

NEW YORK UNIVERSITY
JOURNAL OF INTELLECTUAL PROPERTY
AND ENTERTAINMENT LAW

VOLUME 7

SPRING 2018

NUMBER 2

A JUDICIAL ‘SUPPLEMENT’ TO ADVERTISING LAW:
THE FOURTH CIRCUIT’S GNC DECISION AND POLICY
IMPLICATIONS FOR THE DIETARY SUPPLEMENT
INDUSTRY

GIA WAKIL*

In Brown v. GNC Corp., the Fourth Circuit offered a novel solution to the truth-in-advertising dilemma that plagued the dietary supplement industry. Plaintiffs alleged that claims made in connection with defendant’s joint health supplements were false because the “vast weight of competent and reliable scientific evidence” did not support such representations. The Fourth Circuit rejected this allegation of literal falsity, which hinges instead on the “existence (or not) of scientific consensus.” To survive a motion to dismiss, plaintiffs must allege that all reasonable experts in the field agree that the representations are false. This holding generated criticism from prominent academics, who submitted an amicus brief favoring an alternative result.

This Note argues that the Fourth Circuit’s unanimous holding in GNC is the preferred solution to the age-old truth-in-advertising question, particularly during a period of scientific uncertainty. In reaching this conclusion, this Note surveys the existing patchwork of advertising laws, details the factual background of the GNC case, and addresses problematic aspects of the amicus brief. It

*J.D. Candidate, New York University School of Law, 2018; B.A., Political Science, Columbia University, 2011. The author would like to thank Kenneth A. Plevan for his guidance and support, as well as the invitation to explore this research topic. She thanks Professor Barton Beebe, her faculty advisor, for his edits and insights, and her fellow JIPEL Notes Program participants: Julian Pymiento, Ryan Jin, Vincent Honrubia, and Neil Yap.

concludes by describing the merits of the Fourth Circuit’s decision, which has positive implications for consumers and manufacturers alike.

INTRODUCTION.....	117
I. THE LEGAL LANDSCAPE OF THE SUPPLEMENT INDUSTRY	121
A. <i>Sources of Truth-in-Advertising Law</i>	121
B. <i>The FTC-FDA Regulatory Regime</i>	122
1. <i>FTC Regulation of Supplement Advertising</i>	123
2. <i>FDA Regulation of Supplement Labeling</i>	124
C. <i>The Lanham Act</i>	124
1. <i>Two Modes of False Advertising</i>	126
i. <i>Literal Falsity</i>	126
ii. <i>Literal Falsity by Necessary Implication</i>	127
2. <i>Misleading Advertising</i>	128
D. <i>State Consumer Protection Statutes</i>	129
II. THE GNC CASE AND THE GLUCOSAMINE-CHONDROITIN PROBLEM	130
A. <i>Factual Background</i>	130
B. <i>The Complaint</i>	132
C. <i>Decision Granting Motion to Dismiss</i>	133
D. <i>Plaintiffs’ Appeal</i>	136
III. LEGAL AND POLICY CONSIDERATIONS.....	137
A. <i>Law Professors’ Amicus Brief, with Rebuttal</i>	137
1. <i>Inaccurate Legal Standards</i>	138
2. <i>Misstatement of Precedent</i>	140
3. <i>The Nature of Scientific Evidence</i>	141
4. <i>Jury Instructions</i>	143
B. <i>Additional Merits of the Fourth Circuit’s Decision</i>	144
1. <i>FTC, FDA, and Fourth Circuit Parity</i>	145
2. <i>Fair Competition and Consumer Choice</i>	146
3. <i>Res Judicata Effects</i>	148
CONCLUSION	149

INTRODUCTION

Every home has a story, as the old adage goes, and the story in this Note is set in the modern-day vitamin cabinet. Few items are as ubiquitous in American homes as the pill bottle. From vitamins like A and C, or minerals like iron and zinc, the supplements found in a single household typically run the full alphabet. The majority of adults in the United States take one or more dietary supplements occasionally, or even every day,¹ with sales to American consumers exceeding \$35 billion per year.² Americans rely on supplements to ameliorate nutritional deficiencies or to maintain their health. And yet, despite the prevalence of supplements, concerns abound about their efficacy and the veracity of claims supporting the use of supplements. Oftentimes, the prospect of shorter colds, stronger nails, or improved general health justifies the price of the “gamble” in the minds of many consumers.

It was in similar, health-conscious hopes that consumers in the *In re GNC Corp.*³ case had reached for bottles of glucosamine-chondroitin, two common ingredients in joint health specialty products.⁴ The labels touted that the mixtures “promote[] joint mobility and flexibility” and provide “[c]linical strength for daily long-term use.” GNC allegedly had, and on some labels cited to, a reasonable scientific basis for these claims, though its legitimacy was tarnished in the face of mounting scientific evidence indicating otherwise.

¹ National Institutes of Health, *Dietary Supplements: What You Need To Know*, U.S. DEP’T OF HEALTH & HUM. SERVS. (June 17, 2011), https://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx.

² See National Institutes of Health, *Multivitamin/mineral Supplements: Fact Sheet for Health Professionals*, U.S. DEP’T OF HEALTH & HUM. SERVS. (July 8, 2015), <https://ods.od.nih.gov/factsheets/MVMS-HealthProfessional/> (“In 2014, sales of all dietary supplements in the United States totaled an estimated \$36.7 billion.”).

³ See *Brown v. GNC Corp. (In re GNC Corp.)*, 789 F.3d 505 (4th Cir. 2015), *reh’g denied* Ct. Order Den. Mot. for Reh’g and Reh’g En Banc (July 27, 2015), ECF No. 47.

⁴ There is a well-publicized association between glucosamine-chondroitin and joint health. An article on WebMD states that the natural glucosamine in our bodies “helps keep up the health of your cartilage – the rubbery tissue that cushions bones at your joints.” As we age, levels of the natural compound begin to drop, which leads to the gradual breakdown of the joint. WebMD reports that there is “some evidence” that glucosamine sulfate supplements help counteract this problem, though experts “aren’t sure how.” There are a plethora of glucosamine supplements advertising joint health benefits, such as Osteo Bi-flex and Nature’s Bounty glucosamine-chondroitin compound. The widespread use of glucosamine-chondroitin has even reached our pets, with supermarket giant Trader Joe’s and others proffering a line of the supplement for dogs. *Is Glucosamine Good for Joint Pain?*, WEBMD (Jan. 17, 2018), <https://www.webmd.com/vitamins-and-supplements/supplement-guide-glucosamine>.

After years of medical controversy examining whether glucosamine-chondroitin is effective, lawsuits against a variety of its manufacturers and sellers popped up across the United States.⁵ Perhaps the consumers were tired of “gambling” on glucosamine and thought that the products did not live up to their billing. More likely, plaintiffs’ lawyers had been following the debate, and they believed there were issues to be asserted in the form of consumer class actions.⁶ Multiple false advertising lawsuits against GNC commenced between March and December 2013, with allegations of consumer deception across California, Florida, Ohio, New York, Illinois, Pennsylvania, and New Jersey.⁷

⁵ The glucosamine-chondroitin lawsuits are too numerous to list here, but are discussed later in Section III.B. *See, e.g.*, *Lerma v. Schiff Nutrition Int’l, Inc.*, No. 11-cv-1056 (S.D. Cal. filed May 13, 2011); *Padilla v. Costco Wholesale Corp.*, No. 11-C-7686 (N.D. Ill. filed Oct. 28, 2011); *Quinn v. Walgreen Co.*, No. 12-cv-8187 (S.D.N.Y. filed Nov. 9, 2012). According to TruthInAdvertising.org, at least nine class action lawsuits had been filed by October 2013 claiming that companies were falsely marketing the health benefits of glucosamine supplements. *Consumers Claim This Joint Is Not Jumping*, TRUTH IN ADVERTISING ORGANIZATION (Oct. 22, 2013), <https://www.truthinadvertising.org/consumers-claim-joint-jumping/>. Some of the lawsuits have resulted in settlements. *See, e.g.*, *McCrary v. The Elations Company, LLC*, No. 13-cv-00242 (C.D. Cal. filed Feb. 07, 2013); *Pearson v. NBTY, Inc.*, No. 1:11-cv-07972 (N.D. Ill. filed Nov. 09, 2011). Additionally, there is no indication that these lawsuits will stop being filed. As of December 2017, glucosamine-chondroitin is still a hot topic in false advertising. According to a consumer class action blog, plaintiffs’ firms have commenced investigations into Osteo Bi-flex, Schiff Move Free and Glucosamine, Walmart’s Spring Valley Glucosamine, and Nature Made Triple Flex, among others. Tracy Colman, *Different Brands of Glucosamine Chondroitin May Be Falsely Advertised*, TOP CLASS ACTIONS (Dec. 21, 2017), <https://topclassactions.com/lawsuit-settlements/lawsuit-news/828289-different-brands-of-glucosamine-chondroitin-may-be-falsely-advertised/>.

⁶ It is the author’s suggestion that the facts of these cases offer support for the latter. Section III.B. offers commentary on this aspect of the glucosamine lawsuits.

⁷ Procedurally, these cases are as complex and interesting as the ruling itself. Ultimately, according to the Fourth Circuit’s order, there were five GNC plaintiffs (Howard, Toback, Lerma, Calvert, and Gaatz) and three Rite Aid plaintiffs (Flowers, George, and Gross). *GNC*, 789 F.3d at 509 n.1. The underlying lawsuits were consolidated in the U.S. District Court for the District of Maryland. The consolidated cases are docketed as: *Howard v. GNC Corp.*, No. 14-cv-00002 (D. Md. filed Jan. 3, 2014); *Toback v. GNC Holdings, Inc.*, No. 14-cv-00122 (D. Md. filed Jan. 14, 2014); *Lerma v. GNC Corp.*, No. 14-cv-00120 (D. Md. filed Apr. 18, 2013); *Calvert v. GNC Corp.*, No. 14-cv-00123 (D. Md. filed Jan. 16, 2014). The Rite Aid product case was *Flowers v. Rite Aid*, No. 14-cv-00465 (D. Md. filed Feb. 18, 2014). *Flowers* was effectively a lawsuit against GNC, as the products at issue were manufactured for Rite Aid by GNC, and GNC was contractually obligated to indemnify Rite Aid for the claims at issue in the litigation. Consolidated Amended Complaint at ¶ 2, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No.20. To the best of the author’s knowledge, GNC did not contest this assertion. There are multiple related lawsuits that

The controversy surrounding truthfulness in supplement advertising has only grown louder in recent years, and for good reason. Over the last fifteen years, sales of vitamins, minerals, and nutritional and herbal supplements—which, together, comprise the dietary supplement industry—have surged. In December 2013, McKinsey & Company estimated the global value of the supplement market to be \$82 billion, with a high concentration of that value in the U.S.⁸ High levels of sales appear to correlate with high consumer confidence. The majority of U.S. adults—68 percent—take supplements, and nearly 85 percent of those consumers express “overall confidence in the safety, quality and effectiveness of dietary supplements.”⁹ Competition in the supplement industry is fierce and no one company accounts for more than a five percent share.¹⁰

Unbeknownst to many consumers, the laws governing supplement labeling and advertising are notoriously tricky to navigate. The Food and Drug Administration (FDA) issues rules and regulations regarding supplement labeling, marketing, and safety,¹¹ but there are significant limitations to FDA oversight. For example, the manufacturer or seller does not need to prove that a claim is accurate

were resolved separately, such as *Galvin v. GNC*, No. 14-cv-00810 (D. Md. filed Mar. 21, 2014). Although *Brown v. GNC Corp.*, No. 13-05890 (N.D. Cal. filed Dec. 19, 2013), was also transferred to the district court by the Multidistrict Litigation Panel, the Consolidated Amended Complaint does not include Yvonne Brown (the plaintiff in that action) among the named plaintiffs. *GNC*, 789 F.3d at 509 n.2. *Galvin* was voluntarily dismissed in October 2015, and therefore did not proceed with the other consolidated cases.

⁸ Warren Teichner & Megan Lesko, *Cashing in on the booming market for dietary supplements*, MCKINSEY & COMPANY MARKETING & SALES INSIGHTS (Dec. 2013), <https://www.mckinsey.com/business-functions/marketing-and-sales/our-insights/cashing-in-on-the-booming-market-for-dietary-supplements>.

⁹ Council for Responsible Nutrition, *The Dietary Supplement Consumer: 2015 CRN Consumer Survey on Dietary Supplements*, CRN USA (2015), <http://www.crnusa.org/CRNconsumersurvey/2015/>.

¹⁰ *Country Report: Vitamins in the US*, EUROMONITOR INTERNATIONAL (Nov. 2017), <http://www.euromonitor.com/vitamins-and-dietary-supplements-in-the-us/report>. This insight into the brutally competitive landscape offers some explanation for GNC’s insistence on keeping its joint health tag line. Marketing and advertising claims, such as “promotes joint health,” are valued shortcuts for consumers as they navigate supplement shelves. The alternative is a sea of supplements that are labeled and identified solely by their active ingredient(s), like a bottle that simply reads “Vitamin D” or “Glucosamine-Chondroitin” on the front, without further description of health benefits. A consumer who is unfamiliar with glucosamine-chondroitin may not buy the product, were it not for the “promotes joint health” byline. The explanation provides quick information and incentive to buy.

¹¹ See National Institutes of Health, *supra* note 1.

to the FDA’s satisfaction *before* it appears on the product,¹² and the agency reviews substantiation for claims periodically, as resources permit.¹³ The Federal Trade Commission (FTC) polices health and safety claims made in advertising for dietary supplements,¹⁴ but its oversight is similarly limited by the availability of resources.¹⁵

High sales, patchy government supervision, and dubious marketing practices have created a “perfect storm” on the litigation frontier. False advertising in the consumer class action context is a rapidly growing area of law.¹⁶ *GNC* is a rich case study for exploring issues related to truth in advertising, particularly when dealing with scientific controversy. In *GNC*, the Fourth Circuit held that the existence of a single expert in agreement with a claim bars the statement from being found literally false.¹⁷ Since Plaintiffs did not challenge the validity of GNC’s study that supported the claims found on bottles—even after an opportunity to amend their complaint —

¹² *FDA 101: Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2017), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm050803.htm>.

¹³ *Id.*

¹⁴ See National Institutes of Health, *supra* note 1.

¹⁵ For more information about the FDA and FTC’s roles in policing supplement labeling and advertising, see Section I.B., *infra*.

¹⁶ Kenneth A. Plevan, *Recent Trends in the Use of Surveys in Advertising and Consumer Deception Disputes*, 15 CHI.-KENT J. INTELL. PROP. 49, 61 (2016) (commenting on the “recent explosion of consumer deception lawsuits brought as putative class actions, filed by private plaintiffs under state consumer protection laws . . .”); see also Theodore V.H. Mayer, *Recent Developments and Current Trends in United States Class Action Law*, 826 PLI/Lit 313, 325 (May 24, 2010) (citing Federal Judicial Center, *The Impact of the Class Action Fairness Act of 2005 on the Federal Courts* 4 (4th interim report, 2008)) (“Among the most remarkable trends from the period between 2001 and 2007 [was] . . . the continuing growth of consumer-protection or consumer-fraud class actions, which increased by more than 150 percent and now account for 20 percent of all federal class actions.”) Private plaintiffs have increasingly availed themselves of consumer protection statutes. According to one study of over 17,000 reported federal district and state appellate decisions, “[b]etween 2000 and 2007 the number of [consumer protection act] decisions reported in federal district and state appellate courts increased by 119%. This large increase in CPA litigation far exceeds increases in tort litigation as well as overall litigation during the same period.” See Searle Civil Justice Institute, *State Consumer Protection Acts: An Empirical Investigation of Private Litigation Preliminary Report* (Dec. 2009). An additional concern is the “double litigation” frontier: “There is nothing to prevent a private litigant from filing suit against a consumer product advertiser or manufacturer after a federal regulatory agency, such as the Federal Trade Commission, takes action against the same company and obtains full monetary redress for consumers.” Dana Rosenfeld & Daniel Blynn, *The “Prior Substantiation” Doctrine: An Important Check On the Piggyback Class Action*, 26 ANTITRUST 1, 68 (Fall 2011). Rosenfeld and Blynn state that there is an emerging trend of plaintiffs filing class action complaints that are “virtually identical to or rely heavily upon” FTC complaints or FDA warning letters. *Id.*

¹⁷ *Brown v. GNC Corp.* (In re GNC Corp.), 789 F.3d 505, 515 (4th Cir. 2015).

they could not prove that glucosamine-chondroitin was *not* beneficial to joint health. In other words, at least one reasonable expert or study is sufficient to carry the claim on the bottle, even if the vast weight of scientific evidence suggests otherwise. Furthermore, a “battle of the experts” did not necessitate a jury trial, nor did it forestall judgment in the supplement manufacturer’s favor.

This Note argues that the Fourth Circuit’s holding in *GNC* is the preferred solution to the truth-in-advertising dilemma that is rampant in the supplement industry, particularly in periods of scientific controversy. Scientific evidence is neither static nor consistent; there can be two pools of reasonable evidence on either side of a medical controversy, and the minority position may well be proven right. Reserving judgment for juries beyond the pleadings stage would overestimate juries’ abilities to resolve highly technical scientific controversies. Both consumers and retailers benefit from consistent interpretation of consumer protection measures, and the Fourth Circuit has articulated a workable standard for these various state law claims.

The argument unfolds in three parts. Part I surveys the landscape of advertising laws, with heightened focus on the Lanham Act and state consumer deception statutes. Supplement advertising should be treated as a carve-out amidst this patchwork of laws, and I will argue that the Fourth Circuit’s ruling, if appropriately limited, does no damage to the existing doctrines. Part II offers a detailed description of the *GNC* case, both at the district and appellate court levels. This background serves to illustrate why the unanimous *GNC* judgment is an interesting solution to a difficult truth-in-advertising question. Part III assesses the policy implications of the Fourth Circuit’s decision. It begins by addressing criticism of the *GNC* ruling, which was presented in an Amicus Brief submitted by a prominent group of law professors. It then responds to the criticism provided in the Amicus Brief and counters with the merits of the Fourth Circuit’s holding. The Conclusion reviews the argument and demonstrates why the analysis presented is persuasive.

I

THE LEGAL LANDSCAPE OF THE SUPPLEMENT INDUSTRY

A. Sources of Truth-in-Advertising Law

There is a patchwork of federal, state, regulatory, and common law sources of truth-in-advertising law, in addition to industry-specific trade associations that

advise dietary supplement manufacturers and retailers. Both the FTC and FDA¹⁸ can initiate their own investigations into false advertising and labeling of dietary supplements. Their overlapping jurisdiction and shared enforcement responsibilities are explained further in Section I.B., *infra*. However, since actual oversight by these bodies is notoriously constrained, consumers and business competitors have often resorted to alternative forms of legal redress. Companies may challenge claims made by their competitors under the federal trademark law, Lanham Act § 43(a), discussed in Section I.C., *infra*.¹⁹ While the federal cause of action is not available to consumers, the Lanham Act remains instructive in understanding state deception laws that *are* available to consumers.²⁰ The relationship between the Lanham Act and state consumer protection laws is explored further in Section I.D., *infra*. Lastly, the dietary supplement industry finds guidance from self-regulatory associations: the Council for Responsible Nutrition (CRN) is its primary trade association,²¹ and the Better Business Bureau’s National Advertising Division (NAD) offers alternative forms of dispute resolution.²²

B. The FTC-FDA Regulatory Regime

Congress has entrusted matters of food, drug, and supplement policing to both the FTC and FDA,²³ which have overlapping jurisdiction and work together to ensure consistency in consumer products.²⁴ “In 1971, the agencies issued a memorandum of understanding under which the FTC assumed primary responsibility for advertising and the FDA assumed primary responsibility for labeling of food, medical devices, and cosmetics.”²⁵ Advertising in the FTC’s

¹⁸ Plaintiffs may seek redress from the Federal Trade Commission under the FTC Act, 15 U.S.C. §§ 41-58. Barton Beebe, *Trademark Law: An Open-Source Casebook*, Part IV, 2 (Jul. 20, 2017), <http://tmcasbook.org/wp-content/uploads/2017/08/BeebeTMLaw-4.0-Introduction.pdf>.

¹⁹ Lanham Act § 43(a)(1)(B) is codified at 15 U.S.C. § 1125(a)(1)(B).

²⁰ The state consumer deception statutes are also known as “little” or “baby” FTC Acts. See Beebe, *supra* note 18.

²¹ Denise E. DeLorme, Jisu Huh, Leonard N. Reid & Soontae An, *Dietary supplement advertising in the US: A review and research agenda*, 31 INT’L J. OF ADVERT. 547, 555 (2012).

²² See Beebe, *supra* note 18. See also Joshua M. Dalton & Jared A. Craft, *What You Should Know About NAD False Advertising Claims*, LAW360 (Jan. 4, 2013), <https://www.law360.com/articles/403099/what-you-should-know-about-nad-false-advertising-claims>.

²³ Note that the FDA and FTC are agencies of different stature. Unlike the FTC, the FDA is not an independent entity of the U.S. government. The FDA is nestled under the Department of Health and Human Services and funded by the Department of Agriculture.

²⁴ *Advertising Dietary Supplements*, CONSUMER HEALTHCARE PRODUCTS ASSOCIATION, http://www.chpa.org/DS_Advertising.aspx (last visited Mar. 23, 2017).

²⁵ REBECCA TUSHNET, *ADVERTISING AND MARKETING LAW* 1289 (3rd ed. 2014).

domain includes print and broadcast ads, infomercials, catalogs, and similar direct marketing materials; labeling refers to the information panels on product itself, such as the nutritional content and manufacturer address.²⁶

There is an enormous disparity between what the law permits and what the agencies enforce. Dietary supplements have posed a unique challenge to the joint FTC-FDA working relationship. Neither food nor drug, dietary supplements occupied a “liminal” regulatory category for much of the 20th century.²⁷ By the 1990s, however, Congress overrode attempts by the FDA to regulate supplements more extensively. The resulting legislation paved the way for the modern explosion of supplement products on the American market.²⁸

1. FTC Regulation of Supplement Advertising

The FTC is the federal consumer protection agency charged with safeguarding consumers against “unfair and deceptive trade practices,” under the authority granted to it in Section 5(a) of the Federal Trade Commission Act. It uses two investigative methods to challenge advertising it finds to be false: either compelling information from a potential defendant (for example, in the form of a subpoena), or requesting voluntary cooperation (in the form of an access letter). Notably, consumers do not enjoy the same authority in compelling disclosure of a corporate advertiser’s studies.

The FTC has articulated its own standard for actionable false advertising. The 1972 *Pfizer* doctrine²⁹ is an unsubstantiated theory of liability: no dissemination (of an ad claim) without prior substantiation. For an advertisement to be substantiated, the advertiser must have had a “reasonable basis” for its advertising claims *before* they are disseminated. For health or safety claims, which include representations made in connection with dietary supplements, the Commission has typically required a relatively high level of substantiation. In such cases, the “reasonable basis” must be “competent and reliable scientific evidence,” typically defined as “tests, analyses, research, studies, or other evidence based upon the expertise of

²⁶ U.S. FOOD & DRUG ADMIN. GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE, (revised Jan. 2013), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>.

²⁷ Mark Nichter & J.J. Thompson, *For my wellness, not just my illness: North Americans’ use of dietary supplements*, 30 CULTURE, MED. & PSYCHIATRY 175, 176 (2006). Unlike drugs, supplements can be readily purchased without a prescription in a wide variety of brick-and-mortar stores and online.

²⁸ 15 U.S.C. § 45 (2012).

²⁹ *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

professionals in the relevant area, that has 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.”³⁰ The FTC reaffirmed this standard in its Policy Statement Regarding Advertising Substantiation, and there are numerous representative cases applying the doctrine.³¹

2. FDA Regulation of Supplement Labeling

Unlike drugs, dietary supplements do not need FDA approval before being legally marketed in the United States. Under the Dietary Supplement Health and Education Act (“DSHEA”) of 1994,³² the FDA’s role in regulating the dietary supplement industry is constrained. Under DSHEA, a supplement company is responsible for determining that its products are safe and that any representations made are substantiated by adequate evidence of their truthfulness. A company does not have to provide the FDA with the evidence it relies on to substantiate safety and effectiveness unless specifically requested. Instead, the FDA has relied on a disclosure theory of consumer protection, requiring firms to identify the product as a dietary supplement and include a “Supplement Facts” panel that identifies each ingredient contained in the product.³³

C. The Lanham Act

Congress enacted the Lanham Act (codified at 15 U.S.C. §§ 1051-1127 (2012)) in 1946. It serves both as the federal trademark law and as a primary source of truth-in-advertising regulation. Section 43(a) of the Lanham Act provides that “any person who believes that he or she is or is likely to be damaged” by a false or misleading description or representation of fact may sue.³⁴ The Trademark Revision

³⁰ Lesley Fair, *Federal Trade Commission Advertising Enforcement*, FED. TRADE COMM’N (revised Mar. 1, 2008), <https://www.ftc.gov/sites/default/files/attachments/training-materials/enforcement.pdf>; *see, e.g.*, Brake Guard Products, Inc., 125 F.T.C. 138 (1998); ABS Tech Sciences, Inc., 126 F.T.C. 229 (1998).

³¹ *See, e.g.*, Removatron International Corp., 111 F.T.C. 206 (1988), *aff’d* 884 F.2d 1489 (1st Cir. 1989) (“adequate and well-controlled . . . clinical testing” is required to substantiate claims for hair removal product); Schering Corp., 118 F.T.C. 1030 (1994) (consent order) (tests and studies relied upon as “reasonable basis” must employ appropriate methodology and address specific claims made in the advertisement).

³² Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified in scattered sections of 21 U.S.C.).

³³ *Questions and Answers on Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm480069.html> (last updated Nov. 29, 2017).

³⁴ In its current form, section 43(a)(1)(B) states: (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name,

Act of 1988 substantially broadened the scope of section 43(a) to cover a company's false representations about itself and others.³⁵

Section 43(a) is the core legal protection for those injured by false advertising. The Supreme Court has interpreted standing under section 43(a) to be limited to business competitors; consumers are excluded from filing suits under the Lanham Act. In *Lexmark International, Inc. v. Static Components, Inc.*, the Supreme Court explained that standing to sue for false advertising under the Lanham Act requires pleading "injury to a commercial interest in sales or business reputation," and that injury must be "proximately caused by the defendant's misrepresentations."³⁶ The injury cognized by *Lexmark* is "unfair competition" through false or misleading advertising, rather than consumer deception or confusion. Accordingly, consumers' interests do not fall within the "zone of interests" protected by section 43(a)(1)(B).³⁷ As a result, plaintiffs in these lawsuits are typically commercial competitors of the alleged false advertiser.

Since remedy under the Lanham Act is unavailable to non-competitors, consumers often rely on state consumer protection statutes to bring cases against advertisers. Since these state statutes effectively police the same mischief, federal common law remains instructive in understanding the state law cause of actions.³⁸

Section 43(a)(1)(B) establishes liability for two modes of advertising: advertising that is false and advertising that is misleading. Actionable representations include statements made about one's own goods or services, as well as the commercial disparagement of others. These two categories of advertising, as well as the specific violations that they encompass, are next considered.

symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—. . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act. 15 U.S.C. § 1125(a)(1)(B) (2018).

³⁵ See Beebe, *supra* note 18, at Part IV, 2.

³⁶ 134 S. Ct. 1377, 1395 (2014).

³⁷ *Id.* at 1389; see also J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27.30 (5th ed. 2017).

³⁸ See *Brown v. GNC Corp.* (In re GNC Corp.), 789 F.3d 505, 514 (4th Cir. 2015) (noting that, although consumers cannot invoke the protections of the Lanham Act, the "considerable body of federal common law construing the Act is instructive in construing the state laws at issue here").

1. Two Modes of False Advertising

Courts are tasked with determining whether representations are either false or misleading. Both incur liability under section 43(a), but there are important doctrinal and pleading distinctions. The analysis begins with five basic elements: (i) whether the alleged misrepresentation is false or misleading, as opposed to non-actionable puffery,³⁹ (ii) whether a plaintiff can demonstrate actual deception or capacity for deception as a result of the falsehood, (iii) whether the falsehood or misleading information is material to a consumer’s decision to buy,⁴⁰ (iv) whether a plaintiff was harmed, either by direct diversion of its sales or by a lessening of the goodwill associated with its products, and (v) whether the falsehood or deception occurs in interstate commerce.⁴¹ These elements are conjunctive, and a plaintiff must meet all five to trigger liability.

i. Literal Falsity

Literally false representations communicate one unambiguous message, either verbally or visually, that is untrue or unsupported. These representations violate the Lanham Act without proof of consumer deception; instead, courts presume that the buying public has received the false message.⁴² Consequently, plaintiffs in these

³⁹ Puffery is a safe harbor for advertisers who proffer exaggerated and unsupported (or, perhaps, unsupportable) claims. It is a non-actionable carve-out from the false advertising provisions of the Lanham Act, since the statements are typically so exaggerated that no reasonable consumer could be deemed to rely on them. To fall out of the test for false advertising, statements of puffery are not considered to be statements of fact; consequently, a plaintiff would fail to meet the first element of the test. Courts have different definitions of puffery. In *Time Warner Cable, Inc. v. DIRECTV, Inc.*, the Second Circuit described one party’s internet ads as “inaccurate descriptions” of the television service, but “so grossly distorted and exaggerated that no reasonable buyer would take them to be accurate depictions.” 497 F.3d 144, 159 (2d Cir. 2007). In *United Industries Corp. v. Clorox Co.*, “[p]uffery is ‘exaggerated advertising, blustering, and boasting upon which no reasonable buyer would rely and is not actionable under § 43(a).’” 140 F.3d 1175, 1180 (8th Cir.1998) (quoting *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1145 (9th Cir. 1997)). In other iterations, the puffery doctrine has protected purveyors of “The Best Beer in America,” *In re Bos. Beer Co.*, 198 F.3d 1370 (Fed. Cir. 1999), “The Most Advanced Home Gaming System in the Universe,” *Atari Corp. v. 3D0 Co.*, No. C 94-20298 RMW (EAI), 1994 U.S. Dist. LEXIS 8677 (N.D. Cal. May 16, 1994), and “Better Ingredients. Better Pizza,” *Pizza Hut, Inc. v. Papa John’s Int’l, Inc.*, 227 F.3d 489 (5th Cir. 2005).

⁴⁰ Under *National Basketball Ass’n v. Motorola, Inc.*, the test for materiality is whether the statement “misrepresent[s] an inherent quality or characteristic of a product.” 105 F.3d 841, 855 (2d Cir. 1997).

⁴¹ *Schick Mfg., Inc. v. Gillette Co.*, 372 F.Supp.2d 273, 276 (D. Conn. 2005).

⁴² See *Tushnet, supra* note 25, at 259; see also *Coca-Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982) (“[T]he Court may grant relief without reference to the

cases can avoid the time and expense of preparing consumer surveys regarding the ad's message. The burden of proof in falsity cases is on the plaintiff, and falsity is assessed on the basis of scientific testing or related types of extrinsic evidence.⁴³

A classic example of a literally false representation comes from *Coca-Cola*.⁴⁴ In 1982, Tropicana featured athlete Bruce Jenner in a television commercial for orange juice, squeezing juice out of an orange directly into a Tropicana carton while saying, "[i]t's pure, pasteurized juice as it comes from the orange." In fact, the juice was heated and, in some cases, frozen before packaging. Further, the juice did not in fact come "pasteurized" straight from the orange. The Second Circuit granted preliminary injunctive relief against the "blatantly false" statement. The plaintiff did not have to make a showing that the advertisement would mislead the consuming public.

ii. Literal Falsity by Necessary Implication

A court may evaluate an advertisement for falsity even if the representation is implied by context, rather than stated directly. This category of false advertising is referred to as false by necessary implication. Actionable advertisements of this type convey one unambiguous message. While the message is conveyed implicitly, the meaning of the message is clear and unequivocal. Ultimately, if the impression left on the viewer conflicts with reality, it is effectively treated as if that false impression was directly stated.

The Second Circuit embraced the false-by-necessary-implication doctrine for the first time in *Time Warner Cable, Inc. v. DIRECTV, Inc.*⁴⁵—a case which provides an excellent illustration of this type of actionable falsity. A series of DIRECTV commercials featured celebrities touting the merits of the satellite service provider's 1080i high definition (HD) transmission. A commercial from the "Source Matters" campaign concluded with William Shatner stating that "settling for cable would be illogical." This statement was made in the context of surrounding text ("amazing picture quality of [...] DIRECTV HD") and images (a very clear DIRECTV picture and a far inferior picture from an anonymous second provider, though cable was

advertisement's [actual] impact on the buying public."), *abrogated on other grounds* by Fed. R. Civ. P. 52(a)(6), *as recognized* in *Johnson & Johnson v. GAC Int'l, Inc.*, 862 F.2d 975, 979 (2d Cir. 1988).

⁴³ Consumer surveys are not valid supporting evidence in a falsity case, discussed further in Section I.B.2. The GNC case fits neatly within the question of literally false advertising, as the TriFlex ads and packaging presented explicit, unambiguous statements, and no evidence of consumer deception was presented. *See generally GNC*, 789 F.3d 505.

⁴⁴ *See generally Coca-Cola*, 690 F.2d 312.

⁴⁵ *See Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007).

obviously targeted). Without extrinsic evidence, the district court determined that Mr. Shatner’s assertion (“settling for cable would be illogical”) “could only be understood as making the literally false claim that DIRECTV HD is superior to cable HD in picture quality.”⁴⁶ In reality, however, DIRECTV and cable HD’s picture quality were equivalent. The Second Circuit upheld this ruling for Time Warner, concluding that the impression left on the viewer conflicted with reality.⁴⁷

2. *Misleading Advertising*

The second category of actionable false advertising claims are, while not literally false, deemed misleading to consumers. Such ads contain representations of fact about a product or service that are ambiguous or tend to deceive consumers. The statements may be literally true, and yet have the tendency to mislead. The language of section 43(a) deems merely misleading representations equally as objectionable as those that are literally false, explicitly rendering unlawful a “false or misleading description of fact, or false or misleading representation of fact.”

There are a number of important differences between false and misleading advertising, even though both types of representations violate section 43(a). Although the categories are doctrinally distinct, the evidentiary differences are more significant in practice. Literal falsehoods—those that are false on their face—are actionable without proof of consumer deception, as in the *Coca-Cola* and *DIRECTV* cases previously considered. In a case of misleading advertising, plaintiffs must present extrinsic evidence to establish consumers’ perception of the implied falsehood.⁴⁸ Such proof typically includes consumer surveys, direct consumer testimony, or consumer comments received in the ordinary course of business.

In *Vidal Sassoon, Inc. v. Bristol-Myers Co.*,⁴⁹ the Second Circuit addressed literally false as well as misleading claims. This case provides a clear example of the difference between literal falsity and misleadingness. In a television commercial, a spokesperson states that “in shampoo tests with over 900 women, Body on Tap got higher ratings than Prell for body. Higher than Flex for conditioning. Higher than Sassoon for strong, healthy looking hair.” The literally false claim is that the tests involved over 900 women; in fact, only two-thirds of testers were actually adult

⁴⁶ *Id.* at 152.

⁴⁷ *See id.* at 158. Note that the Second Circuit ruled on numerous commercials and Internet ads in this case, and some of the district court’s opinion was reversed.

⁴⁸ Where an advertisement is literally true but misleading, the advertisement “has left an impression on the listener that conflicts with reality[;]” with proof of consumer confusion, the representations are considered misleading. *See id.* at 153.

⁴⁹ 661 F.2d 272 (2d Cir. 1981). *See also* 2-7 Gilson on Trademarks § 7.02 (2017).

women. The claims regarding higher satisfaction were deemed misleading based on a consumer survey assessing the message of the ad. Consumers surveyed about the commercial said that they thought each tester had tried at least two of the named products in order to compare their quality. Since this was not the actual testing procedure, the court held that consumers were deceived by the ad's claims, and that the claims were actionable as misleading.

D. State Consumer Protection Statutes

Every state has a consumer protection law that prohibits deceptive practices.⁵⁰ Many of these statutes take the form of a "little" FTC Act, incorporating the language of Section 5 of the statute for which they are named.⁵¹ These statutes provide the basic protections for consumers engaging in thousands of transactions across the United States, prohibiting "unfair methods of competition or unfair deceptive trade practices" as well as "all forms of fraudulent, deceptive, and unfair acts." While many statutes track the federal guideline, they nevertheless may vary in form and strength from state to state.⁵² State attorneys general and consumers may bring suits pursuant to these acts.

As mentioned *infra*, the state consumer deception statutes at issue in *GNC* were interpreted in accordance with the great body of federal common law surrounding false advertising and the Lanham Act. There remains a significant difference in the standing requirements: in a Lanham Act lawsuit, the plaintiff is typically a competitor; in putative consumer class action lawsuits, representatives must allege that they were personally deceived to have standing.⁵³ Despite these differences in standing, the laws have been interpreted relatively congruously. The mischief to be corrected, in both cases, is false advertising and unfair competition. However, there is no requirement that each state's consumer deception law track the Lanham Act or federal case law.

⁵⁰ CAROLYN L. CARTER, CONSUMER PROTECTION IN THE STATES: A 50-STATE REPORT ON UDAP STATUTES, 5 (Feb. 2009), http://www.nclc.org/images/pdf/udap/report_50_states.pdf.

⁵¹ 2-7 Gilson on Trademarks § 7.02 (2017).

⁵² CARTER, *supra* note 50, at 5.

⁵³ See Kenneth A. Plevan & Angela Colt, *Consumer Surveys: Certification*, BLOOMBERG BNA PROD. SAFETY & LIAB. REP. 4 (Sept. 12, 2016).

II

THE GNC CASE AND THE GLUCOSAMINE-CHONDROITIN PROBLEM

A. Factual Background

General Nutrition Corporation (GNC), a national nutritional products retailer, has manufactured and sold a line of joint health supplements⁵⁴ for years. These products, which list glucosamine, chondroitin, and various other compounds as the primary active ingredients, are marketed collectively under the “TriFlex” brand. Although the products differ slightly in their total combination of ingredients, they advertise similar claims⁵⁵; essentially, the TriFlex brand improves the health,

⁵⁴ See Consolidated Amended Complaint at ¶ 26-35, In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014) ECF No.20. For reference, the four GNC products at issue, according to the Plaintiffs, were TriFlex, TriFlex Sport, TriFlex Fast-Acting, and TriFlex Complete Vitapak. The six Rite Aid products at issue are Rite Aid Glucosamine/Chondroitin, Rite Aid Natural Glucosamine/Chondroitin, Rite Aid Glucosamine Chondroitin Advanced Complex, Rite Aid Glucosamine Chondroitin, Triple Strength + MSM, Rite Aid Glucosamine Chondroitin + MSM, and Rite Aid Glucosamine Chondroitin Advanced Complex with HA. The court does not distinguish between the GNC and Rite Aid brands, nor does it distinguish between the individual products at issue.

⁵⁵ See Consolidated Amended Complaint at ¶ 26-37, In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. Jun. 20, 2014) ECF No.20; *see also* In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014). The claims on the labels, as presented by Plaintiffs and GNC, are as follows. The GNC TriFlex Dietary Supplement label contains “Maximum strength now with hyaluronic acid” and “Promotes joint mobility and flexibility.” The GNC TriFlex Sport label contains: “Protects joints from wear and tear of exercise,” “Maximum strength joint comfort for active individuals,” and “Clinical strength for daily long-term use.” TriFlex Fast-Acting label contains: “Now with a joint cushioning blend including hyaluronic acid and vitamin C,” “Maximum strength, fast-acting support – works in days,” and “Clinical strength for daily long-term use.” Lastly, the TriFlex Complete Vitapak label contains: “Maximum strength, fast-acting joint comfort—works in days,” “Rebuilds cartilage and lubricates joints,” and “Supports natural anti-inflammatory response.” The Rite Aid Glucosamine/Chondroitin Dietary Supplement label contains “helps rebuild cartilage and lubricate joints.” Each label contains an FDA disclaimer: “This statement has” or “these statements have” “not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” It appears that the only product to include a “here’s proof” claim is TriFlex Fast-Acting. There is a reference to a scientific study that supports GNC’s representations: “Clinically studied doses of glucosamine and chondroitin combined with MSM and a proprietary herbal blend, which is shown to improve joint comfort and function. In a 12-week multi-center, randomized, double blind, placebo controlled study of 60 adults, subjects taking 250 mg/day of the GNC TriFlex™ Fast-Acting Blend showed statistically significant

comfort, and function of joints. The label for one product, TriFlex Fast-Acting, included a “[c]linically studied” establishment claim: a “12-week multi-center, randomized, double-blind, placebo controlled study of 60 adults [. . .] taking 250 mg/day of the GNC TriFlex Fast-Acting Blend” proved that the product was “shown to improve joint comfort and function,” in addition to promising 20% improvement in joint function and 25-30% improvement in joint flexibility.⁵⁶ GNC produced a similar line of products for Rite Aid, which claimed to “promote joint health” and “help[. . .] rebuild cartilage and lubricate joints.” In compliance with FDA guidelines, all of the TriFlex and Rite Aid products included the disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

Beginning in March 2013, class action lawsuits against GNC and Rite Aid popped up across the United States. Plaintiffs in California, Illinois, Florida, New York, New Jersey, Pennsylvania, and Ohio alleged violations of an array of state consumer protection, deceptive practices and/or express warranty statutes in regard to the glucosamine-chondroitin products.⁵⁷ In December 2013, the pending lawsuits were consolidated by the Judicial Panel on Multidistrict Litigation and, pursuant to 28 U.S.C. § 1407, transferred to the U.S. District Court for the District of Maryland.⁵⁸

improvements in measures of joint function and joint flexibility within 30 days compared to subjects on placebo.”

⁵⁶ See Defendant’s Memorandum in Support of its Motion to Dismiss Class Action Complaint, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014) ECF No.38; see also Rebecca Tushnet, *Fourth Circuit Destroys Literal Falsity*, REBECCA TUSHNET’S 43(B)LOG (June 30, 2015), <http://tushnet.blogspot.com/2015/06/fourth-circuit-destroys-literal-falsity.html>. The GNC study was not published or otherwise publicly available, and there is currently no law requiring such disclosure.

⁵⁷ Some of the state consumer protection laws at issue include the California False Advertising Law, § 17500, *et seq.* (“FAL”), the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.* (“UCL”), the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, *et seq.* (“FDUTPA”), Illinois Consumer Fraud and Deceptive Business Practice Act, 815 Ill. Comp. Stat. 502/1, *et seq.* (“ICFA”), the New York Consumer Protection From Deceptive Acts and Practices Law, N.Y. Gen. Bus. Law § 349, *et seq.* (“NYGBL”), Ohio Rev. Code Ann. § 1302.26, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.* (“NJCFA”), Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§ 201-1, *et seq.* (“PUTPCPL”).

⁵⁸ *In re GNC Corp. TriFlex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-120, 2014 U.S. Dist. LEXIS 84184 at *1 (D. Md. June 20, 2014).

B. The Complaint

In the Consolidated Amended Complaint, Plaintiffs alleged that the “*overwhelming weight* of high quality, credible and reliable studies demonstrate that glucosamine and chondroitin...do not provide joint health benefits” (emphasis added).⁵⁹ They stated that the inefficacy of these supplements was “generally recognize[ed]” by the scientific community.⁶⁰ In support of their allegations, Plaintiffs cited to thirteen studies released between 2004 and 2013.⁶¹ In the studies, researchers concluded that (1) glucosamine and chondroitin did not reduce symptoms for osteoarthritic users or chronic joint pain sufferers (who, Plaintiffs alleged, were an appropriate proxy for non-arthritic users), and (2) MSM, another compound found in the TriFlex products, did not provide pain or joint symptom relief for osteoarthritic consumers. Notably, the Plaintiffs did not provide any testing of GNC’s particular products or combination of ingredients. Instead, they relied on the “vast weight of competent and reliable scientific evidence” (i.e., the cited studies) to infer that the “ingredients in GNC’s TriFlex Products do not work as represented” and that the “representations [were] false.”⁶²

⁵⁹ Consolidated Amended Complaint at ¶ 38, In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014) ECF No.20.

⁶⁰ *Id.*

⁶¹ The studies can be found in the Consolidated Amended Complaint at ¶¶ 39-48, In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014) ECF No.20.

⁶² Consolidated Amended Complaint at ¶ 32, In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014) ECF No.20.

Defendants GNC and Rite Aid filed a Motion to Dismiss,⁶³ arguing that the studies did not test the products (or specific combination of ingredients) at issue,⁶⁴ that no representations were made with regard to improving osteoarthritis symptoms, and that osteoarthritis patients were not an appropriate proxy for non-arthritic users, among other deficiencies. Regarding the osteoarthritis issue, Defendants specifically cited to the FDA disclaimer on all of the labels, which state that the products are “not intended to diagnose, treat, cure, or prevent any disease.”⁶⁵

C. *Decision Granting Motion to Dismiss*

In spite of Plaintiffs’ allegations, District Court Judge J. Frederick Motz dismissed the Complaint with leave to amend. He found that Plaintiffs’ allegations regarding the “vast weight of scientific evidence”—in light of GNC’s study to the contrary—could not support the single conclusion that the claims are false.⁶⁶ Under

⁶³ Since this case is considered procedurally significant, it is important to say a word about the legal standard on a motion to dismiss. A Rule 12(b)(6) motion to dismiss challenges the legal sufficiency of a complaint. Fed. R. Civ. P. 12(b)(6); *see also* Presley v. City of Charlottesville, 464 F.3d 480, 483 (4th Cir. 2006). The court has drawn a line between the “mere possibility” and “plausibility” that a defendant has acted unlawfully; plaintiff must meet the latter to survive a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The issue is whether plaintiff has stated enough factual matter, rising above the speculative level, to warrant a claim for relief. To defeat a 12(b)(6) motion, a complaint’s factual allegations must be sufficient to “raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must contain “sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face.” *Ashcroft*, 556 U.S. at 678. The “mere possibility of misconduct” is insufficient to avoid dismissal. *Id.* at 679. Likewise, “[l]abels and conclusions” and “naked assertion devoid of further factual enhancement” will fail to show that plaintiff is entitled to relief. *Id.* at 678. Ultimately, Plaintiffs’ bare assertions were insufficient to establish that the representations are false.

⁶⁴ Notably, similar and even predicate cases challenging the efficacy of glucosamine-chondroitin had been dismissed on similar grounds. *See, e.g.,* *Toback v. GNC Holdings, Inc.*, No. 13-80526, 2013 U.S. Dist. LEXIS 131135, at *16 (S.D. Fla. Sept. 13, 2013) (“Plaintiff’s allegations regarding the inefficacy of glucosamine and chondroitin simply fail to address the efficacy of the TriFlex Vitapak’s multifarious composition in promoting joint health . . .”); *Eckler v. Wal-Mart Stores, Inc.*, No. 12-727, 2012 WL 5382218, at *6 (S.D. Cal. 2012) (plaintiff’s studies did not assess the “overall formulation that’s behind the representations at issue,” and so “the Court would be left with no facts from which to infer that [defendant] is liable for false advertising.”).

⁶⁵ Defendants’ Memorandum in Support of their Motion to Dismiss Consolidated Amended Complaint at 5, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II)*, No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No.25.

⁶⁶ The Consolidated Amended Complaint repeatedly described the TriFlex advertising as “false, misleading, and reasonably likely to deceive the public.” Consolidated Amended Complaint, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II)*, No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No.20. However, to plead that an

the *Twombly/Iqbal* plausibility standard, there was a “fatal flaw” in the allegations of the CAC: it did not allege that “experts in the field” were prepared to testify that, on the basis of the existing scientific evidence, any reasonable expert would conclude from the cited studies that glucosamine and chondroitin are ineffective in non-arthritic consumers.⁶⁷ The “mere existence of a ‘battle of the experts’” was not proof of falsity, but was rather to be “expected.”⁶⁸ The following excerpt from Judge Motz’s Memorandum Decision provides an important glimpse into the Court’s reasoning:

Disagreements between experts, even under the ‘reasonable degree of scientific certainty’ standard, are to be expected. In my judgment, however, the fact that one set of experts may disagree with the opinions expressed by other qualified experts does not *ipso facto* establish any violation of the applicable consumer protection laws. If there are *experts who support* what defendants say in their advertisements, the advertisements are not false and misleading . . . unless the clinical trial relied upon by defendants was itself false and/or deceptive.⁶⁹

In this passage, the Court referenced the “reasonable basis” standard that marketers must adhere to when preparing advertising claims (discussed later in Section III, *supra*). Stated briefly, if scientific evidence points in different directions, the reasonable basis standard will allow for inconsistent messaging. In a footnote to this excerpt, the Court addressed whether this is a burden of proof issue and concluded that it is not, based on the nature of the advertising claims in the case.⁷⁰ The Court contrasted the example to a product liability case, in which plaintiff must establish that a product is defective. There, Judge Motz said, it would be “entirely appropriate for a jury to decide the defect issue” based on expert testimony that, to a reasonable degree of scientific certainty, a product is defective.⁷¹ This distinction

advertisement is misleading, the allegation must be supported by evidence of consumer confusion. Since Plaintiffs did not provide any evidence of consumer confusion, the Court appropriately limited its analysis to a claim of literal falsity.

⁶⁷ Memorandum at 7, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 38.

⁶⁸ *Id.*

⁶⁹ *Id.* (emphasis added).

⁷⁰ *Id.* at n.2.

⁷¹ *See id.*; *see also* Memorandum at 4 n.4, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 51. The significance of this carve-out for advertising cases is discussed further in Part III, *supra*.

is enormously significant for procedural and substantive reasons, reserving for juries their fact-finder role beyond false advertising cases.

By granting the Plaintiffs leave to amend their complaint, Judge Motz offered Plaintiffs an opportunity to revive their claim for literal falsity. He specifically instructed that Plaintiffs must plead that the clinical trial relied on by GNC (1) did not exist at all, (2) exists but did not support any of GNC's representations about TriFlex, or (3) exists and supports the assertions on TriFlex Fast-Acting's bottle, but was not conducted in an appropriately scientific manner.⁷² Only under such a pleading could the Court infer, on the face of the complaint, that the products are ineffective as to non-arthritic users. Otherwise, if at least one expert supported what GNC and Rite Aid said in their ads, the advertisements could not be false.⁷³ Plaintiffs could only file an amended complaint if they could do so in accordance with Fed. R. Civ. P. 11, which requires sufficient due diligence to avoid sanctions.⁷⁴ Absent such a pleading, Plaintiffs' claim of falsity would not be facially plausible.

Six days after the Motion to Dismiss was granted, GNC's counsel sent plaintiffs a letter contending that "qualified experts" support the TriFlex and Rite Aid products' claims.⁷⁵ Plaintiffs rejected the opportunity to amend, and instead filed a motion for reconsideration on the basis of the existing complaint.⁷⁶ Judge Motz

⁷² Memorandum at 7, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 38. An obvious issue, then, becomes whether Plaintiffs could so allege without appropriate discovery. Judge Motz addressed this question in his second Memorandum Decision, denying the motion for reconsideration: "[I]f plaintiffs can specify discovery requests that would aid them in alleging the above facts, they should file a motion setting forth the discovery that they request. Presumably, however, if plaintiffs' experts are of the view that no reasonable expert would reach the conclusion reached by the expert upon whom defendant relies, they are already, by virtue of their asserted expertise, in possession of the relevant factual information." Memorandum at 5, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 51.

⁷³ Memorandum at 4, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 51.

⁷⁴ Memorandum at 8, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 38.

⁷⁵ Exhibit 1 to Plaintiffs' Memorandum of Law in Support of Motion to Correct Mistake of Law Pursuant to F.R.C.P. 60, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 44-1.

⁷⁶ *See* Plaintiffs' Motion to Correct Mistake of Law Pursuant to F.R.C.P. Rule 60, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 43; Plaintiffs' Memorandum of Law in Support of Motion to Correct Mistake of Law Pursuant to F.R.C.P. 60, *In re GNC Corp. Triflex Prods.*

denied the motion and reiterated the rationale presented in the Memorandum Decision. Regarding policy, he added one additional reason to his earlier holding: It would be unfair to consumers who wish to gamble on glucosamine and chondroitin if lay juries could effectively ban the sale (or artificially raise its pricing) simply because evidence of their effectiveness is inconclusive.⁷⁷ Plaintiffs appealed to the Fourth Circuit.

D. Plaintiffs’ Appeal

After oral argument before a three-judge panel, the Fourth Circuit unanimously affirmed the District Court’s decision in favor of GNC.⁷⁸ The Fourth Circuit inexplicably held that “plaintiffs must allege that all reasonable experts in the field agree that the representations are false.”⁷⁹ In other words, a single expert in disagreement bars a statement from being literally false. In the Court’s words:

[I]n order to state a false advertising claim on a theory that representations have been proven false, plaintiffs must allege that all reasonable experts in the field agree that the representations are false. If plaintiffs cannot do so because the scientific evidence is equivocal, they have failed to plead that the representations based on this disputed scientific evidence are false.⁸⁰

Under the Fourth Circuit’s test, “the question of falsity hinges on the existence (or not) of scientific consensus.”⁸¹ Scientific experts may—and often do—disagree

Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 44.

⁷⁷ Memorandum at 4, In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 51; *see also* Brown v. GNC Corp. (In re GNC Corp.), 789 F.3d 505, 512 (4th Cir. 2015).

⁷⁸ There are some important differences between the District Court’s Memorandum Decision and the Fourth Circuit’s Order. First, the Court included alternative grounds for affirming the District Court, noting that Plaintiffs “failed to allege that all of the purportedly active ingredients in each product are ineffective at promoting joint comfort, health, and flexibility.” Second, the Fourth Circuit disagreed with Judge Motz that specific formulations of the GNC and Rite Aid products needed to be tested to assess the truth of the labels’ representations; instead, at the motion to dismiss stage, the scientific studies in the CAC could render the claim facially plausible. Lastly, the court found that the factual dispute regarding the effectiveness of glucosamine-chondroitin for non-arthritic users was not appropriate for resolution on a motion to dismiss. The Fourth Circuit declined to adopt the latter grounds for affirming the District Court’s Order. *See* Brown v. GNC Corp. (In re GNC Corp.), 789 F.3d 505 (4th Cir. 2015).

⁷⁹ *See* GNC, 789 F.3d at 516.

⁸⁰ *Id.*

⁸¹ *Id.* at 514 n.7.

about the truthfulness of a statement, but equivocalness is not falsity.⁸² Regarding Plaintiffs' argument that a "battle of the experts" could not be resolved on the pleadings, the Court retorted:

When litigants concede that some reasonable and duly qualified scientific experts agree with a scientific proposition, they cannot also argue that the proposition is 'literally false.' Either the experts supporting the Companies are unreasonable and unqualified (in which case, there is no real battle of the experts to begin with) or they reflect a reasonable difference of scientific opinion (in which case the challenged representations cannot be said to be literally false).⁸³

Indeed, by characterizing the dispute as a "battle of the experts," the Court held that Plaintiffs (inadvertently) conceded that "a reasonable difference of scientific opinion exists as to whether glucosamine and chondroitin can provide the advertised joint health benefits."⁸⁴ The Fourth Circuit also responded to Plaintiffs' concern that manufacturers might hide behind so-called experts in proffering dubious marketing claims, relying on the Federal Rules of Evidence to ensure relevant and reliable scientific testimony.⁸⁵

III LEGAL AND POLICY CONSIDERATIONS

A. Law Professors' Amicus Brief, with Rebuttal

After the Circuit Court handed down its *GNC* decision, sixteen prominent law professors submitted an Amicus Brief for the Plaintiffs in support of rehearing.⁸⁶ The Amici describe their interest in the case as "promoting truth in advertising, which protects consumers and promotes fair competition."⁸⁷ In the eight-page brief, the law professors⁸⁸ supported Plaintiffs' petition for rehearing and criticized the Fourth

⁸² *See generally id.* at 515-16.

⁸³ *Id.* at 515.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *See* Brief of Law Professors as Amici Curiae in Support of Plaintiffs-Appellants' Petition for Rehearing and for Rehearing En Banc, and in the Alternative, for Modification of Opinion and Judgment, *Brown v. GNC Corp. (In re GNC Corp.)*, 789 F.3d 505 (4th Cir. 2015) (No. 14-1724) ECF No.45.

⁸⁷ *Id.* at 1.

⁸⁸ Professor Rebecca Tushnet, whose advertising textbook is extensively cited in this Note, appears to have been the lead academic on the Amicus Brief. It is co-signed with Brian Wolfman, then a Visiting Professor at Stanford Law School. Other Amici include Mark Lemley of Stanford Law School, Jessica Litman of the University of Michigan Law School, and Barton Beebe of New

Circuit’s decision. The Amici argued that the Fourth Circuit “erred when it disregarded binding precedent” to produce a ruling with adverse procedural and substantive consequences. They further argued that questions of falsity cannot be resolved on the pleadings; instead, the fact finder (presumably a jury) should evaluate competing experts and pools of scientific evidence to determine the truth of a claim.

The brief is problematic in numerous respects. Specifically, the Amici (i) misstate the legal standards in falsity cases, (ii) misstate the nature of “binding” precedent, (iii) mischaracterize the nature of scientific evidence, and (iv) fail to appropriately consider the impact of the suggested alternative on jury instructions. This Note argues that the Amicus Brief, as well as the alternative outcome that Amici support, is a less persuasive answer to the truth-in-advertising dilemma presented by the *GNC* case. Instead, the Amici’s criticism offers insight into the utility and *strengths* of the Fourth Circuit’s logic. This section presents the Amici’s arguments and responds to points addressed in their brief.

1. Inaccurate Legal Standards

The Amicus Brief begins with a “Summary of Argument” that describes the purported standard in literal falsity cases: “Literal falsity is about *how an advertisement is received by consumers*. The adjectives ‘literal,’ ‘explicit,’ and ‘implicit’ (and falsity ‘by necessary implication’) describe *consumer reaction* to a message, which is either *proved by evidence such as surveys* or presumed as a matter of law.”⁸⁹ The italicized portions of this excerpt are problematic and, pun intended, literally false. First, literal and explicit claims are not assessed on the basis of consumer perception; rather they are accepted as literal messages. Second, literal and explicit claims are evaluated based on underlying substantiation, such as scientific testing, regardless of the message received by consumers. These important doctrinal and evidentiary distinctions are reviewed in Section I and, briefly, below.

York University School of Law, who supervised this Note’s completion. Notably, Professor Eric Goldman of Santa Clara University School of Law is not a signatory to the Amicus Brief, although he co-authored the seminal textbook on advertising law, *Advertising & Marketing Law*, with Professor Tushnet.

⁸⁹ Brief of Law Professors as Amici Curiae in Support of Plaintiffs-Appellants’ Petition for Rehearing and for Rehearing En Banc, and in the Alternative, for Modification of Opinion and Judgment at 1-2, *Brown v. GNC Corp.* (In re *GNC Corp.*), 789 F.3d 505 (4th Cir. 2015) (No. 14-1724) ECF No.45. The brief is inexplicably wrought with references to consumer messaging in literal falsity cases. As Amici later state, “To determine if an ad makes a false claim, a court must determine what message consumers will perceive”

As mentioned in Part I, *infra*, two modes of advertising are liable under Section 43(a): advertising that is false, and advertising that is misleading. Within the umbrella of false advertising, courts have generally recognized two types of falsity: (i) advertising that is literally false (based on a clear and explicit misrepresentation of fact), and (ii) advertising that is false by necessary implication (based on a claim that, considered in context, necessarily and unambiguously implies a message). Neither case requires surveys or other proof of consumer deception. Amici's emphasis on "consumer reaction to a message" and "surveys" is misplaced, as both of those issues are irrelevant to a finding of literal falsity.

Amici then describe an example of a potentially misleading representation: "Vitamin B7 can remedy hair loss." Since implied messages can convey multiple messages to the buying public, evidence of consumer confusion is required to determine which message consumers are receiving. While a discussion of misleading advertising can be helpful for comparison purposes, it is not relevant in the *GNC* case. First, the TriFlex claims at issue are literal and explicit: for example, "promotes joint mobility and flexibility" and "protects joints from wear and tear of exercise." Second, there was no survey evidence of the messaging received by consumers, which would be required to sustain a cause of action for misleading representations.⁹⁰

There are subsequent discussions regarding advertising that is false by necessary implication.⁹¹ While actionable, this mode of deception is also irrelevant to the *GNC* case. The claims at issue on the TriFlex label are clear and explicit. Advertisements that are false by necessary implication do not involve an explicit statement of fact, but rather an unambiguous assumption that follows from a claim. Consider a comparison to the claims at issue in *DIRECTV v. Time Warner Cable*, discussed in Part I.C., *infra*. In that case, the court considered other words and

⁹⁰ Perhaps there is some suggestion that Plaintiffs' should have argued that the joint health claims were misleading, rather than literally false. The argument would appear to be that glucosamine-chondroitin is particularly attractive to osteoarthritis patients, who seek to alleviate the pain of their condition. Plaintiffs offered numerous studies that allegedly prove that glucosamine-chondroitin is not beneficial to osteoarthritis sufferers. On that basis, and with an allegation of consumer confusion, the claims could have been deemed misleading to a segment of consumers. However, a claim of misleading advertising would, too, seem to fail, as the District Court noted that "the TriFlex labels expressly disclaim any ability to 'diagnose, treat, cure, or prevent any disease.'" (citations omitted). *In re GNC Corp. TriFlex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 at *3-4 (D. Md. June 20, 2014).

⁹¹ Brief of Law Professors as Amici Curiae in Support of Plaintiffs-Appellants' Petition for Rehearing and for Rehearing En Banc, and in the Alternative, for Modification of Opinion and Judgment at 5, *Brown v. GNC Corp.* (In re GNC Corp.), 789 F.3d 505 (4th Cir. 2015) (No. 14-1724) ECF No.45.

images within the context of the statement that “settling for cable would be illogical;” the necessary implication was that settling for cable would be illogical because DIRECTV offers superior picture quality (it did not). The clear and explicit TriFlex claims simply do not fit into this category of consumer deception.

2. *Misstatement of Precedent*

The Amicus Brief continues with a citation to “binding precedent,” namely *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, which the Fourth Circuit courts allegedly “disregarded” in dismissing the *GNC* case. In the opening paragraph of the Amicus Brief’s “Argument,” Amici state: “This Court has repeatedly held that both inquiries involve questions of fact. *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434 (4th Cir. 1997) (“Whether an advertisement is literally false is an issue of fact.”).” This is both a mischaracterization of the holding as well as the case’s precedential value.

Amici appropriately classify *C.B. Fleet* as a literal falsity case.⁹² At issue were “improved design” and “comparative superiority” claims for SmithKline’s new model of a feminine hygiene product. The Amici presumably provide this quotation in support of the alternative outcome they propose: factual disputes, such as a battle of the experts, should be reserved for juries. However, this proposition is conceptually distinct from the “issue of fact” identified by the *C.B. Fleet* Court. In *C.B. Fleet*, the Fourth Circuit was reviewing the district court’s determinations of falsity on appeal; the quote provided by Amici stands for the proposition that district courts, in their fact-finding role, are given deference in reaching such conclusions.⁹³ Furthermore, there is a citation following the *C.B. Fleet* reference—omitted without acknowledgment in the Amicus Brief—to *L&F Prods. v. Procter & Gamble Co.*, 45 F.3d 709, 712 (2d Cir. 1995). That underlying authority from *L&F Products* states as follows: “The district court’s determination with respect to facial falsity is a finding of fact which we review for clear error.”⁹⁴ In both *C.B. Fleet* and *L&F*

⁹² *Id* at 2.

⁹³ In the discussion that follows that quote, the *C.B. Fleet Court* states: “Fleet challenges the district court’s determinations of no literal falsity on the grounds that the court imposed upon Fleet a wrong—overly stringent—‘burden of proof’ on the issue, and, relatedly, that both of the *ultimate fact findings* were clearly erroneous[;]” “[W]e think that whether an advertising claim implicitly, though not expressly, asserts that it is test-validated must be considered a question of fact whose resolution is subject to clearly erroneous review[;]” “Our standard of review of district court fact findings is greatly deferential under controlling authority[.]” (emphasis added). *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434-436 (4th Cir. 1997).

⁹⁴ *L&F Prods. v. Procter & Gamble Co.*, 45 F.3d 709, 712 (2d Cir. 1995).

Products, the “issue of fact” is raised with respect to the deference due to district courts, rather than juries’ roles in resolving factual disputes.

In fact, the definition of falsity in *C.B. Fleet* does not conflict with the determination made in *GNC*. However, there remains a crucial factual difference between the cases. As the *GNC* Court noted, plaintiffs were given leave to amend the Consolidated Amended Complaint to plead that GNC’s study (1) did not exist at all, (2) existed but did not support any of GNC’s representations about TriFlex, or (3) existed and supported the assertions on TriFlex Fast-Acting’s bottle, but was not conducted in an appropriately scientific manner. The Court specifically instructed that plaintiffs could not rely on the “vast weight of the evidence” to prove falsity. In *C.B. Fleet*, plaintiff met this burden, challenging the scientific reliability of SmithKline’s testing procedures. In *GNC*, by contrast, plaintiffs twice relied on the “weight of the evidence” without attacking GNC’s testing—even after a second bite at the apple.

Although the Amici state that the Fourth Circuit has “repeatedly held that [the falsity inquiry] involve[s] questions of fact,” only *C.B. Fleet* is offered as support. One might reasonably expect a string cite supporting such an assertion. While the Fourth Circuit cemented a new rule for the meaning of literal falsity in supplement cases, its definition is hardly inconsistent with “binding” and “disregarded” precedent. In fact, the issue presented in *GNC* was a matter of first impression before the Court. While Amici’s proposal is a permissible solution to the *GNC* question, it is neither required by precedent nor, as this Note argues, able to achieve a better outcome on policy grounds. The Fourth Circuit’s ruling is a novel but befitting solution to truth-in-advertising questions in the dietary supplement industry.

3. *The Nature of Scientific Evidence*

The most persuasive portion of the Amicus Brief comes in the form of a hypothetical regarding the medical cause of ulcers. Amici present the following scenario: In 1910, a doctor would have said that stress and diet caused stomach ulcers, and that bacteria did not. We now know that this is untrue; the bacterium *H. pylori*—not stress and diet—causes many stomach ulcers.⁹⁵ The Amici use this illustration to argue that, despite expert support for a claim, it may be false. The fear is that corporate defendants may insulate themselves from lawsuits by hiding behind

⁹⁵ Brief of Law Professors as Amici Curiae in Support of Plaintiffs-Appellants’ Petition for Rehearing and for Rehearing En Banc, and in the Alternative, for Modification of Opinion and Judgment at 3, *Brown v. GNC Corp.* (In re *GNC Corp.*), 789 F.3d 505 (4th Cir. 2015) (No. 14-1724) ECF No.45.

one unreliable study. This illustration lends support to Amici’s claim that experts are not infallible, and perhaps that juries serve as a valuable check on expert elitism.

Understood another way, the ulcer hypothesis could be marshaled in support of the Fourth Circuit’s ruling. Indeed, scientific knowledge is always a work in progress, and our understanding of medical issues is constantly evolving in the face of new research and methodology. Consider an alternative analysis of the ulcer illustration. In 1910, the majority of doctors, based on our understanding of ulcers at the time, would have said that the claim that bacteria cause ulcers is literally false. In the decades that followed, medical explanation for ulcers changed in light of evolving research. By 1950, the weight of scientific evidence would indicate that bacteria do, in fact, cause ulcers. Today, it is scientific truth that *H. pylori* is the culprit behind stomach ulcers—a proposition that would have been literally false in 1910 if the “vast weight of scientific evidence” set the standard in falsity cases.

The point is that the minority opinion in a scientific debate may turn out to be correct. The *GNC* holding corrects for the mistaken understanding that a minority position is wrong simply because it is not supported by a majority of scientists at that time. In a 1910 jury trial, the jury would likely—and incorrectly—have discounted the minority position because it would not meet the preponderance of the evidence standard. Then, the question becomes, why should we let a jury decide such matters? In the ulcer case, how and why would a jury have reached a better result?

The Fourth Circuit recognized a key difference between claims that, in light of the existing scientific evidence, are inherently false, as opposed to claims that are reasonably debatable. The *GNC* standard is most receptive to the changing nature of scientific evidence and techniques. Until consensus among duly qualified and reasonable experts emerges around the veracity of a claim, it would simply be premature to rule out the minority opinion as false. The ulcer anecdote, perhaps inadvertently, stands for this proposition.

Amici would likely retort that the *GNC* rule too easily insulates corporate advertisers, hiding behind a single study, in literal falsity cases. However, as the *GNC* Court noted, plaintiffs remain protected due to the rules of evidence and by alternative causes of action. As Judge Floyd explained, “Plaintiffs remain protected from dubious experts by the Federal Rules of Evidence, which ‘ensure that any and all scientific testimony...is not only relevant, but reliable.’” The importance of relevant and reliable scientific testing cannot be overstated, since plaintiff must prove that no reasonable scientific expert could find merit in the advertiser’s claims. The Fourth Circuit is careful to rule out quackery as a source of substantiation. If no *reasonable* study exists in support of a proposition, then the plaintiff meets their

burden of proof in literal falsity cases. Additionally, Judge Floyd noted that “[p]laintiffs who cannot meet the burden of proving literal falsity may avail themselves of a claim regarding misleading representations.” This is helpful to plaintiffs who cannot or do not challenge the scientific legitimacy of a claim, but consider the messaging to consumers to be deceptive. Plaintiffs may then rely on survey evidence to establish consumer deception or confusion regarding an ad claim.

4. Jury Instructions

Finally, a crucial issue is not addressed in the Amicus Brief, but is relevant to the alternative outcome that Amici support: if the *GNC* case were assigned to a jury, what would the jury instructions look like? Juries undeniably serve an important fact-finding role in courtrooms across the United States, but play no part in the *GNC* story. Amici aptly draw attention to this procedural predicament, but serious questions remain if a panel of jurors would have reached a better outcome in the glucosamine case.

GNC is procedurally significant because the Court ruled, on a motion to dismiss, that a literal falsity case could be resolved on the pleadings. The Fourth Circuit articulated a very specific pleading standard with respect to plausibility in falsity cases. To recall, future plaintiffs must allege that no reasonable study (or scientist) exists or supports the challenged advertising claims; reliance on the so-called “vast weight of evidence” is insufficient to survive a motion to dismiss. In so ruling, the Fourth Circuit held that a jury would not resolve conflicting disagreements among experts.

One could say, as Plaintiffs argued, that a battle of opinions among qualified and competent experts creates a genuine issue of material fact, and that juries can handle highly technical scientific evidence. The involvement of juries seems even more urgent when considering the resource limitations of the FTC and FDA. *GNC*’s resolution at the plausibility stage usurped the jury of its central province,⁹⁶ and corporate defendants can more easily evade liability from the FTC, FDA, and courts alike.

While plaintiffs’ argument prevails in principle, it has less purchase in practice. When there is reasonable evidence on both sides of a scientific controversy, why should six jurors decide if a product cannot be sold or advertised? Reserving judgment for juries beyond the pleadings stage would overestimate juries’ abilities

⁹⁶ Plaintiffs’ Reply Memorandum of Law in Further Support of Motion to Correct Mistake of Law Pursuant to F.R.C.P. 60 at 4, In re *GNC Corp. TriFlex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014) ECF No.50.

to resolve highly technical scientific controversies. However, if plaintiffs plead issues related to the credibility or reliability of the defendant’s studies (which the *GNC* plaintiffs did not), a jury’s intervention seems far more befitting. In such case, if the evidence on one side is unreliable, there is no “battle of the experts” to begin with, and we can trust juries to side with the (only) party bearing substantiation. *GNC* preserves this crucial distinction beyond the pleadings stage.

Lastly, the *GNC* holding should be cabined to the dietary supplement area. Judges, academics (including Amici), and others would likely agree with this assertion. The *GNC* ruling does not rob the jury of its fact-finder role in cases involving product liability, wrongful death, and related matters. The District Court specifically addressed this concern, distinguishing the question in *GNC* from other burden of proof issues. In the words of Judge Motz:

I have considered whether the issue is one of burden of proof, and I have concluded that it is not. Rather, the basis of my holding lies in the nature of the claims asserted by plaintiffs that rely upon the falsity, deceptiveness, or unfairness of defendants’ advertisements. In contrast, for example, in a product liability case in which a plaintiff must establish that a product is defective, it would be entirely appropriate for the jury to decide the defect on the basis of expert testimony that, to a reasonable degree of scientific certainty, a product is defective.⁹⁷

As is evident in the Court’s language, the decision is meant to be narrowly construed, and this message appears to have been received by other courts. As of February 2018, the *GNC* holding has not been applied outside of advertising cases.

B. Additional Merits of the Fourth Circuit’s Decision

There is useful criticism of the *GNC* ruling from Amici and others.⁹⁸ On the one hand, the *GNC* ruling seems like a massive victory for corporate defendants — and a massive loss for consumer plaintiffs—on both substantive and procedural grounds. *GNC* arguably imposes a high hurdle on consumer plaintiffs in literal falsity cases; without alleging perfect scientific consensus or attacking defendant’s

⁹⁷ Defendant’s Memorandum in Support of its Motion to Dismiss Class Action Complaint at n.2, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014) ECF No.38.

⁹⁸ *See generally* Brief of Law Professors as Amici Curiae in Support of Plaintiffs-Appellants’ Petition for Rehearing and for Rehearing En Banc, and in the Alternative, for Modification of Opinion and Judgment, *Brown v. GNC Corp.* (In re *GNC Corp.*), 789 F.3d 505 (4th Cir. 2015) (No. 14-1724) ECF No.45; Olamide Orebamjo, Comment, *Brown v. GNC Corp.*: *The Fourth Circuit’s New Standard for Literal Falsity*, 12 J. BUS. & TECH. L. PROXY 1 (2017).

study, plaintiff's case can no longer survive a motion to dismiss. But this is only part of the story.

Prior to the *GNC* decision, the question of what constituted false advertising during a period of scientific controversy was unanswered by the case law. Despite the prevailing criticism, the Fourth Circuit's position is a persuasive solution to a previously unresolved legal dilemma. The arguments that follow address the policy merits of the *GNC* standard for literal falsity in supplement cases. Specifically, this Section argues that (i) the Fourth Circuit's standard fits neatly into the patchwork of pre-existing consumer protection measures, namely those of the FTC and FDA, (ii) the decision promotes fair competition and preserves consumer choice, and (iii) the res judicata effect in these cases is limited, preserving opportunities for future plaintiffs to take a bite at the proverbial apple as scientific knowledge evolves.

1. FTC, FDA, and Fourth Circuit Parity

The falsity standard articulated in *GNC* is consistent with other consumer protection measures, namely, the FTC and FDA's approaches to truth-in-advertising. The Fourth Circuit's holding reflects the policy rationales underlying the FTC's prior substantiation doctrine and the FDA's disclosure regime. Both agencies, which are most directly involved in regulating consumer communications about supplements, would not take issue with the TriFlex ads.

Under the FTC's advertising standards, the TriFlex claims are truthfully advertised. The FTC's prior substantiation rule, discussed in Section I.B., states that an advertiser must have a "reasonable basis" for making objective claims and must "possess substantiation, prior to running the ad, for affirmative product claims."⁹⁹ *GNC* cited to a particular study in its possession on the bottle of one of the TriFlex products. Plaintiffs nowhere alleged that *GNC* did not have a reasonable basis for making the joint health improvement claims; they failed to allege this deficiency even after the District Court granted them leave to amend their complaint. While the FTC has investigated other glucosamine-chondroitin products, the author has no information indicating that the FTC acted (or would need to act) with respect to the TriFlex claims.

GNC was also compliant with the FDA's supplement labeling requirements, since each TriFlex label included the ingredients in each bottle, the standard disclaimer, and other required information. In broader perspective, the Fourth Circuit's ruling is consistent with the FDA's position on supplement labeling and advertising. Consider the evolution of the FDA's approach to regulating the

⁹⁹ *Pfizer*, 81 F.T.C. at 29 (1972).

supplement industry. The 1906 Federal Food and Drugs Act used the label as a tool to empower consumers to have a much better conception of what they were putting into their bodies. In the 1930s, the FDA confronted the question of allowable representations in the face of scientific uncertainty, further extending the “informative labeling” approach: representations could be made, even if not reflective of the consensus of scientific opinion, as long as there was reliable scientific basis behind them. In such cases, the statements would have to be qualified with a disclaimer that reliable scientific opinion differed on such claims.¹⁰⁰ The goal was to preserve freedom of consumer choice, with the agency’s primary concern being the safety of the products. The Fourth Circuit’s ruling follows the hands-off approach that the FDA has taken towards safe and properly labeled dietary supplements.

Sources of truth-in-advertising law are too numerous to recount here, but the Fourth Circuit’s position achieves congruity across axes. Both the District Court and the Fourth Circuit interpreted the state consumer protection laws similarly; the fact that the laws come from different states is a distinction without a difference.¹⁰¹ The overall objective of these statutes remains the same: protecting consumers from false and misleading advertising. It seems reasonable that a federal court seeking guidance on false advertising issues would look to the Lanham Act on regulating advertising and consumer communications. In view of these considerations, an ad that is false under the Lanham Act should likewise be deemed false under a state consumer deception statute. Furthermore, both industry and consumers benefit from consistent interpretations of state consumer protection statutes, which provide adequate notice to both parties about pleading requirements and possible defenses.

2. *Fair Competition and Consumer Choice*

Over the last decade, dozens of false advertising lawsuits have been brought against purveyors of glucosamine-chondroitin. The claims typically reflect the conventional wisdom about improving joint health and flexibility, just as GNC’s TriFlex did. These cases across the United States are undoubtedly expensive for advertisers to defend. Ultimately, the price is borne by the consumer who continues to “gamble” on glucosamine because, in her subjective opinion, it works. Both *GNC* decisions consider this economic dimension, limiting litigation beyond the motion to dismiss stage for cases in which there are two legitimate medical understandings

¹⁰⁰ John P. Swann, *The history of efforts to regulate dietary supplements in the USA*, 8 DRUG TESTING & ANALYSIS 271, 275 (2016).

¹⁰¹ *Brown v. GNC Corp.* (In re GNC Corp.), 789 F.3d 505, 514 (4th Cir. 2015) (“In construing the diverse state statutes at issue here, we apply this broadly shared understanding of the difference between false and misleading representations.”).

of a supplement's efficacy. Furthermore, from a policy perspective, it seems unadvisable to "put out of business" an approach for which there is a sound medical view.

As Judge Motz aptly noted in his Memorandum Decision, "It is unfair to consumers who wish to gamble that glucosamine and chondroitin may be effective if lay juries can effectively ban the sale of glucosamine and chondroitin simply because the evidence of their effectiveness is inconclusive." Satisfied consumers are free to purchase the products, and dissatisfied consumers are, of course, free to seek alternatives. Unlike drugs, which operate under completely different advertising standards, consumers are not required to take supplements. The perspective of jurors adds no value to this highly individual decision. The Court continued: "After all, damage awards and even the cost of defending against high stakes litigation has the effect of increasing the cost of glucosamine/chondroitin pills or, potentially, driving the pills from the market. Should those who choose to purchase the pills have to pay more for them (or be deprived of the opportunity to purchase them at all) when the science is uncertain merely because juries disagree with their own judgment about the pills' efficacy?"¹⁰²

In addition to preserving consumer choice, the *GNC* ruling respects that whether the supplements work is an enormously subjective inquiry. In another case involving glucosamine-chondroitin products, the court neatly summarized the dilemma:

The health and comfort of joints is probably influenced by a number of variables. Did [plaintiff] keep all of them constant, adjust for ones that can't be kept constant (like aging), and then somehow have her cartilage and joints examined? Did she keep precise records of how much [glucosamine-chondroitin] she took, why she took it, and just how long she took it for? Can she document what her physical condition was before and after she took [glucosamine-chondroitin]? Probably not. What's more likely is that she took [glucosamine-chondroitin] casually and just didn't feel much better, but that makes her own claims just as speculative as she alleges [the supplement's] benefits are.¹⁰³

We could, as Amici argue, send these cases to juries and let them decide if the minority view does not hold water. But should we? The Court asked and answered

¹⁰² See Memorandum at 4 n.4, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 51.

¹⁰³ *Eckler v. Wal-Mart Stores, Inc.*, No. 12-727, 2012 WL 5382218, at *8 n.2 (S.D. Cal. 2012).

this very question, stating: juries serve as “a proper check on expert elitism. However, in this case the question is not whether the views of jurors should prevail over the views of asserted experts and judges. Rather the question is whether the views of jurors should prevail over the views of those who choose to purchase glucosamine/chondroitin pills. What is ‘democratic’ in one instance may be tyrannical in another. . . .”¹⁰⁴

Finally, there is a hidden narrative beneath these lawsuits. At first glance, it may seem that consumers are fired up about wasting money on useless products. However, a closer look at the court dockets suggests an alternative story: many of the glucosamine-chondroitin lawsuits seem to be brought by the same lawyers, not consumers. Bonnett, Fairbourn and Denlea & Carton have been heavily involved in various glucosamine-chondroitin product lawsuits. The results have been lucrative for law firms. In the Plaintiffs’ Memorandum supporting its Motion for Reconsideration, counsel noted “at least three nationwide settlements against manufacturers of similar joint relief supplements are in various stages of review.”¹⁰⁵ Should law firms be able to line their pockets from consumers’ purses? The FDA, FTC, state attorneys general, and corporate competitors are better safeguards of truth-in-advertising than plaintiffs’ firms would care to admit.

3. *Res Judicata Effects*

Critics of the *GNC* ruling may rest assured that claim preclusion in false advertising cases is limited to the named plaintiff(s). The *res judicata* effect does not bind anyone to the result aside from the person or persons who brought the suit. If a party sued GNC for its TriFlex claims in Texas today, nothing is settled, and the court is well within its discretion to hear the case. It is particularly important to preserve these opportunities for litigation as scientific knowledge evolves and the conventional wisdom shifts.

On the other hand, the limits of the *res judicata* effects in these cases reveal a troubling pattern. As mentioned previously, there have been dozens of lawsuits across the United States involving glucosamine-chondroitin supplements, many of which were brought within the last ten years. These cases, which have not utilized the *GNC* pleading standard, have resulted in disparate verdicts and settlements. For example, the glucosamine-chondroitin cases in California have come out all over the

¹⁰⁴ Memorandum at 4 n.4, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 51.

¹⁰⁵ Plaintiffs’ Memorandum of Law in Support of Motion to Correct Mistake of Law Pursuant to F.R.C.P. 60, *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.* (No. II), No. 14-2491, 2014 U.S. Dist. LEXIS 84184 (D. Md. June 20, 2014), ECF No. 44.

place: it is entirely possible that a Los Angeles jury would find the claims to be truthful, and a jury in San Francisco would deem them falsely advertised. As a result, glucosamine products may bear dissimilar advertising claims depending solely on the location where the product is purchased. This result seems arbitrary and premature, given the conflicting scientific evidence on the claims at issue.

CONCLUSION

During periods of scientific controversy, how should advertisers, regulators, and courts address truth-in-advertising dilemmas? As the *GNC* case has shown, this is a complex and interesting issue that is worth examining. The Fourth Circuit's answer to this question is a fair and reasonable standard, relying on expert consensus to establish literal falsity. While respected academics and courts have greeted the Fourth Circuit's ruling with caution, advertisers and consumers may be more satisfied with its outcome. Corporate defendants are once again reminded of the prior substantiation requirement in articulating advertising claims and can, with assurance, hang their hats on reasonable scientific testing. Consumers enjoy the continued availability of supplements that, in their subjective opinions, provide symptom relief – without paying for the extra costs associated with consumer class actions. Consumer plaintiffs are also given clear guidance on surviving a motion to dismiss, as the Fourth Circuit neatly articulated the pleading requirements in alleging literal falsity.

The novelty and significance of the *GNC* decision are only beginning to be understood, but it offers compelling policy advantages to proposed alternatives. The Fourth Circuit's ruling fits into the preexisting patchwork of consumer protection measures, announcing similar principles to the FTC's substantiation theory and the FDA's disclosure theory of liability. The solution is well suited to the nature of scientific evidence, which is continually changing in response to new research and technology. It is hard to argue that, if qualified scientists disagree about the efficacy of a dietary supplement, lay juries would achieve a better outcome in determining truth from falsity. Elevating the opinions of six jurors over experts and consumers does not provide any more certainty in arriving at the truthful result.

Questions remain about what impact, if any, the *GNC* decision should have on false advertising law. The author hopes that this unanimous decision by a panel of respected appellate judges will receive thoughtful consideration. In broader perspective, the standard does no damage to the existing falsity doctrines, and can be carefully confined to the dietary supplement space. The new standard articulated in *GNC* may seem like a big pill to swallow, but it is an effective remedy to the truth-in-advertising question that plagued the dietary supplementary industry.