

# Aspartame controversy

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The [artificial sweetener aspartame](#) has been the subject of several controversies since its initial approval by the [U.S. Food and Drug Administration](#) (FDA) in 1974. The FDA approval of aspartame was highly contested,<sup>[1]</sup> with critics alleging that the quality of the initial research supporting its safety was inadequate and flawed and that [conflicts of interest](#) marred the 1981 approval of aspartame.<sup>[2][3][4]</sup> In 1987, the U.S. [Government Accountability Office](#) concluded that the food additive approval process had been followed properly for aspartame.<sup>[2][5]</sup> The irregularities fueled a [conspiracy theory](#), which the "Nancy Markle" email hoax circulated, along with claims, counter to the weight of medical evidence, that numerous health conditions (such as multiple sclerosis, systemic lupus, [methanol toxicity](#), blindness, spasms, shooting pains, seizures, headaches, depression, anxiety, memory loss, birth defects, and death<sup>[6]</sup>) are caused by the consumption of aspartame in normal doses.<sup>[7][8][9]</sup>

Potential health risks have been examined and dismissed by numerous scientific research projects. With the exception of the risk to those with [phenylketonuria](#), aspartame is considered to be a safe food additive by governments worldwide and major health and food safety organizations.<sup>[2][10][11][12][13][14]</sup> FDA officials describe aspartame as "one of the most thoroughly tested and studied food additives the agency has ever approved" and its safety as "clear cut."<sup>[4]</sup> The weight of existing scientific evidence indicates that aspartame is safe as a non-nutritive sweetener.<sup>[10]</sup>

## Origins<sup>[edit]</sup>

The controversy over aspartame safety originated in perceived irregularities in the aspartame approval process during the 1970s and early 1980s, including allegations of a [revolving door](#) relationship between regulators and industry and claims that aspartame producer [G.D. Searle](#) had withheld and falsified safety data. In 1996, the controversy reached a wider audience with a [60 Minutes](#) report<sup>[1]</sup> that discussed criticisms of the FDA approval process and concerns that aspartame could cause brain tumors in humans. The *60 Minutes* special stated that "aspartame's approval was one of the most contested in FDA history."<sup>[1]</sup>

Around the same time, a [Usenet](#) post was widely circulated under the pen name "Nancy Markle", creating the basis for a misleading and unverifiable hoax [chain letter](#) that was spread through the Internet.<sup>[12]</sup> Numerous websites have spread the email's claims, which were not backed by scientific evidence, about safety issues purportedly linked to aspartame, including [Gulf War Syndrome](#) and [lupus](#).<sup>[15]</sup>

## U.S. FDA approval<sup>[edit]</sup>

Aspartame was originally approved for use in dry foods in 1974 by then FDA Commissioner Alexander Schmidt after review by the FDA's [Center for Food Safety and Applied Nutrition](#). Searle had submitted 168 studies<sup>[2]:20</sup> on aspartame, including seven animal studies that were considered crucial by the FDA.<sup>[2]:21</sup> Soon afterwards, [John Olney](#), a professor of psychiatry and prominent critic of [MSG](#), along with James Turner, a public-interest lawyer and author of an anti-food-additive book, filed a petition for a public hearing, citing safety concerns.<sup>[2]:38</sup><sup>[16]:63–4</sup> Other criticisms presented in the 1996 *60 Minutes* special of the Searle studies included assertions of unreported medical treatments that may have affected the study outcomes and discrepancies in the reported data.<sup>[1]</sup> Schmidt agreed, pending an investigation into alleged improprieties in safety studies for aspartame and several drugs. In December 1975, the FDA placed a stay on the aspartame approval, preventing Searle from marketing aspartame.<sup>[2]:28</sup> The Searle studies were criticized by the FDA commissioner as "... at best ... sloppy and suffering from "... a pattern of conduct which compromises the scientific integrity of the studies."<sup>[1]</sup>

U.S. Attorney [Samuel Skinner](#) was requested to "open a grand jury investigation into whether two of Searle's aspartame studies had been falsified or were incomplete."<sup>[17]</sup> Skinner withdrew from the case when he was considering a job offer from the law firm [Sidley & Austin](#), Searle's Chicago-based law firm, a job he later took.<sup>[1]</sup> The investigation was delayed and eventually the [statute of limitations](#) on the charges against Searle expired<sup>[1]</sup> and a grand jury was never convened.<sup>[17]</sup>

In 1977 and 1978, an FDA task force and a panel of academic pathologists reviewed 15 aspartame studies by Searle, and concluded that, although there were major lapses in quality control, the resulting inconsistencies would not have affected the studies' conclusions.<sup>[2]:4</sup> In 1980, a Public Board of Inquiry (PBOI) heard testimony from Olney and disagreed with his claims that aspartame could cause brain damage, including in the developing fetus.<sup>[2]:40–41</sup> The board decided that further study was needed on a postulated connection between aspartame and brain tumors, and revoked approval of aspartame.<sup>[2]:47</sup>

In 1981, FDA Commissioner [Arthur Hull Hayes](#) sought advice on the issue from a panel of FDA scientists and a lawyer. The panel identified errors underlying the PBOI conclusion that aspartame might cause brain tumors, and presented arguments both for and against approval.<sup>[2]:53</sup> Hayes approved the use of aspartame in dry foods. Hayes further justified his approval with a Japanese brain tumor study,<sup>[18]</sup> the results of which, the PBOI chairman later said, would have resulted in an "unqualified approval" from the PBOI panel.<sup>[19]</sup> Several objections followed, but all were denied.<sup>[2]:13</sup> In November 1983, a little more than a year after approving aspartame, Hayes left the FDA and joined

public-relations firm [Burson-Marsteller](#), Searle's public relations agency at the time, as a senior medical adviser.<sup>[5]</sup>

The actions of Samuel Skinner, in taking a job with a law firm retained by Searle during an investigation into Searle, and Arthur Hull Hayes, in taking a job with Searle's public relations agency following aspartame's approval, fueled conspiracy theories.<sup>[17]</sup>

Because of the approval controversy, Senator [Howard M. Metzenbaum](#) requested an investigation by the U.S. [Government Accountability Office](#) (GAO) of aspartame's approval. In 1987, the GAO reported that protocol had been followed and provided a time-line of events in the approval process.<sup>[2]:13</sup> The GAO review included a survey of scientists who had conducted safety reviews; of the 67 scientists who responded to a questionnaire, 12 had major concerns about aspartame's safety, 26 were somewhat concerned but generally confident in aspartame safety, and 29 were very confident in aspartame safety.<sup>[2]:16,76–81</sup>

Food additive safety evaluations by many countries have led to approval of aspartame, citing the general lack of adverse effects following consumption in reasonable quantities.<sup>[20]</sup> Based on government research reviews and recommendations from advisory bodies such as those listed above, aspartame has been found to be safe for human consumption by more than ninety countries worldwide.<sup>[13][14]</sup>

## Alleged conflict of interest prior to 1996<sup>[edit]</sup>

In 1976, the FDA notified then-U.S. attorney for Chicago, Sam Skinner, of the ongoing investigation of Searle, and in January 1977, formally requested that a grand jury be convened. In February, 1977, Searle's law firm, [Sidley & Austin](#) offered Skinner a job and Skinner recused himself from the case.<sup>[21]</sup> Mr. Skinner's successor was in place several months later, and the statute of limitations for the alleged offenses expired in October 1977. Despite complaints and urging from DOJ in Washington, neither the interim U.S. attorney for Chicago, William Conlon, nor Skinner's successor, Thomas Sullivan, convened a grand jury.<sup>[22]</sup> In December, 1977, Sullivan ordered the case dropped for lack of evidence. A year and a half later, Conlon also was hired by Sidley & Austin.<sup>[17]</sup> Concern about conflict of interest in this case inflamed the controversy, and Senator Metzenbaum investigated in 1981 Senate Hearings.<sup>[2]</sup> In 1989, the U.S. Senate approved the nomination of Sam Skinner to be [Secretary of Transportation](#), noting that both Sullivan and Senator Metzenbaum had concluded that Skinner had not acted improperly.<sup>[21]</sup>

Ralph G. Walton, a psychiatrist at [Northeastern Ohio Universities College of Medicine](#), stated in a self-published 1996 analysis of aspartame research that industry-funded studies found no safety concerns while 84 of 92 independent studies did identify safety concerns.<sup>[17][23]</sup> This analysis by Walton was submitted to the television show [60 Minutes](#) and has been extensively discussed on the Internet. An

analysis of Walton's claims showed that Walton left out at least 50 [peer-reviewed](#) safety studies from his review of the literature and that most of the research he cites as non-industry funded were actually letters to the editors, case reports, review articles or book chapters rather than published studies.<sup>[24]</sup> In a rebuttal to Walton's statements, the Aspartame Information Service (a service provided by [Ajinomoto](#), a primary producer and supplier of aspartame), reviewed the publications Walton cites as critical of aspartame, arguing that most of them do not involve aspartame or do not draw negative conclusions, are not peer-reviewed, are anecdotal, or are duplicates.<sup>[25]</sup>

## Internet hoax conspiracy theory<sup>[edit]</sup>

An elaborate [health scare](#),<sup>[7]</sup> involving a hoax [conspiracy theory](#) disseminated on many Internet websites in 1999, attributes a host of deleterious medical effects to aspartame. This theory claims that the FDA approval process of aspartame was tainted<sup>[12][26][27]</sup> and cites as its source an email based upon a supposed talk by a "Nancy Markle" (thought to be Betty Martini, who first circulated the email)<sup>[28]</sup> at a "World Environmental Conference."<sup>[12][26][29]</sup> Specifically, the hoax websites allege that aspartame is responsible for [multiple sclerosis](#), systemic [lupus](#), and [methanol](#) toxicity, causing "blindness, spasms, shooting pains, seizures, headaches, depression, anxiety, memory loss, birth defects" and death.<sup>[6]</sup> A proliferation of websites, many with sensationalist [URLs](#), are filled with anecdotal claims and medical misinformation.<sup>[30]</sup> The Markle hoax and its extended argument on "aspartamekills.com" have not been supported by medical studies.<sup>[31]</sup> The email has been described as an "Internet smear campaign ... Its contents were entirely false, misleading, and defamatory to various popular products and their manufacturers, with no basis whatever in fact."<sup>[8]</sup>

The "Markle" email says that there is a conspiracy between the FDA and the producers of aspartame, and the conspiracy theory has become a canonical example discussed on several Internet conspiracy theory and [urban legend](#) websites.<sup>[12][32]</sup> Although most of the allegations of this theory contradict the bulk of medical evidence,<sup>[26]</sup> the misinformation has spread around the world as [chain emails](#) since mid-December 1998,<sup>[12]</sup> influencing many websites<sup>[32]</sup> as an [urban legend](#) that continues to scare consumers.<sup>[26]</sup> The [Media Awareness Network](#) featured one version of it in a tutorial on how to determine the credibility of a web page. The tutorial implied that the "Markle" letter was not credible and stated that it should not be used as an authoritative source of information.<sup>[6]</sup>

[Dean Edell](#) warned very strongly against the "Markle" letter:

Beware The E-Mail Hoax: The Evils Of Nutrasweet (Aspartame)

A highly inaccurate "chain letter" is being circulated via e-mail warning the reader of the health dangers of aspartame (NutraSweet) diet drinks. There is so much scientific untruth in it, it's scary. Be careful, because others know how to manipulate you by this. Just because something is beyond your comprehension doesn't mean it is scientific.

The e-mail is outrageous enough to state that the Multiple Sclerosis Foundation is suing the FDA for collusion with Monsanto ... Bogus, totally bogus. You've got to be careful of these Internet hoaxes. When you read health information online, be sure to know the source of the information you are reading, okay?<sup>[9]</sup>

## Government action and voluntary withdrawals<sup>[edit]</sup>

In 1997, due to public concerns, the U.K. government introduced a new regulation obliging food makers who use sweeteners to state clearly next to the name of their product the phrase "with sweeteners."<sup>[33]</sup>

In 2007, the Indonesian government considered banning aspartame.<sup>[34]</sup> In the Philippines, the small political party Alliance for Rural Concerns introduced House Bill 4747 in 2008 with the aim of having aspartame banned from the food supply.<sup>[35]</sup> In the U.S. state of [New Mexico](#) a bill to ban aspartame was introduced in 2007, and subsequently rejected.<sup>[36][37][38]</sup> A similar 2008 Hawaiian bill stalled in committee for lack of evidence.<sup>[39][40]</sup> In March 2009, the California OEHHA identified aspartame as a chemical for consultation by its Carcinogen Identification Committee, in accordance with [California state Proposition 65](#).<sup>[41]</sup> So far no conclusions or updates have been published on the OEHHA website.<sup>[42]</sup>

In 2007, the U.K. supermarket chains [Sainsbury's](#), [M&S](#),<sup>[43]</sup> and [Wal-Mart](#) subsidiary [Asda](#), announced that they would no longer use aspartame in their own label products. In April 2009, [Ajinomoto](#) Sweeteners Europe, one of the makers of [aspartame](#) in Europe, responded to Asda's "no nasties" campaign by filing a complaint of malicious falsehood against Asda in the English courts.<sup>[44][45]</sup> In July 2009, Asda initially won the legal case after the trial judge construed the "no nasties" labelling to "not mean that aspartame was potentially harmful or unhealthy."<sup>[46][47]</sup> The decision was reversed in June 2010, upon appeal,<sup>[48]</sup> and was settled in 2011 with ASDA removing references to aspartame from its packaging.<sup>[49]</sup>

In 2009, the South African retailer [Woolworths](#) announced it was removing aspartame-containing foods from its own-brand range.<sup>[50]</sup>

In 2010, the [British Food Standards Agency](#) funded a clinical study of people who claimed to experience side-effects after consuming aspartame.<sup>[51]</sup> The double blind controlled study has been concluded and found no evidence of safety issues or side effects even amongst those volunteers who had previously claimed sensitivity. The FSA's Committee on Toxicity evaluated the results at its meeting in October 2013, and determined that "the results presented did not indicate any need for action to protect the health of the public."<sup>[52]</sup>

The [European Food Safety Authority](#) (EFSA) commenced a re-evaluation of aspartame as part of the systematic re-evaluation of all food additives authorised in the EU prior to 20 January 2009. In May 2011, EFSA was asked by the European Commission to bring forward the full re-evaluation of the safety of aspartame (E 951),

which was previously planned for completion by 2020.<sup>[53]</sup> In September 2011, the EFSA made all 600 datasets it is using in its full re-evaluation available publicly. This includes previously unpublished scientific data, "including the 112 original studies on aspartame which were submitted to support the request for authorisation of aspartame in Europe in the early 1980s."<sup>[54][55][56]</sup> On January 8, 2013, the EFSA released its draft report, which found that aspartame and its metabolites "pose no toxicity concern for consumers at current levels of exposure. The current [Acceptable Daily Intake](#) (ADI) is considered to be safe for the general population and consumer exposure to aspartame is below this ADI."<sup>[53][57]</sup>

## Ramazzini studies<sup>[edit]</sup>

The Cesare Maltoni Cancer Research Center of the [European Ramazzini Foundation of Oncology and Environmental Sciences](#) has released several studies which claim that aspartame can increase several malignancies in rodents, concluding that aspartame is a potential carcinogen at normal dietary doses.<sup>[10][58][59]</sup> Although thirteen [occupational safety and health](#) experts signed an open letter from CSPI to the FDA expressing that the 2007 ERF study merited a reevaluation of aspartame's safety in humans,<sup>[60][61]</sup> these studies have been widely criticized and discounted by the FDA and other food safety agencies.

After reviewing the foundation's claims, the EFSA<sup>[62]</sup> and the FDA<sup>[63]</sup> discounted the study results and found no reason to revise their previously established acceptable daily intake levels for aspartame. Reported flaws were numerous and included, but were not limited to, the following: comparing cancer rates of older aspartame-consuming rats to younger control rats; unspecified composition of the "Corticella" diet and method of adding aspartame, leading to possible nutritional deficiencies; unspecified aspartame storage conditions; lack of animal randomization; overcrowding and a high incidence of possibly carcinogenic infections; and the U.S. [National Toxicology Program](#)'s finding that the ERF had misdiagnosed [hyperplasias](#) as malignancies.<sup>[10]</sup> Reviews by the FDA and EFSA were hampered by the refusal of the Ramazzini Foundation to release all data and pathology slides, but from the materials received, the FDA<sup>[63]</sup> and EFSA<sup>[64]</sup> found that the data did not support the researcher's published conclusions. Evaluation of this research by Health Canada<sup>[65]</sup> and the British government's Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment<sup>[66]</sup> likewise found methodological problems with the research and did not recommend any further reconsideration of the recommended intake of aspartame in their respective countries.

A review of the literature concurred with these evaluations, finding many possible flaws in the study's design and conclusions. These conclusions are also contradicted by other carcinogenicity studies which found no significant danger. This review therefore concluded this research did not constitute credible evidence for the

carcinogenicity of aspartame.<sup>[10]</sup> Another review criticized the Ramazzini Foundation for relying on "[science by press conference](#)" with its release of results through the media before being published in a proper [peer-reviewed](#) journal, thus helping fuel the controversy and publicity about the study in the media.<sup>[67]</sup>

Another carcinogenicity study in rodents published by this foundation in 2010 was evaluated by the EFSA and was found to have multiple significant design flaws and could not be interpreted. The EFSA therefore concluded this study did not provide enough evidence to reconsider previous evaluation of aspartame safety.<sup>[68]</sup>

## See also<sup>[edit]</sup>

- [Canderel](#)
- [Equal \(sweetener\)](#)
- [NutraSweet](#)

## References<sup>[edit]</sup>


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- 66 ^ ["Statement on a Carcinogenicity Study of Aspartame by the European Ramazzini Foundation"](#) (PDF). Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment. Retrieved February 28, 2011.
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## External links<sup>[[edit](#)]</sup>

- [Centers for Disease Control: Evaluation of Consumer Complaints Related to Aspartame Use](#)
- [International Programme on Chemical Safety: Aspartame toxicology evaluation and further evaluation](#)
- Sample anti-aspartame website: <http://aspartamekills.com>