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CRN RESPONDS TO CSPI's ALLEGATIONS OF INCREASED HEALTH RISKS ASSOCIATED WITH SELENIUM

WASHINGTON, D.C., July 7, 2009 – In response to CSPI's recent allegations that there are increased health risks associated with selenium intake, the Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, issued the following statement.

Statement from Steve Mister, president and CEO, CRN:

“It is disappointing to read the kind of fear-mongering that is being attributed to the Center for Science in the Public Interest (CSPI) in connection with its campaign to clarify the permissible health claims that can be made for selenium and certain kinds of cancer. Recently CSPI has been quoted as issuing statements like, ‘*[selenium products] are dangerous to the health of men suffering from prostate cancer,*’ ‘*may increase the risk of diabetes and hypertension,*’ and that, ‘*the [selenium] products pose a health risk to consumers because results from studies associate selenium intake with increased risk of developing diabetes and with increased risk of aggressive prostate cancer.*’

The fact is that the researchers involved in the SELECT trial have themselves been very careful to state that any increased risk of diabetes that might have been associated with the SELECT trial was not statistically significant and may have been due to chance. If the tables were turned and the study showed a similar reduction in the risk of diabetes that was not statistically significant, but CRN or its members were promoting a reduced risk, CSPI would not hesitate to chide the industry for doing so. It is more than a little disingenuous to keep raising the specter of increased chance of diabetes from non-statistically significant data from a single study that may be due to chance.

Likewise, CSPI has speculated about the dangers to ‘*men suffering from prostate cancer.*’ CRN is not aware of any hard data that even remotely suggests that men with prostate cancer are turning to selenium as a cure or treatment. Nor is there data that these men are forgoing their chemo-treatments or cancer drugs in favor of selenium.

Moreover, the recently published study that CSPI cites in support of the allegations that selenium is associated with aggressive prostate cancer (*Journal of Clinical Oncology*, June 2009) does not support that conclusion. First of all, it is a cross-sectional observational study, which the researchers acknowledge is a limitation. Undoubtedly, CSPI would be critical of the view that observational data could be used to demonstrate benefits of supplementation, so why put so much stock in it if the conclusions go the other way? Second, the results differed according to the

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genotype of a particular polymorphism for an antioxidant enzyme—those men with one genotype and higher blood selenium levels actually had a 40 percent reduction in aggressive prostate cancer risk. To the researchers' surprise, the other genotype, combined with higher blood selenium levels, was associated with higher risk. The researchers openly state that this finding was unexpected and has never before been observed. In fact, it contradicts the findings of another study published by the same group back in 2005 (*Cancer Research*, March 15, 2005).

To state, as CSPI does, that “studies” suggest selenium leads to increased risk of aggressive prostate cancer is not only inaccurate, but demonstrates a blatant double-standard. Was the increased selenium in blood serum levels a result of the cancer, the cause of the cancer, or simply an unrelated variable? Again, if industry used a single observational study, with an isolated finding not demonstrated elsewhere to support a claim of reduced risk of cancer, what would be CSPI's response?

Even more critical is that the cited study does not even give support for a causal relationship between selenium and increased cancer risk. As with the SELECT trial, these researchers stated, *'this finding may be a result of chance and warrants further confirmation in humans.'* Moreover, the researchers speculate as to possible causes for their outcomes and one theory argues that if there is not sufficient selenium, that can lead to *'toxicity, oxidation, propensity for DNA damage and increased cancer risk.'* They also consider that, *'the slight positive association for selenium and risk of aggressive disease was a result of patients with worse clinical features taking selenium supplements out of concern about their diagnosis.'* (Note the researchers' speculation is that subjects may have used selenium in addition to—not in lieu of—their traditional cancer treatments.) But for the thousands of consumers who have read CSPI's releases, and the numerous media reports based on them over the past week, they may be left with the misimpression that the connection between selenium and diabetes and aggressive prostate cancer is an established fact.

The real issue that is under scrutiny is whether the claim that selenium can reduce the risk of developing prostate cancer is adequately supported by the evidence. CRN and CSPI can certainly disagree about that and whether particular claims appropriately communicate to consumers their risk of developing cancer; it would be entirely appropriate for CSPI to urge FDA to deny the claim while CRN argues that the data is sufficient to support such a claim. But it's quite disturbing to see CSPI resorting to this kind of hyperbole to attract headlines and divert attention from the real issues.

Finally, it is no secret that there are still some outliers in this industry—products that may contain undisclosed prescription drugs, or may be adulterated for economic reasons, or manufacturing facilities that do not comply with the GMP requirements that are now mandated for most of the industry. It would be nice to see CSPI join CRN in calling for FDA resources to be directed to these kinds of egregious behaviors where there really is the potential for health risks to consumers. When, instead, CSPI calls for FDA to seize selenium products that pose no health threat to consumers despite the fact that the company involved has indicated that it will

discontinue the claims in question, it makes CRN question how CSPI develops its agenda of priorities related to FDA.

For an organization like CSPI that many consumers turn to for scientific analysis—an organization that even has “science” in its name—this is an unfortunate turn of events.”

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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, CRN members also agree to adhere to voluntary guidelines for manufacturing, marketing and CRN's Code of Ethics. Visit www.crnusa.org.