

UPI INVESTIGATIVE REPORT 1987 (BURIED SINCE 1987!) NUTRASWEET: QUESTIONS SWIRL - PART 1

By Gregory Gordon
UPI Investigative Reporter

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(Editor's note: UPI Investigative Reporter Gregory Gordon spent eight months examining industry research into popular artificial sweetener, NutraSweet and the Food and Drug Administration's handling of the product permeating the diet food and drink markets. Here is the first in his three-part report.)

Part 1: DID SEARLE IGNORE EARLY WARNING SIGNS?

By Gregory Gordon

WASHINGTON (UPI) A University of Illinois scientist says he warned the G.D.Searle Co. years before NutraSweet swept the diet food and soft drink markets that the company's new artificial sweetener could heighten risks of brain damage in fetuses and small children.

Dr. Reuben Matalon, a pediatrician and geneticist, said that between 1976 and 1984, he prodded Searle officials several times to do more research on the issue, but Searle never performed the studies suggested.

The Chicago-based company did, however, pursue U.S. government approval for the low-calorie sugar substitute, and got it in a controversial ruling in 1981.

Today, tens of millions of Americans guzzle diet soft drinks stamped with the NutraSweet "Swirl", dump packets of the NutraSweet tabletop sweetener, "Equal" in their coffee and consume NutraSweet-flavored cereal, puddings, gelatins, cheesecake, chewing gum or vitamin tablets.

The Food and Drug Administration, despite receiving more than 3,600 consumer complaints, is so confident of the sweeteners safety that it recently expanded uses to frozen and chilled fruit juices.

Matalon, however, has remained skeptical. In May, he reported that his initial, federally funded tests on 51 adults suggests heavy NutraSweet consumption may increase blood levels of a key amino acid enough to affect attention span, memory and concentration in some people, particularly small children. Pregnant women who are sensitive to the sweetener's main component, the amino acid phenylalanine, also may

face heightened risk that their infants will have birth defects, Matalon said.

More than a dozen other scientists, some of whom are conducting clinical studies, also say they suspect that subtle effects of the sweet powder could pose a major health problem. They believe NutraSweet known generically as aspartame, is linked to brain damage, epileptic seizures, eyesight problems, allergic reactions, headaches or dizziness.

"The likelihood is very strong that aspartame does produce serious and potentially damaging brain effects in a number of people", said Richard Wurtman, a neuroscientist at the Massachusetts Institute of Technology who is studying scores of people who suffered seizures after using NutraSweet.

Facing continuing controversy, The NutraSweet Co., the name adopted by Searle's NutraSweet Division following its 1985 sale to the giant Monsanto Co., vouches for the sweetener.

The firm's president, Robert Shapiro, rejects criticism voiced by Matalon and others, saying, "The fact is that the world scientific community has considered these very specific allegations repeatedly, and has come to the same conclusion as the FDA."

An eight-month United Press International investigation not only turned up scientific concerns, but also raised questions about the way the product was approved, about the independence and depth of the industry-funded research efforts into its safety, and about "revolving door" relationships between FDA officials including former FDA commissioner Arthur Hull Hayes Jr. and the food and drink industries.

Shapiro, who obtained an advance copy of this UPI report, said, "Taken as a whole, the effect of the article is likely to be a thoroughly misleading impression of the state of knowledge of the subject." Company spokesman Thym Smith said the firm is contemplating litigation.

Senator Howard Metzenbaum, D-Ohio, a leading skeptic of the FDA's approval who plans to hold a hearing on NutraSweet in the next few weeks, said, "I don't have hard evidence that the product is not safe. But, I am convinced that there is no hard evidence...that the product is safe."

FDA officials stress they have yet to see hard data disproving the sweeteners safety. For that reason, the agency last year rejected a consumer group's petition to ban it on grounds that 140 users suffered seizures and eye problems.

NutraSweet has been at the center of intense controversy almost since July 18, 1981, the day Hayes approved its use in dry foods. Indeed, in rendering his decision, Hayes overrode six of the nine scientists on two agency review panels who felt studies on its possible links to brain tumors in rats has been inadequate.

Since then, some independent scientists have become unusually outspoken.

Drs. Louis Elsas of Emory University and William Partridge of the UCLA Medical School charged that the diet food and drink industry has engaged in a "whitewash" by rejecting health concerns, manipulating research studies and winning and dining scientific critics.

These and other researchers describe a world of subtle, high-stakes strategy in which the availability of corporate funds and the design of research protocols may have influenced the course of a multibillion-dollar industry and potentially affected the safety of millions of people.

The NutraSweet Co. and a non-profit industry group reject these allegations, asserting they have

commissioned scores of studies to test the product's safety and that decisions on research funding are made solely on merit. Company spokesman Smith said NutraSweet's "phenomenal safety record is the result of the well known nature of the product rather than manipulations of management." Consumer complaints about NutraSweet surged in 1983, after Hayes' deputy, Mark Novitch, with the commissioners support, approved its use in soft drinks such as "Diet Coke" and "Crystal Light", sending consumption soaring.

UCLA's Pardridge noted in a letter to the American Medical Association Journal last year that, with aspartame, the food industry now is adding about five million pounds of phenylalanine "a known neurotoxin" to the food supply every year.

Roy Burry, an analyst with Kidder-Peabody, Inc., said the exploding diet market now accounts for 24 percent of soft drink sales, compared with 10 percent in the 1970's, and is growing at 20 to 25 percent a year.

The NutraSweet Co.'s sales are no longer public, but last year revenues were believed to have exceeded previously stated levels of \$700 million.

So intense has been the NutraSweet advertising campaign that the diet food and beverage industry created a "NutraSweet World Professional Figure Skating Championship."

"Taking good care of oneself makes life a little better- and NutraSweet makes it a little sweeter!" boasted one ad during a TV fitness program.

The NutraSweet Co. also has paid up to \$3 million a year for a 100-person public relations effort by the Chicago offices of Burson, Marsteller, a former employee of the New York PR firm said. The employee said Burson Marsteller has hired numerous scientists and physicians, often at \$1,000 a day, to defend the sweetener in media interviews and other public forums. Burson Marsteller declines to discuss such matters.

Dismissing safety fears, The NutraSweet Co. stresses that its product, which in raw form, is 180 times sweeter than sugar, has been endorsed by the AMA and other scientific bodies worldwide. Actually, the AMA's Council of Scientific Affairs gave a qualified endorsement based on "available evidence", including company-funded studies that were challenged by FDA task forces during investigations of the firm's laboratory practices in the 1970's.

Of 69 scientists who responded to a recent General Accounting Office survey, 28 said they felt more research was needed on NutraSweet and a dozen of those questioned considered it a major health problem.

An "aspartame victims" group has formed, a consumer group has pressed legal challenges and the company faces at least three personal injury suits. In one suit, Jim Stoddard, 32, a diabetic in Grand Rapids, Michigan, charged that his heavy NutraSweet consumption triggered a dozen seizures-the last one so violent he dislocated his shoulder and fractured his collar bone.

Stoddard's lawyer, and his sister, Cynthia, alleged he suffered brain damage and now has trouble understanding words because he consumed a product inadequately tested by Searle. She said she withdrew the suit recently for tactical reasons but would refile it early next year. The company denies the allegations.

Wurtman, who quit his job as a Searle consultant and became a vocal NutraSweet opponent, said he has

been contacted by more than 200 persons who suspect they suffered seizures as a result of NutraSweet use.

He said Dr. Gerald Gaull, a Searle vice president, visited his laboratory in 1985 and threatened to veto funding by ILSI (International Life Sciences Institute), the Washington-based tax-exempt foundation, for his planned study into whether NutraSweet changes brain chemistry, lowering some humans' seizure thresholds.

Gaull said, "there's no way" Searle, with one of 12 votes on the ILSI panel, could veto a grant decision, but he did not deny making the threat.

ILSI ultimately turned away Wurtman on grounds that Searle already had arranged for seizure studies at Yale University and New York's Mount Sinai Hospital studies that have drawn criticism because human volunteers were given aspartame only once or twice.

Wurtman said he is now tapping his laboratory's budget, which is extremely limited, slowing progress on his own studies. "Aspartame may be a serious health hazard," he said, "It's critically important that high quality research now be done to assess this hazard." In his letter to the AMA Journal, Pardridge said no one has fully researched the degree to which aspartame raises phenylalanine levels on the brain and, if so, what the possible effects are. He said in an interview, after he raised questions about the sweetener's effects on children, that ILSI rejected his two grant proposals in 1985. Last year, he said, Gaull pressed him at a conference in Colorado to prove that phenylalanine, one of twenty-one amino acids, causes brain damage.

"It was incredible for him to ask that," Pardridge said. "That was the basis for my ILSI grant (proposal)."

"There's an internal conflict of interest," he said, "when a company, which has profit at the bottom line, is charged with finding out the true safety of its product."

Elsas, who publicly assailed NutraSweet in 1985, said he was put off for a year before ILSI rejected his proposal without stating a reason. ILSI's executive director, Jack Filer, asserted research proposals were rejected because they cost too much or lacked scientific merit.

While denying funding for these aspartame skeptics, the company (G.D.Searle/NutraSweet Co.) and ILSI have financed researchers with whom they have long-running relationships. A number of industry-funded scientists acknowledged that company and ILSI officials originated ideas for their studies or participated in the research design. These studies generally have reported the sweetener is safe.

Consumer lawyer Turner said, "The notion that an industrial company would take large sums of money and parcel it out to scientific consulting firms and university departments, who they consider to be personal and commercial allies is an unconscionable way to ensure the safety of the American food supply."

He said the NutraSweet experience shows that "the entire system of the way scientific research is done needs to be carefully investigated, evaluated, and revamped."

Food industry officials also said most studies financed by Searle or the NutraSweet Co. have been arranged as contracts, rather than grants. Smith said the company often uses contracts "to accomplish a specific research task."

James Scala, former director of health sciences for the General Foods Corp., a major NutraSweet user,

said that a scientist working under contract became "more of an arm of the Searle research group than a grantee."

Scala, now with the Shaklee Corp., also said that most early NutraSweet research consisted of short-term studies that ignored possible "subtle," long-term effects.

Matalon said, "Let us say cigarettes were invented today, and you give 20 people two packs a day and after six weeks, no one has cancer, would you say that it was safe? That's what they did with NutraSweet."

Dr. Martha Freeman, who was a medical officer at the FDA's Bureau of Drugs in the early 1970's, argued in 1973 that the substance (aspartame) was "a new chemical...that doesn't occur naturally" and should only be approved after long-term clinical studies, as if it were a new drug. Her arguments were rejected.

Despite these complaints, the NutraSweet Co. has insisted that the company-funded studies prove that except for people with the rare disease, phenylketonuria, the human body processes phenylalanine in aspartame just like any other food, Thomas Stenzel, a spokesman for the International Food Information Council, a public relations arm for NutraSweet's manufacturers and biggest customers, contended scientific adversaries comprise a small minority.

He said he found it "very important that the leading professional health organizations" have found NutraSweet to be safe.

For example, the American Academy of Pediatrics concluded in 1985 that studies on people given massive aspartame doses showed no dangerous rise in blood phenylalanine levels; the Epilepsy Institute has reported the sweetener "to be safe for people with epilepsy."

Filer, executive director of the industry's main organ, the International Life Sciences Institute, suggested that problems blamed on aspartame may stem from "water load" on the brain resulting from over-consumption of liquids.

Maj. Michael Collings, who was an Air Force F-16 pilot in top physical condition, said he often drank up to a gallon of aspartame-sweetened products when he finished his daily, five-to-eight mile jogs in Nevada's desert heat. After noticing slight trembling in his hands over several weeks, he collapsed unconscious with a seizure on Oct. 4, 1985, a lawyer for Collings said.

Because of the seizure, Collings is grounded as a pilot for life, is on medication and was ordered transferred to Maxwell Air Force Base in Alabama at a \$400-a-month pay reduction, said attorney Bryan Gould, who charged in a state court suit last year that NutraSweet caused the seizure.

"He tells me there's no way to describe the feeling of flight," Gould said. "He loves to fly and now he can't." The NutraSweet Co. denies any link between the sweetener and Collings medical problems.

FDA officials, while publicly endorsing aspartame, are watching the situation closely. In late 1985, the agency took the unusual step of asking doctors nationwide to report adverse reactions to NutraSweet, and another food additive, sulfites a move normally reserved for drugs. Sulfites since have been banned from the market. A FDA spokesman said about 25 doctors filed reports suggesting aspartame links to varying health problems.

The FDA approved NutraSweet products on the condition they carry a compulsory warning to

phenylketonurics, individuals sensitive to its phenylalanine component. But Matalon, Elsas and others worry about millions of "carriers" of the disease who are unaware of their sensitivity. They say NutraSweet could damage fetuses of pregnant women whose bodies have trouble processing the amino acid.

Matalon, on releasing his new study, urged that products be labeled with the amount of NutraSweet they contain so consumers can monitor their intake. In Canada, aspartame is the only food additive for which such quantity food labeling is required.

With consumption soaring, Sanford Miller, chief of FDA's Bureau of Foods, has acknowledged considering a labeling requirement in this country.

Dr. Gary Flamm, the FDA's top toxicologist overseeing food additives, said that beyond labeling, once a food additive such as NutraSweet has won approval, it is far more difficult to restrict its marketing.

"If...our approval of it was a mistake, we couldn't rectify that without data showing that aspartame was unsafe," said Flamm, an aspartame defender.

Even then, he said, the agency would face a new regulatory thicket unless it could be shown NutraSweet posed "an imminent hazard." Consumer lawyer James Turner, who has campaigned for more than a decade for a NutraSweet ban, assailed the FDA's treatment of such safety issues. "Once a product is on the market, whether there by nefarious or honest means," he said, "it is impossible to get it off the market until it has caused severe, undeniable damage that has probably lasted over many years."

Several independent scientists have alleged that the industry has steered research money to allies in the scientific community, while denying funding to those who have raised health concerns.

A number of scientists who pressed for more studies into possible brain damage told UPI they were turned away by Searle and the International Life Sciences Institute, a tax-exempt industry foundation supported by the company, its Japanese aspartame-manufacturing partner and 10 sellers of NutraSweet-flavored products.

In interviews, Drs. Matalon, Wurtman, Elsas, Pardridge, and John Olney of Washington University in Illinois charged that the industry has paid millions of dollars for studies that have skirted the real issues about NutraSweet.

"There are virtually no studies," Turner said, "that have been done by individuals using resources other than the industry's that have given a clean bill of health to aspartame."

University of Illinois researcher Matalon recalled that he couldn't persuade Searle to do the kind of research necessary to put to rest lingering health concerns, neither on his first approach in 1976 nor when he submitted specific grant proposals to more four more company officials beginning in late 1980.

After NutraSweet won FDA approval and began changing the dietary habits of millions of Americans, Matalon said he lost patience in 1984 with the usual encouragement from Searle officials about prospects for future funding. "I felt they were just stringing me along," said Matalon, who obtained a \$180,000 grant from the National Institutes of Health.

Company spokesman Smith said the NutraSweet manufacturer has "not discouraged Dr. Matalon's work, nor anyone else's." While declining to comment on the decision not to fund Matalon's study, Smith said the company spends "between \$30 million and \$35 million annually on research."

