Reviewer's report

Title: Bone Mineral Density (BMD) Changes in a Bone Health Plan Using Two Versions of a Bone Health Supplement: A Comparative Effectiveness Research (CER) Study

Version: 2 Date: 21 June 2010

Reviewer: Jeannette M Beasley

Reviewer's report:

Summary:

This report evaluates two approaches for improving bone health, differing only by the formulation of a dietary supplement named AlgaeCal. Identifying effective interventions that reduce the risk of osteoporosis and can be easily incorporated into the health care system is an issue of great public health importance. It is also critically important to rigorously dietary supplements, which are taken by the majority of the population yet have not been systematically tested for safety and effectiveness. Unfortunately, the description of the components of the interventions, the study design, and the statistical methods do not allow for scientific inference regarding the value of the supplements.

Major Compulsory Revisions:

1. Though this is described as a comparative effectiveness study, the primary comparison is to “expectation” derived based on assumptions about how BMD would change over a 6-month period rather than actual observations. It is not possible to reproduce the expected values from the authors’ description, and it is unclear whether it is appropriate to derive expected values for a particular individual from population-based estimates that might be very different than the study population.

2. Another comparison made by the authors is between the two AlgaeCal supplement formulations. However, the two interventions were conducted sequentially rather than simultaneously, so differences between these two groups could be due to many factors other than the differences in supplement formulations (i.e. differences in DXA measurements, study populations). A table describing participant characteristics would have been useful both to characterize the study populations and draw inferences regarding how comparable the study population was to the target population.

3. The only valid statistical comparisons are the changes from baseline, and other comparisons should be removed. There are many other reasons to conduct a controlled study other than the placebo effect that the investigators have not accounted for in the design of their study.

4. The intervention period was only 6 months, which is a short window in which to identify change in BMD. Yet in presenting their results, the authors present and
describe “annualized changes”. It seems inappropriate to extrapolate beyond the study period to estimate changes in the AlgaeCal.

Minor Essential Revisions

1. Please provide complete descriptions of the DXA equipment, labs where the supplements were tested for validity.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

1. Other components of the health care plan (i.e. health literacy, physical activity) are described but no details are provided regarding the effectiveness of these components. Without this information, it is difficult for readers to assess whether any observed differences were due to these factors.

**Level of interest:** An article of limited interest

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests