits of the same ingredients taken alone.³⁵

Even still, both very broad positions—that all health-related advertising requires controlled clinical trials and that testing must be on the full product—are on shaky legal ground and unlikely to gain traction. As discussed in Section II above, the FTC's current guidance allows any type of scientific evidence to be used as substantiation, as long as it is internally valid, consistent with the totality of available evidence, and relevant to the specific product and claims at issue. This basic formula constitutes a fair interpretation of the underlying law—specifically, the reasonable basis doctrine and the competent and reliable scientific evidence standard, which emanates from that doctrine. What constitutes a reasonable basis and, in turn, competent and reliable scientific evidence, depends on the weighing of various factors, such as the specific product and claims at issue (e.g., how mild or strong the claims might be) and what experts in the field would consider adequate substantiation.³⁶ Neither standard requires the most conclusive evidence available, and neither standard requires a specific type of evidence, *per se*, simply because a claim is “health-related.” In a 2008 case on health-related advertising, Judge Easterbrook, writing for the Seventh Circuit, observed:

scientific opinion, in at least some cases, may be legally defensible.

³³ See Elizabeth Crawford, *Omega-3 Probe Underscores FTC Standard for Claim Substantiation*, THE TAN SHEET, Feb. 22, 2010, at 12-13 (“[Christine Lee DeLorme, an FTC staff attorney] said the best studies test a finished product, not individual ingredients, and test relevant clinical endpoints, the same dose and delivery method, and a representative human population.”).

³⁴ See, e.g., *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 303 (D. Mass. 2008) (acknowledging, “[T]he FTC cites numerous courts 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.’”) (internal citation omitted); Daniel Chapter One, FTC File No. 082-3085, at 23 (compl. counsel's pre-trial brief), available at http://www.ftc.gov/os/adjpro/d9329/090331_ccpretrialbrief.pdf; *FTC v. Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145 (N.D. Ga. 2008), Pl.'s Mem. in Supp. of Mot. for Summ. J., at 40.

³⁵ 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999).

³⁶ See *Pfizer Inc.*, 81 F.T.C. 23, 65 (1972); FTC Policy Statement, *supra* note 4.



Some passages in [the lower court's decision in *FTC v. QT, Inc.*] could be read to imply that any statement about a product's therapeutic effects must be deemed false unless the claim has been verified in a placebo-controlled, double-blind study . . .

*Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not yet been tested in the most reliable way cannot be condemned out of hand. The burden is on the [government] to prove that the statements are false. . . . Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable how much the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products.*³⁷

Judge Easterbrook also noted, "A placebo-controlled, double-blind study is the best test; something less may do (for there is no point in spending \$1 million to verify a claim worth only \$10,000 if true)."³⁸

First Amendment precedent is aligned with the reasonable basis doctrine and further calls into question both a requirement for controlled clinical testing for health-related claims and a requirement for full product testing. A line of First Amendment cases in the D.C. Circuit has held repeatedly that a government entity cannot place the substantiation bar so high for health-related commercial speech that truthful speech is prohibited; if there is "credible evidence," claims cannot be suppressed.³⁹ The new ingredient testing standard, ultimately, may have staying power because it is less expansive or rigid than a *per se* requirement for full product clinical testing.

³⁷ *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008) (emphasis added except for "how much").

³⁸ *Id.* at 862.

³⁹ *Alliance for Natural Health U.S. v. Sebelius*, Civ. Action No. 09-10470 (ESH) (D.D.C. May 27, 2010); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 10-11 (D.D.C. 2002); *Pearson v. Shalala*, 130 F. Supp. 2d 105, 114 (D.D.C. 2001); *Pearson v. Shalala*, 164 F.3d 650, 655, 659-60 (D.C. Cir. 1999).



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