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 it's 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 Pardridge 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 wining 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."

"We do make decisions based on how we understand a study will be conducted and, reasonable scientists may disagree on study designs," he said.

The company has alleged that a number of its critics are seeking to pressure the industry to fund their laboratories.

Faced with sharply differing opinions on the sweetener's safety, the FDA and the National Institutes of Health, the government's chief funding mechanism for private research, have financed few studies on its effects. One former ranking NIH official, Artemis Simopoulos, argued the agency "should have a very extensive program on aspartame so people would know" whether it is safe.

Yet some NIH scientists have served as consultants to the ILSI foundation, helping decide the awards of $500,000 in annual NutraSweet research grants in recent years. Even Simopoulos was a non-paid member of the foundation's board.

But ILSI's "aspartame technical committee," consisting of the NutraSweet Co. and 11 other manufacturers and users of sweetener, have been accused of discriminating against NutraSweet critics in granting awards.

Represented on the ILSI committee are General Foods, the Coca Cola Co., PepsiCo, Inc., the Royal Crown Cola Co. and Seven-Up, Inc.

ILSI insists that the NutraSweet Co. carries no special weight despite its U.S. monopoly on the sweetener. "The NutraSweet Co. is one of our members," said ILSI administrator Sharon Senzik. "Committees operate by Robert's Rules of Order."

Filer collaborated for several years on NutraSweet research with a colleague at the University of Iowa, Dr. Lewis Stegink. Filer pledged that, despite his past ties to the company, as ILSI's head he would "let the chips fall where they may" on research results. Samuel Molinary, co-chairman of ILSI's panel, is Searle's former director of scientific affairs and now Pepsico's research director. Molinary insists that ILSI is not a "lacky and tool" of the NutraSweet Co.

Peter Dews, a Harvard University psychobiology professor named to ILSI's original board of trustees in 1978, has served as an ILSI consultant since then. Dews recently took the trouble to write and promote an article declaring that, based on scientific presentations at an ILSI aspartame conference in Spain last year, "there is now a mass of evidence" that NutraSweet is safe if consumed at FDA-recommended levels.

Dews declined to discuss his ILSI consulting fees, except to say it is "not enough to make any difference in my life." ILSI's 1984 return filed with the Internal Revenue Service showed payments to Dews that year of $31,000.

A lawyer for the ILSI pledged to the IRS in obtaining tax-exempt status for the foundation in 1983, that the organization "does not have any plans to engage in commercially sponsored scientific research." Attorney Roger Middlekauff advised the IRS that ILSI would "direct the research toward benefiting the public" and would release all research results.

But Elsas charged that ILSI "is definitely a front organization to try to make the public believe that there is some non-directed, non-biased research going on," when ILSI studies actually are likely to support NutraSweet's safety.

The industry has invited scientific critics for paid visits to company laboratories, sometimes offering courtesy "honorariums," an industry source said.

The NutraSweet Co. also hosted critics at conferences in resort settings. Matalon briefed ILSI on his research at the meeting in the Costa del Sol region on Spain's southern coast.

In the summer of 1985, the firm flew Wurtman, Elsas, Matalon, Pardridge, several of their wives and other NutraSweet critics to a two-day meeting at a luxurious home in Northeast Harbor, Maine. An afternoon was spent on a yacht, participants said. "This was industry wooing the concerned to shut up." Elsas said.

Pardridge said he was the only strong aspartame critic to accept an invitation in June 1986 to a heavily-attended Searle sponsored conference at a picturesque ski resort in Keystone, Colo. Pardridge said when he tried during the conference to raise his concerns about phenylalanine, the discussion was cut off. "It was just another typical industry whitewash," he said.

UPI Investigative Report: 10-07-87
Seizure, Blindness victims point to NutraSweet

By Gregory Gordon

WASHINGTON (UPI) Susan Yarmey, a free-lance writer from Quincy, Mass., awoke on a hot July morning in 1984 with a large bump on her head and bruises all over her body.

"I had no recollection of what happened. There were marks on the wall, two wooden steps were broken and there was a nice gash on the wall where my head hit," she said.

Yarmey's doctors diagnosed her injuries as resulting from a "classic" epileptic seizure. She and Massachusetts Institute of Technology neuroscientist Richard Wurtman believe the incident may be connected to her consumption of the artificial sweetener, NutraSweet, know generically as aspartame.

"A friend in New York directed me to the possible effects of NutraSweet consumption...I was probably, at that particular time period, doing a liter and a half to two liters (of diet soda with NutraSweet) a day," said Yarmey, who said when she stopped taking NutraSweet her problems disappeared.

Yarmey is not alone. Many NutraSweet consumers, particularly heavy users, who have suffered headaches, tremors, blindness, allergic reactions and seizures, blame NutraSweet for their ailments.

Wurtman says he personally is aware of more than 200 cases in which he suspects NutraSweet has caused health problems such as headaches, dizziness, and seizures.

Wurtman says the problem might be solved simply by stiffening the labeling requirements for NutraSweet products so that certain identified groups can monitor their intake.

"The groups I would identify are pregnant ladies, small children, people with a history of seizures and people who are taking certain drugs that interact with phenylalanine," an amino acid in the sweetener, Wurtman said.

Another former NutraSweet consumer, Shannon Roth, a mother of two who works as a goldsmith in

Ocala, Florida, organized Aspartame Victims and Their Friends, Inc. after suffering blindness in one eye. She said the group now has about 700 members.

"I got up in the morning and had two packs (of Equal, the NutraSweet tabletop version) in each cup of coffee...three or four cups of coffee before noon. Then I'd switch to the iced tea with it," Roth said.

In the summer of 1984, Roth said, she began to experience headaches, sleep and memory loss, and irritability.

After getting out of bed one morning, she discovered she couldn't see when she closed her right eye, Roth said. "I could see like through a black veil. It was like a centralized, almond-shaped black spot," she said.

Doctors' laboratory tests failed to trace the cause of her partial blindness, she said, and one doctor told her not to expect vision to return to her eye.

Roth said she suspected NutraSweet as the cause after learning of a similar case that was allegedly linked to the sweetener, and after about four weeks without NutraSweet, her headaches and other problems ceased. Her sight began to return a few weeks later, she said.

Joyce Wilson, a real estate agent in Stockbridge, Georgia, said she began suffering from high blood pressure, dizziness and other ill effects in 1982 after using Equal in her coffee and eating NutraSweet-flavored puddings. She said that in 1984 and 1985, she lost some vision.

"I'm not blaming this all on NutraSweet," Wilson said. "I'm just saying it's a strange coincidence that when I started using it, I started falling apart."

Dr. Morgan Raiford, an ophthalmologist at Emory University examined both Roth and Wilson and believes their problems stem from consumption of the methyl alcohol in NutraSweet.

Dorris Bookhart, 43, a legal secretary in Lodge, S. Carolina, started having what were later diagnosed as temporal lobe seizures in August of 1984. At the time, she said, she was drinking four 16-ounce bottles of Diet Coke a day, as well as diet lemonade. Both contained NutraSweet.

In January of 1985, after six months of problems, she suffered a grand mal seizure, a convulsive episode in which the victim loses consciousness, she said. Her doctors were mystified by the seizures, but they ruled out epilepsy, Bookhart said.

She said she suspected NutraSweet as the culprit when, at her husband's suggestion, she stopped drinking Diet Coke and the problems ended.

"I've cried a lot of times thinking these people have destroyed my life and there isn't a damn thing I can do," she said.

Another heavy user of the artificial sweetener, Larry Taylor of Arlington, Texas, said he was hospitalized for five or six days to undergo a battery of tests after suffering a grand mal seizure in 1985. He was also a victim of migraine headaches that became more frequent between 1982 and 1984. After his seizures, Taylor, an anesthetist, was not allowed to work until January of this year (1987), a disability he said left him "financially devastated."

What critics say about NutraSweet
By Gregory Gordon

WASHINGTON (UPI) Despite the NutraSweet Co.'s insistence that scores of company studies have "proved" the sweetener is harmless, here's a sampling of concerns from a hard core of scientific critics:

What the critics say about NutraSweet

Dr. Rueben Matalon of the University of Illinois has reported that heavy consumption of NutraSweet's main component the amino acid phenylalanine may cause neurological problems such as loss of memory and concentration. Matalon and Dr. Louis Elsas of Emory University say they fear aspartame consumption by some pregnant women can cause irreversible brain damage in fetuses. They worry most about women among an estimated 4 million to 20 million Americans who are carriers of the genetic disease, phenylketonuria characterized by the liver's inability to process phenylalanine. While there are an estimated 20,000 to 30,000 PKU victims nationwide who are warned not to take NutraSweet, carriers or heterozygotes, do not have the disease and generally are unaware of their sensitivity, they said. The company has said that the Food and Drug Administration concluded, "NutraSweet did not present any additional health risk to pregnant women."

Dr. Paul Spiers, a clinical neuropsychologist at Boston's Beth Israel Hospital, found in a recent pilot study that, after consuming NutraSweet, some subjects with no previous problems failed to show the usual improvement in performance on cognitive tests. He plans further research. But Dr, Harris Lieberman of the Massachusetts Institute of Technology, who has received industry funding for NutraSweet research in the past, said his study of 20 adult males indicates that aspartame "has no measurable effect on mood and performance in normal humans."

In St. Louis, Washington University allergist, Dr. Anthony Kulczycki found that two women given NutraSweet capsules and a placebo suffered allergic reactions to NutraSweet. The women reported hives and other skin reactions after using the sweetener.

Dr. Donald Johns, a neurology resident at Massachusetts General Hospital, reported last year that a "double-blind" study of a woman suffering migraine headaches showed her problems were aggravated by consumption of NutraSweet. NutraSweet, known generically as aspartame, consists of phenylalanine and another amino acid, aspartic acid, linked to a small quantity of methyl alcohol. Scientific critics seem to worry most about phenyalanine.

Dr. Richard Wurtman, Massachusetts Institute of Technology neuroscientist, says heavy NutraSweet consumption may so flood the bloodstream with phenyalanine that other essential amino acids are blocked from reaching the brain, causing chemical changes that can affect behavior and lower the threshold at which many suffer epileptic seizures. Wurtman and Dr. Donald Schomer of Harvard University are testing seizure victims who used NutraSweet, particularly some whose bodies may have trouble processing phenylalanine. The NutraSweet Co. concedes aspartame raises phenylalanine levels, but says no harm results, and that consuming the amino acids in NutraSweet "is just like eating other foods containing the same protein components."

Another Wurtmen protege, Dr. Timothy Maher of Massachusetts General Hospital, supported his mentor by reporting that mice, given a seizure inducing drug and NutraSweet, suffered more seizures than those receiving the drug alone. Dr. Henry Haigler, a scientist in a NutraSweet Co. sister firm, said his similar study showed "no effect on seizure thresholds."

Dr. William Pardridge of the UCLA Medical School, who also has done phenylalanine research, said he

most fears the sweetener's effect on children, who, he says, "are more likely to approach the FDA's acceptable daily intake level of 50 milligrams per kilogram of body weight. If you're a child, seven to twelve years of age, the chances are good you'll have five servings a day" close to the acceptable level, he said. But Dr. Harvey Levy, head of the PKU clinic at Boston's Children's Hospital, wrote the Journal of the American Medical Association that Pardridge made an "inaccurate interpretation" of their data in predicting brain damage effects on fetuses from aspartame. Any danger level, they said, "would seem to be considerably higher" than levels from NutraSweet consumption.

Dr. Woodrow Monte, an Arizona State University food scientist, and Dr. Morgan Raiford, an ophthalmology professor at Emory, worry that a NutraSweet breakdown product, methyl alcohol, could produce severe eye damage. Last year, Raiford examined more than a half dozen persons who said they suffered eye problems after consuming NutraSweet heavily. He said he diagnosed some cases of optic nerve damage and suspects NutraSweet's methyl alcohol is the culprit. The company denies any connection between NutraSweet and eye problems and has offered exams to consumers who complain of such problems.

Dr. Sidney Wolfe, executive director of the Washington-based Health Research Group, said, "The thing that's really worrisome is that it clearly affects brain metabolism in animals, and anyone who disputes that is irresponsible."

Dr. John Olney of Washington University expresses fears about brain tumors a problem he and other scientists say would not show up in humans for 20 years and would be difficult to trace to NutraSweet. Olney said Searle rat studies have shown conflicting brain tumor data. As early as 1971, Olney reported that aspartic acid in aspartame killed cells in the brain's hypothalamus region, which regulates glandular and hormonal functions.

The NutraSweet Company responds to UPI series.

WASHINGTON (UPI) In response to the United Press International series of articles on NutraSweet, The NutraSweet Co. issued the following statement:

A series of articles to be released this week by UPI seriously misrepresents the vast body of scientific evidence, which establishes the safety of aspartame.

Contrary to the impression created by these articles, the scientific record has been carefully reviewed by independent and official scientific and regulatory agencies around the world. Without exception, each of these agencies has concluded that aspartame is a safe sweetener which can be used as a normal part of the daily diet. The following quotations are representative of expert scientific and medical opinion around the world.

U.S. Food and Drug Administration: "The data and information supporting the safety of aspartame are extensive. It is likely that no food product has ever been so closely examined for safety...Few compounds have withstood such detailed testing and repeated close scrutiny, and the process through which aspartame has gone should provide the public with additional confidence of its safety."

American Medical Association Council on Scientific Affairs: "Consumption of aspartame of normal humans is safe..."

American Diabetes Association: "Aspartame has been determined to be safe for the general population

as well as for people with diabetes."

Government of Canada (Health Protection Branch): "Aspartame is one of the most extensively studied chemicals permitted for use in food...Based on the available data it has been concluded that aspartame would not pose a hazard to health when used in accordance with the current provisions of the Canadian food and drug regulations."

Government of Denmark (Danish Food Institute): "Research published in the scientific literature and/or studied in detail by governments and independent scientific committees maintains that the use of aspartame as an additive does not bear any health risk at all...There is, therefore, no toxicological basis for believing the intake of aspartame is soft drinks and food products should give rise to harmful effects in children or adults, even people with high level usage."

Government of Great Britain (UK Committee on Toxicity of Chemicals and Food): "Following detailed consideration of all toxicological data, we see no objection to the use of aspartame in food."

Other scientific agencies that have reviewed the evidence and confirmed the safety of aspartame include the World health Organization of the United Nations; the Scientific Committee on Foods of the European Common Market; the Epilepsy Institute; and the American Academy of Pediatrics.

Aspartame has been reviewed and approved as a safe sweetener by the official food regulatory authorities in all the leading nations of the world, including many which forbid or restrict the usage of other sweeteners.

A recent article by Harvard Medical School Prof. Peter Dews reviewed the "massive evidence" that establishes the safety of aspartame. Dr. Dews concluded: "Many articles of everyday consumption that are known to be safe might not survive the scrutiny of such intensive and continued investigation."

The respected consumer publication Consumer Reports summarized its conclusions this way: "An objective weighing of the evidence suggests that aspartame is the artificial sweetener to be preferred on safety grounds."

The UPI articles also seek to discredit the process by which aspartame was reviewed and approved by the FDA.

These charges have been conclusively rebutted by both the FDA, itself, and by the General Accounting Office, the investigative agency of the Congress. A full GAO report on the approval process concluded that the FDA had properly followed the appropriate procedures and had adequately addressed the scientific issues.

The UPI series is replete with misstatements and distortions, which convey a totally misleading impression of the scientific facts. Any concern or anxiety by consumers who read these articles is absolutely unwarranted. Aspartame is safe as approved by FDA and regulatory authorities around the world. Any contrary impression created by UPI articles is a serious disservice to the public.

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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 second in his three-part report.)

Part 2: NUTRASWEET APPROVAL MARRED BY CONTROVERSY

By Gregory Gordon

WASHINGTON (UPI) Pouring over laboratory rat studies in the spring of 1981 in the government's final safety review of a new artificial sweetener, senior statistician Satya Dubey of the Food and Drug Administration was troubled.

Dubey, a member of a special FDA "commissioner's team" formed to help decide the fate of the product to be known as NutraSweet, wrote an internal memo that brain tumor data from the rat tests was so "worrisome" that he could not recommend approval.

Two other statisticians on the six-member team agreed with Dubey that the Chicago-based G.D. Searle Co. had not proved with "reasonable certainty" the safety of the sweetener, known generically as aspartame. A 1980 Public Board of Inquiry had voted 3-0 to ban aspartame because of similar fears.

But a few weeks later on July 18, 1981, new FDA Commissioner Arthur Hull Hayes, Jr., a pharmacologist who had been in office less than three months and had little background in food additives, overturned the board and approved the use of aspartame in dry foods.

The ruling, one of the first regulatory actions of the Reagan presidency, came at a time of growing concern that the most widely used low-calorie sweetener, saccharin, was linked to cancer. Thus Hayes' approval of NutraSweet profoundly changed the eating habits of millions of Americans, handing Searle a financial bonanza.

It also climaxed a topsy-turvy, eight year FDA review process in which the agency approved the