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The Aspartame / NutraSweet Fiasco

By James S. Turner

Many health-conscious people believe that avoiding aspartame, found in over 5000 products under brand names such as Equal and NutraSweet, can improve their quality of life. The history of this synthetic sweetener's approval by the U.S. Food and Drug Administration (FDA), including a long record of consumer complaints and the agency's demonstrated insensitivity to public concern, suggests they're right.

In October 1980 the Public Board of Inquiry (PBOI) impaneled by the FDA to evaluate aspartame safety found that the chemical caused an unacceptable level of brain tumors in animal testing. Based on this fact, the PBOI ruled that aspartame should not be added to the food supply.

This ruling capped 15 years of regulatory ineptitude, chicanery and deception by the FDA and the Searle drug company, aspartame's discoverer and manufacturer (acquired by Monsanto in 1985), and kicked off another two decades of maneuvering, manipulating and dissembling by FDA, Searle and Monsanto.

In 1965, a Searle scientist licked some of a new ulcer drug from his fingers and discovered the sweet taste of aspartame. Eureka! Selling this chemical as a food additive to hundreds of millions of healthy people every day would mean many more dollars than limited sales to the much smaller group of ulcer sufferers.

Searle, a drug company with little experience in food regulation, began studies to comply with the law — but which failed to do so. Its early tests of the substance showed it produced microscopic holes and tumors in the brains of experimental mice, epileptic seizures in monkeys, and was converted by animals into dangerous substances, including formaldehyde.

In 1974, however, in spite of the information in its files, the FDA approved aspartame as a dry-foods additive. But the agency also made public for the first time the data supporting a food-additive decision. This data was subsequently reviewed by renowned brain researcher John Olney from Washington University in St. Louis, and other scientists.

Dr. Olney discovered two studies showing brain tumors in rats and petitioned FDA for a public hearing. Consumer Action for Improved Foods and Drugs (represented by the author of this piece) also petitioned for a public hearing based on the approval process having been based on sloppy science and the product's having reportedly caused epileptic seizures in monkeys and possible eye damage.

Dr. Olney had already shown that aspartic acid (one aspartame component) caused microscopic holes in the brains of rats after each feeding. Aspartame also includes phenylalinine, which causes PKU in a small number of susceptible children, and methyl, or wood, alcohol which is neurotoxic in large amounts.

Faced with this array of possible health dangers, FDA granted the hearing requests. In lieu of withdrawing its aspartame approval, the agency prevailed on Searle to refrain from marketing the sweetener until after completion of the hearing process. it then proposed that a Public Board of Inquiry (PBOI) review the matter.

In July of 1975, as the FDA prepared for the PBOI, an FDA inspector conducted a routine review of the Searle's Skokie Ill., testing facilities and found many deviations from proper procedures. This report led the FDA commissioner to empanel a Special Commissioner's Task Force to review Searle's labs.

In December of 1975 the Task force reported serious problem with Searle research on a wide range of products, including aspartame. It found 11 pivotal studies conducted in a manner so flawed as to raise doubts about aspartame safety and create the possibility of serious criminal liability for Searle.

The FDA then stayed aspartame's approval. It also contracted, over serious internal objection, with a group of university pathologists (paid by Searle) to review most of the studies, set up a task force to review three studies and asked the U.S. Attorney for Chicago to seek a grand jury review of the monkey seizure study.

The pathologists paid by Searle only reviewed failure to properly report data and not the study's design or conduct. They found no serious problems. The FDA task force found Searle's key tumor safety study unreliable, but was ignored. The U.S. attorney let the statue of limitations run out, then (along with two aides) proceeded to join Searle's law firm.

While these committees met, the FDA organized the PBOI. Searle, the petitioners and the FDA Bureau of Foods each nominated three members for the board and the FDA commissioner selected one member from each list. the board, which convened in January of 1980, rejected petitioners' request to include the commissioner's task force information in its deliberations. Still, in October 1980, based on its limited review, the board blocked aspartame marketing until the tumor studies could be explained. Unless the commissioner overruled the board, the matter was closed.

In November 1980, however, the country elected Ronald Reagan President. Donald Rumsfeld (former congressman from Skokie, former White House chief of staff, former secretary of defense and since January 1977 president of Searle) joined the Reagan transition team. A full court press against the board decision began.

In January 1981 Rumsfeld told a sales meeting, according to one attendee, that he would call in his chips and get aspartame approved by the end of the year. On January 25th, the day the new president took office, the previous

FDA commissioner's authority was suspended, and the next month, the commissioner's job went to Dr. Arthur Hull Hayes.

Transition records do not show why the administration chose Hayes, a professor and Defense Department contract researcher. In July Hayes, defying FDA advisors, approved aspartame for dry foods — his first major decision. In November 1983 the FDA approved aspartame for soft drinks — Hayes' last decision.

In November 1983 Hayes, under fire for accepting corporate gifts, left the agency and went to Searle's public-relations firm as senior medical advisor. Later Searle lawyer Robert Shapiro named aspartame NutraSweet. Monsanto purchased Searle. Rumsfeld received a $12 million bonus. Shapiro is now Monsanto president.

Shortly after the FDA soft-drink approval, Searle began test marketing, and complaints began to arrive at the FDA — of such reactions as dizziness, blurred vision, headaches, and seizures. The complaints were more serious than the agency had ever received on any food additive, At the same time, scientists began looking more closely at this manufactured chemical sweetener.

In 1985, the FDA asked the Centers for Disease Control (CDC) to review the first 650 complaints (there are now over 10,000). CDC found that the symptoms in approximately 25% of the complainants had stopped and then restarted, corresponding with their having stopped and then restarted, either purposely or by accident, aspartame consumption.

The CDC also identified several specific subjects whose symptoms stopped and started as they stopped and started consuming aspartame. The FDA discounted the report. The day the FDA released the CDC report, Pepsi Cola — having obtained an advance copy — announced its switch to aspartame with a worldwide media blitz.

Former White House Chief of Staff Rumsfeld owed a debt of gratitude to former White House confidante and Rumsfeld friend Donald Kendal, Pepsi's chairman. The Pepsi announcement and aggressive marketing (millions of gumballs, a red and white swirl, tough contracts) made NutraSweet known in every home.

At the same time, according to data released in 1995, human brain tumors like those in the animal studies rose 10% and previously benign tumors turned virulent. Searle and FDA's deputy commissioner said the data posed no problem. Two years later this same FDA official became vice president of clinical research for Searle.

From 1985 to 1995, researchers did about 400 aspartame studies. They were divided almost evenly between those that gave assurances and those that raised questions about the sweetener. Most instructively, Searle paid for 100% of those finding no problem. All studies paid for by non-industry sources raised questions.

Given this record, it is little wonder that many health-conscious people believe avoiding NutraSweet improves their quality of life. If and when a scientific consensus concludes that aspartame puts some, if not all, of its consumers at risk, it will be much too late. The point is to eat safely now. Remember: the brain you save may be your own.

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