



FACT SHEET

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Separating Herbal Supplement Fact From Fiction in *Journal of the American College of Cardiology* Review Article

BACKGROUND:

It is unfortunate when bias plays a role in articles in scientific journals. It is equally unfortunate when authors omit important information, pass off their opinions as accepted fact, and frequently don't cite references, or use outdated or irrelevant references to support their statements. Such is the case with the article, "Use of Herbal Products and Potential Interactions in Patients with Cardiovascular Disease," published in the *Journal of the American College of Cardiology* (JACC) on February 1, 2010. The purpose of this fact sheet is to clear up some of the inaccuracies found in this article. The Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, encourages consumers to have a dialogue with their healthcare professionals about the dietary supplements they are taking.

Fiction: The authors suggest that "Treating physicians are often unaware of patients' use of such [herbal] products because patients are not routinely asked about it."

Fact: According to the [2008 'Life...supplemented' Healthcare Professionals \(HCP\) Impact Study](#), 63 percent of cardiologists say that they inquire about the dietary supplements their patients are taking. According to the 2007 "Life...supplemented" HCP Impact Study, 72 percent of physicians inquire about the dietary supplements their patients are taking. The article in JACC does not provide statistics to indicate that physicians and consumers are not discussing their supplement use with physicians. CRN encourages consumers to talk openly with their healthcare professional about the herbal supplements they are using or considering using, particularly if they are on medications. In addition, CRN urges physicians to take seriously consumers' interest in herbal supplements.

Fiction: The authors incorrectly state that "manufacturers are exempt from pre-market safety and efficacy testing before the release of an herbal product and from any post-market surveillance."

Fact: There are a number of requirements in place ranging from pre-market review, to the manufacturing and marketing processes, to post-market surveillance, all to ensure that dietary supplements are safe and effective. Companies wishing to market a new ingredient (marketed after 1994) must submit to the Food and Drug Administration (FDA) a pre-market notification containing safety information for the Agency to review. Furthermore, the issuance in 2007 of newly updated Good Manufacturing Practices (GMPs) specific to dietary supplements ensures that dietary supplements are manufactured to safe, high-quality standards and that what is on the label, is in the bottle. Finally, the Dietary Supplement and Non-Prescription Drug Consumer Protection Act, which went into effect in December 2007, requires dietary supplement manufacturers to report to FDA all serious adverse events they receive and maintain on file all adverse events.

Fiction: The authors incorrectly state, "Most patients believe that the government oversees the safety of CAM; but the fact is that the only requirement is for the manufacturer to send a copy of the product label to the FDA."

Fact: Complementary and Alternative Medicine (CAM), includes, but is not limited to herbal products, as there are many types of CAM, such as acupuncture, yoga and prayer. The Food and Drug Administration (FDA) regulates dietary supplements—including

herbal products—as a category of food and has many tools in place to ensure that dietary supplements are safe. These regulations include robust requirements that cover pre-market review, manufacturing, quality control, labeling, post-market surveillance, facility registration and more to ensure that dietary supplements are safe and effective. Under the law, FDA has authority to remove products from the marketplace if they pose an imminent threat to public health or if there is a significant or unreasonable risk of injury or illness associated with use of the products.

Fiction: The authors state that there are “wide variations in herbal product manufacturing techniques...” and that “...40% of all herbal products... fail to contain as much of their active ingredients as claimed on their labels.”

Fact: There are regulations in place to ensure that dietary supplements are manufactured to safe, high-quality standards and that what is on the label, is in the bottle. The good manufacturing practices (GMPs) specific to dietary supplements establish manufacturing and quality control standards to consistently assure the identity, strength, purity and composition of dietary supplements. The authors reference the 40 percent statistic to an outdated *New York Times* article published in 1999. However, the newspaper article does not mention the 40 percent statistic and there is no further citation listed.

Fiction: The authors misuse an outdated statistic that “less than 1% of adverse events from supplements are reported to FDA.”

Fact: The Dietary Supplement and Non-Prescription Drug Consumer Protection Act, which went into effect in December 2007, requires dietary supplement manufacturers to report any serious adverse events to the Food and Drug Administration (FDA) and to keep records of all adverse events they receive. 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.

Fiction: The authors infer that grapefruit juice, soymilk, tetrandrine, storphanthus, oleander, aconite, gossypol and ephedra are herbal products that patients with cardiovascular disease should avoid.

Fact: None of these are herbal supplements—grapefruit juice and soymilk are conventional foods; tetrandrine, storphanthus and oleander are plant poisons, with oleander being one of the most poisonous plants known in the world; aconite is a homeopathic; and gossypol is a chemical compound found in cotton. Furthermore, ephedra has been banned since 2004.

Fiction: In their conclusion, the authors state that manufacturers should have to register with FDA and provide evidence of GMPs.

Fact: Facility registration is already a requirement per the 2002 Bioterrorism Act and good manufacturing practices (GMPs) specific to dietary supplements are in currently in effect for the majority of the industry and will be required for all manufacturers by June 2010.