

Concurring Statement of Commissioner Joshua D. Wright
In the Matter of i-Health, Inc. and Martek Biosciences Corporation
June 6, 2014

As set forth in the Commission's complaint, i-Health, Inc. and Martek Biosciences Corporation (i-Health) marketed a dietary supplement branded as BrainStrong Adult, which contains docosahexaenoic acid (DHA). In its advertising and marketing, i-Health represented, among other things, that BrainStrong Adult improves memory in adults.¹

As articulated in the complaint, these representations included a general memory improvement claim as well as a specific "episodic" memory improvement claim. I write separately to explain why, in my view, the Memory Improvement with Docosahexaenoic Acid Study (the MIDAS study) does not provide evidence sufficient to substantiate either of those claims.

First, the MIDAS study was not designed to evaluate all the types of memory that would be encompassed within a general memory claim.² As set forth in the complaint, there are several types of human memory, including episodic, sensory, working, semantic, and procedural. Although the MIDAS study included one test of working memory, which found no benefit from supplementation, the study's focus was episodic memory. Therefore, to the extent that consumers took away an understanding that BrainStrong Adult would improve general memory, rather than a single dimension of human memory, that claim was unsubstantiated.

Second, the MIDAS study does not adequately substantiate even a narrower claim of improving episodic memory – for example, that BrainStrong Adult would help consumers recall where they had just left their keys or the reason they left one room to walk into another room. It is correct the MIDAS study was a well-designed attempt to evaluate improvement in episodic memory.³ The shortcoming of the MIDAS study as it relates to substantiation is not study design or methodology but rather that, put simply, its results were inconsistent and insufficiently robust to support claims about noticeable improvement in everyday memory along the lines of the television ad.

Episodic memory is a cognitive construct that encompasses the ability to recall specific autobiographical or personal events or "episodes," as well as the time and place those events occurred. Episodic memories have one or more components (e.g., visual, visuospatial, verbal, auditory, and temporal) and are formed in the brain's hippocampus after it interacts with one or more other brain regions. Identifying and isolating episodic memory can be especially difficult because of the potential influence of interactions with other brain regions, which may make it difficult to know whether and to what extent an improvement in test performance was due to changes to hippocampal function.

¹ Complaint at ¶ 10.

² Complaint at ¶¶ 7 and 11.

³ The study was well designed in the sense that it was a randomized, double-blinded, placebo-controlled evaluation of multiple measures of episodic memory.

Consequently, in order to assess changes in episodic memory, cognitive experts generally conduct studies employing multiple measures of episodic memory. Laboratory tests of episodic memory probe hippocampal function via different modalities (e.g., visual, auditory, verbal, and tactile) and cognitive tasks (pattern recognition, visuospatial memory, verbal recall). Cognitive experts then consider the results of the different tests together, which reduces the impact of the various confounding influences that are associated with each individual test. This standard approach reduces the likelihood that idiosyncrasies in the design or administration of any one test will lead to an erroneous conclusion.⁴

Importantly, cognitive experts would generally accept that the observed effects from the intervention under study reflect changes to episodic memory rather than the influence of other neural pathways or a spurious correlation, when the multiple measures show a consistent trend in favor of treatment. By contrast, cognitive experts evaluating an intervention that generates a small but statistically significant effect for one task but not the other two would generally conclude the collective results are insufficient to demonstrate improved episodic memory.

The MIDAS study properly employed three types of laboratory tasks to test different, but interrelated, aspects of episodic memory – visuospatial memory, visual pattern recognition memory, and visual-verbal memory.⁵ However, because the results of the three laboratory tasks, when evaluated together, did not consistently trend in support of improved episodic memory, the MIDAS study is not sufficient to substantiate i-Health’s improved episodic memory claim.

⁴ Michael S. Humphreys et al., *Measuring Episodic Memory: A Novel Approach with an Indefinite Number of Alternative Forms*, 24 APPL. COGNIT. PSYCHOL. 1080, 1081 (2010) (“[t]he use of multiple tasks provides some insurance against the possibility that different neurological substrates are involved in at least some tasks commonly considered episodic.”) (citing Norman & O’Reilly, 2003).

⁵ Complaint at ¶ 11.