ASPARTAME DISEASE: AN FDA-APPROVED EPIDEMIC

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"Diet" products containing the chemical sweetener aspartame can have multiple neurotoxic, metabolic, allergenic, fetal and carcinogenic effects. My database of 1,200 aspartame reactors--based on logical diagnostic criteria, including predictable recurrence on rechallenge--is reviewed.

The existence of aspartame disease continues to be denied by the FDA and powerful corporate entities. Its magnitude, however, warrants removal of this chemical as an "imminent public health threat." The use of aspartame products by over two-thirds of the population, and inadequate evaluation by corporate-partial investigators underscore this opinion.

As said by Senator Howard Metzenbaum[1]:

> "We had better be sure that the questions that have been raised about the safety of this product are answered. I must say at the outset, this product was approved by the FDA in circumstances that can only be described as troubling."

I have devoted more than two decades to analyzing aspartame disease, a widespread but largely ignored disorder. Its existence continues to be reflexively denied by the Food and Drug Administration (FDA), the American Medical Association (AMA), and many public health/ regulatory organizations.

The medical profession and consumers have been assured by the Council on Scientific Affairs of the AMA[2] and the Centers for Disease Control (CDC) that aspartame is "completely safe." Moreover, the impression is left that reports of serious reactions are a "health rumor" fabrication ... notwithstanding the CDC report in 1984 of 649 aspartame reactors with many attributed disorders[3].

An Overview of Aspartame Disease

As far back as 1988, seven years after the initial release of aspartame, 80 percent[1] of complaints volunteered by consumers to the FDA about supplements involved aspartame products. By April 1995, it had received 7,232 complaints.

I coined the term "aspartame disease" to encompass reactions to the chemical sweetener aspartame, commonly known as NutraSweet(r) and Equal(r). Aspartame was originally conceived, and an application submitted, as a drug to treat peptic ulcer. To place its magnitude in perspective, over two-

thirds of the population now uses thousands of "diet" sodas and products--including an ever-expanding list of new ones having greater potential for adverse effects (e.g., strips placed on the tongue to freshen the breath).

This report summarizes data on the first 1,200 aspartame reactors in my database, coupled with information of considerable clinical significance. I have elaborated on the details in *Aspartame Disease: An Ignored Epidemic* at: http://www.amazon.com/exec/obidos/ASIN/1884243177/optimalwellnessc[4], other books[5-8] and numerous published articles and letters[9-12].

It is my belief that most physicians with active practices frequently encounter its manifestations. But, unaware of the underlying problem, they fail to inquire about aspartame use.

For orientation about the gravity of this public health dilemma, I shall mention just a few of the published associations in aspartame reactors. They include the initiation or aggravation of diabetes mellitus, hypoglycemia, convulsions, headache, depression, other psychiatric states, hyperthyroidism, hypertension and arthritis; the simulation of multiple sclerosis, Alzheimer's disease and lupus erythematosus; increasing aspartame addiction[12]; an apparent causative role in brain tumors[10]; a neurologic condition in overweight young women known as pseudotumor cerebri; and even the carpal tunnel syndrome[11].

In my opinion, lack of awareness of aspartame disease has resulted in gross miscarriage of justice. Examples include attributing the symptoms of weight-conscious women consuming considerable amounts of aspartame to silicone breast implants in expensive litigation[7], and imprisonment for the alleged methanol poisoning of a deceased spouse who consumed large amounts of aspartame.

Having been involved in medical practice, teaching and the authorship of texts for a half century, I do not casually make statements that might jeopardize a longstanding reputation. As a case in point, my first book, Difficult Diagnosis: A Guide to the Interpretation of Obscure Illness[13], was studied and used as a reference by tens of thousands of internists and other physicians.

The following issues are also relevant:

- My best teachers have been perceptive private patients.
- All my studies were corporate-neutral, meaning without grants. I have had to cope with the enormous hurdles of professional and editorial bias stemming from the self-serving interests of corporate power wielded by a multi-billion dollar industry. For example, virtually all my letters challenging the validity of "negative scientific studies" published in peer-reviewed journals were rejected. They were based on flawed protocols, the failure to use "real world" products subjected to prolonged storage and elevated temperatures, and even the nature of the test materials and placebos employed.
- My repeated emphasis to colleagues, the FDA and the Congress that the approval of aspartame for human use has spawned an imminent public health hazard continues to fall on deaf ears.
- A number of concerned doctors were unable to get their "anecdotal" observations published in peer-reviewed journals, some (including the author) having been labeled "media terrorists" disrespectful of "evidence-based" criteria.

About Aspartame

The FDA approved aspartame as a low-nutritive sweetener for use in solid form during 1981, and in soft drinks during 1983. It is a synthetic chemical consisting of two amino acids, phenylalanine (50 percent)

and aspartic acid (40 percent), and a methyl ester (10 percent) that promptly becomes free methyl alcohol (methanol; wood alcohol). The latter is universally considered a severe poison.

Senior FDA scientists and consultants vigorously protested approving the release of aspartame products. Their objections related to disturbing findings in animal studies (especially the frequency of brain tumors), seemingly flawed experimental data, and the absence of extensive pre-marketing trials on humans using real-world products over prolonged periods.

Aspartame reactions may be caused by the compound itself, its three components, stereoisomers of the amino acids, toxic breakdown products (including formaldehyde), or combinations thereof. They often occur in conjunction with severe caloric restriction and excessive exercise to lose weight.

Various metabolic and physiologic disturbances explain the clinical complications. Only a few are listed:

- Damage to the retina or optic nerves is largely due to methyl alcohol exposure. Unlike most animals, humans cannot efficiently metabolize it.
- High concentrations of phenylalanine and aspartic acid occur in the brain after aspartame intake, unlike the modest levels of amino acids following conventional protein consumption.
- Aspartame alters the function of major amino acid-derived neurotransmitters, especially in obese persons and after carbohydrate intake.
- Phenylalanine stimulates the release of insulin and growth hormone.
- The ambiguous signals to the satiety center following aspartame intake may result either in increased food consumption or severe anorexia.
- Large amounts of the radioactive-carbon label from oral aspartame intake have been detected in DNA.

The current "acceptable daily intake" (ADI) of 50 mg aspartame/kg body weight makes no sense. It represents the projection of animal studies based on lifetime intake! This was clearly stated by previous FDA Commissioner Dr. Frank Young during a U.S. Senate hearing on November 3, 1987. Furthermore, it disregards the usual 100-fold safety factor used by the FDA as a guideline for regulated food additives. The maximum daily intake tolerated by most reactors in my series, based on the predictable recurrence of induced symptoms and signs, ranged from 10 to 18.3 mg/kg.

Clinical Data Attributed to Aspartame Products

The clinical features attributed to aspartame products among the first 1,200 reactors in my database appear in Table 1 (reproduced from Reference 4 with permission by the Sunshine Sentinel Press).

TABLE II-1

COMPLAINTS IN 1200 ASPARTAME REACTORS
(ROUNDED PERCENTAGES)
(*indicates data based on the most recent 649 reactors)

Eye	
Decreased vision and/or other eye problems (blurred, "bright flashes," tunnel vision)	302
Pain (one or both eyes)	87
Decreased tears, trouble with contact lens, or both	95
Blindness (one or both eyes)	27

Ear		
Tinnitus ("ringing,""buzzing")	146	(12%)
Severe intolerance for noise	80	(7%)
Marked impairment of hearing	57	(5%)
Neurologic		
Headaches	516	(43%)
Dizziness, unsteadiness, or both	376	(31%)
Confusion, memory loss, or both	376	(31%)
Severe drowsiness and sleepiness	150	(13%)
Paresthesias ("pins and needles, "tingling") or numbness of limbs	183	(15%)
Convulsions (grand mal epileptic attacks)	129	(11%)
Petit mal attacks and "absences"	36	(3%)
Nonclassified seizures	21*	(2%)
Severe slurring of speech	124	(10%)
Severe tremors	101	(8%)
Severe "hyperactivity" and "restless legs"	78	(6%)
Atypical facial pain	70	(6%)
Simulation of multiple sclerosis	28*	(4%)
Psychologic/Psychiatric		
Severe depression	281	(23%)
Suicidal ideas/attempts	46*	(7.1%)
"Extreme irritability"	194	(16%)
"Severe anxiety attacks"	201	(17%)
"Marked personality changes"	167	(14%)
Recent "severe insomnia"	169	(14%)
"Severe aggravation of phobias"	77	(6%)
"Addiction to aspartame"	32*	(5%)
Chest/Heart		
Palpitations, tachycardia, (rapid heart action) or both	193	(16%)
"Shortness of breath"	110	(9%)
Atypical chest pain	85	(7%)
Recent hypertension (high blood pressure)	64	(5%)

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Gastrointestinal		
Nausea	127	(11%)
Diarrhea	106	(9%)
Associated gross blood in the stools... 16		
Abdominal pain	125	(10%)
Pain on swallowing	61	(5%)
Skin/Allergies		
Severe itching without a rash	87	(7%)
Severe lip and mouth reactions	54	(5%)
Urticaria (hives)	47	(4%)
Severe genital itching, rash, or both	25*	(4%)
Lupus erythematosus-type eruption	7*	(1%)
Other rashes	101	(8%)
Marked thinning or loss of hair	71	(6%)
Aggravation of respiratory allergies	17	(1%)
Dual sensitivity to MSG	14*	(2%)
Weight Disorders		
Paradoxic marked weight gain	83	(7%)
Marked weight loss	40	(3%)
Rheumatologic/Muscular		
Severe joint pains	163	(14%)
"Fibromyalgia""	27*	(4%)
Leg and hand cramps	28*	(4%)
Myasthenia gravis	8	(1%)
Endocrine/Metabolic		
Problems with diabetes (loss of control; precipitation of clinical diabetes; aggravation or simulation of diabetic complications)	118	(10%)
Aggravated hypoglycemia ("low blood sugar attacks")	74	(6%)
Menstrual changes	76	(6%)
Severe reduction or cessation of periods ... 42		
Hyperthyroidism (Graves disease)	8*	(1%)

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Fluid/Urinary Disturbances		
Frequency of voiding (day and night), burning on urination (dysuria), or both	126	(11%)
Intense thirst	116	(10%)
"Bloat"	100	(11%)
Fluid retention and swelling (feet and legs)	43	(11%)
Kidney stones	3*	------

Comparison With FDA Data

As of April 1995, the Food and Drug Administration (FDA) had received complaints from 7,232 consumers who attributed their symptoms and signs to the use of aspartame products (Table II-2). As in the author's series, multiple complaints were common. BUT this agency arbitrarily excluded an additional 649 aspartame reactors reported earlier by the Centers for Disease Control (1984).

These findings are noteworthy.

- Gender - 3271 (76%) of the reactors were female; 1160 (24%) were male
- Age - peak age group 30-39 years, with 847 (25.9%) complaints
- Severity of Reactions - 518 (10.6%) classified as "severe"; 4366 (89.4%) classified as "mild to moderate"
- Recurrent Reactors Following Exposure to a Single Aspartame Product – 1139 (27.6%)

Gender and Age Range

There was a 3:1 preponderance of females (72 percent). The various influences that may be operative in this gender preference have been detailed previously[4-6]. The ages of persons at the onset of their reactions ranged from infancy to 92 years. Most were in their 20s to 50s.

Family History

Two or more close relatives of 211 reactors (17.6 percent) were known to have had reactions to aspartame products.

Latent Period

Latent periods of from several weeks to months between the initial consumption, and increased intake of aspartame and the onset of severe symptoms were common. On the other hand, some patients reacted almost immediately, particularly with products conducive to oral/buccal absorption.

Aspartame Intake

Many reactors consumed prodigious amounts of aspartame, especially during hot weather. Conversely, some experienced convulsions, headache, or other severe symptoms after exposure to small amounts (e.g., chewing aspartame gum; placing an aspartame strip on the tongue; babies while breast-feeding as

the mother drank an aspartame beverage).

Interval Between Cessation and Improvement

Nearly two-thirds of aspartame reactors experienced symptomatic improvement within two days after avoiding aspartame. With continued abstinence, their complaints generally disappeared.

Causation

The causative role of aspartame products has been repeatedly shown by (a) the prompt improvement of symptoms (grand mal seizures, headache, itching, rashes, severe gastrointestinal reactions) after stopping aspartame products, and (b) their recurrence within minutes or hours after resuming them. The latter included self-testing on numerous occasions, inadvertent ingestion, and formal rechallenge.

Some aspartame reactors with convulsions purposefully rechallenged themselves on one or several occasions "to be absolutely certain." This was unique among six pilots who had lost their licenses for unexplained seizures while consuming aspartame products. (All had been in otherwise excellent health.) They sought to have their licenses reinstated by such objective confirmation on rechallenge.

High-Risk Individuals

These groups include pregnant and lactating women, young children, older persons, those at risk for phenylketonuria (PKU), the relatives of aspartame reactors (see above), and patients with liver disease, iron-deficiency anemia, kidney impairment, migraine, diabetes, hypoglycemia, and hypothyroidism.

Clinical Implications

Physicians must question patients who present with the aforementioned conditions about aspartame use, particularly when they fail to respond to conventional therapy. If it is being consumed, a brief trial of abstinence should be recommended before initiating expensive tests, consultations and hospitalization.

The following caveats derive from clinical experience:

- Every patient with unresolved neurologic, psychologic, allergic, dermatologic, gastrointestinal and metabolic/endocrine problems should be queried about aspartame intake.
- The diagnosis of multiple sclerosis should be deferred pending at least several months observation in the case of persons consuming aspartame.
- A pregnant woman should not risk the health of her fetus by consuming aspartame products.
- Visual, neurologic or bowel problems in diabetics should not be ascribed to a presumed underlying retinopathy or neuropathy until evaluating the response to aspartame abstinence.
- Cataract surgery ought to be deferred in heavy aspartame users to evaluate for spontaneous improvement after abstinence.
- Patients presenting with seizures, headache, atypical facial or eye pain, the Meniere syndrome, depression, the carpal tunnel syndrome, normal-pressure hydrocephalus, and a host of other unexplained neuropsychiatric problems, or who fail to respond to conventional treatment, must be queried about aspartame use ... especially if invasive studies are planned.
- Young adults who express concern about "possibly having early Alzheimer's disease," based on recent confusion and memory loss, ought to be observed at least one month after stopping aspartame before this diagnosis is pursued.
- Gynecologic surgical procedures to evaluate gross menstrual changes should be deferred pending the response to abstinence.

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