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Dear Editor,

CONTROLLED TRIAL OF CUMULATIVE BEHAVIOURAL EFFECTS OF A COMMON BREAD PRESERVATIVE

We have some questions regarding the recent article by Dengate and Ruben describing the apparent effect of calcium propionate on attention deficit hyperactivity disorder related disorders.¹

1. Although only 27 patients were studied in a double-blind crossover study, the authors chose not to give us the individual data. Instead, the authors cited a summary of the statistical analyses with a final *P*-value of 0.05. The statistical analysis used was quite complex so it would have been useful to have access to more of the raw data. Perhaps belatedly, would the authors send us the computer printout of the data summary and the analysis?

The statistical analysis of cross-over trials needs careful consideration due to the fact that there are potential confounding factors inherent in cross-over designs. Cross-over designs distort results in the presence of outliers. The authors do not report on this. Nor is there mention of the estimate of a 'carry-over' effect (where the effect of the first treatment influences the action of the subsequent treatment). If carry-over effect is significant then this has serious implications on the conclusion of the study.²

2. We noted that the scores from school teachers were omitted from analysis because compliance was difficult and not enough scores were properly completed. Even though the authors state that other papers have demonstrated a tight correlation between parents' and teachers' hyperactivity scores, we would like to see the data collected from the teachers. In particular, when teacher data was available, how often did it agree with the parent data? How often did it disagree?

3. We praise the authors for honestly mentioning that most parents did correctly 'guess' which bread they were using. However, the authors state that in some families, two children were enrolled in the study. Even though the control and test bread were supposedly indistinguishable, perhaps when eaten together side by side an expert mother could find a difference. Also, since test bread contains the calcium propionate preservative, it might be expected to last longer and be less mouldy in the Darwin climate. If so, was the correlation between bread type and behaviour better, worse, or the same, in the families with more than one child in the study?

4. Finally, we wonder why calcium propionate in bread is regarded as an additive chemical? Calcium is ubiquitous, as is propionic acid. The authors have not proposed a mechanism for the detected effect. According to our reading, calcium propionate, a 3 carbon fatty acid that replaces circulating glucose in

ruminants, is a by-product of cheese making and is produced by bacteria taking part in normal fermentation reactions. As such, it seems to be itself a 'food' rather than a chemical. The only article we could find relating propionate consumption in bread to altered physiology was the observation in one paper that it seemed to delay gastric emptying slightly, perhaps endearing itself to diabetics who like to eat bread.³

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Dear Editor,

LACK OF EFFECT OF A COMMON BREAD PRESERVATIVE?

I write concerning the reporting of a controlled trial of cumulative behavioural effects of a common bread preservative by Dengate and Ruben in the August 2003 issue of the Journal.¹

My organization is quoted in the Introduction as stating: According to the Australian Food and Grocery Council, 'conventional scientific wisdom worldwide has not established a link between behavioural problems in children and calcium propionate used as a food preservative'.

It is our contention that this study does not alter that conclusion. The authors do not present sufficient data to permit a complete analysis of their results.

While accepting the difficulties inherent in this type of study, the fact that there was a 'placebo' effect on both treatment (some improved) and placebo (some worsened) suggests that their reported effect is an artefact of the statistics used and lack of power in the study design. The title of the paper should more properly have been 'Lack of effect of a common bread preservative on behaviour in children responding positively to an elimination diet'. Our detailed critique follows.

The authors acknowledge the lack of power in their study when they state that 'due to four placebo responders, there was no significant difference by ANOVA of weighted placebo and challenge behaviours'. Yet they then go on to state that there was a 'statistically significant difference between the proportion of children who worsened on challenge (52%)

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