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Infant Formula Manufacturers Again under Ethical Cloud "Marketing Gimmick" Linked to Serious Illnesses

ARLINGTON, VIRGINIA: A report released today by The Cornucopia Institute presents research indicating that new additives placed in infant formula are seriously endangering the health of some formula-fed newborns and toddlers.

The report, *Replacing Mother—Imitating Human Breast Milk in the Laboratory*, details research questioning the alleged benefits of adding "novel" omega-3 fatty acids, produced in laboratories and extracted from algae and fungus, into infant formulas. The additives raised health and safety red flags during preapproval testing while aggressive marketing campaigns by some infant formula manufacturers appear to have encouraged new mothers to give up nursing for the questionable infant products.

"When I worked in the hospital's neonatal ward, the nurses all called it 'the diarrhea formula'," says Sam Heather Doak, LPN, IBCLC, from Marietta, Ohio. "We've seen infants, tiny little humans, with diarrhea that just wouldn't stop after being given this formula." For infants, virulent and long-term diarrhea is considered a serious and life-threatening medical episode.

The infant formula referenced by Doak was supplemented with Martek Biosciences Corporation's laboratory-produced oils containing DHA and ARA. DHA, an omega-3 fatty acid, and ARA, an omega-6 fatty acid, are naturally found in human breast milk and are considered important nutrients for rapidly developing infants.

But laboratory-produced DHASCO and ARASCO (Martek's names for their proprietary oils) are materially different from the fats found in a mother's breast milk. Martek's products are extracted from fermented algae and fungus, with the use of the synthetic solvent hexane, a neurotoxic chemical. They contain only 40 to 50% DHA and ARA, with the balance being sunflower oil, diglycerides, and nonsaponifiable materials. Some of these components are not

found in human breast milk, and the triglycerides carrying DHA and ARA are not identical to those found in human breast milk—and have never been part of the diet for human infants.

Infant formula manufacturers suggest that DHA and ARA oils in formula are necessary to support proper development, yet serious doubts persist within the scientific community regarding whether these oils actually confer any long-term benefits to an infant's brain and eye development.

“It's true that DHA and ARA are important nutrients for developing infants—that's why they're found in human breast milk. But we have also seen that some infants are experiencing side effects like diarrhea from consuming the manufactured DHA and ARA oils in formula,” says Jimi Francis, Ph.D., a biochemist specializing in DHA in infant nutrition at the Allie M. Lee Laboratory for Omega-3 Research at the University of Nevada at Reno. Also, humans are able to produce DHA and ARA on their own from other fats.

The Cornucopia Institute, a Wisconsin-based farm and food policy research group and corporate watchdog, presented its report, in partnership with the National Alliance for Breastfeeding Advocacy, to government officials and medical professionals at the January 25th meeting of the U.S. Breastfeeding Committee in Arlington, Virginia.

“While infant formula manufacturers claim that these oils are perfectly safe and necessary for proper development, our report aims to provide a more balanced and detailed picture,” said Charlotte Vallaeys, Farm and Food Policy Analyst with the Cornucopia Institute and lead author of the report. “We investigated how a toxic chemical is used as processing agents in the manufacturing process, the inadequate testing for safety, and most importantly, how some infants are experiencing serious adverse reactions from consuming formula supplemented with these oils,” Vallaeys added.

“This report presents a disturbing look at the addition of novel ingredients into infant formula,” says Marsha Walker, Executive Director of the National Alliance for Breastfeeding Advocacy. “The FDA has received scores of reports on the adverse effects of these ingredients, but, to date, the public's only access to these is through Cornucopia's Freedom of Information Act request. This report will help alert the health care community and federal agencies to some of the adverse effects of added DHA and ARA in infant formulas.”

Cornucopia and the National Alliance for Breastfeeding Advocacy also announced that they are calling for a warning label on all formula containing DHA/ARA. The groups are petitioning the FDA for a label alerting parents of the range of possible complications from DHA/ARA-supplemented formula.

“Although many infants seem to be able to tolerate these materials, regardless of their efficacy, we know that some children face serious and even life-threatening impacts,” said Vallaeys. “At a minimum parents need to be informed of the risks so they can immediately pull children off these designer formulas if health complications occur.”

While FDA officials had previously noted studies that reported diarrhea, flatulence, jaundice, and apnea in infants fed DHA/ARA-supplemented formula, they nevertheless did not block the use of the oils. That action gave the green light for infant formula manufacturers to add the oils

to formula. Today, Martek boasts that 90% of formula in the U.S. contains its patented DHA- and ARA-containing oils.

Advertisements touting DHA/ARA-supplemented formula as “closer than ever to breast milk” have sparked another action from Cornucopia and the National Alliance for Breastfeeding Advocacy. The two groups have jointly filed a petition with the Federal Trade Commission alleging that formula companies are engaged in misleading advertising. The ads appear based on shaky scientific evidence.

“Adding these two fatty acids to formula does not make it ‘close to breast milk,’” says Jennifer Thomas, M.D., a pediatrician practicing in Racine, Wisconsin. “Breast milk has nutrients, live cells, and bioactive compounds that are absent from formula,” she added. “These advertisements make it a lot harder for me, as a pediatrician, to convince new mothers to breastfeed if they have seen advertisements or labels implying that formula is just as good as breast milk.

The Cornucopia Institute is especially concerned that these additives are now sold in certified organic formula, a practice that appears to violate federal organic regulations. “This marketing gimmick has no place in organics,” said Mark Kastel, Cornucopia's Codirector.

Federal regulations, Kastel explained, specifically prohibit the use of hexane-extracted ingredients in organic foods. Cornucopia has filed a Freedom of Information Request looking at how the USDA appears to have collaborated with lobbyists for Dean Foods and others in secretly allowing these materials.

The full report can be viewed on The Cornucopia Institute's web page at:

http://cornucopia.org/DHA/DHA_FullReport.pdf

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MORE:

Product Safety

Since its introduction six years ago, the majority of formula in the United States is now supplemented with "novel" omega-3 and omega-6 fatty acids, produced in laboratories, extracted from algae and fungus. Currently, formula manufacturers do not provide any information, on labels or their web sites, on the possibility of adverse reactions in some infants.

The Cornucopia Institute is urging parents of infants who have reacted negatively to formula with DHA and ARA to report these adverse reactions to the FDA's Safety Information and Adverse Event Reporting Program. Reports can be submitted online by following this link: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.

The Cornucopia Institute is collecting this data as well and is encouraging parents who feel their children have been negatively impacted by formula containing DHA/ARA, or health care

providers who suspect that the formula has caused health problems, to send their reports to the organization at cultivate@cornucopia.org.

Organics

In 2006, a compliance officer at the USDA dismissed a formal legal complaint alleging that hexane-extracted algal DHA and fungal ARA oils were illegally added to organic infant formula. This ruling, the latest in a series of industry-friendly interpretations of the organic standards, appears to be in conflict with the law passed by Congress and in violation of the Organic Food Production Act of 1990.

The National Organic Standards Board (NOSB) is charged by Congress to recommend changes to the national organic standards and the list of allowed materials/ingredients, with input from the public. USDA officials must consult the NOSB in matters of this nature. This dismissal of the complaint was considered by some to be equivalent to a green light to formula manufacturers to add a hexane-extracted, unapproved substance to organic products.

The Cornucopia Institute believes that such clandestine changes of the organic rules, subsequent to secret negotiations with industry lobbyists, were illegal and is presently researching avenues for redress.

Hexane-extracted algal oils, known as “Life’sDHA®,” have also made their way into organic milk and organic nutrition bars. Dean Food’s Horizon brand and Stremicks, for example, now sell milk with hexane-extracted algal DHA oils.

All the organic infant formula products and milk in question are certified by the nation’s largest USDA accredited certifier, Quality Assurance International (QAI).

“When I buy organic milk, I expect to pay a little more because I want safe and wholesome food without chemicals or processed with toxic substances. I expect the government to respect and enforce the organic rules, and it upsets me that they are allowing Horizon milk to call itself ‘organic’ when it has these illegal, hexane-extracted ingredients,” says organic consumer Emily Ladow Reynolds, from Boston, Massachusetts.