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MEMO

TO: PAUL  
FROM: ALAN  
RE: SACCHARIN

OVERVIEW

On 9 March, 1977 the FDA announced its intentions to ban the use of saccharin in foods. Saccharin is the only artificial sweetener currently permitted to be used in the United States (at least 5 million pounds a year are used in food, about three-quarters in diet sodas, and the remainder in dietetic foods and as a table-top sweetener in place of sugar). This action was the result of studies, conducted by the Canadian government, which showed that saccharin, fed at high levels to rats (the equivalent of 800 cans of soda a day in human consumption terms), caused malignant bladder tumors. The Delaney amendment to the Food and Drug Act compels the FDA to ban any substance causing cancer in animals or humans, as proven in appropriate tests.

Saccharin has been under review in the United States for the past 6 years, with tests showing no hard evidence that saccharin is a carcinogenic. The Canadian study, sponsored by its Health Protection Branch, released its preliminary results on 7 March in Ottawa.

Canada is taking similar action to that of the FDA.

The crux of the problem lies with the Delaney amendment. Since its enactment in 1958 -- it admits no qualifications to the standards and results of tests. If any test proves at least one instance of cancer -- the law must ban the substance. It becomes an "all or nothing" question. The 6 year American research, conducted by highly reputable and reliable people cannot be taken into account by the FDA.

Sherwin Gardner, Acting Commissioner of Food and Drugs, said:

"Previous animal tests have not demonstrated with any degree of certainty whether saccharin could cause cancer. But these Canadian tests show unequivocally that this substance can produce malignant bladder tumors in rats.

The law is equally clear. It says that no ingredient that causes cancer in man or animals may be added to our food supply.

Science and law dictate that saccharin be removed from our food supply.

Saccharin has been in use for more than 80 years and has never been known to harm people, and since the Canadian data do not indicate an immediate hazard to public health, we do not consider the recall of existing products to be necessary. We, nevertheless, encourage manufacturers to discontinue use of saccharin as soon as possible, even while we are drafting the documents needed to accomplish this action."

Documents proposing the ban will be published in the FEDERAL REGISTER as soon as possible (30 days or less).

CONGRESSIONAL ACTION

Jim Martin (NC) introduced H.Res.395, which states the sense of the House that the proposed FDA ban should not go into effect until the Congress has held hearings and found that normal consumption of saccharin is unsafe.

The Martin measure speaks not only for the 10,000,000 diabetics in the United States who have no available alternative (talk has circulated that saccharin might be available as a "prescription" item) to saccharin as a sweetener, but to the 20 million or more Americans who are overweight, obese and on restricted diets.

The American Heart Association is violently opposed to the ban. Experts feel it will do far more harm than any good it can achieve.

Cardiovascular disease is the major killer in this country, responsible for more deaths than all other causes combined. Cardiologists are concerned about the effects on heart disease. Replacing 10 billion cans of diet soft drink with regular soft drink will lead to an extra two trillion calories--the equivalent of 600million extra pounds of fat in Americans. Obesity is clearly related to high blood-pressure and probably also to the rate of heart disease. Extrapolating from the poundage estimates due to the removal of saccharin, it has been figured that there may be as many as 25,000 extra heart-attacks, and perhaps tens of thousands of extra deaths because of the increased obesity.

Hearings on H. Res. 395 are scheduled for 10am Monday March 21 ~~xxxx~~ by Paul Rogers' Health and Environment Subcommittee of Commerce.

Should those hearings determine that saccharin is safe, legislation would be needed to preclude the Delaney amendment. It will come in the form of providing the FDA with more flexibility. Essentially the result would be that saccharin and other similar substances would be allowed to be marketed, with the FDA stipulation that if taken in unreasonably massive doses, ~~xxx~~ it could produce problems.

\*\*\*You are now a cosponsor to H.Res 395, a copy of which is attached.