

THE REGULATION OF ARTIFICIAL SWEETENERS:  
CORPORATE AND GOVERNMENT STRATEGIES

by

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#### ABSTRACT

This is a case study of the regulation of the artificial sweeteners, cyclamate, saccharin, and aspartame, by the Food and Drug Administration. These substances have been consumed daily by millions of people worldwide, but their consumption is especially prevalent in the United States. Each sweetener has been the focus of scientific controversy. In 1969 the FDA banned cyclamate, alleging that it caused cancer in animal studies. In 1977 the agency proposed restrictions on saccharin's use on the grounds that it too was an animal carcinogen. Public outcry and industry pressure prompted Congress to delay the saccharin decision; today it is still on the market. In 1981 the FDA approved the new sugar substitute, aspartame, for limited uses and in 1983 as an additive in soft drinks.

Participation of non-government groups in the regulatory process was most intense and widespread with saccharin; relatively mild by comparison with cyclamate, and prior to its marketing, almost nonexistent with aspartame. The thesis examines the role of science in the regulatory process. The study focuses especially on government and corporate strategies to influence the outcome during the various stages of each controversy.

Three findings offer some explanation for the divergence in the regulatory status of the sweeteners. First, because the science was uncertain in each case, it became subject to multiple interpretations by interest groups participating in the regulatory process. Second, the availability of a substitute for a threatened, but popular product, will provide one important indication of the likelihood that government restrictions on its use will be effective. Finally, the cases suggest that the strategies of participants in the process to secure their own organizational goals may ultimately outweigh protection of the public's health, the avowed goal of health and safety regulations.

Thesis Supervisor: Harvey M. Sapolsky  
Professor of Public Policy and Organization

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CHAPTER I  
INTRODUCTION

We look to government to protect us from innumerable hazards encountered in daily life. We rely on various federal agencies to monitor business practices by setting guidelines for consumer products, establishing workplace standards, restricting air and water pollution, etc. For the individual the reliance on government simplifies the overwhelming task of risk assessment, but events sometimes indicate that regulatory policies may not provide the assurances that are often taken for granted. Health and safety regulations, designed to guide business behavior, often have protection of the public as their chief intention, but in implementation they sometimes fail to be equal to the task.

This study assesses the degree of conformity between intent and outcome in the area of health and safety policy by examining the regulation of the artificial sweeteners, cyclamate, saccharin, and aspartame. In 1969 the Food and Drug Administration (FDA) banned cyclamate, alleging that it caused cancer in animal studies. In 1977 the agency proposed restrictions that would have led to virtually a total ban on saccharin's use on the grounds that it too was an animal carcinogen. In 1981 the FDA approved the new sugar

substitute, aspartame, for limited uses. Two years later the FDA granted aspartame's manufacturer permission to sell it as an additive for soft drinks.

The Food, Drug and Cosmetic Act of 1958 includes provisions specifically prohibiting the marketing of additives that are unsafe or that are shown to cause cancer in laboratory tests. The FDA's decisions on the three sweeteners used the laws requirements as guidelines. The regulation of cyclamate, saccharin, and aspartame was intended to ensure that the millions of Americans who regularly used a sugar substitute were protected from consuming a hazardous substance.

Each sweetener case was scientifically controversial and generated varying degrees of public and interest group involvement. Participation of non-government groups in the regulatory process was most intense and widespread with saccharin; relatively mild by comparison in response to the cyclamate ban, and, prior to its marketing, almost nonexistent with aspartame.

In these cases the question is raised whether the current artificial sweeteners policy has realized the regulatory intent. The status of each sweetener today suggests that protection of the consumer may not have been well-served. Studies have virtually exonerated cyclamate of the charge that it was a carcinogen, while additional research has corroborated the evidence against saccharin. Public outcry

and industry pressure prompted Congress to delay the saccharin decision; today it is still on the market while cyclamate is not. Aspartame was approved although the recommendations of a board of three prominent scientists recommended that marketing be delayed until further tests could be conducted.

This study is an attempt to understand the discontinuity between regulatory intent and policy outcome in the artificial sweetener cases. It focuses especially on government and corporate strategies to influence the outcome during the various stages of each controversy.<sup>1</sup> More generally, the three cases suggest some limits on what government, regardless of worthy intentions, can actually accomplish by regulations that propose to change behavior or deprive consumers of a popular product for which there is no substitute. In these situations the opportunity is ripe for groups opposed to the regulation to mobilize the public and alter the policy outcome.

### Background

After World War II an industry developed in the United States based on the manufacturing of sugar substitutes and artificially sweetened foods. The popularity of diet foods and beverages remains largely an American phenomenon with sales today totalling \$4 billion a year. Eighty percent of the world's diet soft drink sales occur in the United States.



A major factor limiting the popularity of artificial sweeteners abroad is that the "figure maintenance concept" on which they depend is often absent for cultural or economic reasons. In some affluent countries like Japan, there is little interest in calorie counting, and dieting is seen as an unfashionable, private matter. The popularity of sugar substitutes also depends on economic prosperity. Slimness and weight reduction are irrelevant in countries where subsistence is a major concern.<sup>2</sup>

In many countries the label "diet" denotes illness, an association that was originally true in the United States but that the early manufacturers of artificially sweetened foods worked assiduously to eliminate. In Europe government regulations often restrict the use of "diet" to identify products intended for medical uses. Other countries may also limit the amount of artificial sweetener permitted in foods to levels far below those permitted in the United States. For instance, in Japan the government's restrictions on saccharin have meant that diet soft drinks have only half the calories of sugared brands. In the United States diet drinks commonly contain only one calorie.<sup>3</sup>

The three sweeteners examined here serve an identical purpose: to provide a low or zero calorie alternative to sugar for dieters and diabetics. Cyclamate and saccharin are non-nutritive, non-caloric sweeteners. Aspartame is considered a nutritive sweetener because it is metabolized by

the body as a protein and has a slight caloric value. The term, artificial sweeteners, is generally used to distinguish manufactured sugar substitutes from sweeteners derived from corn, honey, or other natural food sources. Aspartame is being marketed as a "natural" sweetener on the grounds that its constituents are aspartic acid and phenylalanine, two amino acids contained in food proteins. Nevertheless, aspartame is synthesized in industry laboratories, so the distinction is largely a semantic one.<sup>4</sup> (See Table I-A)

In each of the cases policy development occurred in similar stages. First, there was identification of a health concern through scientific study. Cyclamate and saccharin were brought to the attention of government by research findings prompted by the growth in their consumption during the 1960s. (See Table I-B) Aspartame's manufacturer, petitioning the FDA for marketing approval, placed it on government's agenda. In the second stage, interest groups challenged the safety of the sweeteners thereby increasing the pressure on the FDA to reach a decision.

In the third stage the FDA proposed a ruling on each sweetener that provoked a response from the manufacturer. Finally, in the last stage, the manufacturer and the diet food industry adopted a public or private approach to resolving the controversy. If public, the company attempted to enlist the involvement of other firms in the diet industry and extended appeals to the public to resist the proposed government

TABLE I-A

| ARTIFICIAL SWEETENER | DISCOVERY | SWEETENING EQUIVALENT* | COST/LB. | USES  | HEALTH CONCERNS**  | U.S. REGULATORY STATUS  |
|----------------------|-----------|------------------------|----------|---|--|---|
| SACCHARIN            | 1897      | 300x                   | \$4.00   | Baking<br>Beverages<br>Food mixes<br>Tabletop | Bladder cancer   | FDA restrictions on use delayed by Congress; available for all uses |
| CYCLAMATE            | 1937      | 300x                   | \$1.93   | Baking<br>Beverages<br>Food mixes<br>Tabletop | Bladder cancer<br>Embryotoxic effects<br>Testicular atrophy                        | Banned  |
| ASPARTAME            | 1965      | 200x                   | \$85.00  | Beverages<br>Food mixes<br>Tabletop           | Brain lesions<br>Prohibited for phenylketonurics<br>Alterations in brain chemicals | Approved  |

\*Compared to sugar

\*\*Health concerns raised in animal studies

Sources: Beverage Industry Annual Manual 1982Gene Bylinsky, "The Battle for America's Sweet Tooth," Fortune, 26 July 1982Calorie Control Council, Sweetener Fact Sheet

TABLE I-B

U.S. PER CAPITA CONSUMPTION OF NON-CALORIC SWEETENERS  
(IN SUGAR EQUIVALENTS)

| Calendar Year | Population | Cyclamate        | Saccharin | Aspartame | Total non-cal & low-cal sweeteners |
|---------------|------------|------------------|-----------|-----------|------------------------------------|
|               | million    | .....pounds..... |           |           |                                    |
| 1960          | 180.671    | 0.3              | 1.9       |           | 2.2                                |
| 1961          | 183.691    | 0.4              | 2.1       |           | 2.5                                |
| 1962          | 186.538    | 0.4              | 2.5       |           | 2.9                                |
| 1963          | 189.242    | 0.7              | 3.0       |           | 3.7                                |
| 1964          | 191.889    | 1.3              | 3.5       |           | 4.8                                |
| 1965          | 194.303    | 1.7              | 4.0       |           | 5.7                                |
| 1966          | 196.560    | 1.9              | 4.5       |           | 6.4                                |
| 1967          | 198.712    | 2.1              | 4.8       |           | 6.9                                |
| 1968          | 200.706    | 2.2              | 5.0       |           | 7.2                                |
| 1969          | 202.677    | 1.6              | 5.3       |           | 6.9                                |
| 1970          | 205.052    |                  | 5.8       |           | 5.8                                |
| 1971          | 207.661    |                  | 5.1       |           | 5.1                                |
| 1972          | 209.896    |                  | 5.1       |           | 5.1                                |
| 1973          | 211.909    |                  | 5.1       |           | 5.1                                |
| 1974          | 213.854    |                  | 5.9       |           | 5.9                                |
| 1975          | 215.973    |                  | 6.2       |           | 6.2                                |
| 1976          | 218.035    |                  | 6.1       |           | 6.1                                |
| 1977          | 220.239    |                  | 6.6       |           | 6.6                                |
| 1978          | 222.585    |                  | 6.9       |           | 6.9                                |
| 1979          | 225.055    |                  | 7.0       |           | 7.0                                |
| 1980          | 227.704    |                  | 7.1       |           | 7.1                                |
| 1981          | 229.849    |                  | 7.2       | 0.2       | 7.4                                |
| 1982          | 232.057    |                  | 7.3       | 1.0       | 8.3                                |
| 1983          | 234.249    |                  | 7.2       | 2.0       | 9.2                                |

Source: Robert D. Barry, National Economics Division, USDA.

action. If private, the company worked to minimize public attention by handling any controversy within the regulatory process.

#### Influencing the process

The public, convinced by years of advertising that artificial sweeteners were effective aids to dieting, was committed to their availability. When the FDA proposed to restrict saccharin, the public was mobilized to protest because it was the only sweetener left. The restrictions would have sharply curtailed artificial sweetener use, leaving most consumers without sugarless products.

The sweetener manufacturers and the soft drink companies were key participants in the three cases. Other diet food producers, the diabetes associations, and several scientific organizations also supported the availability of artificial sweeteners. The opponents of cyclamate, saccharin, and aspartame included the sugar industry, several consumer advocacy groups, and individual scientists.

The FDA, although responsible for deciding the status of each sweetener, was also a participant in the controversies. Roger Cobb and Charles Elder describe how government's conflict management function does not preclude it from frequently being part of group conflicts.<sup>5</sup> The FDA was not detached from the debates over the sweeteners or from the

pressures that were generated by the other participants to influence its decisions.

In a straightforward food additive case, the FDA's decision-making process would involve review of the scientific findings. The agency could then act in accordance with the law. The artificial sweetener cases, however, were complicated by two important factors. First, the scientific findings about the effects of sugar substitutes were ambiguous. The absence of epidemiological evidence linking artificial sweeteners with bladder cancer contributed especially to the scientific and policy debates. Second, the availability of a substitute was an important factor in generating the public's involvement. Saccharin was on the market when the cyclamate and aspartame decisions were made.

The regulation of artificial sweeteners was characterized by uncertainty. The strategies adopted by the various participants can be viewed as attempts to reduce this uncertainty. The manufacturers wanted the security of having their product on the market, free from health challenges by scientists and consumer advocates and threats of government action. The soft drink industry wanted to ensure stability for its highly profitable diet segment.

Millions of consumers, interested in dieting, wished to have available at least one sugar substitute. Diabetics wanted the convenience of easy access to artificially sweetened products. The risk of future ill-effects from

artificial sweetener consumption disturbed consumer advocates; they recommended reducing the danger by restricting or banning the sugar substitutes.

This study seeks to explain how these groups attempted to influence the FDA's decision-making. It focuses particularly on the strategies adopted by various participants during the regulatory process to provide favorable interpretations of the science, to control the scope of the conflict, to defend past decisions, or to define the public interest.

#### The plan of the study

Open-ended interviews were conducted with officials of the affected companies, FDA staff members, and representatives from relevant trade associations, consumer advocacy organizations, and the national diabetes associations. Congressional staff members and scientists and lawyers in government and industry were also interviewed. (See Appendix for list of persons interviewed)

The next chapter (chapter II) will examine why science has been uncertain in the study of artificial sweeteners and will summarize the data on cyclamate, saccharin, and aspartame. The middle chapters (chapters III-V) will discuss the regulatory history of each artificial sweetener, tracing the policy process as it occurred in each case, and identifying the participants and their influence on the government's decisions.

The cyclamate chapter (chapter III) will also examine the soft drink industry and the major role it played in the development of a diet food industry. The saccharin chapter (chapter IV) will pay particular attention to the food regulatory system in the United States and the role of the FDA. The saccharin chapter will also consider the options available to government in the regulation of popular consumer products and the effect of conflict expansion on policy outcome. The aspartame chapter (chapter V) provides a contrast to the cyclamate and saccharin stories, describing the effect on policy when the sweetener under consideration is a new one rather than one long on the market. The final chapter (chapter VI) will consider what the regulation of artificial sweeteners may reveal about government and corporate strategies to shape policy and the effect on the conformity between intent and outcome.



NOTES: Chapter I

<sup>1</sup> Strategy is used here to refer to a conscious course of action adopted by the participants in an effort to achieve their organizational or individual goals with respect to artificial sweeteners. In the case of large organizations, like the manufacturers of the artificial sweeteners, it is not assumed that the approaches adopted necessarily reflected a company wide policy. The strategies may have been the work of individuals; it was beyond the scope of this inquiry to determine the extent of the company commitment to the response to the FDA decisions.

<sup>2</sup> Carolyn Hulse, "Diet Coke Faces Hurdles as it Spreads Worldwide," Advertising Age, March 14, 1983.

<sup>3</sup> Ibid.

<sup>4</sup> Artificial sweetener is used in this study to refer to a chemical compound that is sweet to the taste not including sugar or any polyhydric alcohol. The definition is taken from Food Additives and Contaminants Committee Report on the Review of Sweeteners in Food by the Ministry of Agriculture, Fisheries and Food (London: Her Majesty's Stationery Office, 1982).

<sup>5</sup> Roger W. Cobb and Charles D. Elder, Participation in American Politics: The Dynamics of Agenda Building (Baltimore: Johns Hopkins University Press, 1972), p. 37.

CHAPTER II  
THE SCIENTIFIC ORIGINS OF A PUBLIC POLICY DEBATE

Hundreds of scientific tests have been conducted on cyclamate, saccharin, and aspartame individually. The mixture of cyclamate and saccharin that was in standard use for almost twenty years in the United States has also been extensively examined. Some of these tests produced bladder tumors or other serious effects in laboratory animals. Despite the vast amount of research, however, the health risks to humans are the subject of intense debate.

Scientific research often produces ambiguous results that generate further research and lead to continued refinement of the data. What is the norm for scientists, however, is an uncomfortable state of affairs for policymakers, especially with regard to decisions that have highly visible outcomes. Those regulatory agencies that make science based policy are often required to act on an issue even as the research continues.

For example, the Food and Drug Administration cannot indefinitely postpone a food additive ruling. The consequences of delay could mean, in the case of an unsafe additive already in use, that the American public is exposed to a health hazard. Or, in the case of a safe additive, a

lengthy approval process could impose undue costs on the manufacturer. The FDA will have to act on the basis of the available information even if, as is usually the case, the data are less than certain.

What will ultimately become apparent in each artificial sweetener case was that the debates were only partly about scientific issues and more significantly about political judgments regarding risk allocation. A former general counsel to the FDA described the dilemma that the agency often encounters: "Given scientific uncertainty, policymakers must confront the question of how much risk (from an additive) we are willing to tolerate."<sup>1</sup>

The policy debate over artificial sweeteners has two basic positions. One side (the FDA with cyclamate and saccharin, some public interest groups, and the sugar industry) finds the negative evidence from animal studies sufficiently convincing to warrant government restrictions. The other (the artificial sweeteners industry, Congress with saccharin, and the FDA with aspartame) finds in the lack of harmful human evidence justification for their unrestricted use.

A position that seemingly occupies the middle ground (held by the American Diabetes Association, the Juvenile Diabetes Foundation, and the American Cancer Society) is represented in the warnings for diabetics, pregnant women, smokers, and children to moderate their consumption of

artificial sweeteners. Actually, these admonitions conceal further support for their unrestricted use. Many products such as toothpaste, mouthwash, and cosmetics, contain saccharin, a fact that is generally unknown.<sup>2</sup> Although it is easy to avoid diet soft drinks or tabletop packages, it would be more difficult for the consumer in a subgroup at risk to eliminate artificial sweetener use altogether. Moreover, the unrestricted sale of diet soft drinks virtually guarantees that children will continue to have unlimited access to sugar substitutes.

Artificial sweeteners have been studied by a variety of organizations. The cyclamate, saccharin, and aspartame manufacturers and the food industry, especially the major soft drink companies, have been the primary sponsors of tests. The cane sugar industry, in attempts to discredit any substitutes for sugar, has also supported research. In addition, the FDA, often because of pressure from the sugar industry or from public interest groups opposed to artificial sweeteners, has conducted studies either within the agency or through other scientific organizations. Partly as a result of all these varying interests, the data have been subject to competing interpretations. Deciding whether an artificial sweetener is safe for human consumption has become a matter for public policy rather than for science. With an indeterminate scientific base, the role of non-scientific factors in the policy process has become decisive.

The groups on both sides of the artificial sweeteners issue have utilized the equivocal aspects of food additive science. The diet industry has, not surprisingly, been the major source for data that contradict the negative findings on sugar substitutes. Beginning with the cyclamate ban, the industry attempted to generate more favorable science through a network of research laboratories, universities and trade associations. Through this network food companies have anticipated and countered unfavorable scientific studies with some success. Alternative explanations for the harmful evidence about artificial sweeteners have been instrumental in the shaping policy debates.

Public awareness that science can be uncertain is a relatively recent phenomenon. After World War II, coverage of scientific events increased, prompted in part by the drama of the space race. Although today scientific news remains a relatively small part of total reporting, it has grown substantially in the past several decades. In the process public skepticism toward science appears to have increased. This may be due in part to the fact that the growth in coverage has been accompanied by expanded reporting of controversy among scientists.<sup>3</sup>

Previously unquestioned scientific procedures have become the object of scrutiny. In the area of food additives, the awareness that scientists are not omniscient has been joined by a growing public realization that all risks cannot be

identified or even quantified.<sup>4</sup> To some extent with cyclamate and more so with saccharin, the FDA's rulings were not greeted with public acceptance. The media and the diet industry focused particular attention during each case on the validity of animal studies and in the process often distorted the issues.

#### The complexity of scientific procedures

In 1902 Dr. Harvey Wiley, later chief of the Bureau of Chemistry, the FDA's predecessor, formed what was called "Wiley's Poison Squad". Wiley assembled teams of young men to test the toxicity of preservatives and coloring agents. For five years these volunteers (Wiley thought young men to be the most resistant to possible adverse effects) ingested a variety of foods, and Wiley collected extensive chemical and physiological data.<sup>5</sup>

Dr. Wiley found that the results of the tests from his "poison squad" were difficult to interpret. Although analytical and statistical methods have greatly advanced, of course, since the turn of the century, the increased sophistication in current scientific techniques has not always made data interpretation less complicated, in part because the problems have become more complex.

The development of the food industry has been assisted by and in turn contributed to an intricate system of food

processing. Until this century food additives were primarily used as preservatives. As the industry grew, the use of chemical additives expanded to include a wide range of applications.<sup>6</sup> The FDA currently has jurisdiction over 3000 direct additives, substances that are added to foods, and as many as 10,000 indirect additives, those that may migrate during processing, packaging, or storage.<sup>7</sup>

The food additives most widely used now are those that enhance the appeal of the food to the consumer. This group includes coloring agents, flavors, flavor enhancers, sweeteners, and acidifiers, all designed to modify the appearance, taste, or odor of food. The use of food additives for cosmetic purposes is often criticized as excessive by consumer advocates who contend that they are intended for the convenience of the retailer or the manufacturer, not the consumer.<sup>8</sup> In 1981 the consumption of food additives in the United States was estimated to be about 139 pounds per capita. Sugar accounted for 80 percent of the total, salt for 10 percent, and preservatives, artificial colors, and flavors for about one percent or approximately 1.5 pounds.<sup>9</sup>

In 1958 the Food, Drug, and Cosmetic Act was amended. Because these amendments constitute the most recent overhaul of the federal food safety laws, the state of scientific procedures during the 1950s often serves as a benchmark in contemporary discussions of food safety. The number of chemicals being tested today is around ten times as many as

were being tested 25 or 30 years ago. The capacity to detect minute quantities of a potentially harmful substance is now at three times the magnitude of the levels of detection in the 1950s.<sup>10</sup> Revisions in cancer testing technology sometimes occur so rapidly that they are altered between the time a test is started and when it is completed.<sup>11</sup>

During the hearings on the 1958 Amendments it became apparent that the state of scientific knowledge at the time was insufficient to establish the absolute safety of any chemical substance.<sup>12</sup> Despite the advances that have occurred since 1958, complete safety is still an unattainable standard.<sup>13</sup> Although it is possible to identify chemicals that are carcinogens, the exact dose level at which each will cause cancer is unknown. In addition, substances that may not cause cancer themselves sometimes act as cancer promoters for other substances.<sup>14</sup>

It is impossible even to know all the risks that may occur from a particular additive. The progress in detection procedures has resulted in the discovery that many chemicals are potentially harmful to certain people under particular use patterns.<sup>15</sup> Even when a hazard is known, it is still unlikely that a cause and effect relationship can be established between consumption of a substance and the development of cancer. Chemically induced cancers have a latency period of ten to forty years from initial exposure to when symptoms of the disease appear.<sup>16</sup> If an individual was to develop bladder



cancer, it would be impossible to attribute the disease to the two packages of saccharin he added to his daily coffee and not to where he lived, the number of cigarettes he smoked, his occupation, or any number of other factors.

It may be possible in the future to single out a particular substance, especially through advances in the field of epidemiology.<sup>17</sup> Ironically, in the meantime, refined scientific techniques have contributed to conflict in the food safety area. For example, industry often attacks the 1958 standards on the basis of modern scientific procedures.<sup>18</sup> Likewise, the FDA has utilized current science to defend past decisions. The agency's cyclamate ruling derived from studies that linked it to bladder cancer. In the years since the ban, a greater scientific concern has developed over the possible teratological and mutagenic effects of the sweetener. In defending the cyclamate ban, the FDA has emphasized the new issues raised by later studies.<sup>19</sup>

Not everyone is optimistic about the potential of establishing cause and effect relationships with carcinogens because of further specialization in the field of epidemiology. A FDA toxicologist termed epidemiology "a methodology, not a discipline", that is used in different ways by practitioners depending on their individual biases. Lawyers both in the FDA and the food industry also see little likelihood that epidemiology will become precise enough to provide sufficient legal grounds for assigning liability in a

food additive case.<sup>20</sup>

The limitations of testing methods

The most widely used methods for assessing the safety of food additives can be grouped into four categories:

molecular structure analysis, short-term tests, tests on animals and epidemiological studies.<sup>21</sup> The molecular structure analyses provide limited information about the cancer potential of a substance through examination of its chemical composition. These tests are not considered as reliable indicators of the risk a chemical may present to humans.<sup>22</sup>

Short-term tests "examine the capacity of a substance to cause mutations or other genetic alterations" in the cells of various biological systems. Short-term tests are useful as screening devices to detect potential carcinogens and they are popular among researchers because of their speed and low cost compared to animal or epidemiological studies.<sup>23</sup> For example, in 1977 the Office of Technology Assessment (OTA) commissioned a battery of short-term tests to study saccharin. They were designed to be completed in three months and were selected partly to illustrate the way that short-term tests can be applied to a regulatory problem.<sup>24</sup>

Short-term tests are not viewed as definitive evidence that a substance does or does not cause cancer, although positive results are considered highly suggestive.<sup>25</sup> In the

OTA battery, seven tests reported negative findings with saccharin, three reported positive, and two were incomplete.<sup>26</sup> The reliability of short-term tests is a function of the degree of test sensitivity, the amount of impurities in the analyzed substance, and the dosage levels among other factors.<sup>27</sup>

Animal studies are regarded as the best available method for evaluation of the cancer-causing potential of a substance. It is acceptable laboratory practice to administer large doses of a substance to test animals in order to compensate for their short life span relative to humans, for the increased rate at which animals metabolize and excrete chemicals, and to minimize the chance of producing a false negative result.<sup>28</sup> Nevertheless, there is no guarantee that a species of animals chosen for a study is the appropriate model from which to extrapolate the conclusions to human beings.<sup>29</sup>

With artificial sweeteners, the species used most often have been rats or mice. Critics of rodents as test animals have argued that the physiological differences between humans and rodents may invalidate the data. The organs of a test animal might be especially sensitive to a carcinogen that would leave the same organs unaffected in humans.<sup>30</sup> One industry scientist noted the resiliency of the human organism, saying that "humans have the best DNA repair system of all animal species."<sup>31</sup>

Even the large numbers of animals commonly used in a

study are insufficient especially in detecting the effect of a weak carcinogen. A FDA advisory committee described the difficulty of minimizing the rate of error:

Although a positive answer to (is the agent carcinogenic?) can be given in some particular instances, no unqualified negative answer is ever possible...Even with as many as 1000 test animals and using 90 percent confidence limits, the upper limit yielded by a negative experiment is 2.3 cancers per 1000 test animals...To reduce the upper limit of risk to two tumors per one million with a confidence coefficient of 0.999 would require a negative result in somewhat more than three million test animals.<sup>32</sup>

Of about 35 chemicals known to cause cancer in people, <sup>34</sup> of these are also known to be carcinogenic in mice and rats.<sup>35</sup> Still, scientists will agree only that a chemical that causes cancer in animals is potentially a cancer hazard for humans for several reasons. The method for administering a chemical usually is designed to replicate human exposure to the substance. Some cyclamate-saccharin studies, however, used pellet implantations, and the results were criticized because artificial sweeteners are consumed orally in humans.<sup>34</sup> Also, cancer that develops at one organ site in animals may occur at a different site in humans. Once a human carcinogen is identified, it is possible to find animal cancers developing in the same organ, but the reverse is not always true.<sup>35</sup> Finally, there is always the uncertainty that every possible effect of a substance has been sought out and identified.<sup>36</sup>

Critics of animal studies, especially the industry's scientists, frequently argue that the maximum tolerated dose

(the highest dose that can be given without altering the animal's normal life span from causes other than cancer) is established at unreasonably high levels. They believe that high dosage levels may affect metabolism and cause unusual toxic responses or cancers that would not occur at lower levels.<sup>37</sup> With artificial sweeteners it has often been argued that a person would have to consume hundreds of cans of diet soft drinks a day to approximate the test dosages.

The disagreements over the applicability of animal study to humans have made it difficult to determine the implications of this kind of data for the regulation of artificial sweeteners. The animal studies on cyclamate and saccharin are often disputed because the epidemiological evidence has failed to reveal any harmful effects from the sweeteners. The principal concern with both sweeteners was that they could cause bladder cancer, but studies of bladder cancer rates since World War II provide contradictory findings.

There are about 30,000 new cases of bladder cancer per year in the United States and about 10,000 deaths per year where bladder cancer is the underlying cause. Seventy-five percent of the cases occur among males, and the incidence is slowly rising for both black and white males. In contrast, the incidence of bladder cancer and mortality rates from the disease are generally declining for females of both races. Artificial sweetener consumption is not considered a significant risk indicator for bladder cancer. Instead, in

the United States the most important risk indicators are smoking and occupation, especially jobs in the dyestuffs and rubber industries where a worker is exposed to the chemicals, benzidine and 8-naphthylamine.<sup>38</sup>

Additional concern with artificial sweetener use has focused on pregnant women and children. When tested in two-generation animal studies, saccharin was found to produce a significant increase in bladder cancer in male rats exposed continuously in utero and throughout their lives.<sup>39</sup> Certain cyclamate studies have also focused on the effect of that sweetener on embryonic development and on second generation test animals.<sup>40</sup> Yet it is unlikely that epidemiological studies would be able today to detect any significant increase in bladder cancer in the children of artificial sweetener users. Diet soft drink consumption increased substantially in this country less than two decades ago, generally too early for the children of women who drink them to have developed bladder cancer.

Epidemiology is a relatively insensitive measure of low level risks from a weak carcinogen like saccharin. Positive results are the most convincing but are exceedingly difficult to obtain. A well-constructed epidemiological study would involve large numbers of people over extended periods of time.<sup>41</sup> Animal studies can be carefully structured to control for genetic homogeneity, randomization of subjects, and other factors that are impossible to ensure in human studies. Even

with careful design and execution, however, it is possible in epidemiological studies only to estimate the degree of risk for an entire population or to tentatively identify certain sub-groups who are potentially at special risk.<sup>42</sup>

The largest epidemiological study of artificial sweeteners involved 9000 cases and was initiated in 1978 in response to a congressional request after the proposed saccharin ban. The study, conducted by the National Cancer Institute (NCI), found no association in the total population between the incidence of bladder cancer and any past consumption of artificial sweeteners. A slightly greater risk appeared as consumption increased, particularly among non-smoking, white females and heavy smoking, white males.<sup>43</sup>

Despite the quality of the study, interpretation of the data has been disputed. Some critics have argued that chance, not any causal factor, explains the positive finding of increased risk for the two subgroups. They contend that it is beyond the current capacity of epidemiology to determine increased risk from low-level hazards like saccharin.<sup>44</sup> Nevertheless, epidemiological studies can be useful in putting an issue into some perspective for a regulatory agency. They can provide the best available estimate of the effect a particular substance has on humans.<sup>45</sup>

Food safety and the FDA

Given the existence of so much uncertainty, what constitutes a sound scientific decision in the study of food additives? The FDA places the responsibility for proving safety on the manufacturer. The 1958 Amendments to the Food, Drug, and Cosmetic Act require that a food additive petition establish that the proposed use of the substance will be "safe", although the term safe is not specifically defined. From the legislative history of the 1958 Amendments, it is apparent that congressional intent was to require "reasonable certainty of no harm."<sup>46</sup>

The agency has considerable discretion in deciding how much proof is required for an additive, and the standards for safety appear to be variably applied. For example, in denying approval of cyclamate, the FDA ruled that: "Once cyclamate were in the home and freely available, there would be inappropriate or excessive use by some individuals over which there could be no meaningful control."<sup>47</sup> By contrast, no such criteria seem to have been applied in the aspartame case. One month prior to the approval of aspartame for soft drink use a study expressed concern to the FDA about possible deleterious effects on human behavior from the sweetener. Although the issue was unresolved, the FDA approved aspartame for soft drink use.<sup>48</sup>

The food additive petition that a company submits to the FDA lists the identity of the new additive, its chemical



composition, the methods of manufacturing the substance, and the analytical methods to be used in detecting and measuring the presence of the additive in the food supply under anticipated levels of use. The data verifying that the additive is safe for its intended use must consist of all available toxicological research including the results of animal feeding studies using at least two species of animals. The petitioner must also identify the estimated average daily intake of the substance and show that the proposed methods of analysis are reliable and suitable for determining compliance with the regulations.<sup>49</sup> By law, the FDA does not have to consider the potential benefits of an additive. The manufacturer only has to demonstrate that an additive is functional, that is, that it will accomplish the intended physical or technical effect in the food. According to the FDA Consumer: "FDA must be satisfied that an emulsifier emulsifies and that a stabilizer stabilizes. But the agency is not authorized to determine whether society needs another emulsifier or stabilizer."<sup>50</sup>

### Cyclamate

In 1969 the Food and Drug Administration banned the artificial sweetener, cyclamate, from food and beverages. The plural form, cyclamates, is occasionally used to refer to the various forms of the substance: cyclamic acid, calcium

cyclamate and sodium cyclamate. The three are considered by the FDA to be chemically and biologically equivalent, but sodium cyclamate was used most frequently in food preparations. Cyclamate is about 30 times as sweet as sugar.<sup>51</sup>

Cyclamate was studied for at least fifteen years prior to the ban, but the scientific concern generated little public attention. (See Table II-A) The Food and Nutrition Board of the National Academy of Sciences (NAS) evaluated cyclamate during the 1950s and 1960s and cautioned the FDA about the greatly increased consumption of the sweetener resulting from the growing popularity of diet soft drinks.<sup>52</sup> In 1962 NAS questioned whether enough information was available to warrant the widespread use of cyclamate in foods and beverages.<sup>53</sup>

During the early years of cyclamate's production it was believed that the sweetener was excreted from the body unchanged. As more sophisticated analytical techniques were developed, however, it was discovered that cyclamate underwent slight changes. In 1966 two Japanese scientists found that although cyclamate was not absorbed by the body, it metabolized in some people into cyclohexylamine, a toxic substance. This finding was contrary to the safety assurances provided by Abbott Laboratories, cyclamate's manufacturer.<sup>54</sup>

FDA researchers found additional evidence of problems with cyclamate. Dr. Marvin Legator, then chief of Cell Biology Research, conducted a study that resulted in findings

TABLE II-A

## CYCLAMATE: SELECTED ANIMAL STUDIES.\*

| STUDY   | TYPE  | RESULTS   |
|---|---|---|
| Oser<br>(sponsored by<br>Abbott Labs)<br>(1969)                   | Chronic toxicity study<br>of the cyclamate-<br>saccharin mixture<br>in rats.        | Evidence of<br>malignant<br>bladder tumors and<br>testicular atrophy.         |
| Bryan<br>(University<br>of Wisconsin<br>Medical School)<br>(1970) | Female mice: bladder<br>implanted with<br>sodium cyclamate-<br>cholesterol pellets. | Carcinogenic<br>response -<br>significant increase<br>in bladder tumors.      |
| Friedman<br>(FDA sponsored)<br>(1972)                             | Animal metabolism study<br>of sodium and calcium<br>cyclamate.                      | Slight evidence of<br>bladder carcinomas<br>in rats fed calcium<br>cyclamate. |

\* These studies are often cited in reviews of the cyclamate ban. The results have been contested on the basis of inadequate testing procedures and other objections.

SOURCE: National Cancer Institute. Review of the Temporary Committee for the Review of Data on Carcinogenicity of Cyclamate (Bethesda: HEW, NIH, February 1976), pp.15-27.

that cyclohexylamine caused breakage in a significant proportion of the chromosomes of test animals. A biochemist in the FDA, Dr. Jacqueline Verrett, reported evidence of deformities in chicken embryos after injections of cyclamate.<sup>55</sup>

The cyclamate ban was not based on the indications of chromosomal and embryonic damage but instead on tests in which laboratory animals developed bladder tumors. In June, 1969, University of Wisconsin researchers reported a significant increase in bladder tumors in female mice implanted with a cyclamate-containing pellet. The results were reported to Abbott, and the company communicated the findings to the FDA. Although the test was not considered by the FDA to be directly relevant to humans, it did focus attention on the bladder as a possible cancer site.<sup>56</sup>

Another study, conducted by Dr. Bernard Oser and sponsored by Abbott, examined the chronic toxicity of the standard cyclamate-saccharin mixture in a 10 to 1 ratio used in most food formulations. The 320 test animals were divided into a control group and three other groups of 80 that were each fed a low, medium, or high amount of the sodium cyclamate and saccharin mixture. No tumors appeared in the control group (fed a standard diet) or in the low or medium dose group. Twelve bladder tumors, of which four to eight were diagnosed as carcinomas, were found in the high dose group. This group had been fed the equivalent of 3000 Sucaryl tablets

per day. Seven of the eight tumors were in animals that converted the cyclamate to cyclohexylamine. The data also revealed fifteen cases of testicular atrophy.<sup>57</sup>

This study precipitated the ban on cyclamate in foods and beverages. Abbott notified the FDA and the National Cancer Institute of the findings on October 13, 1969. The results were forwarded to NAS for evaluation, and NAS scientists recommended the removal of cyclamate from the FDA's list of safe food additives. On October 18, 1969, cyclamate was officially deleted from the list by the Secretary of Health, Education, and Welfare. In September, 1970, the ban was extended to include drugs and all other cyclamate containing products.<sup>58</sup>

The cyclamate ban has received more criticism on scientific grounds than the FDA's subsequent decisions with saccharin and aspartame. The FDA failed to control for the fact that the Oser study was not designed to evaluate cyclamate alone. Abbott argued, plausibly, that either cyclamate, saccharin, or cyclohexylamine might have been the culprit.<sup>59</sup> Before banning cyclamate the agency also failed to verify the results through additional tests. In fact, subsequent animal studies failed to produce statistically significant evidence of bladder tumors.

When the cyclamate-saccharin combination was tested, it was generally assumed that cyclamate was responsible for the negative results. Although critics of saccharin had been

warning of ill effects of one sort or another since its discovery, there was no human evidence to warrant serious concern. Cyclamate was used in greater proportion in the standard mixture which also contributed to the belief that it, rather than saccharin, was at fault. Moreover, for years the NAS studies had repeatedly cautioned against excessive cyclamate use.

Following the ban it became known that the bladder tumors were more likely caused by the saccharin than by the cyclamate. Since 1970 many long term animal studies of cyclamate's carcinogenicity and cocarcinogenicity have been conducted, and all have been negative. The studies of cyclohexylamine to date are inconclusive.<sup>60</sup> Dr. Bernard Oser, who conducted the two-year, chronic toxicity study later expressed doubts about the way in which the results had been employed as the basis for a ban.<sup>61</sup> Five years after the ban, the president of the National Academy of Sciences opened a forum on sweeteners with the remark that the FDA cyclamate decision in his personal view derived from a set of experiments that "were badly designed, were inconclusive with respect to the actual findings, and did not warrant any action at the time."<sup>62</sup>

Since cyclamate was banned Abbott has attempted to refute the scientific evidence and to have the decision reversed. In 1973 the firm submitted new studies to the FDA in a petition for the reinstatement of cyclamate. In 1975 the FDA asked the

National Cancer Institute (NCI) to establish a committee to review the existing data on cyclamate's cancer causing potential. The committee was composed of three working groups - experimental design and toxicology, pathology, and epidemiology.

In their final report the NCI committee concluded that the available evidence "did not establish the carcinogenicity of cyclamate or its principal metabolite, cyclohexylamine, in experimental animals". No conclusion was reached regarding cyclamate's potential carcinogenicity in humans. The report cited the limitations of epidemiological studies and the short exposure time.<sup>63</sup> The committee also recommended further studies and noted that "cyclamate has pushed the technology of carcinogenicity to its limit."<sup>64</sup> The NCI evaluation only contributed further to the debate over cyclamate's safety. The FDA argued that NCI did not make a definitive statement that cyclamate was safe, and Abbott contended that NCI could not have made "a more definitive statement regarding cyclamate's safety."<sup>65</sup>

The FDA, after reviewing the NCI report and other data, denied Abbott's petition in 1976. Abbott began proceedings in 1977 before an administrative law judge that lasted for three years. Finally, in 1980 Donald Kennedy, then commissioner of the FDA, followed the lead set by the administrative law judge who had ruled that cyclamate had not been shown "with reasonable certainty" to be safe. Kennedy ruled that

cyclamate "had not been shown not to cause cancer or heritable genetic damage."<sup>66</sup> Since the ban, the FDA and consumer advocates in support of keeping cyclamate off the market, have continued to emphasize the unresolved questions about cyclamate's chromosomal and embryonic effects.

### Saccharin

Saccharin is manufactured by two processes. An older method begins with toluene or a derivative, orthotoluenesulfonamide (OTS). Toluene is obtained from coal tar and is also used in the production of dyes and explosives. The second method starts with either phthalic anhydride or anthranilic acid, deriving from naphthalene which is also produced from coal tar.<sup>67</sup> Saccharin is 200 to 700 times sweeter than sugar.

Disputes over saccharin's safety started shortly after the sweetener began to be used regularly in foods. Early concerns focused on appetite and gastrointestinal problems reported in an 1886 study conducted in France.<sup>68</sup> From 1920 to 1950 a number of tests were conducted to evaluate saccharin's toxicological effects on laboratory animals. These studies were generally of short duration and did not generate any particular concern about toxicity. The National Academy of Sciences first reviewed saccharin in 1955 and found that if persons adhered to a maximum daily intake of one gram saccharin was unlikely to present a hazard.<sup>69</sup>



From 1960 to 1967 the use of saccharin alone and in combination with cyclamate increased significantly largely due to the growth in diet soft drink consumption. In 1967 at the request of the FDA, a NAS ad hoc committee on nonnutritive sweeteners evaluated saccharin again because of the expanding diet soft drink market. The committee concluded that consumption of saccharin at the one gram level for an adult was still acceptable but recommended further, more sophisticated studies.<sup>70</sup>

Scientific interest in saccharin was heightened following the 1969 cyclamate ban. (See Table II-B) As the only artificial sweetener left, it was anticipated that saccharin consumption would increase. In 1970 NAS suggested several areas of further research: epidemiological studies with special attention to diabetics and pregnant women, comparative metabolic studies in humans and animals, and tests of the toxicologic interactions of saccharin with selected chemicals.

In 1972 a study by the Wisconsin Alumni Research Foundation (WARF), partially sponsored by the Sugar Association, found evidence that saccharin increased the incidence of bladder tumors in male rats, especially in the second generation. Based on the preliminary results from the WARF study, and given the general atmosphere of scientific concern, the FDA removed saccharin from the list of substances it considered acceptable for use in the food supply. Under an interim additive regulation, the agency allowed the use of

TABLE II-B

## SACCHARIN: SELECTED ANIMAL STUDIES \*

| STUDY  | TYPE                      | RESULTS  |
|--|---------------------------|--|
| Wisconsin Alumni<br>Research<br>Foundation (1973)          | 2-generation rat<br>study | Bladder tumors in<br>offspring generation                |
| FDA (1973)   | 2-generation rat<br>study | Bladder tumors in<br>offspring generation                |
| Canadian National<br>Health and Welfare<br>Ministry (1977) | 2-generation rat<br>study | Bladder tumors in<br>parent and offspring<br>generations |

SOURCE: NRC/NAS, Report No.1, pp. 3-18 to 3-22.

|  |  |  |
|--|--|--|
| International<br>Research and<br>Development<br>Corporation (1983) | 2-generation, life<br>time rat study.<br>Largest animal<br>study on saccharin<br>ever conducted. | Benign and malignant<br>bladder tumors in<br>offspring generation<br>exposed from birth. |
|--|--|--|

\* The first three studies cited were influential in the FDA's decision in 1977 to restrict saccharin use.

SOURCE: "Saccharin Carcinogenicity Confirmed by Calorie Control Council Study", Food Chemical News (16 May 1983), pp. 3-8.

saccharin pending further study, but published regulations intended to discourage consumers from continued use of the sweetener.<sup>71</sup>

In April 1977, the FDA proposed to ban saccharin in foods, beverages, cosmetics, and most drugs.<sup>72</sup> Precipitating the FDA action was a long awaited Canadian study that corroborated earlier tests of second generation laboratory animals. The Canadian research showed that saccharin, and not an impurity caused in the manufacturing process, was responsible for the presence of bladder tumors.

In October 1977 the Office of Technology Assessment (OTA) reported the results of its evaluation of cancer-testing technology and saccharin, undertaken at the request of the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources. OTA concluded that saccharin must be considered a potential cause of cancer in humans but that there were no reliable quantitative estimates of the risk it poses to humans.<sup>73</sup> As a result of the Saccharin Study and Labeling Act, passed in November 1977, NAS was asked to evaluate saccharin's risks and benefits and to review federal food safety policy in general. NAS also found saccharin to be a carcinogen of low-potency and a promoter of the cancer-causing effect of some other compounds in laboratory animals. The epidemiological studies examined by NAS did not provide "clear evidence to support or refute an association between past saccharin use and bladder cancer in males." In

assessing saccharin's risks, the NAS report noted that "even low risks to a large number of exposed persons may lead to public health concerns."<sup>74</sup>

In 1979 in an attempt to finally settle the disputes over saccharin's safety, the Calorie Control Council, the trade association of the diet food industry sponsored the largest animal study ever organized. Conducted by the International Research and Development Corporation (IRDC), the study involved over 2000 rats. The Council expected the IRDC test to confirm that the tumors that had occurred in the Canadian study were the result of the high doses and not associated with levels of saccharin connected with human consumptions. The IRDC tested saccharin at levels ranging from 1 to 7.5 percent in the diet. The earlier studies that incriminated saccharin were at 5 and 7.5 percent levels. Instead of exonerating the sweetener, however, the IRDC test appeared to confirm its carcinogenicity. Bladder tumors developed in the test animals and their incidence declined rapidly with a decrease in dose.<sup>75</sup>

The major health concern with cyclamate and saccharin has been the potential that they cause bladder cancer. Unlike the cyclamate studies that were the basis for the FDA ban in 1969, the saccharin studies have constituted a series of carefully refined experiments, confirming its carcinogenicity in animals. Standard scientific practice makes acceptable the extrapolation of the results to humans. Because the

epidemiological evidence, however, is unable to demonstrate the incidence of bladder cancer attributable to artificial sweetener use, the diet food and beverage industry continues to dispute the results of animal studies. (See Table II-C)

### Aspartame

Aspartame, 180 times sweeter than sugar, is composed of two amino acids, the methyl ester of L-phenylalanine and L-aspartic acid. These amino acids occur naturally in many food proteins such as hamburger or milk, but are synthesized in the laboratory for the production of aspartame. Aspartame is absorbed by the body so the FDA classifies it as a nutritive sweetener, although as a protein diabetics are able to use it.

The FDA approved aspartame for use in dry foods and beverages in 1974 with the stipulation that products containing the sweetener carry a warning label for people suffering from phenylketonuria (PKU), an inherited protein metabolizing deficiency affecting approximately one in 15,000 people in the United States that can cause mental retardation if not monitored. Most states require a screening program to detect the disease at birth.<sup>76</sup> In addition the label was required to include the information that aspartame lost its sweetness in cooking or baking. Finally, if sold as a food for special dietary use, the product had to carry a label in compliance with the FDA' special dietary food regulations.<sup>77</sup>

TABLE II-C

## SACCHARIN AND CYCLAMATE: SELECTED EPIDEMIOLOGICAL STUDIES

| STUDY                       | TYPE  | RESULTS   |
|-----------------------------|---|---|
| Burbank and Fraumeni (1970) | Epidemiological time trend analysis of U.S. Bladder cancer rates 1950-1967  | No clear association with rise in consumption during 1960s  |
| Kessler (1970)              | Diabetics   | No evidence of association between bladder cancer and dietary habits of diabetics   |
| Armstrong and Doll (1974)   | Epidemiological - time trend analysis of bladder cancer mortality rates against use of saccharin and cyclamate in United Kingdom from 1911-1970 | No evidence of an increase in bladder cancer mortality. Expected association not found with high consumption during World War II.   |
| Kessler (1976)              | Epidemiological case-control study of bladder cancer and artificial sweetener use matched by sex, race, age, marital status, and hospital       | No statistically significant differences for either sex or both combined in proportion of artificial sweetener users, in mean intake of artificial sweeteners per day or in number of mean years that artificial sweeteners were used. No statistically significant differences in use of diet beverages. |
| Armstrong, et. al. (1976)   | Diabetics   | No evidence of association between bladder cancer and dietary habits of diabetics.  |

SOURCE: NRC/NAS, Report No.1.

TABLE II-C, cont'd.

## SACCHARIN AND CYCLAMATE: SELECTED EPIDEMIOLOGICAL STUDIES

| STUDY          | TYPE  | RESULTS  |
|----------------|---|--|
| Howe<br>(1977) | Canadian matched case<br>control. 632 bladder<br>cancer patients. | No increased risk<br>of bladder cancer<br>associated with<br>artificial<br>sweetener<br>use in females.<br>Males using<br>artificial<br>sweeteners had<br>increased bladder<br>cancer risk. The<br>results are<br>significant only<br>for the tabletop<br>use of artificial<br>sweeteners. |

SOURCE: NRC/NAC, Report No.1.

|  |   |  |
|--|---|--|
| Hoover. et. al.<br>(National<br>Cancer<br>Institute<br>1979) | Epidemiological case<br>control study in U.S.<br>3010 cases ages 21-84,<br>male and female. | No evidence in<br>general population<br>of association<br>between artificial<br>sweeteners and<br>bladder cancer.<br>Some evidence that<br>certain subgroups<br>at increased risk. |
|--|---|--|

SOURCE: Robert Hoover and Patricia Hartge Strasser,  
Progress Report to the Food and Drug Administration from  
the National Cancer Institute concerning the National Bladder  
Cancer Study (1982).

Marketing was delayed, however, when Dr. John Olney, a scientist at Washington University, raised several objections concerning aspartame's safety. At issue according to Olney was whether the sweetener caused nerve cell and brain damage and possibly brain tumors.<sup>78</sup> Olney identified possible toxic effects from the component amino acids in aspartame and from methanol which is released during absorption and digestion.<sup>79</sup> Olney also expressed particular doubts about the safety of aspartame use for children or pregnant women. Finally, he pointed out the possibility that some people unknowingly carry a recessive PKU trait and might be adversely affected despite the warning labels.

In 1979 the FDA established a public board of inquiry composed of three scientists, two from MIT and the other from the University of California in San Diego, to evaluate the available data and provide the commissioner with scientific recommendations. The board considered two allegations against aspartame: that it might entail a risk of brain damage resulting in mental retardation, endocrine dysfunction, or both and that aspartame consumption might increase the incidence of brain tumors.<sup>80</sup> The dispute over aspartame was complicated by charges that Searle falsified data submitted to the FDA.<sup>81</sup> The board, however, accepted the evaluation of the FDA and the results of an audit conducted by the Universities Associated for Research and Education in Pathology that Searle's data were authentic.



On the first issue the PBOI ruled in 1980 that the risk of brain damage associated with aspartame consumption in humans was negligible. On the second issue, whether aspartame could be implicated in causing brain tumors, the scientists found that the the problem was "a complex one and difficult to judge fairly on the basis of available data."<sup>82</sup> Nevertheless, the board decided that the possibility that aspartame contributed to the development of brain tumors could not be ruled out, at least when administered in the quantities employed in the reviewed studies. The FDA commissioner, however, overruled the board, disagreeing with the interpretation of the brain tumor studies. The commissioner also cited a long-term Japanese study assessing aspartame's carcinogenic potential that was submitted after the PBOI issued its decision and that appeared to be negative with regard to brain tumors.<sup>83</sup>

The FDA's initial ruling did not include aspartame's use in beverages because of concern that, in storage for long periods of time, the sweetener broke down into a substance called diketopiperazine (DKP). One possible effect of DKP is the formation of carcinogenic nitrosamines.<sup>84</sup> In July 1983 the FDA granted Searle permission to market aspartame as a sweetener in soft drinks and in certain wet foods such as peanut butter, jelly, canned fruit, and ice cream. The agency was reportedly convinced that Searle would be able to overcome the problem of aspartame's stability in the soft

drink solution.<sup>85</sup>

Scientists in the policy process

Members of the aspartame public board of inquiry found the process to be a difficult, "not particularly happy" experience. Although the board was specifically instructed by the agency not to consider the impact of its decision on industry or others, the participating scientists were well aware of the concerns of all the interested parties. At least two members felt that the process was useful in airing issues and drawing the attention of the FDA to weak or rash arguments. They also felt that the agency should have stressed the advisory nature of their participation "to anyone who would have listened."<sup>86</sup>

By securing the advice of prominent scientists, the FDA attempted to develop an irreproachable basis for a regulatory decision and to avoid an adversarial situation in which according to an agency scientist, "the best lawyers would win." In the end, however, the FDA did not appear enthusiastic about the PBOI even as a mechanism for settling scientific problems. Several agency officials expressed impatience with the board's desire for further study, finding the three scientists "too academic" and unprepared to understand the practical implications of further delay.<sup>87</sup> The agency's complaints about the board, however, appear to be somewhat disingenuous. The PBOI made an important scientific

and regulatory contribution by framing the major concerns with aspartame. The board's review represented an impartial, thorough analysis of the aspartame data. Even though their decision was overturned, the participation of well-respected scientists helped to legitimate the regulatory process.

The use of outside scientific organizations has in general failed to bring more certainty to the artificial sweeteners proceedings. According to Joel Primack and Frank von Hippel, the role of the scientific advisory organization is "to provide information, analysis and critical advice".<sup>88</sup> Temporary groups, however, are unable to provide continuous oversight. Consequently, their involvement is usually restricted to reviewing scientific findings that may be outdated because of rapid changes in technology.<sup>89</sup>

The composition of the panel is generally determined by the sponsoring government agency as well as are the questions to be addressed and the timetable for the panel's deliberations. Primack and von Hippel noted that "scientists (are) often unprepared when they become advisors and find themselves confronted with difficult and unfamiliar decisions, often in an atmosphere of great pressure."<sup>90</sup> It is often to the agency they are advising that the scientist looks for guidelines regarding his role, as occurred with the aspartame public board of inquiry.<sup>91</sup>

Although the scientific panel may expand the range of opinion available to government, the composition of the panel

may provide expansion only in one direction. Consumer or public interest organizations may be represented in some advisory panels that are designed to have a more diverse composition such as occurred with the NAS panels on saccharin and food safety policy. Consumer groups often charge, however, that they are usually excluded from the wholly scientific group whose voice may be influential, particularly in legitimizing a policy.<sup>92</sup>

In the artificial sweeteners case, the principal contribution of the scientific advisory groups has been simply to add to the data or to synthesize existing studies. The results of their participation often seemed to be to allow the FDA or Congress to delay a decision or to corroborate a policy already in existence. For example, the assessment of cancer testing technology and saccharin conducted by the Office of Technology Assessment for Congress in 1977 was well received but has not prompted any further legislation on saccharin or food safety.

In the cyclamate case according to the House subcommittee that reviewed the ban, a medical advisory committee was formed by the FDA only to legitimate the decision:

HEW used an outside advisory body to make recommendations on matters which had already been decided... At the time HEW convened the medical advisory group on cyclamates, the Secretary had already announced publicly that cyclamate sweeteners and cyclamate-containing food products would be available in the future as non-prescription drugs. In affirming the Secretary's decision, the group acted on the same scientific facts that had been considered by the FDA's medical staff in reaching a contrary

conclusion...Similarly, the reconvening of the Medical Advisory group served no valid scientific purpose after the subcommittee's hearings had spotlighted FDA's illegal cyclamate regulations."<sup>93</sup>

The participation of the National Academy of Sciences often enables the government to speak with greater authority about a scientific subject.<sup>94</sup> NAS describes itself as an advisory body whose role does not include telling government how the advice should be used. Over the years, the NAS reports on cyclamate and saccharin appear to have had little immediate impact on FDA actions, either in precipitating a decision or in providing a coherent structure for FDA policymaking. Instead, the FDA has added the NAS work on cyclamate and saccharin to an already enormous data base. The fourteen years (in 1970) of NAS advice on the cyclamate issue have been characterized as "remarkably ineffectual", prompting one author to remark that "it makes one wonder why such advisors keep coming quietly back."<sup>95</sup>

One reason for continued involvement is that NAS activities are prestigious, a mark of professional distinction. In general, serving on a government sponsored scientific committee provides recognition within a scientist's field; there is usually no financial remuneration. The professional incentives for participating may serve, however, to inhibit dissenting views.

Scientific advisors often find themselves pressured by their own research or reputational requirements. The composition of scientific advisory committees tends to be

relatively small with overlapping memberships by several hundred scientists. Continued access to information and resources, maintaining peer respect, and ensuring participation in future scientific groups are all sources of professional motivation.<sup>96</sup> The iconoclast scientist on an advisory panel must weigh the consequences of a dissenting opinion against these considerations.

### Conclusion

Sugar substitutes are often referred to as if they are beneficial for losing weight. The FDA has appeared on various occasions as confused as the public about the validity of this belief, citing the medical benefits of both cyclamate and saccharin.<sup>97</sup> The diet food industry, mainly through advertising, has been largely responsible for associating artificial sweeteners with successful dieting. Saccharin and aspartame (and, in the past, cyclamate) do provide substantial economic benefits to their manufacturers and the soft drink companies. But there is no evidence to support the belief that artificial sweeteners assist the dieter.

There has been little scientific interest in assessing the effectiveness of artificial sweeteners, in part because it would be difficult to identify all the variables or to measure benefits quantitatively. When cyclamate was banned only a few controlled studies had been conducted to test artificial sweeteners and weight loss. None of the studies established a

useful role for artificial sweeteners as weight reducing aides except under very closely controlled conditions.<sup>98</sup>

It was not until Congress mandated a study of saccharin in 1977 that benefits were specifically considered. NAS, which conducted the study, reported that there were no long term, well-controlled clinical trials using saccharin to control obesity or diabetes. NAS was also unable to report on any evaluations of the benefits of cyclamate-saccharin combination that had dominated artificial sweetener use during the 1950-1970 period. Other reputed benefits from artificial sweeteners such as reducing the number of dental caries, improving the palatability of dentifrices and therapeutic drugs, or assisting in the dietary management of chronic diseases also could not be substantiated.<sup>99</sup>

Scientists have also been reluctant to weigh the benefits of sugar substitutes because some are considered "psychological" and therefore highly subjective. The NAS report stated there was insufficient evidence to determine whether the human desire for sweets is an innate biological need, an acquired taste, or some combination of the two. NAS did find "a perceived need or psychological reliance on nonnutritive sweeteners" among certain groups in the population.<sup>100</sup>

One author has proposed that consuming artificial sweeteners may actually increase the body's desire for sugar. According to William Bennett, consumption of an artificial

sweetener may establish a cycle in which a person drinks a diet soft drink, the body expects to receive sugar, feels cheated and responds with a physiological demand for more sugar, and the person responds with more artificial sweetener. Bennett suggested that the diet industry may have created an ideal market, where demand could grow endlessly.<sup>101</sup>

The involvement of the diabetic associations in the artificial sweeteners controversy has contributed to the impression that the sugar substitutes provide a medical benefit. Cyclamate, saccharin, and aspartame are not effective in treating or alleviating diabetes. They are considered to be of assistance in helping the diabetic to adhere to dietary restrictions. The Juvenile Diabetes Foundation and the American Diabetes Association have both testified at congressional hearings about the "lifestyle" benefits artificial sweeteners provide for diabetics.

The belief in the benefits of artificial sweeteners, however misplaced, is firmly entrenched in the American consciousness, and is a major reason why policy in this area has been so controversial, and why the public was moved to protest the saccharin ban. The confusion over benefits continues to be matched by debate over the risks. The uncertainty of the science has contributed to the lack of coherence in artificial sweetener policy.

A scientific comparison of cyclamate and saccharin would suggest that saccharin presents the greater health hazard.



The conclusion is not reflected in the current status of each sweetener. The majority of evidence since the ban indicates that cyclamate is not a carcinogen, but the FDA remains unconvinced. Questions still linger about the carcinogenicity of cyclohexylamine and about possible chromosomal or embryonic damage from cyclamate consumption. Animal studies with saccharin overwhelmingly suggest that it is a potential human carcinogen, but the lack of epidemiological evidence has been used by saccharin supporters to forestall the FDA's attempted ban.

The limitations of science have been exploited by interest groups attempting to draw support for their own perception of what would be a desirable policy for each of the sweeteners. For the Food and Drug Administration sorting out the scientific problems in each of the cases has been complicated by pressures that transformed these scientific problems into political debates.

NOTES: Chapter II

<sup>1</sup> Peter Barton Hutt, "Public Policy Issues in Regulating Carcinogens in Food" in Food Safety: Where are We? by U.S. Senate Committee on Agriculture, Nutrition, and Forestry (Washington, D.C.: U.S. Government Printing Office, July 1979), p. 283.

<sup>2</sup> Committee for a Study on Saccharin and Food Safety Policy, National Research Council/National Academy of Sciences, Saccharin: Technical Assessment of Risks and Benefits Report No. 1 (Washington, D.C.: National Research Council/National Academy of Sciences, November 1978), chap. 2, esp. table 2-2. Hereafter referred to as NRC/NAS, Report No. 1; Interview.

<sup>3</sup> Margareta Cronholm and Rolf Sandell, "Scientific Information: A Review of Research," Journal of Communication (Spring 1981), p. 86.

<sup>4</sup> The public has come to this realization in large part because organizations such as the American Council for Science and Health, an industry supported group, and the Calorie Control Council, the trade association of artificial sweeteners manufacturers and diet food producers, have emphasized the ambiguity of scientific research in the food safety area in various publications. On this point, see "Latest Saccharin Tests Kill FDA Proposal," Science, 208 (11 April 1980), p. 154.

<sup>5</sup> "One Hundred Years of Food Protection" in Food Safety: Where Are We?, chapter 1.

<sup>6</sup> Commission of the European Communities, Food Additives and the Consumer (Brussels: Centre de Recherches Foch, 1980), p. 5.

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<sup>8</sup> See Lehman, FDA Consumer (April, May, June, 1979); Ian C. T. Nisbet, "The Bitter Problem of Sweets," Technology Review (October/November 1977), p. 7.

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CHAPTER III  
CYCLAMATE: THE SOFT DRINK INDUSTRY AND THE CREATION OF A DIET  
MARKET

The widespread use of artificially sweetened foods and beverages is a post-World War II phenomenon. Although saccharin has been more or less continuously available since its discovery in 1879, cyclamate was the first artificial sweetener to be consumed by millions of Americans on a regular basis. Cyclamate was in use in the United States from 1950 to 1969 when it was banned as unsafe by the Department of Health, Education, and Welfare. Almost 18 million pounds of cyclamate were consumed in 1969 in food products with a total value of one billion dollars.<sup>1</sup>

Cyclamate was discovered in 1937 by Michael Sveda, a doctoral student in chemistry at the University of Illinois. Sveda's discovery was the classic scientific accident; he was conducting experiments on sulfamic acid and its salts and noticed a sweet taste on a cigarette that he had left on his laboratory bench. From the twenty compounds he was working on, Sveda identified the sweetener as sodium cyclohexylsulfamate or cyclamate.<sup>2</sup>

Sveda took out a patent on cyclamate which he later assigned to DuPont chemical company where he went to work in

1942. Dr. Ernest Volwiler, president of Abbott Laboratories, a major pharmaceutical firm, heard of Sveda's discovery on one of his periodic visits to DuPont. Because DuPont lacked experience in the marketing of consumer products, the company licensed Abbott to develop cyclamate for commercial use.<sup>3</sup>

In 1950 Abbott asked the Food and Drug Administration for permission to market sodium Sucaryl, a tabletop sweetener containing cyclamate. The approval was delayed because the FDA had reservations about the quality of the safety tests submitted by the company in support of the application. The FDA conducted two years of additional animal feeding studies on its own, and approved Sucaryl as a non-nutritive sweetener that was required to carry the warning label that it was intended for use "only by persons who must restrict their intake of sweets."<sup>4</sup>

Although more expensive than saccharin, cyclamate was considered by the food industry and by many consumers to be an almost ideal sugar substitute. It was free from the bitter aftertaste that was often experienced with saccharin. Cyclamate was also versatile; it could be used in both dry and liquid food applications, and it maintained its sweetness when heated or frozen. Most food and beverage preparations added cyclamate and saccharin in a 10:1 combination, a synergistic mixture in which the two together were sweeter than their simple sum. In the standard mixture cyclamate and saccharin each contributed about half of the final sweetening power.<sup>5</sup>

Before cyclamate became popular, artificial sweeteners were associated with illness. For over fifty years saccharin had been used almost exclusively by diabetics primarily as a sugar substitute in liquids. In its most common tabletop version saccharin resembled aspirin or other tablet drugs. People often carried pill boxes with their own supply to be opened when coffee or tea was served. Moreover, saccharin's bitter aftertaste did nothing to dispel the notion that it was a medicine.

Saccharin consumption was limited also by government regulations. The FDA required that artificially sweetened foods indicate the number of calories contained in a specified portion and display a warning label of the type initially carried on Sucaryl. Before the 1958 amendments to the Food, Drug, and Cosmetic Act, the states were involved with regulatory issues that are now handled by the FDA. Most states required that synthetic sweeteners be identified as products for special dietary purposes, and any foods containing saccharin were labeled "dietetic."<sup>6</sup>

In 1953 only three states allowed artificial sweeteners to be marketed without special regulations. Seventeen states placed limitations on their use; ten states specifically banned saccharin, and the remainder required dietary labeling. In Massachusetts and Florida consumers had to have a doctor's prescription to buy a synthetic sweetener.<sup>7</sup>

Many of these laws were enacted under pressure from soft

drink bottlers and food packagers who had been opposed to saccharin, fearing competition for their higher priced sugared products. However, as cyclamate became increasingly popular, these laws were relaxed or repealed, often at the urging of the same manufacturers who had been against saccharin earlier. In working to repeal the restrictions, Abbott adopted a strategy that it and other companies would follow later in the cyclamate and saccharin controversies. Abbott suggested that the diet industry encourage consumers to lobby for regulatory changes on the industry's behalf. An Abbott executive recommended in a major food trade journal that: "If artificial sweeteners are promoted for use by the people for whom they are intended, it is felt that most states will come to permit their use."<sup>8</sup>

The easing of legal restrictions made it possible to market cyclamate nationwide; by 1955 the sweetener was allowed in all the states.<sup>9</sup> Cyclamate's popularity was also enhanced by the simple but important reason that it tasted much better than saccharin. But the major determinant of its success (and of the continued success of artificial sweeteners to date) was the transformation of sugar substitutes in the public's perception from "medicine" to aids for dieting. This change resulted from the American obsession with slimness that developed after World War II and from the marketing campaigns undertaken by Abbott, the soft drink manufacturers, and other companies that exploited this new preoccupation with dieting.

Before the war, being overweight was not a problem for most Americans who found mere subsistence difficult especially during the Depression years. Dieting was almost exclusively an "upper class sport."<sup>10</sup> The economic prosperity of the post-war years produced a "democratization of obesity". Eating to repletion, a practice previously reserved for the very few, became available to millions of formerly poor Americans who could now afford to overeat.<sup>11</sup>

Prosperity also provided discretionary income that encouraged an interest in fashion among more American women. Fashion advertisements of the 1920s principally used drawings, but by the 1930s the leading fashion magazines had begun to photograph very slender models. By the late 1940s clothes were designed exclusively to accentuate a thin figure.<sup>12</sup>

The popularity of cyclamate and all artificial sweetener use since the 1950s has been underwritten by the largely unexamined assumption that they are an effective aid to dieting. This belief developed during the fifties when obesity was identified in the popular press as a major American health problem: "Almost all doctors firmly believe that obesity is one of the nation's gravest health problems...there are 50 percent more deaths of fat people than of thin or average ones. Fat people are highly susceptible to diabetes, heart, and circulatory disturbances, kidney and gall-bladder diseases and other life-shortening ailments."<sup>13</sup>

The proliferation of dieting advice that began in the

late 1950s helped to create confusion about what was effective for losing weight. In 1960 a review of a dozen various and often conflicting dieting maxims noted the impossibility of prescribing a single dietary solution that would work for everyone: "No doctrinaire solution will work for them all. Each individual has conditioned habits of eating, of taste, of appetite, of expenditure of energy, of nervous rhythms, and most important of all, of metabolism."<sup>14</sup> The American Medical Association called weight reducing in 1959 a "national neurosis."<sup>15</sup> The dieting craze, however, made any clear analysis of what actually worked incidental. With 34 million overweight Americans (one in five at the time) any reducing diet, especially if written by a physician, was likely to find a publisher.<sup>16</sup>

From the beginning of cyclamate's use in this country, the press and the public appear to have accepted a straightforward relationship between simply eliminating one source of calories and losing weight. Because sugar is a major source of calories in the American diet, it has been a common assumption that replacing sugar with an artificial sweetener would lead to weight reduction. A widely read periodical in the 1950s echoed this belief, and by extension, that cyclamate could aid in ameliorating serious illnesses aggravated by obesity:

The significance of Sucaryl's role in the national health picture is obvious...Dietary experts who have studied the problem suggest that the best diets are those which cut down on sugars, starches and fats, and

retain the proteins. It has already been demonstrated that the substitution of Sucaryl for sugar can have spectacular results. There are 120 calories, for instance, in an eight-ounce glass of sugar-sweetened ginger ale, but only seven calories when it is made with Sucaryl. A serving of vanilla ice cream has 110 calories with sugar, only 50 with Sucaryl. Other dishes show similar calorie savings when sugar is left out.<sup>17</sup>

The belief that artificial sweeteners aid dieting has persisted despite the absence of corroborating scientific evidence.

Abbott's introduction of cyclamate was fortuitously timed for the company. Sucaryl entered the market at the start of America's interest in weight control and its popularity with dieters was unanticipated. When Abbott applied to the FDA for approval of Sucaryl, the company filed a new drug application. Abbott intended to market Sucaryl to diabetics and others who had to restrict their sugar intake for health reasons.

The first soft drink manufacturer to use cyclamate was also surprised at the popularity of the low calorie drinks with dieters. Diet soft drinks sweetened with saccharin were produced by the Cott Beverages Corporation in 1947. The sales were insubstantial until the 1950s when Kirsch Beverage introduced its No-Cal soft drink sweetened with Sucaryl. Kirsch intended its low calorie drink to be for diabetics, until the company learned that many of its sales were coming from people concerned about their weight. Kirsch changed its advertising strategy to directly appeal to the dieter. In less than a year, the No-Cal drink was outselling all other Kirsh brands with a production of two million cases.<sup>18</sup>

In 1955 DuPont's patent and exclusive licensing of cyclamate to Abbott expired. Other companies began to produce cyclamate for the bulk market and for home use in tablet or liquid form. After 1955 DuPont, which had produced some bulk cyclamate independently of Abbott, had eight percent of the industrial market, and two pharmaceutical companies, Pfizer and Merck, held fifteen and two percent of the consumer market. Abbott maintained a 75 percent share of the bulk market and a 60 percent share of the tabletop sales during most of the years cyclamate was in production.<sup>19</sup>

Sucaryl was sold through Abbott's distribution organization only to drug stores. Bulk sales were handled through the chemical sales division. Before 1955 the chemical sales division had placed advertisements for Sucaryl only in the trade journals of the food and beverage industries. Direct consumer advertising was limited to displays in drugstore windows and at cash registers. Because Abbott was experiencing competition from other manufacturers, the company's board of directors decided to break with their usual advertising policy that had refrained from direct appeals to consumers and had concentrated on the bulk market.<sup>20</sup> Abbott undertook a campaign specifically to expand the use of Sucaryl from a product for diabetics to one used by overweight or weight conscious people.<sup>21</sup> The company sponsored advertisements in women's magazines that described Sucaryl as a diet aid and as a way for children to avoid the dental



caries associated with sugar.

The interest in dieting that developed in the 1950s gave Abbott the incentive to promote cyclamate as a diet aid rather than as a product for diabetics. The FDA, however, made the new use a success. In 1958 as required by the amendments to the Food, Drug, and Cosmetic Act, the FDA compiled a list of food additives generally recognized as safe (often referred to as the GRAS list). Scientists in a national survey were asked to indicate any reservations about the substances on the list including cyclamate and saccharin. Of the 900 asked about cyclamate, the 355 who responded said they knew of no ill effects from it. As a result, cyclamate was exempted from the testing that was to be required of new food additives. Saccharin was also listed as GRAS.<sup>22</sup>

Under Abbott's initial petition in 1950, cyclamate's use was restricted to special dietary foods carrying a warning label. By placing cyclamate on the GRAS list, the FDA made it possible for manufacturers to use cyclamate in any foods, in unrestricted amounts, and often without any warning label. Once the list was compiled, the diet industry responded to consumer inquiries about cyclamate's safety by citing the fact that the FDA had included it in a group of substances generally recognized as safe.<sup>23</sup>

Without this expanded use it is doubtful that any major controversy would have developed over cyclamate. As a sweetener for diabetics, cyclamate consumption could have

been monitored by physicians and easily regulated by the individual consumer. It is unlikely that the FDA would have felt compelled to ban a product used by a relatively small number of people particularly with the confusion that existed over whether cyclamate had some medical benefits. Moreover, even if the agency had found sufficient evidence to ban cyclamate, its action would have affected a much smaller number of consumers than the millions who eventually included artificially sweetened soft drinks and other food products in their daily diet.

Until the 1950s the diet industry was composed almost entirely of the manufacturers of saccharin and cyclamate. The weight reduction fad encouraged the food and soft drink companies to develop diet products. When it was banned in 1969, cyclamate was an ingredient in over 250 foods. Cyclamate was not always listed as an additive in each of these products. For example, bacon and ham cured with cyclamate or children's vitamins coated with cyclamate carried no warning labels. Eventually, almost 75 percent of American families consumed cyclamate in some form.<sup>24</sup>

The new products and their popularity with consumers drew the attention of the sugar industry and increased concern among the scientific community about cyclamate's safety. The most popular products, tabletop sweeteners and low calorie soft drinks, reinforced cyclamate's new image as a diet aid. By 1963 several national soft drink companies were

manufacturing a diet cola in response to the success the regional manufacturers were experiencing with their cyclamate sweetened drinks.

The Cumberland Packing Corporation of Brooklyn, New York, first produced cyclamate in powdered form for tabletop use. After World War II Cumberland received a contract to package sugar in envelopes for restaurant use. Contract packaging became the basis for the company's growth, but the family who owned and managed Cumberland Packing decided to create their own product. In 1958 artificial sweeteners were available only in liquid and tablet form for tabletop use. Cumberland Packing developed a powdered, cyclamate-saccharin combination (in the 10:1 ratio) that resembled sugar in one serving sizes under the brand name Sweet 'n Low.

Like the Kirsch and Cott beverage companies, Cumberland Packing expected that the convenience of their product would appeal to diabetics. The company was initially surprised to receive letters instead from consumers who praised Sweet 'n Low's taste and described their belief that it helped in dieting. In response, Cumberland Packing modified its advertisements to appeal to America's growing diet consciousness. Although other companies manufactured packaged versions of cyclamate, Cumberland Packing dominated the market.<sup>25</sup>

### The Soft Drink Industry

Artificial sweeteners became controversial as a result of their use in soft drinks. Since 1963 the consumption of soft drinks has more than doubled from about 18 gallons per capita to a 1982 rate of almost 40 gallons. Americans today drink more soft drinks than any other beverage. Coffee was in second place in 1982 at 28 gallons per capita; milk consumption in third place at only 22 gallons. Diet drinks currently account for almost 18 percent of total soft drink sales.<sup>26</sup> (See Figure III-A)

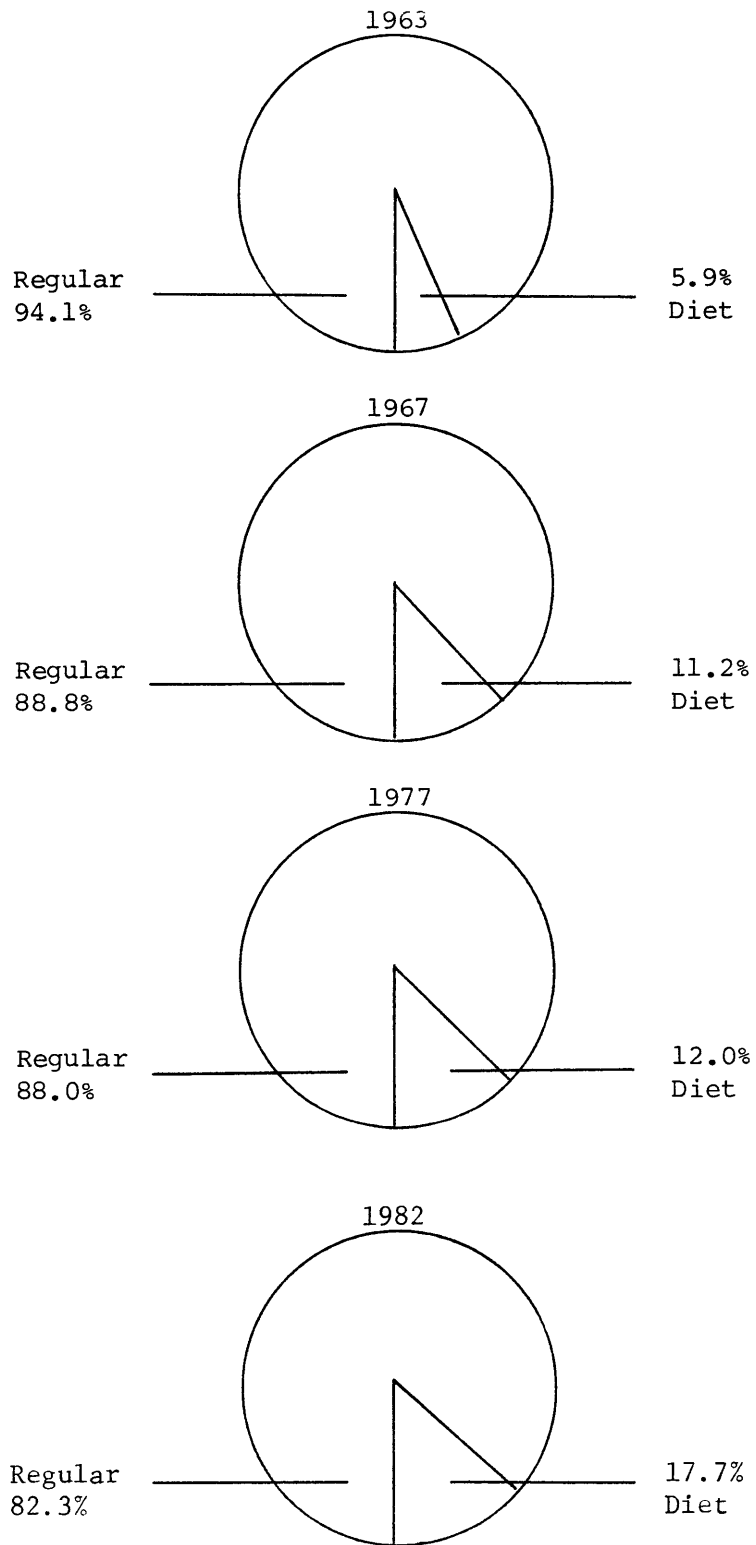
The activities of Coca-Cola and Pepsi, including the constant rivalry between the two giant companies have dominated the soft drink industry. In 1962, sugarless brands accounted for three percent of the soft drink market. A year later Pepsi introduced Patio Diet Drink and Coca-Cola introduced its low calorie brand, Tab:

Pepsi-Cola's new low-calorie soft drink, Patio Diet Drink, ...will hit hard for a share of rising of low-calorie drink market. Coca-Cola, countering quickly, is bringing out Tab as its low-calorie entry. Coke's campaign...is obviously going all out to gain a fat share of the \$18 million low-calorie trade. Coke is the bellwether in the overall soft drink field. Pepsi is the aggressive second place occupant. Now that each has entered strongly into a new area of contention, the resulting advertising clash could have implications for the whole field.<sup>27</sup>

After Coca-Cola and Pepsi brought out their diet products, some analysts estimated low calorie sales would rise by the end of the decade to 30 or 40 percent of the market. This proved overly optimistic, but diet drinks did find a

FIGURE III-A

Soft Drink Industry Regular and Diet Packaged Sales Mix



Source: Beverage Industry Annual Manual and National Soft Drink Association.

receptive audience during the sixties. In The Cola Wars, J.C. Louis and Harvey Z. Yazijian describe one reason this occurred: "The post-war baby boom and a Camelot-enhanced prosperity produced a consumer class voracious for new products to complement leisure-minded lifestyles."<sup>28</sup>

By 1965 the major soft drink manufacturers viewed the United States market as highly segmented. Coca-Cola and Pepsi introduced seven new brands between them in a three year span.<sup>29</sup> The first of the national diet brands, Royal Crown's Diet Rite Cola, held a 45 percent market share in 1963. When Coca-Cola and Pepsi introduced Tab and Patio Diet Drink, Royal Crown's lead began to slip. Diet Rite, which was Royal Crown's flagship brand, permanently lost first place after cyclamate was banned in 1969.<sup>30</sup> Tab and Diet Pepsi, which replaced the faltering Patio Diet Cola, have consistently ranked among the ten top diet drinks since the middle 1960s. In 1982 Tab was the fifth best selling brand among all soft drinks and Diet Pepsi was sixth. Moreover, Tab and Diet Pepsi far outranked the other brands in 1982 in terms of rate of growth with a 10.2 and 11.3 percent rise in sales respectively over the previous year.<sup>31</sup>

Soft drinks have been explicitly linked in advertising with youth, health, vigor and patriotic American themes. For example, until World War II, current events were never depicted in Coca-Cola's advertisements. Instead, Coca-Cola sent the message that Americans were "pleasant people in

pleasant places doing pleasant things as a pleasant nation went pleasantly on its course."<sup>32</sup> It was necessary, however, for the companies to adapt their promotion of diet drinks to fit the less staid sixties and the medium of television. The amount of television versus print advertising began to grow rapidly in the early 1960s. The soft drink firms, particularly Coca-Cola and Pepsi, had the resources to use the "new" medium extensively to support their diet brands with massive advertising campaigns.

Almost from the beginning of its advertising history, Coca-Cola utilized pictures of beautiful women, and the campaign for its diet products continued this tradition. But it was Pepsi whose advertising strategy best echoed the impact that the members of the baby boom generation were having on American culture. In 1963 Pepsi introduced what has been termed "lifestyle advertising" with a campaign called the Pepsi Generation. The Pepsi Generation celebrated young people in everyday activities. These images were combined in the promotion of diet drinks: young, slim, attractive women were shown drinking Diet Pepsi while playing sports or in other commonplace situations.

With the exception of Dr. Pepper, the first low calorie cola drinks did not use the original name of the company's principal cola drink. The companies wished to disassociate their artificially sweetened products from any connotations of illness that the diet label might imply. Although Pepsi

initially feared giving consumers the impression that regular Pepsi was calorie laden, after much agonizing, the company introduced Diet Pepsi as the replacement for Patio.<sup>33</sup>

In Coca-Cola's case, the company was especially interested in protecting its flagship product from the suspicion that it was fattening. It was not until 1983 that Coca-Cola would introduce a brand called Diet Coke. The name, Tab, was selected from a total of 250,000 phonetic combinations because it sounded streamlined. The Tab bottle was carefully chosen. According to company instructions, the bottle had to "make a lasting impression on both the public and packaging industry. Aesthetically it had to imply the same high quality consumers have come to expect of all products from the Coca-Cola company. That this drink was both tasty and easy on the diet also had to be implicit in the design."<sup>34</sup>

It was not simply the immense popularity of diet soft drinks with consumers that accounted for their importance to the industry. The high cost of sugar relative to cyclamate and saccharin and the volatility of sugar prices has also made the artificially sweetened product profitable for the companies and the bottlers. The sugarless brands since their introduction have been sold at the same price as brands sweetened with sugar. This practice of level pricing has been defended by the soft drink firms who contend that the price set for both sugared and artificially sweetened drinks



represents an average of the cost of the ingredients. The firms argue that without level pricing, the sugared soft drinks would be much more expensive.<sup>35</sup> Despite this rationale, the price of artificially sweetened sodas has remained on a par with the sugared drinks regardless of the fluctuations in the cost of sugar or corn sweeteners.

The bottlers have been crucial to the secular growth in soft drink consumption in this country, to the success of sugarfree brands, and to the preeminence of Coca-Cola and Pepsi. The soft drink industry is composed of parent companies, each with their own network of franchised bottlers, who distributed the new diet brands nationwide during the 1960s through hundreds of thousands of easily accessible retail outlets and vending machines.

The production and marketing of soft drinks through independent bottlers began in 1899 when Coca-Cola agreed to let two Atlanta lawyers establish franchises throughout the country. Parent Coke was initially skeptical about the idea of using bottlers to market its soft drink.<sup>36</sup> The company was only fourteen years old at the turn of the century and Asa Candler, Coca-Cola's second owner and an Atlanta druggist, believed soda fountain outlets were the key to success.

In 1902 Pepsi also began to grant franchises. Seventeen years later, Coca-Cola was bought by Ernest Woodruff, an Atlanta entrepreneur, who viewed the bottlers as the best mechanism for achieving growth, and he worked to extend the

network. When the bottlers's sales of Coca-Cola surpassed those in soda fountains for the first time in 1928, the franchise system became a permanent feature of the industry.

The lack of a strong distribution network can hinder growth whatever other assets a company may have. For example, despite Royal Crown's innovative efforts in bringing out the first national brand diet drink and in pioneering the use of aluminum cans, its bottlers have lacked the strength to make the company a major contender to Coca-Cola and Pepsi.<sup>37</sup> The bottlers are fierce rivals for sales within their franchised area. The competition is manifested in constant product differentiation and intense advertising to support new brands.

The parent companies supply the syrup or syrup concentrate which the bottlers mix with carbonated water at the local plant. Traditionally, Coca-Cola purchased sugar directly and sold it to its bottlers at a fixed price. As sugar prices became more volatile during the 1970s, the company attempted to renegotiate its 58 year old contract with the bottlers to have them absorb more of the price increases. The new contract strained the relationship between the bottlers and the parent company. Pepsi and other companies have maintained more flexibility in their syrup pricing arrangements over the years, and their relationships with their bottlers have not been as contentious as Coca-Cola's.

In 1982 Pepsi had 470 franchises nationwide and Coca-Cola had 685.<sup>38</sup> The number of independent bottlers has gradually

declined because of pressure from the parent companies on the smaller franchises to merge with larger ones. In addition the soft drink industry was often confronted by health and environmental challenges during the late 1960s and early 1970s. The bottlers had to absorb the rising costs and uncertainty associated with stricter government regulations and environmental laws that resulted from these concerns.

The soft drink firms have worked diligently to promote their products as wholesome and refreshing. They have usually attempted to avoid direct involvement in the controversies that have developed over various ingredients. In 1982 7UP advertised its flagship brand as caffeine free and was roundly criticized, not just by other soft drink firms, but by the entire food industry. In general, companies fear that focusing on the hazards of one ingredient will lead the public to question other ingredients and eventually generate doubt about the safety of the entire food supply.<sup>39</sup> Seven-Up was charged with using "scare tactics" and with unduly provoking public concern about an additive that had not been proven harmful. Despite the diatribes against 7UP that ran in beverage and advertising industry publications, all the major soft drink firms have since introduced a caffeine-free brand.<sup>40</sup>

Louis and Yazijian noted that Coca-Cola had long experience with what it considered the "volatile mixture of public sentiment and political advocacy." By themselves,

"neither an unorganized public nor government scrutiny" were considered cause for alarm, but the mixture was to be avoided."<sup>41</sup> Around the turn of the century, the company was charged with adding cocaine to Coca-Cola. The accusation was vigorously denied by Asa Candler, but the company quietly switched to the use of spent coca leaves without cocaine in its formula. Beginning with this first controversy over an additive and continuing through each artificial sweetener debate, Coca-Cola has adopted a public air of distant concern while privately working diligently to protect its product.

When the Senate Committee on Nutrition and Human Needs held hearings on soft drinks in the early 1970s, Louis and Yazijian noted that Coca-Cola and Pepsi maintained a low profile:

Their (Coca-Cola's and Pepsi's) responses have been placid, even meek, in proportion to the vast interest they share in the issue's outcome. If anything, the companies have been conspicuously calm, expressing themselves primarily through the National Soft Drink Association or favorable medical channels. Their discretion was a response to a growing struggle within the federal establishment over what the proper American diet should be. That struggle could easily merge with mounting public concern over the same question, and thereby sweep the siblings (Coca-Cola and Pepsi) from their lofty stations in American life to a defensive, embattled stance.<sup>42</sup>

The parent companies used their bottlers to politically protest the cyclamate and saccharin decisions. On the national level Coca-Cola's southern base has given it a traditional tie to the Democratic party although the company has occasionally supported Republican candidates, most conspicuously Dwight

Eisenhower. More recently, when Jimmy Carter ran for president in 1976, he received the help of parent Coke and prominent bottlers. On the other hand, Pepsi's affiliation with the Republican party has been long-standing and was most visible during the Nixon presidency. Donald Kendall, current head of Pepsi, has been a Nixon supporter since 1960 and was a close advisor during the 1968 election.<sup>43</sup>

With artificial sweeteners the national political influence of the soft drink companies has been less useful than the local presence they display through their bottling networks. The bottlers are major employers and they spend heavily in local advertising. Usually prominent in their community, the bottlers are well known to their congressional delegations. The opposition of the soft drink firms to the cyclamate and saccharin decisions was primarily expressed through the appeals of their bottlers to Congress.

#### The Sugar Industry and the Cyclamate Ban

The sugar industry also played a central role in the cyclamate controversy. Cyclamate troubled the domestic producers and refiners of cane and beet sugar even more than saccharin had although saccharin had been around for decades longer. The opposition of the sugar industry to saccharin was instrumental in passage of the state and federal laws that restricted artificial sweetener use and imposed labeling requirements on diet products. Cyclamate's better taste,

however, made it a more formidable competitor than saccharin whose popularity had been limited by its aftertaste.

The caloric sweeteners produced in this country include cane and beet sugars, corn sweeteners, honey and other edible syrups.<sup>44</sup> From 1963 to 1965 when cyclamate emerged as a popular sweetener, the consumption of domestic cane and beet sugars increased but the growth was short lived. Although refined sugar has constituted the largest percentage of caloric sweetener use in the United States, the share of the market held by domestic refiners has slowly, but steadily, declined since 1965. (See Table III-A) In addition, from 1963 to the ban in 1969, cyclamate consumption grew at a very rapid rate. (See Figure III-B)

In the 1960s the soft drink companies led by Coca-Cola were (and remain today) the largest buyers of refined sugar.<sup>46</sup> In 1950 the wholesale price of cyclamate was \$3.85 per pound; in 1955, \$2.95 per pound; and in 1968, \$.55 per pound. In contrast, wholesale refined sugar prices rose during this period from 8.15 cents per pound in 1950 to 10.17 cents in 1968. The 55 cents of cyclamate was equivalent in sweetness to \$3.05 worth of sugar. (See Tables III-B and III-C) With the practice of level pricing among the different brands, the profitability of the diet lines, therefore, was substantially greater than that of the regular, sugar sweetened brands. The sugar companies were quite apprehensive that cyclamate's popularity would have the long term effect of reducing the

TABLE III-A

CALORIC AND NONCALORIC SWEETENERS: PER CAPITA U.S. CONSUMPTION, 1963-80

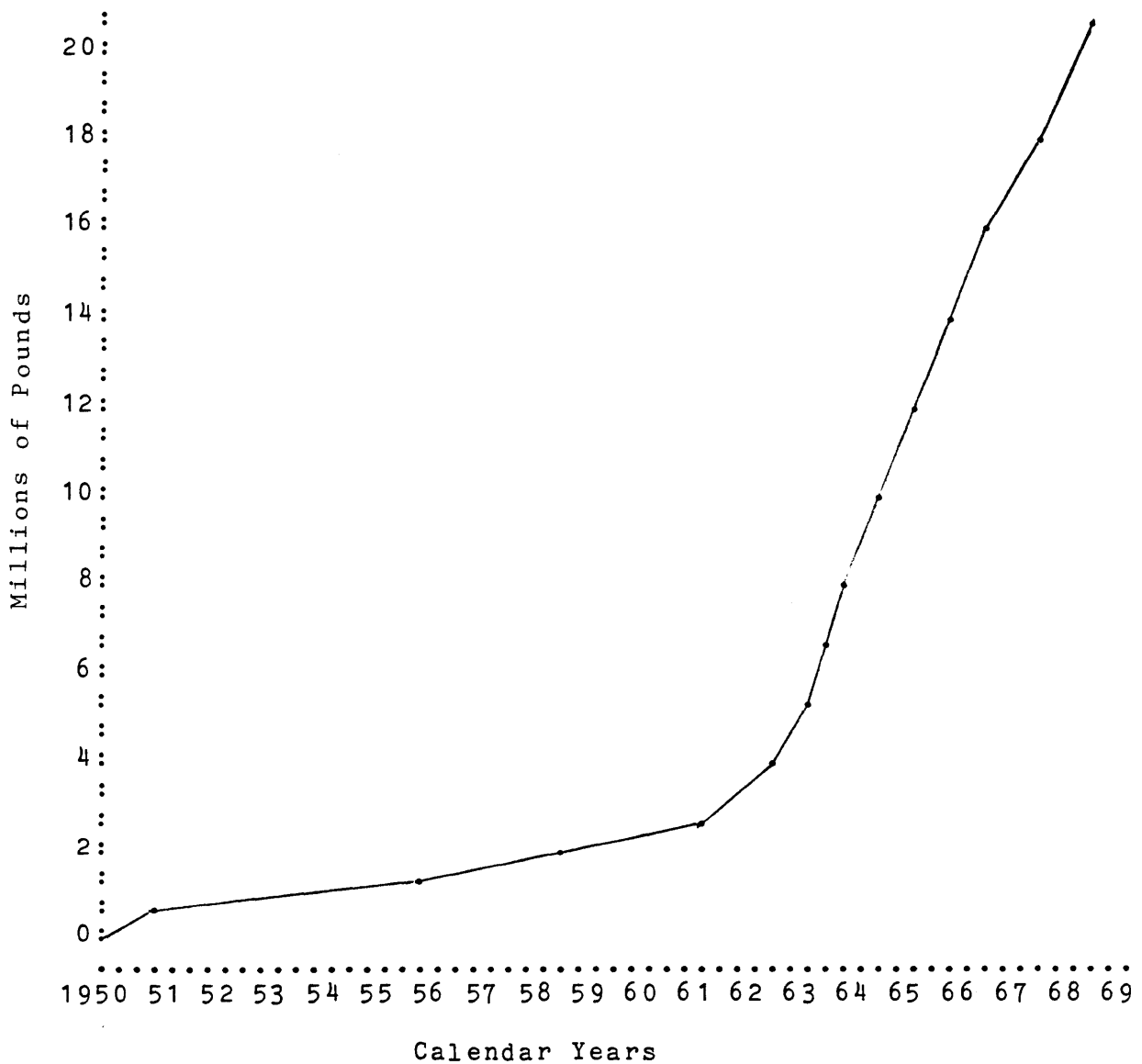
| Calendar                  | Refined cane and beet sugar |            |       |            |       |               | Corn sweeteners <sup>1</sup> |         |           |       | Minor caloric <sup>1</sup> |               |       | Total caloric |
|---------------------------|-----------------------------|------------|-------|------------|-------|---------------|------------------------------|---------|-----------|-------|----------------------------|---------------|-------|---------------|
|                           | U.S. grown sugar            |            |       | Cane sugar |       | Total         | Corn sirup                   |         | Dex-trose | Total | Honey                      | Edible sirups | Total |               |
|                           | Beet sugar                  | Cane sugar | Total | Im-ported  | Total |               | High-fructose                | Glucose |           |       |                            |               |       |               |
|                           |                             |            |       |            |       | <i>Pounds</i> |                              |         |           |       |                            |               |       |               |
| 1963 . . . .              | 27.2                        | 28.2       | 55.4  | 41.9       | 70.1  | 97.3          | —                            | 9.9     | 4.3       | 14.2  | 1.1                        | .7            | 1.8   | 113.3         |
| 1964 . . . .              | 28.6                        | 30.3       | 58.9  | 37.9       | 68.2  | 96.8          | —                            | 10.9    | 4.1       | 15.0  | 1.0                        | .7            | 1.7   | 113.5         |
| 1965 . . . .              | 29.1                        | 30.1       | 59.2  | 37.8       | 67.9  | 97.0          | —                            | 11.0    | 4.1       | 15.1  | 1.1                        | .7            | 1.8   | 113.9         |
| 1966 . . . .              | 28.3                        | 28.7       | 57.0  | 40.3       | 69.0  | 97.3          | —                            | 11.2    | 4.2       | 15.4  | 1.0                        | .7            | 1.7   | 114.4         |
| 1967 . . . .              | 26.6                        | 29.6       | 56.2  | 42.3       | 71.9  | 98.5          | .1                           | 11.9    | 4.2       | 16.2  | .9                         | .5            | 1.4   | 116.1         |
| 1968 . . . .              | 27.8                        | 26.8       | 54.6  | 44.6       | 71.4  | 99.2          | .3                           | 12.6    | 4.3       | 17.2  | .9                         | .7            | 1.6   | 118.0         |
| 1969 . . . .              | 30.3                        | 25.3       | 55.6  | 45.4       | 70.7  | 101.0         | .5                           | 13.2    | 4.5       | 18.2  | 1.0                        | .6            | 1.6   | 120.8         |
| 1970 . . . .              | 31.3                        | 25.0       | 56.3  | 45.5       | 70.5  | 101.8         | .7                           | 14.0    | 4.6       | 19.3  | 1.0                        | .5            | 1.5   | 122.6         |
| 1971 . . . .              | 31.1                        | 22.8       | 53.9  | 48.5       | 71.3  | 102.4         | .9                           | 15.0    | 5.0       | 20.9  | .9                         | .5            | 1.4   | 124.7         |
| 1972 . . . .              | 30.4                        | 25.4       | 55.8  | 47.0       | 72.4  | 102.8         | 1.3                          | 15.6    | 4.4       | 21.3  | 1.0                        | .5            | 1.5   | 125.6         |
| 1973 . . . .              | 30.4                        | 24.9       | 55.3  | 46.2       | 71.1  | 101.5         | 2.1                          | 16.7    | 4.8       | 23.6  | .9                         | .5            | 1.4   | 126.5         |
| 1974 . . . .              | 26.0                        | 21.0       | 47.0  | 49.5       | 70.5  | 96.5          | 3.0                          | 17.4    | 4.9       | 25.3  | .8                         | .4            | 1.2   | 123.0         |
| 1975 . . . .              | 30.5                        | 24.9       | 55.4  | 34.8       | 59.7  | 90.2          | 5.0                          | 17.7    | 5.1       | 27.8  | .9                         | .4            | 1.3   | 119.3         |
| 1976 . . . .              | 32.4                        | 22.7       | 55.1  | 39.5       | 62.2  | 94.6          | 7.3                          | 17.7    | 5.1       | 30.1  | 1.0                        | .4            | 1.4   | 126.1         |
| 1977 . . . .              | 30.3                        | 23.3       | 53.6  | 42.1       | 65.4  | 95.7          | 9.6                          | 17.9    | 4.2       | 31.7  | .9                         | .4            | 1.3   | 128.7         |
| 1978 . . . .              | 27.9                        | 23.3       | 51.2  | 41.9       | 65.2  | 93.1          | 12.3                         | 18.1    | 3.9       | 34.3  | 1.1                        | .4            | 1.5   | 128.7         |
| 1979 <sup>4</sup> . . . . | 27.0                        | 21.5       | 48.5  | 42.6       | 64.1  | 91.1          | 15.4                         | 18.2    | 3.6       | 37.2  | 1.1                        | .4            | 1.5   | 129.8         |
| 1980 <sup>5</sup> . . . . | 26.3                        | 21.7       | 48.0  | 37.6       | 59.3  | 85.6          | 18.9                         | 18.4    | 3.8       | 41.1  | .9                         | .4            | 1.3   | 128.0         |

<sup>1</sup> Dry basis. Recent corn sweetener consumption may be under stated due to incomplete data. <sup>2</sup> Sugar sweetness equivalent—assumes saccharin is 300 times as sweet as sugar, and cyclamate is 30 times as sweet as sugar. <sup>3</sup> Cyclamate food use was banned by the Food and Drug Administration, effective in 1970. <sup>4</sup> Preliminary. <sup>5</sup> Estimate.

Source: Economic Research Service, U.S. Department of Agriculture, Sugar and Sweetener: Outlook and Situation Report.

FIGURE III-B

CYCLAMATE CONSUMPTION IN THE U.S. BY CALENDAR YEAR, 1950-1969



SOURCE: Unpublished data, U.S. Department of Agriculture. Cited by Fred Burbank and Joseph F. Fraumeni, "Synthetic Sweetener Consumption and Bladder Cancer Trends in the United States, Nature 227 (18 July 1970), p.296.



TABLE III-B

## WHOLESALE PRICES OF NONCALORIC SWEETENERS, 1955-68

| Calendar<br>Year       | Calcium<br>Cyclamate<br>[1] | Saccharin<br>[2] |
|------------------------|-----------------------------|------------------|
| <u>Dollars Per Lb.</u> |                             |                  |
| 1955                   | 2.95                        | 1.60             |
| 56                     | 2.95                        | 1.60             |
| 57                     | 2.95                        | 1.60             |
| 58                     | 2.82                        | 1.60             |
| 59                     | 1.95                        | 1.57             |
| 1960                   | 1.95                        | 1.40             |
| 61                     | 1.95                        | 1.48             |
| 62                     | 1.95                        | 1.56             |
| 63                     | 1.86                        | 1.60             |
| 64                     | 1.12                        | 1.52             |
| 65                     | .78                         | 1.40             |
| 66                     | .62                         | 1.39             |
| 67                     | .55                         | 1.30             |
| 68                     | .55                         | 1.30             |

[1] The price was identical for sodium cyclamate and cyclamic acid.

[2] Includes insoluble saccharin and sodium saccharin; does not include calcium saccharin.

SOURCE: Oil, Paint, and Drug Reporter, the chemical marketing newspaper. Published weekly by Schnell Publishing Company, New York, N.Y. Calcium cyclamate, drums, ton lots: Saccharin: Granular, drums. 1.000 pound lots. Data for 1955-65 collected by: Roy A. Ballinger, Noncaloric Sweeteners: Their Position in the Sweetener Industry, Agricultural Economic Report. Table supplied in Steven Plotkin, "The Cyclamate Ban: Science, Politics, and Law" (unpublished Thesis).

TABLE III-C

**COMPARATIVE TRENDS IN SUGAR PRICES, UNITED STATES, 1950-68**

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| Year          | Cal-<br>endar | Raw<br>Sugar | Wholesale Refined [2] |                  |                  |                 | U.S.<br>Average | Retail [3] |
|---------------|---------------|--------------|-----------------------|------------------|------------------|-----------------|-----------------|------------|
|               |               | New<br>York  | North-<br>east        | Pacific<br>Coast | Chicago<br>-West | U.S.<br>Average |                 |            |
|               |               | [1]          |                       |                  |                  |                 |                 |            |
| Cents Per Lb. |               |              |                       |                  |                  |                 |                 |            |
| 1950          |               | 5.93         | 7.94                  | 7.93             | 7.74             | 8.15            | 9.75            |            |
| 51            |               | 6.06         | 8.29                  | 8.28             | 8.03             | 8.48            | 10.12           |            |
| 52            |               | 6.26         | 8.50                  | 8.44             | 8.29             | 8.75            | 10.31           |            |
| 53            |               | 6.29         | 8.57                  | 8.45             | 8.27             | 8.77            | 10.56           |            |
| 54            |               | 6.09         | 8.54                  | 8.22             | 8.17             | 8.61            | 10.51           |            |
| 55            |               | 5.95         | 8.38                  | 8.22             | 8.08             | 8.62            | 10.42           |            |
| 56            |               | 6.09         | 8.53                  | 8.41             | 8.14             | 8.90            | 10.57           |            |
| 57            |               | 6.24         | 8.88                  | 8.75             | 8.35             | 9.37            | 11.03           |            |
| 58            |               | 6.27         | 8.97                  | 8.83             | 8.38             | 9.37            | 11.26           |            |
| 59            |               | 6.24         | 9.00                  | 8.77             | 8.34             | 9.03            | 11.43           |            |
| 1960          |               | 6.30         | 9.07                  | 8.60             | 8.41             | 9.16            | 11.63           |            |
| 61            |               | 6.30         | 9.01                  | 8.45             | 8.20             | 9.01            | 11.77           |            |
| 62            |               | 6.45         | 9.18                  | 8.65             | 8.53             | 9.16            | 11.70           |            |
| 63            |               | 8.18         | 11.49                 | 10.26            | 9.89             | 9.99            | 13.58           |            |
| 64            |               | 6.90         | 10.20                 | 9.37             | 8.90             | 9.90            | 12.81           |            |
| 65            |               | 6.75         | 9.71                  | 8.73             | 8.64             | 9.38            | 11.80           |            |
| 66            |               | 6.99         | 9.82                  | 9.01             | 8.90             | 9.58            | 12.04           |            |
| 67            |               | 7.28         | 10.03                 | 9.52             | 9.10             | 9.95            | 12.10           |            |
| 68            |               | 7.52         | 10.33                 | 9.84             | 9.41             | 10.17           | 12.18           |            |

[1] Contract No. 10, beginning November 21, 1960, replaced Contract No. 7, includes duty paid, if dutiable; New York Coffee and Sugar Exchange.

[2] Northeast, Pacific Coast, and Chicago-West estimated bulk dry refined beet and cane sugar prices. Mostly cane sugar in the Northeast and largely beet sugar in the Chicago-West and Pacific Coast marketing areas.

[3] Five-pound package, Bureau of Labor Statistics (BLS) data.

SOURCE: Raw and U.S. average retail prices are from Sugar Reports, published monthly by Sugar Division, Agricultural Stabilization and Conservation Service, Washington, D.C. Bulk dry refined sugar prices are rough approximations estimated from above sources and trade sources. U.S. average wholesale price refined price is a weighted annual average price of all sugar actually delivered to U.S. confectionery manufacturers -- data annually reported in Confectionery Manufacturers: Sales and Distribution, prepared by Marjorie D. Kennedy in recent years, published annually (about May), by Business and Defense Services, U.S. Department of Commerce, Washington, D.C. Table supplied in Steven Plotkin, "The Cyclamate Ban: Science, Politics, and Law" (unpublished thesis).

demand for sugared drinks and thereby affecting their sales to the soft drink companies.<sup>46</sup>

The high cost of American sugar results in part from outmoded plants, equipment, and processing methods. In the last sixty years there have been no fundamental changes in the sugar industry's structure. With the exception of a few of the largest, most progressive firms, most cane producers and refiners have experienced considerable difficulty staying in business, as have the beet sugar refiners whose industry developed during World War I. Many of the processing factories in existence today are from that period, and they tend to be small, inefficient, and fuel and labor intensive.<sup>47</sup>

Protection of the domestic sugar industry has been part of American agricultural policy at least since the turn of the century. Ironically, the legislative umbrella over American companies ultimately aggravated, rather than resolved the industry's problems. The Jones-Costigan Sugar Act of 1934 and its successor, the Sugar Act of 1948, established import quotas that kept the price of domestic sugar well above the world market price. The Agriculture and Food Act of 1981 which replaced the 1948 Act guarantees domestic sugar growers a minimum market price, with unsold sugar purchased by the government. Corn sweeteners, now the chief competitor to the sugar industry also benefited from the bill because their price follows that of sugar's.<sup>48</sup>

The Act may have provided some protection against foreign

competition, but it has not insulated the domestic sugar industry from competition at home. The sugar quotas that the growers argued would improve price stability were opposed by the soft drink and food processing industries. The artificially high price of sugar, however stable, threatens the profits of the large sugar buyers like the soft drink firms. In 1977 it was estimated that a change of one cent in the price of raw sugar would increase Coca-Cola's costs by \$20 million.<sup>49</sup>

The sugar industry responded to cyclamate's increasing sales by attacking it in two ways: through advertisements that contrasted the artificiality of cyclamate with the "naturalness" of sugar, and through the funding of scientific studies to research cyclamate's harmful effects. The industry's opposition was orchestrated during the 1960s by Sugar Information, Inc., a now defunct organization (its successor organization, the Sugar Association, professes to have had little involvement with artificial sweeteners since the cyclamate ban) that represented cane sugar refiners, beet sugar processors, and raw-sugar producers.<sup>50</sup> In 1964 the president of Sugar Information, described his industry's belief that cyclamates posed a major threat: "... in the long run, the popularity of...low-calorie products must subtract from sugar consumption. (The challenge of nonnutritive sweeteners had to be) faced and beaten back by using all possible means of advertising, public relations,

information, and education."<sup>51</sup>

From the early fifties until the ban, the sugar industry and the artificial sweetener manufacturers and soft drink companies were embroiled in competitive advertising campaigns. For example, in 1964 Sugar Information sponsored advertisements that ran in popular periodicals. The advertisements were also carried in the trade journals of the soft drink, baking, candy, ice cream, food processing, and supermarket industries. The campaign contrasted "synthetically" sweetened soft drinks with "real" sugar, alleging that diet soft drinks robbed children of the energy that sugar provided.<sup>52</sup> (See Figure III-C) Two years later, another sugar campaign asked, "Do you use artificial sweeteners and still gain weight?" These advertisements contended that sugar could actually help the dieter lose weight by curbing the primary cause of overweight, overeating. Sugar was portrayed as benefiting in weight reduction because it provided a means of satisfying hunger with "no aftertaste."<sup>53</sup>

Royal Crown responded with full page advertisements in newspapers across the country that stated: "Guilty of upsetting the sugar cart! We plead guilty...If it's wrong to do millions of people a favor by taking the sugar out of cola...Diet-Rite pleads guilty." Abbott also sponsored a campaign that concentrated on television viewers. Commercials for Sucaryl proclaimed that the consumer could save

FIGURE III-C

Today, Tommy delivered 82  
morning papers.

He swam half a mile,  
hit a homer, had a fight, pedaled  
his kid brother to his music  
lesson.

He needs a sugarless,  
powerless soft drink  
like a moose needs  
a hatrack.

Sugar puts the  
musclepower  
in sweetness.

**SUGAR'S GOT WHAT IT TAKES**

*...18 calories per teaspoon—and it's all energy*

Sugar Information, Inc.



**NOTE TO MOTHERS**

How much energy does your child get from the synthetic sweetener in a bottle of diet soft drink? *Exactly none.* And how much energy does he need? You tell us—and ask yourself if you're doing him a favor when you stock the refrigerator with no-sugar soft drinks. He'll drink them—his thirst craves anything that's cold and wet. But if you want him to have the energy he needs, you'll bring home the kind with sugar.

180 calories daily using it instead of sugar. Other manufacturers increased promotion of tabletop sweeteners, emphasizing their convenience when used in beverages.<sup>54</sup>

The sugar industry was reported to have more than simply run advertisements to discredit cyclamate with the public. Through the Sugar Research Foundation (now called the International Sugar Research Foundation) the industry apparently sponsored a study at the Wisconsin Alumni Research Foundation (WARF). The WARF data suggested that cyclamate caused growth retardation in rats, and the results were publicized. Two years later when a Japanese study reported fetal deaths in animal feeding studies with cyclamate, the results were also reported by the Sugar Research Foundation.<sup>55</sup>

European sugar companies followed the increased usage of cyclamate as well. Eight months before the ban a scientific meeting held in Paris under the sponsorship of the European Committee of Sugar Manufacturers reported on research that indicated that "so far as world health is concerned, sugar is not so guilty nor artificial sweeteners so blameless as has been indicated. The finding was published in the International Sugar Journal.<sup>56</sup> The sugar industry in the Netherlands initiated an advertising war to discredit cyclamate. In the summer of 1969 an Amsterdam district court rebuked the companies for making "disparaging" remarks about cyclamate and for citing dubious scientific data about its ill effects.<sup>57</sup>

Roger Cobb and Charles Elder, authors of Participation in American Politics, describe two basic types of political agendas: the systemic agenda which consists of all issues legitimately within government's jurisdiction, that are perceived by members of the political community as meriting public attention and the formal agenda or the items explicitly under government's consideration.<sup>58</sup> The sugar industry was instrumental in keeping cyclamate on the systemic agenda and moving it to the formal agenda. As Cobb and Elder noted, for an issue to acquire the public recognition necessary to place it on the systemic agenda, its supporters must have sufficient resources to communicate to the public and the access to the media to do so.

The sugar industry's advertising cast doubt on cyclamate's efficacy in weight reduction and as a source of energy, and by implication, on its safety as a food additive. The campaigns increased the attention being given cyclamate, and the industry sponsored research contributed to the scientific debate over cyclamate's safety. It seems likely that without the pressure generated by the sugar industry, the FDA would not have ruled on cyclamate on the basis of the evidence available in 1969. After all, the agency had reason to be concerned about cyclamate since 1950. Other food additives, including some as common as pepper or caramel coloring, were also suspected as presenting a health hazard but were not under active review.



The consumer advocacy movement was also instrumental in prompting the cyclamate ban. A variety of organizations, often formed in the late sixties in response to public concerns about health and environmental issues were influential in Congress and in the regulatory agencies.<sup>59</sup> Beginning in the 1950s the public had grown increasingly concerned about the connection between diet and disease. The cyclamate-cancer link made the disposition of the sweetener of special interest to consumer advocates.

James Turner, a public interest lawyer who had worked with Ralph Nader, investigated the FDA in the months before the cyclamate ban. He was highly critical of the agency's record of protecting the public from abuses by the food industry. One of Turner's principal examples of FDA bias toward industry was the agency's handling of cyclamate which he discussed in his book, The Chemical Feast, published in 1970. The scrutiny of consumer advocates like Turner and public support for stringent regulation of carcinogens increased the pressure on the FDA to rule on cyclamate.

On October 18, 1969, the Secretary of Health, Education and Welfare removed cyclamate from the list of substances considered safe for use in the food supply and ordered the phasing out of existing supplies. Finch stopped short of a total ban by allowing cyclamate's continued availability as an over-the-counter drug. In June 1970, Congressman L.H. Fountain, chairman of the House Intergovernmental Operations

Subcommittee, convened hearings on cyclamate. Fountain concluded that the FDA failed to establish cyclamate's safety, and he recommended that the ban be extended to include all uses of the the sweetener. On September 11, 1970, cyclamate was banned from all products.<sup>60</sup>

The sugar industry fostered doubt about cyclamate's safety. Consumer advocates placed the FDA on the defensive, questioning the agency's record of protecting the nation's health. The public was supportive of regulatory measures that addressed health hazards. These factors contributed to the FDA's decision to ban cyclamate. What made the ban politically tenable, however, was the availability of saccharin as a substitute. As a result, neither the public nor the diet industry with the exception of cyclamate's manufacturer, Abbott Laboratories, was moved to vigorously protest the ban.

#### Since the Cyclamate Ban

The media stressed the suddenness of the ban. Newspaper and magazine stories repeated industry's assertions that there had been no indications of the FDA action. The misperception has persisted since that the regulatory process in this instance imposed an unduly hasty prohibition on a popular substance. Many companies probably were taken unaware by the actual decision because it was made virtually over a weekend. In reality, however, there had been ample warnings for months before the announcement was made that cyclamate was in serious trouble.

Food Chemical News, a weekly journal that has wide circulation in the food processing industry, reported as early as December, 1968, that the status of cyclamate would likely change with the coming of the Nixon administration in January 1969.<sup>61</sup> After the journal described the FDA as "torn" about the most felicitous way to remove cyclamate from the list without undue financial hardship to the industry, the agency was pressured by soft drink manufacturers, canners, and chemical companies to delay any cyclamate action.<sup>62</sup> Despite these forewarnings and their own involvement in postponing a cyclamate decision, the diet industry contended that the FDA decision was "precipitous".

Following the ban, Abbott Laboratories, as the principal cyclamate manufacturer, tried to enlist allies among others in the industry. Abbott's efforts were largely unsuccessful. The availability of saccharin as a substitute served to mute both consumer and industry protest. Many consumers wrote angry letters to the FDA and to Congress, but many also felt "grateful" that the government was protecting them from a potential carcinogen.<sup>63</sup> Public opposition to the ban was much less intense and widespread than the protest that followed the attempt to ban saccharin seven years later.<sup>64</sup>

The ban affected the companies using cyclamate with varying degrees of severity. Abbott sought to make the case that the FDA's decision presented a problem for the entire diet industry in terms of its suddenness and the uncertain

scientific grounds on which it was based.<sup>65</sup> To the extent that a company was ready to reformulate its diet products, it was less likely to be involved in any formal attempt to have the ban rescinded.

Moreover, the industry may have been unsympathetic to Abbott's predicament because Abbott had repeatedly reassured its bulk customers that cyclamate was safe. For example, in the very month in which cyclamate was banned, Abbott had conducted a seminar for fruit and vegetable growers to attest to cyclamate's safety. The company, however, included clauses in its contracts with bulk buyers that vitiated Abbott's liability in case of problems with cyclamate.<sup>66</sup>

Food and beverage companies are zealous about protecting their reputations because their sales are dependent upon public trust. The soft drink industry also had enormous stakes in preserving consumer confidence because the diet segment was so profitable. Soft drink manufacturers quickly issued statements to reassure retail customers that cyclamate sweetened drinks would immediately be removed.

While publicly declaring their surprise and cooperation, the major manufacturers were readying reformulated, repackaged diet brands.<sup>67</sup> On the Monday following the Saturday ban, Coca-Cola announced that a new formulation for Fresca would be ready for distribution in some markets by late the same week. A reformulated version of Tab followed shortly.<sup>68</sup>

Reformulation of an entire line is not any overnight

process. The development of a sweetener for use in the soft drink solution requires testing for stability, safety, and taste and extensive production preparation.<sup>69</sup> The companies would have been unable to respond to the cyclamate ban in a matter of weeks unless they had been readying themselves long in advance. In fact, two weeks before the ban, Coca-Cola had announced to its bottlers that new formulas for Fresca and Tab were under development because of warnings about cyclamate from the FDA.<sup>70</sup>

Although the soft drink industry was worried about consumer response to the taste of a saccharin sweetened drink, its initial fears were quickly allayed. In the Baltimore area, for example, sales dropped to under 200 cases in the week after the ban, increased to 2,614 cases the following week, and 4,481 cases in the second week after the FDA announcement. Any consumer hesitation about saccharin's taste had apparently been permanently overcome. The sales of diet soft drinks, although leveling off in the two years following the ban, have continued to grow steadily since then.<sup>71</sup>

The ban was turned into a marketing device by Coca-Cola and Pepsi. The repackaged diet drinks and new advertising used the absence of cyclamate in slogans that announced: "Cyclamates? Diet Pepsi Can Do Without Them!". The phrase, "Cyclamate Free", was prominently displayed in print advertisements and on packaging.

A Coca-Cola report to its bottlers acknowledged the

preparation that prevented the ban from causing the company major disruption:

On October 18, it could fairly be said that as a result of the cyclamate issue, Coca-Cola USA suddenly became an integrated, professional, production/marketing/sales team, stimulated by the unexpected crisis...The strength and maturity of any organization can be measured by the way it reacts to a crisis. The October 18th ban on the use of cyclamates provided just such a testing ground for Coca-Cola USA and the bottlers of Coca-Cola. Production was stopped on Fresca and Tab, the two products of the Company that contained cyclamates on the same day the announcement was made. Two days later, a new formula for Fresca was in production. In another week, on November 4, bottlers were told that a new formula for Tab was ready. By the end of the first week after the ruling, interim point-of-sale advertising materials were ready and shipments were en route to bottlers.<sup>72</sup>

In the years since the ban there has also been little incentive for the soft drink companies to join in Abbott's efforts to have the ban rescinded. Ideally, they would like to have a wide range of sweeteners available to provide them with flexibility in taste, stability, pricing, etc. But as long as the ban exists, no one company can use cyclamate domestically, and no foreign products sweetened with cyclamate can be imported. There is no competitive advantage in investing the resources required to rescind a ban that would only benefit all producers.

For Cumberland Packing as well as Coca-Cola and Pepsi, the ban eventually helped sales. By the Monday after the Friday announcement of the ban, the company was prepared with a reformulated, cyclamate version of Sweet 'n Low containing saccharin and dextrose, a filler. Cumberland's quick reaction

to the ban gave it prominent shelf space in supermarkets nationwide, and made it until recently the leading tabletop sweetener. Sweet 'n Low became a household word after the cyclamate decision. Its nearest competitor, Alberto-Culver's Sugar Twin, held only a quarter of Sweet 'n Low's market share.<sup>73</sup>

Despite the warnings not every company was able to respond quickly to the ban with new versions of their cyclamate products. The canners and packers of diet fruits, represented by the National Canners Association (the predecessor to the National Food Processors Association), claimed to have suffered the highest losses because their inventory was greater than that of most other producers of diet foods, especially the soft drink companies. The canners argued that they were unable to redesign their complicated labeling and packaging materials to indicate that a product did not contain cyclamate.<sup>74</sup>

The California Canners and Growers (CalCan), a cooperative of 1145 fruit and vegetable producers, initially declared a loss of \$20 million. At least 25 percent of the cooperative's sales were in low-calorie fruits and vegetables.<sup>75</sup> In 1964 CalCan began extensive promotion of their Diet Delight line, some of which was sweetened with cyclamate. By 1968 because of oversupply and other problems, the canning industry generally faced economic difficulties, but the Diet Delight line was performing well. When the

cyclamate ban was announced in October, 1969, CalCan had just packed the year's Diet Delight harvest. The government's decision represented a total loss of all the products sweetened with cyclamate. Some of these losses were eventually recouped through dumping on foreign markets, but the individual California farmer in the cooperative suffered financially.<sup>76</sup>

The "suddenness" of the ban and the resulting financial losses formed the basis of the Cyclamate Indemnification Bill (H.R. 13366) that was introduced in Congress in 1971 to compensate diet food and beverage companies, cyclamate manufacturers, and the canners. The bill had appeared earlier in a Senate version in 1970 but was thwarted by HEW opposition. H.R. 13366 permitted claimants to demonstrate to the United States Court of Claims that their cyclamate losses stemmed from "good faith reliance" on the FDA's GRAS list. Under the proposed bill, the court would have the power to grant compensation for claims of less than \$100,000. Congress was entitled under the bill to award claims in excess of \$100,000; most companies in the diet industry professed to have lost considerably more. The legislation was backed by both the National Canners Association and the National Soft Drink Association.

Small farmers from Cal Can were prominent participants in hearings on the bill. The biggest beneficiaries, however, would have been the soft drink companies and the cyclamate



manufacturers, especially Abbott. In the final version, total damages were estimated at between \$100-120 million, a figure that included indirect losses such as advertising and the conversion of cyclamate equipment.<sup>77</sup>

Among opponents to the bill was the FDA which argued that the government should not reimburse losses resulting from "one of the risks of doing business." The chairman of the House Judiciary Committee, Emanuel Celler, questioned the wisdom of the government rewarding private industry for having been careless of the public's health. Others, including representatives from a public interest group and the consumer advocate, James Turner, pointed out that the diet industry had had ample warning of an impending ban. Despite support from President Richard Nixon, the bill was defeated.<sup>78</sup>

Abbott's decision to fight for cyclamate's use in soft drinks may have cost the company its entire cyclamate market. James Turner argued at the time that artificial sweeteners should only be sold in tabletop form. This limited use was an alternative that might have gained the support of those opposed to cyclamate's unrestricted availability. The scientific community and HEW initially appeared amenable to allowing cyclamate as a tabletop sweetener for diabetics and others whose health required curtailed sugar use. Cumberland Packing offered to support Abbott in any effort to maintain cyclamate's tabletop use, but Abbott decided instead to attempt to have the ban totally revoked.<sup>79</sup>

In the years since cyclamate was removed from the market, Abbott has pursued legal action to have the ban overturned, and it has sponsored further scientific studies. In 1973 the company began formal appeal procedures at the FDA. Abbott submitted a petition that included more than 300 individual toxicology reports and the results of several long term animal feeding studies.<sup>80</sup> The reports failed to prove to the FDA's satisfaction that cyclamate was safe. The agency ruled that the burden of proof rested with Abbott to prove cyclamate's safety. The company rejected the FDA's offer of a public board of inquiry to review the data further. Abbott's petition to reinstate cyclamate was refused by the FDA in 1980. The company is presently continuing its legal efforts to have the ban repealed.<sup>81</sup>

The Calorie Control Council and the National Soft Drink Association (NSDA), later quite active during the saccharin controversy, were unwilling or unprepared to launch a full response to the cyclamate ban. The Calorie Control Council, a trade association of the diet industry, was formed in 1966 to combat the developing cyclamate controversy. Many companies in the industry were initially reluctant to join the Council. They feared the adverse publicity about an organization founded solely to push for the continued use of an additive whose safety was in doubt, especially during a period of intense public worry about carcinogens.

The National Soft Drink Association (NSDA) represents 90

percent of the bottlers, about 600 soft drink sales and distribution outlets, and as associate members, the firms that provide products and services to the industry including the parent companies. Its members are an "integral part of their respective local communities...(and) provide jobs for more than 100,000 people and support many community activities in the towns and cities where they are located."<sup>82</sup> The NSDA maintains a government affairs department that monitors impending regulations and legislation and evaluates their potential effect on the industry. The scientific and technical affairs division plans and monitors research on soft drink ingredients and packaging materials. NSDA also provides information to its members and the public about industry concerns through its public and media relations department.

The NSDA did not mobilize its members to protest the cyclamate ban vigorously as it would later with the proposed restrictions on saccharin. The Association said it was surprised at the "instantaneous" action that HEW took upon receiving the results of only two studies. The bottlers apparently were also wary of promoting continued use of a suspected carcinogen especially because saccharin was available and their parent companies were quickly prepared with reformulated diet syrups.

The cyclamate ban demonstrated to the NSDA and others the vulnerability of the food or drink manufacturer to an additive controversy. Until 1969 the soft drink or food processing

companies generally believed that the manufacturer of a food additive bore the responsibility for its safety; cyclamate changed that belief.<sup>83</sup> James Turner has argued that the cyclamate episode did more than educate the industry about potential problems with food additives. In The Chemical Feast, he contends that public concern about chemicals in the food supply began with cyclamate. There is current evidence to suggest that consumers remain apprehensive about carcinogens.<sup>84</sup> Nevertheless, the public was apparently supportive of the cyclamate ban less because a carcinogen was being removed than because a substitute existed.

### Conclusion

There is now a whole generation of diet soft drink consumers who have never tasted cyclamate. Dr. Michael Sveda, cyclamate's discoverer, fought throughout the 1970s to have it reinstated and his name cleared from the charge of having invented a carcinogen. The financial cost and Sveda's advancing years, however, have caused him recently to cease his participation in cyclamate reviews.<sup>85</sup>

Abbott Laboratories and the Calorie Control Council are the principal organizations still pressuring the FDA to rescind the ban. Abbott continues to be interested in repudiating any health claims against cyclamate and thereby finally clearing its name of any allegations that the company was careless with the public's health. A pharmaceutical

company has special reason to be concerned about maintaining an unblemished safety record. An inadequately tested or contaminated product may cause injury or death. The deleterious effects of a food additive, drug, or over-the-counter preparation receive widespread publicity often with adverse attention given to the manufacturer. Abbott continues to have extensive dealings with the FDA where a company's good scientific record is often essential in approval of a new drug or chemical. Abbott also wishes to recoup whatever it can of the lost cyclamate sales and extensive legal costs accrued over the years.<sup>86</sup>

There is little incentive, however, for the FDA to reverse the ban and admit an error in a decision that is now over a decade old. The doubts about cyclamate's safety still remain. To bring it back on the market when there are currently two other artificial sweeteners available will probably require a more compelling case for its safety and value to the public than can now be made.

One sentiment often expressed by the diet industry is that cyclamate was given away, suggesting that the companies were caught without sufficient time to respond and that they conceded the issue without protest. In reality the diet industry faced the cyclamate ban almost with equanimity because saccharin was available as a substitute and because the cost of fighting for cyclamate's return was too great.

A similar view is also often expressed that "cyclamate

taught industry a lesson." The ban apparently did contribute to an awareness that food and beverage companies could no longer rely on their traditional, lofty approach to controversy. Cyclamate alone was not responsible for this realization, however. A review of substances on the GRAS list begun after the ban, the 1972 food additive hearings of the Senate Select Committee on Nutrition and Human Needs, and the continued concern of public interest groups and consumers about carcinogens in the food supply were also contributing factors.

The cyclamate case established patterns that would be important in subsequent artificial sweetener controversies. The principal interest groups who would be concerned in varying degrees with all three sugar substitutes organized around the cyclamate debate: the diet food industry and its trade associations, the sugar industry, the diabetes associations, and consumer advocates. Two features of the cyclamate controversy, competitive marketing practices and the availability of a substitute, have also proven to be of enduring significance.

The cyclamate episode also provided a lesson for the manufacturers of artificial sweeteners challenged in the future. It demonstrated the potential vulnerability of a defense predicated on scientific issues alone. As one company fighting the ban with a substitute sweetener waiting in the wings, Abbott was unable to find meaningful reception for its

interpretation of the cyclamate data.

FDA decision making in the cyclamate case had two unanticipated consequences for future artificial sweetener policy. First, by placing cyclamate on the GRAS list, the sweetener's use was greatly expanded ultimately creating a regulatory problem. Second, when cyclamate was banned the FDA helped to precipitate the saccharin crisis seven years later, having left on the market the more hazardous, but only sweetener.

NOTES: CHAPTER III

<sup>1</sup> Canner Packer (November 1969), p. 9; Chris Lecos, "The Sweet and Sour History of Saccharin, Cyclamate, and Aspartame", FDA Consumer (September 1981), p. 10.

<sup>2</sup> "Sweeten to Taste," Time, 5 June 1950, p. 43; Dean Jennings, "The New Non-Fattening Sweet," Reader's Digest, December 1953, pp. 118-119.

<sup>3</sup> Jennings, p. 119.

<sup>4</sup> "Cyclamate; Commissioner's Decision", Federal Register (16 September 1980), p. 61475; Disagreement exists as to how careful the FDA was in approving cyclamate. Some have described the agency as acting cautiously by requiring the warning label. For example, see James Fallows, "Picking up the TAB," The Washington Monthly, November 1972, p. 21; John J. Schrogie, "Artificial Sweeteners," FDA Papers (October 1969), p.12. In contrast, James Turner has argued that the agency should never have approved Sucaryl in the first place. Given the FDA's concern about the quality of the testing conducted on cyclamate, he contends that the label provided insufficient protection against any possible ill-effects from the sweetener. See James Turner, The Chemical Feast (New York: Grossman Publishers, 1970), p. 6.

<sup>5</sup> William R. Havender, "The Science and Politics of Cyclamate", The Public Interest (71) Spring 1983, pp. 18-19.

<sup>6</sup> Karl M. Beck, "Low Calorie Ingredients: Big Booster of Dietetic Foods," Food Engineering (June 1954), p. 90.

<sup>7</sup> Robert M. Sandri, "Making Good Sugar-Free Drinks," Food Engineering (May 1953), p. 79.

<sup>8</sup> Beck, p. 126.

<sup>9</sup> Ralph Westfal and Harper W. Boyd, Jr., "Abbott Laboratories", in The Chemical Industry, ed., Conrad Berenson (New York: Interscience Publishers, 1963), p. 367.

<sup>10</sup> Gerald Walker, "The Great American Dieting Neurosis," New York Times Magazine, 23 August 1959, pp. 12; 100.

<sup>11</sup> The Nation, 11 June 1960, p. 511.

<sup>12</sup> Walker.

<sup>13</sup> Jennings, p. 120.



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- 17 Jennings, p. 120.
- 18 "Diet Cola Makers Fatten Up Ad Budgets for a Head-On Fight," Printer's Ink, 31 May 1963, p. 8; Jennings, p. 120.
- 19 Westfall and Boyd, p. 366.
- 20 Ibid., p. 365-366.
- 21 Ibid., p. 367.
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- 23 Turner, p. 9.
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- 28 J.C. Louis and Harvey Z. Yazijian, The Cola Wars (New York: Everest House, 1980), p. 107.
- 29 Louis and Yazijian, pp. 136; 319.
- 30 "The Sweeteners Take Their Lumps", Newsweek 3 November 1969, p. 73.
- 31 Beverage Industry Annual Manual (1983).
- 32 Pat Watters, Coca-Cola: An Illustrated History (New York: Doubleday and Company, 1978), p. 218.
- 33 Louis and Yazjian; Watters, Advertising Age (14 March 1983), p. 1.
- 34 Watters, p. 209.
- 35 Louis and Yazijian, p. 272.

36 In The Cola Wars, Louis and Yazijian use the terms "parent Coke" and "parent Pepsi", to distinguish the headquarters of the companies from their bottlers. The following history of the two companies is based on their book unless otherwise indicated.

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38 Beverage Industry Annual Manual (1982); National Beverage Marketing Directory (1981/82).

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40 Robert Reed and Nancy Giges, "7Up Ads to Hit Artificial Ingredients", Advertising Age, May 1983, p. 2.

41 Louis and Yazijian, p. 253.

42 Ibid., p. 257.

43 Ibid., chapters 14; 17.

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- 64 Parham, pp. 59-62.
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## CHAPTER IV

## SACCHARIN: CONFLICT EXPANSION AND THE EFFECT ON POLICY

In 1977 the FDA proposed a ruling that would have eliminated virtually all commercial uses of saccharin, prohibiting its addition to foods, beverages, cosmetics, and most drugs. The agency left open the possibility of saccharin's continued use as a tabletop sweetener provided the diet food industry could prove it was beneficial to diabetics or dieters. (Because the FDA's proposal was so extensive, it is generally referred to as a ban.) The decision provoked an uproar from the industry and among the public and caused an intense political and scientific debate.

The extent of the saccharin controversy was unparalleled in the history of the FDA's regulation of food additives. Pressured by the widespread opposition, Congress passed a bill that prevented the FDA from restricting saccharin until further research could be conducted on its safety and on the laws governing food additives. President Jimmy Carter signed the Saccharin Study and Labeling Act in November 1977. Often called the saccharin moratorium, the law has been extended three times.<sup>1</sup>

Saccharin has been available for almost 100 years. For

much of its history it was protected from permanent government restrictions because it was the only artificial sweetener available and because it was used principally by diabetics. When cyclamate became commercially available around 1955, its popularity drew much of the attention of scientists and the sugar industry away from saccharin. Once cyclamate was banned, however, there was renewed interest in saccharin especially as the diet food industry continued to grow.

The cyclamate and saccharin controversies had important features in common. Both sweeteners were in widespread use among the same consumers: dieters and diabetics who used the noncaloric sugar substitutes in the belief that they were effective for weight control. The biggest use of both cyclamate and saccharin was in soft drinks. Essentially the same interest groups, including the Calorie Control Council, the National Soft Drink Association, and the American Diabetes Association, were concerned about the effect of both FDA decisions. By the time the FDA decided to ban cyclamate in 1969 and saccharin in 1977, each sweetener had been available for years with no evidence of adverse human effects. In both cases, the principal reason for concern stemmed from studies in which animals fed the artificial sweeteners developed bladder tumors.

Notwithstanding these similarities the status of cyclamate and saccharin are today very different. Cyclamate has not been reinstated despite the continuing legal efforts

of Abbott Laboratories and even though additional evidence supports the claim that it is not a carcinogen. By contrast, saccharin remains available although further studies have corroborated the findings that it causes animal bladder tumors.

Two important features of the saccharin controversy account for its current availability. First, in 1977 saccharin was the only artificial sweetener allowed the American public; any substitute was at least several years away from production. The diet food industry's economic loss would have been substantial if the ban had gone into effect. The public also perceived the loss of saccharin to be costly because of saccharin's reputed benefits as a weight reducing aid.

Opposition to the cyclamate ban was tempered by the availability of saccharin. National surveys conducted after the FDA saccharin decision revealed that consumers overwhelmingly preferred less stringent measures than a ban. The majority of those responding chose a warning label as sufficient indication of saccharin's hazards.<sup>2</sup>

Second, the entire diet food industry, not just saccharin's manufacturer, resisted the FDA's decision. When cyclamate was banned in 1969 the soft drink manufacturers and other producers of artificially sweetened foods responded as individual firms not as an industry. Reformulation and repackaging of their diet brands were the companies' major concerns, not developing a unified response to the ban.

Coca-Cola, Pepsi, and others rushed diet drinks labeled "cyclamate-free" to the market in an effort to turn the ban into an advantage. The diet industry's only attempt at a joint effort was unsuccessful. It backed legislation that was ultimately defeated in Congress to reimburse producers of artificially sweetened foods for their cyclamate losses.

By contrast, the industry opposed the FDA's saccharin decision by challenging the grounds for the ban and adding new issues to the debate. This was accomplished through the funding of scientific research that offered alternative explanations of the saccharin data. For example, the American Council on Science and Health (ACSH), an association of scientists, was formed after the ban with support from the diet food industry, especially soft drink manufacturers. ACSH has made refuting the charges against saccharin a primary activity. Because reputable scientists were organized in questioning the ban, it was more comfortable for prominent health and medical organizations to oppose the decision.

The redefinition of the saccharin issues expanded the scope of the conflict. Through an extensive public relations campaign, the industry mobilized the public to write letters to Congress. Key trade groups and the diabetes associations organized their members in appeals to local congressional delegations. As the public manifested its opposition to the ban, the incentive for congressional involvement became apparent. Once Congress began its review, the nature of the



saccharin issued changed. The problem for the FDA was to determine whether saccharin was a safe food additive. The problem for Congress was to deflect political repercussions from an unpopular decision while maintaining some support for the FDA.

The FDA was cautious in building the case against saccharin because the cyclamate experience had demonstrated that it was imprudent to base a controversial decision on one or two ambiguous studies.<sup>3</sup> There was much less uncertainty in the scientific evidence regarding saccharin's effect on animals than there had been with cyclamate. Ironically, the agency's diligence failed to prevent controversy because, although the scientific basis for the ban was sound, nonscientific factors became the issues on which the merits of the decision were judged.

### History

The oldest nonnutritive sweetener in the world, saccharin was first synthesized in 1879 by Ira Remsen, professor of chemistry at Johns Hopkins University, and a postdoctoral fellow, Constantin Fahlberg. Remsen and Fahlberg noticed the sweetness of a compound called benzoic sulphamide while experimenting with coal tar derivatives. A description of the new compound was published in the American Chemical Journal in 1880. Fahlberg then took out a patent on "Saccharine" giving

Remsen no credit in the discovery. Remsen did not contest the patent, and Fahlberg returned to his native Germany where he founded a company to produce saccharin.<sup>4</sup>

Saccharin was initially used as an antiseptic and food preservative, but its taste (it is 200 to 700 times sweeter than sugar) quickly led to its use as a cheap substitute for sugar especially in canned goods. Within ten years of its discovery, saccharin was widely prescribed in the therapeutic treatment of diabetics and the obese.<sup>5</sup>

Virtually from the beginning of its history, the sweetener has been a source of controversy over its health effects. Early concerns focused on appetite and gastrointestinal problems reported by a French study conducted in 1886. Additional criticism was generated by the sugar industry. Then, as now, saccharin was a cheap substitute for sugar. One pound of saccharin could provide the equivalent sweetening power of 500 pounds of sugar.<sup>6</sup>

In 1907, Dr. Harvey Wiley, head of the Bureau of Chemistry in the Department of Agriculture, began a campaign to ban all derivatives of benzoic acid including sodium benzoate, a popular preservative, and saccharin.<sup>7</sup> Wiley objected to saccharin on the grounds that it was an adulterant and that it was suspected of interfering with kidney function. The canning industry, which had organized early in 1907 into the National Cannery Association (later changed to the National Food Processors Association) protested directly to

President Theodore Roosevelt about Wiley's efforts to ban some of its most widely used additives. Roosevelt initiated a conference and established several panels to review Wiley's claims.

The basis for this earliest saccharin controversy and the method used to settle it were comparable to the saccharin dispute that was to occur 70 years later. In 1907 the principal disagreement was over the validity of the scientific evidence as it would be in 1977. The charges against saccharin were reviewed by representatives from a variety of interests including industry, government and the scientific community. Similarly, in 1977 at congressional request, the National Academy of Sciences would organize a panel composed of scientific and non-scientific members to review the saccharin data. The consumer interest in 1907 was informally represented by President Roosevelt, who was a daily saccharin user. At the outset of the panel's deliberations, TR unequivocally proclaimed his position, declaring that, "Anybody who says saccharin is injurious is an idiot."

Several major participants in the 1907 deliberations had reason to be somewhat less than impartial about the outcome. The conference was chaired by Representative James S. Sherman of New York, who owned a canning firm. A panel of chemists was appointed to review the saccharin charges. Its chairman was Ira Remsen, then president of Johns Hopkins University, who was described as still bitter about his former graduate

student securing a patent for saccharin production. Harvey Wiley was also a member of the panel which was often referred to as the Remsen board. As a chemist in the Department of Agriculture, he had been instrumental in the development of refining techniques for the sugar industry.<sup>8</sup>

In 1910 the Remsen board concluded that there was no evidence to suggest that saccharin was harmful to humans. The reprieve, however, was of short duration. In 1911 saccharin was banned from foods in the United States, not because it was deemed unsafe, but because, under pressure from the sugar industry, the Department of Agriculture ruled that:

In every food in which saccharin is used, some other sweetening agent known to be harmless to health can be substituted, and there is not even a pretense that saccharin is a necessity in the manufacture of food products.

When the discrepancy between the findings of the Remsen board and the Department of Agriculture's ruling became apparent, a new decision was reached. In 1912 Food Inspection Decision 146 allowed the use of saccharin in foods "intended for invalids" and identified by a label. General use was restricted. When sugar shortages developed during World War I, however, saccharin was reinstated.<sup>9</sup>

When sugar was rationed during World War II, saccharin consumption increased dramatically. Soft drink bottlers unsuccessfully asked the FDA for permission to augment their reduced sugar supplies with saccharin. Saccharin's manufacturers found it difficult to meet the wartime demand,

in part because of the severe shortage of a saccharin component, toluene, that was also a basic raw material for explosives.<sup>10</sup>

Until the mid-1950s saccharin's availability was limited by numerous state regulations.<sup>11</sup> Many of these laws had been enacted, not on scientific grounds, but under pressure from soft drink bottlers and food processors who feared competition for their higher priced sugared products. The laws were repealed as diet soft drinks grew in popularity when cyclamate became commercially available. In 1960 saccharin consumption was equivalent to 1.9 pounds of sugar per capita. By 1977 the per capita consumption of saccharin had reached a weight equivalent to sugar of 6.6 pounds per capita.<sup>12</sup>

The infant organic chemical industry in America initially displayed little interest in saccharin, and all of the earliest manufacturers were German. In 1901, the Monsanto Chemical Company in St. Louis, Missouri, began producing saccharin for sale to food processing companies. Six German firms, known as the "dye trust" attempted to halt Monsanto's production by driving down the price of saccharin. Their efforts were unsuccessful, and Monsanto continued manufacturing the sweetener until 1972 when the company phased out several of its operations including saccharin. The journal Science pointed out, however, that there was reason to believe that the increased concern among the scientific community and in the FDA about saccharin's safety contributed to Monsanto's

decision.<sup>13</sup>

Sherwin-Williams, a 117 year old company based in Cleveland, Ohio, is currently the sole domestic producer of saccharin, with 60 percent of the American market and approximately 25 percent of foreign sales. Sherwin-Williams began production in 1966 when it acquired the Maumee Chemical Company, a saccharin manufacturer. Sherwin-Williams supplies saccharin for foods, beverages and industrial uses.<sup>14</sup> In 1981 the estimated worldwide retail value of products containing saccharin was \$3 billion; Sherwin-Williams' saccharin sales were \$70 million, a relatively small part of its total revenues of \$1.5 billion.<sup>15</sup>

Saccharin is also imported from Japan and Korea. The soft drink companies purchase saccharin from foreign sources and from Sherwin-Williams; Cumberland Packing receives most of its saccharin for tabletop package production from Japan.<sup>16</sup> The method of production differs for imported and domestic saccharin. The imported saccharin is manufactured following the Remsen-Fahlberg process; Sherwin-Williams uses the Maumee process that does not result in creation of an impurity that was suspected at one time of being a carcinogen.<sup>17</sup>

The price competition from foreign imports was a factor in Monsanto's decision to cease manufacturing saccharin. Until the spring of 1982 Korean saccharin was given duty free status because of Korea's trade rank as a developing nation. In March 1982 Korean imports exceeded 50 percent of the

saccharin brought into the United States, and consequently Korea became subject to the same duty rates as Japan.<sup>18</sup>

In 1978 it was estimated that fifty to seventy million Americans used saccharin on a regular basis. Nearly seventy percent of this consumption was in soft drinks. When the saccharin ban was proposed, diet soft drink sales totalled \$1.1 billion in the United States. The remaining consumption of saccharin was in the form of tabletop sweeteners, canned fruits and other food uses, and as flavoring for drugs, cosmetics, and toothpaste. (See Table IV-A)

Women generally consumed more saccharin than men in 1978. Among female users those in the childbearing years of 20 to 39 were found to consume saccharin most heavily. Sixty to ninety percent of diabetics were also regular consumers of saccharin. Diabetics also tended to use saccharin with more frequency and in larger amounts than did non-diabetics. A particular cause for concern was the growth in saccharin consumption in the younger age groups especially.<sup>19</sup>

#### Federal regulation of food additives

One of the ways the diet industry expanded the scope of the conflict over saccharin was to link its resolution with reform of the federal Food, Drug, and Cosmetic Act, which establishes safety requirements for the use of food additives. The law was last revised in 1958. The industry argued that

TABLE IV-A

Use of Saccharin in Foods and in Nonfood Items  
in the United States, 1976<sup>a</sup>

| <u>Foods</u>   | <u>Quantity used,</u><br><u>million lbs</u> | <u>Percentage of</u><br><u>saccharin used</u><br><u>in food</u> | <u>Percentage of</u><br><u>saccharin used</u><br><u>for all purposes</u> |
|--|---|---|--|
| Soft drinks  | 2.900                                       | 58  | 45   |
| Tabletop<br>sweeteners   | 1.200                                       | 24  | 18   |
| Other foods (in-<br>cludes fruits,<br>premixes, juices,<br>candy, gum, jel-<br>lies, etc.) | 0.900                                       | 18  | 14   |
|  | <u>5.000</u>                                | <u>100</u>  | <u>77</u>  |
| <br><u>Nonfood Items</u>   |   |   |  |
| Cosmetics (toothpaste,<br>mouthwash, lipstick,<br>etc.)                                    | 0.650                                       |   | 10   |
| Pharmaceuticals (coatings<br>for pills)  | 0.455                                       |   | 7  |
| Smokeless tobacco<br>products (chewing to-<br>bacco and snuff)                             | 0.135                                       |   | 2  |
| Electroplating   | 0.130                                       |   | 2  |
| Cattle feed  | 0.065                                       |   | 1  |
| Miscellaneous  | <u>0.065</u>                                |   | <u>1</u>   |
| SUBTOTAL   | <u>1.500</u>                                |   | <u>23</u>  |
| TOTAL  | <u>6.500</u>                                |   | <u>100</u>   |

Table supplied in Committee for a Study on Saccharin and Food Safety Policy, Saccharin: Technical Assessment of Risks and Benefits (Washington, D.C.: National Research Council, National Academy of Sciences, 1978), Report No. 1, p. 2-5.



the improved capacity to detect minute quantities of a harmful substance and other scientific advances in the last two decades have made the law obsolete. Linking saccharin with a review of the food safety laws is not a new tactic. From the beginning of saccharin's use in this country, its disposition has been tied to legislative reform proposals.

Federal regulation of the food supply began a little over one hundred years ago. In the late nineteenth century several laws were passed to prevent the adulteration of tea and to impose discriminatory taxes on oleomargarine, imitation cheese, and imported flour. The specific intent of this legislation, however, was economic protection of farmers and importers; concern for the consumer was only incidental.<sup>20</sup>

The first safety requirements occurred as a result of the development of a national food industry. Around the turn of the century, the factory rather than the local farm became the source of food production. As the manufacturing of food became increasingly distanced from the consumer, the individual's control diminished over safety and sanitary conditions, and health abuses became more public.

The industrialization of food production also led to a proliferation of preservatives and coloring agents. Shortly after Upton Sinclair published The Jungle and created an outcry about the meatpacking industry, Harvey Wiley began to work for regulation of food additives.<sup>20</sup> Finally, when President Roosevelt included a recommendation for legislation

to regulate interstate commerce in misbranded and adulterated foods in his annual message to Congress, the Food and Drugs Act of 1906 was passed. Under the 1906 law the government's authority was limited to prohibiting the marketing of adulterated food and known toxic products. Unless a substance was determined to be harmful, the government could not act to prevent its use.<sup>22</sup>

In 1938 Congress passed the Food, Drug and Cosmetic Act which partly responded to the weaknesses of the earlier law. The 1938 Act required premarket proof of safety for new drugs but did not address the issue of food additives. After World War II a variety of food products were introduced that used numerous synthetic flavorings and other additives. In 1958 the Act was amended, and the burden of proof to establish an additive's safety was shifted to the manufacturer.

The Food Additives Amendments of 1958 and the Color Additive Amendments of 1960 required the manufacturer to submit animal test data to demonstrate that a substance is safe for its proposed use. Congress, prodded by the food industry, made it clear that benefits were not to be considered in evaluating an additive's safety. The industry was concerned that the FDA would have little reason to approve new food additives that served no additional functions than those already on the market. <sup>23</sup>

One section of the 1958 Amendments, often referred to as the Delaney clause, was cited by the FDA in its 1977 saccharin

decision. Named after its sponsor, James J. Delaney, a Democratic Congressman from New York and chairman in 1955 of the House Select Committee to Investigate the Use of Chemicals in Food, the clause states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal".<sup>24</sup>

Despite the exactness of the language in the Delaney clause, the legislative history reveals that the term "safe" was not intended to require proof of absolute safety. A House committee report stated that "safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive."<sup>25</sup> In 1958, as had occurred in 1907 and would again with the 1977 saccharin debate, it was "impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance."<sup>26</sup>

Not surprisingly, the food industry was opposed to adoption of the Delaney clause, apprehensive that in practice it would impose a heavy financial burden. Also opposed was the Department of Health, Education, and Welfare (HEW), which argued the clause was unnecessary because of the general safety requirements for additives already part of the proposed amendments. HEW also objected to singling out cancer because of concern that other serious disorders such as hypertension, nephritis, or diabetes might be given less attention. In the end HEW agreed with the addition of the Delaney clause because

it wanted to expedite passage of the 1958 amendments.<sup>27</sup>

The Delaney clause has become the center of a scientific and ideological debate over the extent to which government rather than the individual should be responsible for determining or preventing risk. Various scientists have attacked Delaney as an inept statement, asserting that it reduces complex procedures and principles to deceptively simple terms. Other scientists have supported retaining the law. They contend that it does allow scientific discretion, because only if a chemical is found to cause cancer can it be removed from the food supply.<sup>28</sup>

When the saccharin ban was proposed in 1977, the diet food industry included vigorous criticism of the Delaney clause in its protest over the FDA's decision. The industry branded the clause as inflexible and antiquated. The clause was faulted for setting a standard that failed to take into account the degree of dosage used in tests, the sensitivity of detection methods used, the potency of carcinogens, or the risk of exposure.<sup>29</sup> During the publicity over the saccharin announcement, the industry also contended that Americans were capable of deciding for themselves whether the "benefits" of saccharin were worth the alleged slight hazards.

The Delaney clause had strong support from those who believed that it was the government's responsibility to protect citizens regardless of the degree of risk. The two most active of the consumer organizations that supported the

saccharin ban, the Center for Science in the Public Interest and the Public Interest Health Research Group, were adamantly opposed to proposals to change or repeal the clause. They argued that any modifications would increase the number of carcinogens in the food supply, contending that "the law's great strength is its clear standard of safety that discourages compromising by federal agencies."<sup>30</sup>

In reality, the effect of the clause has been largely symbolic; its actual impact on the food industry has been inconsequential. The general safety requirements also in the 1958 law stipulated that any food additive must be found to be safe for human consumption before it can be approved, or in the case of additives already permitted, continue to be used in foods. Most of the controversial actions taken by the FDA against food additives have been based on these provisions, not on the Delaney clause.<sup>31</sup> From 1950 to 1980 the FDA tried to ban nineteen food chemicals. Prior to saccharin, the clause was only invoked twice in rulings, once in 1967 to ban a food packaging adhesive, and again in 1969 to prohibit a food packaging component.<sup>32</sup>

Although the 1958 Amendments formally placed responsibility for ensuring the safety of a food additive on the manufacturer, other events during the late 1960s and early 1970s also made it clear that food companies using a potentially hazardous substance risked embarrassing public exposure. Between 1967 and 1973 Congress passed more than

twenty-five consumer, environmental and other social regulatory laws. Consumer advocacy organizations were at their most influential during this period in Congress, in influencing FDA policy, and in attracting media attention.<sup>33</sup>

For the first time in its history, the food industry received adverse publicity about its use of even common additives such as sugar and salt. The industry responded to these and other controversies with more than their usual strategies which had been generally limited to traditional lobbying tactics. Many companies began actively to support or establish organizations that undertook scientific studies to defend a threatened substance. The findings of these organizations were heavily publicized. For example, several major food companies sponsored scientific review panels to address concerns raised about controversial items on the FDA's list of substances generally recognized as safe (GRAS). When this approach quickly proved redundant, the International Life Sciences Institute (ILSI), an organization of scientists, including some from the soft drink industry, was established to provide a more coordinated defense of challenged additives.<sup>34</sup>

In 1977 the administration of Jimmy Carter placed less emphasis on requiring zero risk and more effort on developing a coherent policy toward carcinogens for all the regulatory agencies to follow. Despite the goal of achieving more flexibility, guidelines were developed under Carter that

proposed fairly stringent standards. Any substance that caused cancer when tested in animals would be considered a potential human carcinogen. For regulatory purposes it was agreed that a single animal test would suffice. The regulatory agencies were instructed not to wait for longer than two years for additional test results before taking action.<sup>35</sup>

The Reagan administration considered the recommendations of Carter's task force "dogmatic", arguing that they were based on scientifically unsupportable statements. Another review was begun in 1982 to evaluate the federal decision-making in the regulation of carcinogens. One result of this most recent effort was a report that suggested that the agencies adopt a standard that distinguishes between carcinogens that affect the cell's genetic mechanism and those that do not, like saccharin. This distinction was considered invalid by many scientists who argue that there is evidence that some carcinogens that do not cause genetic changes are more potent than those that do.<sup>36</sup>

These shifts in the political climate affect the receptivity of the public and Congress to FDA decisions. Neither the public's or Congress' attitudes are shaped independently of the influence of public relations efforts, advertising, biases in news reporting, etc. Science has attributed the confusion about saccharin's carcinogenicity on the part of Congress and the public to the "aggressive effort

of the diet food industry to foster this misunderstanding (of toxicological methodology and the nature of animal testing), and its ability to bring its views forcefully to the attention of Congress."<sup>37</sup>

Before the saccharin controversy there was only tepid political support for changing the Delaney clause. Many in Congress were apprehensive that a vote against Delaney could be construed as a vote for cancer. The widespread opposition to the saccharin decision provided a sympathetic environment for proposals to revise the food laws. In 1977 twenty-seven percent of those persons queried in a nationwide survey favored retaining the Delaney clause; 54 percent supported changing the law.<sup>38</sup> Saccharin made it less risky to support a modified safety standard. Between February and October 1977, 62 bills were introduced in Congress with bipartisan support to amend or repeal the Delaney clause. The chief bill, sponsored by Representative James Martin, had 200 co-sponsors and would have provided that the benefits of an additive be explicitly considered before a ban could be proposed.<sup>39</sup> Because of the complexity of the issue, none of the proposals passed.

Since the saccharin debate, reform of the food laws has generated periodic, but modest interest in Congress. Public opinion has again shifted toward increased support for the Delaney clause, making modifications potentially unpopular. By 1982, 48 percent of persons surveyed thought the law should



be retained; only 32 percent were in favor of changing it.<sup>40</sup> Other food additives have received public attention since saccharin, notably a proposal by the Department of Agriculture and the FDA to phase out sodium nitrite, a carcinogen used in curing meats. As each issue arises there is a flurry of criticism by the food industry and some members of Congress about the food laws and the Delaney clause. However, revisions of the law are difficult, involving highly technical issues. By repeated extensions of the saccharin moratorium, Congress has also avoided a major confrontation on the food safety laws.

Although public opinion and overall congressional interest have varied, the food industry has continued to work assiduously to have the laws revised. Senator Orrin Hatch, chairman of the Labor and Human Resources Committee since 1980, and Congressman Martin have continued to sponsor legislation. Both efforts have received strong support from the food industry, including the soft drink companies. The latest and most significant of these was a bill introduced by Hatch in 1981. Among other provisions it called for a "flexible regulatory response based on the risks and uses associated with a substance."<sup>41</sup> The bill was opposed by the Coalition for Safe Food, an amalgam of three dozen consumer advocacy and labor organizations. Their opposition as well as other issues in Congress of a more immediate nature have prevented the bill from reaching a vote to date.

### The Food and Drug Administration

Under the 1906 law, the Bureau of Chemistry in the Department of Agriculture (USDA) was given responsibility for the regulation of food safety. The Bureau's enforcement activities, however, were circumscribed by the fact that it was organizationally in the part of the government charged with the promotion of food production and distribution. Much of the Bureau's work, especially under Harvey Wiley, was inimical to the efforts of the Department.

The responsibility for enforcement of the Food and Drugs Act also left the Bureau of Chemistry little time for research.<sup>42</sup> In 1927 the research functions of the Bureau of Chemistry were separated from its regulatory and enforcement activities. The latter were placed in a newly created Food, Drug and Insecticide Administration that was established as a separate unit within the Department of Agriculture. In 1930 the name was simplified to the Food and Drug Administration, and in 1940, Franklin Roosevelt moved the FDA out of USDA to the Federal Security Agency. When the Department of Health, Education and Welfare (now called the Department of Health and Human Services) was created in 1953, the FDA was transferred to its jurisdiction.

The FDA has six divisions, one of which is the Bureau of Foods, responsible for the regulation of food additives including saccharin. The agency's basic function is to carry

out statutory mandates through formal and informal procedures. The FDA currently has jurisdiction over almost 3000 direct additives, substances added to foods, and as many as 10,000 indirect additives, those that may migrate during processing, packaging, or storage. This authority includes 80 percent of all processed foods, excluding red meat and poultry.<sup>43</sup> Over the years the agency has shifted its role from policing blatant offenses to approving proper practices.<sup>44</sup>

Much of the FDA's workload is dictated by these statutory requirements. The weight of the regulations is probably not as formidable as it may appear; many are repetitious, and some are inconsistent or conflicting. Additionally, the agenda of the agency is predetermined to some extent by issues that have carried over from the previous administration or that are part of the regulatory routine such as items imposed by the budgetary process or by workload cycles. There are also topics of pressing importance that arise from crises, scandal, or other unanticipated reasons.<sup>45</sup>

Direct public participation in the process of FDA rule making is a consequence of the Administrative Procedures Act of 1946. Among its other provisions, the Act allowed interested parties the opportunity to submit comments to the agency, and in some cases required that public hearings be held on proposed regulations. The participation of consumer advocacy organizations resulting from these provisions has been a consistent feature of the regulation of artificial

sweeteners.

The most significant external control over the agency, however, comes through Congress. Congress can restrict the FDA's authority (as occurred with saccharin). It can require the agency to undertake specific action or it may become involved in FDA activities by exercising continual supervision or conducting periodic investigations. Congress controls the FDA's appropriations, an important mechanism for determining the agency's agenda. It can also affect the operation of the agency through the selection and approval of the Secretary of HHS. Finally, Congress may become involved informally because of the interest of individual congressmen in particular issues as occurred with food safety reform proposals.<sup>46</sup>

Herbert Kaufman has argued in his study of the FDA and other federal bureaus that organizational constraints are especially influential in determining the behavior of the agency.<sup>47</sup> These can include the learned behavior of staff members from professional affiliations, from training, and from established work patterns. A highly stable work force can make these factors especially salient; at the FDA the turnover rate is generally only about 5 percent. The professional orientation of an agency can be an important determinant of regulatory activities. As James Q. Wilson has described some regulatory agencies have tasks that can be performed only by professionals.<sup>48</sup> These professionals, in varying degrees, have acquired distinctive ways of approaching policy problems.

They also tend to be sensitive about their reputation among their professional colleagues.

The FDA is dominated by professionals from various scientific disciplines. They place great importance on maintaining the agency's reputation as a competent scientific organization and on their own personal standing in their individual fields. During the artificial sweeteners controversy there appeared to be some conflict between the professional norms of the scientist and those of the FDA's lawyers. Scientists in the Bureau of Foods spoke of how the debate over the safety of cyclamate, saccharin, and aspartame was often framed as a legal issue. Once that occurred they complained that the regulatory process was reduced to a dispute between lawyers rather than a debate on scientific grounds.<sup>49</sup>

The commissioner of the FDA is not appointed by the president as in other major regulatory agencies but by the Secretary of Health and Human Services. The political climate and the values held by the current administration are often reflected in the choice of commissioner. The FDA commissioner from 1980 to 1983 of the Reagan administration was Arthur Hayes, a physician. Hayes was popular with industry, but his professional orientation was probably less responsible than his advocacy of fewer regulations and greater dependency on voluntary cooperation from industry, guidelines determined not only by his own preferences but also by the Reagan

administration.<sup>50</sup>

The commissioner's background does not appear to be especially important in determining the reception given to the FDA's decisions. For instance, Donald Kennedy, commissioner during the saccharin controversy, was a neurophysiologist with a largely academic career. Kennedy's scientific background was acclaimed as an asset in the press when he was appointed and in Congress, where he scored high marks with his testimony during saccharin hearings.<sup>51</sup> Nevertheless, the fact that a highly respected academic scientist supported the ban did little to appease the widespread criticism of the FDA's decision.

Commissioners have changed frequently at the FDA; Donald Kennedy was the ninth commissioner in 24 years. By contrast, some members of Congress, many congressional staff members, and lobbyists and career civil servants are generally in office much longer.<sup>52</sup> The constellation of interests making demands of the FDA therefore is stable over time. It is relatively easy for a trade association or a consumer advocate to be consistent in their efforts and in the alliances they establish. Each commissioner, however, is likely to bring new influences to bear on the agency. The personal interests of the commissioner can determine some of the FDA's activities as was apparent with Hayes' particular concern about hypertension. But as the regulatory philosophy or priorities shift when commissioners change, the agency's decision can

lose coherence.

The FDA values its reputation as a scientific organization, but the quality of its research is occasionally the focus of attention from the agency's critics in the food industry and among public interest groups. The FDA has periodically responded to the charges that its research efforts are inadequate by establishing review committees.<sup>53</sup> Despite these problems evaluations of the FDA as a scientific organization are not predominantly negative. The top scientists at the agency are often favorably compared to top scientists anywhere by representatives from the food industry and by consumer advocates.<sup>54</sup>

There will inevitably be criticism from affected groups over adverse decisions. A more persistent problem and one that often appears to be at the heart of negative evaluations of FDA performance is the discrepancy between the responsibilities of the agency as mandated by law and the expectations of its active clientele: the food industry and public interest groups. The president of an organization that instructs lawyers about FDA regulations described the food safety system as "inherently adversarial." He noted that because the FDA approves additives and drugs and conducts safety inspections, its relationship with industry is often antagonistic. For example, in 1981 it was found that the FDA took an average of 31.2 months to approve a new additive.<sup>55</sup> Consumer advocates contend that the FDA is dilatory in acting

to restrict potentially hazardous substances in an effort to avoid controversy. The food industry often complains that the cost of this process is prohibitive. Yet the agency's responsibility of protecting the safety of the food supply is not usually compatible with swift action. In addition, the intrusion of political factors into scientific decisions as occurred with each artificial sweetener is further incentive for the FDA to proceed cautiously.

#### The ban

Saccharin use leveled off in the two years following the cyclamate ban but has risen steadily since then. As consumption increased scientific attention focused on the association between saccharin and bladder tumors in animal studies. Although one source of information about saccharin's ill effects was the Wisconsin Alumni Research Foundation, earlier involved with cyclamate, the sugar industry was not as concerned about saccharin's competition as it had been with cyclamate. After the cyclamate ban, the Association found that the expected increase in demand for sugar failed to materialize. Instead, it discovered that cyclamate had created a new market. The consumers of artificially sweetened soft drinks were generally new to the soft drink market rather than former drinkers of sugared beverages.<sup>56</sup>

In 1972 the FDA required that foods containing saccharin carry a warning that they should be used only by persons who



had to restrict their intake of ordinary sweets. The agency also removed saccharin from the GRAS list. In the spring of 1977 the Canadian government released the results of a study that found that an impurity caused during the manufacturing process was not responsible for the bladder tumors. Upon receiving the news, the acting FDA commissioner, Sherwin Gardner, proposed the saccharin ban.<sup>57</sup>

Although the agency went to considerable lengths in its decision to argue that under the general safety provisions of the food law, saccharin would have been banned anyway without the Delaney clause, this was often overlooked in media coverage of the ban. That the FDA was forced to act under the law to restrict saccharin is the most widely given explanation for the decision within the agency and from FDA staff members.<sup>58</sup> This explanation is unsatisfactory. A ban on a harmful substance is a rare event despite the vast numbers of questionable substances.

A more plausible explanation for the saccharin ban was that the agency failed to understand the extent of the public's commitment to artificially sweetened foods and beverages, especially soft drinks. As a result, the FDA did not anticipate the widespread opposition to its proposal. In addition, there were significant pressures on the agency to act. For several years before the saccharin decision, consumer groups and Congress had been especially critical of the FDA's handling of health hazards in food.<sup>59</sup> Faced with substantial

evidence that saccharin was a likely human carcinogen, the FDA felt compelled to recommend restrictions on its use.

In attempting to prevent consumer panic, the FDA issued a statement that minimized the significance of the animal data. The agency said that: "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."<sup>60</sup> Sherwin Gardner described the amount of saccharin used in the studies in terms that made the tests appear ludicrous. Gardner said that the saccharin dose given the test animals "exceeded the average human exposure by at least 800 times, and that the human equivalent would be that of drinking 800 twelve ounce cans of diet soda every day for a lifetime." Instead of preventing the anticipated crisis among consumers, the reassurances became the target of ridicule in the press and from the diet industry, especially the phrase "800 cans a day."

Consumer groups supported the ban but castigated the FDA for minimizing the seriousness of the risk. The Health Research Group disputed the benefits of saccharin pointing to the absence of proof that it is efficacious in weight control. The organization also argued that any increased risk of bladder cancer of less than 30 to 40 percent would probably be undetected. Consumer Reports, a widely read periodical that evaluates the safety of consumer products, stressed the

validity of scientific tests that utilized large doses in animal studies to estimate human effects.<sup>61</sup>

The saccharin question placed the FDA in a difficult position. There were considerable pressures on the agency to act and there was a law that clearly stated a carcinogenic substance was not to be permitted. The FDA, however, must be seen as at least partly responsible for the problems it faced with saccharin. Having banned cyclamate seven years before, the agency made it likely that without an acceptable substitute, restrictions on saccharin would be unpopular.

Although the Delaney clause clearly spells out a strict standard for the agency to follow in the regulation of carcinogens, this guideline has been ignored far more often than it has been enforced. With saccharin, a widely used substance that posed no overwhelming risk, the agency might have more seriously explored other options although short of no restrictions at all, none of the alternatives would have been entirely uncontroversial.

For example, the FDA could have emphasized that saccharin would still be allowed as a tabletop sweetener. In Canada saccharin sweetened soft drinks were banned but saccharin continued to be sold in pharmacies as an over-the-counter substance. Following the ban, the Canadian soft drink bottlers introduced sodas with reduced sugar content, although sales were not as high as they were with the artificially sweetened drinks. Sugarless drinks were also available to which

saccharin could be added.<sup>62</sup>

For the most part, the consumer advocacy organizations in the United States would have accepted the option of preserving saccharin's use as a tabletop sweetener. These groups had argued that the freedom of choice issue was not a compelling one for small children or for those whose mothers had consumed saccharin during pregnancy. Saccharin sold only in tabletop form would mean that consumers were presumably acting with some deliberation.<sup>63</sup>

This policy choice would have done little, however, to appease the diet food industry. For the bottler the cost of sweetening a gallon of syrup concentrate with sugar has consistently been more expensive than the cost with saccharin. The cost of a can of diet soft drink to the consumer, however, was the same as that of one sweetened with sugar. The large soft drink manufacturers and their bottlers were determined to protect this market. Nor would this option have satisfied dieters or diabetics who claimed "lifestyle" reasons for opposing the ban, arguing that it was the accessibility to low-calorie products that made it possible to adhere to a restricted diet.

The FDA could have required the warning label alone on products containing saccharin, although that would have been one of the least effective methods to curtail consumption. In conveying risk, labels are of limited utility in helping consumers to make decisions. Labels can display very little

information, and they necessarily synthesize a great deal in a simplistic fashion. Significant or conflicting data is omitted.

It is also difficult to understand how great is the risk from a food additive described on a label without a comparative context. However, tables of comparative risks are facile, ignoring the degree of uncertainty that may exist and other considerations. Decisions about risk require the consumer to have the ability to probabilistically evaluate rare, but consequential, events.<sup>64</sup> Finally, surveys of consumer response to both the warning labels on cigarette packages and saccharin products have indicated that most consumers never read them. The labels have not adversely affected sales in either instance.<sup>65</sup>

#### Reaction to the ban

The press had a mixed response to the ban. The New York Times and the Wall Street Journal opposed the ban and recommended replacing the Delaney clause with a procedure for weighing risks and benefits. A month later the Times softened its opposition somewhat, noting in cautious support for the FDA that "... for the moment there seems to be no alternative to judgment and action by a government agency like the FDA..." By contrast the Washington Post supported the Delaney clause and the proposed ban.<sup>66</sup> Because most newspaper accounts mentioned the phrase "800 cans of soda" to described the

saccharin dose, the press coverage fostered the impression that the FDA had acted unwisely.

Consumers were overwhelmingly opposed to the ban. A survey of public reaction in 1977 compared to the response to the cyclamate ban in 1969 revealed important changes in attitude. In 1969 87 percent of those surveyed indicated they were "grateful" to the government for protecting them against a suspected carcinogen. A few (18 percent) felt cyclamate's dangers were exaggerated. When the saccharin ban was proposed, only 16 percent indicated that they felt grateful. Sixty-nine percent believed saccharin's dangers had been exaggerated and 47 percent saw the ban as an infringement of their individual rights.<sup>67</sup>

The diet food industry fought the ban in three ways. First, the validity of animal evidence was disputed. The industry utilized the public's lack of understanding about the study of carcinogens, emphasizing in advertisements the absence of evidence that bladder cancer in humans could be attributed to saccharin use.<sup>68</sup>

Second, the "benefits" of saccharin were heavily promoted, especially the impression that they were a medical necessity for diabetics and were effective in weight control. The publicity generated by the Council often mentioned that ten million diabetics would be deprived of diet soft drinks and other artificially sweetened foods. The involvement of the American Diabetes Association (ADA) and the Juvenile

Diabetes Foundation (JDF) in the saccharin controversy was an important factor in linking artificial sweeteners with health in the minds of the public. The attention that these organizations attracted to diabetes contributed to the perception that saccharin was beneficial in treatment of a medical problem.

Representatives from the ADA and the JDF testified extensively against the proposed ban. Their state affiliates organized their members in letter writing campaigns to Congress. The ADA called for a review of the current food safety laws and further study of saccharin, citing a "lack of agreement between the results of animal experimentation and human studies." The ADA recommended the continued availability of saccharin until more information was available and stressed prudent use of the artificial sweetener by pregnant women and young children.<sup>69</sup>

The JDF took the position that a ban would cause its 500,000 members to be set further apart from their peers without convenient access to artificially sweetened soft drinks and foods.<sup>70</sup> At a congressional hearing, the founder of the JDF, Lee Ducat, stated that the sudden ban had the "diabetic population in virtual shock." Moreover, Ducat predicted that a ban would result in increased numbers of diabetics in the United States although there is no scientific evidence to warrant his conclusion.<sup>71</sup>

The American Cancer Society displayed some interest in

the saccharin debate, but its role was a peripheral one with little active participation. In 1980 the Society issued a paper cautioning moderate use of artificial sweeteners, again for the groups potentially most at risk, pregnant women and children. The report noted that if any of the current cases of bladder cancer could be attributed to saccharin consumption, the number must be very small.<sup>72</sup>

The third way in which the diet industry fought the ban was to redefine the issues under debate. Instead of contesting the saccharin data alone, the industry called for an overhaul of federal food safety legislation. Press coverage amplified the idea that the saccharin case was illustrative of the law's inadequacy. The point was often made that to consider saccharin without an appraisal of the Food, Drug, and Cosmetic Act would simply allow similar controversies to occur.

In fact, saccharin is exceptional among food additives that may present a health hazard. There are other substances that can be substituted for many of the additives used by the food industry. In addition, it would be hard to make the case that the public "needs" a particular flavor enhancer or emulsifier. There are also few contested additives that are as widely used as saccharin. With those that are, such as salt and caffeine, product innovations have blunted the demands for strong regulatory actions. Low-sodium, and caffeine-free versions of many standard foods are on the market in response to the various health concerns that have been raised.



The saccharin debate was also redefined as a threat to individual freedom. Instead of whether or not a carcinogenic substance should be banned, the issue became freedom of choice for the consumer. The American Council on Science and Health has made freedom of choice the basis of its objections to a saccharin ban. ACSH recommended that consumers should be informed about saccharin's alleged risks and benefits (presumably through brochures in drugstores and groceries) in order to make an informed judgment. The organization is strongly opposed to the label that saccharin products carry warning that warns that it has caused cancer in laboratory animals. ACSH has focused much of its opposition on contrasting the sanctions against saccharin with those against cigarettes. The message on cigarette packages does not mention the word cancer.<sup>73</sup>

Under the original terms of the debate, the FDA's role was that of decision-maker. After the redefinition as the public and non-industry groups became mobilized in opposition, Congress became the decision-maker. Congressional hearings on the FDA proposal examined the validity of animal tests, the effectiveness of the food safety laws, and saccharin's purported benefits to diabetics and dieters.

Congressional participation increased the visibility of the saccharin issue with the media. Without congressional involvement it is likely that some non-industry groups may have testified at FDA hearings or submitted written comments

to the agency. It is highly unlikely, however, that the number of organizations who participated would have been as great if the issues had not been redefined to appeal to as many diverse groups as possible. Nor is it likely that hearings would have been held by the subcommittees in Congress; the degree of public participation would have been much less.

Sherwin-Williams found strong commercial allies in its opposition to the FDA's decision. The soft drink companies and Cumberland Packing envisioned a collapsing diet market without saccharin. Although a number of alternative sweeteners were under development at the time, approval of an acceptable substitute was perceived to be years away.

The diet industry watched the saccharin issue develop, following closely the studies conducted by the National Academy of Sciences and others over the years. The Calorie Control Council, especially, and the National Soft Drink Association coordinated industry resistance to the ban. Other trade associations, representing canned food and pharmaceutical companies were also involved but figured less prominently in organizing industry and public opposition.

The National Soft Drink Association presented the opposition of its members to the FDA and to Congress. Its state affiliates wrote their various congressional representatives to describe the loss of jobs that would occur in their districts if diet soft drinks were made unavailable.

Television and radio broadcasters were contacted by bottlers who warned of decreased advertising revenues if diet soft drinks were banned.<sup>74</sup>

The Calorie Control Council was more adept at shaping the saccharin controversy than it had been with cyclamate partly because the diet industry gave the Council its full backing with saccharin. The public relations firm of Hill and Knowlton was retained by the Council to coordinate its publicity efforts. Less than a month after the FDA announcement, the Council was estimated to have spent close to one million dollars on its saccharin campaign.<sup>75</sup> The support of the diet industry provided the Calorie Control Council with resources unmatched by any of the groups who supported the restrictions on saccharin.

The Council undertook an extensive campaign to persuade the public that the ban was an example, not of government protection, but of government intrusion into private decisions. The Council ran advertisements opposite the editorial pages in newspapers throughout the country that urged the public to write Congress. (See Figure IV-A) The phrase, "800 cans of diet soda a day," from the FDA announcement of the ban figured prominently in the Council's newspaper advertisements. Millions of unorganized consumers were mobilized into a saccharin constituency. Congressional mail on saccharin was reported to have reached record amounts.<sup>76</sup>

FIGURE IV-A

# Why is the verdict almost in on saccharin when all the evidence isn't?

Shortly, the FDA's proposed ban on saccharin can become a harsh reality.

It is a decision based on insufficient evidence: chiefly, the results of a single unfinished Canadian test of 200 rats that were fed the human equivalent of over 1,250 twelve-ounce beverages a day over a lifetime. Quite frankly, there is considerable scientific disagreement over this test's validity because of the "mega-doses" of saccharin fed to these rats.

On the other hand, and what you may not know, the large body of existing research does not indicate that saccharin causes cancer in animals or humans.

For instance, there have been at least a dozen experiments on animals conducted over the last decade, which the National Academy of Sciences reviewed and concluded no regulatory action against saccharin was indicated.

More importantly, there have been at least six studies involving a large number of humans (more than 60,000) with no evidence that heavy saccharin ingestion results in an increase in bladder cancer.

Of course, the most rigorous "test" could well be the fact that saccharin has been in use for over 80 years without a single case of cancer attributed to it.

If any cancer danger is demonstrated from diet foods and beverages containing saccharin, everyone agrees that they should be taken off the shelves. But, at this point, there appears to be a lot of confusion, controversy and insufficient evidence to ban saccharin. And more time to sort it all out seems justified.

## Your desires as an American are being flagrantly ignored.

The majority of American people disapprove of the proposed ban on saccharin. A recent major national survey confirms it.

However, the FDA intends to ban saccharin in foods, beverages, and all other products. To soften the blow and quiet the voice of protest, the FDA announced it would *consider* allowing saccharin to be sold over the counter as a drug. But...

## It is not certain you will be able to buy saccharin over the counter.

Frankly, the FDA action is confusing and there is a catch. Weigh carefully the statement by Donald Kennedy, Commissioner of the Food and Drug Administration: "I want to make it clear that permanent approval of saccharin for drug use is not automatic."

To run the drug tests, the FDA would require "5 years at a minimum" states Dr. Leonard Humes, President of the American Society of Bariatric Physicians.

The fact is, saccharin is not a typical drug, since its sole function is to provide sweetness without calories. Thus, saccharin may not be as easy to buy as you've been led to believe.

## There is no substitute for saccharin available.

Many people are under the mistaken impression that American industry has a substitute waiting in the wings, ready to go as soon as the saccharin ban goes into effect. *This is totally untrue.*

"No other alternate sweetener is far enough along... there is nothing around the corner next year to look forward to," according to FDA Deputy Commissioner Sherwin Gardner. This means that if saccharin is banned, millions of diabetics may not experience the taste of sweetness for a long time, perhaps ever, in their diet foods and soft drinks. And millions of weight-conscious Americans will have to forego the benefits of low-calorie-sweetened soft drinks, candy, gum, and desserts.

## What Congress does will depend on you.

Both Senator Edward Kennedy and Representative Paul Rogers have suggested that a thorough scientific review should take place. Independent scientists should judge the data on saccharin and especially the validity of the Canadian experiment as it relates to humans.

We think this is a sensible and essential suggestion and we urge you to urge Congress to support that proposal and provide the time necessary to judge all the data.

Without your support, the ban on saccharin will become a reality we'll all have to live with.

## ACT NOW! YOU'VE GOT LESS THAN A WEEK TO BE HEARD.

Below you'll find a list of government leaders who have a special interest in the proposed ban on saccharin. Phone them. Write them; and do it before May 18. That's the date the FDA puts saccharin on trial in a public hearing. Let them know you support postponement of a ban so an independent and thorough scientific review can be made to evaluate the total evidence on saccharin.

Congressman Paul G. Rogers, Chairman  
Sub-Committee on Health and Environment  
2415 Rayburn  
House Office Building  
Washington, D.C. 20515  
(202) 224-3121

Senator Edward Kennedy, Chairman  
Sub-Committee on Health and Scientific Research  
310 Senate Courts Building  
Washington, D.C. 20510  
(202) 224-3121

Donald Kennedy  
FDA Commissioner  
5600 Fishers Lane  
Rockville, Maryland 20852  
301 443-3400

## OR WRITE YOUR CONGRESSMEN:

Address:  
House Office Building  
Washington, D.C. 20515  
202 224-3121

Two years later, when the saccharin moratorium came up for its first extension, the industry and the Calorie Control Council continued their campaign to discredit the science and to mobilize industry and non-industry groups. Coca-Cola sent brochures to its bottlers that described the amount of saccharin fed to the rats in the 1977 Canadian study as the equivalent of 1200 twelve ounce servings of Tab or Fresca per day for two lifetimes, a substantial increase from Coca-Cola's own earlier descriptions of the dosage. This material was accompanied by exhortations to the bottlers to again contact their congressional representatives. 77

The Council consistently depicted the FDA decision as total ban, ignoring the option of selling saccharin in tabletop form. The Council also misled the public about the extent of industry awareness, portraying the soft drink companies and other manufacturers as surprised by a precipitous FDA action. In fact, the industry had known at least since the cyclamate ban, if not before, that saccharin was the subject of a major review. Through the Calorie Control Council and other trade groups, the industry had monitored the test results of the numerous studies on saccharin that had been conducted over the years as well as sponsored research of their own. 78

The Calorie Control Council served as a buffer between industry and the criticism that can occur when a company engages in obvious efforts to lobby on its own behalf through

controversial advertisements. The soft drink firms and the food companies were protected from the publicity of being visibly involved in the debate. Their public participation was limited for the most part to expressions of outrage at the FDA's action.

The company that would have suffered the most if saccharin was restricted was Cumberland Packing. Because sales of Sweet'n Low represented 90 percent of the company's business in 1977, a ban would have eliminated most of the 500 jobs the company provided at its plant in an economically depressed area in New York City. Newspaper coverage during this period, occasionally with the soft drink firms as sources of information, focused attention on the plight of this family owned company and helped to personalize the FDA's decision.

### Conclusion

E.E. Schattschneider has described how the outcome of conflict is determined by its scope of its contagion; "the number of people involved in any conflict determines what happens."<sup>79</sup> He argued that consequently the most important strategy of politics is concerned with controlling the scope of a conflict. Schattschneider further contrasted the effect of the "privatization of conflict" with the "socialization of conflict." In the former case, the conflict becomes almost completely invisible. In the latter, universal ideas in the culture such as freedom of speech, justice or liberty are

often used to form the basis of "appeals to public authority for the redress of private grievances".<sup>80</sup>

The success of the diet industry's efforts to block the saccharin ban resulted from expansion of the scope of the conflict and appeals to public authority, in this case, Congress. The cyclamate ban in 1970 had demonstrated the vulnerability of a defense that rested on too narrow a definition of the issue. In the words of an executive of a major soft drink company, "cyclamate taught industry a lesson." With saccharin the issues were broadly defined. Instead of a fight between one company and the FDA, the saccharin ban was made into the public's battle.

This expansion occurred through redefinition of the issue under debate and through subsidization of the information flow to government and the public. The essential issue in the saccharin debate was a straightforward one. Under the law the FDA was required to ban any substance shown to cause cancer in animal tests. Simply put, the original question was whether there was reasonable certainty that saccharin caused cancer. Determining that answer would only have involved the FDA, a review of the available data, and the standard regulatory appeals process if the decision was contested.

The diet industry redefined this single issue into a series of new questions that confused the scientific and legal aspects of the problem. In Participation in American Politics Roger Cobb and Charles Elder describe how changing the terms

of a debate can amplify the appeal of the controversy, thus involving greater audiences: "The issue should be defined or redefined... as ambiguously as possible, with implications for as many people as possible, involving issues other than the dispute in question, with no categorical precedence, and as simply as feasible."<sup>81</sup>

Under the redefinition of the saccharin issue, the original question was expanded to include at least seven other questions:

- (1) Does the law requiring a ban make sense?
- (2) Are the scientific practices of food safety studies valid and are they applicable to the saccharin case?
- (3) Is the FDA a scientifically competent agency?
- (4) Is it actually possible to protect consumers from all risk?
- (5) Should the government determine whether people can have access to substances they want if the level of risk is low?
- (6) Are there other courses of action government should adopt in these instances?
- (7) Does the government have the right to deny diabetics a "medicine" ?

The new questions did more than just increase the issues under debate. They changed the focus of the controversy so that the central argument was no longer over the merits of the FDA's saccharin decision but over much larger topics: the competency of the FDA, the saliency of federal food safety legislation, and the validity of the scientific procedures used in studying food additives. The bigger issues added dimensions to the controversy that could not be addressed without complex and time consuming proceedings. The efforts to resolve these new topics to any extent have involved many



more individuals and organizations than would have been interested simply in saccharin. In the food industry alone other companies that were not users of saccharin have had major reason to be concerned about the food safety laws, testing procedures, and evaluation of FDA performance.

Moreover, expanding the saccharin issue allowed the diet food industry to furnish answers more favorable to its own interests. The significance of the negative findings on saccharin was diluted by industry supported research that stressed the scientific limitations of the studies.

Alternative explanations were heavily promoted within the industry, to the public, and to Congress. A decision on saccharin was indefinitely postponed because the issue was made more complex and therefore more difficult to resolve.

The redefinition also used slogans to evoke deeply ingrained cultural values, especially the concept of freedom of choice and American individualism. In the process, the subject under debate became confused because the saccharin decision was not an example of government intrusion into individual freedom. For the consumer to have freedom of choice in selecting foods that are potentially hazardous would involve enormous individual investments of time and energy. Instead, the government has traditionally assumed the responsibility of assuring food safety. By portraying the saccharin ban as an infringement of a personal freedom, the industry was skillful in transforming the saccharin debate

into an issue that has great appeal to the American public but that is only weakly connected to whether saccharin should be allowed on the market. The result was to widen the appeal of the debate, enlarging the number of people interested in the outcome of the controversy.

The diet industry bought itself time with the saccharin moratorium. Once saccharin was linked with appraisal of the food safety laws, it became unlikely that the debate would be resolved quickly. Placing saccharin (now subsumed in the review of the food laws) on Congress's agenda gave the appearance of action while effectively sidestepping a decision. Food safety continues to be an issue that has consistently been pushed aside in each congressional session. In the absence of crisis, there is little incentive for Congress to proceed in such a complex area.

A saccharin ban was prevented because the diet industry was able to pressure Congress, to shape the media's perception of the issues, and to galvanize consumers to protest the FDA's decision. These efforts might have been unsuccessful, however, if the industry had not had latent, but overwhelming public support. The FDA inadvertently assisted in creating this support by having earlier removed cyclamate with insufficient consideration of the implications for a saccharin decision. Without a substitute, millions of people, persuaded by over two decades of advertising that artificial sweeteners were effective in dieting, were unwilling to give up saccharin

and willing to accept what they clearly believed was a modicum of risk.

NOTES: CHAPTER IV

<sup>1</sup> S.89 was passed by Congress in April 1983. The bill simply changed the expiration date of the existing law (PL97-42) extending it until 1985. S.89 left intact earlier requirements that saccharin sweetened products and stores selling them display a warning sign. The bill also provided for continued support of saccharin studies. See Elizabeth Wehr, "FDA Move Against Saccharin Barred For Two More Years", Congressional Quarterly (16 April 1983), p. 749.

<sup>2</sup> Time/Yankelovich, Skelly, and White Survey, (19-23 May 1977); Roper Organization, (30 April - 7 May 1977) (New York: Roper Center).

<sup>3</sup> Richard Merrill, "Saccharin: A Regulator's View" in The Scientific Basis of Health and Safety Regulation, eds. Robert W. Crandall and Lester B. Lane (Washington, D.C.: The Brookings Institute, 1981), pp. 157-158.

<sup>4</sup> Robert Friedel and John W. Servos, "The Saccharin Flap of '07", Washington Post, 27 March 1977, p. C1; Dr. Al Lazen, "Saccharin: A Case Study" (National Academy of Sciences, 25 March 1981). Unpublished. Supplied by author.

<sup>5</sup> Ibid., p. C1; Committee for a Study on Saccharin and Food Safety Policy, Saccharin: Technical Assessment of Risks and Benefits (Washington, D.C.: National Academy of Sciences, 1978), Report No.1, p.1-5. Hereafter referred to as Report No. 1.

<sup>6</sup> Report No.1, Chapter 1; Dan J. Forrestal, Faith, Hope and \$5000: The Story of Monsanto (New York: Simon and Schuster, 1977), p. 16.

<sup>7</sup> Friedel and Servos, p. C5.

<sup>8</sup> Ibid., p. C5; Harvey Wiley, "Bitter Sweet: The Story of the Fight Against the Use of Saccharin in Foods", Good Housekeeping (November 1913), p. 689 and Harvey Wiley, An Autobiography (Indianapolis: Bobbs-Merrill Co., 1930) in Terrence Smith, "Saccharin" (Report for the American Council on Science and Health, February 1979), pp. 11-12.

<sup>9</sup> Report No.1, p. ES-1; Lazen, p. 5; Wiley in Terrence Smith, "Saccharin", pp. 11 and 12.

<sup>10</sup> "Saccharin Spurt?", Business Week, 25 July 1942, p. 48.

- 11 Food Engineering (May 1953), p. 79 and (June 1954), p. 90.
- 12 "Sugar and Sweetener: Outlook and Situation" (United States Department of Agriculture: Economic Research Service, May 1982), p. 27.
- 13 Forrestal, chapter 1; B. Culliton and T.H. Maugh, "Academy Panel Could Send Saccharin the Way of Cyclamates", Science (4 May 1973), p. 480.
- 14 Reginald Stuart, "Impact Slight at Sherwin Williams", New York Times, 11 March 1977, p. A28; Interviews.
- 15 Letter to the editor from Sally A. Domm, Director of Corporate Communications, Sherwin Williams, Fortune, 6 September 1982; Annual Report, Sherwin-Williams, 1981.
- 16 Interview.
- 17 Report No.1, pp. 3-7 to 3-11.
- 18 "Korean Saccharin is Subject to Duty Charges Next Quarter", Chemical Marketing Reporter, 22 February 1982, p. 19; "Saccharin Prices May Increase as Korea's GSP is Eliminated", Chemical Marketing Reporter, 26 April 1982, p. 23; Interview.
- 19 Report No.1, chapter 2.
- 20 Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Food Safety: Where Are We? (Washington, D.C.: Government Printing Office, 1979), p. 2.
- 21 Ibid., p. 26.
- 22 Ibid., p. 17.
- 23 Emil Corwin, "Why FDA Bans Harmful Substances", FDA Consumer (Dec 78 - Jan 79).
- 24 Food, Drug, and Cosmetic Act, Sec. 409 (c) (3) (A), (1958) and Congressional Quarterly (26 March 1977), pp. 539-541.
- 25 "Cyclamate: Commissioner's Decision", Federal Register 45 (16 September 1980), p. 61477.
- 26 Ibid.
- 27 Food Safety: Where Are We?, pp. 42-43.

- 28 James Turner, "Principles of Food Additive Regulation" in Consumer Health and Products Hazards - Cosmetics and Drugs, Pesticides, Food Additives, vol.2, ed. by Samuel S. Epstein and Richard D. Grundy (Cambridge: MIT Press, 1974).
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- 31 Peter Barton Hutt, "Public Policy Issues in Regulating Carcinogens in Foods", Food Safety: Where Are We?, p. 284.
- 32 Linda E. Demkovich, "Saccharin's Dead, Dieters are Blue, What is Congress Going to Do?", National Journal (4 June 1977), p. 858.
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- 36 Stein, p. 456.
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- 38 Roper Organization, National Survey (30 April 1977 - 7 May 1977), (New York: Roper Organization).
- 39 Office of Legislative Affairs, FDA and the 95th Congress, January 1, 1977 - December 31, 1978 (Washington, D.C.: HEW), p. 68.
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- 41 S.1442, 97th Congress, 1st Session.
- 42 Food Safety: Where Are We?, p. 15.
- 43 Wayne L. Pines, "The Cyclamate Story", FDA Consumer (December 1974 - January 1975) and Tom Christoffel, Health and the Law: A Handbook for Health Professionals (New York: Free Press, 1982), chapters 3 and 11.
- 44 Interviews; Christoffel, p. 199.
- 45 Herbert Kaufman, The Administrative Behavior of

Federal Bureau Chiefs (Washington, D.C.: The Brookings Institute, 1981), pp. 91; 113-114.

46 Christoffel, p. 39.

47 Kaufman, p. 39.

48 See James Q. Wilson, The Politics of Regulation (New York: Basic Books, 1980), pp. 379-383.

49 Interviews.

50 Wayne Pines, "New Commissioner Finds No Lack of Challenges - or Satisfaction," FDA Consumer (November 1981), pp. 16-19.

51 Kaufman, pp. 145-147.

52 Kaufman, pp. 133-134.

53 See "FDA", National Journal (September 1970), pp. 2045-2047; "FDA Plans New Science Committee", Food Engineering (June 1982), p. 28.

54 Interviews.

55 Grocery Manufacturers of America (unpublished report).

56 Interviews; "Cyclamate Bans", The International Sugar Journal (December 1969), pp. 353-354.

57 The decision included the following provisions: (1) the interim food additive regulation would be revoked that allowed saccharin as an ingredient in prepackaged foods including soft drinks and tabletop sweeteners; (2) an invitation for proposals to continue the marketing of saccharin as a single ingredient drug, available without prescription. If approved such products would have been required to bear a conspicuous warning about the risk of cancer. See "Saccharin and its Salts," Federal Register (15 April 1977), pp.19996-20010. The continued use of saccharin as an over-the-counter drug was reminiscent of its primary use for years in its common tabletop form prior to the introduction of diet soft drinks.

58 Tom Shales, "Tears and Fears: Threat to Saccharin Spurs New Hoarding!", Washington Post, 15 March 1977, pp. B-1 and B-7; Interviews.

59 Merrill, p. 155.

60 Sherwin Gardner statement in press release quoted in

"The Great Saccharin Snafu", Consumer Reports, July 1977, p. 410.

61 Testimony of Sidney M. Wolfe and Anita Johnson, Public Citizen's Health Research Group, Subcommittee on Health, House Commerce Committee Hearings on Saccharin (21 March 1977); Press release, Health Research Group (14 April 1977); "The Great Saccharin Snafu", Consumer Reports, July 1977, pp. 410-414.

62 Sidney Wolfe, "Saccharin and Food Additives: Unresolved Issues in the Conflict between Individual Freedom and Social Control", (Statement at New York Academy of Sciences Conference on Public Control of Environmental Hazards, 29 June 1978), p. 2.

63 William Shultze, Health Research Group, testimony before congressional subcommittee hearing on May 23, 1979.

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## CHAPTER V

## ASPARTAME: THE QUIET CONTROVERSY

When the FDA acted on cyclamate and saccharin, both substances had been in use for years. The diet food industry and the public were accustomed to their availability. In 1969 when cyclamate was banned and again in 1977 when the saccharin ban was proposed, dozens of consumer products were artificially sweetened. Despite government action, health scares and slow growth in overall soft drink sales, the diet segment of the soft drink industry continued to flourish.

A new sugar substitute, aspartame, was approved for dry foods in 1981 and for soft drinks in 1983. The regulatory process for the new sweetener took eight years while charges about its safety were reviewed by the FDA. In comparison to cyclamate and saccharin, the aspartame controversy is of much shorter duration and is less well documented. Aspartame is included here, however, because it provides an interesting contrast to cyclamate and saccharin and an opportunity to consider several questions about policymaking and artificial sweeteners.

First, aspartame shows how the policy outcome may be affected because the sweetener under consideration is a new

one rather than one long on the market. The challenge for aspartame's manufacturer, G.D. Searle and Company, was to defend the sweetener throughout the regulatory process yet, once approved, have aspartame emerge unscathed in the public's perception. Searle had an opportunity to respond differently to controversy than did the producers of cyclamate and saccharin because the initial debate over aspartame's safety occurred before it reached the market.<sup>1</sup>

In contrast to the disputes over its predecessors, aspartame's unsteady route to FDA approval transpired privately, with virtually no public attention. The conflict was contained within the regulatory process. There were no appeals to the public or to Congress and no publicity campaigns sponsored by the Calorie Control Council. The quiet handling of the regulatory conflict contributed to aspartame's introduction virtually free of publicity about health problems.<sup>1</sup>

Second, the aspartame case furnishes a perspective for further understanding the role substitutes have had in the regulation of artificial sweeteners. The availability of a substitute was an important factor in consumer and industry acceptance of the cyclamate ban, just as the lack of a substitute was the key reason for the protest over the proposed saccharin ban. Aspartame was entering a market where health problems had occurred with regularity. In response Searle presented aspartame as a unique sweetener, a

replacement for saccharin with its negative history as well as sugar with its calories.

Finally, of the three sweetener cases consumer advocates were most influential with aspartame in affecting the regulatory outcome. The impact of public interest organizations during the cyclamate and saccharin debates was indirect. Their opposition to artificial sweeteners and their critique of FDA performance added to the pressure on the agency but their efforts did not cause the bans. By contrast, consumer advocates had a direct role in the aspartame case: they blocked its approval, forced a reexamination of the scientific evidence, and in the process delayed the sweetener's marketing for eight years.

### History

The cyclamate ban and saccharin's uncertain future made it apparent that the diet industry would require a new sweetener, free from health concerns. The National Soft Drink Association has described the ideal sugar substitute as: "significantly sweeter than sugar with a pleasant taste and no aftertaste, chemically and physically stable, and colorless, odorless, water soluble. It should be competitive in cost, free of adverse health effects, and compatible with a broad spectrum of food uses."<sup>2</sup>

The Calorie Control Council has advocated a "multiple sweetener concept". According to the Council, a combination of

sweeteners would enable manufacturers to offer consumers a wider range of better tasting products.<sup>3</sup> Multiple sweeteners would also provide industry with greatly enhanced flexibility in product formulations, reducing the health risk from any one while lowering ingredient costs. For example, a more expensive but better tasting substance like aspartame used in combination with a cheaper sweetener like saccharin would maximize the advantages of each.

Several dozen alternative sweeteners have been under development in the United States and in other countries since the mid-1970s.<sup>4</sup> The only sweetener to receive approval in this country has been aspartame. The sweetening power of aspartame was discovered in 1965 by a Searle chemist, James D. Schlatter, although aspartame had been synthesized earlier by the British company Imperial Chemical Industries. Getting aspartame to the American market took Searle 17 years and by 1983 had cost the company \$160 million in research and development activities for the product.<sup>5</sup> Searle has a patent on aspartame's use as a sweetener that will expire in 1992.<sup>6</sup>

In 1977 Searle reported a loss of \$28 million on sales of \$749 million. The company hoped to add significantly to its revenues and earnings through aspartame sales. Financial analysts termed aspartame as "the critical variable at Searle" and "the most important single new product in the company." Aspartame sales apparently have been important to improving Searle's financial health. In 1982 the sweetener contributed

about \$50 million to Searle's earnings; no other product had revenues of over \$30 million.<sup>7</sup> That year Searle earned \$140.4 million on total revenues of \$1 billion.<sup>8</sup> By 1990 aspartame sales are projected to reach \$500 million and by 1996 more than \$1 billion, a figure that would double the current size of Searle.<sup>9</sup>

Leading Searle's revival until recently was Donald Rumsfeld, former congressman from Illinois, former White House chief of staff and Secretary of Defense under Gerald Ford, head of the Office of Economic Opportunity and the Cost of Living Council under Richard Nixon, and special envoy to the Middle East under Reagan. Rumsfeld became president and chief executive of Searle in 1977.<sup>10</sup> Under brothers William and Daniel Searle, the company had been in serious difficulty because of a series of unprofitable acquisitions and the lack of breakthroughs in drug research. Searle also had a tarnished reputation with the FDA resulting from discrepancies in data submitted in support of aspartame.<sup>11</sup>

Aspartame was viewed as an important part of a five year turnaround strategy for Searle by Rumsfeld and his management team, composed in large part of Ford administration veterans. Rumsfeld took several steps to revitalize Searle including trimming staff and increasing long term research efforts. He also concentrated on securing the approval of aspartame, which was languishing in the FDA regulatory process.<sup>12</sup>

In July 1974, three years before Rumsfeld arrived at

Searle, the FDA had approved aspartame for use in dry foods and beverages. A month later Dr. John Olney, professor of psychiatry at Washington University and James Turner, the consumer advocate formerly involved with cyclamate and saccharin, objected to aspartame's safety. In December 1974 the FDA offered to establish a public board of inquiry (PBOI) composed of three outside scientists to review the objections as an alternative to the usual procedure of an evidentiary hearing before an administrative law judge.<sup>13</sup>

The board of inquiry was used for the first time in FDA history to scrutinize the aspartame data and to advise the commissioner. The role assigned to the PBOI was to make recommendations, not to reach an actual decision, which remained the prerogative of the commissioner.<sup>14</sup> Several features of the procedure appeared to favor aspartame's reapproval. The company was able to submit five nominees for the PBOI to the FDA (as were Olney and Turner), and the board members were selected with the concurrence of all parties. The FDA also informed Searle and the others of the issues to be considered by the board and invited comments.<sup>15</sup>

The Bureau of Foods in the FDA, having already approved aspartame in 1974, was still in favor of its reapproval when the board was convened, so Searle was not faced with any agency opposition to a favorable ruling. The board was asked to consider two principal issues: whether aspartame consumption would entail a risk of brain damage causing mental

retardation and whether aspartame use would increase the incidence of brain tumors. Based on the answers to these questions, the board was asked to decide whether aspartame should be approved for use.<sup>16</sup>

The board decided that the risk of brain damage was negligible, but that it could not rule out the possibility that aspartame consumption might contribute to the development of brain tumors. As a result, the PEOI recommended in October, 1980, that aspartame's approval should be withheld until further experiments could be conducted.<sup>17</sup> After the board reached a decision, the Bureau of Foods urged the commissioner "to reverse the PEOI's decision and lift the stay of effectiveness of the aspartame regulation."<sup>18</sup> Searle provided scientific rebuttal to the concerns raised by the board. In July 1981 FDA Commissioner Arthur Hayes overruled the board and approved aspartame for use in dry foods. Hayes disagreed with the recommendation that further research was needed on aspartame's ability to cause brain tumors in rats. He concluded that the available data established "reasonable certainty of aspartame's safety for its proposed use."<sup>19</sup>

In the opinion of scientists who served on the PEOI its purpose also was to inform the public of the health concerns with aspartame. In practice the procedure served to reinforce the privacy of the aspartame debate. The board was charged with detaching itself from public controversy. The three members, all academic scientists, were specifically instructed



not to consider any cost/benefit issues in their evaluation of aspartame and to confine their investigation to scientific concerns.<sup>20</sup> In addition, the board conducted three days of hearings with little public participation. According to the record of the proceedings, testimony was presented primarily by Dr. Olney and representatives from the Bureau of Foods in FDA and Searle. The only other participants were James Turner, who made a brief presentation, Richard Wurtman, professor of nutrition and food science at MIT, and three physicians, two of whom were consultants to the PBOI.<sup>21</sup>

With the exception of a few trade journals, there was also virtually no media coverage given to the board's proceedings. Consequently, the PBOI provided only the illusion of informing the public. The dieters and diabetics who might have provided non-scientific support for a new sugar substitute were officially excluded from the aspartame proceedings because the PBOI was instructed to limit its evaluation to the scientific aspects of the dispute. Theoretically, if a consumer had been interested in participating, he would have been able to do so. Realistically, however, the likelihood was slight that an individual would assume the considerable costs of becoming informed about the complicated, highly technical aspartame controversy.<sup>22</sup>

The support of the Bureau of Foods was significant in aspartame's approval but other factors contributed to a

favorable decision. When Donald Rumsfeld came to Searle, Jimmy Carter was in office, the saccharin controversy was in full swing, and the FDA was headed by Donald Kennedy, widely perceived as pro-consumer. The political environment was not especially conducive for approval of a new artificial sweetener. The arrival of the Reagan administration in 1980 and the appointment of Hayes as FDA commissioner was greeted with enthusiasm by the food and drug industries which believed a more relaxed attitude toward government regulation would follow.

Hayes was inclined to take a different view toward sweeteners than his two predecessors who had been involved in the saccharin ban. Commissioners Jere Goyan and Donald Kennedy were opposed to saccharin partly because they believed its benefits were psychological and therefore less important. As a result Goyan and Kennedy argued against saccharin's continued use because of the evidence about its potential health risks. Hayes, however, held the view that the psychological benefits could be worth the risks.<sup>23</sup>

With saccharin's status still uncertain and with mounting evidence confirming it as an animal carcinogen, the FDA had considerable incentive to support approval of a new sweetener. The years of testing had convinced the agency of aspartame's safety. Moreover, aspartame would provide a substitute should saccharin be banned, potentially blunting consumer opposition.

In addition to the change in regulatory climate, it is

also likely that a Washington veteran like Donald Rumsfeld was able to negotiate the regulatory process more adeptly than his predecessors at Searle. Close observers of the aspartame controversy have suggested that Rumsfeld's solid Republican credentials and his close ties with Vice-President George Bush contributed to the 1981 approval. As likely was that Rumsfeld was long accustomed to political situations in which the desired outcome was threatened by opposing interests and that he was experienced in crisis management.<sup>24</sup>

The FDA required that Searle monitor aspartame's consumption by the American public, but the agency did not establish any levels of use that would trigger special review. There are currently two phases to the company's evaluation of aspartame consumption. First, Searle provides the FDA with quarterly reports of the tonnage of aspartame used in foods and the estimated use of aspartame by age group calculated from a survey of 5000 families. Second, when regular consumption reaches 30 percent of any age group under twelve, the company will measure how much aspartame is used in different products.<sup>25</sup>

#### Marketing a "natural" sugar substitute

When aspartame was launched Searle scrupulously avoided referring to it as an "artificial" sweetener in order to disassociate it from the negative health images of cyclamate and especially saccharin. In introducing aspartame to

consumers, the company followed a strategy that was fairly unusual in advertising campaigns, promoting an industrial product to a consumer audience.<sup>26</sup> Bulk aspartame, sold only to food and beverage companies, was given the brand name NutraSweet. The tabletop sweetener was given the name Equal and was sold directly to consumers. The two brands are managed by separate divisions in Searle, a NutraSweet group in marketing and an Equal group based in the consumer products division.<sup>27</sup>

Advertisements for NutraSweet ran on television and in popular magazines beginning in the spring of 1983. The ads listed the products that would be using the new sweetener, praised its true-to-sugar taste, and stressed that although consumers would be unable to purchase NutraSweet, they were going to love it. Making the rather circuitous claim that "since NutraSweet is a food ingredient, you can only find it in foods and beverages", Searle's promotion helped to create a demand for the products that would contain aspartame.<sup>28</sup>

NutraSweet was initially used in a number of dry products including drink mixes, gum, and cereals. General Foods was one of the first companies to introduce aspartame sweetened products. Sales from these foods were predicted to total between \$100 to \$200 million by the mid-1980s.<sup>29</sup>

Equal was packaged in the same type of serving envelopes used by Sweet 'n Low and Sugar Twin, the saccharin sweeteners. Cumberland Packing, manufacturer of Sweet 'n Low, predicted

that Equal's high cost, almost three times that of Sweet 'n Low, would deter consumers. But price has apparently not been a drawback. By the fall of 1983, a little over a year after it was introduced, Equal was reported to be the best-selling sugar substitute. Having surpassed Sweet 'n Low, the perennial leader, Equal held more than 50 percent of the \$150 million tabletop market.<sup>30</sup>

Searle contended that aspartame was so different from sugar or saccharin that its introduction required special "consumer education". The company's promotion described a "revolutionary new sweetener", never mentioning the word aspartame. Because aspartame is synthesized from two amino acids that are present in many food proteins, Searle claimed that it was a "natural" sweetener. The campaign emphasized that NutraSweet was a substitute not only for sugar but for "artificial" sweeteners, often mentioning saccharin by name. (See Figure V-A) A Searle brochure stated that "Unlike artificial sweeteners, NutraSweet has no bitter chemical or metallic aftertaste."

Through a public relations firm Searle arranged to introduce aspartame to the relevant trade groups and medical and health care professionals. The company also conducted media forums and sponsored fundraising activities for the diabetes associations. Advertisements for NutraSweet claimed that it was effective in weight control. They asserted that by eating fewer calories in aspartame sweetened foods consumers

FIGURE V-A



# “Goodbye saccharin, sugar and calories.”

----The Washington Post

**Introducing Equal. The revolutionary  
sweetener breakthrough.**

The news has been reported everywhere. In newspapers like the *Washington Post*. In national magazines. And on radio and TV. Today, Equal is in supermarkets and drugstores everywhere.

Equal is the first low-calorie sweetener with a true, sweet sugar taste—and no bitter aftertaste. Because Equal contains no saccharin. That's sweet news for anyone who ever used a sugar substitute.

Equal gets its sweetness from NutraSweet™, a breakthrough sweetening

discovery with ingredients like those found naturally in many foods.

One packet of Equal is as sweet as two teaspoons of sugar. Yet it has only 4 calories. The same amount of sugar has 8 times as many calories.

Equal convinced the national media. And it will convince you. With Equal there's no bitter saccharin aftertaste, just a sweet sugar taste.

Taste the difference now and save 30¢ on your first package.

©1982 Seale & Co. brand of sweetener

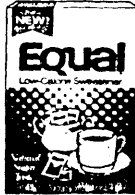
*Welcome to the Sweet Life  
of Equal!*

**SEARLE**  
Consumer Products Co.

**SWEET SAVINGS ON EQUAL  
30¢ OFF ON ANY SIZE**

STORE COUNTEIN

To the Retailer: Seale Consumer Products will reimburse you for the face value of this coupon pack. If the handling involved into and out of store have exceeded with the amount of this coupon offer, Seale's Shipping Suppliers Stock or other coupons presented may be shown on request and Seale will reimburse at our option and all coupons are subject to the sole discretion of this offer. Coupon and if redeemed in other than stated denominations, and in any case of such value when used for other than the stated purpose, Seale will not be liable to the consumer and redemption value is void. Max. amount: \$10.00. Expiration: 12/31/82. This Seale 1982 Terms of "The Sweet Life" offer ends on the date the retailer has redeemed this coupon pack. The Seale Consumer Products Company is not responsible for the loss of this coupon pack. This coupon pack is not redeemable in other countries and coupons are subject to local laws and where being offered. Retailer has not been the Party to be responsible without compliance with the above.



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could expect to reduce their caloric intake while satisfying a taste for sweetness. In this respect Searle's campaign followed the tradition established with the earliest cyclamate publicity that contended that sugar substitutes were an effective aid to dieters. The claim has never been supported with scientific data, but it continues to be an essential part of the advertising of artificial sweeteners in order to appeal to the millions of dieting consumers.

Aspartame's current high price relative to saccharin may be temporary. A study of the product life-cycle in grocery manufacturing noted the price of a product in its introductory stage will be higher initially because the output rates are relatively low, profit margins on sales tend to be relatively high, and technological problems in production are not fully mastered.<sup>31</sup> Part of aspartame's \$80 to \$90 per pound price can be attributed to the cost of product development and to the expense associated with securing approval from the FDA and similar regulatory agencies in other countries.<sup>32</sup> Increases in production and technological improvements are likely to be particularly salient in the future. Searle began construction of an aspartame plant expected to be in use by 1985. Other companies are exploring less expensive methods for synthesizing the amino acids used in aspartame's production.<sup>33</sup>

Sherwin-Williams and the manufacturers of saccharin sweetened foods suggested that aspartame's sales would actually increase their own sales because a new sweetener was

expected to expand the overall sweetener market and many products use a combination of saaccharin and aspartame. Their predictions proved accurate. Searle's marketing research has found that only half of the users of Equal were switching from Sweet 'n Low, the rest had changed from sugar. In one product survey Equal was estimated to have enlarged the artificial sweetener market by 27 percent.<sup>34</sup>

Although NutraSweet and Equal quickly proved to be popular with consumers, Searle still had considerable incentive to pursue soft drink approval for aspartame. The soft drink firms continued to be the biggest commercial buyers of artificial sweeteners. Searle had every reason to be optimistic that aspartame in soft drinks would be well received by consumers. The NutraSweet and Equal campaigns had stressed aspartame's good taste. The long standing disadvantage with saccharin had always been the aftertaste that prevented some consumers from accepting diet soft drinks.

In addition, sales of sugar sweetened drinks had grown slowly since the beginning of the 1980s. Diet drinks, already the fastest growing segment of the market, were expected to accelerate in sales during the rest of the decade. By 1983 diet drinks represented over \$4 billion of the \$25 billion a year American soft drink market. The consumers born after World War II are the most frequent users of artificially sweetened products. As they near middle age and become even more diet conscious, their consumption is expected to increase



further.<sup>35</sup>

The Canadian experience with aspartame in soft drinks set a promising example for Searle. Since the introduction of sodas flavored with 100 percent NutraSweet in 1981, diet drink sales have tripled in Canada and now constitute about 15 percent of the market there.<sup>36</sup> Shortly after receiving permission to sell aspartame in dry form, Searle applied for its use in soft drinks. The FDA granted the approval in the summer of 1983.<sup>37</sup>

Although the market appeared favorable, the difference in price between saccharin and aspartame proved to be more of a barrier to acceptance of NutraSweet by soft drink bottlers than it had been for food companies or consumers. The cost of sweetening 24 twelve ounce cans of soda with 100 percent aspartame was estimated at \$1.04. In comparison, sugar and saccharin would only cost 55 cents and 3 cents respectively.<sup>38</sup>

The reaction of the soft drink industry to aspartame's approval was markedly restrained. With the exception of 7UP, the major companies initially expressed reservations. In the week following the FDA's approval, Coca-Cola and Dr. Pepper announced that they were uncertain about their plans to use the sweetener; Pepsi voiced concerns about aspartame's relatively short shelf-life.<sup>39</sup>

The firms, especially Coca-Cola, made a great deal publicly out of their hesitation, attributing it to their worry about the health effects of aspartame. In an

interesting twist of reasoning, the soft drink industry attempted to present itself as the voice of caution regarding the use of aspartame and the FDA as acting intemperately. A representative from one of the major cola companies in an apparent reference to cyclamate and saccharin warned the FDA, "Make sure you know what you're doing before you saddle us with this one." The National Soft Drink Association appealed to the FDA to delay approval of aspartame in soft drinks until the stability difficulties were resolved.<sup>40</sup>

The fear that aspartame might prove to be a health threat was probably not the complete reason for the lukewarm embrace by the soft drink companies. Some accounts of the MSDA appeal to delay aspartame's approval indicated that it was undertaken on behalf of Coca-Cola and Pepsi in order to allow the the two companies to continue their negotiations for more favorable terms with Searle for purchasing aspartame. In addition, shortly before aspartame was approved, both firms had invested heavily in promoting caffeine-free versions of their leading cola brands. A FDA delay on aspartame would have enabled them to better absorb these expenditures before launching the new NutraSweet flavored brands.<sup>41</sup>

The approval drew objections from other sources as well. Dr. Richard Wurtman, the MIT professor who had presented testimony at the board of inquiry hearings, expressed reservations about the use of aspartame in combination with carbohydrates. Wurtman's concerns focused on behavior changes

that might occur if large amounts of aspartame were ingested, as with the unrestricted use of diet soft drinks.<sup>42</sup>

The Center for Science in the Public Interest also urged the FDA to "proceed cautiously" in view of Wurtman's findings. The involvement of the consumer advocacy organization apparently was prompted by a public relations firm representing Sherwin-Williams. The head of the firm had forwarded Wurtman's reservations to CSPI and to various journalists because of concerns that saccharin sales would be hurt if new problems developed with diet soft drinks.<sup>43</sup>

Despite their public hesitation, less than a month after the FDA granted beverage permission, Coca-Cola signed an agreement with Searle to become the first soft drink company to use aspartame. The new formulation was based on an aspartame-saccharin combination. Although Coca-Cola refused to indicate the amounts of each sweetener, it has been estimated that aspartame replaces about 25 percent of the saccharin in Diet Coke. If Coca-Cola used 100 percent aspartame, bottlers would pay \$4.58 a gallon for the syrup concentrate. The aspartame would cost Coca-Cola \$2.67, and the company's profit would be \$1.66 on each gallon. However, using the considerably cheaper saccharin in combination with aspartame, Coca-Cola's profit would be about \$2.32.<sup>44</sup>

The public interest movement and artificial sweeteners

Consumer advocacy organizations and their representatives were involved in each artificial sweetener controversy, but their participation was a central feature of the aspartame dispute. Even though aspartame was eventually approved, the objections of Olney and Turner forced a careful examination of what was considered the "pivotal" research on the sweetener's safety.<sup>45</sup> Aspartame's first approval in 1974 had followed only a 15 month period in which the agency ostensibly reviewed the "voluminous amounts of data" submitted in Searle's petition.<sup>46</sup>

The board of inquiry, convened only as a result of Olney and Turner's objections, concentrated attention on the several key points that were under dispute. Although the board was overruled, the reservations of the three scientists about aspartame's safety became part of the public record. Ironically, because of Olney and Turner, the FDA and Searle were able to make the claim that aspartame was one of the most thoroughly tested substances in the food supply.<sup>47</sup>

Consumer advocates are frequently criticized for being opportunistic and short-sighted.<sup>48</sup> Yet those prominently involved with artificial sweeteners have been recommending restrictions on their use since the cyclamate ban. For example, James Turner's interest in food additives and the FDA began with his association with Ralph Nader during the 1960s. John Olney's research on the effects of additives on the brain also dates from prior to the cyclamate ban.

The aspartame case provides some insight into the relative weight of participants in the regulatory process. Although their involvement may occasionally be influential, as happened with aspartame, the effectiveness of consumer advocates is often limited to temporary disruptions of a product's marketing. The resources of the public interest organization are no match for those of industry. The lack of finances has not always been a major handicap when the political environment has been sympathetic to consumer concerns, but the public interest organization is much more dependent upon the political mood in the country for its successes than is business. As Michael Pertshuk has pointed out, "for consumer entrepreneurial politics to succeed in the 1960s, consumer goals had to harmonize with public attitudes and the political environment."<sup>49</sup> An unsympathetic or indifferent public can undermine the impact of the consumer advocate.

According to Pertshuk, underlying the popularity of deregulation efforts in the 1980s and the waning of the consumer movement is the endurance of the favored position business occupies in the United States.<sup>50</sup> Beginning in the 1970s, industry mobilized in response to the attacks from consumer advocates, sponsoring scientific studies to counter harmful claims, mounting public relations campaigns, and organizing into political action committees. In the area of food safety, the impact of the consumer advocate has been

curtailed by aggressive business activities that have preempted some of the debate.

Industry sponsored organizations such as the American Council on Science and Health (ACSH) and the International Life Sciences Institute (ILSI) have promoted science favorable to the food industry's views. These groups have actively sought publicity for their opinions often in the popular media and through their own publications. ILSI, for example, has sponsored scientific conferences to examine the data on sodium and caffeine.<sup>51</sup> Prominent scientists are frequent participants in forums held by ACSH and ILSI. They also participate in the organizations as members of the board or through involvement on various committees. Dr. Richard Wurtman, for example, is a trustee on the ILSI board.

### Conclusion

The health problems associated with cyclamate and saccharin helped drive a search for alternative sweeteners. After saccharin became the only noncaloric sweetener available in the United States, there was some indication that growth in the diet segment of soft drink sales would be even stronger if a better tasting sweetener was available. This analysis has apparently been correct as the overall market for low calorie sweeteners has expanded since aspartame was introduced in

1981.<sup>52</sup>

The cyclamate and saccharin cases illustrated the difficulties associated with restricting consumer products that have been in wide use for many years. The conflict over the safety of cyclamate and saccharin occurred at a different point in the policy process than did the debate about aspartame's safety. The older sweeteners had been approved by the FDA for expanded uses long after both were available in the food supply. When the FDA banned cyclamate and later attempted to restrict saccharin, the agency received considerable attention from a variety of interest groups and the public.

By contrast, aspartame was a new product and the objections about its safety occurred before it reached the market. The FDA's decisions to delay approval received little public or interest group scrutiny. The challenges from John Olney and James Turner were channeled through the regulatory process and not debated in a larger forum. As the saccharin case demonstrated, controlling the scope of a conflict can be influential in determining the outcome. The use of the public board of inquiry helped to maintain the privacy of the aspartame debate, confining it to scientific grounds.

Consumer interest in an additive before it is on the market is usually inconsequential. In the aspartame case, however, there was a latent demand for a better tasting sweetener that Searle might have exploited in an effort to

accelerate the regulatory process. For example, the company could have conducted taste tests for consumers and food reporters, enlisted the aid of the diabetes associations, or worked with the Calorie Control Council to drum up interest in aspartame. Sufficiently mobilized, these interest groups might have pressured the FDA for a quicker and favorable ruling. Despite the extended length of the regulatory process, Searle made no attempt to enlarge the conflict by attracting other groups.

There were marketing disadvantages to enlisting the public's help. When aspartame was launched, because of the lack of publicity, there was little indication that the sweetener had been the subject of any health concerns. Most coverage of aspartame's introduction mentioned that the sweetener could adversely affect persons with phenylketonuria and pointed out that a cautionary label was required. The stories generally failed to mention, however, the more serious concern, that aspartame was alleged to cause brain tumors.<sup>53</sup>

There was also little incentive for Searle to make an effort to enlist public participation during the regulatory process because drawing attention to aspartame might have generated interest group opposition to its approval. James Q. Wilson has used the term "interest-group politics" to characterize a situation in which a policy proposal benefits a relatively small group at the expense of another.<sup>54</sup> Because both the costs and the benefits are narrowly concentrated in



such a situation, the groups have incentive to organize in support or opposition to the policy. A major campaign to acquaint consumers with aspartame might have caused the sugar industry to work vigorously against the approval. As recently as 1983 the British government quietly approved the use of three new sugar substitutes, hoping to avoid provoking the sugar lobby in that country.<sup>55</sup>

In the United States the sugar industry was preoccupied with sagging sales. The periodic health controversies over sugar substitutes have temporarily helped sugar's prices, but the benefit was short-lived.<sup>56</sup> Artificial sweeteners were not perceived to be a direct cause of the decline even though ever since cyclamate their competition has been unwelcome.<sup>57</sup> The competition from corn sweeteners and the gradual decline in the consumption of cane and beet sugar that have severely affected the sugar industry have accelerated in recent years.<sup>58</sup> Industrial sugar users have increasingly turned to corn sweeteners as their cost has become cheaper and less volatile than sugar's. As a result, the use of corn sweeteners has grown about 30 percent per year for the past ten years. A major setback for the sugar industry occurred when the large soft drink companies announced plans to use 50-75 percent formulations of high fructose corn syrup to replace the sugar in their beverages. While corn sweeteners now hold a 38 percent share of the total sweetener market in the United States, that share is expected to increase to 50

percent by 1985.<sup>59</sup>

The sugar industry has also been increasingly preoccupied with defending sugar's safety as a food. In the last decade consumer advocacy groups have targeted sugar as a serious health problem. In a survey conducted in October 1978, 28 percent of those polled considered sugar a very serious health threat. Fifty percent rated it as a somewhat serious threat. In contrast, only half as many, 14 percent, gave saccharin a very serious rating, with 42 percent rating the artificial sweetener as a somewhat serious threat.<sup>60</sup>

The aspartame experience underscores a dilemma that has been at the heart of each artificial sweetener controversy. There is no fixed concept of the public interest. In the absence of an absolute safety standard, the acceptability of a food substance can be determined by political factors if sufficient motivation exists for interest group involvement. In each artificial sweetener case the prevailing view of what was best for the public was shaped by participants in the regulatory process. With aspartame there was no urgency to introduce another sweetener because saccharin was still available. The objections raised by Olney and Turner, based on compelling but not incontrovertible scientific arguments, were taken seriously by the FDA which had reason to be cautious based on its unhappy experiences with previous sugar substitutes.

In each case, the public interest became an element of

the regulatory process to be "captured" by the various groups involved. Olney and Turner's most serious objection was still considered sufficiently compelling for the PBOI to recommend that approval be delayed. But their view of what was best for the public proved less influential than the belief by the FDA commissioner that the benefits of a new sweetener outweighed the uncertain evidence of potential harm.

NOTES: Chapter V

<sup>1</sup> After aspartame was approved for soft drink use, a variety of groups charged that it was proving to be a health hazard. In Arizona, the Department of Health Services raised the concern that aspartame may deteriorate into toxic levels of methyl alcohol under certain storage conditions. See Gary Putka, "Searle Sweetener Life is Under Study", Wall Street Journal, 13 January 1984, p.3. These concerns and additional anecdotal accounts of problems with aspartame were also covered on a three part series on the CBS Evening News in January 1984. The Center for Science in the Public Interest charged that advertisements for aspartame-sweetened soft drinks deliberately misled the public. The consumer group called the promotion confusing because only obscure mention was made of the fact that saccharin was still present in the diet drinks. See "Aspartame Poses No Health Threat - FDA", American Medical News (3 February 1984), p. 20.

<sup>2</sup> "Alternative Sweeteners: What's Available and Under Development", Grocery Products, 3 April 1982, p. 8.

<sup>3</sup> Calorie Control Council, "Background: 'Multiple Sweetener' Concept", 13 April 1983.

<sup>4</sup> "Artificial Sweeteners", The Economist, 13 August 1983, p. 61.

<sup>5</sup> Gene Bylinsky, "The Battle for America's Sweet Tooth", Fortune, 26 July 1982, p. 30; Thomas C. Hayes, "Searle's Enriching Sweetener", New York Times, 17 July 1981, p. D1; The Economist, 13 August 1983, p. 62.

<sup>6</sup> A patent on aspartame as an ingredient in livestock feed was granted in October 1982 although no commercial use had been developed. See New York Times, 23 October 1982. According to Searle its patent covers the existing uses of aspartame.

<sup>7</sup> Leslie Wayne, "Searle's Push into Sweeteners", New York Times, 24 October 1982.

<sup>8</sup> "G.D. Searle: A Transfusion of Funds to Revive its Drug Business", Business Week, 4 July 1983, p.87.

<sup>9</sup> "Searle Appoints Head of Its Sweetener Group", New York Times, 19 November 1982, p. D2.

<sup>10</sup> Interview; Thomas Chesser, "It Was Tough Medicine, but G.D. Searle Breathes Easier Now", New York Times, 31 January

1982; "Searle: Rallying a Drug Company with an Injection of New Vitality", Business Week, 8 February 1982, p.98.

11 Mark Potts, "The Emerging Battle for America's Sweet Tooth," Washington Post, 7 September 1982.

12 Business Week, 8 February 1982, pp. 988-99.

13 Chemical Marketing Reporter, 21 January 1980, p. 7.

14 "Aspartame: Summary of Commissioner's Decision," Food and Drug Administration, Department of Health and Human Services, 15 July 1981; Interviews.

15 "Aspartame; Commissioner's Final Decision," Federal Register, 24 July 1981, p. 38286; correspondence from Richard A. Merrill, Chief Counsel, FDA, to Mr. Robert H. Becker, Kleinfeld, Kaplan and Becker (17 October 1975).

16 "Aspartame: Decision of the Public Board of Inquiry" (Department of Health and Human Services: Food and Drug Administration, Docket 75F-0355, p.5).

17 Ibid., p. 49.

18 Bureau of Foods, "Exceptions to the Decision of the Public Board of Inquiry", (Docket 75F-03550).

19 "Aspartame Finally Gets FDA Okay," Chemical Marketing Reporter 20 July 1981, p.26; "Aspartame: Summary of Commissioner's Decision", 15 July 1981.

20 Interviews.

21 Federal Register, 24 July 1981, p. 38286.

22 See Randall Bartlett, Economic Foundations of Political Power (New York: The Free Press, 1973), chapter 2.

23 R. Jeffrey Smith, "Aspartame Approved Despite Risks," Science, p. 987.

24 Interviews; Chesser.

25 Interview.

26 "Adbeat", Advertising Age, 21 March 1983, p. 47; Kenneth Wylie, "Aspartame: How Sweet It May Be", Advertising Age, 9 May 1983.

27 Interview.

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30 Pamela G. Hollie, "Aspartame Builds a Market", New York Times (3 September 1983), p. 30.

31 Gary A. Marple and Harry B. Wissmann, Grocery Manufacturing in the United States (New York: Praeger, 1968), p. 42.

32 "Widespread Use of Aspartame Stymied by its High Cost," Chemical and Engineering News, 13 June 1983, p.8.

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36 Leslie Wayne, "Searle's Push into Sweeteners", New York Times, 24 October 1982; "FDA Approves Aspartame for Use in Carbonated Beverages", Food Processing, August 1983, p.11.

37 "FDA Approves Aspartame Use in Soft Drinks", Advertising Age, 4 July 1983, p. 1.

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40 Nancy Giges and Robert Reed, "Delay Sought on Aspartame," Advertising Age.

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42 Boston Globe, 22 June 1983.

43 Michael L. Millenson, "The Bittersweet Mystery behind Aspartame," Chicago Tribune, 26 June 1983, section 6, p. 3.

- 44 Hollie, p. 30.
- 45 Federal Register, 24 July 1981, p. 38286.
- 47 Ibid., p. 38265.
- 47 Potts; Beverage Industry, 2 October 1981, pp. 6, 8.
- 48 See for example Harold D. Guither, The Food Lobbyists, (Lexington: Lexington Books, 1980) and Ralph K. Winter, The Consumer Advocate versus the Consumer (Washington, D.C.: American Enterprise Institute, 1972).
- 49 Michael Pertschuck, Revolt Against Regulation (Berkeley: University of California Press, 1982), p. 13.
- 50 Ibid.; See Charles E. Lindblom, Politics and Markets (New York: Basic Books, 1977).
- 51 Interviews.
- 52 Beverage World (January 1983), p. 34.
- 53 See for example, Gene Bylinsky, "The Battle for America's Sweet Tooth," Fortune, 26 July 1982, pp. 28-32; Karen DeWitt, "New Sweetener is Approved; to be on Market Next Year," New York Times, 16 July 1981, p. A16; Mark Potts, "The Emerging Battle for America's Sweet Tooth," Washington Post, 7 September 1982; Kim Upton, "Way Cleared for New Sweeteners," Los Angeles Times, 10 December 1981. A few accounts did mention that research linking aspartame ingestion to brain tumors had been a reason for the approved delay. See for example, Michael L. Millenson, "The Bittersweet Mystery Behind Aspartame," Chicago Tribune, 26 June 1983, section 6, pp. 1 and 3; Jane E. Brody, "Judging Safety of Aspartame in Soft Drinks," New York Times, 13 July 1983, pp. C1 and C10.
- 54 James Q. Wilson, The Politics of Regulation (New York: Basic Books, 1980), p. 368.
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- 57 Kevin J. Hannigan, "The Sweetener Report: 1982-1987," Food Engineering (July 1982); Interviews.

58 Keith B. Anderson, et al., Federal Trade Commission Staff Economic Report, The U.S. Sugar Industry (Washington, D.C., 1975).

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## CHAPTER VI

## INTENT AND OUTCOME: THE SHAPING OF REGULATORY POLICY

Various theories exist to explain why regulatory policy evolves as it does. Some political scientists explain the disjuncture between intent and outcome as the result of the "capture" of the federal agency by the regulated industry. The regulatory agency acts almost as a manager of the industry because of the comfortable arrangement developed over a long period of association.<sup>1</sup> Or the industry, the agency, and the relevant congressional committee provide mutual benefits through a cooperative relationship.<sup>2</sup>

For other theorists unintended outcomes often result from the bargaining among interest groups and are a healthy sign in democratic societies.<sup>3</sup> A more recent analysis finds that the array of costs and benefits associated with a proposed policy will indicate the intensity of the dispute and will provide a reasonably accurate prediction of who will benefit.<sup>4</sup> The "original intent" model argues that regulation benefits industry because it was designed specifically to do so.<sup>5</sup> Or because business has more resources to pay attention to the development of regulation, its influence on the outcome will

be especially significant.<sup>6</sup>

This study of the regulation of artificial sweeteners has focused on the actions of the participants involved to explain the policy outcomes. The strategies developed by the government and by the companies to fulfill their own organizational goals were especially significant. For the FDA these goals were to ensure the safety of any sweetener on the market and enhance its own reputation as a scientific organization and as the guardian of the nation's health. For the manufacturers the goal was to ensure the marketing of their sweeteners free from health challenges and the threat of government restrictions.

#### The law, science, and artificial sweeteners

The Food, Drug, and Cosmetic Act of 1958 furnished the legal framework for the FDA's actions in each case. The law's specifications regarding safe additives did not change from cyclamate to aspartame, but the FDA's interpretation of what constituted "reasonable" proof of safety did. In its cyclamate decision, the FDA cited the general safety requirements of the Act. The burden of proof was on the manufacturer to demonstrate that cyclamate use would not be harmful. The agency ruled that "cyclamate has not been shown not to cause cancer" and "it has not been shown not to cause heritable genetic damage."<sup>7</sup>

When aspartame was approved in 1981, however, the FDA

again based its decision on the general safety requirements, but gave its manufacturer greater discretion in proving safety. With aspartame safe was defined as "a reasonable certainty in the minds of competent scientists that the food additive will not be harmful under its proposed uses." The FDA ruled that the manufacturer had met the burden of proof.<sup>8</sup> The aspartame regulation was particularly interesting given that the "competent scientists" chosen by the FDA to review aspartame had recommended its delay rather than its approval.

Even when the scientific evidence was solid, as with saccharin, the law had minor impact on the eventual status of the sweetener. Although the question of cancer had been raised in all three cases, the Delaney clause, a subsection of the 1958 Act specifically prohibiting carcinogens, was only invoked by the FDA with saccharin. Instead of providing support for the FDA's decision, the clause became a red herring in the debate that ensued. Publicity that questioned the usefulness of the clause as a realistic guideline helped to obscure the issue of whether saccharin was a safe food additive. When Congress decided to suspend the saccharin ban, the Delaney clause was rendered ineffectual.

The impact of the science was also diminished at least twice with artificial sweeteners by the predisposition of the FDA stemming from past decisions. Because the agency was on record in support of a particular position, additional scientific evidence was not persuasive in changing the FDA's

attitudes toward cyclamate or aspartame. After the FDA banned cyclamate, the additional data submitted by the manufacturer, in the absence of other pressures, was unsuccessful at inducing a reversal of the decision. By contrast, aspartame had initially been approved by the agency, and the Bureau of Foods maintained its support of the sweetener over the years the case was under review. When favorable data was submitted after the board of inquiry recommended that aspartame's marketing be delayed, the additional information was used to overrule the board.

If the FDA's decisions have not ended the disputes over artificial sweeteners, they have helped to shape the parameters of subsequent scientific debate. The continuing arguments over cyclamate's safety have focused on the issues raised by the agency during the ban. Saccharin studies have been directed principally at an examination of the sweetener as a cause of bladder cancer, the major health issue addressed by the FDA. Much of the debate about aspartame since it has been on the market has been about possible ill effects caused by the sweetener's degeneration in the soft drink solution, the central issue raised during the approval process for aspartame's use in liquids.

Protecting the public's health: government strategies

Because the law and the science were deficient as policy

guidelines, the FDA was subject to considerable pressure from groups on both sides of the artificial sweetener debates. In addition, as a result of the public's commitment to diet soft drinks and other sugarless foods interest in an artificial sweetener was intense. Of the thousands of food additives on the market, only a few have generated public attention; the regulation of most is of concern only to the manufacturer and to the food industry.

The regulatory history of each sweetener reveals that protection of the public's health was an important factor in the FDA's decision-making. When cyclamate was banned the public was intensely concerned about carcinogens in the food supply. Although the ban was prompted in part by agitation from the sugar industry and from consumer advocates, the FDA was very much aware of the widespread fear of cancer. FDA officials have generally placed great emphasis on the agency's reputation as the guardian of the nation's health. This ethos was at work during the cyclamate decision. The agency moved hastily with cyclamate in order to avoid potential criticism that it was neglectful in protecting the public.

The FDA's concern for the health of the public was most apparent with saccharin. The FDA proceeded more cautiously than it had with cyclamate and the scientific findings on which the agency based its proposed ban were far more conclusive than they had been in the earlier ban. Unfortunately for the agency, the saccharin decision was not

judged on scientific grounds but instead on the wisdom of removing the only artificial sweetener still available. Rather than being perceived as acting in the public interest, the FDA's action was viewed as ill-conceived and largely unnecessary. Although saccharin was almost certainly a carcinogen, the lack of a substitute overrode the health concerns.

When aspartame was under consideration, saccharin reduced the urgency for the FDA to approve a new sugar substitute. Because the debate over the saccharin decision had been so intense, the FDA had reason to exercise caution in responding to the concerns about aspartame. With saccharin still in use, the agency could investigate the charges without pressure from the public or from the diet industry, except aspartame's manufacturer, G.D. Searle.

The FDA's commitment to aspartame has never wavered, at least publicly, despite the issues raised about its safety during the approval process and after the sweetener was marketed in soft drinks. As with cyclamate, there is little incentive for the FDA now to acknowledge any misjudgment especially because the evidence against aspartame is controversial. In addition, the status of saccharin is unresolved. The repeated extension of the saccharin moratorium is an unwieldy device that has failed to bring further clarity to the problem. Subsequent research, even that sponsored by the diet industry, has tended to corroborate

the finding that saccharin is a carcinogen, vindicating the FDA. Having aspartame remain unchallenged on the market may mean that the FDA will finally be able to enforce the saccharin ban it proposed years ago.

Influencing regulation: corporate strategies

Without the transformation in their marketing that occurred after World War II, it is doubtful that artificial sweeteners would have emerged as major regulatory issues. Before the war saccharin was consumed principally by diabetics. During the 1950s, however, millions of Americans, newly conscious of their weight, began to use sugar substitutes on a regular basis, in part because of the introduction of the better tasting cyclamate. But in the main the change in consumption patterns occurred because the purpose of low calorie foods was redefined. Cyclamate's manufacturer, Abbott Laboratories, and other companies sponsored advertisements that appealed to dieters, contending that their products were effective for losing weight. These early campaigns permanently dispelled the images that associated artificial sweeteners with illness, and instead linked them with slimness and beauty, themes that would be echoed in all future marketing efforts.

Cyclamate's popularity drew the attention of the sugar industry with consequences for the regulatory process. Through a trade group, the Sugar Association, the industry

attempted to discredit cyclamate. In widely distributed advertisements the Association questioned cyclamate's efficacy as a weight reducing aid, unfavorably contrasted it with sugar as a source of energy, and cast doubt on its safety as a food additive. The strategy apparently inflicted little damage to cyclamate's sales; consumption, especially in soft drinks, increased steadily until the ban in 1969. The advertisements, however, acquainted the public with concerns that previously were of interest only to scientists and the FDA. The Sugar Association also sponsored research on cyclamate's allegedly ill effects that, coupled with its publicity campaign, increased the pressure on the FDA to take action on cyclamate.

Food companies sometimes use quality standards established by the government in advertising their products. Similarly, the manufacturers of competitive sweeteners and the soft drink companies attempted to exploit adverse regulatory decisions for their marketing value. In 1969 diet soft drinks were labeled "cyclamate-free." More recently, products containing aspartame were promoted as "saccharin-free" and "natural" to distinguish them from the health problems attributed to artificial sweeteners.

One apparent lesson from Abbott's failure to reverse the FDA decision was that it demonstrated to the manufacturer of saccharin the vulnerability of a defense that rested on a narrow definition of the issue. Rather than fighting the proposed saccharin ban through the FDA appeal process,



Sherwin-Williams attempted to have the decision repealed by expanding the issues under debate to attract the support of as wide an audience as possible. With the cooperation of the soft drink industry, the bottlers were organized through the National Soft Drink Association, and the diabetes associations recruited their members. The public was mobilized through the Calorie Control Council. The appeals to halt the ban were made directly to Congress, bypassing the FDA.

The Calorie Control Council sponsored advertisements that summarized complicated scientific data in several phrases in daily newspapers across the country. In addition to providing selective information and lowering the cost of obtaining it, the publicity campaign demonstrated the efficacy of using political symbols that are deeply meaningful in the American culture. The Council portrayed the saccharin ban as an example of government intrusion into a private decision and an infringement of personal freedom.

In contrast to the issue expansion approach taken by Sherwin-Williams with saccharin, Searle's response to the aspartame challenge was to contain the conflict. Searle did not attempt to draw the public's attention to the FDA's tardiness in allowing another artificial sweetener on the market. Instead, the company pursued aspartame's approval quietly, sponsoring additional research on the points of contention about the sweetener's safety. The health questions raised by the public interest advocates were addressed in the

regulatory process, not aired where they might linger to mar the public's response to the new sweetener.

Aspartame has been sold under two different names, Equal, the tabletop product for consumers, and NutraSweet, in bulk form for industrial users. The division may have implications for future regulatoru decisions. One lesson demonstrated by the cyclamate and saccharin experiences was that the tabletop and soft drink markets could be segmented into separately defensible units. The FDA initially allowed cyclamate's continued use as an over-the-counter drug, and later was willing to consider proposals to permit saccharin in similar form. Much of the debate over aspartame has developed over its use in soft drinks. Should the controversy result in regulatory action, it is is likely that the manufacturer, Searle, would at least be able to protect the tabletop market because the amounts of aspartame consumed are substantially less than in soft drinks. The different names might also make it possible for Searle to disassociate Equal from any health hazards attributed to NutraSweet.

Sherwin-Williams and Searle undoubtedly benefited from artificial sweetener controversies that preceded their own experiences. A major factor in an organization's survival or decline is the process of organizational learning. Miles has defined organizational learning as: "effective adaptation to the new circumstances that require the acquisition or creation of knowledge about cause and effect, about relative strengths

and weaknesses and about the feasibility and viability of options for adaptation."<sup>9</sup> There is insufficient information to conclude that the responses of Sherwin-Williams and Searle to the challenges to their particular sweeteners are examples of organizational learning. Whether the companies actually "adapted", that is, permanently incorporated in their corporate culture their responses to the artificial sweetener crises, is beyond the scope of this study. Both certainly benefited from previous example and appeared, in devising their own strategies, to have avoided the mistakes of their predecessor(s).

Saccharin and aspartame could be unique situations in the companies' histories. Sherwin-Williams usually faces challenges of kinds other than the alleged health threat of a food additive. The company's problems are more likely to involve foreign competition in chemicals or inroads from domestic rivals into retail paint sales.<sup>10</sup> Although the quality of Searle's research has been questioned in the past, challenges to the safety of a substance are also not a typical problem. More often, the company has been concerned with competition for market share with its pharmaceutical products or the lack of breakthroughs in its research efforts.

Nevertheless, there is an indication that lessons from the artificial sweetener cases and other controversies have been beneficial to the food industry. Until 1969 food and beverage firms relied on the manufacturers of an additive to

ensure its safety.<sup>11</sup> The cyclamate and saccharin bans demonstrated the potential vulnerability of all companies to scientific controversy. Since cyclamate there has been increased emphasis in the industry on safety testing, often through joint research efforts designed to anticipate problems. The companies have also demonstrated greater political acumen, establishing corporate affairs departments, working with consumer groups, and paying closer attention to media coverage.<sup>12</sup>

The competitive advertising practices adopted by various firms helped maintain the public visibility of the artificial sweeteners issues, which at least in the case of cyclamate, contributed to regulatory action. All the manufacturers supplied alternative scientific explanations for negative findings about each sweetener. When those explanations gained credibility, as occurred with saccharin and aspartame, they helped ensure the sweetener's use.

#### The beneficiaries of artificial sweeteners policy

The intent of artificial sweetener regulation, as defined by the FDA's mandate, was to protect the public from a health hazard. Competitive marketing practices, subjective interpretations of the science, and the availability of a substitute were key factors shaping artificial sweeteners policy. But they are also useful in assessing whether there is

a lack of fit between intent and regulatory outcome when the three cases are considered together.

The artificial sweetener cases suggest that the decisions made by the Food and Drug Administration did not protect the interests of the manufacturers. Instead, the regulatory outcome was often troublesome, if not detrimental, for Abbott, Sherwin-Williams, and Searle. Cyclamate remains banned; saccharin is still in use only because Congress overruled the FDA in 1977; and although aspartame is approved for all food uses, the FDA took seven years to grant the initial marketing permission. The manufacturers could not control the source or the timing of challenges to their products. A threat to a substance's marketing can occur at any time, and as the history of all three sweeteners reveals, even well after it is an established part of the food supply.

In addition to having no control over the factors that placed their products on the government's agenda, it would appear that the manufacturers of cyclamate, saccharin, and aspartame had no influence over the FDA's response to the challenges. Cyclamate had been under review for months, but the FDA decided virtually over a weekend to ban the sweetener. The decision to remove saccharin from the market, although again it had been under study for even longer than cyclamate, actually took place almost overnight. The FDA responded almost immediately to the charges against aspartame by rescinding its earlier marketing approval.

The principal beneficiary of artificial sweeteners regulation has probably been the soft drink companies. Since sugarfree sodas were introduced in the mid-fifties, diet soft drink growth has averaged eight percent annually.<sup>13</sup> The "baby-boom generation", the major consumers of diet drinks, are expected to provide the basis for continued growth. Soft drink analysts project that as these consumers age, they will become increasingly diet conscious.<sup>14</sup>

If the regulatory policy in each case did not immediately favor the interests of Coca-Cola, Pepsi, 7UP, and other producers of sugarless drinks, the policy that evolved did. At no point in the history of cyclamate, saccharin, or aspartame were the soft drink firms left without an artificial sweetener. When cyclamate was banned, Coca-Cola and Pepsi had reformulated versions of their diet brands available within two weeks. When aspartame was approved for soft drink use, most of the major companies were ready with aspartame-sweetened formulas. The most serious threat, the saccharin ban, was rapidly neutralized.

When helpful to their own interests, the soft drink companies supported the efforts of the artificial sweetener manufacturers to protect cyclamate, saccharin, or aspartame. When it was not beneficial for the preservation of their diet markets, the soft drink companies disassociated themselves from the controversy. From cyclamate to aspartame, the soft drink firms became increasingly sophisticated about shielding

their own investment in artificial sweeteners without becoming bogged down in the disputes over a particular sugar substitute. Coca-Cola, Pepsi, and the others maintained a very low public profile, using their trade associations to protest the FDA's decisions and never appearing on the front lines of the battles. Instead, they distanced themselves from the regulatory procedures that surrounded each sweetener, leaving those to the manufacturer.

It is debatable whether the public's health has been protected in the artificial sweetener cases, although this is the intent of food additive regulation. By neglecting to consider the implications of a cyclamate ban for future artificial sweetener use, the agency contributed to the impotency of its saccharin decision seven years later. One conclusion that can certainly be drawn from the scientific literature is that, between cyclamate and saccharin, cyclamate poses the least health hazard, yet saccharin continues in widespread use.

From the Canadian experience, it is also apparent that regulations that would have restricted the sale of artificial sweeteners to tabletop form or as over-the-counter drugs, were alternatives that might have protected children or the uninformed public while preserving the access to saccharin of diabetics or those knowledgeable about the risk. Whether or not these approaches were optimal depends on one's

interpretation of the extent of the hazard posed by saccharin consumption. Clearly, any option that would have drastically limited the forms of artificial sweetener consumption were viewed as unacceptable by the soft drink companies whose sugarless markets would have been eliminated.

For those in the public who believe, incorrectly but adamantly, that artificial sweeteners are effective in weight reduction, the regulatory outcome has been to their benefit. The concerns of diabetics who viewed artificial sweeteners as a lifestyle issue, were respected. But for the millions of consumers, including many from the two groups above, who are unaware of possible adverse health effects, it is arguable whether the regulation of artificial sweeteners has served to protect their interests.

#### Further implications

The manufacturers of cyclamate, saccharin, and aspartame adopted marketing scientific, and political strategies to protect their products, often having a decisive effect on the regulatory outcomes. This aspect of the artificial sweeteners controversy has parallels in other cases of threatened consumer products.

The adaptation of the tobacco industry to nearly unanimous agreement about the hazards of cigarette smoking is an obvious example. The tobacco companies have protected their economic health through diversification strategies.



They have blunted the damage of adverse publicity by agreeing to warning labels on cigarette packages and to the removal of cigarette advertising from television. The warning labels offer important protection against lawsuits should a claimant argue that cigarette smoking caused his lung cancer or emphysema. Once the advertisements for cigarettes ceased to run on television, so did many of the public service announcements that warned against smoking and that were affecting sales.<sup>15</sup>

The consumption of foods with a high sodium content or with a high level of saturated fats has been linked to hypertension and heart disease respectively. The publicity about these issues and the heightened concern by government prompted the producers of these foods to develop alternative products. Low-fat milk, polyunsaturated vegetable oils, and margarine were vigorously advertised as healthful alternatives to certain long-standing staples of the American diet. Low-sodium versions of many foods and beverages are also now widely available and routinely advertised as beneficial. The development of substitutes in these cases also served to mitigate the pressure on government to act in response to negative evidence.<sup>16</sup>

These cases also illustrate that although science may not have a major impact on the regulatory outcome, it can be highly influential in producer behavior. Unlike artificial sweeteners they demonstrate that negative science can also

affect consumer behavior. Although cigarette sales have increased since the Surgeon General warned in 1964 that smoking was dangerous, the portion of the adult population who smokes has declined. Consumers have also changed their eating habits in response to the attention given to the links between serious disease and the consumption of foods with high sodium or saturated fat content.

Nor is science always incidental to the regulatory outcome. Although Proctor and Gamble voluntarily recalled its Rely tampon during the toxic shock scare of 1980, it did so under threat of a mandatory federal recall. It was in light of this possibility that the company accepted the FDA's suggestion to undertake a recall of Rely. Proctor and Gamble conducted the largest publicity campaign ever to retrieve Rely from store shelves and to refund consumers.<sup>17</sup>

The artificial sweetener cases reveal several important constraints on what government can actually accomplish in the area of consumer protection, regardless of regulatory intent. First, as the current availability of saccharin attests, there are limits set by the public. When a substitute is unavailable for a popular, but unsafe product, the government probably will find it virtually impossible to enforce a ban. Cigarettes and alcohol continue to be sold despite the health dangers associated with each and the vigorous opposition of some well-organized interest groups. There are no substitutes

for either product, and they are used regularly by millions of Americans. Similarly with saccharin, because no other sweetener was available to the millions of Americans who consumed diet soft drinks and other sugarless products, the FDA's proposed ban was highly unpopular, resulting in a congressional decision to delay its implementation.

Second, when the perceived benefits of a product or a course of action outweigh the perceived costs (regardless of the actual benefits or costs) the government will be hampered in restricting a product. The potential risk from artificial sweetener consumption is generally perceived to be slight and long-term; the odds are in the consumer's favor. Because the belief is so firmly entrenched that artificial sweeteners are effective in losing weight, their value was perceived to be greater than the risk of developing bladder cancer sometime in the future.

Third, government action in the area of consumer protection is limited by the lack of consensus on what constitutes an acceptable risk. There are individuals for whom the perils of skydiving or deep sea exploration are acceptable and others for whom such activities would be considered too dangerous to attempt. Individuals calculate risk consciously in the contemplation of deliberative activities, or more often, unconsciously in hundreds of mundane situations: entering an automobile, crossing the street, or eating processed foods.

For the government agency, however, risk assessment must be viewed as an intentional act, particularly if the process is called upon to later defend a decision. Ultimately, deciding what will be considered acceptable risk, from a sweetener or other consumer product, is a political determination that assesses what degree of jeopardy to the public's health will be worth the benefits. Government has been given the responsibility in part because it would be impossible for the individual to calculate the risks and benefits of the myriad consumer products on the market. The task for the federal agency is complicated by the lack of a single public standard of acceptable risk. Baruch Fischhoff, Sarah Lichtenstein, and Paul Slovic found that "...there is no single all-purpose number that expresses "acceptable risk" for a society. Values and uncertainties are an integral part of every acceptable-risk problem."<sup>18</sup>

The artificial sweetener cases also reveal that health and safety regulations designed to protect consumers may fall short of this goal because of strategies adopted by government agencies or by companies to protect their own interests. With artificial sweeteners these strategies were not always successful in achieving the ends desired by the FDA or by the manufacturers of cyclamate, saccharin, and aspartame. But their efforts did affect the regulatory process and consequently, the current state of artificial sweeteners policy. The FDA attempted to fulfill its responsibility of

ensuring the safety of the food supply while maintaining its political credibility and scientific reputation; the two goals were not always compatible. The manufacturers attempted to keep their products on the market, efforts that were sometimes at odds with the FDA and not always in the best interests of the public's health.

This study and others make clear that the regulation of consumer products is an uncertain process for all involved. The political environment changes, the science is ambiguous, and the existence of a substitute for a product all complicate the process for the FDA. As the artificial sweetener cases demonstrate the relationship between the safety of a product and its regulatory status cannot be assumed. Nor can the public take for granted that its health will be protected. The manufacturer cannot assume that by following established procedures and relying on the science the desired outcome will result.

The federal government began regulating the safety of the food supply at the beginning of the twentieth century. That its efforts have achieved some measure of success is evidenced by a vast system of food production virtually free from obvious dangers - bacterial infections, toxic effects, botulism, etc. Today, however, the problems have changed. The principal challenge for the government now is protection of the American consumer from potential hazards - regulating the use of substances where the risk is ambiguous or long

term. Controlling blatant abuses and violations has given way to monitoring more subtle dangers. The artificial sweetener cases suggest that, as the problems have grown more complex, so too have the strategies to influence the policy outcome adopted by various participants in the regulatory process.

NOTES: CHAPTER VI

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## APPENDIX: INTERVIEWS

Dr. Adams - Pharmaceutical Manufacturers Association

Dr. Robert D. Barry - National Economics Division, USDA

Dorothy Born - Patient Education Coordinatory, American  
Diabetes Association

Carol Brill - Science Associate, Grocery Manufacturers  
Association

Paul Brooke - Analyst, Morgan Stanley

Karen Brown - Vice President for Public Affairs, Food  
Marketing Institute

George M. Burditt - Burditt and Calkins (counsel to Abbott  
Laboratories)

F.E. Butler - General Manager, Chemicals Division,  
Sherwin-Williams

David Carter - President, U.S. Beet Sugar Association

Cartha DeLoach - Vice President, Corporate Affairs, Pepsico

Linda Demkovich - National Journal

Marvin Eisenstadt - Executive Vice President, Cumberland  
Packing

Denise Ertell - Director of Public Affairs, G.D. Searle

Dr. Gary Fflamm - Toxicology Division, FDA

Elaine Franklin - Manager, Corporate Consumer Affairs, Pepsico

Dr. Laura Green - Toxicologist, Massachusetts Institute of  
Technology

Dr. Robert Hoover - Environmental Epidemiology Branch,  
National Cancer Institute

Edward Hopkins - Group Vice President, Sherwin-Williams

Dr. Paul Hopper - Corporate Director of Science, General  
Foods

Peter Barton Hutt - Former chief counsel, FDA

Paul Jones - Special Assistant to Congressman James G. Martin

Richard Kasperson - Vice President, Corporate Regulatory  
Affairs, Abbott Laboratories

David Kessler - Consultant to Senate Committee on Labor and  
Human Resources

Dr. Andrew Laumbach - Division of Food and Color Additives,  
FDA

Dr. Alvin Lazen - Executive Director, Assembly of Life  
Sciences, National Academy of Sciences

Bonnie Liebman - Center for Science in the Public Interest

Robert Longenecker - Industry and Consumer Affairs, Coca-Cola  
Company

Carol Lurie - National Diabetes Advisory Board and Juvenile  
Diabetes Foundation

Dr. Allen Matthys - Director of Labeling and Food Standards,  
National Food Processors Association

Pat Maynard - U.S. Department of Agriculture

Ellen McConnell - Burson, Marsteller (public relations agency)

Dr. Patricia J. McLaughlin - Division of Food and Color  
Additives, FDA

Roger D. Middlekauff - Secretary/Treasurer, International Life  
Sciences Institute

Dr. Sanford Miller - Director, Bureau of Foods, FDA

Dr. John Modderman - Division of Chemistry and Physics, Bureau  
of Foods, FDA

Dr. Andrew Moore - Science Associate, Grocery Manufacturers  
Association

Ainsely Morgan - Public Policy Coordinator, Juvenile Diabetes  
Foundation

Professor Walle J.H. Nauta - Massachusetts Institute of  
Technology

Stuart Pape - Former lawyer in FDA chief counsel's office

Dr. Howard Roberts - Vice President, Science and Technology,  
National Soft Drink Association

Professor Walter Rosenblith - Massachusetts Institute of  
Technology

Andrew J. Schroder III - Senior Vice-President,  
Administration, General Foods Corporation

William Schultze - Lawyer, Public Citizen Litigation Group

Sarah Setton - Director of Public Relations, The Sugar  
Association

Linda Smith - Community Nutrition Institute

Dr. James Stanley - Director, Scientific and Regulatory  
Affairs, Pepsico

John Thomas - Supervisory Consumer Safety Officer, Division of  
Regulatory Guidance, FDA

James Turner - Lawyer, Consumer Activist

Yuli Wexler - National Food Processors Association

Gary Yingling - President, Food and Drug Law Institute

Professor Vernon Young - Massachusetts Institute of Technology