United States Senate
COMMITTEE ON THE BUDGET
WASHINGTON, D.C. 20510

February 3, 1986

The Honorable Strom Thurmond
Chairman, Senate Judiciary Committee
Russell Senate Office Building
Room Number 218
Washington, DC 20510

Dear Strom:

NutraSweet, manufactured by the G.D. Searle Company, is currently being consumed in ever-increasing amounts by over 100 million Americans. Last year, Americans consumed over 20 billion cans of diet soft drinks, the vast majority of which were sweetened with 100 percent NutraSweet. The average consumer assumes that all safety questions surrounding this sweetener had been resolved long before it found its way onto every grocery shelf in America.

A recent investigation undertaken by my office raises serious questions as to whether this is, in fact, the case. These questions can only be resolved by Congressional hearings, with full subpoena power, being undertaken by the Senate Judiciary and Labor Committees.

In addition, the facts uncovered by my investigation coupled with concerns expressed in the scientific community regarding the safety of this food additive, compel the immediate initiation of new, truly independent safety tests on NutraSweet.

My concern focuses on the failure of the U.S. Attorney's Office in Chicago to undertake a grand jury investigation of NutraSweet which was requested by the Food and Drug Administration. The investigation was to focus on possible criminal charges against officials in the G.D. Searle Company

"for concealing material facts and making false statements" in reports of safety tests on NutraSweet and the drug, Aldactone. (Doc # 1).

NutraSweet was first approved by the FDA in July, 1974. However, concerns about the credibility of Searle's tests led the FDA to stay that approval in December, 1975. In 1976, an FDA Investigation Task Force published a report on the testing practices at G.D. Searle Company and concluded: "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 G.D. Searle Company, we have no basis for such reliance now." (Doc # 2).

One of the recommendations of the FDA's 1976 Task Force Report was that the agency should ask the U.S. Attorney in the Northern District of Illinois to institute grand jury proceedings against G.D. Searle.

It is a matter of public record that in January, 1977, the FDA formally requested that the U.S. Attorney conduct a grand jury investigation of tests on two Searle products: NutraSweet and Aldactone, a drug to treat hypertension. It is also known that the U.S. Attorney declined to prosecute in December, 1978. What has not been publicly known until now is what happened in between.

Following an investigation by my office, the following facts have been established.

- The first U.S. Attorney in charge of the case Samuel Skinner did not convene a grand jury. A year after he was initially informed of FDA's interest in prosecuting Searle, and two months after he received the agency's formal request for grand jury action, he "recused" himself from the case, citing preliminary employment discussions with the law firm of Sidley and Austin, the firm which was then defending Searle in the investigation. He asked his subordinates to keep his discussions confidential "to avoid any undue embarrassment upon the firm of Sidley and Austin." (Emphasis supplied).(Doc # 10). Mr. Skinner joined Sidley and Austin four months later.

- Sidley and Austin requested a meeting with Mr. Skinner "prior to the submission to the grand jury of any matters relating to this company" (Doc # 6). When the meeting was held, Mr. Newton Minow attended (Doc # 7). Mr. Minow is the partner at Sidley and Austin who offered Mr. Skinner his job with the firm (Doc # 8). The meeting was held a month prior to Mr. Skinner "recusing" himself from the case.

- In his recusal letter, Mr. Skinner stated his understanding that the decision as to whether or not a grand jury investigation should be conducted would await the arrival of a new U.S. Attorney. (A period which lasted four months). (Doc # 10).

- Reacting to Mr. Skinner's recusal, Mr. Kocoras, an Assistant U.S. Attorney, stated "it would be inappropriate to refrain from conducting necessary investigation by the grand jury during the substantial period of time" which would transpire before the appointment of a new U.S. Attorney. (Doc # 11).

- However, no grand jury action was taken before the appointment of a new U.S. Attorney.

- This four month delay in the grand jury investigation took place at a time when nearly four and a-half years of a five year statute of limitations on the NutraSweet tests cited by the FDA had already expired.

- Shortly after the appointment of the new U.S. Attorney, Mr. Thomas Sullivan, the FDA wrote to Justice noting the delays which had occured in the case and urged the U.S. Attorney to "proceed expeditiously." The FDA also cited additional problems they had discovered with a key NutraSweet safety test and noted "further criminal culpability -- the failure to report these problems to the FDA -- may also be revealed which could require submission to the grand jury." (Doc # 16).

- The Justice Department also wrote to Mr. Sullivan a month after he assumed office complaining about the amount of time which had transpired on the case. Letter states Justice knows of no reason why "grand jury should not at least investigate." (Doc # 17).

- By the time any case against Searle was presented to the grand jury, NutraSweet was dropped from the investigation. This means the issue of whether tests on Nutrasweet were fraudulent, which was raised by the 1976 Task Force Report, was never put to the grand jury.

- We have been informed by Justice there is no record of the U.S. Attorney writing to the FDA to inform the agency that the investigation would proceed on Aldactone alone..

- According to a Justice Department memo, (Doc # 21), Mr. William Conlon, the Senior Assistant U.S. Attorney assigned to the Searle case "reduced or ended" his involvement in the investigation eighteen months after first being assigned to the case. One year later he accepted a position with Sidley and Austin, the firm which represented Searle in the investigation. (Doc # 27).

- Key seizure test on NutraSweet was never investigated by grand jury. During a Searle sponsored monkey test, all the animals receiving medium or high dosages of NutraSweet experienced Grand Mal Seizures (Doc # 28). Searle never performed autopsies. The FDA said Searle made at least four false statements and entries in the report of the study. (Doc # 1). Though the FDA later claimed it did not rely on the study to prove safety, the seizures were never explained. Failure to account for these seizures is of particular significance given current concerns expressed in the scientific community on precisely this issue. In the November 9, 1985, edition of Lancet, a recognized authority on brain chemistry, Dr. Richard Wurtman, cited case studies which suggest an association between NutraSweet and Grand Mal seizures. (Doc # 29).

- Test on key breakdown component of NutraSweet, DKP, was never investigated by grand jury. In July, 1977, the FDA wrote to justice telling them that FDA inspectors were reviewing a key test on DKP, which raised issues that "could require submission to the grand jury." The U.S. Attorney never submitted the test to the grand jury. In the conduct of the study tissue masses were not reported and uterine polyps were discovered. (Doc # 30).

- It is a matter of public record that back in 1970, the G.D. Searle Company drew up a "strategy memo" on how to get NutraSweet approved by the FDA. In the memo, they committed

themselves to obtaining a favorable review of NutraSweet by seeking to develop within FDA personnel a "subconscious spirit of participation" in the Searle studies. The memo emphasized the importance of getting the FDA in the "habit of saying yes", by first submitting to FDA those safety issues involving little or no breakdown of NutraSweet into DKP. (Doc # 31).

- In-House FDA memos showing credibility of key tumor tests were questioned by FDA scientists prior to Commissioner Hayes' approval of NutraSweet. The problems with the credibility of Searle's tests on NutraSweet continued right up to the time FDA Commissioner Hayes overruled a public board of inquiry and approved the food additive in 1981.

Two months prior to approval, the Commissioner was advised by three of his own scientists that three key tumor tests, including the test on DKP, were questionable and that safety had not been proven. (Doc # 26).

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I am attaching to this letter a time-line which will highlight the sequence of these events. I am also including an extensive list of documents relating to the grand jury investigation. These documents raise the question as to whether the investigation of the G.D. Searle Company and in particular, the food additive, NutraSweet, was properly conducted.

We will not be able to answer that question without Congressional hearings, with full subpoena power.

As I mentioned earlier, NutraSweet is a product currently being used by 100 million Americans. The fact that a grand jury never investigated charges that Searle concealed "material facts" and made "false statements" (Doc # 1) on NutraSweet tests is a matter of serious concern. One can only speculate on what a grand jury with full investigative powers would have uncovered and how that information in turn would have affected the credibility of those tests in the approval process.

There are also the concerns being voiced by scientists over whether key questions of safety have been adequately resolved.

I am including a brief synopsis of recent scientific work raising questions about NutraSweet.

In conclusion, we have a grand jury which never investigated whether criminal fraud was committed on NutraSweet tests, coupled with continuing concerns being expressed in the scientific community regarding this food additive's safety.

I urge you, Strom to hold oversight hearings on how this grand jury investigation of Searle was conducted. Only by resolving this issue can we hope to dispel the cloud handing over a food additive presently being consumed in massive quantities by the American people.

Very sincerely yours,

Howard M. Metzenbaum
United States Senator

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Enclosures