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REVISED

September 20, 2005

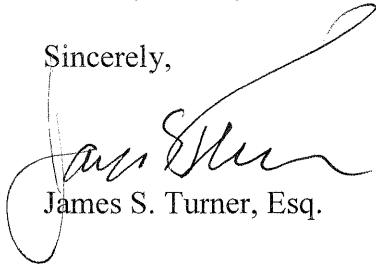
The Honorable Ron Curry
New Mexico Secretary of Environment

Dear Secretary Curry:

I am sending the enclosed **REVISED** letter in hopes that it will benefit your effort to evaluate aspartame in New Mexico. My prior letter was inadvertently sent before was completed. Please forward the enclosed to Barbara Claire before 5:00 pm today.

Thank you for your consideration.

Sincerely,



James S. Turner, Esq.

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To The Honorable Gay Dillingham
Madame Chair, New Mexico Environmental Improvement Board

Dear Ms. Dillingham and Members of the EIB:

I first became aware of the dangers of Aspartame in 1970. During that year I worked closely with the United States Senate Select Committee on Nutrition and Human Needs, to which I subsequently served as special counsel. Dr. John Olney of Washington University in St. Louis, whose information presented to that committee played a key role in the elimination of Mono Sodium Glutamate (MSG) from baby food, informed me that the aspartic acid component of aspartame created the same kind of lesions (holes) in the brains of mice that MSG did. Dr. Olney's information caused me to investigate aspartame further.

In 1969 I was the lawyer in charge of a team of 20 law and medical students investigating, under the direction of Ralph Nader, food safety regulation at the US Food and Drug Administration. *The Chemical Feast: The Nader Report on Food Protection and the FDA*, published in 1970, and which I authored, reported the results of that investigation. The student team gathered proof that led President Nixon's Secretary of Health, Education and Welfare to effectively ban marketing the artificial sweetener Cyclamate by removing its Generally Recognized As Safe (GRAS) designation. President Nixon had a strong interest in food safety and quality.

Dr. Olney's information about the harm caused to mice brains by a component of aspartame—an anti-ulcer drug turned into a new artificial sweetener—looked to me strikingly like the information on cyclamate and other food chemicals that the student team had found unacted-upon in FDA files. The new, Nixon-appointed, FDA Commissioner had welcomed the student investigation, given each team member an official FDA identification badge and instructed FDA employees to cooperate with the study. The officials we knew to be responsible for reviewing aspartame informed me that FDA scientists had serious concerns about its safety.

These concerns included several animal studies showing a significant number of brain tumors in aspartame treated animals but not in controls. Breakdown products created by the digestion of aspartame included known cancer-causing substances. In a study of approximately 20 monkeys *all* high dose animals experienced grand mal (epileptic) seizures. Finally, when the scientific documents were made public—the first and only time FDA made trade-secret food additive evidence public—scientists advising me found also that aspartame-fed animals suffered measurable eye damage and women users experienced statistically significant weight gain.

This information seemed enough to require FDA to reject aspartame approval. However, our Nader FDA study, fueled by despairing stories from FDA scientists, acted as a red flag against relying on FDA. Most particularly, I learned that Dr. Olney's information on aspartame brain

lesions in mice was not part of the record. In spite of Dr. Olney's having briefed Searle scientists on the lesions and watching them find lesions in experiments they did jointly, Searle had not—in spite of its legal obligations—reported the lesions to FDA. The senior FDA food safety official arranged for me to meet Searle representatives to discuss this problem.

My meeting with Searle took place during an era when President Nixon took an interest in food safety and the Senate Select Committee on Nutrition was investigating food additives. The President convened a White House Conference on Food, Nutrition and Health with a Food Safety Panel (chaired by Pepsi's president and on which I served) mildly critical of food additives. The President ordered a (decade long) review of all GRAS listed food chemicals, which found ten percent of the several hundred listed items of dubious safety and raised questions about many others. In this context my meeting with Searle was cordial but non-productive.

Searle swore that its new sweetener would be approved. I said it would not reach the market. FDA did approve aspartame in July 1974. In fact it was the only significant food additive approved during the 1970's. Dr. Olney and I immediately filed petitions to stay the approval until a public hearing could be convened to review the science that we—and FDA scientists—said prohibited FDA from approving aspartame. FDA accepted our petitions, ordered that a Public Board of Inquiry (PBOI) be convened to review our scientific claims and prevailed on Searle to voluntarily refrain from marketing the chemical until the hearing on its legality concluded. The PBOI convened in the last week of January 1980.

Between 1974 and 1980 evidence against aspartame safety piled up. A routine FDA Bureau of Drugs inspection of Searle's Chicago area laboratories found massive violations of sound scientific practice. The FDA Commissioner appointed a task force to rigorously inspect Searle's labs. It found dozens of studies on many products—drugs, the copper wire IUD and 11 pivotal studies on aspartame—that violated both sound scientific practice and food safety law. FDA officially stayed the marketing of aspartame, got a grand jury appointed to investigate Searle's criminal behavior, set up two committees to review Searle science and supported legislation to require registration of research labs.

By 1977 Seale was in financial chaos. At this point it reached out to its former home town (Skokie) Congressman and Ford White House Chief of Staff and Defense Secretary Donald Rumsfeld to work his (political) magic to pull the company out of its free fall toward bankruptcy. I met with Rumsfeld in 1977 to see if there was a way that the ruined studies could be redone and studies that had not been done but should have (at this time FDA did not require studies to rule out possible brain damage from food additives) could be undertaken. Some of Searle's customers and their own legal and policy advisors supported such an effort.

One Searle reviewer of its aspartame submission told me that he had never seen such a poor food additive petition. Six months after my Rumsfeld meeting, the company responded with a robust campaign to win aspartame approval based on the original flawed studies. Searle's law firm approached the US attorney with arguments for aspartame. The official let the statute of limitations run on the grand jury. He and one or two deputies went to work for the law firm. Eventually they renamed the substance NutraSweet—the first branded food additive. They offered (FDA accepted) to pay for the FDA convened pathologists committee to review the studies. Not surprisingly, the committee whitewashed the effort, saying it could not evaluate study design: they would only report on whether Searle misreported the data. They said it had not.

This last point underscores why we are still debating aspartame safety today, when every study conducted by scientists not paid for by Searle has found safety problems. One of the first FDA inspector's concerns about the Searle laboratories was the failure to be sure that animals intended to receive aspartame and only those animals received it. That fact is currently unknown for most, probably all, of the studies done in Searle's labs, the studies on which current assertions of aspartame safety rest. This was a question that the Searle-paid-for FDA pathology committee did not address because the question, it said, was outside its purview.

An in house—paid for by FDA—FDA committee looked at three studies that the Searle-paid committee did not. The FDA in-house committee found that at least one of the studies could not be relied upon because it could not be ascertained with certainty that animals received the aspartame they were supposed to be fed. For this reason the results were inconclusive.

Five independent pathologists looking at the tumor data in several animal studies found a statistically significant higher number of tumors in the aspartame than in the control group. A sixth found no statistical significance—one tumor had moved from the treated to the control group. The study slides disappeared from an FDA sealed file. They turned up in the drawer of a Searle consultant.

When the PBOI—three members, one each from Searle, the FDA and one from myself and Dr. Olney—convened, the scientific record against aspartame was powerful. However, because the PBOI hearing was the responsibility of the FDA Bureau of Foods and the scathing data against safety was in the Bureau of Drugs (Searle was a drug company) the data from the FDA Searle Task Force investigations was not a part of the review. I moved to have it admitted but the board ruled against me. I appealed. The Commissioner denied my appeal. Nonetheless, even on the limited evidence before it, the PBOI ruled unanimously that aspartame should not be allowed to be marketed because the possibility that it caused brain tumors could not be ruled out.

The PBOI released its ruling the first week of October 1980. The FDA Commissioner appointed an in-house FDA committee to review the PBOI findings to determine if he should let them stand or overturn them. In the first week of November 1980, Ronald Reagan was elected President. Republican political activist and Searle president Don Rumsfeld played a prominent role on the Reagan transition team. That team selected, and President Reagan appointed, a relatively unknown Dr. Arthur Hull Hayes as FDA commissioner. His primary qualification appeared to be his service as a contract research physician at the Defense Department while Donald Rumsfeld served as Secretary of Defense.

The FDA Commissioner's review committee told the Commissioner that the PBOI findings were supported by the data and that he should not overturn its ruling. The Commissioner was blocked from taking any actions until his successor took office. The new Commissioner, Dr. Hays, overturned the board's decision in July of 1981 and approved aspartame for dry foods. Two years later, in July of 1983, the FDA approved NutraSweet for liquid—diet soda—uses and Dr. Hays left FDA, becoming senior medical advisor to Searle's advertising agency.

In the early 1990's National Cancer Institute data showed that there had been a ten percent rise in humans of the same kind of brain tumor that most pathologists found in the aspartame animal studies. Dr. Olney and I, this time accompanied by Mike Wallace of "Sixty Minutes," approached FDA to see if it would support doing the new brain studies we had sought in 1977. The FDA official in charge said no, and two years later became Vice President of Clinical Research for Searle. Over the years, several other key decision makers for the FDA have taken

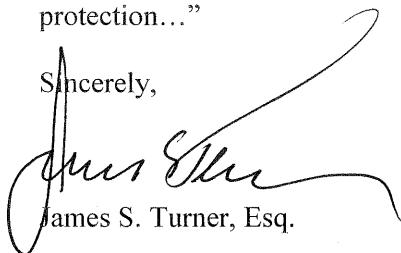
jobs with the soft drink industry association, food companies or others with an economic interest in NutraSweet.

During these past 35 years I have met with, spoken to or corresponded with hundreds of aspartame users who feel that the chemical has caused them great harm—seizures, blindness, migraines and other problems. With over 10,000 consumer complaints filed with FDA, it is the most complained-of food additive. In 1985 FDA asked the Centers for Disease Control to review the first 650 complaints. The agency did, and reported that between 25 and 30 percent of the female users could bring on the symptoms by using NutraSweet and turn them off by stopping. So my standard advice to all complainers has been that if they feel NutraSweet is causing them a problem go scrupulously off it for three to six weeks and see if the symptoms go away. Unfortunately this is not information that's readily available to the average aspartame use.

Given this entire record, I think the citizens of New Mexico would be best served if this board banned the sale of NutraSweet in New Mexico.

Your statutory powers to consider these matters are explicitly set forth in the New Mexico Food Act (25-2-1 through 25-2-19). Poisonous and deleterious food adulteration is the province of the Environmental Improvement Board to delineate; your powers in that regard are very precise. This statute provides, "A food shall be deemed to be adulterated (1) if it contains any poisonous or deleterious substance which may render it injurious, (2) if it contains any added poisonous or added deleterious substance which is unsafe, and (3) if it consists in whole or in part of ... a decomposed substance, or if it is otherwise unfit." The New Mexico Environmental Improvement Act, the act that created the Environmental Improvement Board, in Section 74-1-2, gives you much broader powers to promulgate rules "... in order to ensure an environment that in the greatest possible measure will confer optimum health, safety, comfort and economic and social well-being on its inhabitants; [and] will protect this generation as well as those yet unborn from health threats posed by the environment..." Section 74-1-8A(1) created the EIB "The Board is responsible for environmental management and consumer protection. In that respect the Board shall promulgate rules and standards in the following areas: (1) food protection..."

Sincerely,



James S. Turner, Esq.