Reviewer’s report

Title: Dose and Time Responses of Vitamin D Biomarkers to Monthly Vitamin D3 Supplementation in Overweight/Obese African Americans with Vitamin D Deficiency: A Placebo Controlled Randomized Clinical Trial

Version: 1

Date: 20 June 2014

Reviewer: Connie Weaver

Reviewer’s report:

This paper represents a well-designed trial to study the dose response effects on status and biochemistries of monthly supplementation of vitamin D in overweight African Americans. Vitamin D measures had adequate quality control. Addition of FGF-23 is a novel aspect of this study.

Major:

1. The context of the paper overvalues vitamin D deficiency when no functional measures were made to evaluate adequacy. The introduction begins this overstatement because the authors use the IOM RDA as a cutoff for deficiency which is inappropriate as it includes a safety margin. If a cutoff value is to be used, it would be appropriate to use the EAR of 16 ng/mL. It is true that we have a scarcity of dose response data in blacks, but why assume they have the same criteria for deficiency/adequacy? After all, they have lower fracture risk with lower serum 25(OH)D levels and higher serum PTH on average yet lower fracture risk. The same argument applies for overweight/obese lower vitamin D status but lower risk of fracture.

2. It is disappointing that functional outcome measures were not included in the trial. In the Gallagher studies, functional outcome measures related to bone were not improved despite increased vitamin D status. In references 8 and 9, what was the BMI compared to this study? Was it a factor in response to vitamin D supplementation? The statement on p. 10 “Our results indicated that the current RDA may be inadequate for overweight/obese African Americans with vitamin D deficiency to optimize their vitamin D status” cannot be known without a functional status measure.

Minor:

1. Abstract—specify age range and both male and female.

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
Scientific Advisory for Pharmavite

I am a scientific advisor for Pharmavite, but that role did not influence my review.