



## **DHA and ARA in Infant Formula Dangerous and Unnecessary—Synthetic Additives Have No Place in Infant Foods**

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**Note: Our original report on DHA and ARA in infant formula, published in 2008, is available on our website at [www.cornucopia.org](http://www.cornucopia.org).**

### **DHA Omega-3 and ARA Omega-6 Oils: Documenting Stories of Infant Suffering**

Karen Jensen experienced every new mother's nightmare—watching her helpless newborn in constant distress from severe and chronic gastrointestinal pain, not knowing how to help.

When her daughter was a month old, she suddenly stopped breathing and turned blue. Luckily, Karen discovered her in time and rushed her to the hospital, where she recovered. Desperate to find relief for her baby, who was formula-fed and had cried constantly from gastrointestinal upset since switching to formula, Karen decided to give her daughter a special type of infant formula. A friend had given her some free samples to try—and it so happened that this formula was one of the very few options that did not contain the additives DHA and ARA.

Infant formula makers advertise DHA and ARA, which are added as synthetic nutritional oils to infant formula, as being essential for an infant's brain and eye development, so Karen was hesitant to give her baby formula without them. Although her baby did remarkably better on the day after being given non-DHA/ARA formula, Karen wanted to make sure that her baby received these ingredients. She bought the same brand and type of formula, Neocate, but made sure to buy the kind that contained the highly touted additives.

“Suddenly, it seemed like we were back at square one,” says Karen. “She cried nonstop daily, couldn’t sleep.” As soon as the DHA and ARA additives returned to her baby’s formula, so did her gastrointestinal distress.

When Karen accidentally grabbed a can without DHA and ARA from her store shelves, she went on line to search for DHA and ARA supplements that she could add herself. That’s when she stumbled across the Cornucopia Institute’s original report, released in 2008, which alerts parents to the possibility of adverse reactions from DHA and ARA, and shares adverse reaction reports with the public.

“It sounded just like my baby. So, we went ahead and tried the straight formula without the DHA/ARA in it,” Karen remembers. “Within 24 hours, we had a brand new, entirely different baby. She had no abdominal distress, no gas, she smiled and played and for the first time ever we heard her laugh.”

Karen has been careful to avoid formula with DHA and ARA ever since, and marvels at her baby daughter’s transformation.

Karen’s awful experience with DHA and ARA additives in infant formula is, unfortunately, not unusual.

Holly Schneider, from Taylor, Michigan, put her infant son to sleep every night hooked up to a breathing monitor, as recommended by his pediatrician, in case his constant vomiting should choke him during sleep.

After trying every type and brand of formula, her son’s symptoms stopped almost immediately, at six and a half months of age, after Holly accidentally bought formula without DHA and ARA.

Holly remembers the first months of her son’s life: “He had explosive diarrhea, projectile vomiting, dehydration, excessive gas, weight loss, cried all the time and couldn’t sleep. At every feeding, he would begin squirming and screaming halfway through the bottle, pulling up his legs, and I could hear his stomach churning.” When it was time for her son to feed again, the process would start all over.

Along with hundreds of other mothers and fathers who watched the incredible transformation when they gave their baby formula without DHA and ARA additives, Karen and Holly have alerted the FDA. They believe that the synthetic DHA and ARA additives are the cause of their baby’s suffering, and have shared their stories with the FDA’s Medwatch program, which allows consumers and health professionals to officially send adverse reaction reports to the agency.

Some parents simply state the facts—“Child was given Enfamil with DHA and ARA, developed severe diarrhea. When switched to Enfamil without DHA and ARA, did fine”—states one report.

Other can't help but reveal their anger—"why did FDA allow the formula companies to produce these formulas without long term testing???" writes a parent who reported that her baby was "extremely gassy, fussy, and has terrible gas pains" when given formula with DHA and ARA.

This parent probably never received an answer to her question—why the FDA allowed these additives on the market. Yet the answer is intriguing.

## **Corporate Power—Getting Novel Ingredients on the Market**

### **The FDA Approval Process—Fraught with Shortcomings**

When a company develops a new ingredient, and wants to use it in infant formula, the law requires that they first petition the FDA for "Generally Recognized As Safe" status—or "GRAS" for short.

Martek Biosciences Corporation, based in Columbus, Maryland, developed DHA and ARA additives for infant formula by fermenting cryogenically frozen algae and fungus, extracting the oil with hexane, a neurotoxic petroleum-based solvent, then bleaching and deodorizing it before making it into powder form. They petitioned the FDA for GRAS status for these additives in 1999.

Federal regulations specify that the recognition of safety must be based on the "views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food." Since it is the company's responsibility to write the petition, which includes comprehensive scientific reviews, they are responsible for convening this panel of experts.

The FDA, due to budget and time constraints, does not generally convene its own panel of experts to review a petitioned substance. That these experts are recruited and compensated by the company, rather than the FDA, to serve on the panel to determine an additive's safety should immediately discredit them as being "independent."

Another problem with convening a panel of "experts qualified to evaluate the safety" of additives is that safety can be understood on many levels. Martek's petition for GRAS status is filled with data on toxicology studies, primarily performed on rats. These tests provide proof that very high doses of DHA and ARA oil, when given to rats, do not kill them. The tests did reveal that DHA and ARA affected liver weight and other organs, but Martek's panel arbitrarily dismissed these results as irrelevant.

What none of these tests can reveal, of course, is whether human infants experience gastrointestinal reactions from the small doses of DHA and ARA oils included in formula.

At the time when the panel submitted their review to the FDA, the additives had never been on the American market—so no post-market surveillance data, or post-market reports, were available. The panel based their assessment of Martek's DHA and ARA oils on toxicological studies on non-human animals, primarily rats, and on the outcomes of "at least fourteen well-conducted clinical trials involving over 1500 infants." They noted that "no adverse events have been reported" in these clinical trials.

What they do not mention is that these clinical trials were not designed, and therefore not equipped, to detect and analyze adverse reactions to formula. They were meant to answer the question of whether these additives confer any benefits to the infants' brain and eye development—a questionable proposition that we will explore further. It appears that if adverse reactions did occur, the researchers most likely did not have the correct protocol in place to determine the cause of these adverse reactions in participating infants.

For example, a research group led by Eileen Birch reported in a 2007 clinical trial that 79 infants were enrolled in the trial, but only 68 remained at four months of age because many had symptoms "suggestive of lactose or cow milk protein intolerance." That is a 14% attrition rate. Medwatch reports suggest that reactions to Martek's DHA and ARA are similar to reactions to lactose or cow milk protein intolerance, and it is unclear from the published report whether Birch followed up on these adverse reactions. The infants who reacted negatively to the formula may have been lactose intolerant or allergic to cow milk, but the possibility that they reacted to DHA and ARA remained unexplored by the researchers. Clinical trials conducted prior to 1999, and included in Martek's petition, most likely encountered similar drop-out rates.

In fact, Cornucopia found no data in the scientific literature from researchers who followed through to determine whether withdrawals from clinical trials were related specifically to intolerance to DHA and ARA. A more recent study by Eileen Birch et al., the group that receives funding from Mead Johnson, did include a comparison of the drop-out rates, due to adverse reactions to formula, and found no differences between the group receiving no DHA additives and those that did. However, the researchers did not follow through to determine the cause of any of the adverse reactions in the DHA groups. It is quite possible that, if an infant did react to DHA and ARA specifically, it remained undiagnosed.

It is clear that, when the panel wrote its 1999 GRAS petition, serious and extensive analyses of adverse reactions to formula during clinical trials simply did not exist. Ten years later, they still don't.

### **FDA Voices Serious Doubts and Concerns—Martek Fights Back**

The FDA officials who received and reviewed Martek's petition in 1999, both with Ph.D. degrees, recognized these shortcomings, and voiced serious concerns about allowing GRAS status for these DHA and ARA additives.

A year after they submitted their petition, lawyers representing Martek requested a meeting with the FDA. They communicated their dissatisfaction with the FDA's slow response; the FDA responded that they were not simply dragging their feet, but genuinely concerned with the safety of the additives.

A month after the meeting, the FDA outlined their concerns in a letter to Martek. They described the lack of data supporting the need for DHA and ARA in infant formula, studies reporting unexpected deaths from Sudden Infant Death Syndrome (SIDS), sepsis or necrotizing enterocolitis in infants consuming DHA and ARA, and reports of adverse events and other morbidities including diarrhea, flatulence, jaundice, and apnea in infants fed formula with added DHA and ARA.

Within weeks, Martek responded by largely dismissing the FDA's concerns. Less than two months later, the FDA officials gave in and granted GRAS status to DHA and ARA. The Cornucopia Institute, through a Freedom of Information Act query, requested records of meetings between Martek lobbyists or lawyers and FDA officials, to determine why the FDA would give in so suddenly. FDA responded that records of such meetings, which we know occurred, were unavailable.

All we know, at this point, is that Martek lobbyists met with the FDA officials, behind closed doors, and within months, their additives were on the market.

However, while the FDA granted GRAS status, they did not do so without officially repeating their serious concerns and stressing that they would expect rigorous post-market surveillance and additional safety reports from both Martek and formula manufacturers. Here's what the FDA wrote:

*"It is FDA's view that any evaluation that a use of a food ingredient is safe is a time-dependent judgment that is based on general scientific knowledge as well as specific data and information about the ingredient. For these reasons, FDA would expect any infant formula manufacturer who lawfully markets infant formula containing ARASCO and DHASCO to monitor, through scientific studies and rigorous post-market surveillance, infants who consume such a formula. We also would expect regular reports of such studies and post-market surveillance."*

By expressing that its evaluation of DHA and ARA's safety is a "time-dependent judgment," the FDA officials clearly expected that a change DHA and ARA's GRAS status would be possible, if further information regarding safety problems should come to light in the future. They also expected "rigorous post-market surveillance" of infants who consume formula with DHA and ARA. Their doubts about DHA and ARA's safety could not be any clearer from this letter.

After learning of the hundreds of reports submitted to the FDA by health care providers and parents of infants who became sick from formula with DHA and ARA, The Cornucopia Institute contacted the formula manufacturers directly. Not only were they unwilling to share any data on safety studies or post-market monitoring, but they even vehemently defended DHA and ARA's safety. Although we know of numerous parents who directly contacted the manufacturers, formula manufacturers deny any knowledge of safety problems with these additives.

### **Formula Manufacturers Fail to Perform Post-Market Surveillance**

Perhaps the formula manufacturers did not take the FDA's warning seriously, because they believe that an expectation expressed in a letter from the FDA bears no legal weight. However, monitoring the safety of infant formula is in fact a legal responsibility outlined in federal law and regulations, which state that any manufacturer of infant formula shall have "provisions for the review of any complaint involving an infant formula and for determining the need for an investigation of the possible existence of a hazard to health" (21 CFR 106.100(k)).

These federal rules also state that "when a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint" (21 CFR 106.100(k)(2)).

Therefore, the expectation that formula manufacturers should have performed post-market surveillance on formula with DHA and ARA comes not only from the FDA's 2001 letter, but from existing federal law as well. It was surprising, then, when Mead Johnson responded to Cornucopia's request for information regarding post-market surveillance reports with a complete denial of any problems associated with DHA and ARA.

When The Cornucopia Institute, through FOIA, asked the FDA whether any formula manufacturer had submitted a post-market surveillance report or additional safety study since 2001, the answer was "no." In their own words: "FDA has never received any reports or studies regarding post-market surveillance or scientific studies monitoring or evaluating the safety of DHASCO and ARASCO (Martek's proprietary name for synthetic DHA and ARA oils) in infant formula."<sup>i</sup>

It would be one thing if, nine years after receiving GRAS status from a hesitant FDA, formula manufacturers diligently performed post-market monitoring and safety studies, and concluded that no safety concerns exist. It's another thing when formula manufacturers fail to follow through on their responsibility for post-market monitoring, and apparently ignore any parent who shares with them a report of an infant suffering from an ingredient in their formula.

For these reasons, The Cornucopia Institute has formally asked the FDA to rescind the GRAS status designation of DHA and ARA. Our letter to the FDA is available on our website.

## Phantom Developmental Benefits: DHA/ARA Oils

Of course, it would be irresponsible for a public interest organization like The Cornucopia Institute to request that an additive be taken off the market if it is beneficial to infants. In our 2008 report, we analyzed scientific studies and concluded that there was little evidence to support the claim that DHA and ARA benefit brain and eye development.

Shortly after the release of our report, a comprehensive meta-analysis, published in the *Cochrane Database of Systematic Reviews*, substantiated our conclusion.

The meta-analysis was performed by a team of scientists led by Dr. Karen Simmer, Ph.D. in Perinatal Nutrition and Professor of Newborn Medicine at the University of Western Australia. The scientists tabulated results from all well-conducted clinical trials available at the time, and arrived at the following conclusion:

*“This review found that feeding term infants with milk formula enriched with long-chain polyunsaturated fatty acids [DHA and ARA] **had no proven benefit** regarding vision, cognition, or physical growth.”*

Why, then, do Martek and formula manufacturers like Mead Johnson insist, in marketing materials and on labels, that DHA and ARA are absolutely critical for proper infant development? The answer is fairly simple: these companies profit tremendously when parents buy formula with these additives. As publicly traded corporations, they have a legal responsibility first and foremost to return profits to shareholders. It should come as no surprise, then, that they have done everything in their power to keep parents in the dark about possible side effects, while doing everything possible to promote DHA and ARA as magical nutrients.

Additional research by The Cornucopia Institute reveals that their claims are, essentially, based on the findings of a single research team funded by Mead Johnson, which makes the leading formula brand Enfamil. That nearly every other clinical trial done to date reveals no benefits is, apparently, irrelevant to companies like Martek and Mead Johnson.

Our research helps parents answer the question, “Are DHA and ARA additives necessary in my child’s formula?” by using scientific data. The answer from scientists is very different from the message that parents receive from the companies directly.

If parents listened only to advertisements, they would believe that the answer is a resounding “yes.” Prospective and new parents who express any interest in formula feeding at their doctor’s office are inundated with mailed advertisements and free samples from two major formula brands, Enfamil and Similac. Enfamil’s ads, in the past couple of years, have focused on touting the benefits of DHA and ARA. One

advertisement states that “Enfamil PREMIUM is clinically proven to result in IQ scores that are similar to those of breastfed infants.”

First, nothing is “clinically proven” until findings from one clinical trial have been repeated and corroborated by other scientists. Mead Johnson bases its outlandish IQ claims on the results of one clinical trial, conducted by scientists affiliated with the Dallas-based Southwest Retina Foundation. In a 2007 publication, they shared their results that children who were fed formula with DHA and ARA during the first 17 weeks of life had visual acuity and IQ scores similar to breast-fed infants. This team of scientists is sponsored by Mead Johnson, which has, over the years, supplied not only free formula for the trials, but has granted more than 1 million dollars to support their research.

Nearly every other clinical trial—and close to twenty exist—comes to the opposite conclusion, that adding DHA and ARA to formula provides no benefit. Even those funded by other formula makers, including Abbott Laboratories which makes Similac, have not found differences in mental or visual development between infants fed formula with and without added DHA and ARA.

### Brain Development

Dr. Simmer’s study identified ten well-conducted and good quality clinical trials that measured cognitive development. Of these ten trials, only two found statistically significant differences. One was the Mead Johnson-funded scientists, the other a team from Scotland that found that infants given DHA/ARA formula scored higher on “intentional problem solving.”

The eight other clinical trials found no differences in cognitive development between infants given control formula and those given formula with DHA and ARA, when measured on the Bayley’s scale of infant development. The table below clarifies these findings, and illustrates that the Dallas clinical trial findings cannot be corroborated by other studies. Moreover, when results from the Dallas trials are pooled with the results from all other well-conducted trials, no statistically significant benefits are found.

**Table 1: Clinical trials measuring infant development on the Bayley’s scales of infant development**

|               | Adelaide 1995 | Adelaide 1996 | China 2004 | Dallas 1998 | England 1999 | Netherlands 2005 | Portland 1997 | Portland 2001 |
|---------------|---------------|---------------|------------|-------------|--------------|------------------|---------------|---------------|
| 3 months, MDI |               |               | NO BENEFIT |             |              |                  |               |               |
| 3 months, PDI |               |               | NO BENEFIT |             |              |                  |               |               |
| 6 months, MDI |               |               | NO BENEFIT |             |              |                  |               |               |
| 6 months, PDI |               |               | NO BENEFIT |             |              |                  |               |               |

|                |            |            |  |                |            |            |            |            |
|----------------|------------|------------|--|----------------|------------|------------|------------|------------|
| 1 year, MDI    | NO BENEFIT | NO BENEFIT |  |                |            |            | NO BENEFIT | NO BENEFIT |
| 1 year, PDI    | NO BENEFIT | NO BENEFIT |  |                |            |            | NO BENEFIT | NO BENEFIT |
| 18 months, MDI |            |            |  | BENEFITS FOUND | NO BENEFIT | NO BENEFIT |            |            |
| 18 months, PDI |            |            |  | NO BENEFIT     | NO BENEFIT | NO BENEFIT |            |            |
| 2 years, MDI   |            | NO BENEFIT |  |                |            |            |            |            |
| 2 years, PDI   |            | NO BENEFIT |  |                |            |            |            |            |

MDI: Bayley Scales of Infant Development; Mental Development Index

PDI: Bayley Scales of Infant Development; Psychomotor Development Index

### Visual development

Dr. Simmer identified seven well-conducted clinical trials measuring differences in eye development. Four different teams of scientists worked on trials to determine a correlation between DHA and ARA and eye development. Of the four teams, only the Dallas-based scientists from the Southwest Retina Foundation—funded by Mead Johnson—found differences. One other trial found benefits to adding DHA without ARA, but none in the group that received formula with both additives. As with brain development, claims of DHA and ARA's benefits are based on the findings of a single team of scientists.

|                    | Adelaide 1995                                             | Adelaide 1996     | Dallas 1998    | Dallas 2005    | Portland 1997     | Portland 2001     | Memphis 1996      |
|--------------------|-----------------------------------------------------------|-------------------|----------------|----------------|-------------------|-------------------|-------------------|
| Test A, 4 months   | DHA+ARA: NO BENEFITS FOUND<br>DHA alone: BENEFITS FOUND   | NO BENEFITS       |                |                |                   |                   |                   |
| Test B, 4 months   |                                                           |                   | BENEFITS FOUND | BENEFITS FOUND |                   |                   |                   |
| Test C, 4 months   |                                                           |                   |                |                | NO BENEFITS FOUND |                   |                   |
| Test D, 4 months   |                                                           |                   |                |                | NO BENEFITS FOUND | NO BENEFITS FOUND | NO BENEFITS FOUND |
| Test C, 6 months   |                                                           |                   |                |                | NO BENEFITS FOUND |                   |                   |
| Test D, 6 months   |                                                           |                   |                |                | NO BENEFITS FOUND | NO BENEFITS FOUND | NO BENEFITS FOUND |
| Test A, 7-8 months | DHA + ARA: NO BENEFITS FOUND<br>DHA alone: BENEFITS FOUND | NO BENEFITS FOUND |                |                |                   |                   |                   |

|                   |  |  |                |                |                   |                   |                   |
|-------------------|--|--|----------------|----------------|-------------------|-------------------|-------------------|
| Test B, 12 months |  |  | BENEFITS FOUND | BENEFITS FOUND |                   |                   |                   |
| Test C, 12 months |  |  |                |                | NO BENEFITS FOUND |                   |                   |
| Test D, 12 months |  |  |                |                | NO BENEFITS FOUND | NO BENEFITS FOUND | NO BENEFITS FOUND |
| Test D, 3 years   |  |  |                |                | NO BENEFITS FOUND |                   |                   |

Test A: Steady

Test B: Sweep (logMar)

Test C: Sweep (cycles/degree)

Test D: Teller cards

A more recent meta-analysis, performed by a team of researchers led by Dr. Beyerlein and published in the January 2010 issue of the *Journal of Pediatric Gastroenterology and Nutrition*<sup>ii</sup>, uses a different methodology from Simmer's meta-analysis. The authors note that their meta-analysis method, individual patient data meta-analysis, is regarded as providing "the least biased and most reliable means" to combine results from different studies. After combining and analyzing the results from four different clinical trials, the researchers did not find any statistically significant differences between formula groups in any of the subgroups (e.g. boys, girls, low birthweight, maternal education, etc.). They conclude:

***"The absence of any detectable benefit or disadvantage in Neurodevelopment assessed with BSID at the age of 18 months for all of the children or in any subgroup therefore provides evidence against beneficial effects of LCPUFA [DHA and ARA] supplementation on BSID at 18 months under the conditions of the trials included here (emphasis added)."***

Several recent studies come to the same conclusion. A study of 241 children found that "estimated total intake of DHA in milk up to age 6 months was not associated with subsequent IQ or with score on any other test. The authors, published in October 2009 in the journal *Archives of Disease in Childhood*<sup>iii</sup>, concluded that "differences in children's intelligence according to type of milk fed in infancy may be due more to confounding by maternal or family characteristics than to the amount of long-chain polyunsaturated fatty acids they receive in milk."

The data sets are clear: results from the vast majority of clinical trials suggest that supplementing formula with added DHA and ARA does not benefit brain and eye development for term infants. Nearly every published study that claims benefits do exist is authored by the same set of Mead Johnson-funded scientists.

### **Scientists Disappointed by Finding No Benefits**

Scientists are no less affected by their personal beliefs and wishes than the rest of us, and it is clear that many who found no benefits were disappointed by their

findings. Their ways of coping with their disappointment have varied from reasonable yet misguided, to outrageous.

A study led by a scientist from Abbott Laboratories—makers of Similac—found no differences, and therefore no benefits to adding DHA and ARA. They nevertheless attempted to put a positive spin on their disappointing results. In an article published in *Pediatrics*, often read by pediatricians, they ended the last line of their abstract as follows: “In conclusion, adding both DHA and ARA when supplementing infant formulas with long-chain polyunsaturated fatty acids supports visual and cognitive development through 39 months.”

The conclusion from this article seems to intentionally mislead readers into believing that the researchers found benefits—statistically significant differences—from formula with DHA and ARA. They did not.

Several pediatricians, having read the study and seeing through the deception, wrote to *Pediatrics*’ editors,<sup>iv</sup> pointing out that they could “not find justification for the last sentence in the abstract” and that “this is quite biased” and “misleading at best.”

Another common way for scientists to cope with the disappointment of finding no benefits to adding DHA and ARA to formula is by claiming that they did not add enough of the supplements. If only they had added more, they claim, they would have found statistically significant differences. This may sound like a credible claim, but it does stand the test of available scientific evidence.

Of ten clinical trials measuring brain development used in Karen Simmer’s analysis, eight found no differences on tests of cognitive development, and some of them indeed contained low levels of DHA. The two Portland trials, for example, contained 0.13% DHA, which is the lowest level of all ten trials. However, if low levels of DHA were the cause of the lack of significant findings, why is the trial with the next lowest level of DHA one of the two that did find differences? The Scotland trial also contained low levels of DHA, between 0.15% and 0.25%, and yet this is the trial that found higher “intentional problem solving” scores in infants given formula with DHA and ARA.

If the problem really were low levels of DHA in the trials that found no differences, why are most trials’ DHA levels equal to, or close to, the levels added by the Mead Johnson-sponsored Dallas team? The formula supplied to the Dallas team by Mead Johnson contained 0.36% DHA, which is not that much higher from the 0.35% in the Adelaide trials, the 0.32% in the England trial, and the 0.30% in the Netherlands trial—none of which found differences.

So what could be the real reason for why these clinical trials found no differences? For years, breastfeeding advocates have argued that the benefits of breastmilk cannot be reduced to single ingredients. Tens of thousands of years of evolution,

they argue, have created the perfect food for infants, with thousands of nutrients that interact with one another, and can even change on a daily basis, depending on the infant's particular needs that day. Breastmilk is a matrix of nutrients, and it would be foolish for scientists to presume that they could identify, recreate, and reassemble them in a factory-produced formula.

## **Martek**

If there are so many clinical trials that find no benefits, why would Martek claim that its products have “proven” benefits?

In a 2009 interview with the *Nutrition Business Journal*, a Martek executive said that DHA and ARA are “proven to improve developmental outcomes in infants.”<sup>v</sup> No self-respecting scientist or doctor would take results from just a couple of clinical trials, ignore the ones that make up the vast majority, and conclude that anything has been “proven.”

If the clinical trials on DHA and ARA show anything at all, it is that the scientific consensus clearly tends towards “proving” that DHA and ARA confer no benefits at all.

Of course, if Martek executives were to publicly acknowledge that science does not agree with their conviction that DHA and ARA are beneficial, they risk losing the business upon which their entire profit model is based. It is their job to convince others to buy their products, even if it means twisting scientific data into misleading—even outright false—statements that fit their needs.

As with politics and religion, it is not always the truthfulness of a claim that determines its longevity and popularity, but rather the energy, time and money devoted to promoting it. The claims, as with DHA and ARA, may be false, but Martek executives know very well that if they spend enough time and money in promoting them anyway, it may not matter in the end whether science is on their side.

Martek uses various tactics to mislead people into believing that science is on their side. One is by listing pages of scientific studies as being supportive of their claims, hoping that nobody will actually read the results of the entire studies or question how many studies out there are not included on the list because they show that DHA and ARA confer no benefits at all.

On their website, Martek has a document titled “Research Supporting the Importance of DHA & ARA in Infant Development,” and lists 28 scientific publications. Martek probably hopes that visitors to their website will be impressed by what appear to be 28 separate well-conducted studies that found benefits to DHA and ARA in term infant development. A closer look—summarized below—at the studies listed shows that very few of them actually directly support Martek's claims.

## **Martek's "Supporting Research" for Infant Development is Limited and Unconvincing**

Many of the articles listed on Martek's webpage are observational studies—showing that infants given DHA formula have higher levels of DHA in their blood. These studies say nothing about whether higher DHA levels in an infant's blood actually lead to better development.

Other studies focus on the benefits of breastfeeding—scientists conclude that since breast milk contains DHA, and breastfed infants tend to score better on tests, it must be the lack of DHA in formula that leads to poorer outcomes in formula-fed infants. These studies say nothing about whether DHA in formula actually leads to better outcomes in formula-fed infants.

Martek also includes studies showing that DHA is transferred from the mother's body to the fetus during pregnancy—again, these studies say nothing about the effects of DHA supplementation on formula-fed infants.

When Martek does list clinical trials in their "research supporting the importance of DHA & ARA in infant development," the trials are not always of good quality. The meta-analysis by Simmer et al., in the *Cochrane Database of Systematic Reviews*, which reviewed all data available as of September 2007, was careful to exclude any studies with flawed designs or poor methodology. One study, for example, was excluded from Simmer's meta-analysis because the trial did not separate the DHA group of infants from the non-DHA group of infants until they were a month old.<sup>vi</sup> Yet this study, excluded from the peer-reviewed meta-analysis, found its way on Martek's list. Another study was similarly excluded from Simmer's analysis but included by Martek; in this case the infants were not randomized until they were 6 weeks old.<sup>vii</sup>

Another study was excluded from Simmer's meta-analysis because the authors did not specify the methodology used in their clinical trial. When Simmer requested clarification, the researchers did not honor her request. Whether the methodology used was sound or not remains an open question—yet the clinical trial made its way onto Martek's list of supportive studies.<sup>viii</sup>

Martek also lists studies in which the researchers found benefits at a certain age, but did not find benefits as the infants matured. In one example, infants scored higher on developmental tests at 4 months of age, but repeat assessments at 12 and 24 months of age showed no differences.<sup>ix</sup> Studies such as this one could be used to support both claims—that DHA and ARA benefit infant development, because 4 month olds seemed to score better, but could also support the claim that benefits are not long-lasting and therefore not significant.

The only clinical trials on Martek's list that were considered to be of good quality by Dr. Simmer, and that actually show a statistically significant difference between

cognitive and visual development in infants fed DHA or control formula, are those by the Southwest Retina Foundation scientists—the ones sponsored by Mead Johnson.

Martek's list contains many observational studies, one-paragraph "communications" disguised as scientific studies, studies showing the benefits of breastfeeding, workshop proceedings, and clinical trials that found only short-term, transient benefits. When these are excluded from the list, only two teams of researchers with well-conducted clinical trials are listed as supporting the importance of DHA and ARA.

Predictably, none of the clinical trials that found no benefits were included in Martek's promotion.

### **DHA for Toddlers and Children—Not a Single Study Supports Brain Development Claims**

Having conquered the infant formula market—their DHA and ARA additives are now found in 98% of infant formula—Martek uses the same strategies of misleading advertising to branch out to toddler foods. Martek has sponsored studies attempting to show that toddlers eating foods with their DHA supplements score higher on tests. Not a single study has shown positive results.

Just as the lack of scientific evidence did not stop them from promoting their products to parents of infants, they are not letting a lack of scientific evidence stop them from promoting DHA to parents of toddlers and children. Knowing that every parent wants his or her child to do well in school, and that many parents believe nutritional claims on food packages, Martek is promoting their DHA as magical brain food.

"This idea that you eat to improve your intelligence or long term brain health is a sort of a new idea. When I was a kid we always heard you drink your milk for strong bones, but you didn't hear a lot of, 'If you eat this, you're going to do better on your test or you're going to have better concentration.' The science has continued to develop and parents like the idea that you can eat something to contribute to cognitive and brain," Martek's Public Relations Director recently told a reporter.<sup>x</sup>

Sure, parents like the idea of buying foods to help children do better in school, but where is the science to back up these claims? Just as with their claims regarding infant development, Martek has a document titled "Research supporting the importance of DHA beyond infancy," with 13 references. Not a single listing refers to a study that found toddlers, children or adults performed better on cognitive function tests when given DHA supplements.

Without scientific backing, Martek has apparently decided to simply spin headlines when their clinical trials come back with results showing that their supplement are

useless. Saying that they “spin” the results is actually quite generous—spinning a result 180 degrees should more likely be considered outright dishonesty.

A 2008 article in NutraIngredients.com, an online news service for the food industry, states that “DHA boosts children’s brain powers, says Martek.”<sup>xi</sup> In bold letters, the first paragraph states “Docosahexaenoic acid (DHA) intake can improve mental acuity among pre-school children, according to a Martek BioSciences-funded study.” Those who read on, or actually read the study’s abstract, soon discover that the study actually found no differences in any of the tests of mental development between the group given a DHA additive and those given a placebo.

“Synthetic DHA **does not** boost children’s brain powers” would have been a much more accurate and honest headline.

Clearly, Martek thrives not on having facts and science on their side, but on misleading advertising and marketing. This, however, is already starting to unravel. One of Martek’s main customers, Mead Johnson, was recently found guilty of false and misleading advertising in a lawsuit brought by its competitor, PBM Nutritionals, which makes store-brand infant formula. A jury found that Mead Johnson’s claims that Enfamil LIPIL provides superior nutrition to PBM’s store-brand formula, with statements such as “it’s the only formula shown in published independent clinical trials to: improve brain development, improve eye development” are untrue.

### **European Union Rejects Health Claims for DHA and ARA**

In March 2009, the European Union’s Food Safety Authority (EFSA) rejected a petition by Mead Johnson to allow health claims on formula packaging and advertisements related to DHA/ARA and brain and eye development. Specifically, the Panel concluded that not enough scientific evidence exists to determine a cause and effect relationship between DHA/ARA supplementation of formula and benefits to infant development. Any claims that DHA and ARA benefit brain or eye development are therefore prohibited in the European Union. Martek had filed a similar petition, which was rejected by EFSA in September 2008.

After coming under fire from angry food manufacturers, whose unsubstantiated health claims were repeatedly rejected, EFSA clarified in December 2009 that it would allow vague claims, such as: “DHA can contribute to normal brain development of the foetus, infant and young children.” The reviewers stressed, however, that stronger claims, such as those linking DHA consumption to improved brain development, remain uncorroborated by sound science, and therefore prohibited.

### **Cornucopia requests similar enforcement from the Federal Trade Commission**

Cornucopia petitioned the Federal Trade Commission (FTC) two years ago to investigate formula manufacturers for false and misleading advertising. Since the case is open and under investigation, we plan to file an additional document with

more information, especially our results from closely analyzing scientific data. This letter will be available on our website.

## Organics

Since Cornucopia filed its initial legal complaint with the USDA's National Organic Program in 2008, we have contended that the inclusion of Martek's DHA and ARA in organic foods is illegal.

When organic consumers pay more for products with the green "USDA Organic" label, they are paying for the assurance that ingredients in their food are safer, purer, and less adulterated than the chemicals that masquerade as food in most conventional processed foods.

The National Organic Program has a system in place for protecting the integrity of organic processed foods. Any ingredient must either be an organically produced agricultural product or, if it is synthetic, it must be included as an approved substance on the "National List of Approved and Prohibited Substances." The "National List" ensures that most synthetic ingredients added to conventional foods stay out of organics, unless they have been reviewed and deemed safe and environmentally benign. Lose the List, and organics loses much of its meaning.

But the List can only be as strong as its enforcement. Under the Bush Administration, leadership at the National Organic Program refused to properly enforce the organic law and standards. Though DHA and ARA are not on the List, and legal complaints had been filed with the National Organic Program's Compliance office, government officials under Bush failed to enforce the standards by improperly qualifying DHA and ARA as "vitamins and minerals."

After years of pressure by The Cornucopia Institute to enforce the law and prohibit these additives in organic infant formula, the National Organic Program's new leadership, under the Obama Administration, finally issued a statement clarifying that "its previous interpretation was incorrect." The "previous interpretation" referred to in a statement was the result of a backroom deal between former leadership at the NOP, Dr. Barbara Robinson, and William J. Friedman, a corporate lobbyist.

Friedman, representing formula manufacturers, convinced Robinson to allow DHA and ARA by qualifying them as "vitamins and minerals." Anyone with a basic understanding of nutrition knows that DHA and ARA are not vitamins or minerals, and will never be qualified as such by any respectable scientist or nutritionist. Yet Friedman's lobbying and friendly relationship with Robinson paid off.

When several complaints were filed with the NOP, by unrelated citizens, lawyers and public interest groups, each complaint was readily dismissed. Through the

same Freedom of Information Act request that exposed the backroom deal between Robinson and Friedman, Cornucopia learned that National Organic Program officials, who were asked to investigate these complaints, came to the conclusion that companies were indeed in violation of organic standards by adding DHA and ARA to organic formula. These NOP officials consulted not only with one another—experts in organic regulations—but with FDA officials as well, who assured them that DHA and ARA were not required ingredients in infant formula. These officials had drafted and sent a letter to the certifying agency Quality Assurance International, alerting them of the violations, when Robinson intervened.

Robinson ordered her staff to trash the enforcement letter, and draft a new one. She specified that DHA and ARA should be allowed as “vitamins and minerals,” based on an obscure and long-forgotten 1995 recommendation by the National Organic Standards Board. Although Robinson was known as stressing to certifying agents that only official standards count when certifying organic foods, and that NOSB recommendations carried no weight under the law until adopted as a final rule in the Code of Federal Regulations, she ordered her staff to disregard the official rules and rely on an unofficial recommendation in the case of DHA and ARA. When chastising her staff and ordering them not to enforce the organic standards, she told them exactly what the corporate lobbyist Friedman had suggested to her.

Cornucopia shared these findings with the *Washington Post*, which confirmed and reported on the fact that the inclusion of DHA and ARA in organics foods was the result of insider lobbying. Despite the objections of conscientious employees at the National Organic Program, and without any citizen input, Ms. Robinson single-handedly allowed all infant formula manufacturers to put a hexane-extracted, potentially dangerous additive in organic formula.

When asked by the *Washington Post* reporter, Dr. Robinson dismissed the DHA/ARA issue as a “ridiculous” regulatory matter. Cornucopia believes, however, that protecting babies from potential harm is anything but ridiculous.

Robinson has since been replaced by the Obama/Vilsack administration. With new leadership at the National Organic Program deliberate and pro-industry mismanagement as perpetrated by Robinson is obviously no longer tolerated. Moreover, the National Organic Program now has to slowly clean up the mess created by Robinson and blessed by Bush administration appointees, and stating that DHA and ARA are not allowed in organic foods is a welcome step in this process.

The Cornucopia Institute applauds the National Organic Program for this decision. Despite push-back from companies that currently use Martek’s DHA and ARA in their organic products, Cornucopia believes that it is in the organic industry’s best interest to prohibit DHA and ARA from organics. Consumers need to be able to trust that organic foods are free of conventional additives, and it is crucial that organic foods be able to set themselves apart from conventional foods in this regard. When

people discover that corporate lobbyists have more say in the organic program than the interests of consumers, it severely hurts trust in the integrity of the organic program. Overruling these backroom deals with powerful corporations is a much-needed step toward ensuring consumer trust in the National Organic Program.

Additional concerns with the presence of Martek's DHA and ARA oils in organic foods exist, and include genetic engineering and neurotoxic chemical solvents. As described earlier, the manufacturing process for Martek's oils includes fermenting algae and soil fungus. The medium used to grow these microorganisms, according to Martek, is made primarily of dextrose derived from corn, yeast extract or a hydrolyzed vegetable protein, which is usually derived from soybeans.<sup>xii</sup> Given that available supplies of corn and soybean products in the industrial food supply are produced through genetic engineering, the likelihood that Martek's DHA and ARA oils are grown in a medium of genetically engineered organisms is very high. The use of genetic engineering is, of course, strictly prohibited in organics.

After growing their microorganisms in vats of genetically engineered substances, Martek specifies that they use a neurotoxic chemical solvent, hexane, to extract the oil. Martek writes: "The oil is first extracted by blending the dried biomass with hexane in a continuous extraction process."<sup>xiii</sup> Synthetic solvents such as hexane, which carry serious environmental and occupational safety concerns, are also prohibited in organic food processing.

Keeping organic infant formula truly organic is especially important because DHA-free organic formula can be a powerful gateway food—prompting consumers to switch to organics after negative experiences with DHA in conventional formula. Beatriz Villerreal, from Pearland, Texas, is a perfect example. She was not an organic consumer, but today her baby drinks exclusively organic milk and Baby's Only Organic formula. She has become much more aware of her food and her food choices, and says she buys a lot more organic food. Her son experienced severe side effects from formula with DHA/ARA. Her son's pediatrician prescribed Prevacid, which provided some relief but the symptoms remained. After reading about the possibility that Martek's DHA/ARA additives could be to blame, she decided to try Baby's Only Organic without Martek's oils. The transformation was remarkable, she says.

This is the power that organic foods have. We know that synthetic food inputs, whether they be pesticides, preservatives, or nutrient additives like DHA, often come with side-effects. In most cases, the side-effects won't be felt for years down the line. Martek's DHA is different only in that the side-effects experienced by some consumers are felt immediately—and disappear immediately after switching away from them. A lot of consumers buy organic foods for these reasons, to avoid the unintended consequences from consuming novel, synthetic, untested food inputs.

The USDA organic label should assure consumers that organic infant formula is free from these unapproved additives. Cornucopia urges the National Organic Program

to move ahead quickly with issuing the draft guidance and issuing the final rule, and to make the transition period for manufacturers as short as possible. Restoring the integrity of the organic label should not be delayed. One mother, Suzanne Stock, contacted us to share her story, which clearly demonstrates the need for quick enforcement and strong organic rules. Through our report, she knew about the possibility of DHA causing adverse reactions, which is why she always bought Baby's Only Organic formula for her daughter. Baby's Only does not contain Martek's oils. When the family ran out of formula, her husband went to the store. He knew to look for the organic seal, but unlike his wife, had not taken the time to thoroughly research formula brands, and didn't know that some organic brands include Martek's DHA, while others don't. He picked up a can of Earth's Best, an organic infant formula brand with the organic seal that contains Martek's DHA. Their daughter experienced diarrhea, which disappeared as quickly as it had appeared, when her mother quickly returned her to Baby's Only Organic without DHA, two days later.

Consumers should be able to trust the organic label, which is why The Cornucopia Institute is urging the National Organic Program to move quickly in enforcing the law.

It appears that leadership at the USDA may be open to accommodating industry with a long phase-out period. In a statement to the Wall Street Journal, for example, USDA Deputy Secretary Kathleen Merrigan said that, "we don't want an industry that acted in good faith to be harmed" by this decision. However, hiring a lobbyist to work out an illegal deal at the National Organic Program, some would suggest, was not acting "in good faith."

Moreover, documents obtained, through a FOIA request, by The Cornucopia Institute also indicate that infant formula manufacturers had received letters of noncompliance from their organic certifying agent, Quality Assurance International, before any formal legal complaints were even filed. Rather than taking out the unapproved "accessory nutrients," as their certifying agent requested them to do, the manufacturer pressured their certifier (again through a lawyer/lobbyist) to approve them. And when they received a letter from the National Organic Program, through their certifier, alerting them of the illegality of their "accessory nutrients," the infant formula industry responded not by following the law, but by requesting a meeting between the National Organic Program and its lawyers in an effort to reverse the USDA's decision.

These were clearly deliberate attempts to circumvent the organic law, and should hardly be described as acting "in good faith." The USDA's Deputy Secretary's characterization of the infant formula industry shows that industry-friendly decisions, though transparent and legal, need to be guarded against. Cornucopia has since shared documentation with the Deputy Secretary so she could understand the full scope of the corporate behavior in this incident.

### **Organic Products containing Martek's DHA**

Organic consumers should watch out for the following products, which contain the controversial DHA oil from Martek.

In the Dairy Case:

- Horizon Organic milk with DHA (Dean Foods)
- ZenSoy "Soy on the Go" soymilk with DHA
- Stremicks Heritage Foods organic milk with DHA

*For alternatives to these milk and soy milk products, view Cornucopia's Organic Dairy Scorecard and Organic Soy Scorecard, available at [www.cornucopia.org](http://www.cornucopia.org).*

Toddler Foods:

- Happy Bellies
- Plum Organics

Infant Formula:

- Earth's Best
- Similac
- Vermont Organics
- Bright Beginnings
- Parent's Choice (Wal-Mart's brand)

*For more information on organic infant formula, and alternatives to organic formula containing Martek's DHA, see table below.*

### **Information on Organic Formula**

Few consumer choices are as sensitive and important as an organic mother's choice of infant formula. The Cornucopia Institute understands that, while breastfeeding is universally recognized as providing nutrition that is far superior than formula, some mothers struggle with breastfeeding due to no fault of their own. Ranging from health problems to financial pressures to return to work full-time, many mothers who would prefer to breastfeed are nevertheless faced with the decision of choosing a formula for their infants.

The Cornucopia Institute provides some answers to commonly asked questions about organic formula in the table below. For example, many parents like to know who manufactures their organic formula, and many would be surprised to learn that the same company that produces all conventional, store-brand formula, such as Wal-Mart's Parent's Choice®, also manufactures Earth's Best's® organic formula. And while a new brand, Vermont Organics®, can at first glance appear to be manufactured by a small firm in Vermont, it is in fact manufactured in the same

factory that makes Wal-Mart's Parent's Choice®, Earth's Best® and Bright Beginnings®.

Only two companies responded to The Cornucopia Institute's organic dairy survey, which is used to tabulate a score on the Organic Dairy Scorecard. Baby's Only Organic® and Similac® Organic scored well, with a four-cow rating for Baby's Only Organic® and a three-cow rating for Similac®. The other brands received a zero-cow rating—due to lack of transparency.

As far as the synthetic DHA and ARA are concerned, only Baby's Only Organic® can tout that it is free from these additives. All other brands of organic formula are continuing to benefit from the backroom deal between the former head of the National Organic Program and a corporate lobbyist, despite the recent statement from the National Organic Program that this interpretation of the rules was "incorrect."

| Brand                           | Company                  | Manufacturer        | Martek's DHA and ARA?                   | Rating on Organic Dairy Scorecard                                                     |
|---------------------------------|--------------------------|---------------------|-----------------------------------------|---------------------------------------------------------------------------------------|
| <b>Baby's Only Organic®</b>     | Nature's One             | Nature's One        | Natural source of precursors to DHA/ARA |    |
| <b>Similac® Organic</b>         | Abbott Laboratories      | Abbott Laboratories | Contains Synthetic DHA/ARA              |  |
| <b>Parent's Choice® Organic</b> | Wal-Mart                 | PBM Nutritionals    | Contains Synthetic DHA/ARA              | Zero                                                                                  |
| <b>Vermont Organics®</b>        | PBM Nutritionals         | PBM Nutritionals    | Contains Synthetic DHA/ARA              | Zero                                                                                  |
| <b>Earth's Best®</b>            | The Hain Celestial Group | PBM Nutritionals    | Contains Synthetic DHA/ARA              | Zero                                                                                  |
| <b>Bright Beginnings®</b>       | PBM Nutritionals         | PBM Nutritionals    | Contains Synthetic DHA/ARA              | Zero                                                                                  |

<sup>i</sup> FOIA request 2009-3310. Signed by Hilario R. Duncan, sent June 5, 2009.

<sup>ii</sup> Beyerlein, A, Hadders-Algra M, Kennedy K, Fewtrell M, Singhal A, Rosenfeld E, Lucas A, Bouwstra H, Koletzko B, von Kries R (2010) Infant Formula Supplementation With Long-chain Polyunsaturated Fatty Acids Has No Effect on

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v <http://blog.nutritionbusinessjournal.com/nbj/2009/04/14/martek-biosciences-working-to-eliminate-dha-deficiency-in-children/>

vi Horby Jorgensen M, et al. Effect of formula supplemented with docosahexaenoic acid and gamma-linolenic acid on fatty acid status and visual acuity in term infants. *J Pediatr Gastroenterol Nutr*, 1998. 26(4):412-21.

vii Birch EE, et al. A randomized controlled trial of long-chain polyunsaturated fatty acid supplementation of formula in term infants after weaning at 6 weeks of age. *Am J Clin Nutr*, 2002. 75:570-80

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x <http://blog.nutritionbusinessjournal.com/nbj/2009/04/14/martek-biosciences-working-to-eliminate-dha-deficiency-in-children/>

xi <http://www.nutraingredients.com/Research/DHA-boosts-childrens-brain-power-says-Martek>

xii GRAS Panel Evaluation of DHASCO and ARASCO. Section 5.1.2.

xiii GRAS Panel Evaluation of DHASCO and ARASCO. Section 5.1.3.