

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."

"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 "lucky 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 phenylalanine.

Dr. Richard Wurtman, Massachusetts Institute of Technology neuroscientist, says heavy NutraSweet consumption may so flood the bloodstream with phenylalanine 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 Wurtman 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 in 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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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 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

sweetener, then banned it and demanded a grand jury investigation of its manufacturer, only to reverse course again after reexamining the issue at least five times.

Now, six years after Hayes' ruling, its uses expanded, the sweetener is widely consumed in diet sodas, puddings, cereal, drink mixes, and even chewing gum and vitamins. Yet NutraSweet and its FDA approval remain at the center of controversy, the sweetener's safety questioned by a small corps of independent scientists; defended by its manufacturer and the diet food and drink industry.

In a recently released report, the General Accounting Office concluded that the FDA "adequately followed" its food additive approval process on NutraSweet.

Congress's investigative arm did not evaluate the sweetener's safety. A federal appeals court also has rejected court suits by consumer groups challenging the NutraSweet approval.

United Press International has learned that more than 10 federal officials involved with the NutraSweet review have taken private sector jobs linked to the industry among them, Hayes, an acting FFDA commissioner and former chiefs and acting chiefs of the agency's Bureau of Foods.

In addition, many of the scientists who have produced favorable studies or served as outspoken advocates of NutraSweet's safety have received grants or consulting fees from Searle and the industry.

Consumer lawyer, James Turner, who has unsuccessfully pressed petitions for a NutraSweet ban as part of an 11 - year campaign against the sweetener, asserted, " NutraSweet is an opportunity for the entire country to look in great detail at how we make food safety decisions. It is a rickety, 19th Century process."

G.D. Searle began to study the artificial sweetener aspartame soon after a company laboratory chemist, James Schlatter, stumbled on the compound when he licked it off his finger while conducting ulcer research in 1965.

In a memo on Dec. 28, 1970, a Searle official laid out a plan for winning FDA approval for the sweetener. " We must create an affirmative atmosphere in our dealing with them," Herbert Helling wrote senior company executives. Helling suggested that Searle representatives carefully order proposals to the FDA to put Bureau of Foods officials "into a yes saying habit." If FDA officials could be swayed to do Searle some favor, he asserted, it would "help bring them into a subconscious spirit of participation."

On July 26, 1974, just 15 months after Searle petitioned for approval, FDA commissioner Alexander Schmidt approved aspartame use in dry foods, allowing a 30-day period for public hearings and comment. He acted on a strong endorsement from the Bureau of Foods, now called the Center for Food Safety and Applied Nutrition (CFSAN).

At that point, consumer attorney Turner, author of a 1970 book about food additives, objected to the short comment period. Turner was joined in his protest by a now-defunct public interest group and by Dr. John Olney, a Washington University neuropathologist who had linked aspartame to brain lesions in mice.

Schmidt promptly froze the approval. In an action that was the first of its kind, he ordered that a Public Board of Inquiry be named to look into aspartame.

Schmidt also had been alerted to conflicts between Searle research reports and conclusions from independent animal studies that the firm's anti-infective drug, Flagyl and its cardiovascular drug

Aldactone may cause cancer. He named a Bureau of Drugs task force to investigate.

Philip Brodsky, the unit's since-retired lead investigator, said aspartame was included in a broad inquiry into Searle animal studies on five drugs and the Copper-7 intrauterine device to surprise the company. "We didn't think they'd expect us to cover it."

The task force assailed Searle's conduct of research on most of the products, including aspartame, in a searing, 84-page report.

"At the heart of the FDA's regulatory process," the report said, "is its ability to rely upon the integrity of the basic safety data submitted by sponsors of regulated products. Our investigation clearly demonstrates that, in the G.D. Searle Co., we have no basis for such reliance now."

The task force charged, for example, that the company removed tumors from live animals and stored animal tissues in formaldehyde for so long that they deteriorated. Instead of performing autopsies on rhesus monkeys that suffered seizures after being fed aspartame, the company had financed a new monkey study with a different methodology that showed no problems.

For the next seven years, Searle's petition was tied up in reviews by the task force and other sharply critical FDA panels. At the task force's request, Richard Merrill, the FDA's general counsel, demanded in a letter that Samuel Skinner, the U.S. attorney in Chicago, open a grand jury investigation of Searle and three of its employees.

One Searle official named by Merrill was Robert McConnell, who had been director of Searle's Department of Pathology and Toxicology and oversaw most of the company's aspartame research.

McConnell's Detroit lawyer, Gerald Wahl, said that as the inquiries heated up, his client was suddenly awarded a \$15,000. bonus and asked to take a three-year sabbatical by director Wesley Dixon. Wahl said Dixon told McConnell he had become a "political liability," a remark Dixon later denied making.

McConnell received his annual salary of more than \$60,000 during the sabbatical at the Massachusetts Institute of Technology, but he never got his job back, and ended up suing the company, Wahl said.

"I've represented hundreds of executives, but I've never seen anybody get the deal that McConnell got," he said. "When you boil it all down, they were looking for continued support from McConnell during the inquiries."

Wahl said McConnell had felt pressure to hurry his research because of the "profit motive," but the company never ordered him to alter test results.

Chief investigator Brodsky said that "politicized" handling of the task force disclosures, at hearings chaired by Sen. Edward Kennedy D-Mass., was one reason he retired in 1977. He said the main witnesses, Searle executives, and top FDA officials uninvolved in the investigation gave "the wrong answers to the wrong questions"...They didn't even let the experts answer the questions.

The FDA, rocked by controversy, established a set of "good laboratory practices" minimum standards for future corporate research work.

Richard Ronk, deputy Bureau of Foods chief, stressed that Searle practices were typical of the industry at the time, "not the worst on the block."

Searle's fortune did not begin to change until 1977, when Donald Rumsfeld, White House Chief of Staff under Gerald Ford, was named its new president.

Turner alleged that Searle chose, with Rumsfeld's hiring, not to redo the questioned studies on belief he could handle aspartame as "a legal problem rather than a scientific problem."

The company also hired another Ford White House official, William Timmons, as a Washington lobbyist.

Before deciding on Merrill's grand jury request, U.S. Attorney Skinner and an aid agreed in February 1977 to meet with lawyers for Searle, including Newton Minow, a partner in the law firm of Sidley & Austin.

A month later, Skinner, a Republican appointee who was looking for a job as a result of Jimmy Carter's election, informed aids in a memo that he had begun preliminary employment discussions with the law firm.

Withdrawing from the Searle matter, Skinner suggested his designated successor, Thomas Sullivan, be left to decide whether to open a grand jury inquiry—a move that delayed action for at least four months. Sullivan took office just 12 weeks before expiration of the statute of limitations for prosecuting alleged false statements on aspartame. While the grand jury inquiry ultimately was convened, those allegations were not explored.

Skinner denies any conflict of interest.

Assistant U.S. Attorney William Conlon worked with the grand jury until October 12, 1977, two days after the statute of limitations expired on the aspartame allegations. No indictments were brought on the few matters investigated. Conlon, who declined comment, joined Sidley & Austin 15 months later.

Following issuance of the task force report back in March 1976 and facing a dilemma as to how to proceed, the FDA sought new reviews of several "pivotal" studies long term animal tests to see whether aspartame causes cancer.

A new five-member internal FDA task force analyzed three of these studies, and Universities Associated for Research and Education in Pathology, Inc., a consortium formed by 15 universities, was contracted to look at another dozen.

Much like the earlier team, the five-member FDA task force, headed by veteran Chicago inspector Jerome Bressler, assailed the quality of animal tests into whether the substance might cause birth defects and tumors.

The report said Searle laboratory employee Raymond Schroeder, who worked on related research, first told investigators the feed in the study of the aspartame breakdown product DKP (diketopiperazine) was so inadequately mixed it appeared the rats could "discriminate" and avoid eating the DKP.

Schroeder, who has worked for another company since 1975, later backed off his statement. He told UPI, "I just didn't feel qualified to speak on something I didn't work on...There's no one twisting my arm."

Bressler criticized the company's "sloppiness" on all three studies. "The question you've got to ask yourself," he said in an interview, "is: Because of the importance of this study, why wasn't greater care taken? The study is highly questionable because of our findings. Why didn't Searle, with their scientists,

not closely evaluate this, knowing fully well that the whole society, from the youngest to the elderly, from the sick to the unsick...will have access to this product?" Howard Roberts, acting director of FDA's Bureau of Foods, appointed a five-person task force to review the Bressler team's findings pending a decision on whether to throw out the three tumor and birth-defect studies.

Jacqueline Verrett, a senior scientist on the review team, said members were barred from stating opinions about the research quality. "It was pretty obvious that somewhere along that line they (bureau officials) were working up to a whitewash," she said. "I seriously thought of just walking off of that task force."

Verrett, now a private consultant, said that she and other members wanted to "just come out and say that this whole experiment was a disaster and should be disregarded."

But on September 28, 1977, the panel reported that deviations between Searle's raw data and its FDA submissions were "not of such magnitude as to alter its conclusion."

Verrett said the bureau's intent seemed to be "to tone down what was really found." She noted the bureau felt pressure because safety concerns also had been raised about cyclamate, another alternative for the cancer-linked sugar substitute, saccharin.

In October, 1978, a year after ordering the review that helped get Searle's petition back on track, Robert's (acting Director of Bureau of Foods) quit to become vice president at the National Soft Drink Association. The NSDA's members later marketed a stream of NutraSweet-flavored diet soft drink products.

Reached at NSDA, Roberts dismissed Verrett's criticism, asserting the task force report "really was of no importance." He said he had no concerns about the appearance of his taking the NSDA job, stressing he does not represent NSDA before the FDA. "I sleep well at night," he said.

Negotiations for an additional, outside review of Searle's studies had begun with an August 4, 1976 meeting between Searle and 10 FDA officials. During the meeting, Searle officials said they desired to help pick the consultant to perform the review, and internal FDA memo said.

Agency memos show the FDA soon was negotiating with the Universities Association for Research and Education in Pathology for a half-million dollar, company-funded "validation" of a dozen Searle studies.

The pathology organization's review concluded that Searle's studies were authentic and the discrepancies largely inconsequential.

Adrian Gross, an investigative consultant to the 1975 task force, later said the 16-month review was "at best, irrelevant" because the group was limited to analyzing "whether Searle lied about the data in its tests".

"It was not our task to challenge the validity of the experimental methods, since the FDA had itself already accepted the methodology", the group's executive director, Kenneth Endicott, said.

Jere Goyan, who was FDA Commissioner in 1980, said he would have put less weight on the review than on the findings of FDA's task forces. Goyan also suggested that, after approving aspartame in 1974, the FDA's Bureau of Foods may have "felt they had to keep their previous position."

Regardless, the pathology groups findings carried major weight in the final approval decision. The chairman of the 1980 Public Board of Inquiry, Dr. Walle Nauta of the Massachusetts Institute of

Technology, said the board had to rely on those findings because it was denied access to the task force reports by FDA officials.

"There was absolutely no way in which we could decide who was right here," Nauta said. "We simply had to accept the data as they stood."

Nauta was joined on the panel by Drs. Vernon Young of MIT and Peter Lampert of the University of California at San Diego.

Before voting 3-0 to ban NutraSweet on the narrow cancer issue, the board itself was drawn into allegations of bias because two of the three members came from MIT as did Bureau of Foods Chief Miller and several scientists involved in the controversy.

Between 1979 and 1982, four more FDA officials who participated in the approval process took jobs linked to the NutraSweet industry: Pape; acting FDA commissioner Sherwin Gardner; Albert Kolbye, who was associate director of the Bureau of Foods for toxicology, and Mike Taylor, an FDA lawyer who represented the bureau before the Board of Inquiry. All four denied any conflict of interest.

After the Board of Inquiry ruled against NutraSweet on Sept. 30, 1980, Searle waited until January 21, 1981, the day after President Reagan's inauguration, to press for a reversal of the FDA commissioner assuring the new administration would decide the issue.

Jere Goyan, Hayes' predecessor as commissioner, said he found the delay curious because, after eight years of legal battles, financially struggling Searle "obviously was most anxious to have this thing approved."

Robert Dormer, a lawyer for the NutraSweet Co., said there was nothing special about the Jan. 21 date or the papers filed that day.

But with Reagan's election, it was virtually assured that a republican-appointed commissioner would replace Goyan and decide the appeal- and Searle had strong GOP connections with Rumsfeld at the helm.

Goyan had set up a five-member "commissioner's team" of scientists with no prior involvement in the issue to review the board's ruling.

On May 10 and 13, 1981, a month after Hayes took office, scientists Satya Dubey, Douglas Park, and Robert Condon each laid out concerns about the sweetener's safety in memos to team lawyer Joseph Levitt.

Dubey not only expressed reservations about reported incidence of brain tumors in one key Searle rat study, but also said key data in another study appeared to have been altered. Dubey, who still works at FDA, refuses to discuss the matter.

Condon, another statistician on the team, and Park, staff science advisor in the agency's Office of Health Affairs, each said the available evidence failed to prove NutraSweet's safety or lack of safety.

Park said that Levitt hurried the panel to decide the issue. "They wanted to have the results yesterday," he said. "We really didn't have time to do the in-depth review we wanted to do."

Park said Levitt met frequently with Hayes and "was obviously getting the pressure to get a resolution

and a decision made."

Sources have said the office of Sen. Howard Metzenbaum, D-Ohio, has received allegations of political influence in Hayes' final decision-making process.

In a letter written after the FDA cleared NutraSweet, one former Searle saleswoman, Patty Wood-Allott, asserted the Rumsfeld told his sales force shortly after Reagan took office that if necessary, "he would call in his markers and that no matter what, he would see to it that aspartame would be approved that year." Rumsfeld declined to return phone calls.

With three of five scientists on the commissioner's team opposing approval, it was decided to bring in a toxicologist for his opinion on isolated issues.

Goyan said if the decision were his, he never would have enlarged the team. While the panel did not vote, it ended up split 3-3.

Levitt, who normally would have been expected to draft an options paper spelling out scientific evidence on key issues, took an unusual tact. He circulated an approval recommendation and only backed off when Dubey, Park and Condon objected, team members said.

Levitt said he was not directed to draft the approval memo, but did so as a "tactical" step to break the team's week-long impasse by forcing each scientist to state his views.

"It worked didn't it?" said Levitt, who later was promoted to a post as an executive assistant to the FDA commissioner.

One team member said that during discussions, Hayes, appeared to be abandoning the agency's traditional standard of "reasonable" proof of safety and looking for "proof of hazard."

Hayes' July 1981 approval decision came in the face of a Searle threat to file a suit challenging the regulatory delays.

His ruling relied in part on a late rat study of brain tumors submitted by Ajinomoto, a Japanese company that manufactures aspartame for Searle. That study, however, tested Wistar rats, a strain that some scientists said is more tumor resistant than the Sprague-Dawley rats used in earlier research.

In his decision, Hayes wrote: "Few compounds have withstood such detailed testing and the repeated close scrutiny and the process through which aspartame has gone should provide the public with confidence of its safety."

In late 1982, Searle petitioned for FDA approval to use the sweetener in diet soft drinks and children's vitamins. On a day when Hayes was away, Novitch approved the petition, increasing the acceptable daily intake level for humans by nearly half, from 34 mg to 50 mg per kilogram of body weight.

Novitch, now in private industry, said he and Hayes had worked together on the matter, but declined to say why he was left to sign the approval.

Just weeks later, Hayes resigned under the cloud of an internal Dept. of Health and Human Services investigation into his acceptance of gratuities from FDA-regulated companies including free rides aboard jets owned by a major NutraSweet user, the General Foods Corp.

Shortly after being named Dean of the New York Medical school, Hayes also became a consultant to the New York-based public relations firm of Burson-Marsteller, which represents the NutraSweet Co. and several major users.

Hayes' former top spokesman, Wayne Pines, who previously had joined the firm, said he approached Hayes because he thought him "an added value" to clients.

Hayes, now president of the E.M. Pharmaceutical Co. in Hawthorne, N.Y., declined comment for this series of articles. He has in the past denied any impropriety in his consulting role, which sources said paid him more than \$1000. per day.

Burson-Marsteller vice president, Buck Buchwald stressed that Hayes was not involved in NutraSweet issues and worked but 10 to 15 days a year. But a former Burson-Marsteller employee, who requested anonymity, said Hayes was hired precisely because of his decision on NutraSweet and other issues affecting company clients.

Sen. Metzenbaum said it was "at the very least...unbecoming, at the very most, it probably was inappropriate" for Hayes to accept the position.

In July 1986, Anthony Brunetti, a FDA consumer product officer who drafted the 1983 notice approving NutraSweet use in soft drinks, also took an industry job, joining the soft drink association as a science advisor. Brunetti said he cleared the move with the FDA's ethics officer.

"My situation," he said, "is no different than many, many people...that go through the revolving door. It can be made to look like there is some duplicity going on. In terms of my own conscious, I have no problem."

Ron Lorentzen, an FDA toxicologist who was asked by current Bureau of Foods chief Sanford Miller to perform a separate, internal review of the agency's handling of aspartame, described it as a "tortured" story.

But despite the myriad questions and revolving door issues, he asserted the FDA responded to each issue "in a way, perfectly reasonable." Other questions have arisen over the company and industry's funding of researchers who have invariably supported NutraSweet's safety with the exception of people with the rare disease phenylketonuria. Independent studies have often raised health concerns.

Dr. Lewis Stegink, a pediatrics professor at the University of Iowa who repeatedly has produced studies, that he says, support aspartame's safety, has received more than \$1.3 million dollars in research grants and gifts, including lab equipment, from the NutraSweet) company since the early 1970's, limited university records show.

Metzenbaum said, "If it is a fact that no questions were raised and more than a million dollars was spent, you have to wonder whether their job was done thoroughly as it should be done."

Stegink's longtime research collaborator, Dr. Jack Filer, serves as executive director of the ILSI (International Life Sciences Institute), the Washington foundation that funds aspartame research.

Filer said he sees no conflict in his dual roles as ILSI's executive director and a company researcher, but declined to disclose his ILSI consulting fees. He said all the Iowa research money has gone to Stegink.

Filer also said the company (NutraSweet) paid him and Stegink "\$2,000. to \$3,000." to edit a book,

"Aspartame," about research on the sweetener, and another \$1,000. or \$1,500. to each of the contributors, including researchers whose studies helped the company win FDA approval. The book states that "the extensive research program carried out to demonstrate aspartame safety may serve as a new standard for the study of food additives." Filer said he had been "maligned over the years for taking money from corporations," but that the funding source never has influenced his findings.

Dr. David Hunninghake of the University of Minnesota was picked to study aspartame's effect on the liver by former Searle research director Daniel Azarnoff, once Hunninghake's mentor at the University of Kansas, a Hunninghake associate said. He said Searle helped design the study.

Susan Schiffman, named to head a Searle-funded Duke University medical School study into NutraSweet's link to headaches, is a former General Foods and Searle consultant. Her research at Duke, where the medical school has a new Searle Center, has fallen under the office of university vice president William Anylan, a former Searle director. Schiffman said Anylan had no role in Searle's promise to cover all costs of the study, which is expected to cost "hundreds of thousands of dollars." She said she took no salary for her work.

Another industry-backed researcher has been Ann Reynolds, now chancellor of California State University at Long Beach. Dr. John Olney asserted that in a 1971 study, Reynolds confirmed his findings that the sweetener destroyed nerve cells in infant mice, but Searle did not notify the FDA until 1975 or 1976, after the FDA's initial review. Dr. Daniel Azarnoff, Searle's former science director, and other Searle officials have denied withholding any studies from the government.

Reynolds also co-authored a Searle monkey study that contradicted earlier aspartame research leading to seizures in monkeys. Dr. Olney alleged that Reynolds, who did not return phone calls, and several other company-funded researchers "have a pattern of avoiding" scientific peer review. Industry spokesmen contend that few studies by scientific critics of NutraSweet have undergone peer review. But few such clinical studies have been completed because of a funding shortage.

George Liepa, a nutrition professor at Texas Woman's University said he was required to discuss his findings with Searle before reporting that NutraSweet "is safe" for diabetics on hemodialysis. Dr. David Horwitz, an associate professor of medicine at the University of Illinois, who studied NutraSweet and diabetics, said the company did not influence the outcome, But, "The results were favorable... Obviously, that is perhaps why Searle was eager to fund an additional study of ours."

Dr. Richard Wurtman was an ardent defender of NutraSweet's safety at public hearings six years ago (1981). Now he is one of the artificial sweetener's harshest critics.

"I think the likelihood is very strong that NutraSweet does produce serious and potentially damaging brain effects in a number of people," the nationally known neuroscientist from Massachusetts Institute of Technology said in a recent series of interviews.

Wurtman's seemingly enigmatic flip-flop from a position as a G.D. Searle Co. consultant to a role as a foe urging restrictions on marketing the firm's best-selling product appears to be much at the center of the controversy over NutraSweet's safety.

Wurtman says his views simply changed with the evolution of his scientific studies and his growing skepticism of industries attitude toward research.

His sometimes stormy relationships with the company and an industry-funded foundation, the ILSI, provide a glimpse of the maneuverings surrounding research into a major food additive.

Wurtman, a brash-talking, hard-driving head of a major research laboratory, said he unilaterally severed his consulting relationship with Searle in 1985 after he grew concerned about NutraSweet's effects and the company's inaction. He said he rejected several approaches by the firm, (the NutraSweet Co.) since its sale that year to the Monsanto Corp., to rekindle the consulting arrangement.

Wurtman accuses NutraSweet Co. officials of "misrepresenting" the nature of company-financed studies into links between the sweetener, generically known as aspartame, and epileptic seizures, of sidestepping key safety issues, and of threatening to veto his grant application to ILSI's aspartame committee.

A spokesman for the NutraSweet Co. described Wurtman's public attacks as a "political issue," but declined to elaborate.

Wurtman's relationship with Searle, The NutraSweet Co., and many of the companies that sell NutraSweet-flavored products dates to 1978. Beginning that year, according to public records, ILSI provided more than \$200,000. to finance his research on caffeine, a common beverage ingredient that was under FDA scrutiny.

Wurtman said he found no ill health effects during his caffeine research, and his relationship was "excellent" with ILSI a spinoff of the National Soft Drink Association.

During the same period in 1978, he said he rejected a Searle offer of financial support for research on amino acids. Phenylalanine and aspartic acid, two such amino acids, are the main components of NutraSweet.

He said Dr. Sanford Miller, chief of FDA's Bureau of Foods, later sought his testimony before a 1980 Public Board of Inquiry because he openly stated his belief that neither glutamate nor aspartic acid, a similar compound to that in NutraSweet, would not cause brain damage. Wurtman strongly defended aspartame at the hearing.

He said he did not focus on phenylalanine until about 1983, when he learned the FDA was considering expanding use of the low-calorie sweetener, approved two years earlier for dry foods, to include carbonated soft drinks.

From his caffeine research, Wurtman said, he was aware of the exploding soft drink market and concluded "that the use of aspartame was going to go up considerably."

"I was genuinely concerned that there might be an increase in brain phenylalanine levels."

Wurtman said that, while phenylalanine is vital to the brain, it can serve as a barrier to 20 other amino acids that provide protein.

At a meeting in July 1983, Wurtman said he told National Soft Drink Association officials that "if you put large amounts of aspartame in soft drinks and people drink as much as I think they will, there are going to be problems."

Wurtman said that after the industry accepted his idea for combining NutraSweet with saccharin to cut the danger level, he accepted a Searle offer to serve as consultant and relations were "all very friendly and chummy".

Wurtman said he became "convinced that these people really want to know the extent to which their product may be a real problem".

Shortly after he took the consulting job, he began getting letters from seizure victims who believed their problems stemmed from NutraSweet.

Wurtman said he when advised Dr. Gerald Gaull, Searle vice president for nutrition and medical affairs, in the Spring of 1985 that he thought there was a link, "there was a very rapid souring of their relationship".

During a visit to his MIT laboratory, Wurtman said, Gaull asked him to review a proposal for a seizure study by him and his collaborator, Harvard University neurologist Donald Schomer. He charged that when he advised Gaull the pair would seek funding from ILSI, Gaull "got very angry" and said, "We (meaning Searle), are active members of the ILSI and we will veto your study".

"I was incredulous that he would say it to me, and I was dumbfounded that he would say it in front of a witness," Wurtman said.

Schomer said he did not recall the comment. Gaull said, "There is no way that I can veto anything at ILSI," because Searle has only one of 12 votes on the ISLI aspartame committee. He did not deny making the threat.

Wurtman charged that Gaull later advised ISLI that two company-funded seizure studies already were under way, and the foundation declined to approve Wurtman's grant.

In July of 1985, Wurtman said, he and three other scientists who had expressed concerns about NutraSweet were among a group invited to Gaull's home in Northeast Harbor, Maine, for a two-day conference.

"I left there with the conclusion there was no way these people were going to do an honest job in assessing the possibility that aspartame contributed to seizures," Wurtman said.

He said he also was skeptical because, as a company consultant, Searle had asked him to chair its scientific advisory committee, a role in which the company could use his name to defend the integrity of its own research. But, he said, Searle refused to let him see protocols and data from its studies.

"They wanted the name, but not the reality," he said. Frustrated by these developments, Wurtman said he wrote a letter to Robert Shapiro, president of Searle and later of the NutraSweet Co.

"Dear Bob," the letter said, "I know you'll agree that my value to Searle... derives in part from my telling the company some things that it would rather not hear...and then from helping the company to deal with those things."

"One such thing is that some consumers may develop significant medical symptoms after consuming very large amounts of aspartame, particularly if they happen, concurrently, to be on a low-calorie, low-protein, weight-reducing diets... If Searle-supported studies are going to contribute to our understanding of these people and their symptoms, then the studies have to include them, and not be restricted to people who have a can or two of soda per day."

He said Shapiro never answered the letter.

Wurtman said he resigned his consulting role a short time later and rejected company efforts in the ensuing months to reinstate the arrangement.

UPI INVESTIGATIVE REPORT 1987 (BURIED SINCE 1987!) NUTRASWEET: QUESTIONS SWIRL - PART 3

By Gregory Gordon
UPI Investigative Reporter

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Part 3: SWEET CORPORATE VICTORIES

By Gregory Gordon

WASHINGTON (UPI) In October 1982, Sen. Howell Heflin, D-Ala, proposed an obscure amendment altering the laws covering U.S. patent extensions, a move affecting only one company and one product, the artificial sweetener, aspartame.

Without mentioning aspartame, which is sold under the name NutraSweet, the senate passed the amendment to the Orphan Drug Act, extending G.D. Searle Co.'s domestic monopoly on aspartame sales for another five years, 10 months, and 17 days.

"We think it's an excellent amendment," remarked Sen. Orrin Hatch, R-Utah, wrapping up a five-minute discussion on the Senate floor.

When the House approved the same language a month later, it all but cinched another \$3.5 billion to \$4 billion in revenues for the Chicago-based, Searle.

It helped Searle's stockholders sell the company's assets, including its lucrative NutraSweet division and the two domestic use patents, for \$2.7 billion to the Monsanto Corp. in the summer of 1985.

Sponsors of the measure found their campaign committee, enriched.

Heflin's 1984 reelection committee received contributions totaling at least \$9,000. from Searle's top officers and its political action committee, more than any others among a long list of Searle beneficiaries in Congress, federal Election Committee records show.

Hatch's committee received at least \$3,000. the records show.

Heflin defended his sponsorship of the measure, saying Searle had been victimized by regulatory delays that ate up most of its 17-year patent.

But a spokesman for the U.S. Patent Office said Heflin's legislation marked one of only a handful of instances in the last three decades in which a company's patent has been extended by a private bill in Congress.

It also provided a glimpse of the adeptness with which Searle, Monsanto, and their lobbyists have guided the artificial sweetener through the obstacles of government regulatory bureaucracies to capture big financial rewards.

Headed by Donald Rumsfeld, the former Ford White House Chief of Staff, Searle repeatedly demonstrated its political acumen on other front, too, in the years prior to the sale to Monsanto.

In 1981, the company overcame a controversy-snarled, eight year review process to win Food and Drug Administration approval for NutraSweet.

In 1984, Searle parried an assault on the sweetener's safety from Arizona food scientist, Dr. Woodrow Monte after hiring Arizona Gov. Bruce Babbitt's former chief of staff as a lobbyist. Searle officers passed along campaign contributions of \$2,000. to a key lawmaker, and the company soon had won passage of legislation crushing Monte's efforts to force tough state restrictions on the sweetener.

"I don't know of any company that has apparently covered all of its bases as well as has Searle," said Sen. Metzenbaum (D-Ohio). "Whether it has to do with the scientists or lawyers, or non-profit institutions, or universities, or whatever; in every instance, I have found that they have expended their dollars very carefully and very wisely, but without apparent restraint as to the amount."

Indeed, besides Searle's hiring of up to a dozen lobbyists, UPI traced nearly \$200,000. in federal campaign contributions between 1973 and 1986 from its officers and political action committee.

The political intervention in the patent process drew the ire of several small companies seeking to enter the aspartame market, triggering charges that a corporate giant benefited from unjustified or preferential treatment.

"I think its obvious they (Searle officials) used political muscle," Alan Kligerman, president of Lactaid, Inc., a New Jersey diet food manufacturer, said of the patent extension. He said his firm had been interested in manufacturing aspartame until the patent was extended, but "Searle was well wired in."

"It is possible that they (the Senate) did not know what they were passing," he said. "I don't know how they got that through, except with the right phone calls."

"I would not hesitate to say," Metzenbaum said, "that the manner in which that five-year extension of the patent rights was put through on the floor of the U.S. Senate was totally inappropriate."

"It should not have been without the entire body being advised that, that issue was going to be on the floor of the Senate."

Metzenbaum said that the Senate has an "alert" system under which all legislation is cleared with individual senators before it is brought to the floor, but the system was bypassed.

Jerry Ray, a spokesman for Heflin, asserted the offices of key senators, including Metzenbaum, approved the measure before it went to the floor. But Ray offered no explanation for the failure to fully disclose the contents and impact of the measure.

Ray quoted Heflin, Chairman of the Senate Ethics Committee, is saying Searle representatives never mentioned campaign contributions in asking him to sponsor the amendment.

Heflin said he has "supported all patent restoration bills" because regulatory delays have created "a chronic problem" in which companies get so little use out of their 17-year patents, they are reluctant to put money into research.

Heflin said, in Searle's case, "almost 35 percent of the patent term had been used on a long series of administrative hearings, trials, and appeals (in) which, in the end, the corporation finally prevailed. To not restore some of the patent term lost would unfairly penalize them."

G.D. Searle sought an extension of its patent on grounds that the Food and Drug Administration's handling of its aspartame approval petition was "an unparalleled instance of unnecessary regulatory delay, which worked a great injustice to Searle".

Critics argue that, to the contrary, the FDA suspended its 1974 approval allowing Searle to market the sweetener because of evidence the company's animal studies were flawed and the results were misrepresented to the FDA in the early 1970's.

The evidence prompted FDA chief counsel Richard Merrill to ask the U.S. Attorney's office in Chicago to open a grand jury investigation into possible fraud by the company. While a grand jury investigated similar allegations related to Searle drug products, no such inquiry was ever begun into the aspartame testing. But the FDA was concerned enough about Searle's research to appoint two task forces, a university research group, and a Public Board of Inquiry to review various studies.

In 1981, shortly after taking office, FDA commissioner Arthur Hull Hayes, Jr. overturned the three-man Board of Inquiry and approved sale of NutraSweet in dry foods. Two years later, Hayes' deputy, Mark Novitch, approved the use of aspartame in soft drinks.

Kligerman dismissed as "crap" Searle's contention it had been victimized by the FDA bureaucracy, which delayed a decision from 1975 to 1981.

"The FDA had reason for doing this," Kligerman said of the intense review process. "It was not an unnecessary delay. It was Searle's fault this happened."

For Purification Engineering, Inc. of Columbia, Md., which raised money from private investors and built a plant solely to manufacture aspartame for Searle, the congressional action ultimately turned out to be devastating.

Gary Calton, a senior vice president for Purification Engineering, said that on Jan. 4, 1985, Searle notified the firm its contract would not be renewed. Seven months later, the firm was sold to Rhone-Poulenc Co., a French firm.

"My company would have been worth a great deal more if it had not been for that (patent) extension," Calton said. (Note: Searle sold The NutraSweet Co. to Monsanto in 1985) Calling the action unfair, he said, "I don't think Congress should go around passing laws making G.D. Searle rich any more than they should go around making me rich."

Searle officials declined to discuss the patent extension, but a company lobbyist, former White House official William Timmons, said the company "felt there was an injustice" in the delays following aspartame's 1974 approval. He said the company "took an advocacy role by talking to a lot of members of Congress".

In May of 1984, FEC records show Heflin's reelection committee received \$1,000. donations from Daniel Searle, the chief executive officer of the giant pharmaceutical company; his wife, Dain; William Searle, Searle's brother who was a company director; William Searle's wife, Sally; Suzanne Searle Dixon, a sister of the Searles; and her husband, Wesley Dixon, who also was a company director.

Heflin also received \$1,000. from William Searle prior to the general election, and \$2,000. in Searle PAC contributions, FEC records show.

On November 1982, a week after his reelection and a month after praising the amendment in the Senate chambers, Hatch's committee received \$2,000. in contributions from top Searle officers, the records show.

Sen. Robert Byrd (D-W.Va.), who brought the amendment up for a vote on Heflin's behalf, also received a \$1,000. campaign contribution from Daniel Searle on Sept. 25, 1981.

Hatch received contributions of \$1,000. each from Daniel Searle, Wesley Dixon, and William Searle on Nov. 11, 1982, days after he was reelected to a second term in which he continued as chairman of the Labor and Human Resources Committee that oversees the FDA.

As chairman of the panel until last January, Hatch repeatedly blocked Sen. Metzenbaum's calls for new hearings into the safety of NutraSweet.

Prior to his reelection, Hatch also received \$2,500. in contributions from the soft drink PAC.

Rep. Henry Waxman (D-Calif.), who sponsored the Orphan Drug Act covering research for treating rare diseases and who carried Heflin's patent amendment to the bill in the House, received \$1,500. in campaign contributions from the soft drink PAC, including \$500. two days before the measure's introduction in the House.

Like Heflin, Waxman made no mention of aspartame in describing the Senate amendments to the drug act on the House floor.

Searle also flashed its political prowess after Arizona scientist Woodrow Monte stirred up a furor in 1984 by publicly assailing NutraSweet's safety.

The ensuing events, Monte charged, "reflected exactly what Searle has been doing all along. They've been buying their way into the hearts and minds of America. They've been using their financial acumen to get their way."

Within months, legislative rules were swept aside one day in early 1985 and, in a swift, subtle maneuver without notice to the public, Monte's campaign for state regulations on the sweetener was sidetracked.

Monte was a leading national advocate in the drive to block marketing of NutraSweet until his own credibility was damaged in 1984 with disclosures he had invested in "put options" that would have earned profits if Searle's stock dropped.

He now concedes his options trading was a mistake, but denies it influenced his research.

Monte said he was convinced in 1983, when the FDA okayed use of NutraSweet in carbonated beverages, that the sweetener would break down into poisonous quantities of methyl alcohol in diet sodas left in the Southwest sun.

Monte, director of the Food Science and Nutrition Laboratories at Arizona State, and two consumer groups petitioned the Arizona Dept. of Health Services to ban the sweetener.

Monte said his rat studies had shown that chronic ingestion of methyl alcohol causes brain damage similar to that in humans suffering from Multiple Sclerosis, including seizures, amnesia, optic neuritis, numbness, and dizziness. In the desert heat, Monte said, methanol degrades faster into toxic methyl alcohol.

Searle and FDA officials have argued that aspartame contains too little methanol to pose a health hazard.

When Monte and the consumer groups pressed their legal challenge for more than a year, Searle flexed its muscle: The company dispatched a coterie of lobbyists to the state capitol, among them Andrew Hurwitz, Gov. Babbitt's former Chief of Staff; prominent Arizona lobbyist Charles Pine; company lawyer Roger Thies, and another company official, David West.

Between August 23, and Sept. 21, 1984 company officers Daniel Searle and his brother-in-law, Wesley Dixon, each contributed \$1,000. to the campaign of State House Majority Leader Burton Barr, later a GOP candidate for governor, reports to the Arizona Secretary of State's office records show.

Campaign disclosure forms show revealed that, during the same period, several House Republicans received contributions from the Committee to reelect Barr, including State Reps. Don Aldridge, Karen Mills, and Jan Brewer, all among the Health Committee members who voted 13-0 to pass the measure affecting NutraSweet. The trio received \$1,500., \$1,000. and \$750. respectively from Barr, who for years has enhanced his influence by donating to colleagues' campaigns.

Barr and Arizona State University Regent William Reilly contacted the school's president, J. Russell Nelson, and Academic Vice President Jack Kinsinger to inquire into Monte's public attacks on NutraSweet, published reports said. Kinsinger insisted that the issue caused no delay in his decision to grant Monte tenure. Barr did not return phone calls.

When Monte's first petition was rejected and he filed for reconsideration, Hurwitz wrote a letter offering legal advice to the Dept. of Health Services (DHS) about its response, and sent copies to Barr and aides to Gov. Babbitt.

In April of 1985, about the same time Monte and his associates finally were to be granted a hearing before the state agency on their petition, they learned that the Arizona Legislature had used a rare maneuver to change the law, without public notice to bar state regulation of FDA-approved food additives. The measure passed under the misleading title of a toxic waste bill.

Monte's campaign to ban NutraSweet in Arizona prompted the State Dept. of Health Services to conduct a study to determine how much NutraSweet soft drinks degraded in high-temperature conditions. The study, completed in July 1984, found that methanol levels were highest (9.4 ppm), in Diet 7-Up samples stored the longest time in the warmest temperature, 99° F heat.

Present and former Arizona state officials have told UPI that the study concerned DHS officials enough

that they discussed a NutraSweet ban.

But Norman Peterson, manager of the DHS's Office of Chronic Disease and Environmental Health Services, said that the agency concluded that "the FDA address the methyl alcohol question and had all sorts of supporting data. We had no basis for saying that the data they had presented in support was not correct or adequate."

Another source said Peterson was distressed enough that, during a meeting attended by DHS director Donald Mathis, he proposed being allowed to recommend that pregnant woman, and children, limit their consumption of NutraSweet.

Peterson would not confirm the episode, but recalled that he "was upset about the fact that there were so many unanswered questions".

Mathis, who since left the agency, said he was satisfied that it "wouldn't be humanly possible" to ingest levels of NutraSweet that would produce a toxic reaction.

In September 1984, Monte and his associates file suit to force the DHS to impose storage and labeling requirements or ban NutraSweet altogether. But a proposed settlement under which the agency would hold a public hearing was scuttled because it lacked the approval of Mathis' successor, Lloyd Novick.

After more negotiations, the DHS agreed to hold a hearing. But before it could take place, the issue was killed by the legislative change.

House Speaker James Sossaman later admitted that the GOP-controlled House violated its own rules in passing a so-called "strike all" amendment. Chairman Bart Baker of the Health Committee engineered the action, in which an existing bill was stripped, replaced with the NutraSweet language and brought to a vote without the required 24 hours public notice.

For Monte, the development was all the more staggering after he had gotten into a jam over his stock purchase. Monte said that, after reviewing files at the FDA and consulting with his lawyer in 1983, he invested less than \$2,000. on Searle options, hoping to raise money to support his costly legal battles against the sweetener. He said he ended up losing \$1,224.

Lawyer Rick Faerber also invested in part, he said, because of Monte's knowledge of an upcoming CBS story critical of the FDA's approval of aspartame. He said stock analysts had phoned Monte inquiring about his Arizona petitions and apparently got the idea the developments would depress the stock value.

Faerber said he regrets telling Monte that he "didn't think there was anything wrong" with investing, particularly because pro-NutraSweet forces apparently learned of their dealings. CBS employees also bought "put options" but a Securities and Exchange Commission investigation did not lead to any charges.

Shortly after news stories about the investment appeared, Rep. Bob McEwen, (R-Ohio), assailed CBS and Monte for "irresponsible reporting and conflicts of interest" in a brief speech on the floor of the U.S. Senate. McEwen charged that the "false report" about NutraSweet was aired solely for profit.

But in his speech, Rep. McEwen did not mention that his top assistant Charles Greener, is the son of William Greener, Jr., Searle's vice president for corporate communications.

Charles Greener who said he was "unaware" of Rep. McEwen's floor speech until after it occurred, said

his father never has handled NutraSweet matters and that McEwen did not know any Searle officials.

The success of the Searle family business, founded 80 years ago, is all the more astounding when compared to the company's predicament in 1977 when it plucked Rumsfeld as its president. Facing a company mired in debt, Rumsfeld, a native Chicagoan and former Illinois congressman, quickly hired three other outgoing Ford Administration officials to join him.

As executive vice president, he named John Robson, a former partner in the law firm of Sidley & Austin who had served as President Ford's chairman of the Civil Aeronautics Board. Robert Shapiro, Robson's special assistant at the Transportation Department, was tapped as general counsel. Rumsfeld also hired William Greener, Sr., who had been a spokesman in the Ford White House and Rumsfeld's chief spokesman at the Pentagon.

The pharmaceutical company suddenly was being run by lawyers and politicians.

Stomaching a \$28 million net loss in his first year, Rumsfeld slashed Searle's operations, selling off more than 30 subsidiaries worth more than \$400 million.

Before Rumsfeld could mount a full scale effort to lift a FDA freeze on the sale of NutraSweet, Searle was hit with serious new problems. Suits filed on behalf of 780 women, alleged the company's Copper 7 intrauterine device had caused them to develop pelvic inflammatory disease, an infection of the reproductive tract that can lead to sterility, even death.

Before the suits could be settled, Searle sold out to Monsanto.

The huge, St. Louis-based chemical company and its officers were promptly met with stockholder suits alleging they had failed to explore potential safety problems with Searle's biggest moneymakers- Copper 7 IUD and NutraSweet.

Rejecting criticism of the acquisition, Earl Harbison, Jr., executive vice president of Monsanto and Chairman of the Board of its Searle pharmaceutical subsidiary, said in October 1985, that Monsanto "studied this situation (Copper 7 litigation) very closely prior to acquiring Searle, including consultations with independent physicians".

"We satisfied ourselves with the safety and efficacy of the product," he said.

Since then, Copper 7 has been pulled off the market. Some lawyers likened the resulting legal morass to the failure of the Dalkon Shield that drove the Richmond-based A.H. Robins Co. into Chapter 11 bankruptcy protection.

But a former Monsanto official, who requested anonymity, said that as part of the sale agreement, Searle set aside reserves to cover the IUD lawsuits. Thanks to NutraSweet, Searle family members Daniel and William Searle and their sister, Suzanne Searle Dixon, to date appear to have walked away unscathed from all the crises and legal battles.

And even if NutraSweet were proved hazardous, the purchase agreement provided "no escrow, reserve or holdback for liability stemming from the potential health hazards attributed to the NutraSweet product line," says one lawsuit filed by Chicago lawyer Robert Holstein on behalf of a Monsanto stockholder.

And Rumsfeld emerged from his nine years with the company in solid financial condition. Securities and Exchange Commission records show that for his guiding the sweeping turnaround, he earned more than \$

2 million in salaries and more than \$1.5 million in bonuses between 1979 and 1984.

"Banana plants don't make NutraSweet," the television announcer noted wryly, and the image of an exotic bird perched in a jungle tree filled the screen.

"Neither do cows," said the voice, as the camera cut to a robust-looking heifer wagging its tail. "But they might as well. If you've had bananas and milk, you've eaten what's in NutraSweet."

True, bananas, milk and NutraSweet all contain phenylalanine, one of 21 amino acids that form the "building blocks" of protein. But that doesn't tell the whole story. Dr. Richard Wurtman, a neuroscientist at the Massachusetts Institute of Technology, says that because NutraSweet lacks other important amino acids normally found in foods, the brain absorbs unusually high levels of phenylalanine that could increase the likelihood of epileptic seizures.

Referring to an ad proclaiming that the body treats the ingredient of the artificial sweetener "no differently than if they came from a peach or a string bean or a glass of milk," Wurtman said, "That's not true."

Dr. Louis Elsas, director of medical genetics at Emory University, groans at the industry arguments that eating or drinking NutraSweet (aspartame) is just like eating a hamburger.

"Phenylalanine is a known toxin to the brain,' Elsas said. "Aspartame is phenylalanine, and drinking aspartame is like drinking phenylalanine as an individual amino acid."

A spokeswoman at the New York offices of Ogilvy and Mather, the lead ad agency on the sweetener account for the Chicago-based NutraSweet Co., declined comment on the allegation. The drumbeat of NutraSweet advertisements has been steady. Beverage Industry, a trade publication, labeled the NutraSweet blitz "probably the largest advertising campaign ever designed around a product ingredient."

Industry sources say that since 1984, The NutraSweet Co. alone has spent \$30 million to \$40 million a year on advertising, and ads by diet soft drink manufacturers and other companies, who's products carry the swirl trademark of the sugar-free sweetener, would easily send that the figure past \$100 million a year.

The campaign has worked to make NutraSweet a household word.

Football stars Joe Montana and Dan Marino and boxer Marvin Hagler have pitched products containing the artificial sweetener on television. Former Democratic vice presidential candidate Geraldine Ferraro has appeared in advertisements endorsing a product containing NutraSweet, as have numerous celebrities, including Bill Cosby, Raquel Welch and Billy Crystal.

