440 1st St. NW, Ste. 520,
Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
www.npanational.org

November 23, 2020
Kate Denison
Department of Justice
1162 Court St. NE
Salem, OR 97301

RE: Public Comment on Adopting Rule on Novel-Infectious-Coronavirus-Related Representations Regarding Health Benefits of Goods

Dear Kate Denison,

The Natural Products Association (NPA), the largest and oldest trade association striving to achieve a broader, more accessible marketplace for natural products that will improve the quality of life for consumers. We are the leading trade association for dietary supplements, natural health & sports nutrition, medical & functional foods, probiotics, and natural personal and home care products. Founded in 1936, we represent over 700 members accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health and beauty aids. On behalf of our members 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 OAR 137-020-0260:

The rule states:

"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."

COVID-19 and the FTC

NPA was the first trade association in the natural products space to recognize the importance of taking action against nutritional supplements claiming to "treat or prevent infection by the coronavirus." On January 27, we submitted a letter to the FDA and FTC urging the agency and commission, respectively, to take action against fraudulent product claims. Both the FDA and FTC have federal authority over labeling claims for dietary supplements and it is illegal for dietary supplement manufacturers to claim their products "prevent, treat, or cure" any illness[1].

[1] NPA Urges FDA Action on Products Claiming to Treat or Prevent Infection by Coronavirus https://www.npanational.org/news/npa-urges-fda-action-on-products-claiming-to-treat-or-prevent-infection-by-coronavirus/

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Since this letter was submitted, both the FDA and FTC have done a tremendous job monitoring the market and protecting consumers from allegedly unsubstantiated COVID-19 claims. As recently as November 12, the FTC has sent warning letters to businesses about unsupported COVID-19 prevention or treatment claims. As explained in these warning letters, it is a violation of the FTC Act to represent expressly or by implication that a product or service can prevent, treat, or cure a disease unless the advertiser has competent and reliable scientific evidence, including, when appropriate, "well-controlled human clinical studies, substantiating that the claims are true at the time they are made." For COVID-19, no such study is currently known to exist for the products or services identified in the more than 330 warning letters issued to businesses making unsupported claims and lacking competent and reliable scientific evidence. While we agree that it is important to protect consumers from unsubstantiated claims that products may prevent, treat, diagnose, mitigate, or cure COVID-19, this rule burdens small businesses, subjects the industry to private right to action, and is duplicative of federal law.

Federal Regulator Expertise vs Private Right to Action

While the natural products industry has existed for decades, it has only recently – since the late 1980s – transformed into a major engine of economic growth, customer satisfaction, and job creation throughout the United States, including here in Oregon. Today, America is the undisputed global leader in natural products. But that leadership position will be lost forever with overreaching regulatory proposals like this one.

Our members are deeply concerned with this proposal for several reasons. First the proposed rule, as written, does not explicitly define "competent and reliable scientific evidence." This language is intentionally vague and puts the onus on Oregon businesses to fend for themselves against potential plaintiffs' interpretation of "competent and reliable scientific evidence." As a result, this will dissuade businesses from offering meaningful information that will increase consumer confusion about natural products. The language in the proposed rule indicates that it would require local retailers to review every claim related to their products and also have access to and a reasonable understanding of the body of scientific evidence supporting each claim. Should a retailer selling Vitamin-C have intimate knowledge of peer-reviewed case studies that support the widely accepted health claim that taking Vitamin-C supports immune health? As written, the proposed rule suggests that every single retailer who sells Vitamin-C would be responsible for conducting independent research to substantiate the claim that Vitamin-C supports the immune system.

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This would be an absurd and unnecessarily cost-prohibitive request on small businesses to endure when federal authorities already have enforcement on false and misleading claims. Federal authorities, like the Federal Trade Commission (FTC) have the experience and expertise necessary to bring a lawsuit that is based on an alleged lack of substantiation. These federal actors are uniquely equipped with the expertise necessary to impartially consider scientific evidence while weighing public health benefits. While there is no pre-established formula as to how many or what types of studies are needed to substantiate a claim, both FDA and FTC will consider what the accepted norms are in the relevant research areas and consult experts from various disciplines[2]. If the DOJ were to move forward with the proposed rule, it would substantially increase costs for retailers who would then pass these incurred costs on to consumers.

Secondly, this proposed rule leaves room for interpretation by arbiters and other private parties who are not as experienced as federal authorities. As we have seen in other states, private right to action such as this proposal opens the flood gates for baseless litigation putting significant economic strain on business. Retailers have been crippled enough by regulatory burdens and the economic strain COVID-19 has put on local economies. This proposed rule would be a stepping-stone for the Department of Justice to then expand their reach into qualified health claims which are currently regulated by the FDA and FTC.

Duplicative Language

As the state's own economic impact analysis states, FTC has national enforcement responsibility for false claims on products and FTC is the authority with regards to regulation in order to ensure the goal of a uniform national standard[3]. Uniform standards are essential because they allow businesses to make claims with confidence that they are in compliance with federal standards for claims. This is particularly true if persons can profit from what they, and inconsistent court rulings, could deem as state regulatory violations. The FTC standard of competent and reliable scientific evidence has been defined in FTC case law as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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."[4] As such, this rule could place a unique burden on Oregon-based businesses, particularly retailers who do are not versed in peer-reviewed scientific case studies.

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[2] 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).

[3] Fair Packaging and Labeling Act 16 C.F.R.. Part 500: Regulations Under Section 4 of the Fair Packaging and Labeling Act: FPLA directs the Federal Trade Commission and the Food Drug Administration to issue regulations requiring that all "consumer commodities" be labeled to disclose net contents, identity, of commodity, and name and place of business of the product's manufacturer, packer, or distributor. The Act authorizes additional regulations where necessary to prevent consumer deception with respect to descriptions of ingredients, slack fill of packages, use of "cents-off" or lower price labeling, or characterization of packages sizes.

[4] See, e.g., POM Wonderful LLC, 155 F.T.C 56, 193 (2013), aff'd in part, 777 F.3d 478, 504-05 (D.C. Circ. 2015), cert. denied, NO. 15-525, 2016 U.S. Lexis 20991 (May2, 2016); Telebrands Corp., 140 F.T.C. 278, 347 (2005), aff'd, 457 F.3d 354 (4th Circ. 2006); Novartis Corp., 127 F.T.C. 580, 725 (1999), aff'd, 223 F.3d 783 (D.C. Cir. 2000); Brake Guard Prods., Inc., 125 F.T.C. 138, 256 (1998)

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Furthermore, because the state's fiscal and economic impact analysis set forth no basis for its claim of minimal impact its improper to assume there will be minimal damage on industry. The current draft of the proposed rule does not utilize or even address available information to project the significant economic effect on small businesses in the natural products industry[5]. The state's fiscal and economic impact is just as vague as the proposed rule itself. While the language might be specific to COVID-19, there is no assurance that the state will interpret and apply the language the same way the FTC does. Additionally, the analysis does not take into consideration readily available data that indicates the significant economic damage private right to action has had on small business[6]. As such, regulatory compliance costs would increase, which is especially true if private parties are given any role in enforcing via litigation.

Conclusion

If the COVID-19 pandemic has taught us anything, it is that dietary supplements, such as Vitamin-C, that make health claims are an important element to supporting the healthy lifestyles of the American people[7]. NPA believes the Proposed Rule is unnecessary and duplicative as federal regulators already enforce against companies making false or misleading claims about a product. Additionally, advertising crosses state lines and is subject to the interstate commerce clause, which means that nothing in federal law would permit Oregon to enforce its advertising regulations. The text of the propose rule is not based on language in current statutes and would also appear to be in violation of the administrative procedures act on the basis that it does not accurately or adequately set forth the fiscal or economic impact on the state and businesses. Particularly since under well-established law, expert evidence would be required to show what constitutes competent and reliable scientific evidence. Under the Touhy rule, a state cannot require a federal agency to provide such testimony[8]. The Oregon Department of Justice should not adopt the proposed rule as written and should rely on federal regulators to enforce substantiations in order to uphold a uniform national standard.

Thank you for your consideration,

Dr. Daniel Fabricant Ph.D.

President & CEO

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[5] Preparation of Fiscal Impact and Revenue Impact Statements. ORS 183.335. Units of local government and the public that may be economically affected by the adoption, amendment or repeal of the rule and estimate of that economic impact on state agencies, units of local government and the public. In considering the economic effect of the proposed action on the public, the agency shall utilize all available information to project any significant economic effect of that action on businesses which shall include a cost of compliance effect on small businesses effected.

[6] Center for Accountability in Science 2018 Proposition 65 State Impact Report. "Instead of protecting public health, Proposition 65 has evolved into a tool for trial lawyers to earn millions at the expense of small businesses whose products don't actually put consumers in harm's way."

[7] Carr, A.C., & Maggini, S (2017). "Vitamin C and Immune Function." Nutrients vol. 9,11 1211. 3 Nov. 2017, doi: 10.3390/nu9111211

[8] United States ex rel. Touhy v. Ragen, 340 U.S. 462 (71 S. Ct. 416, 95 L.Ed. 417)

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