NO. 76463-2-2

COURT OF APPEALS, DIVISION I
STATE OF WASHINGTON

STATE OF WASHINGTON,

Respondent,

v.

LIVING ESSENTIALS, LLC, a Michigan limited liability company, and INNOVATION VENTURES, LLC, a Michigan limited liability company,

Appellants.

BRIEF OF *AMICUS CURIAE* COUNCIL FOR RESPONSIBLE NUTRITION IN SUPPORT OF APPELLANTS

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INTEREST OF AMICUS CURIAE

The Council for Responsible Nutrition ("CRN") is the leading trade association for the dietary supplement industry. CRN represents more than 175 companies worldwide that manufacture either dietary ingredients or dietary supplements, or provide services to those manufacturers. CRN members manufacture popular national brands of dietary supplements, in addition to store brands marketed by major supermarket, drugstore, and discount chains. CRN members also include mainstream direct selling companies and companies marketing products through natural food stores.

CRN has a special interest in this case because one of the key issues at stake is the appropriate standard for substantiating claims made about dietary supplements. Should the Court adopt the State's position, Appellants Living Essentials, LLC, and Innovation Ventures, LLC, would not be the only entities harmed; rather, the entire dietary supplement industry, including CRN's membership, stands to suffer significant harm.

Although Defendants' brief describes the appropriate legal standard, its primary focus is to demonstrate that Defendants cannot be held liable with regard to the particular product at issue. Defendants' brief therefore may not fully represent the interests of the broader dietary supplement industry in preventing the adoption of legal standards that will

set a harmful precedent for the entire industry. Given CRN's active engagement with a broad range of dietary supplement companies, CRN believes it offers an important perspective on these issues.

STATEMENT OF THE CASE

Amicus CRN relies on the parties' statement of the case.

SUMMARY OF ARGUMENT

When it enacted the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325, the federal government set a clear policy in favor of consumer choice and access to dietary supplements, and, importantly, access to information about those supplements. Congress enacted this statute against a backdrop of heavy-handed FDA regulation of dietary supplements that threatened to undermine consumers' access to the most current and accurate information about dietary supplements, access that empowers individuals to make decisions about their own health and wellness. Indeed, that was one of the statute's primary objectives. These same policy objectives reflect the core rationale upon which First Amendment commercial speech doctrine is based: the free flow of information to consumers.

The trial court's adoption of a rigid substantiation standard under Washington's Consumer Protection Act ("CPA"), however, threatens to upend both the constitutional protection of commercial speech to which

dietary supplement manufacturers are entitled, as well as Congress's policy objectives in enacting DSHEA. The trial court adopted, and the State now urges this Court to accept, a substantiation standard that would suppress information about dietary supplements unless that information is "clearly established" scientific fact. But this standard is at odds with the approach adopted by the Federal Trade Commission ("FTC"), the Food and Drug Administration ("FDA"), and federal courts. This standard, moreover, would make it impossible for many dietary supplement manufacturers to engage in constitutionally protected commercial speech, thereby thwarting public access to vital health and wellness information.

ARGUMENT

I. Federal Law Prohibits The Suppression Of Commercial Speech About The Benefits Of Dietary Supplements.

A. Congress Has Adopted A Clear Mandate In Favor Of Facilitating Individual Health And Wellness Decision Making By Maximizing Public Access To Information About Dietary Supplements.

Congress enacted DSHEA in 1994 amid a growing public debate about the importance of dietary supplements and consumers' freedom to obtain information about those supplements.[1] Acting under its pre-DSHEA authority, the U.S. Food and Drug Administration ("FDA") had

[1] *See* Amber K. Spencer, *The FDA Knows Best . . . or Does It? First Amendment Protection of Health Claims on Dietary Supplements: Pearson v. Shalala*, 15 BYU J. Pub. L. 87, 97 (2000); Melinda Ledden Sidak, *Dietary Supplements and Commercial Speech*, 48 Food & Drug L.J. 441, 450-51 (1993).

sought to impose rigid regulations on the flow of information to the public about the health benefits of dietary supplements. Among other things, the agency demanded near scientific consensus before permitting manufacturers to make claims about their supplements. *See* I. Scott Bass & Anthony L. Young, *Dietary Supplement Health and Education Act: A Legislative History and Analysis* 14-15, 17-21 (1996); Amber K. Spencer, *The FDA Knows Best . . . or Does It? First Amendment Protection of Health Claims on Dietary Supplements: Pearson v. Shalala*, 15 BYU J. Pub. L. 87, 97 (2000).

Congress roundly rejected the FDA's rigid approach. Congress clarified in DSHEA that "dietary supplements are not drugs" and should not be regulated as such. S. Rep. No. 103-410, at 19 (1994); *see* 21 U.S.C. § 321(g)(1). As one federal court emphasized, "[c]oncern over excessive regulation of dietary supplements and the suppression of truthful information drove the passage of the DSHEA, and the mandates and tone of the DSHEA signal a shift toward a more permissive approach to health claims on labels." *Nutritional Health All. v. Shalala*, 953 F. Supp. 526, 528 (S.D.N.Y. 1997), *aff'd*, 144 F.3d 220 (2d Cir. 1998).

DSHEA brought this more permissive approach into effect by, among other things, exempting certain dietary supplement claims from the FDA's claim pre-approval process and requiring a lower threshold of

scientific backing. Rather than requiring that manufacturers submit proposed claims about their drugs to the FDA for pre-approval, as is the case under other circumstances, *see* 21 C.F.R. § 101.70, DSHEA allows manufacturers to make "***structure/function claims***" without preapproval. The statute defines structure/function claims as statements that:

> describe[ ] *the role of a nutrient or dietary ingredient intended to affect the structure or function in humans*, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or *describes general well-being from consumption* of a nutrient or dietary ingredient . . . .

21 U.S.C. § 343(r)(6) (emphases added).[2] In contrast to structure/function claims, dietary supplement manufacturers must obtain preapproval to make "***disease claims***," which are statements "claim[ing] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. §§ 321(g)(1)(B), 343(r)(6)(C).[3]

A manufacturer making a structure/function claim need only ensure that it has "substantiation that such statement is truthful and not misleading." *Id.* at § 343(r)(6)(B)-(C); *see* 21 C.F.R. § 101.93. In

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[2] Examples of "structure/function claims" include: "Helps promote urinary tract health," "helps maintain cardiovascular function and a healthy circulatory system," "helps maintain intestinal flora," and "promotes relaxation." Regulations on Statements Made for Dietary Supplements, 65 Fed. Reg. 1000-01, 1012 (Jan. 6, 2000).

[3] Examples of "disease claims" include: "protective against the development of cancer," "reduces the pain and stiffness associated with arthritis," "decreases the effects of alcohol intoxication," or "alleviates constipation." Regulations on Statements Made for Dietary Supplements, 63 Fed. Reg. 23,624-01, 23,626 (Apr. 29, 1998).

addition, Congress consciously rejected any requirement that there be scientific consensus before manufacturers may make dietary supplement claims. *See* S. Rep. No. 103-410, at 24 ("[S]cientific agreement on the validity of [a] claim does not have to be complete."). Congress sought to create a regulatory regime permitting manufacturers to make dietary supplement claims that have a reasonable scientific basis, even where there is disagreement in the scientific community about those claims.

In rejecting the FDA's heavy-handed suppression of information about dietary supplements, Congress emphasized the importance of maximizing public access to information about the benefits of dietary supplements. DSHEA's lead Senate sponsor explained that "consumers should be able to purchase dietary supplements and companies should be able to sell these products so long as the labeling and advertising are truthful, nonmisleading, and there exists a reasonable scientific basis for product claims." 103 Cong. Rec. S4577 (1993). "[H]eavyhanded" prohibitions on the kind of information consumers are provided would leave them "uninformed," causing the loss of "millions of dollars for health care that could have been saved though disease prevention." *Id.*

DSHEA's House sponsor noted that the FDA approach would have "severely restricted" information about nutrients and dietary supplements." 103 Cong. Rec. E920 (1993). DSHEA, he added, would

permit dietary supplement manufacturers to share truthful information about their supplements "based upon a reasonable level of scientific evidence," rather than the more rigid standards applicable to prescription drugs. *Id.* In addition, Congress declared in its findings:

> [T]here is a growing need for emphasis on the dissemination of information linking nutrition and long-term health; consumers should be empowered to make choices about preventative health care programs based on data from scientific studies of health benefits related to particular dietary supplements; . . . [and] the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing . . . accurate information to consumers[.]

Pub. L. No. 103-417, § 2(7), (8), (13). Reflecting the bipartisan consensus in favor of the legislation,[4] President Clinton signed DSHEA lauding the statute's "reform[s] [to] the way the Government treats consumers and these supplements in a way that encourages good health." Statement on Signing the Dietary Supplement Health Education Act (Oct. 25, 1994).[5]

Congress had compelling reasons to be wary of heavy-handed suppression of health and wellness information. Lack of scientific consensus to support a claim is far from proof that the claim is false or misleading. More important, demanding such consensus has public health implications. For instance, although researchers had discovered a

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[4] DSHEA was passed by voice vote in the Senate and without objection in the House.

[5] Available at www.presidency.ucsb.edu/ws/?pid=49370.

relationship between cholesterol and heart disease as early as the 1950s,[6] the FDA for decades refused to permit claims related to cholesterol and health. The agency insisted that, under its stringent standards, "[a] causal relationship between blood cholesterol levels and these diseases has not been proved." Status of Articles Offered to the General Public, 24 Fed. Reg. 9990, 9990 (1959). As one observer pointed out, "Had the FDA permitted such statements to appear in food labeling beginning in the 1950s rather than actively suppressing them for nearly forty years, . . . the public health benefits potentially would have been substantial." Sidak, 48 Food & Drug L.J. at 456.

Congress similarly faulted the FDA for "restrict[ing] the information that the public may receive about [folic acid] supplements." S. Rep. No. 103-410, at 16. The Senate report accompanying DSHEA explains that in 1991 the Centers for Disease Control issued a recommendation that all women have adequate folic acid to prevent birth defects, and the Public Health Service issued a similar recommendation a year later. The Report notes that the FDA, however, only started permitting folic acid claims two years later in 1993. *Id.* Indeed, "[a] study of the scientific literature on several dietary supplements contradicted the

[6] *See, e.g.*, Ancel Keys, *Atherosclerosis: A Problem In Newer Public Health*, 20 J Mt Sinai Hosp 118 (1953).

conclusions of the FDA . . . [and] much of the information the FDA restricts as health 'claims' are, rather, statements of fact to which the public should have access." *Id.* at 18.

B. The First Amendment Strongly Favors The Free Flow Of Information To Consumers.

DSHEA strongly echoes the core First Amendment principles upon which the protection of commercial speech is based. In elucidating those principles, the United States Supreme Court explained that "[t]he First Amendment, as applied to the States through the Fourteenth Amendment, protects commercial speech from unwarranted governmental regulation." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of NY*, 447 U.S. 557, 561-62 (1980). "[S]peech does not lose its First Amendment protection because money is spent to project it, as in a paid advertisement of one form or another." *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761 (1976). Accordingly, the government is strictly circumscribed in its power to suppress commercial speech, defined as "expression related solely to the economic interests of the speaker and its audience." *Central Hudson*,447 U.S. at 561.

The Supreme Court explicitly recognized commercial speech as a protected form of speech in *Virginia State Board*, which involved a challenge to a Virginia statute prohibiting pharmacists from advertising

drug prices. 425 U.S. at 770. In striking down the statute, Justice Blackmun's majority opinion articulated the compelling rationales animating the First Amendment's protection of commercial speech.

First, the Court emphasized that extending the First Amendment to commercial speech safeguards the "consumer's interest in the free flow of commercial information." *Id.* at 763; *see also Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1985) ("[T]he extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides."); *Central Hudson*, 447 U.S. at 561-62 (noting that commercial speech "not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information"); *cf. Associated Press v. United States*, 326 U.S. 1, 20 (1945) ("[T]he widest possible dissemination of information from diverse and antagonistic sources is essential to the welfare of the public[.]"). In *Virginia State Board*, the Court cited, for instance, the value to consumers of the information the government sought to suppress: "Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged . . . [who] are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent." 425 U.S. at 763.

Second, "an individual advertisement, although entirely 'commercial,'" may nonetheless implicate non-commercial matters of "general public interest." *Id.* at 764. Illustrating this species of commercial speech, the Court noted advertisements for legal abortions; artificial furs promoted as an alternative to natural furs; and domestic products promoted as an alternative to imports that threaten local jobs. *Id.* (citing cases). Commercial speech is often tied up with non-commercial speech about matters of public concern. Prohibitions on the former invariably sweep up the latter.

Third, the Court explained that "so long as we preserve a predominantly free enterprise economy, . . . the free flow of commercial information is indispensable." *Id.* at 765; *see also Edenfield v. Fane*, 507 U.S. 761, 767 (1993) ("The commercial marketplace . . . provides a forum where ideas and information flourish. . . . . [T]he speaker and the audience, not the government, assess the value of the information presented."); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 791 (1985) (Brennan, J., dissenting from denial of certiorari) ("When immersed in a free flow of commercial information, private sector decision making is at least as effective an institution as are our various governments in furthering the social interest in obtaining the best general allocation of resources."). Because the "allocation of our resources in [a

free market economy] will be made through numerous private economic decisions[,] [i]t is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed." *Virginia State Board*, 425 U.S. at 765.

Finally, the Court considered the competing interests that supposedly justified the government ban on drug-price advertising. Among other similar claims, advocates of the ban insisted that, "if the pharmacist who wishes to provide low cost . . . services is permitted to advertise, . . . too many unwitting customers . . . will choose the low-cost, low-quality service and drive the 'professional' pharmacist out of business." *Id.* at 769. Consumers, the argument went, "will go from one pharmacist to another, following the discount, and destroy the pharmacist-customer relationship," and "[a]ll this is not in [the consumers'] best interests." *Id.* at 769-70. The Court rejected the "highly paternalistic" assumptions of this reasoning. *Id.* at 770. "[A]n alternative" to this paternalism, the Court pointed out, "is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." *Id*; *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996) ("[A] State's paternalistic assumption that the public will use truthful,

nonmisleading commercial information unwisely cannot justify a decision to suppress it[.]").

It bears note that *Virginia State Board*, the leading U.S. Supreme Court case on commercial speech, dealt with a restriction on purveyors of products that are useful to the health and wellness of consumers. Like the pharmaceuticals at issue in *Virginia State Board*, the dietary supplements at issue in this case, and surely to be affected by this Court's decision, are useful to the health and wellness of consumers. This Court cannot consider the trial court's ruling outside the context of the stringent constitutional protections for health and wellness-related claims.

II. The Lower Court's Substantiation Standard Is At Odds With The FTC and FDA Approach And Threatens The Free Flow Of Information About Dietary Supplements.

A. The Lower Court Misconstrued The Substantiation Standard.

The parties disagree on whether the prior-substantiation doctrine applies to claims brought under Washington's Consumer Protection Act ("CPA"); whether or not that doctrine applies, however, the trial court simply misconstrued the FTC and FDA substantiation standard.[7]

As a threshold matter, the core of the statements challenged here—that 5-Hour Energy contains certain vitamins and amino acids that

[7] CRN takes no position as to whether the specific scientific evidence marshalled by the Appellants in the trial court satisfies the substantiation standard; it argues only that the trial court applied the incorrect standard.

improve "energy," "focus," and "mood"—are precisely the kinds of claims that Congress long ago explicitly permitted manufacturers to make without FDA pre-approval. The challenged statements are plainly not disease claims, as they do not suggest that 5-Hour Energy may "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6)(C). The trial court concluded that the statements at issue "require high level of substantiation" because they "relate to consumer health," CP 8105, but the court did not consider what distinguishes disease claims from other types of claims, and why disease claims are subject to a higher standard.

"[T]he level of substantiation for a structure/function claim and a health claim is markedly different." *Johns v. Bayer Corp.*, 2013 WL 1498965, at *24 (S.D. Cal. Apr. 10, 2013). In regulations that complement FTC regulations,[8] the FDA has made clear that, unlike disease claims, structure/function claims are adequately substantiated so long as they are supported by "competent and reliable scientific evidence." Food & Drug Admin, *Guidance for Industry: Substantiation for Dietary*

[8] In regulating dietary supplements under the Federal Trade Commission Act—the CPA's federal analogue—the Federal Trade Commission "works together" with the FDA; "the FDA has primary responsibility for claims on product labeling" and "[t]he FTC has primary responsibility for claims in advertising." Fed. Trade Comm'n, *Dietary Supplements: An Advertising Guide For Industry* 10-16 (2001). Both agencies have explained that they will apply consistent standards in regulating dietary supplements. *See id.* 26 n.2 (explaining the FDA's distinction between structure/function claims and disease claims).

Supplement Claims (2008);[9] Fed. Trade Comm'n, *Dietary Supplements: An Advertising Guide For Industry*, 9 (2001) ("FTC Guide").[10] The trial court rotely recites this language—"competent and reliable scientific evidence"—at several junctures in its analysis. *See, e.g.*, CP 8107, 8114. But in actually applying the standard, the court raised the bar, seeking evidence that the challenged claims have been "clearly establish[ed]," CP 8104, and that they are "established scientific fact," CP 8106. That is not the standard applicable to dietary supplements.

That error materially affected the trial court's conclusions. For instance, in reviewing Appellants' superior-to-coffee claim, the court itself conceded that "[t]he 2015 Paulus study compared 5-Hour ENERGY® to a Starbucks DoubleShot and to caffeine itself" and "found that the 5-Hour ENERGY[®] group outperformed the other two groups." CP 8105. Applying its rigid substantiation standard, however, the trial court "f[ound] the methodological problems, specifically the lack of blinding of the participants and lack of other controls, to be significant enough to render the Paulus Study results unreliable." *Id.* But the requirements of the competent-and-reliable standard are not so rigid. Nor are they so

[9] Available at www.fda.gov/food/guidanceregulation/guidancedocumentsregulatory information/ucm073200.htm.

[10] Available at www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf.

exacting as to permit courts to second-guess the reasonable scientific judgments of experts in the field.

Rather, to satisfy the competent-and-reliable standard, the FTC only requires "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." FTC Guide, at 10. Importantly, unlike the stricter and more rigid standard applicable to disease claims, the FTC recognizes that "randomized clinical trials are not required." *See id*; *see also, e.g.*, *United States v. Bayer Corp.*, 2015 WL 5822595, at *3 (D.N.J. Sept. 24, 2015). Indeed, "[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration." FTC Guide, at 9. The FTC explains that, although "well-controlled human clinical studies are the most reliable form of evidence," the agency "consider[s] all forms of competent and reliable scientific research when evaluating substantiation," even including "[r]esults obtained in animal and *in vitro* studies." *Id.* at 10.

Federal courts have subsequently added further clarity to what constitutes adequate substantiation. For instance, in *F.T.C. v. Garden of Life, Inc.*, the FTC challenged a manufacturer's claim that its dietary

supplement "'helped support' a child's 'brain development,' 'cognitive function,' 'eye health & vision,' and 'positive mood & behavior.'" 516 F. App'x 852, 854 (11th Cir. 2013) (brackets omitted). The FTC claimed that the manufacturer "relied on insufficiently rigorous studies, or studies of populations other than healthy children over the age of two, and that, therefore, there was not enough substantiation for the . . . claims." *Id.* at 856. In rejecting the FTC's position, the Eleventh Circuit agreed with the district court, that the FTC cannot assert an inadequate-substantiation claim "solely because another well-respected expert defines 'brain development' differently or disagrees with certain aspects of a study's 'trial design.'" *Id.*

Along similar lines, other courts have made clear that the competent-and-reliable standard does not envision scientific unanimity and certainly does not require, as the trial court held, that a claim be "established scientific fact":

> "Unanimity of opinion in the scientific community, on virtually any scientific question . . . is extremely rare. Only slightly less rare is a strong majority." Consequently, the Agreement "does not require [the advertiser] to only make representations that are supported by uncontroverted evidence." Instead, it "merely requires [the advertiser] to possess competent and reliable evidence that substantiates its claims."

Basic Research, LLC v. Fed. Trade Comm'n, 2014 WL 12596497, at *10 (D. Utah Nov. 25, 2014) (quoting *United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978), and *Garden of Life*, 845 F. Supp. 2d at 1337)); *see also Bayer*, 2015 WL 5822595, at *14.

As articulated by the FTC, FDA, and reinforced by federal courts, the substantiation standard applicable to claims such as the ones at issue here stands in stark contrast to the standard applied by the trial court.

B. The Lower Court's Stringent Substantiation Standard Unduly Burdens The Free Flow Of Information.

Consumer protection statutes like the CPA punish actual wrongdoing; they are not intended to provide a means by which the government may suppress the dissemination of scientific views merely because they are not "clearly established" or not supported by a majority of the scientific community.

In the analogous context of the federal False Claims Act ("FCA"), which broadly prohibits the submission of false claims to the government, courts have consistently held that a claim is not "false" merely because one side of a scientific debate disagrees with that claim. *See, e.g., U.S. ex rel. Morton v. A Plus Benefits, Inc.*, 139 F App'x 980, 983 (10th Cir. 2005); *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992), *overruled on other grounds*, *U.S. ex rel. Hartpence v. Kinetic*

Concepts, Inc., 792 F.3d 1121 (9th Cir. 2015); *United States v. AseraCare Inc.*, 176 F. Supp. 3d 1282, 1285 (N.D. Ala. 2016).

The Ninth Circuit explained in *Wang* that, by prohibiting the "knowing presentation of what is known to be false[,]" the FCA does not mean to forbid that which is "scientifically untrue"; rather, it prohibits that which is "a lie." 975 F.2d at 1421. "What is false as a matter of science is not, by that very fact, wrong as a matter of morals. The [FCA] would not put either Ptolemy or Copernicus on trial." *Id.*; *see also In re GNC Corp.*, 789 F.3d 505, 511 (4th Cir. 2015) (affirming dismissal of claims brought under various analogous state consumer protection statutes, and holding that "a manufacturer cannot be liable for false advertising so long as at least one qualified expert opines that the representations made are truthful, even if the overwhelming weight of scientific evidence is to the contrary"); *AseraCare,* 176 F. Supp. 3d at 1285 (declining to "allow[ ] a mere difference of opinion among physicians alone to prove falsity").

As the Supreme Court emphasized in *Sorrell v. IMS Health Inc.*, "[a] 'consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue," and "[t]hat reality has great relevance in the fields of medicine and public health, where information can save lives." 564 U.S. 552, 566 (2011). The Court yet again underscored that same principle very recently in *National*

Institute of Family & Life Advocates v. Becerra, 2018 WL 3116336, at *10 (U.S. June 26, 2018). Rejecting a state law requiring healthcare professionals to disseminate certain information to their patients, the Supreme Court explained that "[t]he best test of truth is the power of the thought to get itself accepted in the competition of the market, and the people lose when the government is the one deciding which ideas should prevail." *Id.* at *11 (internal quotation marks omitted). The FDA's suppression of cholesterol claims for decades demonstrates the folly in finding a claim false, and thereby suppressing it, merely because the claim was not "clearly established." Where drug safety is not a concern (as was the case here), and where there is no claim that the manufacturer made *actual* falsehoods (as was also the case here),[11] the rigorous substantiation standards governing prescription drugs do not, and should not, apply.

In light of the constitutional protection that commercial speech enjoys, as well as Congress's clearly expressed policy interests, any attempt to suppress the dissemination of health and wellness information related to dietary supplements must be grounded in something more than a dispute about the methodology employed in a clinical trial.

[11] As Appellants note, the State declined to pursue any claim that the statements at issue here were actually false and decided instead to assert a claim for inadequate substantiation. *See* Appellants' Opening Brief, 12-13.

Dated: July 5, 2018

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Appellants.

CERTIFICATE OF SERVICE

I certify that on this5th day of July 2018, I filed the foregoing Brief of *Amicus Curiae* Council For Responsible Nutrition In Support Of Appellants with the Court of Appeals, Division II, and served the same on all counsel of record by first class mail.

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