FEDERAL TRADE COMMISSION

[File No. 122 3067]

i-Health, Inc. and Martek Biosciences Corporation; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before July 9, 2014.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/ihealthconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''I-Health, Inc. and Martek Biosciences Corporation—Consent Agreement; File No. 122 3067'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/ihealthconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Keith Fentonmiller, Bureau of Consumer Protection, (202–326–2775), 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for June 9, 2014), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before July 9, 2014. Write ''I-Health, Inc. and Martek Biosciences Corporation—Consent Agreement; File No. 122 3067'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/ihealthconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''I-Health, Inc. and Martek Biosciences Corporation—Consent Agreement; File No. 122 3067'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before July 9, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order from against i-Health, Inc. and Martek Biosciences Corporation (hereafter ''the companies'').

The proposed consent order (''proposed order'') has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the companies' advertising for the BrainStrong Adult

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

dietary supplement containing algal docosahexaenoic acid (''DHA''), an omega-3 fatty acid. The Commission's complaint alleges that, based primarily on a randomized, controlled trial called the ''Memory Improvement with Docosahexaenoic Acid (DHA) Study'' (the ''MIDAS study''), the companies advertised that BrainStrong Adult improves memory and prevents cognitive decline in adults, and is clinically proven to improve memory in adults. Human cognitive function consists of at least five different types of memory, as well as non-memory abilities such as executive function, attention, processing speed, and reasoning. The MIDAS study objectively tested only two types of memory (episodic and working memory) and the cognitive ability of executive function, and was not designed to test DHA's effect on cognitive decline in aging adults.

The complaint alleges that the companies violated Sections 5(a) and 12 of the Federal Trade Commission Act by making the unsubstantiated representation that BrainStrong Adult improves memory in adults. According to the complaint, the MIDAS study did not show that BrainStrong Adult improves working memory or the cognitive ability of executive function. In addition, results from the tests of episodic memory did not yield a pattern of statistically and clinically significant improvement in the DHA group relative to the placebo group. For the same reasons, the complaint also alleges that the companies violated Sections 5(a) and 12 by making the false or misleading representation that BrainStrong Adult is clinically proven to improve memory in adults.

Finally, the complaint alleges that the companies violated Sections 5(a) and 12 by making the unsubstantiated representation that BrainStrong Adult prevents cognitive decline in adults. According to the complaint, a subject's performance on laboratory tasks that measure only one type of memory (*i.e.,* episodic) does not fully capture the overall state of his or her cognitive function, which includes other types of memory and non-memory cognitive abilities. In the MIDAS study, subjects treated with DHA for twenty-four weeks performed worse than placebo on a task of executive function, a non-memory cognitive ability. Moreover, a twenty-four-week study is an insufficient duration to test the impact of DHA on cognitive decline. Because the placebo group in the MIDAS study showed no evidence of cognitive decline, the study could reach no conclusion about DHA's ability to prevent or slow that condition.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. For purposes of the order, ''Covered Product'' means any dietary supplement, food, or drug promoted to prevent cognitive decline or improve memory, or containing DHA, including, but not limited to, BrainStrong Adult, except for infant formula or ingredients when sold specifically for use in infant formula. As additional fencing-in relief, the order requires the companies to follow appropriate recordkeeping and compliance reporting requirements, as well as document preservation requirements for human clinical studies that they conduct or sponsor on the Covered Product.

Part I of the proposed order prohibits any representation that the Covered Product improves memory or prevents cognitive decline in adults, unless it is non-misleading and supported by competent and reliable scientific evidence. Such evidence must consist of human clinical testing that is sufficient in quality and quantity, based on standards generally accepted by experts in cognitive science, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. The testing must have been conducted by qualified researchers, and have been randomized, double-blind, and placebo-controlled. In addition, the companies must maintain all underlying or supporting data that cognitive science experts generally would accept as relevant to an assessment of such testing.

Part II of the proposed order prohibits any representation about the health benefits, performance, safety, or efficacy of the Covered Product, unless it is non-misleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted by a qualified person in an objective manner and are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of a human clinical trial, the companies must maintain all underlying or supporting data and documents that experts in the field generally would accept as relevant to an assessment of such testing.

Part III of the proposed order prohibits the companies from misrepresenting, including through the use of a product name, word or phrase such as ''clinically shown'' or ''clinically proven,'' endorsement, depiction, illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, including misrepresenting that the benefits of the product are clinically proven or that the product is clinically proven to improve memory in adults.

Part IV of the proposed order provides a safe harbor for representations permitted under any tentative or final standard promulgated by the Food and Drug Administration (''FDA''), any new drug application approved by the FDA, or FDA regulations pursuant to the Nutrition Labeling and Education Act of 1990 or the FDA Modernization Act of 1997.

Part V contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III of the order.

Triggered when the human clinical testing requirement in either Part I or II applies, Part VI of the proposed order requires the companies to secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a ''Reliably Reported'' test defined as a test published in a peer-reviewed journal that was not conducted, controlled, or sponsored by any proposed respondent or supplier. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Parts VII through IX of the proposed order require the companies to: deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to

modify the proposed order's terms in any way.

By direction of the Commission, Commissioner Ohlhausen dissenting and Commissioner McSweeny not participating.

Donald S. Clark,

Secretary.

Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill

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-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.

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

[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.

[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.'').

[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

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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.

Statement of Commissioner Maureen K. Ohlhausen, Dissenting in Part

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 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]

The complaint offers two reasons why the MIDAS study, despite being well-conducted and having statistically significant results, does not substantiate

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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.

[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 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's DHA 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 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).

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]

Concurring Statement of Commissioner Joshua D. Wright

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.

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.

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[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).

[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.

[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.