Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill
In the Matter of i-Health, Inc. and Martek Biosciences Corporation
June 6, 2014

We write to explain our support for the complaint and order imposed against respondents i-Health, Inc. and Martek Biosciences Corporation (collectively, "i-Health") with respect to advertising claims that their BrainStrong Adult dietary supplement improves adult memory and is clinically proven to do so. Section 5 of the FTC Act requires that advertisers have a reasonable basis for the claims they make to ensure that their claims are truthful and non-deceptive.[1] We have reason to believe that i-Health fell short of this standard.

i-Health advertises a dietary supplement, BrainStrong Adult, containing docosahexaenoic acid ("DHA"), with broad and prominent claims that the product is "[c]linically shown to improve memory." Its advertising also makes the general efficacy claim that BrainStrong improves memory. Consumers would likely have reasonably interpreted these claims broadly to include a wide variety of promises of real-life improvements in memory, such as the ability to remember the location of one's sunglasses or why one entered a room – which is the precise scenario depicted in i-Health's television ad.[2] We do not believe that i-Health possessed the evidence necessary to back up such reasonable interpretations by consumers. Accordingly, we allege that i-Health's efficacy claim was unsubstantiated and that its establishment claim was false and misleading.[3]

i-Health's establishment claim that BrainStrong Adult is clinically proven to improve adult memory requires, by its own terms, a well-controlled human clinical study.[4] Its efficacy claim about its dietary supplement must be supported by competent and reliable scientific evidence.[5] In support of these claims, i-Health relies primarily on a double-blind, placebo-

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[1] *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648 (1984)) ("*Substantiation Statement*") ("[W]e reaffirm our commitment to the underlying legal requirement of advertising substantiation – that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated."), *aff'd*, 791 F.2d 189, 193 & 196 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

[2] *See* FTC, *Dietary Supplements: An Advertising Guide for Industry* 3-4 (Apr. 2001) ("*Dietary Supplements Guide*"), *available at* http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry ("When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each interpretation."); *see also id.* at 12.

[3] The Commission also alleges that i-Health made the unsubstantiated claim that BrainStrong prevents cognitive decline in adults. Because the Commission has unanimously voted in favor of this allegation, we do not address it here.

[4] *Substantiation Statement* at 839 ("When the substantiation claim is express (e.g., 'tests prove,' 'doctors recommend,' and 'studies show'), the Commission expects the firm to have at least the advertised level of substantiation."); *Removatron Int'l Corp.*, 111 F.T.C. 206, 297-99 (1988) ("If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth."), *aff'd*, 884 F.2d 1489 (1st Cir. 1989).

[5] *Dietary Supplements Guide* at 9.

controlled clinical study published in a peer-reviewed journal – the Memory Improvement with Docosahexaenoic Acid Study ("MIDAS study"). The study purports to show that DHA "improves episodic memory" and "memory function." The MIDAS study's principal investigator and author was an employee of respondent Martek.[6]

As an initial matter, regardless of the methodology and purported findings of the MIDAS study, the first question we ask is what the study was designed to measure and demonstrate. Stated differently, and more directly for our purposes, does the study, assuming it was well-conducted, substantiate i-Health's broad claims that BrainStrong improves memory and that it was "clinically shown" to do so? Contrary to the view of Commissioner Ohlhausen, we do not think it does.

As detailed in the complaint, there are several types of human memory, including episodic memory, sensory memory, working memory, semantic memory, and procedural memory. Importantly, the MIDAS study tested tasks associated with only two types of memory: episodic memory, the recollection of specific personal events linked to a time and place, such as where someone left her car keys; and working memory, the short-term mental manipulation of information, such as the ability to follow a story or discussion. Notably, the study reports only a very small improvement from BrainStrong in relation to episodic memory – the positive result was essentially limited to performance on a single test of one of three types of episodic memory that were measured (visuospatial). The study did not reveal any improvement in working memory. In light of the narrow scope of the study and its limited results, we have reason to believe that i-Health's marketing claims that BrainStrong improves "memory" broadly speaking would likely mislead consumers, as there is no basis to conclude that it has any impact whatsoever on other important facets of memory, such as the ability to remember the meaning of words (semantic memory) or to follow an exchange of dialogue (working memory). This alone would be reason enough for us to conclude that the MIDAS study does not adequately substantiate i-Health's general memory improvement claims.

But our concerns extend even further. As we have also alleged in the complaint, the MIDAS study did not show a pattern of statistically and clinically significant improvements on the episodic memory tasks among subjects who took BrainStrong's DHA, relative to the placebo group. Specifically, it failed to show meaningful, statistically significant improvements on two of the three episodic memory tasks measured. Further, it failed to demonstrate that the very small, statistically significant improvement on one of those tasks that it did report correlates with improvements in memory tasks outside of the laboratory.[7] We believe that reasonable consumers would likely be misled that BrainStrong will result in the kinds of real-life improvements depicted in i-Health's advertising.

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[6] Karin Yurko-Mauro et al., *Beneficial Effects of Docosahexaenoic Acid on Cognition in Age-Related Cognitive Decline*, 6 Alzheimer's & Dementia 456 (2010).

[7] *See Dietary Supplements Guide* at 12 ("Some results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health.").

It is correct, as Commissioner Ohlhausen notes in her dissent, that some of the statements made by the study's authors in the "Results" and "Discussion" sections of the MIDAS study use language similar to that in i-Health's memory improvement claims. However, we disagree that the Commission must accept at face value these statements as supportive of the claims in i-Health's advertising. Doing so would be inconsistent with the Commission's obligation to assess the quality and reliability of the scientific evidence underlying challenged advertising claims.[8] Our conclusions are based on extensive consultations with experts in the cognitive science and biostatistics fields. Consistent with the requirements of Section 5 and our past practice,[9] we undertook an evaluation of the results of the MIDAS study to assess whether they substantiated i-Health's advertising claims and did not simply defer to the authors' interpretations of their results.[10]

For all of the foregoing reasons, we have reason to believe that i-Health lacked adequate substantiation for the broad marketing claims that BrainStrong Adult improves adult memory, that i-Health's clinical-proof claims are false and misleading, and that the relief set forth in the proposed order is appropriate.

[8] Commissioner Ohlhausen also observes that the complaint does not take issue with how i-Health conducted the clinical testing component of the trial, *i.e.*, that it was a large, multi-center trial that was randomized, placebo-controlled, and double-blinded. However, sometimes such studies ultimately yield inconclusive or weak findings, as was the case with the MIDAS study.

[9] *See, e.g., Schering Corp.*, 118 F.T.C. 1030, 1084, 1095 (1994). *See also Unither Pharma, Inc.*, 136 F.T.C. 145, 161 (2003).

[10] In addition to the MIDAS study, our experts in the cognitive science and biostatistics fields also reviewed the totality of other evidence that i-Health proffered on DHA and memory, finding those results to be inadequate to back i-Health's claims as well.