

HEALTH AND STRESS

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THE TRIUMPH OF PROMOTION AND POLITICS OVER PUBLIC PROTECTION

KEYWORDS: Brain tumors, epilepsy, multiple sclerosis, lupus, "excitotoxins", formaldehyde cocktails, Dr. Marcella Fierro, Senator Orin Hatch and his "Hatchlings", Samuel Skinner's Grand Jury Investigation, Dr. Arthur Hull Hayes

It is quite clear that powerful pharmaceutical manufacturers have had spectacular success in promoting and profiting from products that they as well as the FDA knew posed significant health hazards. We have objected to many of these in prior Newsletters and the ban on Ephedra, Vioxx recall and imposition of black box warnings for antidepressants are recent examples of changes we have repeatedly urged over the past few years. While some might view these achievements as a victory, the sad fact is they are "too little and too late". Furthermore, they are just the tip of the iceberg of drug company deceptions that have been facilitated by FDA fraud along with the collusion and connivance of other agencies and public officials. This is such an extensive problem that it will be necessary to devote two Newsletters to provide the comprehensive coverage this topic deserves. This issue will focus on the incredible covert conspiracies that led to the approval of aspartame for unrestricted use despite violation of two Federal statutes.

Aspartame is one of the most monstrous and scandalous illustrations of how the public has been deceived and harmed by vested interests with control over regulatory agencies. Aspartame is an artificial sugar substitute that is sold as Nutrasweet, Equal, Spoonfuls, and DiabetiSweet in the U.S., Canderal in Europe and NatraSweet in South America. It is also found in around ten thousand products, including: instant

breakfasts and cereals, breath mints, chewing gum, desserts, juices, diet soft drinks and sodas, as well as laxatives, multivitamins, prescription and over-the-counter drugs and supplements

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A Dangerous And Deadly Drug That Is Masquerading As A Food Additive

Aspartame is particularly popular with diabetics, pregnant women and people who want to prevent weight gain. The facts are

that it has been found to precipitate clinical diabetes and aggravate or simulate diabetic complications, cause a variety of birth defects including mental retardation and promote paradoxical weight gain. Of even greater concern is compelling evidence of its link with brain cancer, seizures, and over 90 other adverse side effects such as: memory loss, vertigo, insomnia, numbness, blurred vision, blindness and other eye problems, tinnitus and hearing loss, slurred speech, personality changes, severe depression, suicidal tendencies, hyperactivity and aggressive behavior (especially in children), fatigue, muscle cramps, joint pain, rashes and other skin lesions.

Aspartame can trigger, mimic, or cause several dangerous diseases, including: epilepsy, lupus, fibromyalgia, multiple sclerosis, Chronic Fatigue Syndrome, Alzheimer's, Attention Deficit Disorder (ADD), non-Hodgkins lymphoma, Meniere's disease, Lyme disease, Lou Gehrig's disease (amyotrophic lateral sclerosis), hyperthyroidism and hypothyroidism. Hard to believe? After all, this is a chemical consumed by over 200 million Americans because it is certified as safe by the FDA, and recommended by several prestigious organizations. How could it possibly cause so many different disorders and, if true, how could these serious side effects and complications have been concealed for decades? The answer to these questions is an incredulous story of deception, fraud and bribery that is unparalleled in my experience.

Aspartame is banned in Japan and for use in all children's products on the European Common Market and in other countries. This has not happened in the U.S. because its manufacturers have paid off the FDA, the American Medical Association, The American Dietetic and Diabetic Associations, powerful members of Congress and government officials and virtually anyone who might get in their way. Since aspartame is approved as a "food additive" rather than a drug it is exempt from continued safety monitoring and side effects do not have to be reported. The FDA has admitted that only approximately 1% of people know how to, or do, file complaints with them. Nevertheless, **85 % of all complaints registered with the FDA are for adverse reactions to aspartame, including five reported deaths**. The fact that over 10,000 complaints about aspartame were received implies that over one million people have experienced problems with aspartame. I suspect that this is conservative since although some people can have immediate reactions to aspartame, most side effects are rarely recognized because they are cumulative so that symptoms do not occur until months or years. Here is why it is so dangerous and deadly.

The three components of aspartame are:

1. **Phenylalanine** (50%) - an amino acid normally found in the brain. Persons with the genetic disorder, phenylketonuria (PKU) cannot metabolize phenylalanine, which leads to dangerously high levels that can be lethal. Chronic aspartame use has also been shown to produce increased levels of phenylalanine in normal people that can reduce brain serotonin, resulting in depression and other emotional complaints. In one published report, a previously healthy individual who often drank 6 to 8 diet sodas a day started to notice memory loss and frequent headaches. He also began to crave more aspartame sweetened drinks and became increasingly irritable and subject to wide mood swings and feelings of rage. Even though he did

not suffer from PKU, his blood levels of phenylalanine were alarmingly high. Other tests showed abnormal brain function and damage consistent with this elevation. His symptoms improved dramatically and eventually disappeared after he kicked his aspartame habit. Phenylalanine buildup in animals from aspartame is not apt to produce problems since rodents metabolize phenylalanine much more efficiently. In addition, average animal brain phenylalanine levels are not relevant since in humans, this damaging chemical tends to concentrate in specific areas like the hypothalamus and medulla. This can seriously impair brain development in the fetus as well as young children. One distinguished neurosurgeon who has written a book on the subject with over 500 scientific references stated that excessive brain phenylalanine can cause seizures and schizophrenic symptoms. He believes that excessive use of aspartame may account for the increased sales of antidepressant serotonin re-uptake inhibitors and drugs to control schizophrenia and seizures.

2. **Aspartic acid** (40%) - an amino acid that significantly raises blood levels of aspartate and glutamate known to cause brain damage, especially during periods when the cerebral cortex is developing. Aspartate and glutamate are neurotransmitters that transmit information between neurons in the brain. Too much of either can kill certain neurons by allowing the influx of too much calcium that increases the generation of damaging free radicals. Aspartate and glutamate are often referred to as "excitotoxins" because they "excite" or stimulate brain cells to death. The blood brain barrier which normally protects the brain from excess toxins like glutamate and aspartate a) is not fully developed during childhood, b) does not fully protect all areas of the brain, c) is damaged by numerous chronic and acute conditions and d) allows seepage of excess glutamate and aspartate into the brain even when intact. This excess glutamate and aspartate causes a slow and steady destruction of brain cells but 75% or more neurons in a particular area of the brain need to be damaged before any clinical symptoms are noticed. Infants, children, pregnant women, the elderly, and persons with certain chronic health problems are at particularly high risk. Two of the most common complaints in adults are memory loss and headache. Some of the chronic illnesses that these "excitotoxins" have been shown to contribute to include multiple sclerosis, Alzheimer's and Parkinson's disease.
3. **Methanol or wood alcohol** (10%) - a deadly poison that caused some "skid row" alcoholics to end up blind or dead. The Environmental Protection Agency considers methanol to be "a cumulative poison" due to the low rate of excretion after it is absorbed and recommends limiting consumption to no more than 7.8 mg/day. **A one-liter aspartame-sweetened beverage contains about 56 mg of methanol and heavy users of aspartame-containing products consume as much as 250 mg of methanol daily or 32 times the EPA limit.** Methanol poisoning can cause headaches, tinnitus, dizziness, memory lapses, weakness, nausea and other GI complaints, numbness and shooting pains in the extremities and behavioral disturbances. The most serious complications from chronic ingestion are

blurred and misty vision, progressive contraction of visual fields, retinal damage, and blindness. Methanol breaks down in the body into formic acid, the venom in ant stings, and formaldehyde, a deadly neurotoxin used as embalming fluid. Formaldehyde is also a known carcinogen, causes retinal damage and interferes with DNA replication that can lead to birth defects. Due to the lack of certain key enzymes, humans are many times more sensitive to the toxic effects of methanol than animals so that such animal studies may have little clinical relevance. As one authority pointed out **"There are no human or mammalian studies to evaluate the possible mutagenic, teratogenic, or carcinogenic effects of chronic administration of methyl alcohol."**

Diketopiperazine (DKP) is another aspartame breakdown product that has been shown to cause brain tumors and uterine polyps. The unexplained progressive rise in human brain tumors similar to those seen in animals correlates with increased aspartame consumption over the past two decades. DKP also alters DNA and in laboratory studies produced morbidly obese and sexually dysfunctional third generation animals; similar problems are increasingly being seen in humans. Confidential internal company memos indicated concern over the lack of toxicological data on DKP and it is important to emphasize that the brain tumor studies were not revealed when FDA approval for aspartame was applied for.

While aspartame breaks down into DKP and methanol, the absorption of methanol into the body is considerably increased if free methanol is ingested. It is important to emphasize that free methanol is created whenever aspartame is heated to above 86°. This occurs during the manufacture of aspartame-containing baked goods and products like Diet Jello or if aspartame beverages are improperly stored. The National Soft Drink Association opposed aspartame in a 30-page protest published in the 1985 Congressional Record because it was "inherently and uniquely unstable" and violated a statute making it illegal to put anything in carbonated beverages that decomposes or adulterates the drink. Nevertheless, manufacturers added aspartame to diet sodas and other beverages anyway. The Desert Storm troops were "treated" to **large amounts of aspartame-sweetened cans of diet soda that often sat for weeks in temperatures up to 120° in the Arabian sun, turning them into formaldehyde cocktails. Many returned home with symptoms similar to those seen in people poisoned by formaldehyde.** The free methanol in these drinks may have been a contributing factor in some Gulf War Syndrome symptoms as well as in the following death.

Did Wife Get 50 Years For Murder In A Death That Was Due To Aspartame?

Charles Fleming was a 37 year old athlete from Richmond, Virginia who played basketball four times a week, had been drinking 8-10 cans of diet soft drinks a day for years and used powdered aspartame (NutraSweet or Equal) to sweeten other food and drinks. Shortly after New Year's 2000, he added Gatorade and creatine to his dietary regimen. Six months later he died suddenly from methanol poisoning. In addition to diet sodas and powdered aspartame he had been taking Met-Rex that also contained aspartame, Ripped Fuel, an ephedra-containing product that interacts with aspartame, as well as Gatorade mixed with creatine to help build muscle mass. On their way home from church on a Sunday afternoon in June, he and his wife Diane

stopped off to buy a case of Gatorade and creatine. Fleming mixed a bottle of warm Gatorade with triple the amount of recommended creatine since he misread the directions that called for a teaspoon rather than a tablespoon. Diane recalls that her husband didn't like the taste, but put the bottle in the refrigerator and took off to play basketball.

For about a month prior to his death, Fleming had complained to his wife about shortness of breath and intermittent nausea. For years, in addition to his daily consumption of 8 or more cans of diet soft drinks he usually had 2-4 mixed drinks of bourbon and Diet Sprite in the evenings. He drank very little water and avoided tea or coffee. While on his fitness regimen, he ate various protein health bars and took a multivitamin with iron. When he returned from basketball, Fleming ate a bowl of ice cream, mixed creatine into the remaining three bottles of Gatorade and went to bed early. The next morning he woke up feeling ill but went to work. He took three of the four bottles of Gatorade with him but drank only a third of one bottle before returning home because of nausea that he attributed to the flu. His condition continued to deteriorate and by late afternoon the following day, Diane called 911 and her husband was rushed to the hospital. He lapsed into a coma and was removed from life support three days later and pronounced dead. An autopsy confirmed methanol poisoning as the cause of death but the report was delayed for several months. Investigative authorities questioned the family about Fleming and his habits and had the Gatorade tested. The bottles of Gatorade each contained measurable amounts of methanol.

Diane was not initially suspected of murdering Chuck, but thirteen months later she was arrested and indicted. This was to have been a special week for the Fleming family. Their son Jeff was graduating from High School and Diane's parents had arrived from another state to join the occasion. It seems ridiculous that if you were going to poison your spouse that you would pick this time to deliberately destroy the celebration. But if Diane did not poison her husband where did the methanol in his body come from? At trial it was decided that the methanol came from a gallon of unopened windshield washer fluid found in the garage. The jury was somehow persuaded to believe that Diane added it to the Gatorade/creatine mixture even though the methanol found in the sealed container of Krystal Kleer windshield wiper fluid was not matched forensically to the methanol found in the Gatorade concoction. The four bottles of Gatorade were found to contain methanol in concentrations that ranged from 3.3 percent to 4.07 per cent (by weight) but only half of one bottle had been consumed. A toxicologist at the trial testified there wasn't enough methanol in all four bottles to kill Fleming. One-third of a bottle at the concentrations determined could never have been the cause of his death from methanol poisoning.

Her family, including in-laws and friends were dumbfounded. Diane, who was a Sunday school teacher and devoted wife and mother, had cooperated fully with authorities, passed a lie detector test with flying colors, and it was inconceivable to anyone who knew her that she could have committed such a crime. Fleming's diet soda habit was not questioned and several reports of sudden death in professional athletes mirror his case but the defense attorney was not aware of the toxic effects of aspartame and the possibility that this was the source of his methanol poisoning. Otherwise, he would not have spent the majority of his time in a one-day trial continually insisting that Diane's son, the stepson of Charles Fleming, had committed

"the murder". Aspartame is a cumulative poison, and it seems most likely that Fleming's addiction to aspartame-laced diet drinks accumulated the methyl alcohol in his body and finally overcame him. There can be little doubt that he probably had elevated levels of aspartame decomposition toxins in his system that were not tested for. In addition, he had mixed much too much creatine into his Gatorades and did not drink any water as the manufacturer had clearly recommended, which may also have played a role.

All of this information was subsequently revealed on appeal when affidavits from distinguished medical doctors and peer-reviewed articles were submitted to substantiate aspartame poisoning as the cause of Charles Fleming's death. However, Diane Fleming's hopes that her murder conviction would be reversed were dashed on March 2, 2004. Dr. Marcella Fierro, the chief medical examiner for the state of Virginia refused to consider the aspartame evidence, and told Fleming's attorney that there was no evidence to link Fleming's January 2000 death to aspartame consumption. Dr. Fierro had also refused to consult with or talk to experts on aspartame poisoning, such as Dr. H.J. Roberts whose book *Aspartame Disease, An Ignored Epidemic* cited similar cases and Dr. Betty Martini, who had forwarded a 14-page, peer-reviewed article by Dr. Woodrow Monte of the Arizona University Food and Science Laboratory published in *The Journal of Applied Nutrition* entitled "Aspartame: Methanol and the Public Health", which also provided strong support. Both Martini and Roberts have filed formal complaints regarding Fierro's conduct with the State of Virginia. Martini's complaint cited events leading up to the hearing and offered solid scientific evidence to support Diane Fleming's innocence. Martini alleged that "Dr. Fierro's unprofessional and arbitrary conduct requires a full and open examination of the mechanisms of aspartame/methanol toxicity as they relate to the death of Charles Fleming. There are literally volumes documenting how aspartame triggers methanol poisoning. It is obvious **by refusing to look at the evidence, Dr. Fierro doesn't want it on the record. The question is, Why?**" Lots of other people are also interested in the answer to that question. Two film crews, one from the Netherlands, have interviewed Diane Fleming in prison and the 2 hr. film "Sweet Misery: A Poisoned World" by Sound and Fury Productions released in August should dispel any doubts about her innocence.

Pharmaceutical Company Control Over Regulatory Agencies And Officials

Dr. Marcella Fierro had previously come under criticism for suspected tampering with or not considering compelling evidence. As Virginia's chief medical examiner she has final jurisdiction over autopsy findings in all death cases. In 1993 she authorized a revised autopsy report in the death of Vince Foster, President Clinton's Chief of Counsel, that allowed his apparent murder from a gun shot wound to the head to appear as a suicide. Had the original entry location stood, the suicide conclusion would have been hard to explain since suicide victims rarely shoot themselves in the back of the head. Foster's controversial death was thoroughly investigated by journalist Ambrose Pritchard. As he noted in *The Secret Lives of Bill Clinton*, the X-rays of Foster's skull that were referred to in the original autopsy report verified the precise location of the bullet's entry into the skull but they "mysteriously disappeared." This is also not the first time Dr. Fierro's testimony has kept an innocent woman behind bars. Beverly Monroe was recently released after spending seven years in prison when it was determined her murder conviction was based on

false forensic evidence presented by the state of Virginia's expert witness, Dr. Fierro.

Some are suspicious that Fierro's refusal to consider the aspartame evidence may have something to do with her friendship with Senator Orrin Hatch, who has long been on the payroll for stumping for NutraSweet and effectively blocking proposed legislation to investigate aspartame's adverse health effects. Three congressional hearings were attempted because of numerous complaints of people being poisoned by aspartame that Hatch repeatedly refused to allow. The first was in 1985, when Senator Howard Metzenbaum, a member of the Senate Committee on Labor and Human Resources, introduced a bill that would have put a moratorium on aspartame until the NIH could conduct independent studies on reported problems such as interactions with drugs, seizures, birth defects and neurological and behavioral disorders in children. As Chairman of this committee, Hatch was able to squelch this and in a February 11 press release entitled "Hatch Says No to Committee Hearings on Aspartame", explained that "it would serve no useful purpose to commit Committee resources to this issue at this time." Understandably upset, Metzenbaum sent Hatch a letter on February 26 that began,

"Dear Orrin:

I am at a loss to comprehend the thrust of your recent letters on my request for hearings on the safety concerns raised in the scientific community regarding NutraSweet. When I sent you a 110-page report on February 6 on the failure of the U.S. Attorney to hold a grand jury investigation, you replied the same day that there were no health issues raised. You then asked that I share with you all information raising safety issues. Orrin, the report I sent you included a summary of current health concerns raised by nine different scientists. My report contained all the relevant references to medical journals and other citations. Now you have sent me another letter, dated February 18, in which you again request evidence."

The letter went on to provide some reports that Metzenbaum had just received as well as additional evidence that clearly confirmed the health hazards of aspartame that clearly would be difficult to ignore but no action was taken. That's not surprising, since the *Wall Street Journal* noted that Hatch has "given his strong support of the pharmaceutical industries" and so have the "Hatchlings." The paper points out that David Kessler, FDA Commissioner under presidents Bush and Clinton, was once an aide to Hatch. Hatch's former campaign manager and aide, C. McClain Haddow, was sentenced to prison for conflict-of-interest charges arising from his work as a Reagan administration health official. Thomas Parry, Hatch's former chief of staff, is a lobbyist for 30 clients including major drug companies who have enriched Senator Hatch's campaign coffers in return for various documented favors.

NutraSweet was discovered in 1965 by a Searle chemist who was working on a new ulcer drug and accidentally spilled some aspartame on his fingers. When he instinctively licked it off he noted that it tasted very sweet and analysis revealed that it was almost 200 times sweeter than sugar and had no calories. Searle, a drug company with no experience in food additives, began safety tests to comply with FDA approval and in the first study of seven monkeys fed aspartame, one died and five others had grand mal seizures. In 1971, Dr. John Olney, a distinguished neuroscientist whose research led to the removal of MSG from baby foods, informed Searle that aspartame caused "holes in the brains of mice". Searle disputed this and

had their own researchers repeat the study with the same results. Additional animal research revealed that aspartame was converted into dangerous substances such as formaldehyde. In 1973, after spending tens of millions of dollars conducting safety tests, Searle Company applied for FDA approval of aspartame and submitted over 100 studies that they claimed support its safety but did not include the above and other negative data in their files. One of the first FDA scientists to review the application stated that "the information provided is inadequate to permit an evaluation of the potential toxicity of aspartame" and emphasized that further clinical tests are needed in order to be certain that aspartame is safe. In May 1974, Jim Turner, a consumer advocate attorney who was instrumental in getting the sweetener cyclamate taken off the market because of health concerns met with Searle representatives to discuss Dr. Olney's confirmed disturbing mouse study but received no satisfactory response. In July, the FDA granted aspartame its first approval for restricted use in dry foods based on Searle's reassurance that their studies had "raised no health problems." In August, Turner and Olney filed the first of many objections to aspartame's approval detailing numerous reasons. Based on this and its own investigation of Searle's research studies, the FDA put aspartame approval on hold in December 1974.

In 1976, more complaints triggered an extensive FDA review of Searle's laboratory practices. Their own investigators described the aspartame testing procedures as being shoddy, full of inaccuracies and "manipulated" test data and reported that they "had never seen anything as bad as Searle's testing." **In January 1977, the FDA formally requested U.S. Attorney Samuel Skinner to begin a Grand Jury investigation to determine whether indictments should be filed against Searle for knowingly misrepresenting findings and "concealing material facts and making false statements" in aspartame safety tests.** This was the first time that the FDA had ever requested a criminal investigation of a manufacturer.

Donald Rumsfeld And His Political Pals Come To The Rescue

Things looked bleak until a few weeks later, when Searle announced in March that it had hired Donald Rumsfeld as CEO. A former Congressman and Secretary of Defense in the Ford Administration, Rumsfeld quickly brought in several of his influential Washington cronies as top management. In August, the Bressler report commissioned by the FDA was released documenting numerous additional deficiencies and deceptions in Searle's safety tests reports, such as not reporting malignancies and deaths in aspartame treated animals. Surprisingly, no action was taken. Dr Jacqueline Verrett, the Senior Scientist in the FDA team that was created to review the Bressler report said: **"It was pretty obvious that somewhere along the line, the bureau officials were working up to a whitewash."** She was right. In December 1979, the Searle Grand Jury probe was dropped because Skinner and other attorneys supposedly working on the case had stalled the investigation long enough for the statute of limitations on the aspartame charges to expire.

Mounting public pressure forced the FDA commissioner to establish a Public Board of Inquiry (PBOI) composed of three scientists to rule on the questionable safety issues. Their September 1980 report concluded that there was **"no proof of reasonable certainty that aspartame is safe for use as a food additive" and NutraSweet should not be approved until the issue of brain tumors in animals had been thoroughly resolved.** This appeared to be the final blow but a few months later,

Donald Rumsfeld told a sales staff meeting that he would "call in a few markers" and use his political pull in Washington, rather than scientific means to insure that aspartame got approved. Ronald Reagan was sworn in as President on January 21, 1981 and immediately suspended the FDA commissioner. The following day, Searle re-applied to the FDA for approval to use aspartame as a food sweetener with "ten new studies". Dr. Monte was skeptical, noting that, "It is impossible that they could have conducted those studies in four months . . . Obviously they'd previously done those studies but hadn't officially submitted them, although much of the information in those studies was informally presented to the board of inquiry."

Reagan's transition team, which included Rumsfeld, hand picked Dr. Arthur Hull Hayes Jr. to be the new FDA Commissioner. Armed with the "new tests", Hayes acted as though critical, overriding evidence had now proven the safety of aspartame and in March, appointed a five member Scientific Commission to review the Public Board of Inquiry's decision. When it became clear that they would also uphold the ban by a 3 - 2 decision, he installed a sixth member that he knew would cause a tie and deadlock. (Two FDA officials later declared that Hayes was determined to clear all obstacles to NutraSweet approval and one said that "people at the top" refused to respond to questions concerning the quality of the tests submitted by Searle.) **In one of his first official acts as the new FDA commissioner, Hayes overruled the Public Board of Inquiry, ignored the recommendations of his own internal FDA team and approved NutraSweet for use in dry foods and as a tabletop sweetener.** The next year Searle filed a petition for aspartame to be approved for use in carbonated beverages and other liquids that led to more protests and further investigations with unbelievable results - stay tuned to learn what happened!

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