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CONGRESSIONAL RECORD — SENATE

S 5489

Mr. DOMENICI. I see no reason whatsoever. The President has twice sent the compact to the Congress and I would strongly resist any implication that he has not sincere in doing so. In the discussions with the administration leading to this resolution, the original assumption contained in the President's budget that funding would occur in function 350 in the Department of State was dropped by the administration. The assumption of this resolution is the same as has twice been agreed upon by the Budget Committee, and that is that funding for the freely associated states will continue in function 800 in the Department of the Interior. I can not conceive of the Department of the Interior, with the full support of the Office of Management and Budget, not transmitting the necessary supplemental in sufficient time for enactment prior to fiscal year 1986. I would like to commend the Senator for his strong support for the compact, and it is a tribute to him and also to the distinguished Senator from Louisiana, Senator JONESTON, that the compact has twice been reported unanimously to the Senate. I look forward to its early passage as reported by the committee and can assure the Senator of my full support in enactment of the necessary supplemental which the President will request.

SACCHARIN STUDY AND LABELING ACT AMENDMENTS OF 1985

The PRESIDING OFFICER. Under the previous order, the hour of 4 p.m. having arrived, the Senate will turn to the consideration of S. 484, which the clerk will state by title.

The assistant legislative clerk will read as follows:

A bill (S. 484) to amend the Saccharin Study and Labeling Act.

The Senate proceeded to consider the bill which had been reported from the Committee on Labor and Human Resources, with an amendment:

On page 2, line 3, strike "1985", and insert "1987".

So as to make the bill read:

S. 484

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 1 of the Saccharin Study and Labeling Act (21 U.S.C. 348 nL) is amended by striking out "During the period beginning on the date of enactment of this Act and ending twenty-four months after the date of enactment of the Saccharin Study and Labeling Act Amendment of 1983" and inserting in lieu thereof "During the period ending May 1, 1987".

Mr. HATCH. Mr. President, I bring to the floor for final consideration S. 484, which extends the Saccharin Study and Labeling Act for 2 years. It is subject to a time agreement worked out between myself and the committee majority.

The Labor and Human Resources Committee ordered the bill reported on April 17, 1985 without opposition.

The Saccharin Study and Labeling Act was passed in 1978 in response to a proposal by the Food and Drug Administration to remove saccharin from the market. This proposal followed a study report implicating saccharin in increased bladder tumor incidence in rats. At that time saccharin had been in use as an artificial sweetener for over 80 years and had never been causally linked to any illness or death in humans. It was an important factor in the physical and emotional health of diabetics and others who need to control their weight or caloric intake.

The FDA proposal prompted considerable congressional interest. After pursuing its own inquiry, Congress felt that the evidence at that time was insufficient to conclude that saccharin was a significant health risk in humans, and found that it conferred real benefits on a significant portion of the population. Congress response was the Saccharin Study and Labeling Act, which forbade FDA from moving against saccharin solely on the basis of data available when it was enacted. This step clearly conveyed to FDA Congress' intent that the agency have more solid and substantial evidence of a human health risk before it restricted or eliminated the use of the sweetener.

Despite the passage of 7 years, the essential conditions have not changed, thus S. 484's extension of the act is completely appropriate. Specifically, though several important studies have been completed since that time, no scientists at the hearing on the bill felt that saccharin has been demonstrated to be a significant human health risk or that the current evidence warrants its removal from the market. Additional studies are currently underway to try to determine saccharin's mechanism of action in humans. But 7 years after passage of the original act, there is still no evidence that saccharin is a carcinogen in humans, despite an unusually long marketing history. And the Commissioner of the Food and Drug Administration testified:

(As in the past, we still do not adequately know the answer to all of the questions and uncertainties giving rise to the original 1977 saccharin moratorium. The actual risk, if any, of saccharin to humans still appears to be slight, however.

Further, saccharin's importance to the health of diabetics and others, while somewhat diminished in several applications by the availability of aspartame, remains significant. Thus, the American Diabetes Association and the Juvenile Diabetes Foundation, among others, support the extension.

I note in conclusion that the so-called moratorium in the Saccharin Study and Labeling Act is not absolute, but simply imposes certain limitations on regulatory action against the sweetener. Should information come available during the next 2 years

demonstrating a public health risk from continued use of saccharin, under S. 484 the FDA retains the authority to take regulatory action.

Thus I have no hesitation in asking my colleagues to support this bill. It is a bipartisan bill, and it is passed out of committee without an opposing vote.

We have agreed to a time agreement on this bill with one amendment.

Mr. President, I reserve the remainder of my time.

Mr. KENNEDY addressed the Chair. The PRESIDING OFFICER. Who yields time?

Mr. METZENBAUM. Mr. President, I yield the Senator time.

Mr. KENNEDY. Mr. President, I support this bill to extend the Saccharin Study and Labeling Act.

Saccharin is an important part of the diets of many Americans who need to avoid sugar intake. It is particularly important for diabetics.

While some things have changed in the artificial sweetener field since the last extension of this legislation—including the development of aspartame and new studies suggesting cyclamates may not be carcinogenic—there does not appear to be a fully satisfactory substitute for saccharin currently available.

The committee hearings we held reinforced my belief that an extension of the saccharin ban moratorium is appropriate at this time.

Senator METZENBAUM will be offering an amendment to require quantity labeling of aspartame in soft drinks. While the FDA has found aspartame to be generally safe, the center for disease control has recommended that further tests of aspartame be conducted to determine whether some groups may suffer harmful effects from aspartame consumption—particularly at high dose levels.

Our committee report mandates that these tests occur. It seems to me appropriate that consumers should be able to monitor their own consumption of aspartame.

Mr. President, I hope that the Members of this body will support Senator METZENBAUM's amendment to insure that the consumers of this country would be able to make that determination in terms of their own consumption.

Mr. President, on the bill itself, was there not time yielded to the Senator from Massachusetts?

The PRESIDING OFFICER. I did not catch the request of the Senator from Ohio.

Mr. KENNEDY. On the bill itself, is not the time divided between the Senator from Utah and the Senator from Massachusetts?

The PRESIDING OFFICER. It is divided between the Senator from Utah and the Senator from Ohio or their designee. I did not catch how much time the Senator from Ohio yielded.

Mr. KENNEDY. I thank the Chair.

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Mr. METZENBAUM. Mr. President, I appreciate the support of the distinguished Senator from Massachusetts, whose record in the field of health legislation is second to none in this Congress. We have before us the bill to extend the period of exemption from the Delaney Act for the continued use of saccharin. I supported that extension because the distinguished chairman of the committee was kind enough to set a hearing not alone on the issue of saccharin but on the issue of saccharin and other sweeteners, including cyclamate and aspartame.

Out of that hearing, the Committee concluded that there should be an extension of the saccharin exemption, not for 3 years but for 2 years. In addition, the Committee provided that the Food and Drug Administration must report to the Congress on how the label laws for saccharin are being observed. It is a fact that some companies are complying with the law while others are not. For others it is a question of degree—some labels are in typeface so tiny that it is almost impossible to read.

The real issue that we have before us here today, Mr. President, relates to the aspartame labeling amendment which I shall shortly send to the desk. What this amendment would do is amend the Saccharin Study and Labeling Act to provide that any soft drink which contains aspartame shall state the total number of milligrams of aspartame contained in such serving of such soft drink.

I want Members of this body to understand where we stand on this issue. I shall not raise my voice during this debate. I shall not implore Senators to vote for my amendment. I shall ask them only to consider the merits of the issue. If they consider the merits of the issue, then they have to vote for the amendment because, on the merits, people have a right to know how much aspartame is in the product that they are drinking. That is all.

Nobody is saying that consumer cannot use aspartame. I point out to my colleagues that, as a matter of fact, the National Soft Drink Association, the organization that represents all of the soft drink people, at one point was prepared to take a position totally opposed to the use of aspartame in soft drinks. They never took quite that position as I shall discuss later.

Mr. President, if this amendment passes, the industry will have 18 months to implement its provisions. We are willing to give the industry adequate time to make the changes on the cans so that people may learn what is in the product that they are ingesting.

Mr. President, let me at the beginning deal with a prevalent misconception about this amendment. Lobbyists have been on the telephone, scurrying around all over the Hill, calling Members of this body, telling everyone that this amendment will, in some way, injure the bill. They have indicated

that there is an urgent need for the saccharin extension and that my amendment will slow the bill down and even kill it.

I want Members of this body to understand that that claim is totally absurd. The FDA Commissioner, Dr. Young, testified at our hearing as follows:

I must emphasize that even if the ban were not extended, it would take a period of time for FDA to evaluate its action and then proceed through preliminary and final rulemaking which would be in itself, a couple of years' process . . . with the most rapid action it is 180 days to a year.

It appears my colleague, with whom I worked very well, the chairman of the committee, wrote a letter on this subject. He indicated in that letter that the attachment of my amendment to this bill would jeopardize the bill's fate in the House. I thought that was an important statement for him to be making, so I called the distinguished chairman of the House committee having jurisdiction over this matter.

I am pleased to report to my colleagues that he does not confirm that it would cause delay. Actually, he said that until he knows what the amendment specifically provides, he is hardly in a position to make any such indication. However, there is certainly no indication that it would kill the bill.

Mr. SIMON. Would my colleague yield for 1 minute?

Mr. METZENBAUM. I do indeed yield.

Mr. SIMON. I thank him for yielding.

Mr. President, I think the point he made a moment ago needs underscoring. He mentioned lobbyists contacting Members of the Senate on his amendment. They were contacting on the basis that he had a 6-month time limitation. In fact, with that 18 months, there should be no difficulty for any bottler to accommodate to this reality. It just seems to me that the Senator's amendment can do no harm and very well may do some good in safeguarding the people of this country, particularly some who may have some very real problems with this particular ingredient.

Mr. METZENBAUM. Mr. President, I very much appreciate the comments and the support of my friend and colleague from Illinois. I have no reservation in saying that, indeed, at one point, we were contemplating 6 months.

The Senator from Illinois had indicated his concern about that being too short a period of time. I agreed with the Senator's contention, and therefore I put in the 18-months figure. However, the issue is not so much how long the industry will have to implement the amendment. The issue is can we prevail upon the industry to disclose how much aspartame is in the can or the bottle?

Mr. SIMON. I thank the Senator from Ohio.

In his leadership on this matter as in many others, I have referred to him, half in jest and half not in jest, as the tiger of the Senate. He is that. He gets hold of an issue and fights for the cause. He has been fighting for the health of the people of this country. I commend him, and I am pleased to support his amendment.

Mr. METZENBAUM. I appreciate the support of the Senator from Illinois, who has served well and with distinction in the Congress of the United States, and we are happy to have him in this body.

Mr. President, I should like now to get to address the substance of this issue.

During the committee hearing, we had an aspartame scientific panel as well expert FDA testimony on aspartame. Aspartame issues were examined in extensive detail. This amendment evolved from that hearing and I would now like to offer three basic reasons for its passage.

Reason No. 1 is the consumer's right to know. People have a right to know about the makeup of the products they consume. It is no secret that the distinguished Senator from Florida [Mrs. Hawkins] and I have a bill pending which has to do with the labeling of products generally.

Reason No. 2, the FDA as well as doctors around the country have received hundreds of complaints from people who believe that they have had adverse physical reactions to NutraSweet.

Professor Wurtman of MIT made a very strong case at the hearing for quantity labeling, on the basis that physicians treating these complaints would at least know how much has been consumed. They will be able to take into consideration, in making their diagnosis, whether the taking or the use of aspartame was a factor.

Professor Wurtman also argued that those with symptoms who consumed large amounts of NutraSweet will be able to gauge their consumption, and those who think they have symptoms but in reality have consumed only small amounts of NutraSweet would be able to stop worrying.

Third, significant medical and safety questions have been raised about NutraSweet, and I will get into some of those questions as we proceed in the debate this afternoon.

Clearly, we need to provide people with more information about this product than they already have. With respect to the criteria of aspartame or NutraSweet safety, the food and safety law is clear. The Government does not have to prove that a particular food additive or artificial sweetener is harmful. The Government does not have that burden of proof. The manufacturer must prove that it is safe and that there is reasonable certainty that no harm will result from its use.

I should like to share with my colleagues the history of NutraSweet. In

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1977, the Food and Drug Administration recommended that Searle—it is their product—be brought before a grand jury, on the basis that its testing procedures were irregular and that false statements were made. It was the FDA that made that recommendation. These tests included many of the key NutraSweet tests.

In 1980, a public board of inquiry recommended that NutraSweet not be approved until further tests on brain tumors could be dealt with. The FDA Commissioner rejected that finding and approved NutraSweet. I will return to that issue at a later point in the debate.

At the hearing, we referred to in-house FDA memos which showed that three of the six FDA scientists advising the Commissioner, the so-called Commissioner's team, recommended that NutraSweet not be approved because certain tests were still dubious. We have, in addition, the concern expressed by Dr. Wurtman about the effects on brain chemistry of aspartame, concerns which the Soft Drink Association itself cited in its draft objection to NutraSweet in 1983. I will return to that draft objection of the Soft Drink Association subsequently, as well.

Clearly, questions surround this product.

In addition to those questions having to do with the testing and approval of NutraSweet, there is also the issue of the ADI for NutraSweet, or the acceptable maximum daily intake.

I should like to quote from an FDA memorandum dated January 8, 1983:

The Bureau of Foods had previously evaluated the results of data from an extremely comprehensive animal testing program and established the acceptable maximum daily intake, the ADI, for aspartame to be 20 milligrams per kilogram of body weight per day. This figure is based on application of a hundredfold safety factor to the no-effect dose, 2,000 milligrams per kilogram, in a chronic rat study.

What does that mean? It means that the FDA normally applies a hundred fold safety factor to regulated food additives. In the case of aspartame, they made an exception. They increased the ADI to 50 milligrams per kilogram, and they said they had the tests to prove that this could be done safely.

What does an ADI really mean?

What an ADI means is this: If you weigh 150 pounds, you would have to drink 17 cans of diet soda with 100 percent NutraSweet to hit the acceptable maximum daily intake.

I do not really believe that many people drink 17 cans of diet soda with 100 percent NutraSweet and hit the ADI. However, if you are a child weighing 25 to 30 pounds, you would hit that limit with three or four cans of soda. That is not something that is going to happen to all kids. But certainly large numbers of children are likely to consume NutraSweet at these levels.

Nobody is saying that someone is going to keel over if they exceed the

ADI on a given day. But with all the concerns raised about the safety of NutraSweet, does it not make sense, is it not logical, for individuals and their physicians to know how much NutraSweet is in the diet soda?

What could be so terrible about stating the amount? How else will the user or the physician know if the person is exceeding reasonable consumption limits, particularly during the summer months?

Some would say, "Well, even if we told them the amount, they wouldn't understand." Some would. Some would not. But what in the world is so horrific? What in the world is so terrible? Why is it such a problem for the industry, within 18 months, to change their cans to indicate the amount of aspartame—that is NutraSweet—in the product?

Some would say, "Why label only soft drinks?" The answer to that is soft drinks are the major source of NutraSweet consumption.

Those who argue against the amendment on the basis that it singles out soft drinks are very quick to point out that they do not support labeling of any products containing NutraSweet.

Besides, if we mandate labeling of soft drinks, do you not think the other manufacturers will get the message and seriously consider implementing their own labeling?

Some would argue—and it has been stated—"Why don't you indicate how much sugar there is on the label?" As a matter of fact, if somebody cares to offer an amendment or to suggest such labeling, I would have no problem with that. I am one who firmly believes that the more the individual is able to know about the food he or she consumes, the better chance that individual has in seeing to it that the food ingested by him or her will be healthful and not dangerous to his or her life.

Dr. Roberts, of the National Soft Drink Association, testified at the hearing and said if a consumer wants to know how much NutraSweet is in a can of diet soda, they can write the National Soft Drink Association in Washington to find out. He said:

We like people to have this information so we have no objection whatsoever, and, in addition, we try to provide additional information by putting our associated kinds of brochures.

So they are saying, "You can get the information, we are willing to give it to you, we might even make up a brochure, but we don't want to put it on the can."

Why? Is it that there is no room on the can? Is it that the people are just too nosy, to find that out?

I went to a can of Diet Coke to see what was on the can. Mr. President, they have enough reading material on the can to fill the CONGRESSIONAL RECORD.

On the front label they say, "100 percent NutraSweet brand sweetener." They say, "Saccharin-free, low-calorie

cola; "phenylketonurica," contains "phenylalanine."

Let us take a look at the back of the Diet Coke label.

Nutrition information per serving	
Serving size (ounces).....	6 oz.
Servings per container.....	3
Calories per serving.....	0
Protein.....	0
Carbohydrate.....	0
Fat.....	(*)
Sodium (milligrams).....	0
* Less than 1 gram.	

And it continues on. They have a lot of material on the back of that label.

Percentage of U.S. recommended daily allowances (U.S. RDA): contains less than 2 percent of the U.S. RDA of protein, vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron. Contains carbonated water, caramel color, aspartame, (NutraSweet brand), phosphoric acid, potassium benzoate preservative, natural flavors, citric acid, caffeine.

That is not all. It has more on the back label. "NutraSweet and the NutraSweet symbol," says the back label, "are the trademarks of G.D. Searle & Co. Consumer information: call 1-800-GET-COKE," and then the number "438-2633."

Well, I guess it would not be too much of an imposition for the soft drink industry to indicate that there are 180 to 200 milligrams of NutraSweet in that can of Diet Coke. It would not ruin the can or its appearance.

Now, the Soft Drink Association has also said that if consumers want to know how much aspartame is in a can of Diet Coke, they can call the number on the can; 1-800-GET-COKE.

Now, my staff did just that. At 9:09 a.m. on May 1, my staff called the Coke consumer information line, 1-800-GET-COKE, and after listening to a jingle, the operator came on the line. She was a very nice woman. Her name was Pat. My staff asked her the following question: "Can you tell me how much NutraSweet is in the can?" Her reply, "No, I'm sorry, I don't have that information." My staff then asked, "Is there any limit to the amount you should consume?"

Reply: "No. You can drink 40 cans a day." My staff asked her about kids. Could they drink that amount? Her reply, "No problem."

Now, FDA's acceptable maximum daily intake for a 150-pound person is 17 cans, and for a 25- to 30-pound person, 3 to 4 cans.

So I say that dialing 1-800 GET-COKE does not get you very far in obtaining information on how much NutraSweet is in a can of Diet Coke. Would the Chair be good enough to advise how much time the Senator from Ohio has remaining?

The PRESIDING OFFICER. The Senator has 32 minutes remaining.

Mr. METZENBAUM. I thank the Chair.

I ask my colleagues to keep in mind that the soft drink association, which is strongly opposed to letting consum-

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do know how much NutraSweet they are consuming, is the same association which in 1983 prepared a draft legal document objecting to NutraSweet ever being allowed on the market, citing serious and unresolved questions about the public health.

Let me explain the significance of that statement. The National Soft Drink Association, along with the law firm of Patton, Boggs & Blow, prepared a document that was to be submitted before the U.S. Department of Health and Human Services, Food and Drug Administration. The document was entitled "Objections of the National Soft Drink Association to a Final Rule Permitting the Use of Aspartame in Carbonated Beverages and Carbonated Beverage Syrup Bases and a Request for a Hearing on the Objections." The issue before the Food and Drug Administration at that time, according to this draft objection was aspartame; food additives for direct addition to human food. 48 Federal Register 31376, July 8, 1983.

I want to explain to my colleagues that the draft legal document was not filed, but it was prepared and I ask unanimous consent that at the conclusion of my remarks the entire contents of that draft objection be included in the Record.

The PRESIDING OFFICER. Without objection, it is so ordered. (See exhibit 1.)

Mr. METZENBAUM. Although it was not filed, that does not mean that it was not the position of the organization at that time. It does not mean that the findings and the conclusions reached in that document were not valid. It only indicates that for reasons best known to them, unquestionably business reasons, they decided not to file it.

But they were not objecting to labeling, which is all that my amendment would do. My amendment would only indicate the amount of aspartame that is in the product.

Their objection took the position that aspartame should not be included in soft drinks. That draft objection indicates that the organization had significant health concerns with the product before it was approved for soft drinks.

Let me direct your attention to some of the things that they said in that draft document:

G.D. Searle and Company has not demonstrated to a reasonable certainty that the use of aspartame in soft drinks, without quantitative limitation, will not adversely affect human health as a result of the changes such use is likely to cause in brain chemistry and under certain reasonable anticipated conditions of use.

For these reasons, Searle has not met its burden of demonstrating to a reasonable certainty that the unlimited use of aspartame, especially in combination with carbohydrates, will not adversely affect human health.

It went on to say that:

The questions posed by Dr. Wurtman are significant because of the seriousness of the

potential effects *E.O.*, changes in blood pressure and because of aspartame's anticipated widespread use—one that includes consumption by potentially vulnerable subgroups, such as children, pregnant women, and hyperactives.

They went on to say in that document:

Specifically, Searle has not met its burden under section 408 . . . to demonstrate that aspartame is safe and functional for use in soft drinks.

And they further stated:

Collectively, the extensive deficiencies in the stability studies conducted by Searle to demonstrate that aspartame and its degradation products are safe in soft drinks intended to be sold in the United States, render those studies inadequate and unreliable.

Now, the National Soft Drink Association in August 1983, thought that aspartame should not be used in soft drinks. But so many of my colleagues have been called recently and told that they should not vote for this amendment. Yet this amendment does not provide that the product should not be sold, only that the people who use the product have a right to know how much of it they are consuming.

Now, I think that it is important to know what occurred at the Department of Health and Human Services when aspartame was approved. I would like to share with my colleagues a memo dated May 19, 1981, from the Acting Associate Commissioner for Health Affairs on the subject of aspartame to the Commissioner of the Food and Drug Administration.

In this memo, they state the following:

The first and primary agenda item relates to the brain tumor issue. This was the point on which the Public Board of Inquiry concluded that safety had not been shown. A first draft "final decision" on this issue is attached.

They went on to say:

The major issue discussed at the hearing was the background rate for spontaneous brain tumors in the specific strain of rat used by Searle.

They talked about the conduct of the study.

The conduct of all three rat studies has been criticized by Dr. Olney. Some of the staff scientists believe the studies were adequately conducted, while others tend to agree with Dr. Olney that one or more of the studies was severely flawed. Again, the different positions are documented.

Mr. President, I ask unanimous consent that the FDA memo be printed in the Record at the conclusion of my remarks.

The PRESIDING OFFICER (Mr. GORTON). Without objection, it is so ordered.

(See exhibit 2.)

Mr. METZENBAUM. Now, Mr. President, my colleagues may go ahead and defeat this amendment. But I hope they will remember this debate in the months ahead. I do not claim children will develop brain tumors. I do not know that. I do know that the FDA was worried about it. I

do know that three of the six FDA scientists advising the FDA Commissioner on final approval were sufficiently worried about it that they were not willing to approve the product. The FDA's own scientists were split on the issue.

So what we are talking about is, do we agree that there will be labeling indicating how much aspartame is in the product or do we close our minds to all the questions surrounding this product and turn our backs on the consumer's right to know.

I am frank to tell you I stand on the floor and I do not have all the answers. But I believe that this body has some responsibility to the children, grandchildren, and adults who are consuming these soft drinks. And all I am asking for here today is that which I consider to be the very minimum. To tell the people who are drinking these diet sodas how much aspartame is in the product.

Now I might note that some have said that the Diabetes Association opposes this amendment. My staff spoke with their Washington representative today. They do not oppose this amendment. Their official position is to advise caution for pregnant women and children for both aspartame and saccharine consumption.

In conclusion, Mr. President—and I will confess that I have spoken at some length, but I speak at some length because I am concerned about what aspartame may do to people if ingested in too great quantities. I am concerned about the possibility of brain tumors and other forms of brain damage. Those who studied the issue at the FDA were concerned as well.

This amendment is basic. It is simple. It does not really ask for much, and for the life of me, I cannot understand why the Soft Drink Association has spent so much time and has done so much lobbying. What have they got to hide? All we are asking is how much aspartame is in the soft drink. And we are saying take 18 months. If you need that amount of time, in order to change your cans in order that we will not place an economic burden on your business.

My amendment is no big deal. It is not going to save the world. It is not going to solve problems in Nicaragua and it is not going to balance the budget. But it is one little step in the right direction. We will be providing people with the minimum amount of information they deserve about a substance which poses many unanswered questions about basic consumer health and safety.

Mr. President, I do not wish to delay the Senate with lengthy debate. I would like to submit for the record a number of scientific and other submissions relating to aspartame. I ask unanimous consent that they be printed in the Record.

