April 10, 2020

Ellen Rosenblum
Attorney General
Oregon Department of Justice
1162 Court St. NE
Salem, OR 97301-4096

RE: Update to Proposed Health Benefit Substantiation Rule

On behalf of the Council for Responsible Nutrition ("CRN")[1], the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers, and the American Herbal Products Association (AHPA),[2] the national trade association and voice of the herbal products industry, we appreciate the opportunity to submit additional comments on the Proposed Rule entitled, "Representations Regarding Health Benefits of Goods" ("Proposed Rule").[3] CRN and AHPA participated in the initial rulemaking comment process, submitting a comment on November 13, 2019, and CRN appeared in person to give testimony before the Oregon Department of Justice ("DOJ") on November 14, 2019.[4] In both the comments and testimony, CRN and AHPA emphasized our significant concern that the Proposed Rule would create a private right of action for enforcement of the Proposed Rule's prohibition on making "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." In other words, if finalized in its proposed form, the regulation would permit enforcement not only by the

[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. CRN 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] AHPA is the national trade association and voice of the herbal products industry. AHPA's members include domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products marketed as foods, dietary supplements, drugs, cosmetics, and other types of products in the United States and in other countries.

[3] This rulemaking would add to the Oregon Administrative Rules a new Rule 137-020-0900 and was first initiated in September 2019. The Oregon Department of Justice recently updated this rulemaking via email.

[4] Nov. 13, 2019 Letter to E. Rosenblum, Oregon Department of Justice from M. Olsen, Council for Responsible Nutrition, and M. McGuffin, American Herbal Products Association.

qualified public servants of the State of Oregon but also by private plaintiffs motivated by the potential for recovery rather than the public interest.

On March 3, 2020, the DOJ notified interested parties by email that the agency intended to move forward with the Proposed Rule, with the following changes:

(1) Language was added to the fiscal impact statement as indicated below.

> *"Another possible fiscal impact, identified in the comments to the rulemaking, was the possibility of people filing private causes of action against advertisers and sellers making health claims about a good, as the rule is necessarily promulgated under ORS 646.608(1)(u), containing a private right of action via ORS 646.638."*

(2) Language was added to the Proposed Rule itself as highlighted below (added language is underlined).

> *"Representations Regarding Health Benefits of Goods*
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> *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. <u>It is the intent of the rule that in construing the meaning of the term 'competent and reliable scientific evidence,' the courts be guided by decisions of federal courts and final orders of the Federal Trade Commission</u>."*

While CRN and AHPA appreciate the DOJ's updates to the Proposed Rule, the updates do not address—indeed, they barely acknowledge—the significant industry concerns presented to the DOJ last Fall regarding the private right of action that would result from the promulgation of the Proposed Rule, even as amended. The amendment to both the language of the Proposed Rule and the fiscal impact statement fail to address these significant concerns in any meaningful manner. It is difficult to overstate the immensely harmful effect that the Proposed Rule's private right of action would have on Oregon businesses.

Oregon DOJ Could Accomplish Its Rulemaking Objectives by Limiting Enforcement to Oregon Regulators

To be clear, CRN and AHPA emphasize that we share the DOJ's concern about false and fraudulent claims made by opportunists and other bad actors taking advantage of this current crisis. As explained in the November 13, 2019 letter, the DOJ currently possesses the ability to take action against such bad actors on the basis that their statements are simply and clearly false, without the need for an additional cause of action based on a lack of substantiation.

For example, in an email message to an industry representative communicating the need to expeditiously promulgate this Rule due to the impacts of the COVID-19 pandemic, a DOJ representative wrote, "Especially as we have already seen unsubstantiated health claims related to COVID-19, we feel it is more urgent than ever that this rule is finalized."[5] This message included, as purported support, a hyperlink to

[5] Mar. 27, 2020 Email Message from C. Hiemstra (DOJ) to P. Sparks (Oregon Business & Industry).

a March 18, 2020 news story[6] about a recent DOJ action taken against a Portland CBD retailer who displayed on a sandwich-board sign outside the store "COVID" followed by "LUNG SUPPORT IMMUNITY TINCTURES." The story included the following:

- "The investigator told the owners the sign violated the Unlawful Trade Practices Act. According to Kristina Edmundson with the AG's office, the sign also violates the 'substantiation rule,' which is set to go into effect April 3. It requires scientific evidence to support promotional health claims -- much like the one the … store was claiming."
- "'We were very pleased that the store was willing to remove their sandwich board sign when our investigator explained that it could be in violation of Oregon law,' Edmundson said."
- "The Attorney General's office has not had other complaints about coronavirus-related CBD advertising . . . ."

While purportedly used to support the initial denial of an extension to the comment period, the story actually demonstrates, in the DOJ's own words, the full adequacy of its existing statutory authority to address concerns about consumer fraud stemming from health-benefit claims. We were also alarmed at the AG office's comments, as of March 18, that the DOJ apparently planned to finalize the Rule on April 3[7]—i.e., one day after the close of the comment period. That statement raises concerns that the DOJ's haste to implement this Rule comes at the cost of its ability to conduct a meaningful review of stakeholder comments, make additional modifications to the Proposed Rule in response, and conduct adequate fiscal impact analyses necessary to ensure the rulemaking complies with Oregon law and procedure.

As discussed below and in the associations' previous comments, expanding the DOJ's authority as contemplated in the Proposed Rule would have the unintended and undesired consequence of creating a private right of action that opportunistic plaintiffs' lawyers could abuse to extort Oregon businesses with the threat or initiation of costly and uncertain litigation challenging their substantiation for health benefit claims. Without question, the Proposed Rule would provide the opportunistic plaintiff's bar with an incentive to shake down Oregon businesses for their own gain by filing countless fishing-expedition lawsuits, which could in turn strain Oregon's court system to the detriment of the efficient administration of justice in the State.

In their original comment, the associations also raised concerns that the Proposed Rule would create a private right of action to the detriment of not only their businesses but also public health.[8] Nowhere in the DOJ's updated rulemaking documents or communications is this serious concern addressed. By

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[6] Mila Mimica, Attorney General forces Portland CBD store to take down misleading COVID-19 advertising, KGW-TV (Mar. 18, 2020).

[7] *See* Mila Mimica, Attorney General forces Portland CBD store to take down misleading COVID-19 advertising, KGW-TV (Mar. 18, 2020) ("According to Kristina Edmundson with the AG's office, the sign also violates the 'substantiation rule,' which is set to go into effect April 3. It requires scientific evidence to support promotional health claims -- much like the one the … store was claiming.").

[8] *See, e.g.*, CRN/AHPA November 13, 2019 Letter, pages 2-3 (noting that "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.")

continuing to move forward with this Proposed Rule without eliminating the private right of action, or even meaningfully engaging the issue, the DOJ would undermine the State's authority and deputize private actors to act in the government's rightful role.

If the DOJ determines that this rulemaking is essential for it to safeguard residents of Oregon, the DOJ should limit such private authority and reserve the ability to enforce the Proposed Rule to the State and its agencies as CRN and AHPA originally requested. This would place such power and discretion in the hand of the State's consumer protection and public health authorities who possess relevant expertise and are motivated by the public interest, rather than the magnitude of recoveries. Upon CRN's and AHPA's review, nothing in the Oregon Revised Statutes—including ORS 646.608 nor ORS 646.638—prohibits the DOJ from including in its rulemaking a provision that enforcement is limited solely to the government. Accordingly, if the DOJ insists in advancing the Proposal Rule, it should include such a limitation.

If DOJ does not believe it has the authority to limit enforcement of this Proposed Rule to just State regulators, that position should be clearly communicated to stakeholders as part of the rulemaking record. As noted above, it is not clear what, if any benefit, this Proposed Rule would provide to the consumer protection activities of the DOJ. However, any potential benefits would be far outweighed by the harms to both businesses and consumers alike by the creation of a private right of action. As such, the statutory mechanism the DOJ is relying on to create this Proposed Rule is simply not appropriate. Its effect would be to amend through administrative rulemaking Oregon's Unlawful Trade Practices Act in a manner that gives private citizens broad, new rights to sue businesses without any threshold allegation or showing of a potential violation of false advertising law – a power reserved solely to state legislators or the public through direct initiatives. We are not aware of any other rulemaking that the DOJ has attempted under the authority it cites for this Proposed Rule that would have created such a broad private right of action as is the case here. Doing so likely violates the intent of Oregon legislators and is likely to invite extreme scrutiny of the DOJ's actions.

Oregon DOJ's Updates Fail to Address Significant Public Health and Fiscal Impacts from the Private Right of Action that the Proposed Rule Would Create

As CRN and AHPA highlighted, this Proposed Rule would create a private right of action that would 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 support for that claim. Such a result would run counter to the well-settled laws of other U.S. jurisdictions and recognized public health considerations as well as the general principle that only regulators can bring a lawsuit based on an alleged lack of substantiation for advertising claims. Finalizing this Proposed Rule without limiting its enforcement to Oregon regulators, as CRN and AHPA advocated in its original comments, ignores this critical issue and stands to harm the public health.

Similarly, the associations raised concerns that this Proposed Rule would have a significant fiscal impact on consumer product companies in Oregon. In response to these concerns, the DOJ simply noted that "[a]nother possible fiscal impact . . . [is] the possibility of people filing private causes of action against advertisers and sellers . . . ." Outside of this speculative statement, the DOJ entirely neglected this key

concern. This deficiency would render any finalized version of the Proposed Rule vulnerable to legal challenge and subsequent invalidation.[9]

The public health and fiscal impacts of this rulemaking, however, are not speculative concerns. CRN's and AHPA's comment already provided evidence demonstrating the significant real-world, detrimental impact this Rule could have on consumers' health. As the DOJ has not addressed either the public health or fiscal concerns, we are offering additional evidence to help demonstrate the potential fiscal impact of this Rule.

In 2013, CRN's education non-profit the CRN Foundation ("CRNF") commissioned a study by Frost & Sullivan to determine the economic impact from dietary supplement use on health care costs. The report analyzed how dietary supplement use could reduce health care costs. The report authors looked at a number of supplement categories and reviewed the economic impact from products for which the scientific literature had demonstrated a reduction in the occurrence of disease-related events among targeted population groups. Supplements used in this review included products that have been extensively studied for age-related eye diseases, osteoporosis, and heart disease. The review found these supplements were associated with significant health care cost savings and estimated that their use could reduce health care costs by over $35 billion in the United States over a seven-year period. We are providing a copy of this report with this letter.[10] Companies concerned about the cost of defending baseless lawsuits by private plaintiffs that this Rule would encourage would be less likely to share important health information with consumers that could reduce health care costs.

Further detrimental effects from unchecked private litigation have already surfaced in the most concerning ways in the midst of the U.S coronavirus crisis. While the Centers for Disease Control and Prevention (CDC) continue to recommend the use of alcohol-based hand sanitizers by consumers and, crucially, healthcare workers, companies that manufacture these products are facing legal challenges brought by private plaintiffs over claims made for these products. We do not take a position on the claims

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[9] Mere speculation fails to satisfy Oregon's statutory requirement for a fiscal impact statement under section 183.335 of the Oregon Revised Statutes. The purpose of the fiscal impact statement is to "provide protections against arbitrary and inadequately publicized government conduct" by providing sufficient information to "allow the public and affected businesses [to] assess their particular positions and financial situations and determine the likely impact on them." *Bldg. Dep't, LLC v. Dep't of Consumer & Bus. Servs.*, 43 P.3d 1167, 1170 (Or. Ct. App. 2002) (internal quotations omitted). Where the fiscal impact statement fails to do so, the rule must be declared invalid. *See id.*; *see also Dika v. Dep't of Ins. & Fin.*, 817 P.2d 287, 287 (Or. 1991). Here, the DOJ's added language highlights only a "possible" fiscal impact related to the new private right of action, which, as discussed below, completely dismisses and disregards the real economic impact that the addition of a new private right of action will have on consumer product companies in Oregon. In so doing, the State has failed to "utilize available information to project [the] significant economic effect of [its] action on businesses" (as required by the statute) and, instead, conveys only that the exact extent of the effect is undetermined at this time. Or. Rev. Stat. § 183.335(2)(b)(E); see also *Bldg. Dep't, LLC* at 1170 (finding the State's fiscal impact statement to be inadequate where the statement acknowledged only that the public and industry could be affected by the proposed rules but concluded that the exact nature of the effect was undetermined at this time). Accordingly, the State's fiscal impact statement is insufficient under the statute where it fails to "allow potentially affected parties to evaluate their positions and understand what information, if any, [a stakeholder] might need in order to make an informed decision." *See Bldg. Dep't, LLC* at 1170.

[10] *Smart Prevention – Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements: An Economic Case for Promoting Increased Intake of Key Dietary Supplements as a Means to Combat Unsustainable Health Care Cost Growth in the United States*, prepared by Frost & Sullivan, 2013.

made for these products at issue in that litigation, but we highlight this situation simply to demonstrate the harm that can be caused when private plaintiffs – not regulators – make enforcement decisions regarding health-benefit claims issues. Rather than focusing on ensuring these products are accessible to consumers and healthcare workers, these companies must now divert resources and attention to other, less-critical activities. As a body of legal research has noted, private plaintiffs' "singular focus on advancing private interests means that private enforcement ignores the costs and benefits to others."[11]

We understand that the DOJ wishes to move forward promptly with this rulemaking to help combat unsubstantiated product claims, including about the novel coronavirus and COVID-19. We applaud this goal generally, but, as discussed above, the DOJ has already publicly conceded that its current authorities suffice for this purpose. It would be a mistake for the DOJ to advance a Rule that will have far-reaching collateral effects on Oregon businesses when the DOJ already has adequate authority to fight bad actors making false and misleading claims about their products, and when the Rule implicates complex legal and policy questions that all stakeholders cannot carefully and fully address at this time due to the COVID-19 pandemic.

In short, as currently written, the Proposed Rule only stands to harm businesses with the potential to create a flood of frivolous lawsuits from the opportunistic plaintiffs' bar that could overwhelm Oregon's court system, while likely providing only marginal additional benefit to the State in achieving its ultimate goal of protecting consumers. At a minimum, we ask that the DOJ limit enforceability of this Proposed Rule to Oregon regulators, but we further urge that the Proposed Rule is unnecessary and should be withdrawn.

Sincerely,

Megan Olsen
Vice President & Associate General Counsel
Council for Responsible Nutrition

Michael McGuffin
President
American Herbal Products Association

cc: Cheryl Hiemstra, Assistant Attorney General: Cheryl.Hiemstra@doj.state.or.us
Angie Emmert, Rules Coordinator: Angie.Emmert@doj.state.or.us
Caleb Gray, Executive Assistant to the Attorney General: Caleb.L.Gray@doj.state.or.us

[11] Elysa M. Dishman "Enforcement Piggybacking and Multistate Actions," 2019 B.Y.U. L. Rev. 421, 438.