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CRN REACTS TO JAMA'S SELECT TRIAL ON VITAMIN E

WASHINGTON, D.C., *October 11, 2011*—*In response to the published study, “Vitamin E and the Risk of Prostate Cancer; The Selenium and Vitamin E Cancer Prevention Trial (SELECT),¹” published in JAMA (the Journal of the American Medical Association), 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:

“Men shouldn’t rush to judgment about vitamin E based on this study, but instead should consider the body of evidence, the amount being taken, and their individual medical history.

The study itself, in the confines of the drug model, appears to be well-designed and well-executed; however, it also evidences the risks of examining a nutrient in isolation. With a reductionist approach to the benefits of nutrition, the study showed that a dose of 400 IU vitamin E was not likely to provide benefit for preventing cancer, and the authors found an increased risk for developing prostate cancer. Interestingly, when vitamin E was combined with selenium, the risk was reduced to a non-significant statistic, perhaps even the result of chance. This reinforces the theory that vitamins work synergistically and that drug-like trials of nutrients, when used in isolation from other nutrients, may not be the most appropriate way to study them.

Because the results of this study are different from other studies, they are not a reason for men to stop using their vitamin E. The authors acknowledge other research has demonstrated the benefits of vitamin E for Alzheimer’s disease, and age-related macular degeneration. Even with respect to prostate cancer, two other studies (cited within the article) had different results: one demonstrated a 35 percent risk reduction for prostate cancer in men taking 50 mg (75 IU) vitamin E daily for six years and another resulted in no effect on risk.

Even taking the results of this SELECT research at face value, although ‘statistically significant’ to a statistician, one wonders if an absolute increase in the risk of prostate cancer of 1.6 cases per 1,000 person-years is really a ‘significantly increased risk of prostate cancer’ as noted in the article.

This study provides an important addition to the knowledge base, but we should be reminded it is one study. We will be interested to see the results of the serum level analysis which the researchers have indicated will be published at a future date as that will provide even further information about the role of vitamin E and prostate cancer.

Cancer is a multi-factorial disease and the fact is there is a lot that we still don’t know about cancer, including prostate cancer. The authors acknowledge there is no apparent biological explanation for their findings and speculate that selenium may in fact have a protective effect on vitamin E. The original SELECT trial data did not demonstrate this negative effect for vitamin E; and the possibility that selenium may have slightly increased the risk of diabetes (as found in the earlier data) has evaporated in the most recent results. This is the nature of science—it constantly evolves—thus the need not to rush to judgment.

¹ JAMA, October 12, 2011—Vol 306, No. 14

Further, last week's recent news highlighting the United States Preventative Services Task Force's recommendations that we change screening protocols for prostate cancer, and the possibility that as a society we've been over diagnosing prostate cancer, seem to underscore that it is a bit premature, even with a well-done study, that we would rush to judgment, focusing on vitamin E as the lone culprit for increasing cancer risk.

Vitamin E is an essential nutrient required for all functions of the body. It is fairly common for people not to meet the Recommended Dietary Allowance (22.4 IU or 15 mg) and it is particularly difficult for people to meet the RDA from food alone without exceeding a reasonable caloric intake. Men should be aware of their vitamin E intake, but typical doses commonly found in multivitamins should not be a concern. There are also many single vitamin E supplements sold that are far below the 400 IU that the researchers identified as a concern.

For questions about vitamin E, consumers should talk with their physician, nurse practitioner, pharmacist or other healthcare practitioner.

Finally, at the end of the study, there is a gratuitous dig about dietary supplements being 'unregulated,' which, aside from being false, forces us to engage in discussion that goes beyond what the study itself says. It concerns us that underlying bias from the publication about the dietary supplement industry and the fact that these products are not regulated like drugs may provide an ulterior motive for which studies are published and how study results are presented."

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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.