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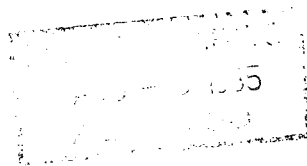
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(A) provide new budget authority or spending authority described in section 401(c)(2)(C) of such Act;

(B) relate to revenues; or

(C) specify the amount of the statutory limit on the public debt.

(7) section 405 of such Act, as added by section 4(q) of this Act, shall apply with respect to fiscal year 1988; and

(8) section 1104(c)(2) of title 31, United States Code, as added by section 5(b) of this Act, shall apply with respect to fiscal year 1988.

By Mr. METZENBAUM:

S. 1557. A bill to provide the public with information concerning the use of products containing aspartame, to provide for the conduct of studies to determine the health effects of using products containing aspartame, and for other purposes; to the Committee on Labor and Human Resources.

ASPARTAME SAFETY ACT

Mr. METZENBAUM. Mr. President, today I am introducing a bill entitled "the Aspartame Safety act of 1985." I consider this legislation the absolute minimum that Congress needs to do in order to protect the health and safety of the 100 million American consumers who are using this chemical sweetener under its better-known brand name of "NutraSweet."

In 1984, Americans consumed over 7 million pounds of aspartame, which is equivalent to 1.4 billion pounds of sugar. This year we will consume over 20 billion cans of diet soft drinks, the vast majority of which are 100 percent NutraSweet. We had better be sure that the questions which 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 which can only be described as troubling. The FDA originally approved aspartame in 1974. However, that decision was stayed after concerns were raised about health and safety problems. In March of 1976 a special FDA task force released its report on testing practices at G.D. Searle Co., the manufacturer of aspartame. That report contained the following conclusions:

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.

Through our efforts, we have uncovered serious deficiencies in Searle's operations and practices which undermine the basis for reliance on Searle's integrity in conducting high quality animal research to accurately determine or characterize the toxic potential of its products.

"... The studies we investigated reveal a pattern of conduct which compromises the scientific integrity of the studies."

Now, Mr. President, one might ask what does a 1976 report on testing practices at G.D. Searle have to do with aspartame, a chemical sweetener approved by the FDA in 1981? The answer is simple. Over 90 percent of the tests submitted by G.D. Searle to

the FDA in order to get aspartame approved were submitted prior to March 1976, when the report was issued. In addition, of the 25 Searle tests examined by the FDA task force, 11 were tests done on aspartame. One of the major questions hanging over the approval process is this question of how the FDA resolved the issues raised by its own task force in 1976. There are serious questions about the quality of tests used to approve this chemical sweetener.

Mr. President, the questions do not stop with the 1976 task force report. For in 1977, the FDA wrote to the U.S. attorney in Chicago requesting a grand jury investigation of G.D. Searle Co. I quote from the letter sent by the chief counsel of the FDA, Richard Merrill:

We request that your office convene a grand jury investigation into apparent violations of the Food, Drug, and Cosmetic Act . . . and the False Reports to the Government Act, 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, 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 1980, the FDA established a public board of inquiry on aspartame. What did they conclude? "The Board has not been presented with proof of a reasonable certainty that Aspartame is safe for use as a food additive under its intended conditions of use."

In May 1981, 2 months before the FDA Commissioner, Arthur Hayes, approved aspartame for use in dry foods, three FDA scientists informed the Commissioner that they did not believe that aspartame had been proven safe beyond a reasonable doubt. They questioned the reliability of key brain tumor tests which were submitted by G.D. Searle. These three FDA scientists comprised half of the so-called "Commissioner's Team" which was set up to advise the Commissioner on aspartame approval.

Despite all the questions raised by the chronology I have outlined, the FDA Commissioner decided to approve aspartame in July of 1981. He later approved aspartame for use in soft drinks in July 1983.

In May of this year I asked the GAO to undertake a full investigation of the aspartame approval process. That investigation is now under way and I have high hopes that it will shed some light on the questions surrounding the Commissioner's decision to approve this product.

Pending the completion of that report, however, there are a number of steps which Congress should take with relation to aspartame. The bill I am introducing today outlines the minimum steps I feel are necessary.

The bill mandates that independent tests on aspartame be conducted under the auspices of the National Institutes of Health. These tests will focus on

the general effects which aspartame has on brain chemistry as well as the specific behavioral and neurological reactions experienced by individuals—headaches, mood alterations, memory loss et cetera.

The tests will also examine the health effects of aspartame on pregnant women and fetuses and whether aspartame consumption can lower the threshold for seizures. Another important area for investigation is how aspartame reacts to medicines particularly MAO inhibitors which are used in the treatment of depression, dopa used in the treatment of Parkinson's disease, and aldomet used in the treatment of hypertension.

Under the bill, there will be a moratorium imposed on new uses of aspartame in foods and drugs pending the completion of independent test or for the period of 1 year—whichever comes sooner.

These are credible questions which have been raised by eminent scientists, regarding aspartame.

Dr. Richard Wurtman of MIT has examined questions relating to aspartame's effect on brain chemistry. Dr. William Pardridge of UCLA has expressed his concerns about fetal IQ. Dr. Elsas of Emory University has warned us about groups in the population at high risk from large concentrations of phenylalanine in the blood. Dr. Matalon at the University of Illinois is particularly concerned about individuals who are genetically susceptible to phenylalanine—PKU carriers—and who may be a sizable risk group as far as aspartame is concerned. Nearly 5 million Americans are PKU carriers.

Two researchers in Philadelphia, Profs. Gautieri and Mahalik, have done studies on mice which show that aspartame affected the vision of newborn mice whose mothers had been exposed to the chemical sweetener.

Mr. President, I ask unanimous consent that reports and statements concerning these scientists be placed in the RECORD following my statement.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. METZENBAUM. Mr. President, one final point concerning tests. The Journal of the American Medical Association recently published a report on aspartame which, with some significant disclaimers, stated it was safe for most people. I wish that this report could ease my concerns. It does not. It merely restates the FDA position which relies solely on the tests conducted by G.D. Searle. As I have indicated, these tests are under a cloud. In addition, the concerns raised recently by the scientists I mentioned above were not even considered in the report.

Mr. President, the FDA is content to have the manufacturer of aspartame, G.D. Searle, conduct these studies. How absurd. We do not need the

people who are making millions of dollars on aspartame telling us it's safe.

Has the FDA forgotten that in 1977 it sought to have a grand jury investigation into allegations that Searle conducted fraudulent tests on aspartame? Doesn't anyone in the agency know they are presently considering prosecuting that company for withholding information on adverse effects from another one of their drugs, Theo-24?

It is a sad fact that the current FDA is a mere shadow of what that agency used to be. Now it is more of a handmaiden to the food and chemical industry than it is a defender of the health and safety of American consumers.

In addition to mandating independent tests, my bill will require labeling which will inform consumers how much aspartame they are ingesting. This information is important not only for consumers who wish to regulate their intake of aspartame but also for physicians who may be treating individuals who feel they have experienced side effects. Such side effects are likely to be dose related and the physician will want to know how much aspartame has been consumed. In addition, consumers have a basic right to know the makeup of the foods which they consume.

The label will also contain the maximum allowable daily intake established by the FDA. How many consumers even know that the FDA has attached such a limit to aspartame consumption? The current ADI is 50 mg per kg. of body weight. It was originally 20 mg/kg. However, in 1983 the FDA decided to ignore its standard 100-fold safety factor by more than doubling the maximum allowable daily intake. Why did they decide to make an exception for aspartame? In 1983, they approved aspartame for soft drinks, so they decided to increase the limit knowing consumption was bound to increase. The justification the FDA used for violating its standard 100-fold safety factor was that the tests showed it was safe at the new levels of consumption. And guess who was responsible for all the tests—G.D. Searle Co., of course.

I intend to fully investigate the manner in which the FDA altered its safety standard for this product. In the meantime, consumers have a right to know at least that some such standard exists. Sure, if you weigh 130 pounds you would have to drink 4 to 5 liters of diet soft drink to hit the limit. But if you are a child who weighs 30 pounds, you hit that limit with 3 to 4 cans of diet soft drink. That's even without the gum, pudding, breakfast cereal—all sweetened with aspartame.

Under this bill, the Secretary will be responsible for deciding how best to express the ADI on the label so consumers can understand what it means. For example, on diet soft drinks the label might read: "Maximum Allowable Daily Intake: 3 cans per 25 lbs. of body weight." There may be better

ways to express this concept. The Secretary can work on that but consumers have a right to this information particularly since the advertising for this product has left the impression that everyone in the population, including children, can consume as much as they want of this chemical sweetener and still remain within the standard FDA recommended range of a 100-fold safety factor.

My bill designates one other labeling requirement. The label will advise that aspartame is not intended for infant feeding.

Mr. President, I would like to quote from an FDA document dated February 28, 1980:

Nevertheless, in consideration of the remote possibility that a parent might use aspartame as a non-sugar sweetener in the infant formula or food, there may be some merit in the inclusion of a statement on the label to the effect that aspartame-containing foods are not intended for use in infant feeding. Such labeling may provide added assurance that aspartame will not be fed to infants.

Did the FDA ever follow up on this recommendation? Of course not. Too troublesome for industry. How remote is the possibility that a parent will give nutrasweet to a child? A little diet coke in a bottle? Some pudding? A little kool-aid? Maybe some cereal?

This bill ensures that parents will know that aspartame-containing foods are not intended for infant feeding.

Finally, Mr. President, my bill will establish a Clinical Adverse Reaction Committee within the FDA. Consumers who feel they have experienced side effects from aspartame should have the right to have their complaint investigated.

The FDA claims such complaints have declined to almost zero. Isn't that interesting. What the FDA doesn't tell us is that since February of 1984, G.D. Searle has not forwarded any complaints they have received to the FDA. In addition, we learn that the FDA informed its regional office to forward only "serious complaints." IEA complaint sever enough to require the attention of a physician. And did the FDA notify physicians that they were interested in collecting and analyzing reports of adverse reactions to aspartame? Absolutely not. So how are physicians to know they should even be notifying the FDA of such reports? The only notification physicians around the country have received is a medical bulletin from G.D. Searle quoting the FDA that aspartame is completely safe.

Now, however, the FDA has informed myself and Senator HEINZ that they are considering establishing a Clinical Adverse Reaction Committee to collect and evaluate reports of side effects.

This bill makes it easy for the FDA. It mandates the FDA to collect and study reports of side effects and to alert physicians around the country that they are interested in knowing about such reactions.

Only then can we get an accurate picture of the problem.

Mr. President, I said at the outset this bill represents a minimum response to the questions which surround a response to the FDA which recently sent me a letter rejecting proposals for labeling and informing me that G.D. Searle's tests are insufficient to settle the questions raised.

To put it mildly, that response was totally unsatisfactory. We have an agency desperately attempting to explain away its unwillingness to protect the safety of American consumers. Clearly, at today's FDA politics and ideology come before the public health.

I know there are career FDA personnel who are committed to doing a good job. They are trying to be honest and professional. Their task is becoming impossible under the weight of leadership which has raised political interference to an art form. On the issue of aspartame, as on the issue of food dyes and infant formula, there are those of us in Congress who will not rest until this agency meets its responsibilities to the American consumer. That, I can promise.

Mr. President, I ask unanimous consent that the text of the bill, the letter, and scientific studies mentioned during my remarks, and other supporting materials be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 1557

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Aspartame Safety Act of 1985".

LABELING REQUIREMENTS

SEC. 2. (a) Section 403 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new paragraph:

"(q)(1) If it contains aspartame, unless its label and labeling—

"(A) specify the total number of milligrams of aspartame contained in each serving;

"(B) specify the allowable daily intake of aspartame (in milligrams) for each kilogram of human body weight, as established by the Secretary; and

"(C) bear the following statement: 'THIS PRODUCT CONTAINS ASPARTAME, WHICH IS NOT INTENDED FOR USE IN INFANT FEEDING'".

"(2) The Secretary shall by regulation require that the information required by subparagraph (1)(B) to be specified on the label and labeling of any food containing aspartame be included on such label and labeling in a manner which is the most useful to individuals who consume such food.

"(3) The statement required by subparagraph (1)(C) shall be located in a conspicuous place on the label and labeling of each food containing aspartame as proximate as possible to the name of such food and shall appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling."

