FIT AT FORTYFIFTY- SIXTY AND BEYOND

REPORT

BY DR. TED BROER

The in-depth health and nutrition analysis

Volume 1 Number 2

ASPARTAME: A CHRONICLE OF CRIME

- How did a laboratory accident make it into our food supply?
- Methanol is 10% of Aspartames molecular structure!
- Every single monkey in one study developed seizures!
- From brain Cancer to Depression, why were we not told the truth?

Last year the Food and Drug Administration (FDA) passed the Truth in Food Labeling Act which mandated that food manufacturers disclose a complete list of their products ingredients, and that titles on food labels must honestly represent the contents within the package. This means that a Low Fat product must, in fact, be low in fat and that "light" means that the product is lighter in calories, not just in package. Thus, I am astonished that a product marketed as an artificial sweetener can carry the name NutraSweet, when 1) it is not nutritive by definition, and 2) it is shown to be a hazardous chemical causing severe side effects including headaches, seizures and even birth defects in laboratory animals. One would think that our government would protect us from products that are known to harm us, but in the case of Aspartame, which is marketed under the name of NutraSweet, they have not. If the public fully understood the irregularities in the research and development of aspartame and Food and Drug Administration's (FDA) approval process of this chemical, the cries of conspiracy would be heard far and wide. The path that took this chemical from the laboratory to your kitchen table is one wrought with deception and blatant conflicts of interest, not to mention what could be considered a conspiracy to market a product to Americans which has been proven to be harmful.

Many are not aware, buNutraSweet was not the product of researchers seeking a healthy sugar substitute to benefit society. It was actually an accidental discovery by James Schlatter, Ph. D. who was conducting research for the G.D. Searle company on a drug designed to treat ulcers. In December, 1965, while Dr. Schlatter worked in the laboratory of his prospective anti-ulcer medication, he mixed a substance in a container, called aspartame, with methanol (wood alcohol) when some of the substance accidentally spilled to the outside of the flask. When Dr. Schlatter picked up the flask, the substance rubbed onto his fingers. A few moments later, when Dr. Schlatter licked his finger to pick up a piece of paper, he reported noticed a very strong sweet taste. Not knowing exactly what has happened or where the sweetness came from, Dr Schlatter soon discovered it had come from the contents of his experiment. From this laboratory accident a legacy of deception has been forged against the American people which can only be considered a crime against humanity. You will find in the pages that follow a chronology of the FDA approval process of aspartame., as well as numerous documented irregularities, deceptions and conflicts of interest. You will also find a full discussion of the deleterious effect of aspartame on the human body which will lead you to question whether the Food and Drug Administration (FDA) is really looking out for the health and well being of your family or whether it is merely a puppet of big business.

Under regular FDA guidelines, when a new chemical designed for human consumption is invented in the United States it normally takes a long time to get from the laboratory to the kitchen table. Under most circumstances these chemicals are tested extensively on laboratory animals and then tested on human subjects before they are ever allowed to be manufactured and sold for human use. If the chemicals are found to be reasonably safe (" reasonably safe" meaning that they are found to cause cancer in less than three (3) in one million people) it is allowed to be marketed for human consumption. Chemicals that are not shown to be safe for human use are not supposed to earn FDA approval. These products must go back to the laboratory for further research and development, which is a very costly venture for the manufacturer. If the chemical is found to be hazardous to ones health after it has been authorized for marketing, the chemicals are supposed to be pulled from the market, as was the case for Red Dye #19. If the product is not recalled, a warning label must be attached, as is the case of saccharine. NutraSweet, touted as the most tested product in the world, has managed to beat this system. Unknown to the general public, the company that manufactures aspartame has been accused of providing falsified test results to the FDA and even unethical deal making with prosecutors from the United States Attorney General's office, All the while, reports of adverse patient reactions including headaches, memory loss and seizures, and even confirmed death continue to mount while these reports are being kept from the general public.

Investigations into the early stages of aspartame testing for human consumption reveals that serious questions regarding its safety began to surface as early as 1970. As much as twenty-six years ago, top researchers for Searle laboratories addressed their genuine concerning over safety questions discovered while studying this chemical. Their initial concern revolved around the fact that they discovered a complete absence of legitimate study on the possible toxic effect aspartame could have on the human body. They also learned that no research was conducted on the possible toxic effects of the by-products of aspartame metabolism in the body.

For example, unknown to most NutraSweet consumers, aspartame breaks down in the body into its component chemicals, including methanol, aspartic acid, phenylalanine and a little known chemical called diketopiperazine (DKP). ² Each of these component parts is in itself a known toxin. Apparently, this fact was not made completely clear by those won originally sought to

gain aspartame's approval. David Baine, associate director U.S. GAO stated that methyl alcohol was not even included in the initial description of aspartame provided by Searle when the company applied for FDA approval.

Methanol, also known as wood alcohol, has caused blindness in countless alcoholics. It is often used as a paint thinner and industrial cleaner. When methanol is metabolized by the body, it is broken down into formaldehyde (yes, just like embalming fluid) and formic acid. STEDMANS Medical Dictionary describes methanol as "a toxic, mobile liquid used as an industrial solvent, antifreeze and in chemical manufacture; ingestion may result in severe acidosis, visual impairment and other effects of the central nervous system." ³ The Environmental Protection agency includes methanol in their Community Right To Know List which is a list of toxic chemicals that must be clearly identified on manufacturers labels when certain hazardous chemicals are used in a product. Amazingly however, methanol is not even mentioned on any of the labels of products containing aspartame. 4 Effects in the body from human consumption of methanol include lethargy, fainting, headache, nausea and vomiting, blindness, cough, breathing difficulties, and other vision problems. Methanol has been shown to cause birth defects in developing fetuses, as well as other reproductive defects. According to the Sax's **Dangerous Properties of Industrial Materials**, the "main toxic effect [of methanol] is exerted upon the nervous system, particularly the optic nerve, and possibly the retinae which can progress to permanent blindness. Once absorbed, methanol is only very slowly eliminated. Coma resulting from massive exposures may last as long as 2-4 days. The products formed in the body by its oxidation are formaldehyde and formic acid, both of which are toxic. Because of its slow elimination, methanol should be regarded as a cumulative poison. Though single exposure to methanol may cause no harmful effect, daily exposure may result in the accumulation of sufficient methanol in the body to cause illness. Death from ingestion of less than 30 ml has been reported". To bring things into perspective, just one little blue packet of NutraSweet, (1 gram) breaks down into 100 mg of methanol. Researchers have shown that a child who consumes 700 mg of aspartame (or less than of one little blue packet) would be ingesting almost 10 times the Environmental Protection Agency's (EPA's) recommended daily limit of methanol consumption.⁶ The results can be worse if the product has been exposed to heat or left for a long time on the shelf because these factors promote the breakdown of aspartame into its toxic components. Considering these facts, researchers are concerned that when high consumption levels combined with aspartame's unstable shelf life, methanol can easily reach toxic levels in the systems of the millions of people who consume this product.^{7,8}

Additional little-known facts concerning NutraSweet are as follows: Aspartic acid, a component of aspartame, is a known neurotoxin and an active part of the poison administered by ant stings. According to Dr. John Olney this byproduct of aspartame caused holes to develop in the brains of lab animals fed the chemical. The researcher also documented that the chemical caused chromosomal damage which did not become evident until the animals reproduced and their genetic expression was evident. Phenylalanine is an amino acid or a basic element of protein. Phenylalanine is an amino acid or a basic element of protein. Phenylketonuria is a genetic disorder in which the person is unable to metabolize the amino acid phenylalanine. When blood levels of this amino acid rise, the toxicity causes irreversible brain damage. Because of this, people with phenylketonuria are particularly at risk of serious brain damage if they consume just one liter of aspartame sweetened soda pop in a day; thus the warning on the label. However, anyone who overwhelmed his or her body's ability to metabolize phenylalanine by consuming large quantities of aspartame could as well be at risk of irreversible brain damage in a similar manner. The toxic effects of this chemical are cumulative and do not often show up in short term testing. Phenylalanine can alter normal brain levels of serotonin, the neurotransmitter responsible for emotional brain activity, causing symptoms including PMS, insomnia, mood swings, carbohydrate cravings and severe depression.^{9,10}

Despite these hazards, Searle went forward with the process of receiving the FDA's approval for the use of aspartame as an artificial sweetener.¹¹ After only a year and a half, aspartame received an initial limited FDA approval for its use in dry foods and chewing gum. This action was granted by Alexander Schmidt, M.D., who was then commissioner of the FDA. Objection by consumer watchdog groups were voiced immediately. James Turner, a consumer safety attorney, and Dr. John Olney, Research Psychiatrist at the Washington University School of Medicine, filed legal objections to aspartame's The team presented documented approval. evidence that animals fed the chemical during research conducted by Dr. Olney at Searle's request, developed brain tumors. The health advocates demonstrated that aspartame ingestion could easily cause brain damage and mental retardation in humans. Turner and Olney requested that an immediate Public Board of Inquiry on the safety of aspartame be held by the FDA. 13,14 In response to these objections and because it was evident that Searle had submitted false information on their animal research to the FDA in order to win approval, Commissioner Schmidt of the FDA appointed a task force to investigate Searle's animal studies on aspartame. Six months later the FDA's task force report was in. The scathing report stated that some of Searle's research practices were too inappropriate to even be considered legitimate scientific research. The report went on to say that Searle's reports to the FDA were too unreliable to determine whether the product was safe for human consumption. Because of these findings, the FDA initially withheld approval of aspartame. However, these actions also delayed the Public Board of Inquiry requested by Turner and Olney. 15,16 Finally, in March 1976 the FDA's task force presented a completed report to Chairman Schmidt. The task force reported, "At the heart of the FDA's regulatory process is its ability to rely upon the integrity of the basic safety data submitted by sponsors of regulated products. Our investigation clearly demonstrates that, in the G.D. Searle company, we have no basis for such reliance now.....Some of our findings suggest an attitude of disregard for the FDA's mission of protection of the public health by selectively reporting the results of studies in a manner which allays the concerns of questions of an FDA reviewer."17 Because of these damaging findings, the FDA deepened its investigation of the research studies on aspartame. 18

The situation began to look grim for the G.D. Searle company and for any further FDA approval of their product. In January 1977, U.S. Attorney, Sam Skinner was contacted by the Chief Counsel of the FDA, Richard Merrill. Chief Counsel Merrill requested that a grand jury be convened to investigate Searle for "violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(e), and the False Reports to the Government Act, 18 U.S.C. 1001 for their willful and knowing failure to make reports to the Food and Drug Administration required by the Act, 21 U.S.C. 355(I), and for concealing material facts and making false statements in reports of animal studies conducted to establish the safety of (aspartame)." FDA Chief Counsel Merrill specifically cited two of Searle's studies. One study was on the effects of aspartame on monkeys while the other examined aspartame toxicity in hamsters. In the instance of the primate study, the FDA task force discovered that some of the monkeys fed aspartame suffered seizures, a fact that was never reported to the FDA when Searle applied for the approval of aspartame. In what many could consider an attempt to cover up the true cause of the seizures, researchers disposed of the primates without ever completing autopsies to determine the true cause of this erratic brain activity. ¹⁹

In this investigation, Searle was represented by a prestigious and powerful Chicago law firm, Sidley and Austin. Just two weeks after Merrill's letter was sent to Skinner, the office of Sidley and Austin contacted U.S. Attorney Skinner and requested a private meeting prior to the grand jury hearing.²⁰ Seven days after their private meeting, Sidley and Austin offered Skinner a high paying position within their law firm.²¹ It is important to note here that the statute of limitations for prosecution against the G.D. Searle company for their alleged violations was rapidly drawing near.²² Without Skinner's immediate action, any legal avenues of prosecution against Searle would be lost forever. U.S. Attorney Skinner was personally reminded by the Justice Department of the urgent need to proceed with the grand jury investigation due to the statute of limitations.²³ Unfortunately, without going forward with the investigation, Skinner left his post with the U.S. Attorney General's office on July 1, 1977, and joined the law office of Sidley and Austin, not leaving sufficient time for his successor to launch the grand jury investigation before it was too late.²⁴

In August 1977, another team of FDA investigators, under the direction of Jerome Bressler, investigated Searle's research practices on the safety of aspartame and published the Bressler report. This report cited that during one Searle animal research program on the safety of aspartame, which was never reported to the FDA. 98 of the 196 animals died during the study. That is 50%! The FDA investigators found that rather than try to discover what killed these lab animals immediately, Searle researchers did not perform autopsies until in some instances over one full year after the animals' deaths. Obviously, if the company had any interest in your safety, they would have immediately searched for a complete explanation. Food and Drug Administration investigators also found blatant discrepancies between the pathology records they were provided and those maintained in the laboratory. number of reported brain lesions and tumors found during the autopsies in the animals fed aspartame were markedly different between reports submitted by Searle to the FDA, and those found in the research laboratory. Several other inconsistencies in Searle's reporting were also discovered. In one instance, a specific rat was reported to be alive for a number of days, then the rat died. Later, however, the same rat in the same study was reported to be alive again, only to die a second time. At the very least, this is evident of sloppy research, and arguably, complete fraud. The FDA investigators also discovered cases of tumors, uterine growths, and ovarian growths which were documented on laboratory held reports, but were not noted in Searle's reports to the FDA. When the FDA's Center for Food Investigations later conducted research on aspartame, they found that uterine polyps or growths, occurred in at least 15% of the lab animals in their study (a fact consistent with the reports found in Searle's labs which were withheld from the FDA).²⁵

The FDA investigation and the Bressler report were under the oversight of the FDA Bureau of Foods, chaired by H.R. Roberts who was the highest ranking recipient of the report. Completely disregarding the obvious discrepancies outlined in the Bressler report, Roberts announced that he would consider Searle's research as acceptable and apparently authentic for the FDA. In this decision. considered unconscionable by many, Roberts overrode the discoveries and recommendations of the Bressler report and recommended further FDA approval of the controversial chemical. Because of his position in the FDA, this meant that Roberts' decision would largely go unchallenged. However, in an apparent conflict of interest, H.R. Roberts subsequently left the FDA and became the vice president of the U.S. National Soft Drink Association. 26,27,28,29 The benefits that the approval of aspartame for use in carbonated beverages would offer to the soft drink industry made its approval a multi-billion dollar prospect.

In June 1979, five years after Olney and Turner's request, the FDA finally established the Public Board of Inquiry (PBI). The stated purpose of this board was to investigate and rule on safety issues surrounding NutraSweet.³⁰ It was not until January 1980 that the PBI finally began actually holding its hearings. However, the evidence against aspartame was so conclusive, that the PBI recommended to the FDA that NutraSweet should not be approved until further investigations have been conducted on the incidence of brain tumors in animals. The FDA-organized board further reported that there was no decisive evidence that aspartame was at all safe as a food additive.^{31,32,33}

As a result of the board's report, the FDA itself began to become more and more skeptical of the Searle's reported research. An FDA commissioner's panel composed of six high-level

scientists was established in order to review the issues raised by the PBI. After months of study, three of the six FDA scientists working on the panel, Dr. Robert Condon, Dr. Satya Dubey, and Dr. Douglas Park, all strongly recommended that NutraSweet not be approved as a food additive for human consumption. These research scientists stated that the tests conducted by Searle were totally unreliable and were not adequate to determine the safety of aspartame for human use.³⁴

Once again, the legitimate concerns and questions raised by the PBI and FDA scientists were largely ignored by the hierarchy of the FDA. On July 15, 1981, then FDA commissioner, Dr. Arthur Hayes, overruled the PBI's motion and approved NutraSweet for use in dry products. Completely undermining the efforts of his own board, Hayes stated he believed that aspartame had been shown to be safe for its proposed uses. Hayes cited additional evidence justifying his position, including a study which addressed the potential of aspartame causing cancer. Haves stated that when other scientists performed lab rat experiments like Dr. Olney's, aspartame did not cause brain lesions or cancer in these rats. (Dr. Haves attributed this finding to the use of a different strain of rats.) Not mentioned by Dr. Hayes is the fact that studies he cited were funded and conducted by Ajinomoto, the Japanese manufacturer of aspartame. 35,36,37

By October of 1981, aspartame had been approved for use as a tabletop sweetener in tablets, cold breakfast cereals, dry bases for beverages, instant coffee and tea, gelatins, puddings, fillings, dairy-product-analog toppings, and flavor enhancer for chewing gum. Most alarming of these approved uses are those products which are served hot like hot chocolate, coffee and tea because heat speeds the breakdown of aspartame. Going forward with its efforts to expand the market of NutraSweet worldwide, Searle petitioned the FDA to approve aspartame for use as a sweetener in carbonated beverage syrup bases and other liquids. 40,41

However, at this time even the National Soft Drink Association (NSDA) was not comfortable with Searle's request. In July of 1983, the NSDA urged the FDA to delay approval of aspartame for carbonated beverages pending further testing because temperature had been shown to speed the breakdown of aspartame. The NSDA's concern was due to the fact that when their products were shipped or stored, it was very difficult to regulate their temperature. On hot summer days, a bottle of beverage in the back of a closed semi-trailer sitting in the sun can become extremely hot. The FDA responded that they were aware of the problem with temperature and aspartame, but that the FDA

believed proper shipping and marketing procedures would "solve" the problems. 42

In spite of these objections, on July 8, 1983, NutraSweet was approved for use in carbonated beverages and carbonated beverage syrup bases by acting commissioner of the FDA, Mark Novitch. Approval was granted despite the knowledge that when aspartame sweetened beverages are stored for as little as 8 weeks even at reasonably cool temperatures below $\overline{68^{\circ}}$ F up to 20% of the aspartame would be broken down to its basic elements. (The "lost" aspartame degrades to DKP, methanol (methyl alcohol), aspartic acid, and phenylalanine.)⁴³ According to the 1985 Congressional Record, when aspartame laced products are stored or heated above 85° for a period as short as a few weeks (such as when products are produced, stored, shipped to the marketplace, stored on shelves, purchased by consumers, left in the pantry or garage until desired) absolutely no aspartame is left in the beverage, only its byproducts.44 Later the same month, the NSDA drafted an objection to the FDA's final ruling and requested a hearing on their objections. The association believed that Searle failed to provide reasonable certainty that aspartame and its degradation products were safe for use in soft drinks. However, the drafted document was never filed with the FDA.⁴⁵ This raises a very important question: What role, if any, did H.R. Roberts play in this decision?

In September of 1983, FDA commissioner, Dr. Arthur Hayes, who had previously overruled the FDA Public Board of Inquiry's motion to withhold the approval of aspartame and subsequently approved NutraSweet for use in dry products, resigned his post. In another apparent conflict of interest, Dr. Hayes then accepted a position with Burson-Marsteller, Searle's public relations firm, as senior scientific consultant earning what was conservatively estimated to be \$1,000.00 a day.

In the meantime, concerns over the safety of aspartame use continued to grow. In the July 1984 issue of <u>Common Cause</u> magazine, Florence Graves, vice president of publications and editor, wrote "NutraSweet has been touted as the most tested food additive in history, but our investigation reveals such serious flaws in the government's approval of NutraSweet that Congress should begin its own investigation immediately." By this time, the Center for Disease Control (CDC) had received almost <u>600 reported cases</u> of adverse health complaints from patients after ingesting aspartame, but because of the overwhelming number, CDC had only been able to review 213 of the reports.

Patients ranged from four-month-old children to 77-year-old senior citizens. More than 25% reported experiencing similar ailments each time they consumed a product containing aspartame. Symptoms varied, however, many reported disorientation, hyperactivity, extreme numbness, excitability, memory loss, seizures, suicidal tendencies, and severe mood swings.

In a special report, the Center for Disease Control recommended that future aspartame research focus on the neurological, emotional, and human behavior problems manifested in their patients' complaints.⁴⁸ Ironically, in complete conflict with his own organization's report, Frederick L. Trowbridge, an executive for the CDC, added an unsolicited appendix to the report. In his annex, Trowbridge argued that "Currently available information based on data with limitations as described in the report, indicated a wide variety of complaints that are generally of a mild nature. Although it may be that certain individuals have an unusual sensitivity to the product, these data do not provide evidence for the existence of serious, widespread, adverse health consequences to the use of aspartame."⁴⁹ How can reports of patient problems such as aggressive behavior, disorientation, hyperactivity, extreme numbness, excitability, memory loss, loss of depth perception, liver impairment, cardiac arrest, seizures, suicidal tendencies and sever mood swings be considered "of a mild nature"?

It is obvious that genuine concern for our well being is not everyone's priority. I shudder to think what motivates someone to ignore the plight of honest citizens who suffer genuine health problems when they ingest a product supposedly harmless to them. The irregularities, conflicts of interest and apparent fraud have somehow been largely ignored by the mainstream news media. Even Editor and Publisher Magazine, a periodical for journalists, in the July 13, 1985 issue reported "The Food and Drug Administration NutraSweet cover up" as one of the most under-reported stories of the year. 50

In October of 1985, the Monsanto Company purchased the Searle Company for \$2.7 billion. Until this time, aspartame was still manufactured under Searle's pharmaceutical operations; not a food related subsidiary. Under the control of Monsanto, the separation of NutraSweet from its pharmaceutical origins was accomplished, giving aspartame a more gentle appearing, less chemical oriented parent company. Despite this, concern over the adverse effects of aspartame continued to grow and broaden. In 1986, George R. Verrilli, M.D. and Anne Marie Mueser published

a book for expectant mothers entitled While Waiting: A Prenatal Guidebook. In this book, Dr. Verrilli and Ms. Mueser raised concern over the effects aspartame could have on babies growing in the womb. The team wrote "aspartame is suspected of causing brain damage in sensitive individuals. A fetus may be at risk for these effects...some researchers have suggested that high doses of aspartame may be associated with problems ranging from dizziness and subtle brain changes to mental retardation." 52

As time progressed, the justification for public concern continued to intensify. On February 3, 1986, Senator Howard Metzenbaum released documents from a congressional investigation of aspartame and the G.D. Searle Company. In these documents, the senator discovered that during at least one Searle research project on primates, every monkey that received either medium or large doses of NutraSweet suffered debilitating seizures. This was just another fact withheld from the FDA,⁵³ yet the product remains on the market. On July 17, 1986, consumer attorney, James Turner, filed a petition on behalf of the Consumer Nutrition Institute seeking to force the FDA to reconsider its regulations regarding safe use of aspartame and to change the current regulations.⁵⁴ Three months later, in a legal maneuver, Turner filed a citizen's petition over aspartame citing that use of the chemical inherently had hazards of seizures and possible eye damage.⁵⁵ Without having the evidence of NutraSweet's adverse reactions presented for any evaluation, the FDA denied the petitions.⁵⁶ Only one week later, ever pressing in on its efforts, aspartame was approved by the FDA for use in concentrated fruit juices and fruit flavored drinks, frozen popsicles, breath mints, and teas.⁵⁷

The very next month the FDA declared aspartame, provided labeling meets certain specifications, as safe for use as an inactive ingredient. By calling aspartame "inactive," the FDA completely disregarded all the evidence which has demonstrated the toxic effects of aspartame and the apparent cover-up conducted by researchers.⁵⁸ In a bizarre contradiction, the same month the FDA labeled aspartame as "an inactive ingredient," the FDA published a list of 73 adverse symptoms associated with aspartame use, which included four deaths attributed to its use. Two weeks later, in January 1987, a FDA quarterly report on the adverse reactions associated with aspartame was released. This report cited that the FDA had received 3,133 consumer complaints of adverse reactions associated with aspartame use. The FDA publication cited that the majority of the complaints

referred to neurological symptoms including sever headache, dizziness, numbness and loss of memory.⁵⁹

On June 18, 1987, the General Accounting Office (GAO) released a report raising two very important issues. The report stated that 12 of 69 scientists responding to a GAO poll on the inherent safety or dangers associated with aspartame use in humans maintained grave reservations about aspartame safety. The report also brought Dr. Olney's research findings to official government attention. The report revealed that during an examination of aspartame animal studies, Dr. Olney discovered that of the 320 rats experimentally given aspartame in his program, 12 developed brain tumors, while he found that no brain tumors had developed in a group of 120 similar rats not fed aspartame.⁶⁰

Members of the FDA's own staff has even begun to publicly speak out. Dr. Jacqueline Verrett, a toxicologist for the FDA and an original member of the FDA task force charged with the Searle investigation, was outraged at the propagation of Searle's so-called research and the FDA's final acceptance of their clearly questionable reports. In her testimony before U.S. Senate hearings on aspartame safety, Dr. Verrett stated that the tests Searle used to win FDA approval for aspartame were so inappropriate that they should have been completely discarded. Verrett further stated the original study results reported to the FDA by Searle indicated the possibility of birth defects associated with the chemical's use, which has not been thoroughly examined. Dr. Verrett testified that when her FDA task force was sent to investigate the integrity of Searle's research, the team was specifically directed by FDA supervisors not to be concerned with the overall validity of that research. She said the task force found Searle's researchers had committed "serious departures from acceptable toxicological protocols." Dr. Verrett testified that any one of the many unscientific procedures found documented by her team would completely compromise any genuine research study, much research on a product destined for human consumption. The toxicologist further testified that questions on the safety of human consumption of aspartame and its breakdown products are still unanswered. Concerns of the hazards associated with the breakdown products of aspartame, which breaks down more rapidly in liquids and when heated, is the original reason aspartame was never intended for use in liquids. Dr. Verrett testified that because of the danger associated with NutraSweet's by-products, it was decided that aspartame was too unstable to be used in diet drinks and hot liquids such as coffees and hot chocolates, a fact long forgotten along this controversial pathway.

While discussing the breakdown products of aspartame, Dr. Verrett shed some new light on the effects of primate consumption of DKP. Previously it had been discovered that female primates experienced a greater incidence of uterine tumors with aspartame, however, other studies had indicated that DKP could also elevate blood cholesterol, a health risk unacceptable for any American, where heart disease is the number 1 killer. 61

By the beginning of 1988, almost 500 products directly marketed to American consumers contained the potentially lethal chemical. Another FDA quarterly report on adverse reactions associated with aspartame was released on October 1, 1988. This report stated that the FDA had received over 4,200 consumer complaints against aspartame ingestion. As with previous information of the hazards associated with the use of this chemical, this report did not generate any action to truly evaluate aspartame safety risks by the government office designed to protect your health. 63,64

Numerous specialists in the health field have spoken out against aspartame use. Of these are Woodrow Monte, R.D., Ph.D., and director of the Arizona State University Food Sciences and Nutrition Laboratory. When I spoke with Dr. Monte in December of 1994, he expressed his vehement objection to the methanol content of aspartame, calling aspartame a "crime against humanity." Monte argued that "humans are 100 times more sensitive to methanol than are animals. This means when studies of the effects of aspartame on animals are compared for human use, the adverse effects must be multiplied 100 times. When a person ingests aspartame, it breaks down into methanol within one hour of ingestion. Methanol is formed as soon as aspartame is added into a solution and continues to form the longer it is in solution."

Dr. Monte also expressed concern over the widespread use of NutraSweet in America because heat speeds the breakdown of aspartame into methanol. According to Dr. Monte, who has conducted countless hours of research and experimentation of this chemical, if aspartame is added to a hot beverage, say hot chocolate, coffee or tea at 80°C (145°F), one half of the amount of aspartame originally added breaks down into methanol in less than 10 minutes. Dr. Monte is very concerned about the FDA's 1993 approval for the use of aspartame in baked goods and other

heated products, not to mention the products like flavored coffees and hot chocolates which have been on the market for several years now. Reminding me that aspartame began its existence as a product for a prescription medication, Dr. Monte stated that he believes aspartame was mislabeled from the beginning. "Aspartame is a drug, not a food additive," he informed me. "One hundred million people, from pregnant women to little babies to the elderly, are consuming this stuff in megadoses. This product is being consumed more than it ever would if it were labeled as a drug, like it was originally intended to be." "65"

Dr. Monte is not the only one to be concerned. In fact, the proceedings of the National Academy of Sciences of the United States of America stated that aspartame should not be used as a sweetener when the product will be exposed to elevated temperatures or acidic ph. ⁶⁶ (Diet cola is acidic by pH and will eat the corrosion from the terminal of a car battery.)

Despite the reassuring claims the makers of NutraSweet provide, researchers Ralph Walton, M.D., Robert Hudak, Ph.D., and Ruth J. Green-Waite experienced a great deal of difficulty in their experiment on the safety of aspartame. Recently this team conducted a research study of the problems associated with the ingestion of aspartame on people with mood disorders. Their study was admittedly small, including a total of 13 subjects (8 test subjects and 5 controls), however, the results were dramatic. All of the test subjects suffered from depression. The control group consisted of hospital employees, including the hospital administrator.

For the experiment, the hospital's pharmacy prepared capsules of aspartame for some participants and sugar placebos for others. The amount of aspartame used was equivalent to 10 to 12 cans of diet soda. Some would say this is an extreme quantity, however, it has been my experience that many soft drink users can easily consume a two-liter bottle daily, if not more. The results of the study were shocking. According to Dr. Walton, the team's research was halted after only 20 days because the symptoms of those receiving the aspartame were so severe, they could not ethically continue. Despite the abbreviation of the study, the researchers found that patients taking aspartame suffered a dramatic increase of headaches and that people who were dealing with symptoms of depression or emotional issues suffered a significant increase in their symptoms. The research team concluded those individuals with mood disorders; depression or other emotional problems should be discouraged from using aspartame. It is interesting to note that when the researchers approached the manufacturers of aspartame to purchase samples for their experiment, NutraSweet refused to sell them their product. Perhaps the people at NutraSweet already knew what these researchers soon found out.⁶⁷

While Dr. R. Walton was chief of psychiatry at New York's Jamestown Hospital, he treated a 54-year-old female who had suffered a grand mal seizure with no prior history of seizure activity. Following the seizure, the patient's behavior became bizarre and uncharacteristic. Dr. Walton could find no clinical reason for the patient's mental status change, and began to question her on any changes she may have experienced in her daily lifestyle. It appeared that the woman generally drank about a gallon of sugar sweetened tea daily for years. However, shortly before her seizure she had replaced the sugar in her tea with NutraSweet in order to lose some weight. Dr. Walton advised his patient to refrain from using the chemical product and within a very short period of time, she became like her old self again. Today, Dr. Walton does not trust the research Searle produced to win FDA approval. The doctor stated, "I know it causes seizures. I'm convinced also that it definitely causes behavioral changes. I'm very angry that this substance is on the market. I personally question the reliability and validity of any studies funded by the NutraSweet Company.'

In fact, several studies have shown that aspartame can decrease the brain's ability to control erratic brain wave activities which cause seizures. Laboratory studies showed that animals fed aspartame demonstrated increased seizure susceptibility. Simply put, when the lab animals were given aspartame, a much smaller stimulus would evoke a seizure than was the case when the animals were not given the chemical. In one of these studies, a particular drug was given to the lab animals, which is known to cause seizures. This was so that a threshold or minimum dose that would cause the animal to go into a seizure could be measured. Following these measurements, the animals were fed aspartame and then again given the seizure causing medication. Amazingly, after aspartame ingestion, rats began having seizures when they were given only _ the original threshold measure of the drug.⁶⁹ Pinto, et al. (see end note), demonstrated that aspartame ingestion actually could alter the neurotransmitter (brain chemicals) knows to protect against seizures. In his study, calculated the levels of brain neurotransmitters prior to and after aspartame consumption and found once again that aspartame ingestion in rats significantly increased their seizure threshold. 70

An internal medicine physician practicing in the state of Florida, Dr. H.J. Roberts, produced a work reporting several cases of individuals who had been adversely affected by consuming aspartame. Dr. Roberts described one horrible incident where a college honor student was irreversibly debilitated due to destruction left in the wake of aspartame use. In this case history, Dr. Roberts told the story of how this 18-year-old college student sought his treatment in 1986 because of "profound intellectual deterioration." According to Dr. Roberts, the patient was previously an outstanding student at a major university, a skilled typist and a pianist. However, her skills had rapidly declined and she had suffered a loss of 20 IQ points by the time of her first visit to his office. She went to the doctor complaining of severe headaches, inability to sleep restfully, suicidal depression and an itching in the She also suffered a burning genital region. sensation when she urinated, a dramatic change in her personality, stomach pain and nausea. The female patient had stopped having monthly periods and experienced an ironic 15-pound weight gain while dieting.

Dr. Roberts immediately began a battery of extensive physical, blood and neurological tests on the woman. Following this exhaustive array of tests, the doctor could not find any patterns consistent with a known form of organic brain problem or schizophrenia. The patient's problems fit no known scenario or normal pattern of disease, which at first baffled Dr. Roberts. Upon observing the patient, Dr. Roberts noted that she became drowsy after she drank a diet soda with aspartame. Upon investigation, the patient revealed that she consumed a large quantity of diet soda and had done so for a period of time. At that point, the physician advised his patient to avoid aspartame products completely. Following abstinence from NutraSweet laced products, the patient was also advised to follow a diet rich in complex carbohydrates and with few refined sugars to prevent fluctuations in her blood glucose. According to Dr. Roberts, avoidance of aspartame relieved her symptoms, but the apparent brain damage remained. Ultimately, this patient had to be placed in a half-way type program for the mentally challenged.⁷¹

In August of 1987, Mary Stoddard organized The Aspartame Consumer Safety Network. Ms. Stoddard's efforts were the direct result of her personal debilitating experience after consuming products made with NutraSweet. Ms. Stoddard noticed that her general health began to

decline in 1984 after she decided she needed to go on a diet. In her writings, Ms. Stoddard articulates how she began to experience dozens of strange symptoms that she had never felt before, including blurred vision, depression, ringing in her ears, muscle tremors, weakness in her arms and legs with cramping of those muscles, a nervous type twitch in her body, congested ears, sores on her skin, sinus congestion, joint pains, and even a loss in her hearing. Stoddard emphatically states that she did not have symptoms prior to starting a diet to shed some unwanted weight. It was during this diet she began using diet products that contained aspartame on a regular basis for the first time. While her diet progressed, she continued to use more and more diet products containing the chemical and observed that her symptoms became worse. Ms. Stoddard sought medical help, but received no beneficial advice or relief. Eventually, Mary Stoddard began to look into her diet for a clue. After ruling out other sources, she realized that her symptoms began shortly after beginning her diet. She began to suspect that the products she consumed containing aspartame were the roots of her health problems. On that hunch, she decided to eliminate NutraSweet from her diet completely and reported that she began to feel better immediately. Unfortunately, it took six months for all of her symptoms to completely recede. During her recovery, Ms. Stoddard unknowingly ate a product that used aspartame as a sweetener and she reported that her symptoms returned, proving to her that aspartame was at the root of her troubles. In 1987, Mary Stoddard formed the Aspartame Consumer Safety Network to help others afflicted with aspartame sensitivity problems.⁷²

Currently Ms. Stoddard focuses much of her attention on pilots and the aviation industry in general. "I shudder to think of what would happen if just one of our airline pilots suffered a seizure while in the cockpit," Ms. Stoddard stated at a recent meeting. "I am receiving literally hundreds of calls from pilots who have either lost their flight status due to symptoms, especially seizures, from consuming NutraSweet, or who have experienced sever reactions but have been able to cover up their problems from FAA physicians. Countless pilots have told me personally of nearly disastrous events that occurred while flying under the influence of aspartame." The July issue of General Aviation News headlines read, "Anecdotal reactions to artificial sweeteners are grounding some pilots, but FDA can't help—it approved aspartame as a food, not a drug."73 It appears that numerous pilots have experienced seizures and other bizarre health changes as a result of consuming beverages sweetened with NutraSweet. Once a pilot has any type of a seizure he or she is usually grounded for life and their career is over. The U.S. military has begun to express genuine concern over the issue of NutraSweet and its pilots. Scientists at the U.S. Armed Forces Institute of Pathology (AFIP) have examined the research and papers written on NutraSweet since 1970 and warn that consuming aspartame may lead to blood pressure instability and disturbances in visual perception. spokesperson for AFIP expressed grave concern for pilots. When a pilot experiences any difficulties with visual perception while in the cockpit, much less seizures, the results could be a national tragedy.⁷⁴ The official Air Force safety magazine Flying Safety and the Navy's Navy Physiology have both published warnings to their pilots to refrain from using the chemical. Perhaps one of the most frightening circumstantial events surrounding aspartame and flight safety came from the voice recorder onboard USAir Flight 427 which crashed near Pittsburgh International Airport on September 8, 1994, killing all 132 people on board. Conversation in the cockpit was quite normal until the pilot, Capt. Peter Germano ordered a beverage. According to the Associated Press, the infamous black box recorded that Capt. Germano consumed a national brand diet soft drink just 10 minutes before the crash. Other pilots have reported having seizures while in flight following their use of diet sodas, narrowly escaping the same fate. We are only left to speculate what role aspartame played in this tragic event, if any. However, according to FAA investigators, the aircraft itself was not to blame in the crash.

Another frightening correlation is the relationship of the introduction of NutraSweet to the American public and the surge in incidence of human brain tumors. In the Journal of Advancement in Medicine, scientists and researchers have cited that according to National Cancer Institute records, there has been a dramatic rise in the incidence of brain tumors in the United States beginning in 1985, just two years after NutraSweet became available in diet sodas. During that time the incidence of these brain tumors increased 60%! And the rise has continued every year since that time. Researchers also point to aspartame in some cases of Alzheimer's Disease. On Call, a medical society journal, draws attention to the amino acids in aspartame and their relation to the amino acids used as neurotransmitters in the brain. The article states that the phenylalanine, aspartic acid, methanol and metabolites have been shown to "alter binding of excitatory amino acids to neuronal membranes and dysfunction of amino acid-derived neurotransmitters." The authors continue that "these findings raise concern as to whether aspartame might initiate or aggravate Alzheimer's Disease."

The years that have followed the release of this toxic substance on the American population have been met with literally thousands of consumer complaints of adverse health effects associated with consumption of products containing aspartame. In February of 1994, the Department of Health and Human Services Report on Adverse Reactions Attributed to Aspartame for 1993, reported 6,888 consumer complaints, including 649 reported by the Centers for Disease Control and another 1,305 reported by the FDA. Currently, aspartame accounts for over 75% of all the complaints in the Adverse Reaction Monitoring System. Yet, the use of this product grows every day and your FDA does nothing.

With all the controversy aspartame and its marketed product, NutraSweet, have generated, I am truly startled that it has remained on our store shelves. I am very dismayed that those government agencies we have trusted to protect us have done so little. The unquestionable corruption surrounding the approval and marketing of aspartame nauseates me. What is more alarming is a question ringing in the back of my mind: If aspartame made it to our store shelves with this much confirmed negative research, what other dangerous products is our government deceiving us about?

- Stegnik, L.; Filer, L.J. Jr. Aspartame Marcel Dekker, Inc. 1989.
- G.D. Searle Company, Confidential Internal Memorandum Entitled Food and Drug Administration and other Drug Sweetener Strategy. Documents supplied by Sen. Howard Metzenbaum's office, December 28, 1970.
- STEADMAN'S Medical Dictionary, 25th edition, William and Williams, Baltimore, 1990.
- Louis, R.J., Sax's Dangerous Properties of Industrial Materials, Eighth edition, New York: Van Nostrand Reinhold, 1992, pp. 4. 2251-2252.
- IBID 5.
- Monte, W., Aspartame: Methanol and Public Health, J Appl Nutr 36:42-54, 1984.
- Thomas-Doberson, D., "Calculation of Aspartame Intake in Children." Journal of the American Dietetic Association 89(6): 831-
- 8 Federal Register 44:31716-31718, June 1, 1979.
- Thomas-Doberson, op set.
- Koehler, S.M.; Glaros, a. "The Effect of Aspartame on Migraine Headache." Headache 28(1): 10-13, 1988. 10.
- Federal Register 38: 5921, March 5, 1973.
- Federal Register 39: 27317, July 25, 1985. 12.
- Federal Register 46: 38285, July 24, 1981.
- U.S. Court of Appeals for the District of Columbia Circuit, No. 84-1153. Community Nutrition Institute, et al., Petitioners v. Dr. Mark Novitch, Acting Commissioner, Food and Drug Administration, Respondent, G.D. Searle Co., Inventor, Petition for Review of an Order of the Food and Drug Administration, No. 84-5253. Community Nutrition Institute, et al., Appellants v. Dr. Mark Novitch, Acting Commissioner, Food and Drug Administration, Appellee, September 24, 1985.
- 15. Documents supplied by Sen. Howard Metzenbaum's office, February 6, 1986.
- 16. Federal Register 40: 56907, December 5, 1975.
- Food and Drug Administration, Searle Investigation Task Force Chaired by Carlton Sharp, "Final Report of Investigation Review of G.D. Searle Company." March 24, 1976.

 18. Federal Register 44: 31716-31718, June 1, 1979.
- Letter from Richard A. Merrill, Chief Counsel, Department of Health, Education, and Welfare, Food and Drug Administration, to Honorable Samuel K. Skinner, U.S. Attorney, Northern District of Illinois, requesting that Skinner's office convene a Grand Jury investigation into G.D. Searle Co. for submitting false reports dated January 10, 1977.
- Letter from Howard J. Trienens, Sidley & Austin, to Samuel K. Skinner, U.S. Attorney, Northern District of Illinois, January 26,
- Documents supplied by Sen. Howard Metzenbaum's office, February 6, 1986.
- Confidential memorandum from Samuel K. Skinner, U.S. Attorney, Northern District of Illinois, to William Conlon and Fred Branding. Document supplied by Sen. Howard Metzenbaum's office, March 8, 1977.
- 23. Memorandum from Charles P. Kocoras, First Assistant U.S. Attorney, to Samuel J. Skinner, U.S. Attorney, regarding the G.D. Searle Company, April 13, 1977.
- 24. Documents supplied by Sen. Howard Metzenbaum's office, February 6, 1986.
- Food and Drug Administration, Bressler, J., The Bressler Report, Investigation of Searle Laboratories, August 7, 1977.
- Memorandum from Bureau of Foods Task Force, Food and Drug Administration, to Howard R. Roberts, Ph. D., Acting Director, Bureau of Foods, regarding "Authentication Review of Data in Reports Submitted to the Food and Drug Administration Concerning Aspartame." September 28, 1977.
- U.S. General Accounting Office, "Briefing Report to the Honorable Howard Metzenbaum, U.S. Senate, Food and Drug Administration, Six Former HHS Employees' Involvement in Aspartame's Approval." GAO/HRD-86-109BR, July 1986.
- 28. Documents supplied by Sen. Howard Metzenbaum's office, February 6, 1986.
- U.S. General Accounting Office, "Report to the Honorable Howard Metzenbaum, U.S. Senate, Food and Drug Administration, Food Additive Approval Process Followed for Aspartame." GAO/HRD-87-46, Common Cause, June 1987.
- Federal Register 44:31716-31718, June 1, 1979.
- Food and Drug Administration Public Board of Inquiry, Nauta, W.J.H., Lampert, P.W., Young, V.R. "Aspartame (Docket No. 75F-0355): Decision of the Public Board of Inquiry." September 30, 1980.
- Federal Register 48: 54993-54995, December 8, 1983, and Federal Register 46: 38288-38289, July 24, 1981. 32.
- 33. U.S. Court of Appeals for the District of Columbia Circuit, No. 84-1153.
- Internal memoranda from three Food and Drug Administration scientists: Dr. Robert J. Condon, Dr. Satya D. Dubey and Dr. Douglas Park, to Joseph A. Levitt, Food and Drug Administration, advising against approval of NutraSweet, May 19, 1981.
- 35. Federal Register 46: 38285, July 24, 1981, and Federal Register 48: 54993-54995, December 8, 1983.
- Hiroyuki Ishii, "Incidence of Brain Tumors in Rats Fed Aspartame." Life Science Laboratories, Central Research Laboratories, Ajinomoto Co., Inc., Yokohama, Japan.
- Food and Drug Administration, Public Health Service, Department of Health and Human Services. "Aspartame (Docket No. 75F-0355): Summary of Commissioner's Decision." July 15, 1981.
- Committee on Labor and Human Resources. "NutraSweet—Health and Safety Concerns Hearing before the Committee on Labor and Human Resources, U.S. Senate, One Hundredth Congress, First Session on Examining the Health and Safety Concerns of NutraSweet (Aspartame)." November 3, 1987.
- 39. Federal Register 46: 50947, October 16, 1981.
- U.S. Court of Appeals for the District of Columbia Circuit, No. 84-1153.
- 41. Federal Register 47: 46140, October 15, 1982.
- 42. Food and Drug Administration, "Aspartame in Carbonated Beverages Approved." FDA Talk Paper, July 1, 1983.
- Federal Register 48: 31376, July 8, 1983. 43.
- 44 Congressional Record 131(58): S5489-S5517, May 7, 1985.
- 45. IBID S5509-S5510.

- 46. U.S. General Accounting Office. "Briefing Report to the Honorable Howard Metzenbaum, U.S. Senate: Food and Drug Administration, Six Former HHS Employees' Involvement in Aspartame's Approval." GAO/HRD-86-109BR, July 1, 1983.
- 47. Graves, F., "Results of Common Cause Magazine Investigation of FDA's Approval of Aspartame." Common Cause, July 1984.
- Centers for Disease Control, Division of Nutrition, Center for Health Promotion and Education. "Evaluation of Consumer Complaints Related to Aspartame Use." November 1984.
- 49. IBID
- 50. Zaslow, J., "Searle's John Robson to Remain in Two Posts Until After Merger." Wall Street Journal, October 1, 1985.
- IBID
- 52. Verrilli, G.R.; Muser, A.M., While Waiting: A Prenatal Guidebook, St. Martin's Press, 1986.
- 53. Documents supplied by Sen. Howard Metzenbaum's office, February 6, 1986.
- 54. Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to James S. Turner, Swankin & Turner, denying the Community Nutrition Institute's petition to seek administrative reconsideration of the FDA's regulations concerning aspartame, November 21, 1986.
- 55. Committee on Labor and Human Resources, November 3, 1987.
- 56. Letter from John M. Taylor, November 21, 1986.
- 57. Letter from F. Owen Fields, Ph. D., Novel Ingredients Branch, Division of Product Policy, Center for Food Safety and Applied Nutrition, Department of Health and Human Services regarding "Pre-1988 Aspartame Approvals." February 25, 1994.
- U.S. General Accounting Office, "Report to the Honorable Howard M. Metzenbaum, U.S. Senate: Food and Drug Administration, Food Additive Approval Process Followed for Aspartame." GAO/HRD-87-46, June 1987.
- Department of Health and Human Services, Health and Injury Related Surveillance Subprogram Postmarketing Surveillance System. "Quarterly Report on Adverse Reactions Associated with Aspartame Ingestion." Submitted to Health Hazards Evaluation Board, January 2, 1987.
- U.S. General Accounting Office, "Report to the Honorable Howard M. Metzenbaum, U.S. Senate: Food and Drug Administration. Food Additive Approval Process Followed for Aspartame." GAO/HRD-87-46. Common Cause. June 1987.
- Testimony of Dr. Jacqueline Verrett, Food and Drug Administration Toxicologist, before the U.S. Senate Committee on Labor and Human Resources, regarding "NutraSweet Health and Safety Concerns." November 3, 1987.
- 62. NutraSweet Co., "U.S. Consumer Products Containing NutraSweet Brand Sweetener." February 2, 1988.
- Food and Drug Administration, Department of Health and Human Services. "Quarterly Report on Adverse Reactions Associated with Aspartame Ingestion." October 1, 1988.
- Department of Health and Human Services, "Report on All Adverse Reactions in the Adverse Reaction Monitoring System." February 25 and 28, 1992.
- 65. Monte, W., Aspartame: Methanol and Public Health, J Appl Nutr 36: 42-54, 1984.
- Boehm, M.F., Bada, J.L. "Racemization of aspartic acid and phenylalanine in the sweetener aspartame at 100 degrees C." Proceedings of the National Academy of Sciences of the United States of America, 81(16): 5263-6, August 1984.
- 67. Walton, R.G.; Hudak, R.; Green-Waite, R.J. "Adverse Reactions to Aspartame: Double-Blind Challenge in Patients from a Vulnerable Population." Biological Psychiatry 34: 13-17, 1993.
- 68. Walton, R.G., "Seizure and Mania After High Intake of Aspartame." Psychosomatics, March 1986.
- Maher, T.J., Wurtman, R.J. "Possible Neurological Effects of Aspartame, a Widely Used Food Additive." Environmental Health Perspectives, 75: 53-7, November 1987.
- Pinto, J.M., Maher, T.J. "Administration of aspartame potentiates pentylenetetrazol-and fluorothyl-induced seizures in mice." Neuropharmacology, 27(1):51-55, January 1988.
- 71. Roberts, H.J., Aspartame (NutraSweet): Is It Safe., The Charles Press, 1990.
- 72. Mary Nash Stoddard, Aspartame Consumer Safety Network, PO Box 780634, Dallas, TX 75378 (214) 352-4268.
- 73. Hicks, Megan. "NutraSweet...too good to be true?" General Aviation News, July 31, 1988.
- Gaffney, C., Armed Forces Institute of Pathology, "Aspartame in Aviation." Paper presented at the 57th Annual Scientific Meeting of the Aerospace Medical Association, April 1986.
- 75. Roberts, H.J., M.D. "New Perspectives Concerning Alzheimer's Disease." On Call, August 1989.