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Reply to Dr. Blumenthal's Letter

George B Kudolo

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Dear Editor:

I am writing in response to Mr. Mark Blumenthal's letter to you, regarding my paper which was published in *Clinical Nutrition*.

As I personally explained to Mr. Blumenthal, EGb 761 was used simply as a scientific term or abbreviation for *Ginkgo biloba* extract and there was no intention to ascribe the results of this study to the EGb 761 from Willmar Schwabe Pharmaceutical Co. of Karlsruhe, Germany. In the first line of the *Introduction* in the paper, I explained that the term EGb 761 was "coined" by this company. I, like some investigators in the literature, have used this term loosely, regrettably, simply as an abbreviation.

In the 2 papers (1,2) published in your journal and in others elsewhere (3–6), I have provided the analytic constituents of our *Ginkgo biloba* extract to which I have ascribed our outcomes to. I believe the constituents of our extract compare favorably with the standardized 50:1 extract EGb 761.

I have provided the source of our Ginkgo extracts in other publications. In the open label studies (3–6), the Ginkgo extract, in tablet form, was supplied by Walgreens pharmacy, which is found in practically every city in the United States. In the randomized, placebo-controlled trials, however, the extracts and placebos were supplied by Whole Health nutritional stores (accessible from the internet) which was supplied in the form of capsules (1,2,7,8). As the principal investigator of these studies, I also take responsibility for the decision to use a vegetable-based placebo instead of an "inert compound". I believe this to be a superior design because any changes in the outcome could be ascribed to the active ingredients of the Ginkgo extract, rather than to some non-specific plant constituents, e.g. from a subjects' diet. I believe trace phytochemicals in the form of co-factors and micro-nutrients may modulate responses to herbal products and the subjects' vegetable eating habits cannot be controlled during the study. Additionally, I wanted to color-match the Ginkgo extract since study subjects may open the capsules. Moreover, the study design is a randomized, double-blind, placebo-controlled **CROSS-OVER** study in which each subject ingested the alfalfa "placebo" material in one cycle and the Ginkgo extract in the other. While I can see the merit in using an "inert" compound as placebo, on this issue, I respectfully disagree with Mr. Blumenthal.

In conclusion, I appreciate the vigilance of Mr. Blumenthal and his interest in our work. I hope it is understood that there was no intention to ascribe the results of these studies to the Schwabe Ginkgo extract. The results reflect outcomes from ingesting a "generic" *Ginkgo biloba* extract.

Thank you.

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