Making Governmental Policy under Conditions of Scientific Uncertainty: A Century of Controversy about Saccharin in Congress and the Laboratory

PAUL M. PRIEBE AND GEORGE B. KAUFFMAN

FROM almost the moment of its discovery and subsequent laboratory synthesis in 1878, saccharin (*ortho*-benzosulfimide) has been a subject of sustained and often heated discussion. In general, this controversy has followed two rather distinct paths. The first, that of the historians, centres on the circumstances surrounding the initial discovery and the men responsible for it—Constantin Fahlberg[1] and Ira Remsen.[2] In fact, it was a contested lawsuit involving Fahlberg which, in the late 1890s, first brought widespread public attention to saccharin.[3]

Scholars continue to be interested in the discovery itself, but recent events have also given prominence to the second side of the discussion about saccharin, namely, the medical and pharmacological debate concerning the effects of its use. It is here that governmental and public concern have been most apparent. Put simply, the question is: is the consumption of saccharin hazardous to human health, and, if so, what regulatory steps should be taken by governmental officials to control the public's access to this most widely used of artificial sweeteners?[4] In 1907, saccharin came under examination and criticism by the United States Department of Agriculture (USDA); the controversy has not ceased since then. Beginning in 1972, the United States Food and Drug Administration (FDA) has been pressing the saccharin industry, and an outright prohibition on the sweetener has become a real possibility for the first time in history.

[1] Fahlberg was born in Germany in 1850. After completion of a Ph.D. in chemistry at Leipzig University in 1873, he emigrated to the United States. A period of collaboration with Ira Remsen in January 1878 led to their joint discovery of saccharin later that year. See "Constantin Fahlberg", *Berichte der Deutschen Chemischen Gesellschaft*, XLIII (1910), p. 2,784; "Constantin Fahlberg", *Der Grosse Brockhaus*, 15th edn. (Leipzig: A. Brockhaus, 1930), VI, p. 20.

[2] Noyes, William A., "Ira Remsen", *Science*, LXIV, 1707 (16 September, 1927), pp. 243–246; *Journal of the Chemical Society (London) Transactions*, XLII, 2 (1927), pp. 3,182–3,189. Malone, Dumas (ed.), *Dictionary of American Biography* (New York: Charles Scribner's Sons, 1935), XV, pp. 500–502; Getman, Frederick H., "Ira Remsen—Erstwhile Dean of Baltimore Chemists", *Journal of Chemical Education*, XVI, 9 (August 1939), pp. 353–360; Fullmer, J. Z., "Ira Remsen", in Gillespie, Charles C. (ed.), *Dictionary of Scientific Biography* (New York: Charles Scribner's Sons, 1975), XI, pp. 370–371.

[3] For a detailed account of the discovery of saccharin and the circumstances regarding its patenting see Kauffman, George B., and Priebe, Paul M., "The Discovery of Saccharin: A Centennial Retrospect", *Ambix*, XXV, 4 (November 1978), pp. 191–207.

[4] Young, James Harvey, "Saccharin: A Bitter Regulatory Controversy", in Evans, Frank B. and Pinkett, Harold T. (eds.), *Research in the Administration of Public Policy* (Washington, D.C.: Howard University Presss, 1975), pp. 39–49, 210–212.

Discovery and Initial Use of Saccharin

Saccharin was first isolated in 1878 through the joint efforts of Ira Remsen and Constantin Fahlberg, and recognition should go to both for their respective roles in the discovery.[5] Initially, neither discoverer interested himself in the possible economic or commercial uses of the sweetener. Between 1882 and 1884, however, Fahlberg obtained financial support and took out American[6] and German[7] patents for saccharin. Firms were established in New York and Magdeburg, and the first large-scale commercial production began in 1886.[8]

Advertisers and sellers of saccharin claimed at first that it possessed almost miraculous powers. In addition to its sweetness, they claimed that saccharin could cure a wide range of ailments including cystitis, gastritis, and various infections.[9] As was the case with so many other chemical substances introduced into American life during the nineteenth and early twentieth centuries, the use of saccharin went unchallenged for several decades.

In 1907, the United States Department of Agriculture began a series of investigations which have continued, under one federal agency or another, down to the present day. The initial investigation was the direct result of the enactment of the Pure Food and Drug Act of 1906. By the end of the nineteenth century, the leaders of American public opinion had raised their voices against the almost countless examples of abuses then extant in the meat-packing, canning, dairy and pharmaceutical industries. Congress finally acted, but it was assumed in many quarters that the 1906 legislation would become a dead letter and that the federal government would do little, if anything, to enforce the law and to punish violators.

The Pure Food and Drug Act did not become a dead letter largely because of the persistence of Harvey Washington Wiley,[10] director of the

[5] Kauffman, G.B. and Priebe, P. M., *op. cit.*, pp. 202–203.

[6] Fahlberg, Constantin, "Assignor of One-Half to A. List, Leipsic, Germany, Manufacture of Saccharine Compounds", U.S. Patent 319,082, applied for 7 August, 1884, issued 2 June, 1885; Fahlberg, Constantin, "Saccharine Compound", U.S. Patent 326,281, applied for 16 August, 1884, issued 15 September, 1885.

[7] Fahlberg, Constantin, and List, Adolph, *Deutsches Reich Patent* 35,717, applied for 16 August, 1884; *Friedländer Fortschritte der Teerfarbenindustrie,* I (1877–87), p. 593; French and Belgian patents were also applied for on 16 August, 1884.

[8] For technical details on the commercial production of saccharin, see Hemple, A. and Cohn, G., "Benzoesäuresulfinid", in Ullmann, Fritz (ed.), *Enzyklopädie der Technischen Chemie* (Berlin: Urban and Schwarzenberg, 1928), 2nd edn., II, pp. 246–254.

[9] Rhein, Reginald W., Jr. and Marion, Larry, *The Saccharin Controversy: A Guide for Consumers* (New York: Monarch Press, 1977), p. 17.

[10] By the time of his appointment as head of the Food and Drug Inspection Office, Wiley had gained high repute as a food chemist. He had received an M.D. degree from Indiana University in 1871 and a second B.S. degree from Harvard two years later. From 1883 to 1912 he was chief of the bureau of chemistry at the United States Department of Agriculture. During this time he specialised in three major fields of food research: chemical analysis of sugar and sugar-producing crops; development of agricultural analysis methods; and, most importantly, detection of impurities and adulterants in food. See Ihde, Aaron J., "Harvey Washington Wiley", in Malone, Dumas (ed.), *Dictionary of American Biography* (New York: Scribner's Sons, 1936), XX, pp. 215–216; "Harvey Washington Wiley", in Charles C. (ed.), *Dictionary of Scientific Biography* (New York: Gillespie, C. Scribner's Sons, 1976). XIV, pp. 357–358; "Harvey W. Wiley", *The National Cyclopaedia of American Biography* (New York: James T. White and Company, 1931), XXI, pp. 72–74; Anderson, Oscar E., Jr., *The Health of a Nation: Harvey W. Wiley and the Fight for Pure Food* (Chicago: University of Chicago Press, 1958).

bureau of chemistry in the United States Department of Agriculture. Wiley had been instrumental in bringing about the passage of the Pure Food and Drug Act, and he did his best to see that it was enforced.[11] He had long suspected that saccharin was injurious to health. It was, after all, a coal tar derivative, and other such derivatives chemically related to saccharin had produced toxic results when consumed by humans or animals.[12] Wiley was aware that saccharin had been used as an antiseptic, a food preservative, a treatment for diabetics, and in the canning industry as a sweetener.[13]

Wiley's suspicions were more than just the doubts of a scientist confronted with a substance which, its supporter claimed, could cure a wide range of ailments. The French government had ordered an investigation of saccharin, and importation of the substance was banned when the scientific committee which conducted the investigation found that it was a hazard to digestion.[14] Wiley also relied on the testimony of pharmacists and physicians whose findings indicated possibly harmful effects.

First Attempts at Governmental Regulation

The first confrontation came in 1908, when Wiley clashed openly with the headstrong 26th President of the United States, Theodore Roosevelt. Wiley attended a meeting which industrial users of preservatives had called in order to refute his charges that benzoate of soda (sodium benzoate) was injurious to human health. When saccharin was discussed, Wiley condemned the substance as harmful. President Roosevelt, who attended the meeting, replied with considerable anger, "Anybody who says saccharin is injurious is an idiot. Dr. Rixey [Roosevelt's personal physician] gives it to me every day."[15] Criticism of Wiley by the industry grew, and a board of food and drug inspection was established to circumvent Wiley's decisions. The debate continued throughout President Roosevelt's term of office. First the board, then Wiley, and then the board again seemed to gain the upper hand. On 29 April, 1911, Food Inspection Decision 135 was cleared for application to begin 1 July, 1911. Henceforth, foods which contained any amount of saccharin would be considered adulterated. As expected, manufacturers and commercial users

[11] Young, J.H., *op. cit.*, p. 39.
[12] Rhein, R.W., and Marion, L., *op. cit.*, pp. 17–18.
[13] Daly, John Charles, Gardner, Sherwin, Martin, James G., Rauscher, Frank J. and Wolfe, Sidney, *The Saccharin Ban: Risks vs. Benefits* (Washington, D.C.: American Enterprise Institute, 1977), p. 1. In 1893, the Fahlberg, List & Co. saccharin factory at Salbke-Westerhüsen (near Magdeburg) published a 210-page work titled *Saccharine Benzoyl Sulphonic-imide*. This compilation collected and described all of the supposed uses of saccharin. It claimed that saccharin was not only harmless, but actually was beneficial for treatment of malnutrition, diabetes, gout, and bladder disorders. This volume was compiled by Dr. Adolph List, "a partner of the firm".
[14] Young, J.H., *op. cit.*, p. 40.
[15] *Ibid.*

of saccharin immediately launched a campaign to undo any harm they might suffer from the decision.[16]

In March 1912, a new regulation—Food Inspection Decision 142—was issued. This decision was the result of considerable negotiations on the part of attorneys, businessmen, pharmacists, and governmental officials. It was a victory for those in favour of saccharin, since the decision conceded that there existed no incontrovertible scientific evidence that saccharin was harmful. Nevertheless, the regulation did forbid the use of saccharin in normal foods.[17]

By 1914, there was a stalemate between those who proposed a total prohibition of the use of saccharin and those who sought to free the substance completely from any type of governmental control. Two important factors determined the lack of any clear-cut decision by the government. First, there existed no incontrovertible scientific evidence to prove that moderate amounts of saccharin are toxic. Both sides of the controversy could point to experimental results which seemed to bolster their respective claims. An objective, acceptable test for the effect of saccharin on the body had not yet been devised. A second cause of the stalemate lay in the role of the federal government. Sixty-five years ago, the federal government of the United States had considerably less power over the individual and the economy than it does today. Business enterprises had much more freedom than they have now. The machinery for enforcement was also much weaker at that time than it is now.

However, during the First World War, saccharin again became an object of widespread discussion and a rather lengthy legal suit. Following the outbreak of war between the Entente and the Central Powers, the United States experienced a shortage of sugar. The prohibition of the use of saccharin in processed foods, which was enacted during the administration of President William H. Taft, was suspended.[18] Nevertheless, Carl Lucas Alsberg,[19] Wiley's successor as head of the United States Department of Agriculture bureau of chemistry, brought suit in 1916 against Monsanto Chemical Works of St. Louis, Missouri. Alsberg's action failed, and no serious governmental attempt to block the use of saccharin was initiated by the federal government until 60 years later.

Saccharin after the Second World War

Scientists continued sporadically to investigate the sweetener and its possibly harmful side-effects; most of this work was directed toward the use of saccharin by the relatively small number of Americans under treatment for diabetes. In fact, the consumption of saccharin and its

[16] *Ibid.*, pp. 43–44.
[17] *Ibid.*, p. 44.
[18] Rhein, R. W., and Marion, L., *op. cit.*, p.18.
[19] Davis, Joseph S. (ed.), *Carl Alsberg, Scientist at Large* (Stanford: Stanford University Press, 1948); Gorman, Mel, "Carl Lucas Alsberg, 1877–1940", in Miles, Wyndham D. (ed.), *American Chemists and Chemical Engineers* (Washington, D.C.: American Chemical Society, 1976), pp. 7–8.

production remained almost constant during the interwar years. However, with the entry of the United States into the Second World War in 1941 and the ensuing shortage of sugar, the production of saccharin increased greatly, and by the end of the war, further studies had been undertaken to determine possible dangers to health.

Had the use of saccharin declined after 1945, as it had after 1918, there would have been little or no governmental concern. But tastes had changed greatly, and the increased demand for sweeteners, both natural and artificial, was alarming to nutritionists and health officials. American women ceased to prepare all of their meals at home from wholly raw ingredients. More and more, they turned to foods manufactured completely or in part by the food-processing industry. The United States became a "nation of sugar addicts". Pre-sweetened prepared foods were being widely consumed.[20]

It was this drastic increase in the consumption of sugar and artificial sweeteners which called the attention of the Food and Drug Administration to cyclamates[21] and saccharin in the mid-1960s. By 1967, Americans were consuming five million pounds of saccharin annually, and cyclamate consumption was also very high.

The large increase in the consumption of sweeteners prompted governmental investigation. By the mid-1960s, however, inquiries into the possible hazards of artificial sweeteners had shifted their focus. From Theodore Roosevelt's administration to the 1950s, systemic toxicity had been the major subject for study. Some scientists had thought that the consumption of saccharin could result in disturbance of the alimentary canal, plasma toxification, and hormonal imbalance. Studies carried out by the National Academy of Sciences during President Eisenhower's administration ruled these out.[22] But in the 1960s the possible carcinogenic consequences were receiving wider and more serious consideration. Studies were again undertaken—in 1968 and in 1972–73—in an effort to establish or disprove a link between cancer of the bladder and the use of saccharin. The second of these investigations, that of 1972–73, intensified the controversy.

In 1969, experimental results obtained by the laboratories of the Food and Drug Administration in 1948 and 1949 were retrieved from the files. E. L. Long and R. T. Habermann examined the microscopic slides of the

[20] Cantor, Michael B. and Eichler, Richard J., "Sweetness–a Supernormal Reinforcer", *Journal of Chemical Technology*, VII, 4 (April 1977), p. 214.

[21] Cyclamate is the group name for noncaloric, non-nutritive, synthetic sweetening agents derived from cyclohexylamine or cyclamic acid. Sodium cyclohexylsulphate was first prepared in 1937 by Michael Sveda, while he was a graduate student at the University of Illinois. The first cyclamate sweetener was introduced to the public by Abbott Laboratories, North Chicago, Illinois in May 1950. It was given the trade name "Sucaryl". As a result of findings that cyclamates form the toxic cyclohexylamine and that high dosages of cyclamates produce genetic damage in chick embryos as well as cancer in rats, their use in beverages and food products was prohibited in the United States in 1969.

[22] Rhein, R. W., and Marion, L., *op. cit.*, pp. 20–21.

tests made in 1948–49.[23] Their findings themselves instigated further controversy, since the conclusions were somewhat contradictory and tentative, leading to more speculation. Out of 54 test animals fed a diet of 5 per cent. (by weight) saccharin for two years, seven were found to have developed thoracic lymphosarcomas. In addition, Long and Habermann reported a series of findings on the incidence of kidney lesions present among animals tested in 1948–49. They concluded that no observable adverse effects were present at dosages of less than the 5 per cent. and that this latter dosage was only slightly toxic. They noted the unusually high incidence of abdominal lymphosarcomas. The conclusions of Long and Habermann were less dramatic than those of the original investigators.[24] These reports were closely studied by the National Academy of Sciences, but the Academy made no further additional comment.[25]

Moreover, during its investigation in 1974, the National Academy of Sciences considered a second study, also conducted in 1948–49. This investigation provided for a group of 40 Boots-Wistar rats to be fed concentrations of 0, 0.005, 0.05 and 5 per cent. saccharin for two years. The investigator concluded that incidence of tumours was normal at all dosages.[26] The National Academy of Sciences also declined to comment on this second experiment in 1948–49.

While the Academy was studying these cancer experiments with saccharin, the Food and Drug Administration was taking steps of its own to stop the almost uncontrolled production and use of artificial sweeteners. This action was taken in July 1973, while the National Academy of Sciences was still studying the results of the tests of 1948–49. In 1972, the staff of the Food and Drug Administration commissioner estimated that the diabetic food-processing industry would lose from $600 millions to $1.96 billions a year. In addition, the industry, it was estimated, would incur increased costs of production of at least $97.8 millions annually.[27]

Thus, by 1972, diverse and powerful groups had been drawn into the controversy about saccharin. These were the Food and Drug Administration, the National Academy of Sciences, which was examining the results of the tests of 1948–49 and which refused to condemn saccharin, the saccharin industry which sought to discredit any findings which asserted

[23] Long, E. L. and Habermann, R. T., *Review of Tumors in Rats Treated with Saccharin and Control Rats Used in Studies of Artificial Sweeteners* (Washington, D.C.: 3rd International Congress of Food Science and Technology, 1969).

[24] Fitzhugh, O. G., Nelson, A. A. and Frawley, J. P., "A Comparison of Chronic Toxicities of Synthetic Sweetening Agents", *Journal of the American Pharmaceutical Association,* XL, 7 (July 1951), pp. 585–586.

[25] For an examination of the conclusions reached by Long and Habermann, see National Academy of Sciences, *Safety of Saccharin and Sodium Saccharin in the Human Diet,* Publication No. PB 238–137 (Springfield, Va.: National Technical Information Service (NTIS), 1974).

[26] Congress of the United States, Office of Technology Assessment, *Cancer Testing Technology and Saccharin* (Washington, D.C.: Office of Technology Assessment, October, 1977), p. 63.

[27] Department of Health, Education and Welfare, Office of the FDA Commissioner, *Inflation Impact Statement of the Proposed Rulemaking, Office of Planning and Evaluation* (Washington, D.C.: U.S. Government Printing Office, 8 April, 1972).

the harmfulness of saccharin, the consumer movement, which was divided, and the independent medical and pharmacological research workers who entered the dispute because the federal government and the industry were convinced that unbiased research sponsored by the other was impossible. The issue was greatly complicated by the refusal to agree on the reliability of the experimental evidence. From 1972 to the present, no satisfactory agreement has been reached on what type of test or experiment for carcinogenesis induced by saccharin would be valid. The Food and Drug Administration, the National Academy of Sciences, independent scientists, the saccharin industry, and the organisations forming the consumer movement have refused to agree on the criteria for a generally acceptable test. This is part of the larger failure of medical science to define the causes and epidemiology of cancer itself. In this situation, tremendous demands are being made upon scientific research to provide the answer which it is thought uniquely able to do because of its characteristic virtues of objectivity and scrupulousness. It is these very virtues, however, which force scientists to assert that they do not have the answer.

The "Delaney Clause"

In 1972, the Food and Drug Administration was convinced that it had enough evidence to link saccharin to cancer; the result was the placing of saccharin in an "interim" category, which meant that no additional uses of the sweetener would be allowed until a final decision had been reached. Although the Food and Drug Administration did not explicitly mention the Delaney clause, it was to this regulation that the Food and Drug Administration had turned in seeking to justify its restriction of 1972.

In July 1950, Representative James J. Delaney, a Democrat from New York State, headed a United States House of Representatives select committee to study food additives. This committee listened for 39 days to scientists representing a wide range of specialities. Two years of further investigation resulted in a recommendation that Congress establish tests for food additives.[28] For the first time, cancer was mentioned in connection with food additives, and during the next five years, Delaney and his allies gathered support for congressional action.[29] One issue in particular was important for Representative Delaney; he demanded that any new legislation involving additives should contain a clause which would force the Food and Drug Administration to prohibit the use of carcinogenic substances in foods. This became known as the "Delaney clause", and on 13 August, 1958, it received an overwhelming vote of approval in the House of Representatives. Subsequently, it became part of the Food Additives Amendment enacted in 1958.

[28] Rhein, R. W., and Marion, L., *op. cit.*, pp. 34–35.

[29] For an examination of the issue from the committee's viewpoint, see U.S. House of Representatives, *Report of the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics* (Washington, D.C.: U.S. Government Printing Office, 29–30 June, 1952).

When the Food and Drug Administration first issued its warning against the use of saccharin in 1972 and restricted its use, cancer and the "Delaney clause" were not explicitly mentioned, but authority for the order came from the "Delaney clause" and the Food Additives Amendment which followed from it. The "Delaney clause" had in fact been invoked in 1969, when the Food and Drug Administration prohibited cyclamates.[30] The ban on cyclamates came in October of that year following the publication of two studies. The first had been conducted by the National Academy of Sciences and the second at Albany Medical College.[31] Mr. Robert Finch, then secretary of the Department of Health, Education, and Welfare proclaimed the prohibition on 23 October, 1969, invoking the "Delaney clause". Mr. Finch based his decision on medical testimony provided by the National Cancer Institute. On the basis of the same evidence, the Food and Drug Administration urged Finch to act.[32]

The ban on cyclamates was important in the history of the regulation of saccharin for two reasons. First, cyclamates were artificial sweeteners, like saccharin. If scientific research had led to the ban on cyclamates, it was perhaps logical that further investigation might show that saccharin is a carcinogen. The two substances were coupled by being artificial sweeteners. In fact, however, the chemical composition of cyclamates is quite different from that of saccharin. But a prohibition against cyclamates —urged by the National Cancer Institute—may well have been the important link to the Institute's increased interest in saccharin. Secondly, the "Delaney Clause" had been invoked against cyclamates. During the 1970s this ruling was reintroduced into the dispute over saccharin. The fact that it was used in the ban of cyclamates was mentioned in the arguments for invoking it against saccharin.

Restrictions on the Use of Saccharin

Almost immediately after the decree on the prohibition of cyclamates had been issued, the debate on saccharin flared up once more, this time with much greater heat.[33]

Three physicians at the division of oncology of the University of Wisconsin Medical School published the results of an extensive clinical study of the effects of saccharin on laboratory mice.[34] Dr. George T. Bryan and his associates concluded that the incidence of bladder cancer associated with the consumption of saccharin was equal to that observed for cyclamates. The test animals exposed to saccharin exhibited signifi-

[30] Anderson, Kenneth N., "After Cyclamates: What's next on the FDA's Food Target List?", *Science Digest*, LXVII, 2 (February 1970), p. 23.
[31] "Artificial Sweeteners–A Questionable Safety", *Consumer Bulletin*, LII, 2 (February 1969), pp. 12–13.
[32] "Cyclamates Banned", *Science News*, XCVI, 17 (25 October, 1969), pp. 369–370.
[33] Anderson, K. N., *op. cit.*, pp. 22–23.
[34] Bryan, George T., Ertürk, Erdoğan and Yoshida, Osamu, "Production of Urinary Bladder Carcinomas in Mice by Sodium Saccharin", *Science*, CLXVIII, 3936 (5 June, 1970), pp. 1,238–1,240.

cantly higher incidence of carcinomas of the bladder (47 and 52 per cent.) than did the animals in the control groups (13 and 12 per cent.).[35] This evidence became known as the "Wisconsin study" and played a significant role in later events. Further studies were undertaken under the aegis of the Wisconsin Alumni Research Foundation. In 1972, seven experiments on the effects of saccharin on test animals were in progress at various universities, medical schools, and research laboratories.[36] In January 1972, the Food and Drug Administration removed saccharin from its list of food additives "generally recognised as safe".[37] A similar action had preceded the ban on cyclamates in 1969.[38] The chief legal counsel of the Food and Drug Administration, Mr. Peter B. Hutt, declared that the question of the amount of saccharin ingested was irrelevant. In his opinion, "If it causes cancer—whether it's 875 bottles a day or 11—it's going off the market".[39]

Of course, the chief producers and consumers of saccharin in the United States were alarmed. The Monsanto Co., Sherwin-Williams Co., and Lakeway Chemicals, Inc., which were threatened with considerable financial losses began to assemble evidence—from scientists, consumers, and governmental officials—to resist further restrictions on saccharin. Other large firms like Coca-Cola, Royal Crown, and Pepsico expected to be seriously affected. "Diet food" manufacturers who used saccharin in their products were also threatened by large reductions in their sales.[40]

Those who claimed to be the spokesmen for consumers were divided. Some viewed governmental intervention as an unjustifiable infringement on private enterprise and the free market. Others were particularly incensed because saccharin played an important role in the control and reduction of bodily weight. To remove saccharin would result, they claimed, in severe health hazards for millions of overweight and diabetic Americans. Still others viewed the positions of the Food and Drug Administration as correct; they asserted that the saccharin industry was trying to deny a possible link between saccharin and cancer.

The Role of the National Academy of Sciences

During 1972, the controversy abated somewhat while both sides waited for the results of further testing. Nine studies in all were to be presented to the National Academy of Sciences. Two of these were being conducted in Holland and Canada. The results were to become available in 1973. Until further notice the imposition of a prohibition of additional uses of

[35] *Ibid.*, p. 1,240.
[36] "Is Saccharin Safe?", *Newsweek*, LXXIX, 7 (14 February, 1972), p. 53.
[37] *Federal Register*, XLII, 22 (1 February, 1972), pp. 1,186–1,187.
[38] "Diet Foods Fear a Saccharin Ban", *Business Week*, XLV, 2216 (19 February, 1972), p. 45.
[39] *Ibid.*
[40] Culliton, Barbara J., and Maugh, James H., II, "Academy Panel Could Send Saccharin the Way of Cyclamates", *Science*, CLXXX, 4085 (4 May, 1973), p. 480.

saccharin was to remain in force.[41] In April 1973, a report linking saccharin to uterine cancer in mice was issued at the 165th national meeting of the American Chemical Society in Dallas by Dr. Phillip H. Derse of the Wisconsin Alumni Research Foundation.

In 1973, the National Academy of Sciences began its work through its subcommittee headed by Dr. Julius Coon of the Thomas Jefferson University Medical School in Philadelphia. The studies of the Wisconsin Alumni Research Foundation and the Food and Drug Administration of 1972 and 1973 were examined. The subcommittee of the National Academy of Sciences concluded that although the studies by the Wisconsin Alumni Research Foundation and the Food and Drug Administration indicated cancer concomitant with high levels of consumption of saccharin,[42] saccharin could not be clearly blamed on the basis of the data then available. The subcommittee further complicated the issues by stating that major questions in other areas of pathology needed to be examined. These included possible links between saccharin and transplacental carcinomas, urine level, and bladder stones.[43]

The subcommittee was expected to report in 1973. Actually, it was not until April 1975 that any significant statement was forthcoming, and that statement only announced that even more consideration was to be given to the results of the previous tests and that further studies were to be undertaken. It was evident from this report that the National Academy of Sciences wanted to avoid any suggestion that it was rushing to a judgement on saccharin. Such charges had been made against the National Academy of Sciences and the Food and Drug Administration when they abruptly announced their adverse findings on cyclamates in 1969. Once again, the Food and Drug Administration reminded the saccharin producers that the restraint on the increased use of saccharin issued in 1972 was still in force.

The Food and Drug Administration Acts

In March 1977, the Food and Drug Administration and the National Academy of Sciences proposed to ban saccharin. They cited the "Canadian study" completed several months earlier. This study caused a great sensation in the press and led to one of the harshest controversies between scientists and governmental officials in American history.

The "Canadian study" had been commissioned in December 1974 by the National Academy of Sciences. The investigators were asked to study three groups of rats. One group received pure saccharin at prescribed levels; another received a saccharin by-product—*ortho*-toluenesulfonam-

[41] "The Bitter and Sweet of Saccharin Research", *Science News,* CIII, 9 (3 March, 1973), pp. 133–134.

[42] For the extensive clinical findings of WARF and the FDA studies of 1972, see WARF Institute, *Preliminary Report: Chronic Toxicity Study—Sodium Saccharin* (Glen Cove, New York: April 26–28, 1972); and the Food and Drug Administration, *Sodium Saccharin: Combined Chronic Feeding and Three-Generation Reproduction Study in Rats. Preliminary Report on the Chronic Feeding Study* (Washington, D.C.: U.S. Government Printing Office, May, 1973).

[43] "Saccharin Study: No Substitute for Data", *Science News,* CVII, 4 (25 January, 1975), p. 53.

ide (OTS); and a control group received no saccharin. Results indicated that the first group had significantly higher rates of cancer than the other two groups.[44] Following its examination of the "Canadian study", the Food and Drug Administration, through Deputy Commissioner Sherwin Gardner, issued a statement that the law required the cessation of the use of saccharin in food. This came on 9 March, 1977. The deputy commissioner cited the "Delaney clause" of the Food Additives Amendment to the Food, Drug, and Cosmetics Act.[45]

The Sherwin-Williams Co., at that time the sole producer of saccharin, announced its intention to increase production until the prohibition became effective. In Congress steps were taken immediately to alter the "Delaney clause" and thereby to enable consumers and producers of saccharin to evade the prohibition.[46] Complete uncertainty continued because it was thought that new tests would be ordered, that Congress would act to rescind the prohibition and that the courts would decide against it. The outcome was a combination of these three possibilities.

Frank J. Rauscher, vice-president for research of the American Cancer Institute, was asked to study the entire issue of testing for cancer. The task was assigned to the Congressional Office of Technology Assessment, which immediately began a comprehensive survey of all significant laboratory techniques for the determination of carcinogenesis. Once again, the fundamental questions had to be asked: who determines what is cancer? Who determines what substances are carcinogenic? How do they decide?

For the most part, those who said they spoke on behalf of consumers were against the ban. They pointed out that carcinogenesis had resulted only in test animals forced to ingest massive quantities of saccharin. These amounts were proportionally far in excess of those taken by even the users of the most excessive amounts of saccharin. They refused to believe that results of tests conducted with animals were valid when extended mechanically to humans.[47]

On 24 March, 1977, in a speech to the National Flexible Packaging Association, Deputy Commissioner Gardner emphasised the careful preparations and long years of study which had gone into the decision of the Food and Drug Administration. He mentioned the Wisconsin Alumni Research Foundation and the Food and Drug Administration Studies made in 1972 and the seven others examined between 1972 and 1977. At several points, he proposed that the Food and Drug Administration should gather additional evidence.[48] His speech is significant because it

[44] Congress of the United States, Office of Technology Assessment, *op. cit.*, p. 131.
[45] *Ibid.*
[46] "Proposed Saccharin Ban Stirs Up Congress", *Chemical and Engineering News*, LV, 13 (28 March, 1977), p. 22; Clark, Matt and Gosnell, Marianna, "How Good are the Tests?", *Newsweek*, LXXXIX (21 March, 1977), p. 67.
[47] "Saccharin Ban: Sour Reception", *Science News*, CXI, 12 (19 March, 1977), p. 182.
[48] Gardner, Sherwin, "How Much is Enough? Saccharin and the Law", *Vital Speeches of the Day*, XIII, 15 (15 May, 1977), pp. 457–459.

indicates just how aware the Food and Drug Administration was of the complexities of the issue, especially the difficulties in interpretation of animal test results when applied to human beings.

Responses to the Prohibition

In the meantime, Congress acted. On 18 March, 1977, Edward M. Kennedy, Democratic senator for Massachusetts, who was chairman of the Senate sub-committee on health and scientific research, requested that the Office of Technology Assessment study the findings of the Food and Drug Administration and report to his subcommittee.[49] In June of that year Senator Kennedy declared his support for those resisting the enforcement of the prohibition. Representative Paul G. Rogers, a Democrat from Florida, introduced legislation (H.R. 7599) which would delay the date of enforcement until January 1979. This bill would return the entire issue to the Institute of Medicine of the National Academy of Sciences. The task of the Institute would be to determine whether the results of animal tests can be validly applied to human beings.[50] In that same month, two more studies were published which only aggravated the controversy. Both parties to the controversy claimed to be vindicated, and the results were indeed indeterminate enough to give each party confidence that it was in the right.

The first study was done in Canada. It examined 821 "newly diagnosed" primary human bladder cancers detected in three Canadian provinces in April 1974 and June 1977. The results showed that saccharin-using males had a higher incidence of cancer of the bladder than males not using the sweetener. There was no evidence that saccharin-using females were more prone to cancer of the bladder than females who did not use saccharin.[51]

In June 1977, the American Health Foundation released its study. This experiment had been conducted since early 1973 with 132 male and 21 female human beings whose medical histories were available for a period beginning 15 years earlier. Thirteen of the 132 males and five of the 31 females developed cancer of the bladder. All of the 153 subjects had been saccharin-users. In a second control group of 153, 16 out of 124 males and five of 29 females developed bladder cancer. The conclusion here was that there was no "statistically significant rate of carcinogenesis" among the saccharin-users when compared to non-users.[52] The Canadian study findings paralleled the epidemiological results of tests with laboratory animals. In the majority of these tests on animals, males but not females

[49] Congress of the United States, Office of Technology Assessment, *op. cit.*, p.132.
[50] "Saccharin Ban Reversal Gains More Support", *Chemical and Engineering News*, LV, 25 (20 June, 1977), p. 19.
[51] For a statistical analysis of the Canadian experiment, see Congress of the United States, Office of Technology Assessment, *op. cit.*, Appendix.
[52] *Ibid.*, p. 148.

were more susceptible to carcinogenesis when saccharin was part of the diet.[53]

The findings of the Canadian study and the study of the American Health Foundation were added to the reams of experimental data which had accumulated since the first experiments in 1948. In Congress, alignments were being formed to block the plans of Representative Rogers and Senator Kennedy to generate further studies; Senator Kennedy in particular advocated an 18-month moratorium on any prohibition of saccharin by the Food and Drug Administration. On 10 June, 1977, Senator Kennedy stated that "The scientific community is deeply and evenly divided over whether the risks of leaving saccharin on the market outweigh the benefits. Persons with impeccable scientific credentials reach exactly the opposite conclusions after reviewing the same data."[54]

Representative Rogers and Senator Kennedy had proposed opening hearings on saccharin on July 15, 1977, but at the insistence of other congressmen they began them on 27 June. Prior to the opening of the hearings, several significant agreements were reached. The two legislators agreed to complete their work on the proposal of a moratorium before the prohibition could go into effect. Deputy Commissioner Gardner promised to take no further action until the legislative hearings were complete. In fact, the Food and Drug Administration had already decided to postpone action because it wanted to evaluate the findings of the Canadian study.[55]

During late June and early July 1977, Representative Rogers' subcommittee on health and the environment held exhaustive hearings on the entire range of subjects related to saccharin. The testimony dealt with the issues raised by three bills, H.R. 7753, H.R. 8012, and H.R. 5166.[56] The first bill directed the Institute of Medicine of the National Academy of Sciences to conduct a 12-month review and evaluation of the relevance of tests on animals for carcinogenesis to tests on human beings; particular emphasis was to be placed on research on saccharin. The bill would also require a moratorium for 18 months on any prohibition of saccharin.[57] H.R. 8012 regulated the use of saccharin in the interval, and H.R. 5166 authorised an evaluation of the risks of the use of saccharin and permitted its sale until the assessment was complete.

The witness and experts who testified before the House of Representatives subcommittee included Dr. Donald Kennedy, commissioner of the Food and Drug Administration, Dr. Guy R. Newell, director of the National Cancer Institute of the National Institutes of Health; and Dr.

[53] *Ibid.*, p. 149.
[54] Rhein, R.W., and Marion, L., *op. cit.*, p. 45.
[55] *Ibid.*, pp.47–48.
[56] United States Congress, *Moratorium on Saccharin Ban. Hearing Before the Subcommittee on Health and the Environment. Committee on Interstate and Foreign Commerce* (Washington, D.C.: U.S. Government Printing Office, 27 June, 1977).
[57] *Ibid.*, p. i.

David M. Hamburg, president of the Institute of Medicine of the National Academy of Sciences. In addition, documents were submitted by such groups as the American Pharmaceutical Association, the American Medical Association, and the American Dental Association.[58]

In his testimony on behalf of the Food and Drug Administration, Dr. Kennedy said that the results of laboratory tests on animals:

> on their own, provided sufficient reason to remove this artificial sweetener from our food supply. The new Canadian epidemiology study gives additional cause for concern. While there does not appear to be an imminent risk to humans which would require complete and immediate removal of saccharin from the market, prolonged delays must be avoided.[59]

Dr. Newell concluded:

> the recent animal studies have been performed, in our opinion, by the most up-to-date bioassay procedures; the Food and Drug Administration, then, we believe, paid appropriate attention to these scientific results. The data show that saccharin causes bladder cancer in rats. Until we have better technology to provide more precise data for humans, we believe that in order to err on the side of prudence, we must assume that a substance that causes cancer in laboratory animals is also a human carcinogen.[60]

Dr. Hamburg of the National Academy of Sciences was reluctant to call for a prohibition of saccharin; he urged further testing.[61]

Further Agitation and Legislation

The legislative hearings continued for several weeks. The subcommittee could not be accused of failing to take evidence and testimony from all sides under consideration. In November 1977, Congress proposed legislation which provided for a moratorium, warning labels, and further testing. The House of Representatives and the Senate approved it on 4 November, and President Carter signed the law on 23 November. The law was entitled "The Saccharin Study and Labeling Act of 1977".[62] The new law required warning labels to be attached to all containers of food and drink listing saccharin as an ingredient. The warning was to include statements to the effect that saccharin had been found to cause cancer in tested animals. In addition, vending machines and supermarkets where "diet soft drinks" containing saccharin were sold were required to exhibit warnings. The Food and Drug Administration was ordered to conduct additional tests on the effects of saccharin on health and report their results to Congress.[63] The moratorium on the prohibition was to run until 23 May, 1979.

[58] For the documentation submitted by these associations, see *ibid.*, pp. 108–143.
[59] *Ibid.*, p. 43.
[60] *Ibid.*, p. 46.
[61] *Ibid.*, pp. 46–51.
[62] The complete text and legislative history of the Saccharin Study and Labeling Act of 1977 are found in *United States Code, Congressional and Administrative News, 1977,* III, pp. 3,921–3,947 (Public Law 95-203).
[63] *The New York Times,* 24 November, 1977.

On 25 January, 1978, representatives of the National Cancer Institute and the Food and Drug Administration announced a new study of the possible links between the use of saccharin and bladder cancer. Three thousand bladder cancer patients and their medical histories would be compared with 6,000 individuals in a control group. The study would be the largest human epidemiological study of its kind. Geographic, occupational, and environmental factors would be taken into account.[64]

During 1978, while the moratorium continued and the labelling of products which contained saccharin was in effect, the scientific controversy continued. In April 1978, at a meeting of the American Association for Cancer Research, a group of medical research workers from St. Vincent's Hospital in Worcester, Massachusetts reported that saccharin might promote as well as cause carcinogenesis. They found that rats fed a certain carcinogen—FANFT (N-formamide)—developed cancer at predictable rates. When saccharin was added to the diet, the rate of carcinogenesis in the bladder increased significantly. The investigators claimed, however, that saccharin alone caused no increase in bladder cancer over that observed in the control groups.[65]

A second study by Dr. Irving Kessler and colleagues at the Johns Hopkins University School of Medicine, published at the end of June 1978, implied that bladder cancer was not caused by saccharin. Kessler's team examined the case histories of 518 residents of the area of Baltimore with verified bladder cancers. An equal number of patients without cancer was selected as a control. Kessler concluded that "our findings suggest that ingestion of NNS (non-nutritive sweetener), at least at the moderate dietary levels reported by the patient sample, is not associated with an increase of bladder cancer. It is concluded that neither saccharin nor cyclamate is likely to be carcinogenic in man."[66]

That autumn, the results of a survey conducted by the Calorie Control Council showed that some 44 million Americans were using saccharin, and six million of these had started to do so since the controversy had been given widespread attention in the press a year earlier.[67] On 4 November, 1978, the National Academy of Sciences concluded that saccharin "must be viewed as a potential cause of cancer in humans".[68] It declared that several important findings were presented: saccharin is a carcinogen in animals, although one of low potency; the compound itself and not impurities from manufacturing are responsible for carcinogenic

[64] *The New York Times*, 26 January, 1978.
[65] "Saccharin May Be a Tumor Promoter", *Chemical and Engineering News*, LVI, 15 (10 April, 1978), p. 19.
[66] Kessler, I. I. and Clark, J. Page, "Saccharin, Cyclamate and Bladder Cancer", *Journal of the American Medical Association*, CCXL, 4 (28 July, 1978), pp. 349–355.
[67] "Forty-four Million Americans Sweet on Saccharin", *The Fresno Bee*, 18 October, 1978.
[68] "Science Academy Calls Saccharin a Cancer Risk", *The Fresno Bee*, 5 November, 1978.

activity; and there is no evidence that the sweetener offers any significant health benefits.[69]

Dr. Donald Kennedy, commissioner of the Food and Drug Administration, immediately declared "The report's main conclusions fully reinforce those reached by the FDA and the Congressional Office of Technology Assessment—namely, that saccharin is a weak carcinogen".[70]

This report was the fifth which the National Academy of Sciences had made concerning saccharin since 1955. The four previous reports had all been very noncommittal. The report of the Institute of Medicine which was to be completed in late February 1979 was the second major assessment ordered by Congress in its legislation of 23 November, 1977.[71]

By the spring of 1979, the various governmental agencies involved in the saccharin issue were filing their preliminary findings and recommending what action should be taken in preparation for the expiration of the moratorium. The first to speak out was Dr. Donald Kennedy. The Food and Drug Administration had been the strongest advocate of prohibition of saccharin. But in February 1979, Commissioner Kennedy appeared to withdraw from the earlier position when he called for revisions of the "Delaney clause" and the Food, Drug, and Cosmetics Act of 1958. He noted that since the Act had been passed over two decades ago, scientific detection has developed to the point that even trace amounts of additives can now be detected. When the "Delaney clause" was passed by Congress, gross adulteration had been the target. The Act and the "Delaney clause" were never meant to apply to minute amounts of substances. He suggested in particular that the restrictions be relaxed for substances, such as saccharin, which have beneficial results which may outweigh the risks.[72]

Several weeks later, on 27 February, 1979, the American Council on Science and Health released its conclusions based on an extensive epidemiological and laboratory study. This "non-profit" group was composed of 45 independent scientists without any ties to government, industrial firms or consumers' pressure groups. Dr. Elizabeth Whelan of Harvard University declared that the Council agreed in part with the conclusions of the National Academy of Sciences of November 1978, but she and her Council believed that saccharin should be declared safe for human consumption.[73]

Within five days of Dr. Whelan's statement the National Academy of Sciences sent its recommendations to Congress. The Academy urged that the Food and Drug Administration be given greater discretion in carrying out the stipulations of the "Delaney clause". This was consistent with

[69] "NAS Report Tags Saccharin Carcinogenic", *Chemical and Engineering News,* LVI, 46 (13 November, 1978), p. 6.
[70] *Ibid.*
[71] "NAS Saccharin Report Sweetens FDA Position, But Not by Much", *Science,* CCII, 4370 (24 November, 1978), pp. 852–853.
[72] "Delaney Clause May be Changed", *Chemical and Engineering News,* LVII, 8 (19 February, 1979), p. 18.
[73] "Saccharin Wins Support", *The San Francisco Chronicle*, 28 February, 1979.

Commissioner Kennedy's request of February 1979 for such latitude in considering action on food additives. The National Academy of Sciences agreed with the Food and Drug Administration that federal regulation of food "has become complicated, inflexible, and inconsistent".[74] The Academy recommended that Congress should not ban saccharin, and it suggested ways in which the substance might be made available, within limits, to consumers. And on 8 March, 1979, Dr. Wayne Pines, speaking for the Food and Drug Administration, declared that an actual ban on saccharin—if it were to take place at all—should not be enforced until at least 12 to 15 months had passed. He stated that the Food and Drug Administration planned no precipitate action on saccharin when the moratorium expired. There would be plenty of time for Congress and everyone else to look at the whole question of food safety.[75]

As it turned out, Dr. Pines was correct. On 23 May, 1979, the moratorium expired, but no steps were taken to put the prohibition into effect. Dr. Kennedy declared: "There is no possibility that any regulatory action could occur before 15 to 20 months from now".[76]

In late June 1979, the House of Representatives Commerce Committee prohibited the Food and Drug Administration from forbidding saccharin until mid-1981.[77] In September 1979, the Senate also approved the action of the House of Representatives.[78]

At the present time—February 1981—the use of saccharin is assured until May 1981. The results of recent studies, released in December 1979 by the National Cancer Institute and the Food and Drug Administration, indicated that both saccharin and cyclamates "pose a 60 per cent. increased risk of bladder cancer in heavy users".[79] The investigators were careful to conclude that saccharin and cyclamate are not "strong carcinogens but should be considered potential risk factors".[80] They recommended further study to "separate with precision the effects of saccharin and cyclamate".[81]

Other investigations, published as late as 1980, clearly contradicted the National Cancer Institute's claim that saccharin and cyclamate are "potential risk factors". Dr. Alan S. Morrison and Dr. Julie E. Buring of the Harvard University School of Public Health conducted a study of the "relation beween cancer of the lower urinary tract and the use of artificial sweeteners.[82] Five hundred and ninety-two bladder cancer patients and 536 controls were examined. This study concluded that "Taken together

[74] "Study Recommends No Saccharin Ban", *The Fresno Bee*, 3 March, 1979.
[75] " Any Saccharin Ban Won't Happen Soon", *The San Francisco Chronicle*, 8 March, 1979.
[76] "Saccharin Ban", *Los Angeles Times*, 23 May, 1979.
[77] "Extension of Saccharin Life Approved", *Chemical and Engineering News*, LVII, 27 (2 July, 1979), p. 16.
[78] "House Approves Ban on Saccharin Moratorium", *The Fresno Bee*, 26 July, 1979.
[79] "After Reprieve Saccharin Faces New Verdict from FDA", *Los Angeles Times*, 24 January, 1980.
[80] *Ibid.*
[81] *Ibid.*
[82] Morrison, Alan S., and Buring, Julie E., "Artificial Sweeteners and Cancer of the Lower Urinary Tract", *The New England Journal of Medicine*, CCCII, 10 (6 March, 1980), pp. 538–541.

the results to date support the conclusion that the use of artificial sweeteners is not an important risk factor for bladder cancer".[83]

These findings were apparently corroborated by a second survey, also published in March 1980. The authors, Dr. Ernest Wynder and Dr. Steven D. Stellman of the American Health Foundation, presented "data on the relation between artificial sweetener (AS) and diet beverages (DB) use and bladder cancer".[84] A total of 367 patients suffering from bladder cancer was compared with 5,597 patients in a control group. The conclusion was: "No association was found between use of artificial sweeteners or diet beverages and bladder cancer".[85]

When asked about these results, Dr. Robert Hoover, director of the National Cancer Institute, replied, "All this material gives us confidence that there is no need to panic".[86] And yet, Dr. Hoover continued to urge that young children, pregnant women, and the elderly abstain from saccharin use. After a century of controversy, the case of saccharin remains open.

Conclusion

Over the past century, and especially over the last three decades, a bitter dispute over saccharin has developed among scientists and governmental officials. Even with the tremendous advances which have been made in pharmacology and the related medical sciences, a solution seems no closer today than when the findings of Long and Habermann were published in 1949. As recently as 1978–80, distinguished research institutes and hospitals have issued evaluations, based on the findings of careful studies, which are somewhat contradictory. The vast amounts of time, materials, and money which have been devoted to research on saccharin have yielded no incontrovertible results. This situation raises several issues which lie at the heart of the complex relationship between science, government, and society.

Non-scientists in government and in society at large believe that contemporary science, with all of its vast resources, should be able to answer the question: is saccharin injurious to human health? For the layman, science is objective and rigorous; the scientist need only devise the right experiment, and accurate and valid results will come forth. In the case of saccharin, however, this has not been possible. Saccharin was linked with cancer in test animals in 1948–49. Since that time, the scientists themselves have disagreed as to whether or not feeding rats in laboratories with excessive doses of saccharin is a legitimate test of the allegedly carcinogenic nature of saccharin. Many research workers have questioned

[83] *Ibid.*, p. 540.
[84] Wynder, Ernest L., and Stellman, Steven D., "Artificial Sweetener Use and Bladder Cancer: A Case Control Study", *Science*, CCVII, 4436 (14 March, 1980), p. 1,214.
[85] *Ibid.*
[86] Clark, Matt, and Hager, Mary, "Saccharin: Now Safe?", *Newsweek*, XCV, 10 (17 March, 1980), p. 102.

the validity of findings derived from experiments on animals in the laboratory.

As scientists, governmental officials, and consumers began to doubt these conclusions, the focus shifted in 1977 to epidemiological studies of human beings suffering from cancer of the bladder. In some cases, physicians associated the use of saccharin with higher rates of cancer. In other studies no such connection was supported. By 1980, the bulk of epidemiological research has indicated that saccharin has not caused cancer. Still, no final, definitive verdict has been reached because the relationship of environment and genetics to cancer is still poorly understood. When experiments with animals in laboratories have been carried out, saccharin has been "proved" to be carcinogenic. Nevertheless, epidemiological studies of human beings with cancer have tended to exonerate the sweetener as a significant cause of cancer. Even in the epidemiological findings there is still enough ground for doubt so that no categorical answer can be given. Up to the present, medical scientists do not know enough about the causes of the disease to devise a single, uniformly acceptable test to apply to saccharin.

Meanwhile, governmental agencies and consumer groups continue to demand an answer. These groups seek to control dangerous substances and to enforce the regulations issued by the Food and Drug Administration concerning toxic food additives. But even governmental scientists and the research workers conducting investigations on the behalf of independent organisations which purport to represent the interests of consumers have not been able to make a clear-cut decision on the issue. Complicating the controversy are the undeniable benefits which artificial sweeteners provide for diabetics and persons who are overweight. Even if saccharin were proved to be slightly carcinogenic, its controlled use by certain patients might be preferable to a complete prohibition. This is an issue which scientific knowledge alone cannot decide.

No one questions the good intentions of all those currently involved in research on saccharin. But governmental administrators and consumers are wrong to expect science to render an authoritative judgement enjoying the consensus of all qualified scientists, at least not for the present. Similar situations exist at many points where science and the making of governmental policies come together.