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How Aspartame Became Legal - The Timeline

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From Norfolk Genetic Information Network (Taken from Welcome to the Spin Machine by Michael Manville <http://www.freezerbox.com/archive/2001/04/biotech/> <http://www.freezerbox.com/>)

In 1985 Monsanto purchased G.D. Searle, the chemical company that held the patent to aspartame, the active ingredient in NutraSweet. Monsanto was apparently untroubled by aspartame's clouded past, including a 1980 FDA Board of Inquiry, comprised of three independent scientists, which confirmed that it "might induce brain tumors."

The FDA had actually banned aspartame based on this finding, only to have Searle Chairman Donald Rumsfeld (currently the Secretary of Defense) vow to "call in his markers," to get it approved.

On January 21, 1981, the day after Ronald Reagan's inauguration, Searle re-applied to the FDA for approval to use aspartame in food sweetener, and Reagan's new FDA commissioner, Arthur Hayes Hull, Jr., appointed a 5-person Scientific Commission to review the board of inquiry's decision.

It soon became clear that the panel would uphold the ban by a 3-2 decision, but Hull then installed a sixth member on the commission, and the vote became deadlocked. He then personally broke the tie in aspartame's favor. Hull later left the FDA under allegations of impropriety, served briefly as Provost at New York Medical College, and then took a position with Burston-Marsteller, the chief public relations firm for both Monsanto and GD Searle. Since that time he has never spoken publicly about aspartame.

The Aspartame/NutraSweet Timeline

<http://www.swankin-turner.com/aspartame.html> <http://www.swankin-turner.com/hist.html>

Aspartame/NutraSweet: The History of the Aspartame Controversy

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Timeline

December 1965-- While working on an ulcer drug, James Schlatter, a chemist at G.D. Searle, accidentally discovers aspartame, a substance that is 180 times sweeter than sugar yet has no calories.

Spring 1967-- Searle begins the safety tests on aspartame that are necessary for applying for FDA approval of food additives.

Fall 1967-- Dr. Harold Waisman, a biochemist at the University of Wisconsin, conducts aspartame safety tests on infant monkeys on behalf of the Searle Company. Of the seven monkeys that were being fed aspartame mixed with milk, one dies and five others have grand mal seizures.

November 1970-- Cyclamate, the reigning low-calorie artificial sweetener -- is pulled off the market after some scientists associate it with cancer. Questions are also raised about safety of saccharin, the only other artificial sweetener on the market, leaving the field wide open for aspartame.

December 18, 1970-- Searle Company executives lay out a "Food and Drug Sweetener Strategy" that they feel will put the FDA into a positive frame of mind about aspartame. An internal policy memo describes psychological tactics the company should use to bring the FDA into a subconscious spirit of participation" with them on aspartame and get FDA regulators into the "habit of saying, "Yes"."

Spring 1971-- Neuroscientist Dr. John Olney (whose pioneering work with monosodium glutamate was responsible for having it removed from baby foods) informs Searle that his studies show that aspartic acid (one of the ingredients of aspartame) caused holes in the brains of infant mice. One of Searle's own researchers confirmed Dr. Olney's findings in a similar study.

February 1973-- After spending tens of millions of dollars conducting safety tests, the G.D. Searle Company applies for FDA approval and submits over 100 studies they claim support aspartame's safety.

March 5, 1973-- One of the first FDA scientists to review the aspartame safety data states that "the information provided (by Searle) is inadequate to permit an evaluation of the potential toxicity of aspartame". She says in her report that

in order to be certain that aspartame is safe, further clinical tests are needed.

May 1974-- Attorney, Jim Turner (consumer advocate who was instrumental in getting cyclamate taken off the market) meets with Searle representatives to discuss Dr. Olney's 1971 study which showed that aspartic acid caused holes in the brains of infant mice.

July 26, 1974-- The FDA grants aspartame its first approval for restricted use in dry foods.

August 1974-- Jim Turner and Dr. John Olney file the first objections against aspartame's approval.

March 24, 1976-- Turner and Olney's petition triggers an FDA investigation of the laboratory practices of aspartame's manufacturer, G.D. Searle. The investigation finds Searle's testing procedures shoddy, full of inaccuracies and "manipulated" test data. The investigators report they "had never seen anything as bad as Searle's testing."

January 10, 1977-- The FDA formally requests the U.S. Attorney's office to begin grand jury proceedings to investigate whether indictments should be filed against Searle for knowingly misrepresenting findings and "concealing material facts and making false statements" in aspartame safety tests. This is the first time in the FDA's history that they request a criminal investigation of a manufacturer.

January 26, 1977-- While the grand jury probe is underway, Sidley & Austin, the law firm representing Searle, begins job negotiations with the U.S. Attorney in charge of the investigation, Samuel Skinner.

March 8, 1977-- G. D. Searle hires prominent Washington insider Donald Rumsfeld as the new CEO to try to turn the beleaguered company around. A former Member of Congress and Secretary of Defense in the Ford Administration, Rumsfeld brings in several of his Washington cronies as top management.

July 1, 1977-- Samuel Skinner leaves the U.S. Attorney's office and takes a job with Searle's law firm. (see Jan. 26th)

August 1, 1977-- The Bressler Report, compiled by FDA investigators and headed by Jerome Bressler, is released. The report finds that 98 of the 196 animals died during one of Searle's studies and weren't autopsied until later dates, in some cases over one year after death. Many other errors and inconsistencies are noted. For example, a rat was reported alive, then dead, then alive, then dead again; a mass, a uterine polyp, and ovarian neoplasms were found in animals but not reported or diagnosed in Searle's reports.

December 8, 1977-- U.S. Attorney Skinner's withdrawal and resignation stalls the Searle grand jury investigation for so long that the statute of limitations on

the aspartame charges runs out. The grand jury investigation is dropped.

June 1, 1979-- The FDA established a Public Board of Inquiry (PBOI) to rule on safety issues surrounding NutraSweet.

September 30, 1980-- The Public Board of Inquiry concludes NutraSweet should not be approved pending further investigations of brain tumors in animals. The board states it "has not been presented with proof of reasonable certainty that aspartame is safe for use as a food additive."

January 1981-- Donald Rumsfeld, CEO of Searle, states in a sales meeting that he is going to make a big push to get aspartame approved within the year. Rumsfeld says he will use his political pull in Washington, rather than scientific means, to make sure it gets approved.

January 21, 1981-- Ronald Reagan is sworn in as President of the United States. Reagan's transition team, which includes Donald Rumsfeld, CEO of G. D. Searle, hand picks Dr. Arthur Hull Hayes Jr. to be the new FDA Commissioner.

March, 1981-- An FDA commissioner's panel is established to review issues raised by the Public Board of Inquiry.

May 19, 1981-- Three of six in-house FDA scientists who were responsible for reviewing the brain tumor issues, Dr. Robert Condon, Dr. Satya Dubey, and Dr. Douglas Park, advise against approval of NutraSweet, stating on the record that the Searle tests are unreliable and not adequate to determine the safety of aspartame.

July 15, 1981-- In one of his first official acts, Dr. Arthur Hayes Jr., the new FDA commissioner, overrules the Public Board of Inquiry, ignores the recommendations of his own internal FDA team and approves NutraSweet for dry products. Hayes says that aspartame has been shown to be safe for its' proposed uses and says few compounds have withstood such detailed testing and repeated close scrutiny.

October 15, 1982-- The FDA announces that Searle has filed a petition that aspartame be approved as a sweetener in carbonated beverages and other liquids.

July 1, 1983-- The National Soft Drink Association (NSDA) urges the FDA to delay approval of aspartame for carbonated beverages pending further testing because aspartame is very unstable in liquid form. When liquid aspartame is stored in temperatures above 85 degrees Fahrenheit, it breaks down into DKP and formaldehyde, both of which are known toxins.

July 8, 1983-- The National Soft Drink Association drafts an objection to the final ruling which permits the use of aspartame in carbonated beverages and syrup bases and requests a hearing on the objections. The association says that

Searle has not provided responsible certainty that aspartame and its' degradation products are safe for use in soft drinks.

August 8, 1983-- Consumer Attorney, Jim Turner of the Community Nutrition Institute and Dr. Woodrow Monte, Arizona State University's Director of Food Science and Nutritional Laboratories, file suit with the FDA objecting to aspartame approval based on unresolved safety issues.

September, 1983-- FDA Commissioner Hayes resigns under a cloud of controversy about his taking unauthorized rides aboard a General Foods jet. (General foods is a major customer of NutraSweet) Burson-Marsteller, Searle's public relation firm (which also represented several of NutraSweet's major users), immediately hires Hayes as senior scientific consultant.

Fall 1983-- The first carbonated beverages containing aspartame are sold for public consumption.

November 1984-- Center for Disease Control (CDC) "Evaluation of consumer complaints related to aspartame use." (summary by B. Mullarkey)

November 3, 1987-- U.S. hearing, "NutraSweet: Health and Safety Concerns," Committee on Labor and Human Resources, Senator Howard Metzenbaum, chairman.

<http://groups.yahoo.com/group/aspartameNM/message/857> RTM:
www.dorway.com: original documents and long reviews of flaws in aspartame toxicity research 7.31.2 rmforall

<http://www.dorway.com/upipart1.txt> UPI reporter Gregory Gordon: 96K 3-part expose Oct 1987

"Survey of aspartame studies: correlation of outcome and funding sources," 1998, unpublished: <http://www.dorway.com/peerrev.html> Walton found 166 separate published studies in the peer reviewed medical literature, which had relevance for questions of human safety. The 74 studies funded by industry all (100%) attested to aspartame's safety, whereas of the 92 non-industry funded studies, 84 (91%) identified a problem. Six of the seven non-industry funded studies that were favorable to aspartame safety were from the FDA, which has a public record that shows a strong pro-industry bias. Ralph G. Walton, MD, Prof. of Clinical Psychology, Northeastern Ohio Universities, College of Medicine, Dept. of Psychiatry, Youngstown, OH 44501, Chairman, The Center for Behavioral Medicine, Northside Medical Center, 500 Gypsy Lane, P.O. Box 240 Youngstown, OH 44501 330-740-3621 rwalton193@aol.com
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