Will the European Food Safety Authority (EFSA) Blindly Accept Aspartame Manufacturer (Monsanto/Ajinomoto) Research?

Statement by Mark D. Gold,
November 30, 2011
Aspartame Toxicity Information Center
(http://www.holisticmed.com/aspartame)

> **U.S. Food and Drug Administration (FDA) Toxicologist and Investigator, Dr. Adrian Gross:**
> *"They [aspartame manufacturer] lied and they didn't submit the real nature of their observations because had they done that it is more than likely that a great number of these studies would have been rejected simply for adequacy. What [the manufacturer] did, they took great pains to camouflage these shortcomings of the study. As I say filter and just present to the FDA what they wished the FDA to know and they did other terrible things for instance animals would develop tumors while they were under study. Well they would remove these tumors from the animals."*[1]

On November 24, 2011, the European Food Safety Authority (EFSA) made available on their web page over 500 Megabytes of *aspartame manufacturer* research as part of its commitment to "openness and transparency."[2] The manufacturers of aspartame at the time of most of these industry studies were Monsanto (NutraSweet/G.D. Searle) and Ajinomoto.

The conduct of these aspartame manufacturer studies was so poor that the FDA convened two investigations, one FDA in 1975 led by FDA Investigator, Phillip Brodsky[3] and one in 1977 led by FDA Investigator, Jerome Bressler[4]. EFSA has been sent: 1) Quotes and information about the FDA Brodsky investigation; 2) the complete Bressler Report from the FDA; 3) hundreds of pages of additional independent information demonstrating deceptive practices in aspartame manufacturer research; and 4) independent information demonstrating the toxicity of aspartame. As of this date, none of that information has made it onto EFSA's web page or in any of their reports.

As part of their commitment to "openness and transparency" will EFSA publish on their web site the full FDA 1975 and 1977 investigation reports? Will EFSA publish quotes from these investigations in their final report? Or will EFSA will rely primarily on aspartame manufacturer (Monsanto/Ajinomoto) "science" to continue the approval of a chronic poison for ingestion by the European population.

> **Former FDA Commissioner, Dr. Alexander Schmidt:**
> *"....incredibly sloppy science. What we discovered was reprehensible."*[5]

There was such chaos in the manufacturer laboratories that animals were reported to have died and come back to life numerous times[6]:

Animal	Status	Date
J24HM	Found Dead	3/21/71
	Alive	5/19/71
	Dead	5/16/71
	Alive	7/14/71
	Dead	8/11/71

K18LF	Alive	4/22/71
	Vanished (Dead?)	5/20/71
	Alive	6/17/71
	Vanished (Dead?)	7/15/71
M25CF	Found Dead	3/6/71
	Alive	6/18/71
	Dead	7/16/71
	Alive	9/10/71
	Alive	10/8/71
	Dead	11/5/71
H28MF	Alive	7/13/71
	Vanished (Dead?)	8/10/71
H15CF	Alive	7/13/71
	Vanished (Dead?)	8/10/71
G2HM	Found Dead	3/10/71
	Alive	8/9/71
A15MM	Found Dead	3/13/71
	Alive	5/3/71
	Dead	6/1/71
	Alive	8/23/71
	Dead	9/20/71
G16HM	Found Dead	3/9/71
	Alive	8/9/71
	Dead	9/7/71
A6HM	Found Dead	2/25/71
	Alive	5/3/71
	Dead	6/1/71
	Alive	8/23/71
	Dead	9/20/71
G23HM	Found Dead	3/7/71
	Alive	8/9/71
	Dead	9/7/71
E15MM	Found Dead	1/21/72
	Alive	2/25/72
G8MM	Found Dead	9/3/71
	Alive	11/29/71
	Dead	12/27/71
B19HF	Alive	6/29/71
	Vanished (Dead?)	7/27/71
	Alive	8/24/71
	Vanished (Dead?)	9/21/71
	Alive	10/19/71
	Vanished (Dead?)	11/16/71
	Alive(?)	2/22/72
B21HF	Found Dead	2/25/71
	Alive	8/24/71
	Dead	9/21/71
	Alive	10/19/71
	Dead	11/16/71
	Alive	2/22/72
B14MF	Killed	7/30/71
	Alive	10/19/71
	Dead	11/16/71
	Alive(?)	2/22/72
B12HF	Found Dead	9/2/71

	Alive	10/19/71
	Dead	11/16/71
	Alive(?)	2/22/72
B4CF	Found Dead	9/12/71
	Alive	10/19/71
	Dead	11/16/71
	Alive(?)	2/22/72
D30LF	Found Dead	1/22/72
	Alive	2/22/72
B15HF	Found Dead	1/25/72
	Alive	2/22/72
C29LM	Found Dead	3/29/71
	Alive	6/2/71
	Dead	6/30/71
C12HM	Found Dead	8/10/71
	Alive	10/20/71
	Dead	11/17/71

These changes to the alive / dead status of the test animals are based on the FDA review of only a small percentage of the aspartame and drug studies that were being conducted by the manufacturer at the time. Thousands of additional cases of inaccurate alive / dead status may have been found had all of the hundreds of studies been investigated in a similar manner. These examples show that the manufacturer laboratory was in a state of chaos.

> **Dr. Marvin Legator, Professor and Director of Environmental Toxicology at the University of Texas and the pioneer of mutagenicity testing at the FDA from 1962 to 1972:**
> *"[All tests were] scientifically irresponsible [and] disgraceful. I'm just shocked that that kind of sloppy [work] would even be sent to FDA, and that the FDA administrators accepted it. There is no reason why these tests couldn't have been carried out correctly. It's not that we are talking about some great scientific breakthrough in methodology."*[7]

The investigation of aspartame manufacturer research by the FDA demonstrated chaos as it related to the appearance and disappearance of tumors as described by the testimony of FDA Toxicologist and Investigator, Dr. Adrian Gross[8]:

> *"What may be added here is that the live / dead status of the experimental animals is not the only 'careless' type of error present in the Observation for Drug Effects. The following are merely a few samples of the way entries are kept on externally visible tissue masses in these animals; most of such tissue masses turn out to be benign or malignant mammary tumors.*
>
> 1. *Animal M21 (a control female), is said to have developed a tissue mass in the left cervical area; the mass is said to have been initially detected on 6/18/71; at the next observation period on 7/17/61 this animal is checked off as having no tissue masses; however, the next animal on the list (M22 - an exposed female) is now listed as having its tissue mass 'larger' (presumably than at the previous observation period); but this particular animal had not been listed as having exhibited any such masses at any time in the past; at the next observation period on 8/13/71, the tissue mass in the control animal is said*

to be 'larger' while the exposed animal is said to have no tissue mass whatsoever.

2. *Animal J16 is said on 2/23/72 under 'Tissue Masses - Lesions' to have an abscess in the left inguinal region which is 'larger'; no mention of any such abscess is evident for any prior observation.*

3. *Animal B26 is said on 12/14/71 under 'Tissue Masses - Lesions' that its mass is larger. But no tissue mass in this animal is previously reported. Four weeks later on 1/12/72 a tissue mass is said to have been initially detected on that day.*

4. *Animal B27 is said on 9/21/71 to have developed a tissue mass initially detected on that day; at the next observation period on 10/19/71 the mass is said to be unchanged; at the next observation period on 11/16/71 the mass is said to have regressed; at the next two observation periods on 12/14/71 and 1/12/72 this animal is said to be free of tissue masses; on 2/8/72, the next observation period, the mass for this animal is said to be the 'same'(!)*

5. *Both animals A2 and A3 are said on 9/20/71 to have developed tissue masses initially detected on that day; at the next observation period, on 10/8/71 both of these animals are indicated to be free of any tissue masses; at the next observation period on 11/5/71 it is indicated that both of these masses regressed.*

6. *Animal E3 is said on 7/1/71 to have developed a tissue mass initially detected on that day; the following are the results of the six subsequent examinations:*

   7/29/71 - animal is free of any masses
   8/26/71 - mass is the same (as what?)
   9/23/71 - mass is the same
   10/21/71 - animal is free of any masses
   11/08/71 - mass is the same
   12/06/71 - mass regressed

7. *Animal E9 is said on 9/23/71 to have developed a tissue mass initially detected on that day; the following are the results of the four subsequent examinations:*

   10/21/71 - mass regressed
   11/18/71 - animal is free of any masses
   12/16/71 - mass regressed
   1/13/72 - animal is free of any masses

8. *Animal D29 is said on 7/1/71 to have developed a tissue mass initially detected on that day; the following are the results of the seven subsequent examinations:*

   7/29/71 - animal is free of any masses
   8/26/71 - animal is free of any masses
   9/23/71 - mass is the same
   10/21/71 - animal is free of any masses
   11/18/71 - mass regressed
   12/16/71 - mass is the same
   1/13/72 - animal is free of any masses

9. *Animals H26, D12, K25, D5, K17, and D19 each are indicated to have developed more than on tissue mass; in each case, however, observations made subsequently fail to distinguish to which tissue mass they apply.*

10. *Animal H19 is said on 11/2/71 to have developed a tissue mass initially detected on that date; the subsequent observation dated 11/30/71 indicates this animal to be free of any tissue masses; at the next observation made on 12/28/71 the mass in this animal is said to be the 'same.'*

"This list of 10 examples involving some 16 animals could be extended further but it is sufficient to make the point that records maintained at Searle on the appearance, persistence or 'regression' of tissue masses do not give one much assurance on their reliability.

"One may ask -- can this sort of thing be shrugged off as merely 'careless' observations made by those who were supposed to make such observations? Or was this a situation that could be expected to have occurred, given the policy and practice in force in the Department of Pathology and Toxicology at Searle?

"A review of the names of the 'observers' entered on these sheets referring to 'Observations for Drug Effects' reveals different names for subsequent observations. Question: If whoever observed the animals on a given day and who recorded such observation in his or her notebook, is someone else than the one having observed them at the previous observation period, who made similar observations in some other notebook, how can it be said that a certain tissue mass is the 'same' or 'larger' or 'unchanged'? After a certain period in the experiment no names of any observers appear on these records.

"Searle maintains in their last communication (line 10, page 15) 'In the truest sense, the errors identified by the FDA (in these records) were completely irrelevant to the scientific conclusions of the study...' We note this evaluation of 'irrelevant' by Searle but we cannot agree with it, and the reason for this is very clear:

"The title printed on these 'Observation for Drug Effects' is 'Statistical Work Sheet'; this says that it is reasonable to expect that these 'careless' entries must have formed the basis for input for statistical operation which are crucial to the 'scientific conclusions of the study.' The methodology used in these statistical operations at Searle (the Horton and Sachs Life-Table procedures) depend completely on the time a certain tissue mass (tumor) is observed and on the time the animals with the mass (and all other animals in that group) died. Now, if the live / dead status of each animals was 'carelessly' entered on these 'Statistical Work Sheets' as conceded by Searle and if its status as a tumor-bearer at any time was largely in doubt (as demonstrated here) of what value are any of the statistical computations based on this kind of raw input data and would this not affect the 'scientific conclusions of the study'?

"Searle complains (line 2, page 14) that these records 'became a subject of considerable levity at the hearing.' I believe, however, that the members of the Subcommittee are sufficiently knowledgeable in the ways of the world to realize that animals seldom die more than once. However, I would tend to agree with Searle here, that the state of their records on observations collected during the course of this study is indeed no laughing matter."

G.D. Searle [aspartame manufacturer] Pathologist:
"You should have seen things when this study was run -- there were five studies being run at one time -- things were a mess!"[9]

A few additional and alarming findings of the FDA Investigations of the aspartame manufacturer research:

1. "Excising masses (tumors) from live animals, in some cases without histologic examination of the masses, in others without reporting them to the FDA." Searle's representatives, when caught and questioned about these actions, stated that "these masses were in the head and neck areas and prevented the animals from feeding." [10, 11, 13]

   "Failure to report to the FDA all internal tumors present in the experimental rats, e.g., polyps in the uterus, ovary neoplasms as well as other lesions." [12]

2. G.D. Searle stored animal tissues in formaldehyde for so long that they deteriorated. [13]

3. Instead of performing autopsies on rhesus monkeys that suffered seizures after being fed aspartame, the company had financed a new monkey seizure study with a different methodology that showed no problems. [15]

4. "Reporting animals as unavailable for necropsy when, in fact, records indicate that the animals were available but Searle choose not to purchase them." [16]

5. “In the Aspartame 46 weeks hamster study, blood samples reported in the submission to FDA as 26 week values (for certain specified animals) were found by our investigators as being, in fact, values for different animals which were bled at the 38th week. Many of the animals for which these values were reported (to the FDA) were dead at the 38th week.” [14]

6. “Selecting statistical procedures which used a total number of animals as the denominator when only a portion of the animals were examined, thus reducing the significance of adverse effects.” [13]

7. G.D. Searle told the FDA that 12 lots of DKP were manufacturered and tested in one study, yet only seven batches were actually made. [14]

8. “Significant deviations from the protocols of several studies were noted which may have compromised the value of these studies . . . In at least one study, the Aspartame 52 weeks monkey study, the protocol was written after the study had been initiated.” [14]

9. “Presenting information to FDA in a manner likely to obscure problems, such as editing the report of a consulting pathologist . . . Reporting one pathology report while failing to submit, or make reference to another usually more adverse pathology report on the same slide.” [13]

10. Animals were not removed from the room during the twice per month exterminator sprayings. [14]

11. Often the substance being tested which was given to the animals was not analyzed or tested for homogeneity. No records were found to indicate that any treatment mixtures used in the studies were ever tested or assayed for pesticide content . . . Running inventory records for either treatment mixtures or the test compounds used in treatment mixtures are not maintained. [14]

12. In the Aspartame (DKP) 115 week rat study the written observations of the pathology report was changed by the supervising pathologist, Dr. Rudolph Stejskal even though he was not physically present during the autopsies and could not have verified the observations of the pathologist who did perform the autopsies. The pathologist who did perform some of the autopsies had no formal training for such procedures. [14]

13. “Contrary to protocol, slides were not prepared of this [unusual lesion] from the Aspartame (DKP) study) tissue for microscopic examinstions . . . .” [14]

14. “Searle technical personnel failed to adhere to protocols, make accurate observations, sign and date records, and accurately administer the product under test and proper lab procedures.” [13]

15. “[There were] clerical or arithmetic errors which resulted in reports of fewer tumors.” [13]

16. “[G.D. Searle] delayed the reporting of alarming findings.” [13]

> **FDA Toxicologist and Investigator, Dr. Adrian Gross:**
> *“At the heart of 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 (case of the) GD Searle Company, we have no basis for such reliance now. We have noted that Searle has not submitted all the facts of experiments to FDA, retaining unto itself the unpermitted option of filtering, interpreting, and not submitting information which we would consider material to the safety evaluation of the product . . . Finally, we have found instances of irrelevant or unproductive animal research where experiments have been poorly conceived, carelessly executed, or inaccurately analyzed or reported. Some of our findings suggest an attitude of disregard for FDA's mission of protection of the public health by selectively reporting the results of studies in a manner which allay the concerns of questions of an FDA reviewer.”*[17]

The manufacturer employee responsible for reviewing most of the reproduction studies had only one year of prior experience, working on population dynamics of cottontail rabbits while employed by Illinois Wildlife Service. In order to prepare him for this title of “Senior Research Assistant in Teratology” (fetal damage) the manufacturer bought him books to read on the subject and sent him to a meeting of the Teratology Society. The manufacturer claimed that this qualified him to submit 18 of the initial tests to the FDA, in addition to training an assistant and 2 technicians. He must have kept them busy because the manufacturer claimed that 329 teratology examinations were conducted in just 2 days.[18]

> **Dr. Gregory Palmer, scientific consultant to the aspartame manufacturer:**
> *“Even following the track you did, it seems to me you have only confounded the issue by a series of studies most of which have severe design deficiencies or obvious lack of expertise in animal management. Because of these twin factors, all the careful and detailed examination of fetuses, all the writing, summarization and resummarization is of little avail because of the shaky foundation.”*[19]

On January 10, 1977, the FDA Chief Counsel, Richard Merrill requested that the United States Attorney convene a Grand Jury to investigate apparent crimes of the aspartame manufacturer[20]:

> *“We request that your office convene a Grand Jury investigation into apparent 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, by G.D. Searle and Company and three of its responsible officers 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 the drug Aldactone and the food additive Aspartame."

In 1978, Dr. Jacqueline Verrett, an FDA Toxicologist and Senior Scientist at the FDA Bureau of Foods was appointed to lead a task force to review an FDA Investigation of the aspartame manufacturer. Below is an excerpt of testimony by Dr. Jacqueline Verrett in regards to several studies conducted by the aspartame manufacturer including one key study related to the aspartame metabolite "DKP" and cancer[21]:

1. *There was no protocol written until the study was well underway.*
2. *Animals were not permanently tagged to avoid mixups over the course of the study.*
3. *Changes were introduced in some laboratory methods during the study with inadequate documentation.*
4. *There was either sporadic or inadequate reporting and monitoring of both feed consumption and animal weights.*
5. *In some cases, tumors were removed, and the animals then returned to the study.*
6. *Animals were recorded as dead and then subsequent records, after varying periods of time, indicated the same animal was still alive--almost a certain evidence of mixup.*
7. *Many animal tissues, a significant number, were autolyzed, that is, decomposed, before any post mortem examinations were performed.*
8. *And finally, of extreme importance is that in the DKP study there was evidence, including pictures found in notebooks at Searle, that the diets were not homogeneous, and that the animals could discriminate between feed and the included particles of DKP. In other words, they may or may not have been eating what it was assumed they were eating.*

"Almost any single one of these aberrations would suffice to negate a study designed to assess the safety of a food additive, and most certainly, a combination of many such improper practices would, since the results are bound to be compromised."

Dr. Verrett was later quoted in the press as saying [22]:

"It seemed pretty obvious that somewhere along that line they (bureau officials) were working up to a whitewash. I seriously thought of just walking off of that task force. [Task Force members wanted to] just come out and say that this whole experiment was a disaster and should be disregarded."

Senator Edward Kennedy, United States Senate Hearings:
"The extensive nature of the almost unbelievable range of abuses discovered by the FDA on several major Searle products is profoundly disturbing." [23]

While numerous independent research studies have demonstrated that aspartame is a chronic poison and can cause a wide variety of toxicity symptoms, even one aspartame manufacturer study published by the EFSA demonstrates that aspartame may cause brain tumors as described by Dr. John Olney [24]:

> *"There were other problematic aspects of the brain tumor data. In the pre-1975 records that I reviewed, it was clear that several competent pathologists had carefully examined the original microscopic slides from the first study and agreed that there were 12 brain tumors in the NutraSweet-fed rats and zero brain tumors in the controls. When the FDA conducted a task force investigation of these laboratories in 1975, they singled out these studies for further investigation and ordered that all laboratory records, including microscopic slides etc. be impounded under FDA seal. Several years later when a group of pathologists (UAREP) was sent to authenticate these studies, they could not find the microscopic slides. The UAREP pathologists were finally taken to a laboratory where the slides were not supposed to be and there they found some but not all of the original slides. Clearly they had not been kept under FDA seal and by mysterious coincidence the slides that were finally presented to the UAREP pathologists contained evidence for 11 brain tumors in Nutrasweet-fed rats and 1 tumor in contols. It is important to recognize that if there are zero tumors in the controls, it is very difficult to argue that the tumor incidence in the control and Nutrasweet-fed rats is the same. But if there is 1 tumor in the control group, it is possible with statistical acrobatics to reach the conclusion that the incidence is the same. And, indeed, this is exactly the argument that the manufacturer and the FDA Bureau of Foods pressed at the Public Board of Inquiry. They accepted the finding of 1 brain tumor among the controls even though the authentic record showed zero brain tumors in the controls, then they proceeded to break down the animals into smaller and smaller sub groups according to sex, dose level etc. and finally the 1 brain tumor in one sub group of control animals appeared to be not significantly different from 2 or 3 tumors in each of the experimental sub groups. I seriously doubt whether this method of data analysis would stand the scrutiny of competent disinterested statisticians. Even more seriously I wonder why FDA allows microscopic slides to disappear (while supposedly impounded) and why they do not question the de novo emergence of a brain tumor among the controls when the slides reappear."*

Questions for the EFSA:

1. To help balance out EFSA's publication of 500 MB of aspartame manufacturer research, will the EFSA publish the full FDA Investigation reports led by Dr. Phillip Brodsky and by Dr. Jerome Bressler and have an equally prominent press release regarding these publications?

2. Will the EFSA disclose the funding source of the research it relies on in its report and whether the researchers have been paid consultants or employees of the

aspartame manufacturer or aspartame manufacturer trade groups such as International Life Sciences Institute (ILSI)?

3. Will the EFSA discuss the independent research demonstrating significant formaldehyde exposure and accumulation when ingesting aspartame. Will EFSA discuss the synergistic toxic effects of formaldehyde + excitotoxin exposure obtained from ingesting aspartame? Or will it rely primarily on comments by aspartame manufacturer consultants and public relations statements regarding fruit and methanol to dismiss this research?

Cited References:

1. Wilson, Steve, 1985. "Sweet Suspicions," Television broadcast and interviews regarding aspartame. Transcript reprinted in the U.S. Congressional Record (1985b, page S10826-S10827).

2. European Food Safety Authority (EFSA): Call for Scientific Data on Aspartame (E 951), aspartame industry research available on November 24, 2011 at: http://www.efsa.europa.eu/en/dataclosed/call/110601.htm . EFSA Press Release available at: http://www.efsa.europa.eu/en/press/news/111124a.htm .

3. Schmidt, Alexander M., 1976. Statement by Alexander M. Schmidt, Commissioner, U.S. Food and Drug Administration before the U.S. Senate Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, "Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 3," No. Y4.L11/2:P49/2/976/pt.3, CIS# S541-12, page 3-56. (Specific reference on page 3.)

4. Bressler Report (FDA Investigation) available online at the following web addresses:
http://www.mpwhi.com/complete_bressler_report.pdf
http://www.holisticmed.com/aspartame/complete_bressler_report.pdf
http://dorway.com/history-of-aspartame/the-bressler-report/
http://dorway.com/history-of-aspartame/the-bressler-report/the-bressler-report-continued/
Discussion of Bressler Report available on Page 497 of US Senate 1987. U.S. Senate Committee on Labor and Human Resources, November 3, 1987 regarding "NutraSweet Health and Safety Concerns." Document # Y 4.L 11/4:S.HR6.100.

5. Graves, Florence, 1984. "How Safe is Your Diet Soft Drink," Common Cause Magazine reprinted in the U.S. Congressional Record 1985. "Saccharin Study and Labeling Act Amendments of 1985," Congressional Record, Volume 131, No. 58, May 7, 1985, page S5489-S5519. (Specific reference on page S5497.)

6. Schmidt, Alexander M., 1976. Testimony of Alexander M. Schmidt, Commissioner, U.S. Food and Drug Administration before the U.S. Senate Joint Hearings before the

Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, “Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 2,” No. Y4.L11/2:P49/2/976/pt2, CIS# S541-82, page 4-49. (Specific reference on page 21.)

7. Graves, Florence, 1984. “How Safe is Your Diet Soft Drink,” Common Cause Magazine reprinted in the U.S. Congressional Record 1985. “Saccharin Study and Labeling Act Amendments of 1985,” Congressional Record, Volume 131, No. 58, May 7, 1985, page S5489-S5519. (Specific reference on page S5498.)

8. Gross, Adrian, 1976. Memorandum from Mr. Adrian Gross, Scientific Investigations Staff to Mr. Carlton Sharp, Chairman, Searle Investigation Task Force, March 15, 1976, Reprinted in U.S. Senate Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, "Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 3," No. Y4.L11/2:P49/2/976/pt.3, CIS# S541-12, page 310-376. (Specific reference on pages 353 - 359).

9. Graves, Florence, 1984. “How Safe is Your Diet Soft Drink,” Common Cause Magazine reprinted in the U.S. Congressional Record 1985. “Saccharin Study and Labeling Act Amendments of 1985,” Congressional Record, Volume 131, No. 58, May 7, 1985, page S5489-S5519. (Specific reference on page S5500.)

10. Schmidt, Alexander M., 1976c. Statement by Alexander M. Schmidt, Commissioner, U.S. Food and Drug Administration before the U.S. Senate Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, “Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 3,” No. Y4.L11/2:P49/2/976/pt.3, CIS# S541-12, page 3-56. (Specific reference on page 4.)

11. Buzzard, James A., 1976a. Testimony of James A. Buzzard, G.D. Searle, before the U.S. Senate Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, “Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 2,” No. Y4.L11/2:P49/2/976/pt2, CIS# S541-82, page 168.

12. Gross, Adrian, 1987. Letter from Dr. Andrian Gross, Former FDA Investigator and Scientist to Senator Howard Metzenbaum regarding pre-approval tests by G.D. Searle, October 30, 1987, Reprinted in US Senate 1987, page 430-439: US Senate 1987. U.S. Senate Committee on Labor and Human Resources, November 3, 1987 regarding “NutraSweet Health and Safety Concerns.” Document # Y 4.L 11/4:S.HR6.100. (Specific reference on page 437.)

13. Schmidt, Alexander M., 1976. Statement by Alexander M. Schmidt, Commissioner, U.S. Food and Drug Administration before the U.S. Senate Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, “Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 3,” No. Y4.L11/2:P49/2/976/pt.3, CIS# S541-12, page 3-56. (Specific references of pages 23-27.)

14. Gross, Adrian, 1985. Statement from Dr. Andrian Gross, Former FDA Investigator and Scientist, "Aspartame Safety Act," U.S. Congressional Record, Volume 131, No. 106, August 1, 1985, page S10835-S10840.

15. Gordon, Gregory, 1987. “NutraSweet: Questions Swirl,” UPI Investigative Report, 10/12/87. Reprinted in U.S. Senate Committee on Labor and Human Resources, November 3, 1987 regarding "NutraSweet Health and Safety Concerns." Document # Y 4.L 11/4:S.HR6.100, pages 483-510. (Specific reference on page 496.)

16. Schmidt, Alexander M., 1976. Statement by Alexander M. Schmidt, Commissioner, U.S. Food and Drug Administration before the U.S. Senate Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, “Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 3,” No. Y4.L11/2:P49/2/976/pt.3, CIS# S541-12, page 3-56. (Specific reference on page 5.)

17. Gross, Adrian, 1987. Letter from Dr. Andrian Gross, Former FDA Investigator and Scientist to Senator Howard Metzenbaum regarding pre-approval tests by G.D. Searle, October 30, 1987, Reprinted in US Senate 1987, page 430-439: US Senate 1987. U.S. Senate Committee on Labor and Human Resources, November 3, 1987 regarding “NutraSweet Health and Safety Concerns.” Document # Y 4.L 11/4:S.HR6.100. (Specific reference on page 431.)

18. Gross, Adrian, 1985. Statement from Dr. Andrian Gross, Former FDA Investigator and Scientist, "Aspartame Safety Act," U.S. Congressional Record, Volume 131, No. 106, August 1, 1985, page S10835-S10840. (Specific reference on page S10838.)

19. Gross, Adrian, 1985. Statement from Dr. Andrian Gross, Former FDA Investigator and Scientist, "Aspartame Safety Act," U.S. Congressional Record, Volume 131, No. 106, August 1, 1985, page S10835-S10840. (Specific reference on page S10838.)

20. Merrill, Richard, A., 1977. Memorandum from Richard A. Merrill, Chief Counsel, Food and Drug Administration to U.S. Attorney, Samuel K. Skinner, January 10, 1977, Reprinted in Congressional Record 1985b, page S10827-S10835. (Specific reference on page S10827.)

21. Verrett, Jacqueline, 1987. Statement of Dr. Jacqueline Verrett, Former Toxicologist, U.S. Food and Drug Administration before U.S. Senate Committee on Labor and Human Resources, November 3, 1987 regarding “NutraSweet Health and Safety Concerns.” Document # Y 4.L 11/4:S.HR6.100, page 383-390. (Specific reference on page 385.)

22. Gordon, Gregory, 1987. “NutraSweet: Questions Swirl,” UPI Investigative Report, 10/12/87. Reprinted in U.S. Senate Committee on Labor and Human Resources, November 3, 1987 regarding "NutraSweet Health and Safety Concerns." Document # Y 4.L 11/4:S.HR6.100, pages 483-510. (Specific reference on page 497.)

23. Kennedy, Edward M., 1976. Testimony of U.S. Senator Edward M. Kennedy at the U.S. Senate Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary, “Preclinical and Clinical Testing by the Pharmaceutical Industry, 1976, Part 3,” No. Y4.L11/2:P49/2/976/pt.3, CIS# S541-12, pages 1-2.

24. Olney, John W. 1987. Letter from Dr. John W. Olney, Neuropathologis, Washington University School of Medicine, to Senator Howard M. Metzenbaum, December 8, 1987, Presented in the record before the U.S. Senate Committee on Labor and Human Resources, November 3, 1987 regarding “NutraSweet Health and Safety Concerns.” Document # Y 4.L 11/4:S.HR6.100, page 468-476. (Specific reference on pages 473-474.)

The European food safety authority (EFSA) reconfirmed that aspartame was safe. Having reviewed the new Italian study, its scientific experts decided that it had a number of flaws that undermined the validity of its findings.Â The industry says the review closes the book on the safety of aspartame. "The opinion from EFSA is completely consistent with the global scientific consensus that aspartame is safe. Extensive scientific research over decades and regulatory reviews conducted by numerous national and international food safety authorities, together with a history of more than 20 years of safe use, support the conclusion that aspartame is safe," the Aspartame Information Service, an industry website says. The European Union's conclusion that a potentially dangerous weed-killer was in fact safe to sell was based on scientific evidence written by manufacturer Monsanto, an...Â EFSA's assessment was based on a report written by the German Federal Institute of Risk Assessment (BfR), which evaluated all available scientific literature on the herbicide. In one chapter of the BfR's report, the German agency uses the "ghostwritten" study to conclude the active ingredient glyphosate is "considered to be of low toxicological concern." Bigger not better for @MonsantoCo facing Roundup #glyphosate cancer lawsuits; court filing today notes at least 991 plaintiffs with remand? pic.twitter.com/KUQqvBOlMp. â€” carey gillam (@careygillam) May 1, 2017. The European Food Safety Authority (EFSA) is the responsible authority of European Union (EU) risk assessment for food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks. EFSA is an independent European agency funded by the EU budget that operates separately from the European Commission, European Parliament and EU Member States. Independent scientific advice on food and feed safety. The European Food Safety Authority (EFSA) was establ