November 13, 2019

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RE: Public Comment on Proposed Health Benefit Substantiation Rule

On behalf of the Council for Responsible Nutrition ("CRN")[1], the leading trade association that represents dietary supplement and functional food manufacturers and ingredient suppliers, and the American Herbal Products Association (AHPA),[2] the trade association and voice of the herbal products industry, we are submitting comments on the following proposed rulemaking by the Oregon Department of Justice, which would add, to the Oregon Administrative Rules, a new Rule 137-020-0900 (the "Proposed Rule"):

"Representations Regarding Health Benefits of Goods

"It is unfair and deceptive for an advertiser or seller to make a representation of fact about a health benefit of a good without first having competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation."

Comments on Proposed Rule

[1] The Council for Responsible Nutrition ("CRN"), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

[2] Founded in 1982, the American Herbal Products Association ("AHPA") is the national trade association and voice of the herbal products industry. AHPA is comprised of more than 350 member companies, consisting primarily of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products as foods, dietary supplements, cosmetics, and non-prescription drugs, and also including companies that provide expert services to the herbal trade. AHPA's mission is to promote the responsible commerce of herbal products to ensure that consumers continue to enjoy informed access to a wide variety of herbal goods. www.ahpa.org.

CRN and AHPA support the comments that are being submitted by the Oregon Liability Reform Coalition, NW Grocery Association, Oregon Chambers of Commerce, dietary supplement trade associations – including CRN and AHPA – and numerous other industry representatives ("November 2019 Industry Coalition Letter").

In addition, CRN and AHPA are extremely concerned that the Proposed Rule could have a substantial, albeit unintended, negative impact on public health, as explained in more detail below. CRN and AHPA, as representatives for dietary supplement and functional food companies, are able to provide a unique perspective on how this Proposed Rule could affect public health by limiting consumers' access to truthful, beneficial information about the health benefits of dietary supplements.

CRN and AHPA are further concerned that a number of terms in the Proposed Rule are ambiguous and would place additional burden on Oregon businesses, as well as deter them from providing important information to consumers. Finally, CRN and AHPA believe that this rule is unnecessary as Oregon regulators already have authority under current Oregon laws to deter bad actors who are making false and misleading claims about the benefits a product provides, including health benefits.

The Proposed Rule Would Create a Private Right of Action Detrimental to Public Health

CRN and AHPA are very concerned that the Proposed Rule will create a private right of action that could allow private plaintiffs to initiate a lawsuit simply by alleging – without engaging in scientific evaluation or public interest analysis – that a company making a health benefit claim does not have competent and reliable scientific evidence to support the claim.[3] The Notice of Proposed Rulemaking notably does not recognize this substantial consequence of the proposed rule or indicate that it was discussed during the consultation process leading to the rule's introduction. If it was, there is no mention in the assessment of the Fiscal and Economic Impact or the Cost of Compliance sections of the onerous burden that a private right of action would place on small and large businesses or its impact on public health.

Fundamental considerations compel CRN, AHPA, and others, to highlight this serious consequence of the rule as proposed. A private right of action would stand as an aberration from the practices of numerous jurisdictions supported by their respective courts – that only regulators can bring a lawsuit based on an alleged lack of substantiation.[4] Private plaintiffs, on the other hand, must prove that the claim being made is actually false. This distinction between public and private actions serves critical functions. Not only does it protect businesses from the burden of defending baseless litigation, but more importantly, it has the primary purpose of protecting public health by ensuring that substantiation is reviewed by government actors who are uniquely equipped with scientific expertise and a public interest mindset. Specifically, the distinction appropriately recognizes that government actors are best positioned to consider, impartially, complex bodies of scientific literature and issue uniform pronouncements while weighing the public health benefits.

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[3] Once the Oregon Department of Justice has promulgated a regulation pursuant to ORS § 646.608(4) defining a practice as "deceptive" under ORS § 646.608(1)(u), that practice becomes eligible for enforcement by private parties, as well as the AG, pursuant to ORS § 646.638(1). *See, e.g.*, *Scharfstein v. BP W. Coast Products, LLC*, 423 P.3d 757, 762 (Or. App. 2018).

[4] *See e.g., Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.,* 107 Cal. App. 4th 1336 (2003); *Kwan v. SanMedica Int'l*. 854 F.3d 1096 (9th Cir. 2017); *In re GNC*, 789 F.3d 505 (4th Cir. 2015); and *Quinn v. Walgreen Co.*, 958 F.Supp.2d 533 (S.D.N.Y. 2013).

Given the complexities of nutrition science and regulators' unique expertise and public health mindset and motivation, this discrete group should continue to be the sole arbiters in weighing substantiation. If private actors are independently allowed to demand substantiation and seize on any inconsistency or weakness that might be found in a complex body of research to allege that an advertiser does not have competent and reliable scientific evidence to support a claim, both advertisers – and consumers who rely on their products – stand to be harmed. Allowing a patchwork of conflicting private actor-driven decisions on any single dietary ingredient stands to dilute the significance and authority of expert government actors and discourage manufacturers from innovating in the nutrition space, or disseminating health benefit claims at all.

This concern is not idle speculation. There are a number of illustrative cases in which allowing private actors to determine via litigation whether a claim was supported likely would have been substantially detrimental to public health. A notable example is the Food and Drug Administration's ("FDA") approval process for a health claim regarding folic acid. That case study clearly illustrates the complexity of nutritional science and why, as a matter of public policy, our regulatory system entrusts experts with the authority to weigh the science with public health considerations in mind -- which they routinely do to the benefit of all society.[5]

In determining whether to authorize a claim associating folic acid intake with reduced risk of neural tube defects, FDA convened a subcommittee of scientists to assist in its review and sought comments from stakeholders, including other agencies, healthcare professionals, and industry. At the time, only a small number of studies demonstrated a link between folic acid and reduced risk of neural tube defects. FDA reviewed numerous comments representing divergent views – even its own convened subcommittee did not reach consensus on authorizing the claim. Despite the divergent views, FDA authorized a claim, determining that enough consistent evidence existed and "it . . . expected that consumption of adequate folate will avert some, but not all, neural tube defects."[6] At the same time, based on the available scientific evidence, FDA mandated that enriched cereal grain products be fortified with folic acid.

The increased awareness of and access to folic acid has no doubt significantly affected public health positively. Between 1995 and 2011, the Centers for Disease Control reported a substantial 28 percent reduction in neural tube defects and an even higher 35 percent reduction among programs with prenatal ascertainment.[7] Had private parties possessed the means of independently contesting FDA's decision and directly suing companies that complied with the regulator's carefully-considered judgment, however, this triumph for public health would not have been possible. The thoughtful process engaged in by government officials motivated by concern for public health – as opposed to maximizing recoveries in litigation – demonstrates how if health-related science is not assessed with flexibility by experts with a public interest mindset, consumers and the general welfare stand to lose.

If the Proposed Rule were to move forward, CRN and AHPA emphasize that limiting the regulation to enforcement only by regulators, such as the Oregon Department of Justice, is necessary to help avoid

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[5] FDA has the authority to authorize "health claims", which are claims that associate a dietary substance with a reduction in a disease risk. 21 U.S.C. § 343(r)(1)(B); 21 CFR § 101.14(a)(1).

[6] 61 Fed. Reg. 8752, 8780 (Mar. 5, 1996).

[7] Williams, *et al.* Update Estimates of Neural Tube Defects Prevented by Mandatory Folic Acid Fortification – United States, 1995-2011 (Jan. 16, 2015).

unintended negative consequences for public health and consumer welfare. The evidence underlying health benefit claims for dietary supplements, food, and other products is often extremely complex, with studies utilizing a variety of designs and sometimes yielding inconsistent results. Regulators are uniquely equipped with appropriate expertise not only to assess equivocal or conflicting science, but also consider claims in the context of factors including the nature and cost of the product and potential public health implications.

The Proposed Rule Contains Ambiguous Language and Is Duplicative

In addition to these concerns, there are additional points to be emphasized regarding the arguments made in the November 2019 Industry Coalition letter, specifically as related to the ambiguous nature of the Proposed Rule's language and its duplicative nature.

The Proposed Rule uses a number of terms that are undefined and could be construed in an ambiguous manner, such as "health benefit" and "competent and reliable scientific evidence." "Health benefit" could, for example, refer to claims made about the nutrients in a product that are already defined claims, such as "high in" and "good source of" that particular nutrient. These claims already have defined support requirements, such as that they must include a certain percentage of the ingredient for which the claim is being made and the product cannot include certain amounts of other nutrients that may have a negative effect on consumer health.[8] The Proposed Rule could be interpreted as mandating that other types of substantiation are required, in addition to or in conflict with the already well-established federal standards.

"Competent and reliable scientific evidence" is a term developed through Federal Trade Commission ("FTC") precedent and guidance, but it does not have a regulatory or statutory definition.[9] Rather, the FTC when evaluating whether a claim is supported determines whether the advertiser has a "reasonable basis" to make the claim. The FTC acknowledges that this is a flexible standard that "depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified," along with other factors.[10] To the extent the Notice of Proposed Rulemaking discusses the FTC standard, it does so in passing and does not acknowledge the important uncertainty surrounding the FTC's definition as a matter of law.

Adding further uncertainly, the FTC has defined "competent and reliable scientific evidence" differently over time. For example, in a 2010 consent order against Nestle Healthcare Nutrition, the FTC defined "competent and reliable scientific evidence" for certain claims as "at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence are sufficient to substantiate that the representation is true."[11] Elsewhere in this order, competent and reliable scientific evidence for other types of claims was defined as "test, analyses,

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[8] *See e.g.*, 21 C.F.R. § 101.13.

[9] *See e.g., Dietary Supplements: An Advertising Guide for Industry*, available at, https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry ("FTC Dietary Supplements Guide").

[10] *Id.*

[11] *In the Matter of Nestle Healthcare Nutrition, Inc.,* File No. 092 3087 (May 18, 2010 Agreement Containing Consent Order).

research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons that are generally accepted in the profession to yield accurate and reliable results." In a 2019 order against the same company, competent and reliable scientific evidence for certain claims was defined as requiring human clinical testing, but did not define how many studies were necessary to support the claims in question.[12] In deciding to import FTC terminology and concepts that remain unsettled as a matter of law, even as applied by the very agency that created these concepts, Oregon invites confusion and courts conflict in its own marketplace.

Not only would the Proposed Rule introduce such problems into Oregon's regulatory environment, but it would do so unnecessarily. Oregon already has in place statutes – enforceable by the Department of Justice – that prevent false and misleading claims about a product. Specifically, Oregon Revised Statutes 646.608(1)(e) makes it an unlawful practice to "[r]epresent[] that . . . goods . . . have characteristics, ingredients, uses, benefits, quantities or qualities that the . . . goods . . . do not have." Rather than using ambiguous terms that will place unnecessary burdens on companies doing business in the state and create uncertainty about how to support claims that provide important information to consumers, Oregon regulators should rely on their current authority to prevent false and misleading claims.

Conclusion

CRN and AHPA believe the Proposed Rule is unnecessary as Oregon laws already prevent companies from making false or misleading claims about a product. If, however, Oregon regulators move forward with the Proposed Rule, CRN and AHPA strongly urge the state to limit enforcement to state government regulators only to protect the public health and ensure that ambiguous terms in the statute are adequately defined.

Sincerely,

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[12] *FTC v. Gerber Products Co.* 2:14-cv-06771-SRC-CLW (June 28, 2019 Stipulated Final Judgement and Order for Permanent Injunction and Other Equitable Relief) (Gerber was a subsidiary of Nestle).