

**FOR RELEASE**

Contact: Trainor Walsh, 202-204-7671

**CRN SAYS LAW PROVIDES BALANCE OF SUPPLEMENT
SAFETY AND ACCESS FOR CONSUMERS
—Responds to NEJM Article on Supplement Industry Regulation—**

WASHINGTON, D.C., January 26, 2012—In response to the guest commentary, “Assessing Supplement Safety – The FDA’s Controversial Proposal,” by Pieter Cohen, M.D., in the Jan. 25 on-line edition of the *New England Journal of Medicine*, the Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, issued the following statement:

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

“We are well-aware that some people share Dr. Cohen’s perspective that dietary supplements should be regulated like pharmaceutical products, and his personal call for pre-market approval legislation for our industry is not new. Nor is it a viewpoint shared by the majority of consumers who take dietary supplements. According to CRN’s annual Consumer Survey on Dietary Supplements, 97 percent of supplement users report they are ‘confident about the safety, quality and effectiveness of nutritional or dietary supplements.’ The Dietary Supplement Health and Education Act (DSHEA) provides a balance between ample regulatory authority for FDA and the ability for consumers to have access to the variety of safe, affordable products these consumers choose to take.

Dietary supplements are typically more affordable than pharmaceutical products and dietary supplement companies do not enjoy the same intellectual property protection enjoyed by the pharmaceutical industry. If the supplement industry were subjected to pharmaceutical industry-like regulation, consumers would bear the burden of increased costs and reduced availability to a wide variety of products.

Additionally, a pharmaceutical-like regulatory framework is inappropriate for dietary supplements because dietary supplements do not have the same immediate and dramatic effects as pharmaceuticals, and in general, they have a wider margin of safety.

Unfortunately, Dr. Cohen’s article provides a bit of a bait and switch, perhaps unwittingly. In calling for more stringent oversight of legitimate supplement products, he holds up a poster child for the problem of illegally spiked products. The product Dr. Cohen references in his commentary, by law is illegal and not a dietary supplement. Dr. Cohen refers to the manufacturer of this product as a ‘respected company’ when in fact it is a company that broke a myriad of existing laws, including adding undeclared ingredients—specifically drugs—to the product. We agree with Dr. Cohen that this is a dangerous situation for [consumers](#) and further believe the criminals responsible for these dangerous acts should be put in jail. However, these dangerous acts are not reflective of the overwhelming majority of dietary supplement companies legally selling safe and beneficial products, and as importantly [this is not a problem that will be solved by more stringent new dietary ingredient guidelines](#).

Clearly, FDA is resource-challenged—both staff-wise and time-wise—and those calling for a new regulatory system that would be unnecessarily burdensome on responsible industry, resource-exhaustive for the agency, and still provide no added protection for consumers, should consider joining CRN and other FDA-regulated industries in encouraging Congress to provide more funding for FDA to enforce the current laws.”

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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 75+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN’s Code of Ethics. Visit www.crnusa.org.