Separate Statement of Commissioner Maureen K. Ohlhausen
Dissenting in Part
In the Matter of i-Health, Inc. and Martek Biosciences Corporation
June 5, 2014

The Commission has long interpreted Section 5 of the FTC Act[1] to require an advertiser to have a reasonable basis for making an objective claim about its product.[2] As we execute this mandate, we must be mindful of what we are trying to accomplish, however. As former FTC Chairman Robert Pitofsky stated, the overall goal of evaluating advertising claims is not "a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn will facilitate an efficient and reliable competitive market process."[3]

I dissent in part from today's action because it imposes an unduly high standard of substantiation on a safe product. This unduly high standard not only risks denying consumers useful information in the present but may also, in the long term, diminish incentives to conduct research on the health effects of foods and dietary supplements and reduce the incentives of manufacturers to introduce such products.[4] The majority's approach may ultimately undermine an efficient and reliable competitive market process and make consumers worse off. [5]

The complaint in this matter challenges the efficacy claim that BrainStrong Adult (a DHA supplement) improves memory in adults and the establishment claim that BrainStrong Adult is clinically proven to improve memory in adults.[6] Advertisers must support claims of efficacy of dietary supplements with "competent and reliable scientific evidence."[7] For establishment

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[1] 15 U.S.C. § 45(a).

[2] FTC Policy Statement Regarding Advertising Substantiation (appended to *Thompson Med. Co., Inc.*, 104 F.T.C. 648, 840 (1984)).

[3] Robert Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV. 661, 671 (1977).

[4] *See* Statement of Commissioner Maureen K. Ohlhausen, Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc., et al.*, FTC Docket No. C4456, at 2 (Jan. 7, 2014) ("Although raising the requirement for both the number and the rigor of studies required for substantiation for all health- or disease-related claims may increase confidence in those claims, the correspondingly increased burdens in time and money in conducting such studies may suppress information that would, on balance, benefit consumers.").

[5] *See id.* ("If we demand too high a level of substantiation in pursuit of certainty, we risk losing the benefits to consumers of having access to information about emerging areas of science and the corresponding pressure on firms to compete on the health features of their products."); FTC Staff Comment Before the Food and Drug Administration In the Matter of Assessing Consumer Perceptions of Health Claims, Docket No. 2005N-0413, at 5-6 (2006) (noting the FTC's advertising enforcement seeks to avoid "unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions.") *available at* http://www.ftc.gov/be/V060005.pdf.

[6] The complaint also challenges the efficacy claim that BrainStrong Adult prevents cognitive decline. I agree with the majority that the proffered study does not support this claim.

[7] The FTC's *Dietary Supplements: An Advertising Guide for Industry* defines competent and reliable scientific evidence as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." It further states that well-controlled human clinical trials are the "most reliable form of evidence." *See Dietary Supplements: An Advertising*

claims, where advertisements refer to a certain level of support, advertisers "must be able to demonstrate that the assertion is accurate [and] have the level of support that they claim, expressly or by implication, to have."[8]

In this matter, the defendant offers as the primary substantiation for its claims the MIDAS study, a placebo-controlled, randomized, double-blind, parallel, multi-center, six-month, peer-reviewed, journal-published study of 485 subjects with statistically significant results.[9] Specifically, the MIDAS study concluded:

- "This clinical study demonstrated that 900 mg/d of DHA supplementation improved episodic memory and learning in healthy, older adults with mild memory complaints…. The DHA effects are significant in that they represent an objective demonstration of improved memory in [age-related cognitive decline]."[10]
- "Our results are the first to clinically confirm that DHA significantly improves episodic memory and learning functions in healthy adults with [age-related cognitive decline]."[11]
- "Our study results demonstrate that DHA is well tolerated and may have significant positive effect on gradual memory loss…."[12]

These conclusions match up well with the "improves memory" efficacy claim and the "clinically proven to improve memory" establishment claim.[13] Thus, I believe this study, in the context of other supporting studies involving DHA and memory,[14] provides a reasonable basis for the "improves memory" claims.[15]

Guide for Industry at 9 ("*Dietary Supplements Guide*"), *available at* http://business.ftc.gov/sites/default/files/pdf/bus09-dietary-supplements-advertising-guide-industry.pdf.

[8] *Id*.

[9] *See* Karin Yurko-Mauro *et al.*, *Beneficial Effects of Docosahexaenoic Acid on Cognition in Age-Related Cognitive Decline*, 6 ALZHEIMER'S & DEMENTIA 456 (2010) ("MIDAS study").

[10] *Id.* at 461.

[11] *Id.* at 463.

[12] *Id.*

[13] BrainHealth Adult product packaging also included language stating, "A recent clinical study showed that adults over 55 with a mild memory complaint who took 900mg/day of life'sDHA for 6 months improved their short-term memory."

[14] Martek cited many studies, including: a wide body of animal and cell culture studies that are consistent with the importance of DHA in cognitive function and suggest a potential mechanism for DHA's ability to support memory; numerous epidemiological studies identifying a correlation between DHA consumption and cognitive function; multiple clinical trials with generally supportive (although not wholly consistent) results; and seven reviews by independent expert bodies confirming the importance of DHA in supporting cognitive function. Not all of these studies are squarely on point, and some of them contain methodological weaknesses or inconclusive results. As such, their probity varies, but taken together they are supportive of DHA's positive role in brain function. The FTC must evaluate the well-conducted, statistically significant MIDAS study within the totality of this supportive evidence. *See Dietary Supplements Guide* at 14 ("Studies cannot be evaluated in isolation. The surrounding context of scientific evidence is just as important as the internal validity of individual studies.").

[15] Because the claims at issue here closely parallel the conclusions of the MIDAS study, this case differs from others where companies possessed well-conducted clinical trials yielding statistically significant results but made claims beyond the trials' ability to support. *Cf. Nestle HealthCare Nutrition, Inc.*, 151 F.T.C. 1 (2011) (defendant claimed

The complaint offers two reasons why the MIDAS study, despite being well-conducted and having statistically significant results, does not substantiate Martek's claims for BrainStrong Adult. First, the complaint argues that the "improves memory" claim is unsubstantiated because the MIDAS study did not show that BrainStrong Adult improved performance for all types of memory. However, the MIDAS study did demonstrate a statistically significant improvement in performance on episodic memory tasks. An improvement in episodic memory is indeed an improvement in memory, and the claim accurately conveys the study's findings in consumer vernacular.

Second, instead of criticizing the study's methodology, the complaint criticizes its conclusions. The complaint asserts that the MIDAS study "did not yield a pattern of statistically and clinically significant improvement" in memory.[16] This conclusion is based on the opinion of experts retained by FTC staff. The eight MIDAS study co-authors clearly disagree with this conclusion, as demonstrated by their own conclusions in the study.

The fact that some experts may disagree with the conclusions of a well-conducted study does not render that study unreliable or incompetent, nor make claims based on the study unsubstantiated. Specifically, Martek's reliance upon the MIDAS study, which was both well-conducted and consistent with other research, is not rendered unreasonable by the existence of some disagreement among experts. Indeed, "some disagreement" is the usual state of science.[17]

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its product reduced the duration of acute diarrhea in children up to the age of thirteen; studies only applied to infants and could not be extrapolated to older children); *Kellogg Co*., FTC Docket No. C-4262 (2009) (defendant claimed that children who ate Frosted MiniWheats for breakfast were "nearly 20%" or "up to 18%" more attentive three hours later than children who ate nothing; study calculated average increased attention as ~10% and over half of children showed no benefit from eating the cereal).

[16] It is undisputed that the MIDAS study's primary endpoint (the CANTAB Paired Associate Learning, or "PAL," test) yielded statistically significant results, with a p-value of 0.032. As the Commission has stated, "significance with a p-value that is less than or equal to 0.05 is the recognized standard to show that a study's hypothesis has been proven." *POM Wonderful LLC*, Opinion of the Commission, 2013 FTC Lexis 6 at *77 (2013). Furthermore, the MIDAS study demonstrated that the difference in PAL scores between the test group and the placebo group was equivalent to a net 3.4-year improvement in performance, offering evidence of a clinically significant result.

[17] "The game of science is, in principle, without end. He who decides one day that scientific statements do not call for any further test, and that they can be regarded as finally verified, retires from the game." Karl Popper, THE LOGIC OF SCIENTIFIC DISCOVERY 32 (Taylor & Francis Group, 2005).