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Federal Trade Commission
c/o Office of the Secretary
600 Pennsylvania Avenue, N.W.
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Washington, DC 20580

Via Overnight Mail
and Electronic Filing: https://ftcpublic.commentworks.com/ftc/ihealthconsent/

Re: In the Matter of i-Health, Inc. and Martek Biosciences Corporation
File No. 122 3067

Dear Chairwoman Ramirez and Commissioners:

The Organic and Natural Health Association ("ONHA"), a trade association of business and consumer groups, is dedicated to creating and promoting transparent business practices that safeguard access to organic and natural food, products and services. ONHA encourages research and clinical studies in the natural products industry to support development of rational standards for claims substantiation and the communication of truthful and non-misleading information. ONHA is pleased to submit these comments in response to the Federal Trade Commission's ("FTC" or "Commission") proposed settlement agreement containing a consent order ("Proposed Settlement")[1] in the Matter of i-Health, Inc. and Martek Biosciences Corporation (the "Companies"), File No. 122 3067.

While ONHA supports the Commission's efforts to protect consumers from false and misleading advertisements, ONHA respectfully disagrees with the Commission Staff's allegations, as set forth in the draft complaint,[2] that the Companies violated Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act")[3] by making the unsubstantiated representations that BrainStrong Adult ("the Product") improves memory in adults or prevents cognitive decline, when

[1] Federal Trade Commission, *i-Health, Inc. and Martek Biosciences Corporation; Analysis of Proposed Consent Order To Aid Public Comment*, Proposed Consent Agreement, 79 Fed. Reg. 33919 (June 13, 2014).
[2] *See*, Federal Trade Commission, *In the Matter of i-Health, Inc. and Martek Biosciences Corp*., Draft Complaint, *available at* http://www.ftc.gov/system/files/documents/cases/140609i-healthcmpt.pdf (alleging that the Companies violated Sections 5(a) and 12 of the FTC Act by making false or misleading representations that BrainStrong Adult "improves memory in adults", "prevents cognitive decline in adults", and is "clinically proven to improve memory in adults").
[3] 15 U.S.C. § 45.

such representations were based upon the results of the *Memory Improvement with Docosahexaenoic Acid (DHA) Study* ("MIDAS Study"). In a 485-person study, the MIDAS Study objectively tested both episodic and working memory, as well as the cognitive ability of executive function and demonstrated a statistically significant improvement in performance on episodic memory tasks. An improvement in episodic memory is indeed an improvement in memory, and, as Commissioner Ohlhausen pointed out in her dissent, "the claim accurately conveys the study's findings in consumer vernacular."[4]

The draft complaint and Proposed Settlement rest on the Commission Staff's attempt to second-guess the conclusions in the MIDAS Study, which ONHA respectfully submits is not sufficient to demonstrate that the Companies have violated the FTC Act by failing to have a "reasonable basis" to substantiate their claims.[5] The reasonable basis standard is a flexible one, and determination of what constitutes a reasonable basis depends on the claim, product, and views of experts in the field. Additionally, the claims must be viewed within the context of the advertising as a whole, with attention to factors such as "the entire document [and] the juxtaposition of various phrases in the document."[6] Pursuant to this substantiation standard, OHNA submits that the totality of clinical testing, studies, and expert evaluations provided by the Companies constitute a "reasonable basis" for the claims regarding BrainStrong Adult, and therefore, ONHA believes that the Companies have not violated the FTC Act as alleged in the draft complaint.

Further, the Proposed Settlement should be withdrawn because initiation of an enforcement action against the Companies in this case raises significant constitutional concerns and, therefore, is not in the public interest. The proposed order would ban claims drawn directly from the MIDAS Study. As discussed more fully in these comments, for the Commission to prohibit the Companies from disseminating advertisements based solely upon disagreement with the conclusions reached by experts in a published clinical study would violate the Companies' First and Fifth Amendment rights. A regulatory framework in which the FTC could ban commercial speech entirely by second guessing the conclusions of a randomized, peer-reviewed, and published clinical study would violate the intermediate scrutiny standard applicable to such commercial speech claims. Moreover, since the Commission has never established procedures or defined substantive criteria for determining what constitutes "competent and reliable scientific evidence" that is sufficient to

[4] *In the Matter of i-Health, Inc. and Martek Biosciences Corporation* June 5, 2014 (Commissioner Ohlhausen dissenting in part).
[5] It is well-established that when evaluating substantiation for advertising claims, the Commission requires a "reasonable basis" for advertising claims before they are disseminated. *See, e.g.*, FTC Policy Statement Regarding Advertising Substantiation (Mar. 11, 1983) appended to *Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987), *available at* http://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation.
[6] *See* In re Cliffdale Associates, Inc., 103 F.T.C. 110 (1984), *available at*: http://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception.

substantiate a claim, the Commission's regulatory framework is void for vagueness under the Fifth Amendment as applied to the Companies' claims because the Commission provided no information by which the Companies could conform their conduct to the FTC's interpretation of the law.

For these reasons, ONHA submits that the draft complaint and Proposed Settlement are not in the public interest, and ONHA requests that the Commission withdraw the Proposed Settlement in this matter and close this investigation. ONHA trusts that the Commission will consider seriously the arguments raised herein so that the comment period provided for in Rule 2.349(c) has a meaningful purpose, and ONHA thanks the Commission for its time and attention.

I. The Companies Provided Competent and Reliable Scientific Evidence to Support Their Dietary Supplement Claims

The standard for determining whether advertising claims are properly substantiated in accordance with Section 5 of the FTC Act, 15 U.S.C. § 45, is whether the advertiser has a "reasonable basis" for the claims it makes.[7] As the Commission stated in *In re Pfizer*, what constitutes a "reasonable basis" is a factual determination that depends on a variety of factors including: "the type of claim, the product . . . the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable."[8] The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with "competent and reliable scientific evidence."[9] This standard is flexible and has been defined broadly by the Commission to mean "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."[10]

As former FTC Chairman Robert Pitofsky has pointed out, the overall goal of evaluating advertising claims is not "a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn will facilitate an efficient and

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[7] The reasonable basis doctrine requires that firms have substantiation before disseminating a claim; however, the Commission noted that it may exercise discretion to consider supporting materials developed after disseminations. *See, e.g.*, FTC Policy Statement Regarding Advertising Substantiation (Mar. 11, 1983) appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987), *available at* http://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation.

[8] *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972).

[9] *See* FTC, *Dietary Supplements: An Advertising Guide for Industry*, ("*Dietary Supplements Guide*") *available at* http://business.ftc.gov/sites/default/files/pdf/bus09-dietary-supplements-advertising-guide-industry.pdf.

[10] *In re NordicTrack, Inc.*, 121 F.T.C. 907 (June 17, 1996).

reliable competitive market process."[11] Similarly, former Consumer Protection Bureau Director William MacLeod criticized overly zealous state agencies and public interest groups advocating for absolute scientific certainty. He expressed a fear that, under that line of analysis, "[t]he perfect could end up being the enemy of the good."[12]

a. The Evidence Required to Meet the "Competent and Reliable Scientific Evidence" Standard is a Question of Fact to be Determined by Experts in the Field

As numerous federal courts have held, the standard of what constitutes competent and reliable scientific evidence under Section 5 is a question of fact to be determined by experts in the field, not one of law. For example, in *FTC v. QT, Inc*. 512 F.3d 858, 861 (7th Cir. 2008), the Seventh Circuit explicitly held that "[n]othing in the Federal Trade Commission Act … requires placebo-controlled, double-blind studies. … [p]lacebo-controlled double-blind testing is not a legal requirement for consumer products." *See FTC v. Direct Marketing Concepts, Inc*., 624 F.3d 1, 9 (1st Cir. 2010) ("To be sure, there may be other scientific evidence that could be sufficient, and we may assume for these purposes that a double-blind study is not necessarily required."); *In re POM Wonderful*, Docket No. 9344, 2012 LEXIS 106, *538-542 (May 17, 2012) (level of substantiation question of fact determined by experts, not one of law). For establishment claims, where advertisements refer to a certain level of support, advertisers "must be able to demonstrate that the assertion is accurate [and] have the level of support that they claim, expressly or by implication, to have."[13]

FTC Commissioners have made clear in public speeches and opinions alike that the Commission has not departed from the basic principles of substantiation articulated in the *Pfizer* case, and that the amount and nature of substantiation required will in all instances depend on the nature of the product and on the type of claims being made. For example, in the *POM Wonderful* case (FTC Docket No. 9344), Commissioner Ohlhausen issued a concurring opinion disagreeing with the proposed order, which required a higher level of substantiation for certain health claims. She also cautioned that if the Commission is "too quick to find stronger claims than the ones reasonable consumers actually perceive, then we will inadvertently, but categorically, require an undue level of substantiation for those claims."[14]

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[11] Robert Pitofsky, Beyond Nader: Consumer Protection and the Regulation of Advertising, 90 HARV. L. REV. 661, 671 (1977).
[12] *MacLeod Discusses FTC's Analysis in Substantiating Advertisements,* 56 Antitrust & Trade Reg., Rep. (BNA) 672 (May 4, 1989).
[13] *See* FTC*, Dietary Supplements Guide*, at 9.
[14] *See In the Matter of POM Wonderful,* January 10, 2013 (Commissioner Ohlhausen, Concurring Statement).

Indeed, in an even more recent case involving *Genelink* (FTC File No. 112 3095), Commissioner Ohlhausen issued a dissent questioning the Commission's wisdom of imposing an "unduly high standard" of substantiation. She noted that "adopting a one-size-fits-all approach to substantiation by imposing such rigorous and possibly costly requirements for such a broad category of health and disease-related claims may, in many instances, prevent useful information from reaching consumers in the marketplace and ultimately make consumers worse off."[15] Commissioner Ohlhausen, citing the *Pfizer* factors, correctly observed that one of the goals of the *Pfizer* analysis is to "balance the value of greater certainty of information about a product's claimed attributes with the risks of both the product itself and the suppression of potentially useful information about it."[16] This balancing test is substantially similar to those all federal regulatory agencies must apply under the First Amendment in assessing claims for products sold to consumers.[17]

Here, the Companies meet the "competent and reliable scientific evidence" standard based on the results of the MIDAS Study, a published, peer-reviewed, placebo-controlled clinical trial which objectively tested both episodic and working memory, as well as the cognitive ability of executive function. Though the Commission disagrees with some of the conclusions reached by the authors of the MIDAS Study, the test for adequate substantiation of a dietary supplement claim is not scientific unanimity. Prohibiting such important clinical information from being communicated would deprive consumers of important, relevant, and substantiated information about brain health. To again quote Commissioner Ohlhausen's statement in *GeneLink*:

> If we demand too high a level of substantiation in pursuit of certainty, we risk losing the benefits to consumers of having access to information about emerging areas of science and the corresponding pressure on firms to compete on the health features of their products.[18]

Similarly, Commissioner Wright also encouraged the Commission to "explore more fully whether the articulation and scope of injunctive relief … strikes the right balance between deterring deceptive advertising and preserving for consumers the benefits of truthful claims."[19] He

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[15] *See In the Matter of GeneLink, Inc.*, January 7, 2014 (Commissioner Ohlhausen, Dissenting in Part and Concurring in Part).
[16] *Id.*
[17] *See, e.g.*, *Pearson v. Shalala*, 164 F.3d 650, 651 (1999).
[18] *See* Statement of Commissioner Maureen K. Ohlhausen, Dissenting in Part and Concurring in Part, In the Matter of GeneLink, Inc., et al., FTC Docket No. C4456, at 2 (Jan. 7, 2014) *available at* http://www.ftc.gov/sites/default/files/documents/cases/140107genelinkstatementohlhausen.pdf.
[19] *See* Statement of Commissioner Joshua D. Wright, In the Matter of GeneLink, Inc., et al., FTC Docket No. C4456, at 1(Jan. 7, 2014) *available at* http://www.ftc.gov/sites/default/files/documents/cases/140107genelinkstatemenwright.pdf

went on to note that the "optimal amount and type of evidence to substantiate a future claim will vary from case to case."[20]

II. The Commission's Second-Guessing of Published Clinical Studies Chills Commercial Speech in Violation of the First Amendment

If the Commission pursues an enforcement action against the Companies based upon questioning the analysis in the published MIDAS Study, it will establish a regulatory paradigm that will adversely affect consumers because advertisers will refrain from providing truthful and nonmisleading information about their products for fear of government prosecution. While the Commission has authority to prohibit false and misleading advertising, if it were to continue to construe the substantiation standard to punish the Companies for making these claims and prohibit further communications to consumers, it would trample the First Amendment by suppressing claims in advertisements that are backed by a randomized, peer-reviewed and published clinical study.

a. The Proposed Over-Zealous Application of the Commission's Substantiation Framework Would Have a Chilling Effect on Commercial Speech

As stated above, the Commission possesses authority under the FTC Act to limit false or misleading advertisements by requiring advertisers to possess a "reasonable basis" for all product claims.[21] In the context of dietary supplement advertisements, this standard has been interpreted to require "competent and reliable scientific evidence," for which a wide range of evidence may satisfy the standard, depending on the claim at issue. Case law construing the substantiation standard provides dietary supplement advertisers with guidance as to the type of evidence that is likely to be required to ensure their claims are not false and misleading under the law, and the Companies' published clinical study comfortably satisfies that standard.

In accordance with the "competent and reliable scientific evidence" standard, the Companies based their advertising claims on the results of the MIDAS Study. Despite the Companies' process to substantiate product claims, the Commission is now changing its application of the substantiation standard by second guessing the conclusion reached in the study.

This kind of regulatory framework, one by which the Commission may pursue enforcement action against advertisers if the Commission's undisclosed experts happen to question the conclusions of a published clinical study, would leave all advertisers in constant fear that their

[20] *Id.*
[21] 15 U.S.C. § 45; *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972).

truthful and nonmisleading speech will be subject to civil and administrative penalties. With respect, the Commission does not have the statutory authority, expertise, or resources necessary to make an accurate assessment of the conclusions of published scientific studies. The risk that the Commission will bring similar enforcement actions will have the effect of deterring advertisers from engaging in commercial speech of value to consumers – thereby chilling speech related to the safety and efficacy of foods and other health products. The regulatory scheme would also likely have the perverse effect of disincentivizing advertisers from spending the time, money, and resources required to develop clinical studies to support their claims.[22]

In delegating to the Commission the authority to regulate false and misleading advertisements under the 1938 Wheeler-Lea Amendments,[23] Congress expressly emphasized the constitutional concerns posed by a law that penalized an advertisement regarding the truth of which qualified opinion differs. Specifically, Congress noted that:

> [I]f Congress were to provide that a representation, as to the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view, but not misleading if the jury agreed with the experts holding the other view, it will be seen that the advertiser would not be able to tell in advance whether his advertisement violated the statute.[24]

In addition to the due process concerns under the Fifth Amendment, which are discussed further below, this assessment demonstrates Congress's concern that the fear of government investigation and liability based upon divergent views of qualified experts would have the effect of limiting advertisers from engaging in truthful and non-misleading speech. Initiating an enforcement action against the Companies, based on its disagreement with the conclusions drawn by the authors of the peer-reviewed MIDAS Study, would create pervasive uncertainly regarding whether the FTC might pursue enforcement action in other cases after evaluating and questioning the particular methods used in a clinical study. This chilling uncertainty would trample the First Amendment by imposing a *de facto* ban on truthful and non-misleading speech, including in this case, the Companies' speech for BrainStrong Adult.

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[22] *See In the Matter of i-Health, Inc. and Martek Biosciences Corporation* June 5, 2014 (Commissioner Ohlausen, e Dissenting in Part) (asserting that an "unduly high standard not only risks denying consumers useful information in the present but may also, in the long term, diminish incentives to conduct research on the health effects of foods and dietary supplements and reduce the incentives of manufacturers to introduce such products").
[23] Wheeler-Lea Act of 1938, ch. 49, Pub. L. No. 75-447, 52 Stat. 111(1938).
[24] House Report H.R. Rep. No. 1613, p. 6 (Aug. 19, 1937).

b. The Commercial Speech at Issue Is Protected by the First Amendment

The First Amendment protects commercial speech including advertising.[25] Only where the speech is "inherently" misleading "or where the record indicates that a particular form or method of advertising *has in fact* been deceptive does the First Amendment protection lapse."[26] Courts have long cautioned that in order "to avoid chilling protected speech, the government must bear the burden of proving that the speech it seeks to prohibit is unprotected."[27] To be sure, allegations that speech is "potentially misleading" are not sufficient to render the speech devoid of First Amendment protection.[28]

The disagreement between the MIDAS Study's authors and the FTC's experts concerning the substantiation for BrainStrong Adult does not render the advertising inherently misleading. The Supreme Court has categorized speech as "inherently misleading" only in situations where evidence in the record makes the deception self-evident or the speech itself is misleading on its face. For example, in *Ohralik v. Ohio State Bar Ass'n*,[29] the Supreme Could held that in-person solicitation by lawyers of accident victims was inherently misleading because of a demonstrated potential for exertion of pressure; however, public advertisements that provide "an opportunity for comparison and reflection," which do not raise the same concerns, cannot be inherently misleading.[30] Subsequent case law makes clear that commercial speech is not automatically declared as "inherently misleading" on the government's say-so or the say-so of its undisclosed experts who may interpret test results differently than the authors of a published study.[31]

Indeed, even advertising that raises significant dangers of misleading consumers cannot be prohibited and punished "if the information also may be presented in a way that is not deceptive."[32] As discussed above, the Companies' advertising provided consumers a significant source of truthful and accurate information about important brain functioning.

Similarly, there is no evidence that the claims made by the Companies have in fact been deceptive. To the contrary, the Companies have "gold standard" substantiation—the results of a randomized, double-blind study published in a peer-reviewed medical journal and expert opinions based on that study to substantiate its claim.

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[25] *See Va. State Rd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).
[26] *In re R.M.J.*, 455 U.S. 191, 202 (1982) (emphasis added); *see id.* at 203; *Peel*, 496 U.S. at 105-06 (plurality opinion).
[27] *Illinois ex rel. Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 620 n.9 (2003).
[28] *Cen. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of New York,* 447 U.S. 557, 566 (1980).
[29] 436 U.S. 447 (1978).
[30] Id. at 457.
[31] *See, e.g.*, *Ibanez v. Fla. Dep't. of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 146 (1994); *Pearson v. Shalala,* 164 F.3d 650, 655 (1999).
[32] *R.M.J.*, 455 U.S. at 203.

c. The Commission's Speech Restriction Would Not Survive First Amendment Scrutiny under the *Central Hudson* Test

As the D.C. Circuit emphasized in *Pearson v. Shalala*,[33] even where commercial speech is "potentially misleading," the Court must apply the First Amendment analysis set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*[34] to determine the constitutional validly of a commercial speech restriction.[35] To justify a speech ban the government must bear the burden of proof in demonstrating the misleading nature of the speech. The Supreme Court does not allow "rote invocation" of the phrase "potentially misleading" to justify speech bans.[36] The *Pearson* court recognized that the First Amendment protects people from government suppression of commercial information if that prohibition on communication rests upon the "paternalistic assumption" that an ordinary consumer is unable to make an informed independent judgment about the truthfulness of health claims for dietary supplements.[37] Indeed, from the beginning of the development of its First Amendment commercial speech doctrine set forth in *Central Hudson,* the Supreme Court has repeatedly cautioned that the "First Amendment directs [the Court] to be especially skeptical of regulations . . . that seek to keep people in the dark for what the government perceives to be their own good."[38] "[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented."[39]

Given the First Amendment's strong preference for access to information rather than suppression of speech, the regulation of protected commercial speech will only survive First Amendment scrutiny under *Central Hudson* if the government satisfies its burden of proving that: (1) the government's asserted interest in regulating the speech is "substantial"; (2) the restriction seeks to "directly advance" the asserted interest; and (3) is not broader than necessary to achieve that interest.[40] Even assuming that the Commission has a "substantial" interest in restricting misleading advertising to protect against consumer deception and limit economic harm to consumers, the FTC's attempt to ban the Companies' speech based upon a disagreement of the conclusion expressed in a published clinical study would not be sufficient to carry its constitutional burden of proof under the *Central Hudson* factors.

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[33] 164 F.3d 650 (1999).
[34] 447 U.S. 557, 566 (1980).
[35] *See Pearson,* 164 F.3d at 655.
[36] *See Ibanez v. Fla. Dep't. of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 146 (1994); *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 376 (2002).
[37] *Pearson,* 164 F.3d at 655.
[38] *Sorrell v. IMS Health, Inc.*, 131 S.Ct. 2653, 2671 (2011) (quoting *44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484, 503, 116 S.Ct. 1495, 134 L.Ed.2d 711 (1996) (opinion of Stevens, J., joined by Kennedy, J., and Ginsburg, J.).
[39] *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).
[40] *Central Hudson*, 447 U.S. at 566.

i. The Commission would not "directly advance" a "substantial interest" in restricting the Companies' speech

Though preventing consumers from suffering economic injuries and preventing deception in the marketplace is an important governmental interest that may be achieved by restricting misleading speech, in this case, the Commission would have faced difficulty demonstrating that the Companies' speech is misleading and, therefore, would result in any harm to consumers. Further, in order to satisfy First Amendment scrutiny, the Commission must demonstrate that its tactics used to prohibit the Companies' speech (*i.e.,* second-guessing the analysis of the MIDAS Study) will "directly advance[]" the government's interest, a burden that "is not light."[41] Specifically, the Commission must present "substantial evidence" showing that the speech restriction will "in fact alleviate [the harms] to a material degree;" it cannot rely on "mere speculation or conjecture."[42] Here, the Commission has not provided any evidence that the Companies' Product does not work or that the speech would otherwise harm the public to a material degree. Accordingly, a ban on this speech would not directly advance any substantial governmental interest.

Under *Central Hudson,* the Commission would be required to demonstrate that it has a "substantial interest" in banning speech that relates to the conclusions of a double-blind, published, peer-reviewed study regarding cognitive health benefits—a significant challenge given the facts of this case. In order to meet its burden, the FTC first would have to demonstrate that the Companies' speech is misleading in a manner that will result in economic harm or fraud on the public, and therefore, the government has an interest in suppressing the speech. The Supreme Court emphasized the government's heavy burden under this *Central Hudson* prong in *In the Matter of R. M. J.* when it held that a particular attorney advertisement could not be "prohibited entirely," because there was nothing the record to show that the ad was either inherently likely to deceive or that the ad had "in fact been deceptive."[43] *Central Hudson* and its progeny emphasize that the government cannot shift or avoid its burden of proof by requiring an advertiser—who has already satisfied its burden to provide a "reasonable basis" to substantiate claims—to also prove that is speech is not misleading.

While it may be reasonable to assume that the Commission would have a substantial interest in prohibiting health claims that are not backed by *any* credible scientific evidence (and therefore likely misleading), in this case, the government would face an uphill battle in demonstrating that consumers are likely to be "harmed to a material degree" if they are permitted access to conclusions based upon a published peer-reviewed clinical trial on brain health. Courts are directed to be "particularly skeptical" of speech restrictions that limit consumers' ability to

[41] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1218, 1222 (D.C.C. 2012).
[42] *Edenfield v. Fane*, 507 U.S. 761, 767, 770-771 (1993).
[43] 455 U.S. 191, 202 (1982).

compare and evaluate information.[44] The Commission's entire case rests on a scientific disagreement; such a dispute would not be enough for the government to meet its to burden in demonstrating that the Companies' speech is false or misleading in a manner that is likely to cause consumer harm, or that the government's choice to suppress that speech will alleviate any alleged harm.

When applying the *Central Hudson* factors, reviewing courts have also required that the speech restriction meet certain standards of consistency and rationality to "directly advance" the government's interest.[45] In this case, even assuming *arguendo* that the Commission's ban directly advances its interest in preventing deception, the ability of the Commission to constantly second guess the conclusions reached in a published clinical study effectively would permit the Commission to pick and choose on an arbitrary basis which peer-reviewed clinical studies will be deemed to satisfy its substantiation standards. Such a framework will result in an inconsistent application of the amount, type, and strength of scientific evidence that is necessary to support a particular claim—resulting in inconsistent bans on speech and a consequent substantial chill on protected commercial speech. Accordingly, the Commission's approach fails the "direct advancement" prong of *Central Hudson* and violates the First Amendment.

ii. The FTC's Ban is more extensive than necessary to achieve its interest

Central Hudson's third prong, analyzing whether the government's speech restriction is more extensive than necessary, requires a consideration of whether there is a "reasonable fit" between the Commission's asserted interest and the means chosen to advance that interest. In so doing, the courts will look to see if the restriction "disregard[s] far less restrictive and more precise means" of achieving the interest asserted. Based upon analysis in *Pearson v. Shalala*, a case with substantially similar facts to the instant situation, and cases relying on *Pearson*, the FTC's attempt to impose a broad ban on the Companies' speech because of a scientific disagreement will not satisfy the "reasonable fit" standard.

In *Pearson v. Shalala*, the FDA sought to prohibit a dietary supplement manufacturer from making health claims about its product on the grounds that the scientific support for such claims did not satisfy FDA's "substantial scientific agreement" standard.[46] In response to the manufacturer's assertions that the speech restriction violated the First Amendment, the Court applied *Central Hudson* to determine whether the government's ban on speech could withstand constitutional

[44] *See Sorrell,* 131 S.Ct. at 2671.
[45] *See Greater New Orleans Broad. Ass'n, Inc. v. United States* 527 U.S. 191, 193-94 (rejecting a ban on casino advertising that prohibited certain types of casino ads but not others, noting that speech restrictions that suppress the speech of one group of speakers while allowing virtually identical messages was "in serious tension" with the First Amendment).
[46] *Pearson,* 164 F.3d at 651.

scrutiny.[47] The Court held that even assuming the government had a substantial interest in regulating the speech and its ban directly advanced that interest, the prohibition on speech violated the First Amendment because a preference to prohibit speech (rather than considering mere disclosures) was not a "reasonable fit" between the government's interest and the means chosen to achieve that interest.[48] The *Pearson* court emphasized that where the government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure an allegedly misleading statement—government disregards a "*far less restrictive means*" of achieving its asserted interest and thereby violated the First Amendment.[49]

Similarly, in *Whitaker v. Thompson,*[50] the court found that where a proposed health claim for a dietary supplement was not inherently misleading, the "FDA ha[d] failed to carry its burden of showing that suppression of the [claim was] the least restrictive means of protecting consumers against the potential of being misled by the Claim."[51] The court suggested that "any complete ban of a claim would be approved only under narrow circumstances, *i.e.*, when there was almost no qualitative evidence in support of the claim and where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer." Relying on *Pearson*, the *Whitaker* court emphasized the well-established proposition that bans on commercial speech will generally not withstand constitutional scrutiny unless the government can prove that the speech is inherently misleading and not subject to First Amendment protection.

Applying *Pearson* and *Whitaker* to the facts of this case, the FTC's preference to ban the Companies' speech rather than consider the conclusions expressed in a published study to support product claims demonstrates an unwillingness to consider "a far less restrictive means," to achieve the government's interest in preventing consumer fraud and deception. While the First Amendment prevents the Commission from barring speech based on clinical results where there exists clear agreement in the scientific community that such results relied on methods or analysis that have been debunked by the scientific community, the clinical evidence presented by the Companies stands in a fundamentally different position.

Accordingly, the Commission's preference essentially to ban speech, rather than considering the possibility that these alternative conclusions can provide truthful and non-misleading information, expressly violates the principle that "any restrictions imposed on deceptive commercial speech can be no 'broader than reasonably necessary to prevent the deception.'"[52] As

[47] *Id*. at 655.
[48] *Id*. at 656
[49] *Id*. at 657 (emphasis added).
[50] 248 F.Supp.2d 1 (D.D.C. 2002).
[51] *Id*. at 8.
[52] *Brown & Williamson*, 778 F.2d at 43 (quoting *R.M.J.*, 455 U.S. at 203).

with *Pearson*, the government's failure to consider a less restrictive means of regulating speech would cause the FTC's actions to fail the third prong of *Central Hudson*, thereby rendering the restriction on the Companies' speech unconstitutional.

III. As Applied Here, the FTC's Substantiation Framework Violates the Due Process Clause of The Fifth Amendment

An attempt to punish the Companies for advertising the conclusions of this clinical study would also conflict with the Due Process Clause of the Fifth Amendment because the FTC's substantiation standard would be unconstitutionally vague. The Supreme Court has repeatedly held that the regulated parties must know what is required of them so they may act accordingly. In the context of speech restrictions, this requirement is particularly critical because the Commission's failure to provide such clear standards unconstitutionally chills protected speech.

As applied to the Companies' speech, the FTC's second guessing of the conclusions reached in a published study violates the Due Process Clause because no notice was provided to the Companies that these conclusions would not substantiate the claims for BrainStrong Adult. Further, the FTC's construction of the substantiation standard to allow questioning of published clinical study data is unconstitutionally vague because advertisers lack clarity or guidance as to the criteria the FTC might demand when reviewing the adequacy of substantiation. The denial of due process would be manifest here where the Companies possess a peer-reviewed controlled clinical study to support their claims.

a. The FTC Failed to Provide the Companies Sufficient Notice Regarding the Substantiation Requirements

In considering the adequacy of substantiation for dietary supplement claims, the Commission does not have explicit statutory authority to assess the scientific reliability of randomly controlled tests or the expertise to make an independent assessment of the validity of peer-reviewed medical studies published in bona fide medical journals. The Commission relies instead on its general power provided by Section 5 of the FTC Act to prevent deceptive behavior as the basis for its claimed ability to review published medical studies and make an independent determination whether they provide adequate substantiation for a claim made by a vendor of a dietary supplement. Section 5 does not set forth any criteria the Commission must follow in conducting the assessment of whether such a claim is appropriately substantiated, and the FTC has not adopted any rules that inform entities of the procedures it will follow or the standards it will apply in determining what constitutes competent and reliable scientific evidence for a claim. Rather, the Commission has left regulated entities in a void. It has provided vendors of dietary supplements with no notice of the criteria it will apply to judge whether their claims are substantiated. As a result, they are unable to conform their actions to the law to be applied.

While the FTC has long maintained a flexible substantiation standard by permitting a wide range of competent and reliable scientific evidence, the Commission's attempt to now proscribe the Companies' speech by second guessing published studies, without adequate prior notice violates the Due Process Clause.[53] A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. Precision in informing the public of the standards to be applied is required so that those enforcing the law do not act in an arbitrary or discriminatory manner.[54] Where speech is involved, the Supreme Court notes that "rigorous adherence" to these principles is "necessary to ensure that ambiguity does not chill protected speech."[55]

The Supreme Court's decision in *Lanzetta v. State of New Jersey*[56] is one of the earliest of a long line of Supreme Court cases insisting that the government provide fair notice of the offending conduct.[57] The *Lanzetta* court was called on to decide whether, by reason of vagueness and uncertainty, a New Jersey statute violated due process when the law made it a crime for a person known to be a member of "any gang" to be "not engaged in lawful occupation."[58] The *Lanzetta* court found that the term "gang" was not reasonably defined by the statute so that an individual could not have adequate notice of whether he or she was in violation of the law.[59] In striking down the statute, the Supreme Court emphasized "[l]iving under a rule of law entails various suppositions, one of which is that '[all persons] are entitled to be informed as to what the State commands or forbids.'"[60]

Citing *Lanzetta*, the Supreme Court in *FCC v. Fox Television Stations, Inc.* ("*Fox II"*), evaluated whether the Federal Communication Commission's changed interpretation of its indecency policy to prohibit so called "fleeting expletives" was unconstitutionally vague, when the broadcasters were not provided with adequate prior notice that they would be fined for

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[53] *See United States v. Williams*, 553 U.S. 285, 304, 128 S.Ct. 1830, 170 L.Ed.2d 650 (2008).
[54] *See Connally v. Gen. Constr. Co*., 269 U.S. 385, 391 (1926) ("[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law"); *Papachristou v. Jacksonville*, 405 U.S. 156 (1972).
[55] *See FCC v. Fox Television Stations*, 132 S. Ct. 2307 (2012) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108-109 (1972)).
[56] 306 U.S. 451 (1939).
[57] *Papachristou v. Jacksonville*, 405 U.S. 156, 162 (1972).
[58] The statute at issue in *Lanzetta* was challenged on due process grounds under the Fourteenth Amendment, the Supreme Court has interpreted those two clauses identically, as Justice Felix Frankfurter once explained in a concurring opinion: "To suppose that 'due process of law' meant one thing in the Fifth Amendment and another in the Fourteenth is too frivolous to require elaborate rejection." *Malinski v. New York*, 324 U.S. 401, 415 (1945) (Frankfurter, J., concurring).
[59] *Id*. at 458; *see also Connally v. General Constr. Co*., 269 U.S. 385 (1926) (overturning an Oklahoma statute related to hourly wage requirements given the lack of clarity regarding the type of conduct proscribed by the statute).
[60] *Fox II.* (citing inter alia *Champlin Rfg. Co. v. Commission*, 286 U.S. 210, 242, 243).

broadcasting such speech.[61] The *Fox II* Court overturned the FCC's enforcement action against the broadcasters because the FCC's changed interpretation "fail[ed] to provide a person of ordinary intelligence fair notice of what is prohibited" and was therefore unconstitutionally vague under the Fifth Amendment. In so holding, the *Fox II* Court emphasized that clarity in regulatory enforcement is particularly heighted where the regulations touch upon "sensitive areas of basic First Amendment freedoms."[62] Similarly, in *Reno v. American Civil Liberties Union*,[63] the Supreme Court struck down an FCC statute aimed at prohibiting standards of "patently offensive" and "indecent" speech over the internet. It held that "the absence of a definition of either term . . . will provoke uncertainty among speakers about how the two standards relate to each other and just what they mean", which would have an "obvious chilling effect on speech" in violation of the First Amendment.[64]

In this case, the Fifth Amendment due process concerns set forth in *Lanzetta* and *Fox II,* and the related First Amendment concerns emphasized in *Reno,* are implicated because the Companies did not have sufficient notice that the government would second guess the results of a published study to support the Companies' claims.

b. An Enforcement Action Based on Second-Guessing a Randomized, Peer-Reviewed and Published Clinical Study Design Violates the Void-for-Vagueness Doctrine for Failure to Provide the Companies with Adequate Notice of the Substantiation Standard To Be Applied

If the FTC was permitted to pursue an enforcement action every time its experts had divergent views as to the methods and analysis used in a peer-reviewed study, it would create a regulatory framework with such uncertainty that advertisers would have no way of determining whether their claims may be construed by the Commission as a false advertisement in violation of Section 5 of the FTC Act. Such a regime would not pass constitutional muster under the Due Process Clause.

As stated above, when designating the Commission authority to restrict false advertising, Congress noted the constitutional concerns raised by a policy which permitted the FTC to find an advertisement false and misleading based upon differing opinions between experts regarding the truthfulness of advertisements. Specifically, Congress noted that were the statute to render a claim false or misleading in the event that experts disagreed over the claim, "there would therefore exist

[61] 132 S. Ct. 2307 (2012).
[62] *See id.* (quoting *Baggett v. Bullitt,* 377 U.S. 360, 372 (1964); *see also Reno v. American Civil Liberties Union,* 521 U.S. 844, 870-871 (1997) ("The vagueness of [a content-based regulation of speech] raises special First Amendment concerns because of its obvious chilling effect").
[63] 521 U.S. 844 (1997).
[64] *Id*. at 871.

the kind of uncertainty which would invalidate the [FCT Act]."[65] Accordingly, Congress declined to provide the FTC the authority to prohibit speech merely because experts disagreed.

The framework that Congress intended to impose is consistent with fundamental legal principles; otherwise, advertisers would have no way of knowing whether—at any time—the Commission might determine that it disagreed with the findings of a clinical study and that the thereby had violated Section 5. The Fifth Amendment directs the Commission to provide clarity regarding when and whether an advertiser will be considered in violation of the FTC Act. Further, courts have found that the views of an FTC expert do not inherently receive deference under the law. For example, in *FTC v. Garden of Life*,[66] the court of appeals deferred to the lower court's assessment regarding a so-called "battle of the experts" case. It concluded that the FTC had failed to establish that the advertiser violated a contempt order when the FTC disagreed with the advertiser's expert regarding the accuracy of scientific data to support claims.[67]

Consistent with case law and Congress's findings, expert opinions can differ with respect to the validity of science to support advertising claims. As Commissioner Ohlhausen noted in dissenting from the proposed complaint here, this is the nature of science.[68] Accordingly, a framework in which the FTC's substantiation requirements depend ultimately on whether a particular government expert accepts the validity of the method, analysis, and conclusions in a published clinical study would leave advertisers constantly wondering whether their substantiation is sufficient so as to avoid government prosecution and penalties—even in cases where the advertiser has relied on a well-controlled clinical study. To leave substantiation completely at the discretion of a government consultant expert without any further guidance on what elements, methods, or analysis are required in clinical studies would be to create a regulatory requirement that is impermissibly vague in violation of the Fifth Amendment.

IV. Conclusion

The Commission's draft complaint and Proposed Settlement with i-Health, Inc. and Martek Biosciences Corporation rests on the Commission Staff's attempt to second-guess the conclusions in the Companies' MIDAS Study. This ground alone is not sufficient to demonstrate that the Companies have violated the FTC Act by failing to satisfy their burden to provide a "reasonable basis" to substantiate their claims for BrainStrong Adult. Further, a regulatory framework in which the FTC may ban commercial speech by second guessing the conclusions of a randomized, peer-reviewed, and published clinical study would violate both the First and Fifth Amendments. If

[65] House Report H.R. Rep. No. 1613, p. 6 (Aug. 19, 1937).
[66] 516 Fed. Appx. 852 (11th Cir. 2013).
[67] *Id.*
[68] *In the Matter of i-Health, Inc. and Martek Biosciences Corporation* June 5, 2014 (Commissioner Ohlhausen dissenting in part) ("disagreement is the usual state of science").

challenged, ONHA respectfully submits that the government would fail to meet its burden under the First Amendment to demonstrate that speech supported by such scientific data is false or misleading in a manner that is likely to cause consumer harm, or that the government's choice to suppress the speech will alleviate any alleged harm. Moreover, a structure in which the FTC's substantiation requirements depend ultimately on whether a particular undisclosed government expert accepts the validity of the conclusions reached in a published study is impermissibly vague under the Fifth Amendment because it would confuse all advertisers as to whether their substantiation, even if in the form of a well-controlled clinical study, is enough to avoid Commission enforcement.

For the foregoing reasons, ONHA respectfully requests that the Commission withdraw the Proposed Settlement and close this investigation consistent with principles set forth in these comments.

Respectfully submitted,

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