

November 22, 2022

Nancy Brown, AHA Chief Executive Officer <u>nancy.brown@heart.org</u> Mariell Jessup, M.D., FAHA, AHA Chief Science and Medical Officer <u>mariell.jessup@heart.org</u> Eduardo Sanchez, M.D., M.P.H., FAAFP, AHA Chief Medical Officer for Prevention <u>eduardo.sanchez@heart.org</u>

Re: AHA Role in Promoting the SPORT study

Dear Ms. Brown, Dr. Jessup and Dr. Sanchez:

The American Heart Association (AHA) plays a critical role in public health by raising public awareness of cardiovascular disease and supporting scientific research to better understand how to prevent and treat serious illness. Healthcare providers, researchers, consumers, and other stakeholders, including our own organization, the Council for Responsible Nutrition (CRN),<sup>1</sup> respect and admire the AHA's important work. That's why we were dismayed to see AHA lend its credibility to the promotion of the flawed "Supplements, Placebo, or Rosuvastatin" (SPORT) study that frankly misleads both healthcare practitioners and the broader public. See <a href="https://newsroom.heart.org/news/6-common-heart-health-supplements-ineffective-at-lowering-cholesterol-compared-to-statins?preview=1c2c">https://newsroom.heart.org/news/6-common-heart-health-supplements-ineffective-at-lowering-cholesterol-compared-to-statins?preview=1c2c</a>.

The SPORT study, which was funded by AstraZeneca, inappropriately compared the effects of 5 mg daily of rosuvastatin with placebo and six dietary supplements on low-density lipoprotein-cholesterol (LDL-C) over a 4-week period. As indicated in our <u>statement</u>, SPORT completely misses the point of supplementation by comparing the effects of a prescription drug to dietary supplements in a short-term study. Dietary supplements support health through consistent use over time, and in conjunction with a healthy diet, physical activity, and regular visits with a healthcare provider. Their effects on cardiovascular health may not be revealed in a 4-week intervention. The study design shows at best, a fundamental lack of understanding of how nutritional interventions work, and at worst, a deliberate attempt to discredit nutritional interventions via an inappropriate study design.

It is well-recognized that statins are effective in the treatment of high LDL-C. For patients diagnosed with high cholesterol, dietary supplements are not intended to replace statins or other medications to quickly restore healthy levels. But both prescription drugs and dietary supplements have beneficial roles to play in improving health. Particularly for patients identified with borderline cholesterol issues, dietary supplements, in conjunction with dietary changes and exercise can reduce their risk of developing the condition. In fact, FDA recognizes the cholesterol-lowering benefits of plant sterols and plant stanols by authorizing a <u>health claim</u> for these products, under a tremendously rigorous standard—health claims are only conferred when there is "significant scientific agreement" on the data supporting this relationship.

<sup>&</sup>lt;sup>1</sup> The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing more than 200 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. For more information, visit <u>www.crnusa.org</u>. Follow us on Twitter <u>@CRN\_Supplements</u> and <u>LinkedIn</u>.

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The outright dismissal of dietary supplements by the authors of the SPORT study is a disservice to public health, and we are disappointed that AHA provided a platform for irresponsible messaging based on research that was not designed to properly evaluate supplements for their effects on cardiovascular health. Fortunately, several media outlets chose not to cover this research because they saw the obvious flaws and bias in the study. However, the damage has been done, as seen in articles like, <u>Don't</u> <u>bother with dietary supplements for heart health</u>, study says, published by CNN. The AHA's own press release confuses a range of cardiovascular benefits with cholesterol lowering as a sole marker of heart health, and the study's researchers abused the platform the AHA conference afforded them to extrapolate far beyond the actual study in their comments to the media.

In choosing to position the presentation of this study at your November 6 conference as a wholesale dismissal of dietary supplements for cardiovascular health, the AHA also ignored a range of benefits that dietary supplements confer beyond cholesterol control. Supplement ingredients like magnesium, niacin, vitamin D, vitamin K2, omega-3 fatty acids, Coenzyme Q10 (CoQ10) and fiber are well-recognized for their positive effects on lowering triglycerides, controlling blood pressure, reducing inflammatory markers and other heart-healthy effects. CoQ10, is widely acknowledged to not only independently provide cardiovascular benefits, but also to address the CoQ10 depletion that often accompanies statin use.

Rather than playing a role in promoting questionable research on dietary supplements, the AHA should focus its efforts on educating both healthcare providers and their patients about the available approaches to maintain heart health and prevent or treat heart disease. In addition to medications and medical treatment, a balanced diet, regular exercise, supplementation, and other healthy habits can contribute to good health. If individuals are hesitant to take statins, rather than outright dismissing their concerns, physicians should encourage an open dialogue with their patients, educate them about the roles that prescription drugs and dietary supplements can play in heart health, and develop a plan both the patient and healthcare provider are comfortable with to achieve their shared goal of better health.

We welcome the opportunity to discuss this with you further.

Sincerely yours,

Anduk

Andrea Wong, Ph.D. Senior Vice President, Scientific & Regulatory Affairs

Ster M. Mister

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cc: Raymond P. Vara, Jr. Chair of the Board of the American Heart Association <u>raymond.vara@hawaiipacifichealth.org</u> or <u>rvara@lhsnet.com</u> Michelle A. Albert, MD, MPH, FACC, FAHA, President michelle.albert@ucsf.edu