IN THE COURT OF APPEALS OF THE STATE OF OREGON

STATE OF OREGON, *ex rel.* ELLEN F. ROSENBLUM, in her official capacity as Attorney General for the State of Oregon, Plaintiff-Appellant and Cross-Respondent, v. LIVING ESSENTIALS, LLC, a Michigan limited liability company, and INNOVATION VENTURES, LLC, a Michigan limited liability company, Defendants-Respondents and Cross-Appellants.	Multnomah County Circuit Court No. 14CV09149 CA A163980

BRIEF OF *AMICUS CURIAE*
COUNCIL FOR RESPONSIBLE NUTRITION

Appeal from the Judgment of the Circuit Court for
Multnomah County
The Honorable Kelly Skye, Judge

(continued)

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IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Council for Responsible Nutrition ("CRN") is the leading trade association for the dietary supplement industry. CRN represents more than 150 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 challenging claims made for dietary supplements. The State of Oregon urges this Court to adopt a standard that violates the United States Constitution, contravenes past precedents, and defies the U.S. Congress's mandate for the free flow of commercial information as provided in the Dietary Supplement Health and Education Act of 1994. Should the Court adopt the State's position, Defendants Living Essentials, LLC, and Innovation Ventures, LLC, would not be the only entities harmed; rather, the entire dietary supplement industry, including members of CRN, stand 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 are likely to set a harmful precedent for the entire industry. Given CRN's active involvement and 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.

STATEMENT OF FACTS

Amicus CRN relies on the parties' summary of facts.

SUMMARY OF ARGUMENT

When the U.S. Congress enacted the Dietary Supplement Health and Education Act ("DSHEA"), our 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 policy objectives reflect the rationales upon which First Amendment commercial speech doctrine is based. The Supreme Court has repeatedly emphasized that the First Amendment protects commercial speech primarily as a means to ensure the free flow of information to consumers—a primary objective of DSHEA.

The State's interpretation of the Unlawful Trade Practices Act ("UTPA"), however, threatens to upend both the constitutional protection of commercial speech to which dietary supplement manufacturers are entitled, as well as the policy objectives Congress sought to accomplish with DSHEA. The State urges the Court to adopt a falsity standard that would make it impossible for many dietary supplement manufacturers to engage in constitutionally protected commercial speech, and would thereby thwart consumers' access to vital health and wellness information. Plainly, that falsity standard violates the First Amendment because it is not narrowly tailored to fit the State's interest in regulating statements about dietary supplements.

The State similarly runs afoul of the First Amendment by claiming that it may proceed on a claim under the UTPA regardless of whether the challenged false or misleading statements are material to consumers' purchasing decisions. The State's interest in regulating speech about dietary supplements is based entirely on its protection of consumers from commercial harm. Absent a *material*

falsehood, however, consumers suffer no such harm, and the State's justification for restricting speech loses any legitimacy.

ARGUMENT

I. Federal Law Prohibits The Suppression Of Commercial Speech, Including 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.

In 1994, Congress enacted the Dietary Supplement Health and Education Act[1] amid public debate about the importance of dietary supplements and consumers' freedom to obtain information about those supplements. *See* I. Scott Bass & Anthony L. Young, *Dietary Supplement Health and Education Act: A Legislative History and Analysis* 14-15, 17-21 (1996) [hereinafter *DSHEA Legislative History*]; 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 LJ 441, 450-51 (1993).

The Food and Drug Administration ("FDA") had sought, under its pre-DSHEA authority, to impose rigid regulations on the flow of information to the public about the health benefits of dietary supplements. Among other things, the

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[1] Pub L No 103-417, 108 Stat 4325 (codified in various sections of 21 USC).

agency demanded near scientific consensus before permitting manufacturers to make claims about their supplements. *See DSHEA Legislative History* at 14-15; Spencer, 15 BYU J Pub L at 97. Congress roundly rejected this 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 USC § 321(g)(1). Accordingly, Section 403(r)(6) of the statute permits manufacturers to make truthful claims that describe how a dietary supplement affects the normal structure or function of the human body—*i.e.*, "structure/function claims"—or its effect on the human body's general well-being. *See* 21 USC § 343(r)(6)(A). And DSHEA permits such claims to be made without FDA preapproval.[2] *See Id.*

[2] In contrast to "structure/function claims," dietary supplements may not make "disease claims"—*i.e.*, statements "claim[ing] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases"—as these claims are reserved for FDA-approved drugs and require prior FDA authorization. 21 USC §§ 321(g)(1)(B), 343(r)(6)(C). 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). 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). The trial court was not asked to determine whether the statements at issue here are "structure/function claims," as that classification was created by DSHEA, not Oregon law. CRN brings DSHEA's structure/function classification to the Court's attention only to emphasize the well-accepted nature of the types of statements at issue here under federal law.

§ 343(r)(6). Furthermore, 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."). Thus, 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.[3]

In rejecting the FDA's heavy-handed approach to suppressing information about dietary supplements, Congress echoed the same core First Amendment principles upon which the protection of commercial speech is based. *See infra* Section I.B. DSHEA's lead sponsor in the Senate 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

[3] FDA requires scientific consensus and prior approval only for claims that characterize a relationship between a food, a food component, or dietary ingredient and risk of a disease (for example, "adequate calcium throughout life may reduce the risk of osteoporosis"). Food & Drug Admin, *Label Claims for Conventional Foods and Dietary Supplements* (2018), www.fda.gov/food/labelingnutrition/ucm111447.htm.

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

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

Health Education Act of 1994 (Oct. 25, 1994), www.presidency.ucsb.edu/ws/?pid=49370.

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.[5] More important, demanding such consensus has public health implications.

For instance, although researchers had discovered a 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 for the Control or Reduction of Blood Cholesterol Levels, 24 Fed Reg 9990, 9990 (1959). As one observer pointed out, "Had the FDA permitted such

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[5] Neither the FDA nor the Federal Trade Commission requires scientific consensus to support statements about dietary supplements. *See* Food & Drug Admin, *Guidance for Industry: Substantiation for Dietary Supplement Claims* (2008), www.fda.gov/food/guidanceregulation/guidancedocumentsregulatory information/ucm073200.htm; Fed Trade Comm'n, *Dietary Supplements: An Advertising Guide For Industry* 10-16 (2001), www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf.; Letter from Donald S. Clark, Sec'y, Fed Trade Comm'n, to Jonathan W. Emord, at 5 (Nov. 30, 2000), www.ftc.gov/sites/default/files/attachments/press-releases/announced-actions-december-5-2000/001205dietletter.pdf.

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

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 LJ 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 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 Commercial Speech Doctrine Strongly Favors The Free Flow Of Information To Consumers.

The policy objectives that set Congress on the path towards DSHEA are firmly rooted in the First Amendment and are consistent with those underpinning

Article I, section 8 of the Oregon Constitution.[7] The United States Supreme Court has long recognized 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 US 557, 561-62, 100 S Ct 2343, 65 L Ed 2d 341 (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 US 748, 761, 96 S Ct 1817, 48 L Ed 2d 346 (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 US at 561; *see also, e.g., Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 US 626, 651, 105 S Ct 2265, 85 L Ed 2d 652 (1985).

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[7] The free speech clause of the Oregon State Constitution is broader than the U.S. Constitution's First Amendment. *See State v. Henry*, 302 Or 510, 515, 732 P2d 9 (1987). For example, although the U.S. Constitution forbids Congress from enacting any law "abridging the freedom of speech," Article I, section 8, of the Oregon Constitution prohibits any law "restricting the right to speak, write, or print freely on any subject whatever . . . ." Furthermore, it is well-established that, "for purposes of Article I, section 8, the Oregon courts make no distinction between commercial speech and non-commercial speech. Commercial speech is afforded the same constitutional protection as is non-commercial speech." Op Atty Gen 8256 (Apr. 27, 1998) (citing, among other cases, *Moser v. Frohnmayer*, 315 Or 372, 377-78, 845 P2d 1284 (1993), and *Ackerley Commc'ns, Inc. v. Multnomah Cnty.*, 72 Or App 617, 620, 696 P2d 1140 (1985), *rev denied* 303 Or 165 (1987)).

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 US at 770. In striking down the statute, Justice Blackmun's majority opinion articulated the 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," which is very often "as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id.* at 763; *see also Zauderer*, 471 US at 651 ("[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 US 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 US 1, 20, 65 S Ct 1416, 89 L Ed 2013 (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 in that case: "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 US at 763.

Second, according to the *Virginia State Board* Court, "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 US 761, 767, 113 S Ct 1792, 1798, 123 L Ed 2d 543 (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 US 749, 791, 105 S Ct 2939, 86 L Ed 2d 593 (1985) (Brennan, J., dissenting from denial of certiorari) ("When immersed in a free flow of commercial information, private sector decisionmaking 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 US at 765. Advertising, the *Virginia State Board* Court noted, facilitates intelligent consumer decision making, as it is little more than the "dissemination of information as to who is producing and selling what product, for what reason, and at what price." *Id.*

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 US 484, 497, 116 S Ct 1495, 134 L Ed 2d 711 (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 in this case, are useful to the health and wellness of consumers. This Court cannot consider the ruling below and the State's radical interpretation of the UTPA outside the context of the stringent protections for health and wellness-related claims provided by the U.S. Constitution, the U.S. Congress, and the Oregon Constitution.

II. The State's Interpretation Of The UTPA Threatens The Free Flow Of Information And Otherwise Runs Afoul Of The First Amendment.

A. The Falsity Standard Urged By The State Would Impede Manufacturers' Ability To Communicate Truthful Information About Dietary Supplements And Violate The First Amendment.

The UTPA prohibits advertisers from making false representations about their products. ORS 646.608(1). The trial court considered whether the

challenged statements were false or misleading under ORS 646.608(1)(e) by weighing the scientific evidence and concluding that "[t]he greater weight of th[e] scientific evidence favors the State's position." ER-66; *see* ER-70, 78. Although it ultimately concluded that Defendants were not liable on other grounds, the falsity standard adopted by the trial court—weighing the scientific evidence—would significantly curtail dietary supplement manufacturers' ability to share critical health and wellness information with consumers.

First, the core of the statements challenged here—that 5-Hour Energy contains B-vitamins, amino acids, and enzymes that improve "energy," "focus," and "mood"—are precisely the kinds of claims that Congress long ago explicitly permitted manufacturers to make without FDA preapproval; Congress imposed no requirement that a scientific consensus exist in order to disseminate such claims. *See* Regulations on Statements Made for Dietary Supplements, 65 Fed Reg 1000-01, 1012 (Jan 6, 2000); *see also supra* Section I.A. Given its stated objective of maximizing public awareness of dietary supplements and their health benefits, Congress sought to maximize consumers' access to scientific information about supplements. Should the Court conclude nonetheless that these statements are false or misleading under the UTPA, based on its own weighing of the scientific evidence, consumers would be denied scientifically supported information about this product and its health benefits.

Second, statutes like the UTPA punish actual wrongdoing; they are not intended to provide a forum for scientific debates. For instance, in the 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.*, *US ex rel Morton v. A Plus Benefits, Inc.*, 139 F App'x 980, 983 (10th Cir 2005); *Wang v. FMC Corp*, 975 F2d 1412, 1421 (9th Cir 1992), *overruled on other grounds, US ex rel Hartpence v. Kinetic Concepts, Inc.*, 792 F3d 1121 (9th Cir 2015); *United States v. AseraCare Inc.*, 176 F Supp 3d 1282, 1285 (ND 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 F2d 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 AseraCare*, 176 F Supp 3d at 1285 (expressing concern about "allowing a mere difference of opinion among physicians alone to prove falsity").

As the trial court pointed out, Defendants' claims are supported by "several scientific studies and a literature review [Defendants] procured," including a double-blind, placebo-controlled, human clinical trial that considered 5-Hour Energy's effect on cognition. ER-69; *see also* Defs'-Resp't's Answering Br. at

8-9. This suffices to preclude any finding of falsity. The FDA's experience with cholesterol claims demonstrates the folly in finding a claim false and thereby suppressing it, merely because some scientists, even a majority of them, disagree with that claim.

Third, demanding anything more than this level of scientific support would amount to an improper suppression of truthful speech under the First Amendment. To sustain a restriction on commercial speech, the First Amendment requires the government to satisfy the test set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Commission of New York*, 447 US 557 (1980). The *Central Hudson* test has four elements: (1) the commercial speech "must concern lawful activity and not be misleading"; (2) the proposed speech restriction must be supported by a "substantial" governmental interest; (3) the restriction must advance the asserted governmental interest in a direct and material way; and (4) the proposed speech restriction must be narrowly tailored and "not more extensive than is necessary" to serve the asserted governmental interest. *Central Hudson*, 447 US at 566; *see also Lorillard Tobacco Co. v. Reilly*, 533 US 525, 554, 121 S Ct 2404, 150 L Ed 2d 532 (2001); *44 Liquormart*, 517 US at 499; *Zauderer*, 471 US at 638, 651; *Edenfield*, 507 US at 767; *POM Wonderful, LLC v. FTC*, 777 F3d 478, 501-02 (DC Cir 2015).

At minimum the State's suppression of speech here is by no means narrowly tailored. The case of *Pearson v. Shalala*, 164 F3d 650 (DC Cir 1999), is illustrative. In *Pearson*, the FDA declined to authorize four separate claims about dietary supplements. 164 F3d at 651. Although there was scientific evidence supporting the claims at issue, the agency, applying a "significant scientific agreement" standard, concluded that "[t]he problem with the[ ] claims . . . was not a dearth of supporting evidence; rather, . . . the evidence was *inconclusive* for one reason or another and thus failed to give rise to 'significant scientific agreement.'" *Id.* at 653 (emphasis added). The agency did not find the claims in question misleading because they lacked any scientific support; rather, as the State also appears to claim in this case, the FDA insisted the claims in *Pearson* were misleading simply because the admittedly *truthful* scientific support provided was, in the agency's view, inadequate. *See id.* at 654, 656. The agency also refused to consider the manufacturer's "suggested alternative of permitting the claim while requiring a corrective disclaimer such as 'The FDA has determined that the evidence supporting this claim is inconclusive.'" *Id.* at 654.[8]

[8] As in this case, the FDA did not assert that the dietary supplements in *Pearson* "in any fashion *threaten* consumer's health and safety"; the agency simply concluded that the scientific evidence supporting the claims at issue was inadequate. *Pearson*, 164 F3d at 656 (emphasis in original).

The FDA argued in *Pearson* that a claim that does not have "significant scientific agreement" is "*inherently misleading*"; the agency maintained that such claims "have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*." *Id.* at 655 (first emphasis added). The D.C. Circuit correctly viewed this argument as "almost frivolous," as it relied on the "paternalistic assumption" that that consumers could not exercise sound judgment if provided the relevant information. *Id.* at 655 (citing *Peel v. Att'y Registration and Disciplinary Comm'n of Ill.*, 496 US 91, 105, 110 S Ct 2281, 110 L Ed 2d 83 (1990)). Plainly, a statement is not false or misleading and therefore outside the First Amendment's protection simply because it lacks significant scientific agreement. *See 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").

The *Pearson* court ultimately held that the FDA's suppression of speech under these circumstances was not narrowly tailored under *Central Hudson*'s fourth factor. In light of the "general First Amendment preference for disclosure over suppression," the court found it dispositive that the FDA resorted to a *total*

suppression of speech, rather than requiring a disclaimer alerting consumers of the limitations or caveats associated with the manufacturer's claims. *Id.* at 655-56.

To the extent the State of Oregon believes Defendants' claims about 5-Hour Energy are false, it is obligated, at minimum, to seek a reasonable fit between its ends and the means it chooses. The State has not demonstrated why the complete suppression of speech about dietary supplements is the proper course under these circumstances. *See Zauderer*, 471 US at 651. Insisting that health and wellness information be withheld from consumers to protect their own interests is paternalistic and unavailing for the same reasons Congress emphasized when it enacted DSHEA. *See supra* Section I.A. As the *Pearson* court warned, "[t]he First Amendment directs [courts] to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good." 164 F3d at 656. A similar skepticism is warranted here.

B. The First Amendment Does Not Permit Government Suppression Of Commercial Speech That Is Not Material To Consumers' Purchasing Decisions.

The State of Oregon also falls well short of satisfying *Central Hudson*'s second factor, under which the State must demonstrate that it has a "substantial" interest that justifies the suppression of speech. *Central Hudson*, 447 US at 566. The State insists that, in order to protect Oregon consumers from being misled by

dietary supplement claims, it may suppress those claims even where the purportedly false or misleading claims do not affect consumers' purchasing decisions. The claim is self-refuting.

The Supreme Court has explained that "the typical reason why commercial speech can be subject to greater governmental regulation than noncommercial speech" is "in preventing commercial harms by regulating the information distributed [to consumers]." *City of Cincinnati v. Discovery Network, Inc.*, 507 US 410, 426, 113 S Ct 1505, 123 L Ed 2d 99 (1993). But there is no such "commercial harm," nor is there so much as the *potential* for it, where purported false or misleading statements are not material to consumers' purchasing decisions. The State has alleged that, as a result of Defendants' purportedly false or misleading statements, there is a likelihood of confusion or misunderstanding among consumers about 5-Hour Energy. The State claims in effect that consumers are likely to be misled into purchasing 5-Hour Energy based on Defendants' purportedly false or misleading statements. The State cannot then insist that it does not matter whether those purportedly false or misleading statements would even be *material* to consumers' purchasing decisions. If consumers are not likely to purchase 5-Hour Energy based on Defendants' purportedly false or misleading statements, then certainly those statements did not cause them any commercial harm.

Indeed, the government's burden of "justifying" its suppression of speech "is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them *to a material degree*." *Edenfield*, 507 US at 770-71 (emphasis added); *see also Ibanez v. Fla. Dep't of Bus. and Prof. Regulation*, 512 US 136, 146, 114 S Ct 2084, 129 L Ed 2d 118 (1994) (rejecting attempt to suppress speech where government failed to "point to any harm that is potentially real, not purely hypothetical"). Consequently, the UTPA cannot be interpreted to prohibit every incidentally or potentially misleading statement. To violate the UTPA, a statement must be material to consumers' purchasing decisions. Thus, although the State of Oregon may have a legitimate interest in preventing consumers from being misled about Defendants' claims, its suppression of speech under the UTPA does not "directly advance" that interest under *Central Hudson*.[9]

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[9] Indeed, materiality is often considered an *inherent* component of any claim predicated on false or deceptive conduct; accordingly, federal courts routinely require materiality for statutory causes of action that prohibit such conduct, even where materiality is not explicitly required in the statute. *See, e.g.*, *United States v. Bourseau*, 531 F3d 1159, 1170-71 (9th Cir 2008) (concluding that federal False Claims Act requires materiality even in the absence of specific reference to materiality in the statutory text); *United States v. Alferahin*, 433 F3d 1148, 1156 (9th Cir 2006) (holding that statute prohibiting unlawful procurement of citizenship "contains a requirement of materiality").

CONCLUSION

For the foregoing reasons, *amicus curiae* CRN urge the Court to affirm the judgment in favor of Defendants.

Dated: January 31, 2018

Respectfully submitted,

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