### PERSPECTIVES

# Federally-funded Analysis Attempts to Undermine Vitamin and Mineral Supplements

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n November 12, 2013, the United States Preventive Services Task Force (USPSTF) decried that evidence does not support a role for vitamin and mineral supplementation in protecting against cancer and cardiovascular disease.<sup>1</sup> Not surprisingly, the mainstream media regurgitated the USPSTF's findings with ill-advised headlines such as "Do You Take Vitamin Pills? This is Why You Should Stop."<sup>2</sup>

Unfortunately, health-conscious individuals cannot rely on government-funded panels and mass media outlets for the interpretation of scientific evidence.

#### **ABSURD DEFINITION OF "MULTIVITAMINS"**

The chances that any health-conscious American would consider a combination of only 3 vitamins and minerals a "multivitamin" are slim to none. Not so for the USPSTF. In their analysis, the USPSTF allowed categorization of studies utilizing only 3 nutrients to be considered "multivitamin" trials. Cancer and cardiovascular disease are extremely complex conditions that involve perturbations of multiple biological processes. It is extremely unlikely that a few nutrients in isolation would sufficiently modulate the underlying causes of cancer or cardiovascular disease enough to render robust risk reduction in a clinical trial.

Within their manuscript, the USPSTF researchers admit "... physiologic systems affected by vitamins and other antioxidant supplements are so complex that the effects of supplementing with only 1 or 2 components is generally ineffective ...." Accordingly, they also note that "... the best support for

benefit of supplementation came from 2 multivitamin trials that used physiologic doses of a wider variety of agents."

Further conceding the limitations of their analysis, the USPSTF researchers note, "Future studies of multivitamin supplements should ... use a multivitamin that is reasonably similar to the popular brands in the current market ...." This is sound advice but bodes poorly for the durability of their current conclusions, which were based in part upon the imprudent foundation of 3-nutrient combinations constituting a "multivitamin."

## STUDY DESIGN TAILORED TO PHARMACEUTICAL DRUGS. NOT NUTRIENTS

The authors of the analysis remark, "This is a review of trials, a study design used primarily to evaluate drug therapy. This design might not be ideally suited to evaluating nutrients." By design, the type of analysis the USPSTF conducted is meant to ascertain the effectiveness of drugs, not vitamins and minerals. This approach inherently limits the scope of evidence upon which conclusions about the effects of nutrients can be based.

Assessing the effects of nutrients requires an approach that takes into consideration variables such as the multifarious actions of nutrients and the impossibility of having a true "placebo group" in a trial of vitamins or minerals due to their natural occurrence and presence in the diet, which can vary considerably even among individuals in the same study.<sup>3</sup>

## CONCLUSIONS BASED ON LIMITED DATA ANALYSIS

The USPSTF's decision to utilize methodology designed to assess the efficacy of drugs in this analysis of vitamins and minerals caused copious data to be ignored. By adhering to standards used for drug assessment, the USPSTF researchers determined that only 2 trials were methodologically sufficient for inclusion in their analysis of multivitamin efficacy. Moreover, while the USPSTF analysis set out to assess the effects of 16 nutrients, including nutrient combinations and individual nutrients, their analysis encompassed only a total of 26 studies.

Dismissing vast amounts of evidence about the effects of vitamin and mineral supplements, just because studies in which they were investigated do not adhere to the methodological framework of pharmaceutical drug trials, provides an overly narrow and skewed view of the body of research on these nutrients. Worse yet, only a single trial in the USPSTF analysis of multivitamin efficacy included women, and the "multivitamin" in the trial consisted of only 5 ingredients. In addressing this point, the USPSTF researchers allow that "... it could be argued that there are no data on a 'true' multivitamin in women [included in this analysis]."

Not surprisingly, however, this has not stopped mainstream media from espousing generalized headlines discouraging the use of multivitamins for everyone based upon the USPSTF's findings.

#### **INSUFFICIENT TRIAL DURATION**

Cardiovascular disease and cancer are the result of decades of accumulated damage caused by a vast array of health insults. Intervening in these processes to delay or prevent the overt onset of these diseases is a primary goal of preventive medicine and especially dietary supplementation. By this virtue, it is questionable to expect that relatively short-term multivitamin supplementation will dramatically impact the emergence of age-related disease like cancer and cardiovascular disease.

#### FLAWED DATA INCLUDED IN ANALYSIS

The USPSTF included in their analysis at least 1 trial known to be fundamentally flawed. This likely influenced their conclusions considerably. The analysis included the Selenium and Vitamin E Cancer Prevention Trial (SELECT), which examined the effects of L-selenomethionine and all-racemic  $\alpha$ -tocopherol acetate, alone or in combination, on the risk of prostate cancer and other health outcomes in relatively healthy men.<sup>4</sup>

In SELECT, men supplemented with all-racemic  $\alpha$ -tocopherol experienced significant  $\gamma$ -tocopherol depletion. A careful review of the full-text SELECT manuscript reveals  $\gamma$ -tocopherol depletion among those men supplemented with all-racemic  $\alpha$ -tocopherol. Men supplemented with all-racemic  $\alpha$ -tocopherol and  $\alpha$ -tocopherol plus selenium experienced a 45% and 48% depletion in  $\gamma$ -tocopherol levels, respectively, by 6 months—levels that were sustained in the course of this 5-year trial.

Many supplement users know the importance of  $\gamma$ -tocopherol in dramatically lowering the risk of developing prostate cancer<sup>5</sup>—in fact, a study of 10 456 men showed that men who had the highest blood levels of  $\gamma$ -tocopherol were 5 times less likely to get prostate cancer.<sup>6</sup>

## REPORT DOWNPLAYS THE RESEARCHED BENEFITS OF VITAMINS AND MINERALS

Despite conclusions drawn by the USPSTF, several trials included in their analysis showed protection against cancer and cardiovascular disease. For example, the Physician's

Health Study II (PHS-II) found that multivitamin supplementation was associated with an 8% reduction in reduction in overall cancer incidence and a 12% reduction in cancer death after 11.2 years of follow-up. In addition, the Supplementation in Vitamins and Mineral Antioxidants Study (SUVIMAX) found a 31% reduction in total cancer incidence in men who supplemented with a multivitamin. When SUVIMAX's results in men were combined with the PHS-II results, the risk for all cancer incidence was reduced over 10 years of follow-up. However, the USPSTF researchers failed to present the details of this pooled analysis.

The PHS-II study also found a 39% reduction in fatal heart attack risk in those taking a multivitamin. In addition, 1 trial found a 58% reduced incidence of cancer for those supplementing with vitamin D plus calcium over 4 years.

## USPSTF ANALYSIS REINFORCES SAFETY OF VITAMIN AND MINERAL SUPPLEMENTATION

In addition to attempting to evaluate the efficacy of vitamins and minerals, the USPSTF researchers also examined the safety of these nutrients. The researchers reaffirm the overall safety for multivitamins, noting, "We found little consistent evidence of harm across studies," and " ... no consistent pattern of harm from nutritional dosages of multivitamins." The analysis also discredited concerns raised by some researchers about calcium and cardiovascular disease. The authors conclude, " ... available studies are insufficiently consistent to permit the conclusion that calcium supplementation is harmful ...."

#### CONCLUSION

Based upon an analysis of this study and the existing research, Life Extension continues to recommend supplementing with a high quality multivitamin containing physiologic doses of a broad array of vitamins, minerals, and vegetable/fruit complexes for optimal health.

#### **AUTHOR DISCLOSURE STATEMENT**

Authors worked on behalf of Life Extension.

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