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RE: Proposed Rulemaking – Permanent Adoption of OAR 137-020-0260

On behalf of the Council for Responsible Nutrition (CRN)[1], the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers, we appreciate the opportunity to submit comments on the Oregon Department of Justice's (DOJ) proposal to permanently adopt OAR 137-020-0260. This rule – entitled the "Novel-Infectious-Coronavirus-Related Representations Regarding Health Benefits of Goods" – was adopted as a temporary rule on April 17, 2020.

The temporary rule that the DOJ has proposed to make permanent reads as follows:

> *Novel-Infectious-Coronavirus-Related Representations Regarding Health Benefits of Goods*
>
> *It is unfair and deceptive for an advertiser or seller to represent that a good that is or may be obtained primarily for personal, family or household purposes will prevent, treat, diagnose, mitigate, or cure coronavirus, COVID-19 or a related condition, without first having competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation. It is the intent of the rule that in construing the meaning of the term "competent and reliable scientific evidence," the courts may be guided by decisions of federal courts and final orders of the Federal Trade Commission. It is also presumed that any specific good with approval or emergency use authorization by the United States Food and Drug Administration has competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation.*

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[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.

First and foremost, CRN shares the Oregon DOJ's concerns regarding opportunists and other bad actors taking advantage of this ongoing crisis and applauds the DOJ's efforts to combat false and fraudulent coronavirus and COVID-19 claims.[2]

CRN, however, continues to be concerned that the current rule creates a private right of action for enforcement of the rule's requirement that "[i]t is unfair and deceptive for an advertiser or seller to represent that a good that is or may be obtained primarily for personal, family or household purposes will prevent, treat, diagnose, mitigate, or cure coronavirus, COVID-19 or a related condition, without first having competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation." In other words, the regulation does not limit enforcement to actions brought by the qualified public servants of the State of Oregon, but would extend that right to private plaintiffs motivated by the potential for recovery rather than the public interest.[3]

CRN took similar issue with a private right of action provision that had been included in an October 2019 proposed rulemaking that would have prohibited "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."[4] In the current rulemaking, just as with the broader "health benefit" rulemaking, CRN believes that the private right of action is unnecessary, harmful to the public health, and sets concerning precedent that usurps DOJ's authority.

CRN also supports changes to the temporary rule language that were proposed by a Rulemaking Advisory Committee that was convened by the DOJ on October 5, 2020. These changes, which were originally provided by email to DOJ staff after the October 5, 2020 meeting, are reproduced below in Section II of this letter.

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

To be clear, CRN emphasizes that we share the DOJ's concern about false and fraudulent coronavirus and COVID-19 claims. CRN, however, continues to have grave concerns with any regulation that does not limit

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[2] Industry Coalition Reminds Consumers, Retailers that Dietary Supplements May Not Claim to Cure, Prevent Coronavirus, Feb. 11, 2020, https://www.crnusa.org/newsroom/industry-coalition-reminds-consumers-retailers-dietary-supplements-may-not-claim-cure (noting that "[w]hile there is well established research demonstrating how dietary supplements can play a role in supporting immune health, direction for prevention and/or treatment of Coronavirus should come from qualified healthcare professionals or public health authorities").

[3] CRN also continues to believe that this rule is unnecessary as the DOJ currently possess the ability to take action against bad actors make false coronavirus/COVID-19 claims on the basis that their statements are simply and clearly false, without the need for this additional cause of action based on lack of substantiation.

[4] This rulemaking was commenced on September 30, 2019 for a rule entitled" Representations Regarding Health Benefits of Goods" and would have made it and "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." CRN also maintained that this rule was unnecessary because the DOJ already possesses the ability to take action against bad actors under Oregon Revised Statutes 646.608(1)(e) (making it an unlawful practice to "[r]epresent[] that . . . goods . . . have characteristics, ingredients, uses, benefits, quantities or qualities that the . . . goods . . . do not have").

the ability of private parties to enforce the rule, which undermines the State's authority and deputizes private actors to act in the government's rightful role.

As the DOJ moves forward with a permanent rule, it should limit such private authority and reserve the ability to enforce this rule to the State and its agencies, as CRN has continued to request. This would place such power and discretion in the hands 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, as CRN explained in detail in our November 13, 2019 comments regarding the DOJ's September 30, 2019 rulemaking.[5]

Nothing in the Oregon Unfair Trade Practices Act (UTPA) found in the Oregon Revised Statutes (ORS)—including ORS §§ 646.608(1)(u) and 646.608(4), under which the DOJ purports to enact this regulation—prohibits the DOJ from including in its rulemaking a provision that enforcement is limited solely to government actors. Section 646.608(1)(u) broadly prohibits "[e]ngag[ing] in any other unfair or deceptive conduct in trade or commerce; but, ORS § 646.608(4) limits the ability to bring an action or lawsuit under this section "unless the Attorney General has first established a rule in accordance with the provisions of ORS Chapter 183 declaring the conduct to be unfair or deceptive in trade or commerce."

Once the DOJ has promulgated a regulation that defines a specific practice as "deceptive" under 646.608(1)(u), that practice can be challenged by the DOJ. The UTPA also appears to provide that such practices purportedly become eligible for challenge by private parties.[6] But notably, the UTPA is silent as to the DOJ's ability to explicitly limit enforcement, by including language in the regulation itself, to state regulators only.

Other Oregon state agencies have in fact enacted regulations that contain a limitation on private enforcement. For example, the Oregon Department of Consumer and Business Services, which oversees, among other things, insurance practices, promulgated Or. Admin. R. 836-080-0170, which requires insurers to establish a system related to recommendations regarding annuity products. The rule explicitly states that "[n]othing in [the rule] shall be construed to create or imply a private cause of action for a violation of [the rule]."

If the DOJ were to make this temporary rule permanent while also limiting any private right of enforcement, the resulting rule would be no more restrictive than the law already allows. Because it is the DOJ who defines the scope of a violation under ORS § 646.608(i)(u), it stands to reason that in doing so they have the implicit authority to define such violations as enforceable only by the DOJ. The DOJ crucially would not be limiting a right or privilege provided by the legislature, but appropriately defining the contours of a rule they have created, in order to maximize its intended beneficial purpose and limit unnecessary collateral consequences—precisely what careful rulemaking should do. The DOJ certainly has the expertise to determine where such a limitation would be necessary, such as here, where the need for truthful claims must be balanced, as CRN explained in detail in its comments on the September 2019

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[5] *See* Letter to E. Rosenblum from Council for Responsible Nutrition and the American Herbal Products Association, Nov. 13, 2019.

[6] *See e.g., Scharfstein v. BP W. Coast Products, LLC*, 423 P.3d 757 (Or. App. 2018), review denied, 431 P.3d 90 (Or. 2018) and cert. dismissed, 18-1256, 2019 WL 1438377 *U.S. July 19, 2019) (holding "the legislature had granted the Attorney General broad rulemaking authority under the UTPA to protect consumers and that the rule promulgated governing the marketing or gasoline was enforceable by private lawsuit").

rulemaking, with the complex regulatory environment for healthcare claims so that consumers will not be deprived of important, truthful health information.

II. Language Changes Recommended by Rulemaking Advisory Committee

CRN also supports the changes to the regulatory language that were suggested by the rulemaking advisory committee that meet on October 5, 2020. This changes are highlighted below in red:

Temporary Rule for Novel-Infectious-Coronavirus-Related Representations ~~Regarding Health Benefits of Goods~~

> It is unfair and deceptive for an advertiser or seller to represent to consumers that a good that is or may be obtained primarily for personal, family or household purposes will prevent, treat, diagnose, mitigate, or cure coronavirus, COVID-19 or a related condition, without first having competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation and have all applicable federal and state regulatory approvals or authorizations. It is the intent of the rule that in construing the meaning of the term "competent and reliable scientific evidence," the courts may be guided by decisions of federal courts and final orders of the Federal Trade Commission. It is also presumed that any specific good with approval, authorization, or emergency use authorization by the United States Food and Drug Administration has competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation.

CRN believes these are all common sense suggestions that would clarify the purpose of the rule, eliminate confusion about undefined terms, and better align the rule with federal regulatory requirements. These changes would benefit both businesses governed by this rule and consumers, by helping eliminate confusion that could chill speech and discussions about important public health information.

We appreciate the Oregon DOJ's considerations of these comments and continue to ask that the DOJ limit enforceability of OAR 137-020-0260 to Oregon regulators.

Sincerely,

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