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CRN QUESTIONS ACCURACY OF HERBAL PRODUCTS ARTICLE

WASHINGTON, D.C., February 1, 2010 — *In response to the publication of a review article, “Use of Herbal Products and Potential Interactions in Patients with Cardiovascular Disease,” published in the Journal of the American College of Cardiology, the Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, issued the following statement:*

Statement by Douglas MacKay, N.D., vice president, scientific and regulatory affairs, CRN:

“We question how a peer-reviewed publication would even accept an article such as this, given the fact that the authors make conclusions about ‘herbal remedies’ based on their own uninformed, inaccurate, and outdated interpretation of the law which covers dietary supplements, including herbal supplements. The article contains sweeping generalizations, often not backed by relevant citations, and copious factual errors, including a reference to products—some of which are not actually herbal supplements—that produce adverse effects on the cardiovascular system.

In particular, the article does not acknowledge important changes in the law and regulations governing dietary supplements that make many of the statements in the article irrelevant or flat-out wrong. For example, the Dietary Supplement and Non-Prescription Drug Consumer Protection Act, passed in 2006, requires dietary supplement manufacturers to report any serious adverse events to the Food and Drug Administration (FDA). This post-market surveillance tool—in addition to the issuance in 2007 of newly updated Good Manufacturing Practices (GMPs) for all dietary supplements—greatly strengthened regulations for this industry.

According to CRN, 24 percent of American adults take herbal supplements each year¹ and there is no basis for the authors’ conclusions about their lack of safety. In fact, in the first full year that the law requiring manufacturers to report serious adverse events was in effect, FDA reported receiving 1,080 adverse event reports, only 672 of which were considered serious—for **all** dietary supplement products (vitamins, minerals, herbals, sports supplements, weight loss supplements and specialty supplements). For the same year, FDA received over 526,000 adverse event reports related to drugs and biologic products, over 300,000 of which were considered serious, including close to 50,000 deaths.

CRN encourages consumers to talk openly with their physician about the herbal supplements they are using or considering using, particularly if they are on medications. According to the 2008 ‘Life...supplemented’ Healthcare Professionals (HCP) Impact Study², 63 percent of cardiologists say that they inquire about the dietary supplements their patients are taking. Furthermore, the study shows that 73 percent of cardiologists agreed that a regimen of healthy eating, dietary supplements, exercise and other smart lifestyle choices is key to maintaining heart health.

This article represents a biased, poorly written and contrived attack on herbal supplements. Many herbal supplements offer healthful benefits, and fiber, garlic, and Hawthorne provide heart health benefits, and the potential risk for a drug interaction can be eliminated by speaking openly with your doctor. If consumers are buying from reputable companies, they can feel confident in the quality and safety of these products. Herbal supplements should not replace medications or the need for smart lifestyle choices like healthy diet and regular exercise, but instead should be integrated as part of a total health regimen.”

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Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 70+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN's Code of Ethics. Visit www.crnusa.org.

¹ According to data from the 2009 CRN Consumer Survey on Dietary Supplements. The survey was conducted August 26 through September 1, 2009 by Ipsos Public Affairs and funded by CRN. The survey was conducted on-line and included a national sample of 2,043 adults aged 18 and older from Ipsos' U.S. on-line panel. The survey has been conducted annually since 2000. Weighting was employed to balance demographics and ensure that the sample's composition reflects that of the U.S. adult population according to Census data and to provide results intended to approximate the sample universe. A survey with an unweighted probability sample of this size would have an estimated margin of error of +/- 2.2 percentage points.

² According to results from the 2008 "Life...supplemented" HCP Impact Study. The study went public in November 2008 and comprise three separate surveys -- 300 cardiologists, 300 dermatologists and 300 orthopaedic specialists. Margins of sampling error at a 95 percent confidence level are +/- 5.7 percentage points for each of the specialty groups of healthcare professionals surveyed (dermatologists, cardiologists and orthopaedic specialists). A nominal honorarium was given to each healthcare professional completing the survey. Ipsos Public-Affairs conducted the survey online. The first "Life...supplemented" HCP Impact Study of primary care physicians, OB/GYNs and nurses was conducted online in November 2007.