



March 27, 2013

**VIA FEDEX**

Charles A. Harwood, Acting Director  
Bureau of Consumer Protection  
Federal Trade Commission  
600 Pennsylvania Ave. N.W.  
Washington, DC 20580

Re: Deceptive Advertising of SpeechNutrients speak™ Marketed by NourishLife

Dear Mr. Harwood:

It is estimated that as many as six million children in the United States suffer from speech delays.<sup>1</sup> Because such delays can have a devastating impact on personal, social, emotional, academic and, later on, vocational life,<sup>2</sup> it is not surprising that parents are typically desperate to help their children overcome such speech difficulties. This is where NourishLife, LLC and its subdivision, SpeechNutrients (collectively "NourishLife") come in.

NourishLife markets "a patented nutritional formula developed by a pediatrician to support normal and healthy speech development and maintenance." The supplement is called SpeechNutrients speak™ ("Speak"), and contains vitamin E and K, omega-6, and "pharmaceutical grade" omega-3. According to some of the testimonials on the NourishLife website (which are accompanied by beautiful photographs of families), Speak can improve speech within hours of the child taking the first dose. Parents with doubts about the efficacy of this supplement are directed to another website - [www.apraxiaresearch.com](http://www.apraxiaresearch.com) - which "provides resources and information for parents and professionals regarding past and present research developments for the treatment of verbal, oral and motor Apraxia."<sup>3</sup>

The problem is that much of what is said in the preceding paragraph about Speak is simply false.

- There is no patented formula for the Speak vitamin and never has been.

- There is no competent and reliable scientific evidence to support a claim that Speak supports normal and healthy speech development and maintenance.
- All but one of the “family” photos associated with the testimonials regarding the effectiveness of Speak are fakes – professional photos that were purchased from iStock.com.
- There is no such thing as “pharmaceutical grade” omega-3.
- The independent Apraxia Research site that parents are referred to is just another marketing tool used by NourishLife to sell Speak.
- And, in addition to this deception, the amount of vitamin E contained in Speak far exceeds the tolerable upper intake level set by the Food and Nutrition Board, and may be hazardous to the health of children.

In short, NourishLife uses deceptive advertising tactics to sell a potentially harmful supplement to children with disabilities. Truth in Advertising, Inc. (“TINA”)<sup>4</sup> brought this matter to the company’s attention on March 19, 2013, requesting that it correct the deceptive advertising of its product and alert its Speak customers of the issues by March 26, 2013. The company did not comply with TINA’s requests. Thus, TINA now brings this matter to the attention of the Federal Trade Commission (FTC) in the hopes that it will act in the best interests of children with speech delays and their parents, and put an end to NourishLife’s unfair and deceptive acts and practices.

Below, TINA sets forth in detail the unfair and deceptive practices that NourishLife uses to market its supplement Speak. Also attached to this letter is a draft complaint that the FTC could immediately utilize to take action against NourishLife and its founder.<sup>5</sup> In addition, TINA has filed a complaint with the U.S. Food and Drug Administration (FDA), as well as Illinois Attorney General Lisa Madigan. Further, because NourishLife touts its rating and affiliation with the Better Business Bureau, and prominently displays the Children’s Hospital & Research Center Oakland logo and its connection with pediatrician Dr. Claudia Morris, TINA has sent letters to this contingent in the hopes that they will also work to stop NourishLife from continuing with its deceptive marketing campaign for Speak.

## **I. What is Speak?**

Speak is marketed and sold by NourishLife, an Illinois corporation founded by a Chicago businessman and “natural entrepreneur,” Mark Nottoli.<sup>6</sup>

The supplement contains omega-3 fatty acids (in the form of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)), vitamin E (in the form of d-alpha tocopherol and gamma tocopherol), vitamin K1 and K2, and omega- 6 (in the form of



gamma linolenic acid (GLA)).<sup>7</sup> According to the Supplement Facts on the product package, two capsules of Speak contain 5,000% of the daily value of vitamin E for children under the age of four, and 1,665% of the daily value of vitamin E for children over the age of four.<sup>8</sup> NourishLife suggests that, after a short introductory period, parents give their children between two and six capsules of Speak per day.<sup>9</sup>

The supplement, which was originally placed on the market in 2008, is promoted as a treatment for childhood speech delays,<sup>10</sup> and is primarily targeted at children with apraxia and/or autism.

NourishLife, which reports to have sold thousands of boxes of Speak,<sup>11</sup> primarily advertises the supplement directly through its website, [www.speechnutrients.com](http://www.speechnutrients.com). The company also advertises the product through, among other mediums, electronic newsletters,<sup>12</sup> Google advertisements,<sup>13</sup> its Facebook page,<sup>14</sup> its Twitter page,<sup>15</sup> a website called ApraxiaResearch.com, and promotional booths at trade shows and conferences.<sup>16</sup>

The company uses a number of different strategies to advertise Speak, including:

- Claiming that the Speak formula is a patented formulation;
- Referring to and touting its relationship with Children's Hospital & Research Center Oakland, and a pediatrician at the hospital, Dr. Claudia Morris;
- Posting testimonials with accompanying iStock photographs of families on its website;
- Citing to studies that allegedly support its claim that Speak treats speech delays;
- Claiming that Speak contains "pharmaceutical grade" omega-3;
- Using another website, ApraxiaResearch.com, that poses as an independent resource for apraxia research, while promoting the Speak formula.

Each of these tactics is problematic.

## **II. NourishLife's Fraudulent and Deceptive Claims Regarding Speak**

NourishLife makes a number of deceptive and misleading claims, both expressly and by implication, regarding Speak. By way of example, five such types of deception are explored below.

## A. Rejected patent application

In numerous places on its website, as well as on its product package, NourishLife states that Speak is a “patented” formula.<sup>17</sup> It explains that a “noted pediatrician . . . developed the precise formula that led to the patented formulation, now available as SpeechNutrients speak™.”<sup>18</sup> In addition to stating that it has an exclusive license from CHRCO to use the “patented” Speak formula,<sup>19</sup> NourishLife also prominently displays CHRCO’s logo throughout the website, as well as on large trade show booth posters.<sup>20</sup>

However, to date, there is not and never has been a patent for the Speak formula.<sup>21</sup> Though Dr. Claudia Morris, a pediatric emergency medicine physician at CHRCO and the alleged inventor of an omega-3/vitamin E formula,<sup>22</sup> filed patent application in February 2008 with the U.S. Patent and Trademark Office,<sup>23</sup> the application was never granted. In fact, it was officially rejected in December 2011.<sup>24</sup> Accordingly, NourishLife’s representations that it is selling a “patented” formula are deceptive, to say the least. Further, because there is no patent, NourishLife’s use of the CHRCO logo and the publicizing of its relationship with the Hospital and Dr. Morris is misleading.

## B. Deceptive testimonials

On its website, NourishLife lists over thirty-five testimonials regarding the effectiveness of Speak that are portrayed as having been sent in from parents who have purchased Speak for their speech-delayed children.<sup>25</sup> The testimonials include comments such as:



### **INCREASED SELF-AWARENESS AND DEEPENING OF COMMUNICATION SKILLS**

... We tried Speak the morning of February 15. In TWO HOURS, while we were playing [my son] looked me in the eye, initiated conversation--"Look mom!," and had a non-echolalic conversation. . . .



### **ADDED SENTENCE COMPLEXITY**

Since beginning the speech nutrients nearly 3 months ago, twice per daily, we have noticed significant progress in our son's speech development (age 5.5). Our family has been exceptionally pleased with his progress since beginning the speech nutrients; we have noticed an added level of complexity to his sentences and length of conversations he is able to carry with us and peers to be more intelligible. . . .





### **GREAT RESPONSE TO SPEAK**

I am very happy to let you know that my son responded very well to Speak. He is copying everything, he is much better in the social area, he is trying to Speak much more, he seems to understand better and he pays more attention to everyone, I am really impressed with the progress in only 1 week. Thank you.<sup>26</sup>

The detailed testimonials are undoubtedly intended to give hope to parents hoping to achieve similar results for their own children. However, there are three significant issues with the testimonials on NourishLife's website: (1) all but one of the photographs that accompany the testimonials regarding the effectiveness of Speak are professional stock images, (2) some of the testimonials have been edited over time, and (3) the testimonials imply that Speak can treat speech delays in children.

#### **i. Photographs that accompany the testimonials are stock images**

Twenty-four of the 37 testimonials regarding the effectiveness of Speak currently on NourishLife's website are accompanied by a beautiful photograph of what appears to be the child of the parent who sent in the testimonial. However, all but one of the photographs are stock images (i.e., professional photographs that are bought and sold for commercial design purposes). Specifically, twenty-three images on the testimonial page also appear on [www.istockphoto.com](http://www.istockphoto.com), a large database of stock images.<sup>27</sup> Additionally, a testimonial appearing in one of NourishLife's electronic newsletters is also accompanied by a stock image.<sup>28</sup>

#### **ii. Testimonials have been edited over time**

In addition to the store bought photographs, several of the testimonials have been edited over time.<sup>29</sup> As shown in Exhibit 34, a total of 10 testimonials were edited since 2010. In more than half of those cases, the testimonials were edited to remove the references to speech therapy, a proven method of helping children with speech delays.<sup>30</sup>

#### **iii. Testimonials imply that Speak can treat childhood speech delays**

Many of the testimonials posted by NourishLife on its website make treatment claims. For example, one testimonial claims that a speech-delayed five-year-old boy started speaking within two hours of taking Speak.<sup>31</sup> Another testimonial claims that a five-year-old boy made significant progress in his speech development within three months of taking Speak for the first time.<sup>32</sup> The testimonial appearing in the

electronic newsletter credits Speak for getting a speech-delayed 12-year-old girl to have lengthy conversations, and states that the supplement “has been almost miraculous.”<sup>33</sup> The unmistakable message, after reading the testimonials, is that Speak can treat childhood speech delays, such as apraxia.

### **C. Claims regarding effectiveness of Speak and the lack of scientific support**

NourishLife has made and is currently making a number of statements about the effectiveness of Speak.

First, on its website, NourishLife states, among other things, that Speak is:

“a patented nutritional formula developed by a pediatrician to support normal and healthy speech development and maintenance. Mounting clinical evidence and hundreds of parental reports indicate this special blend of nutrients provides targeted benefits including:

- Nutritional support of verbal and motor skills
- Reduction in oxidative stress
- Promotion of a healthy inflammatory response”<sup>34</sup>

The website also states:

“The only omega-3 and vitamin E speech development formula that provides the precise serving and ratio of the important nutrients needed for normal and healthy speech and coordination.”<sup>35</sup>

Second, as described above, NourishLife makes numerous cure and treatment statements in the testimonials it posts.<sup>36</sup>

Third, NourishLife makes deceptive statements on its social media pages about the effectiveness of Speak. On its Facebook page, NourishLife states, among other things, “NourishLife speak™ is a patented nutritional formula developed by a pediatrician to support normal and healthy speech development and maintenance.”<sup>37</sup> On its Twitter page, NourishLife states, among other things, “#omega3 that actually help with #apraxia and #autism[,] [www.SpeechNutrients.com](http://www.SpeechNutrients.com) Order your supply today!” and “Check out the new study that shows omega-3 and vitamin E to be 97% effective in children with Apraxia! [www.speechnutrients.com](http://www.speechnutrients.com).”<sup>38</sup>

The central problem with all these statements (in addition to the fact that the formula is not patented and that the referenced testimonials should be viewed with some suspicion) is that they are not supported by any competent and reliable scientific studies.



**i. Morris and Agin study**

On its website, NourishLife touts a study conducted by two physicians, Dr. Claudia Morris and Dr. Marilyn Agin, as the primary support for its claims that the Speak formula treats apraxia. On the Scientific Research page on its website, NourishLife states:

A study published in the July/August 2009 journal ***Alternative Therapies in Health and Medicine*** describes the benefits noted in 97% of participants while taking a nutritional combination comprised of omega-3 and vitamin E.<sup>39</sup>

In this study, *Syndrome of Allergy, Apraxia, and Malabsorption: Characterization of a Neurodevelopmental Phenotype that Responds to Omega 3 and Vitamin E Supplementation*, Claudia Morris, M.D. and Marilyn Agin, M.D. (hereinafter “Morris and Agin study”), Drs. Morris and Agin examined 187 children with verbal apraxia between the ages of 2 and 15. The children were given varying doses of vitamin E, as well as varying doses and brands of polyunsaturated fatty acids (PUFAs).<sup>40</sup> The families of the children then shared their experiences with the supplements either by filling out an online questionnaire or by personal communication.

According to the study, 181 families (i.e., 97% of the studied population) reported “dramatic improvements in a number of areas including speech, imitation, coordination, eye contact, behavior, sensory issues, development of pain sensation, and GERD symptoms.”<sup>41</sup> Despite these seemingly promising results, the study has limitations, including:

- The study was not a randomized, double-blind, placebo-controlled trial. In fact, the researchers did not use any sort of control group whatsoever to determine whether the perceived improvements were caused by the supplement or by something else, such as the placebo effect;
- The results of the study were based purely on subjective responses by parents;
- The children in the study were given widely varying doses of the supplements under investigation. For example, the doses of vitamin E ranged from 400 International Units (“IU”) to 3000 IU a day;
- The authors of the study admit that many of their conclusions are speculative; that there were major limitations in their report; and that further controlled research is warranted in order to determine the effect of the supplement on children with apraxia;<sup>42</sup>

- The study includes very little information about the type of questionnaire used and does not explain the nature of the questions (e.g., multiple-choice, open-ended, check boxes);
- The study is silent with respect to how the questionnaire results were tallied and analyzed, and does not indicate whether the children's histories, such as other interventions used, were recorded or even considered;
- The study does not include any information regarding the length of time (e.g., weeks, months) the children were instructed to take the supplements at issue;
- The study does not include the same ingredients that are contained in the Speak supplement. Specifically, vitamin K, one of the key components of Speak, was not part of the Morris and Agin study.

In short, the Morris and Agin study does not provide any competent and reliable scientific support for NourishLife's claims regarding Speak.

#### **ii. Richardson and Montgomery study**

NourishLife also lists another study on its website, *The Oxford-Durham Study: A Randomized, Controlled Trial of Dietary Supplementation with Fatty Acids in Children with Developmental Coordination Disorder*, Alexandra J. Richardson, and Paul Montgomery (hereinafter "Richardson and Montgomery" study), to support its claim that Speak treats apraxia.<sup>43</sup> However, this study also has its limitations. While this study was a randomized, double-blind, placebo-controlled trial, it did not examine speech delays or the effect of vitamin E or vitamin K. Rather, the Richardson and Montgomery study only examined the effect of omega 3 and omega 6 on children with developmental coordination disorder (DCD), a childhood disorder that leads to poor coordination and clumsiness.

This study concluded that the fatty acid supplementation had no effect on motor skills, but improved reading, spelling, and behavior in children with DCD. The study does not indicate whether fatty acid supplementation has any effect on speech delays, let alone what the effects of a supplement like Speak might have with respect to healthy speech development.

#### **iii. "Additional References"**

In small print on its "Scientific Research" page, NourishLife lists 38 "additional references" that purportedly support Speak and its claimed benefits.<sup>44</sup> However, none of the references cited support the claim that a supplement made up of Omega-3s, vitamin E, vitamin K, and Omega-6 improves speech in children with apraxia. In fact, TINA is not aware of any clinical, double-blind studies that show that a mix of



Omega-3, Omega-6, and high doses of vitamin E and vitamin K improve speech in children with apraxia.

#### **D. Misleading use of term “pharmaceutical grade”**

On its website, NourishLife states that Speak contains “pharmaceutical grade” omega-3.<sup>45</sup> However, this term is misleading because the FDA has not defined what would constitute a pharmaceutical grade fish oil product, and thus the term is meaningless.<sup>46</sup>

#### **E. Deceptive use of ApraxiaResearch.com website**

As discussed above, NourishLife refers to the Morris and Agin study as support for its claims about Speak. Under its short description of the study, the website states: “To learn more about this study, [click here.](#)” When readers click on the highlighted link, they are brought to a separate website, [www.apraxiaresearch.com](http://www.apraxiaresearch.com). In its own words, the site

“provides resources and information for parents and professionals regarding past and present research developments for the treatment of verbal, oral and motor Apraxia. In cooperation with researchers, ApraxiaResearch is leading an initiative seeking to understand how certain nutrients play a key role in reducing inflammation and oxidation which appears to be a formidable issue in individuals with this challenging speech disorder.”<sup>47</sup>

Readers are lead to believe that they are no longer on a NourishLife website, but rather on an independent website devoted to research for apraxia. However, ApraxiaResearch.com is registered and owned by NourishLife,<sup>48</sup> and the website is devoted to promoting “a patented omega-3/vitamin E speech supplement.”<sup>49</sup> Thus, NourishLife’s use of the ApraxiaResearch.com website as a way to market its Speak supplement is misleading.

### **III. Health and Safety**

In addition to NourishLife’s deceptive claims and practices regarding Speak, there are also some significant health and safety concerns associated with giving Speak to children.

#### **A. Vitamin E**

##### **i. Amount of vitamin E in Speak**

One capsule of Speak contains 250 IU of vitamin E in the form of d-alpha tocopherol and 150 IU of vitamin E in the form of gamma tocopherol.<sup>50</sup> NourishLife suggests that, after a short introductory period, parents give their children between two and six capsules of Speak per day, meaning that children taking the supplement are

ingesting between 500 IU and 1500 IU of vitamin E in the form of d-alpha tocopherol, and an additional 300 IU to 900 IU of vitamin E in the form of gamma tocopherol on a daily basis.<sup>51</sup>

The tolerable upper intake level (i.e., the maximum daily intake unlikely to cause adverse health effects) for vitamin E set by the Food and Nutrition Board (FNB) at the Institute of Medicine of The National Academies is 300 IU for children between 1 and 3 years of age, and 450 IU for children between 4 and 8 years of age.<sup>52</sup>

This means that children between the age of one and three taking Speak are exceeding the tolerable upper intake level for d-alpha tocopherol by 66% to 400% (depending on whether they take two, four, or six capsules per day), and children between the age of four and eight are exceeding the tolerable upper intake level for d-alpha tocopherol by 11% to 233%. Further, by NourishLife's own calculations, children under the age of four taking Speak are receiving between 5,000% and 15,000% of the daily value of d-alpha tocopherol, while children over the age of four are receiving between 1,665% and 4,995% of the daily value.<sup>53</sup>

Of note, the FNB's vitamin E intake levels are for d-alpha tocopherol alone. They do not include the appropriate intake levels for gamma-tocopherol.<sup>54</sup>

## ii. Dangers associated with high doses of vitamin E

These extremely high doses of vitamin E are alarming. The NIH reports that high doses of alpha-tocopherol supplements can cause hemorrhaging, as the supplement is a blood thinner.<sup>55</sup> The NIH also cites to two clinical trials that have found an increased risk of hemorrhagic stroke in participants taking alpha-tocopherol.<sup>56</sup>

In another study, researchers found that healthy men who took 400 IU of vitamin E per day (which is 400 IU *less* than the *minimum* amount of vitamin E children on Speak are taking) had a significantly increased risk of prostate cancer.<sup>57</sup> In yet another study, researchers at Johns Hopkins University found that use of high-dose vitamin E supplements, again, in excess of 400 IU, is associated with a higher overall risk of dying.<sup>58</sup>

In an interview with CBS News, Edgar R. Miller III, MD, PhD, one of the lead researchers of the Johns Hopkins study, explained that there are several theories regarding why vitamin E increases the risk of death.<sup>59</sup> One theory is that vitamin E is a blood thinner and increases the risk of bleeding, which, in turn, increases the risk of a stroke. Another theory is that when vitamin E is given in high doses, the vitamin stops working like an antioxidant (which removes harmful molecules in the body) and instead becomes a pro-oxidant, promoting the production of harmful molecules. A third theory suggests that high doses of vitamin E "wipe out other antioxidants, which disrupts the body's natural antioxidant protection system."<sup>60</sup> Dr. Miller then stated that, even without a clear explanation of how vitamin E may increase mortality, people should not take the vitamin.<sup>61</sup>



Based on this research, there can be no question that there are health concerns associated with giving children between 800 and 2400 IU of vitamin E per day.<sup>62</sup> As for the other components of Speak – vitamin K and Omega-3 and 6 – see endnotes 55 and 63.

**B. Adverse effects reported by NourishLife and by parents of children taking Speak**

Given the elevated doses of vitamins in Speak,<sup>63</sup> it is not surprising that some parents have reported that their children experienced adverse effects after taking the Speak supplement. One mother reported that her 11-year-old son regressed after taking Speak, while another mother reported that her 3-year-old daughter experienced seizure-like behavior for the first time after taking Speak.<sup>64</sup> Further, according to NourishLife, healthy children taking Speak can experience diarrhea, and moodiness, irritability, and emotional outbursts.<sup>65</sup> In short, Speak may pose a health risk to children.

**IV. Conclusion**

For the reasons stated in this letter, TINA urges the FTC to move quickly in order to halt NourishLife's deceptive advertising and marketing of Speak. This measure is not only necessary to protect consumers from deception, but is a public health necessity. TINA further requests that the FTC require NourishLife to run corrective advertising to dispel any lingering deceptions caused by NourishLife's fraudulent and misleading marketing efforts.

Sincerely,



Laura Smith, Esq.  
Legal Director  
Truth in Advertising, Inc.



Bonnie Patten, Esq.  
Executive Director  
Truth in Advertising, Inc.

Cc: Mary Engle, Associate Director for Advertising Practices

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<sup>1</sup> *Evaluation and Management of the Child with Speech Delay*, Alexander K.C. Leung, M.B.B.S., June 1, 1999, American Family Physician, available at <http://www.aafp.org/afp/1999/0601/p3121.html> (hereinafter "AFP article") (estimating that between 3 and 10 percent of children have speech delays) (Exhibit 1); *Speech Delay*, available at <http://www.keepkidshealthy.com/welcome/conditions/speechdelay.html> (stating that about 5-10% of children have a developmental disability that causes a delay in their speech and language development) (Exhibit 2); Central Intelligence Agency World Factbook, available at <https://www.cia.gov/library/publications/the-world-factbook/geos/us.html#People> (indicating that the United States population of children under the age of 15 is 62,770,631) (Exhibit 3).

<sup>2</sup> AFP article (Ex. 1); *Speech Delay in Kids Linked to Later Emotional Problems*, Denise Mann, WebMD Health News, June 28, 2010, available at [www.webmd.com/parenting/news/20100628/speech-delay-in-kids-linked-to-later-emotional-problems](http://www.webmd.com/parenting/news/20100628/speech-delay-in-kids-linked-to-later-emotional-problems) (Exhibit 4).

<sup>3</sup> Verbal apraxia, or apraxia of speech, is a neurological condition involving difficulty coordinating mouth and speech movements.

<sup>4</sup> TINA is a nonprofit consumer advocacy organization dedicated to empowering consumers to protect themselves against deceptive advertising.

<sup>5</sup> Draft United States District Court Complaint (Exhibit 5).

<sup>6</sup> <http://www.speechnutrients.com/about/key-leadership/> (Exhibit 6).

<sup>7</sup> <http://www.speechnutrients.com/products/speak/>, under the "Supplement Facts and Dosage" tab (Exhibit 7).

<sup>8</sup> These daily value percentages pertain only to the d-alpha tocopherol form of vitamin E. See Photograph of Speak product package – Supplement Facts (Exhibit 8). It does not pertain to the gamma tocopherol levels in Speak. The Food and Nutrition Board (FNB) at the Institute of Medicine of the National Academies has not set intake limits and dosages for this form of vitamin E.

<sup>9</sup> Speak Fact Sheet (Exhibit 9); <http://www.speechnutrients.com/products/speak/>, under the "Frequently Asked Questions" tab (Exhibit 10). In the "Frequently Asked Questions" section of its website, NourishLife suggests consulting a healthcare provider before administering more than four capsules of Speak per day to children, and before administering Speak to children who have certain health issues, such as cerebral palsy, autism, neurological disorders, developmental regression, seizures, or sleep apnea. *Id.*

<sup>10</sup> It is important to note that identifying the root of a speech delay can be complicated as there are many different causes of this disability, including:

- Neurological disorders, such as autism and apraxia;
- Neurological injuries, such as cerebral palsy (a movement and posture disorder caused by abnormal development of, or damage to, parts of the brain), and receptive and expressive aphasia (loss of the ability to understand and express speech, caused by brain damage);
- Structural/anatomical problems, such as a cleft lip or palate, or vocal chord abnormalities;
- Intellectual disability (i.e., mental retardation);
- Environmental psychosocial deprivation, such as poverty, abuse, neglect, and malnutrition;
- Hearing impairments;
- Developmental/maturation delays;
- Learning disabilities; and
- Selective mutism.



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AFP article (Ex. 1); *Speech and Language Delay and Disorder*, University of Michigan Health System, available at <http://www.med.umich.edu/yourchild/topics/speech.htm> (Exhibit 11).

<sup>11</sup> <http://www.speechnutrients.com/products/speak-starter-kit/> (Exhibit 12).

<sup>12</sup> NourishLife's February 26, 2013 electronic newsletter (Exhibit 13).

<sup>13</sup> Google advertisements for Speak (Exhibit 14).

<sup>14</sup> SpeechNutrients' Facebook page (<http://www.facebook.com/speech.nutrients>) (Exhibit 15).

<sup>15</sup> SpeechNutrients' Twitter page ([http://twitter.com/#!/nl\\_speak](http://twitter.com/#!/nl_speak)) (Exhibit 16).

<sup>16</sup> Photograph of Speak trade show booth display (Exhibit 17).

<sup>17</sup> <http://www.speechnutrients.com/> (Exhibit 18),

<http://www.speechnutrients.com/products/speak/> (Exhibit 19),

<http://www.speechnutrients.com/about/about-chrco/> (Exhibit 20); photograph of Speak product package – front (Exhibit 21); photograph of Speak product package – side (Exhibit 22).

<sup>18</sup> <http://www.speechnutrients.com/products/speak/>, under the "Formulation" tab (Exhibit 23).

<sup>19</sup> See, e.g., <http://www.speechnutrients.com/about/about-chrco/> (Ex. 20),

<http://www.speechnutrients.com/products/speak/>, under "Formulation" tab (Ex. 23), and

<http://www.speechnutrients.com/about/accreditations/> (Exhibit 24).

<sup>20</sup> See, e.g., <http://www.speechnutrients.com> (Ex. 18); photograph of Speak trade show booth display (Ex. 17).

<sup>21</sup> On ApraxiaResearch.com, a website owned by NourishLife, the company specifically refers to U.S. Patent Application 20080213239 as the patent application that was filed for the formula in Speak. See <http://www.apraxiaresearch.com/clinical-research> (Exhibit 25); see also whois.net domain registration for ApraxiaResearch.com, available at <http://www.whois.com/whois/apraxiaresearch.com> (Exhibit 26).

<sup>22</sup> Though Speak contains vitamin K and omega-6 fatty acids, in addition to omega-3 fatty acids and vitamin E, the Speak formula is touted as an omega-3/vitamin E formula, since, according to NourishLife, those are the two active ingredients.

<sup>23</sup> Patent application filed with U.S. Patent and Trademark Office (Exhibit 27).

<sup>24</sup> Rejection of Patent Application – Summary (Exhibit 28); Detailed Rejection Statement (Exhibit 29). In April 2012, following the final rejection, the patent application was amended. No official action has yet been taken with respect to the amendment.

<sup>25</sup> <http://www.speechnutrients.com/community/testimonials/> (Exhibit 30).

<sup>26</sup> *Id.*

<sup>27</sup> Screenshots showing comparison of testimonial images and iStock images (Exhibit 31).

<sup>28</sup> NourishLife's February 26, 2013 electronic newsletter (Ex. 13); screenshot showing that photograph in electronic newsletter is from iStockphoto (Exhibit 32).

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<sup>29</sup> TINA obtained the archived data through Internet Archive Way Back Machine. The testimonials that appeared on the Speak website in 2010 are available at [http://web.archive.org/web/20090623045758/http://www.speechnutrients.com/testimonials\\_speech.aspx](http://web.archive.org/web/20090623045758/http://www.speechnutrients.com/testimonials_speech.aspx) (Exhibit 33).

<sup>30</sup> *Childhood Apraxia of Speech*, American Speech-Language-Hearing Association, available at <http://www.asha.org/public/speech/disorders/childhoodapraxia.htm#tx> (Exhibit 35); *Apraxia of Speech: How is it Treated?* National Institute on Deafness and Other Communication Disorders, available at [http://www.nidcd.nih.gov/health/voice/pages/apraxia.aspx#apraxia\\_05](http://www.nidcd.nih.gov/health/voice/pages/apraxia.aspx#apraxia_05) (Exhibit 36); *Here's How to Treat Childhood Apraxia of Speech*, Margaret Fish, Part II Foundations of Effective Treatment for Childhood Apraxia of Speech: P.R.I.S.M., available at <http://www.pediastaff.com/resources-book-excerpt-from-heres-how-to-treat-childhood-apraxia-of-speech--featured-february-28-2011> (Exhibit 37).

<sup>31</sup> <http://www.speechnutrients.com/community/testimonials/> (Ex. 30).

<sup>32</sup> *Id.*

<sup>33</sup> NourishLife's February 26, 2013 electronic newsletter (Ex. 13).

<sup>34</sup> <http://www.speechnutrients.com/> (Ex. 18).

<sup>35</sup> <http://www.speechnutrients.com/products/speak/> (Ex. 19).

<sup>36</sup> <http://www.speechnutrients.com/community/testimonials/> (Ex. 30).

<sup>37</sup> SpeechNutrients' Facebook page (Ex. 15).

<sup>38</sup> SpeechNutrients' Twitter page (Ex. 16).

<sup>39</sup> <http://www.speechnutrients.com/research/> (Exhibit 38).

<sup>40</sup> Omega-3s are a type of PUFA.

<sup>41</sup> Morris and Agin study (Exhibit 39), at 36.

<sup>42</sup> "Many of our conclusions are speculative in the absence of controlled clinic trials. A better understanding of the underlying mechanisms accounting for these benefits is needed, and controlled research in apraxia and autism is warranted. The subjective nature of parental report and varied doses of supplements used are major limitations of this report. Future investigations should use validated and reliable outcome measures to determine the potential benefits of these nutritional interventions." Morris and Agin study (Ex. 39), at 41.

<sup>43</sup> Richardson and Montgomery study (Exhibit 40)

<sup>44</sup> <http://www.speechnutrients.com/research/> (Ex. 38).

<sup>45</sup> <http://www.speechnutrients.com/products/speak/>, under "Formulation" tab (Ex. 23).

<sup>46</sup> Product Review: *Fish Oil and Omega-3 Fatty Acid Supplements Review (Including Krill, Algae, and Calamari Oil)*, ConsumerLabs.com. (Exhibit 41).



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<sup>47</sup> <http://www.apraxiaresearch.com/> (Exhibit 42).

<sup>48</sup> Whois.net domain registration for ApraxiaResearch.com, available at <http://www.whois.com/whois/apraxiaresearch.com> (Exhibit 26).

<sup>49</sup> <http://www.apraxiaresearch.com/clinical-research>(Exhibit 25).

<sup>50</sup> <http://www.speechnutrients.com/products/Speak/>, under the “Supplement Facts and Dosage” tab (Ex. 7). Note that NourishLife lists the amount of gamma tocopherol in Speak in terms of milligrams. TINA has converted the milligrams to IU for the sake of consistency and ease of reference.

<sup>51</sup> <http://www.speechnutrients.com/products/speak/>, under the “Frequently Asked Questions” tab (Ex. 10); *see also* Speak Fact Sheet (Ex. 9).

<sup>52</sup> NIH Office of Dietary Supplements, Dietary Supplement Fact Sheet: Vitamin E, available at <http://ods.od.nih.gov/factsheets/vitamine/> (Exhibit 43).

<sup>53</sup> These percentages do not include the additional amount of vitamin E in the form of gamma tocopherol children on Speak are receiving.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* NourishLife confirms this fact by stating that vitamin E acts as a blood thinner, and to thus “exercise caution” and to avoid taking ibuprofen, aspirin, and Coumadin while taking Speak. *See* [www.speechnutrients.com/products/speak/](http://www.speechnutrients.com/products/speak/), under the “Frequently Asked Questions” tab (Ex. 10) and the “Supplement Facts and Dosage” tab (Ex. 7). NourishLife also indicates that it added vitamin K to the supplement in order to balance the vitamin E, because vitamin K assists in blood clotting. (Ex. 10).

<sup>56</sup> NIH Office of Dietary Supplements, Dietary Supplement Fact Sheet: Vitamin E, available at <http://ods.od.nih.gov/factsheets/vitamine/> (Ex. 43); *Vitamins E and C in the Prevention of Cardiovascular Disease in Men*, The Physicians’ Health Study II Randomized Controlled Trial, Howard D. Sesso, ScD, MPH, et al., JAMA, Nov. 12, 2008, Vol. 300, No. 18 (Exhibit 44); *The Effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and Other Cancers in Male Smokers*, The Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group, New England Journal of Medicine, Apr. 14, 1994, Vol. 330, No. 15 (Exhibit 45).

<sup>57</sup> *Vitamin E and the Risk of Prostate Cancer*, The Selenium and Vitamin E Cancer Prevention Trial (SELECT), Eric A. Klein, M.D., et al., JAMA, Oct. 12, 2011, Vol. 306, No. 14 (Exhibit 46). The men in this study were given vitamin E in the form of all rac-alpha tocopherol, otherwise known as dl-alpha tocopherol.

<sup>58</sup> *Meta-Analysis: High-Dosage Vitamin E Supplementation May Increase All-Cause Mortality*, Edgar R. Miller III, MD, PhD, et al., Annals of Internal Medicine, Jan. 4, 2005, Vol. 142, No. 1 (Exhibit 47). Because this study examined several different clinical trials, it is not clear whether all the participants were given the alpha-tocopherol form of vitamin E. Also, a limitation of the study is that a large portion of the participant population was over the age of 60 and had a pre-existing health condition.

<sup>59</sup> *Vitamin E May Shorten Life*, CBS News, available at <http://www.cbsnews.com/stories/2004/11/10/health/webmd/main654887.shtml> (Exhibit 48).

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<sup>60</sup> *Id.*

<sup>61</sup> In the study, the researchers noted that “[o]n the basis of [their] study, high-dosage vitamin E supplementation is clearly unjustified.” Miller study (Ex. 47), at 43. They later noted that “any high-dosage vitamin supplements should be discouraged until evidence of efficacy is documented from appropriately designed clinical trials.” *Id.* at 45.

<sup>62</sup> To date, the studies that have examined the effects of taking vitamin E have all been conducted on adults. (Children are generally not used in clinical studies.) However, the current research on adults suggests that extreme caution should be taken when giving the vitamin to children, a much more vulnerable population.

<sup>63</sup> In addition to elevated doses of vitamin E, Speak also contains high doses of vitamin K (i.e., 1 mg of vitamin K1 and 150 mcg of vitamin K2 per capsule). These amounts, especially when doubled, quadrupled, and sextupled, are dramatically higher than the daily adequate intake recommendation set by the FNB (i.e., 30 mcg for children ages 1 to 3, and 55 mcg for children ages 4 to 8). *Vitamin K Fact Sheet, Dosage*, NIH Medline Plus, available at <http://www.nlm.nih.gov/medlineplus/druginfo/natural/983.html#Dosage> (Exhibit 49) (the FNB has not yet established a recommended daily allowance or a tolerable upper limit for vitamin K). According to some sources, high doses of vitamin K may trigger allergic reactions and should not be taken without a doctor’s recommendation. *See, e.g., Vitamin K*, WebMD, available at <http://www.webmd.com/vitamins-and-supplements/lifestyle-guide-11/supplement-guide-vitamin-k> (Exhibit 50).

Further, based on the opinions of some experts regarding proper dosages of omega-3s, Speak contains an elevated dose of fish oil. (Upper limits and intake levels have not yet been established for this supplement.) According to the NIH, high doses of fish oil may reduce the immune system’s activity, thereby reducing the body’s ability to fight infections. High doses can also increase cholesterol levels in some people, and doses exceeding 3 grams (3,000 mg) may prevent blood from clotting. *Fish Oil*, National Institutes of Health, available at <http://www.nlm.nih.gov/medlineplus/druginfo/natural/993.html> (Exhibit 51).

<sup>64</sup> *Speech experts wary of untested supplement sold as a speech aid for kids with verbal apraxia*, Deborah L. Shelton, Chicago Tribune, Sep. 16, 2010, available at [http://articles.chicagotribune.com/2010-09-16/health/ct-met-speech-supplements-20100915\\_1\\_dietary-supplements-speech-therapy-vitamin-e-supplements](http://articles.chicagotribune.com/2010-09-16/health/ct-met-speech-supplements-20100915_1_dietary-supplements-speech-therapy-vitamin-e-supplements) (Exhibit 52).

<sup>65</sup> <http://www.speechnutrients.com/products/speak/>, under the “Frequently Asked Questions” tab (Ex. 10) and the “Supplement Facts and Dosage” tab (Ex. 7).