

46. Report on 2,4,5-T, p. 65.
47. "PSAC Hiccoughs Over 2,4,5-T," *Nature*.
48. Epstein, *Hearings on Chemicals and the Future*.
49. Nicholas Wade, "2,4,5-T Committee: Bias Untested, Academy Embarrassed", *Science* 173 (1971) p. 611.
50. U.S. Environmental Protection Agency, *Report of the Advisory Committee on 2,4,5-T*, May 7, 1971, p. 69.
51. Constance Holden, "Critics Weigh EPA Herbicide Report, Find it Wanting," *Science* 173 (1971) p. 312; see also: Committee for Environmental Information, "Critique of the Report of the Advisory Committee on 2,4,5-T," *Environment*, September 1971, p. 24.
52. Nicholas Wade, "Decision on 2,4,5-T: Leaked Reports Compel Regulatory Responsibility", *Science* 173 (1971) pp. 610-615.
53. Terri Aaronson, "Gamble", *Environment*, September 1971, p. 21.
54. Dow Chemical Co. v. Ruckelshaus, 477 F. 2d 1317 (C.A. 8th Cir. 1973).

The Politician's Helper: Legitimizing the Cyclamates Decision

It is discouraging to find such conduct among public officials at the very time we are trying to impress upon our young people the importance of law and order.

—Representative L. H. Fountain
on releasing the report of
his subcommittee on federal
regulation of cyclamate
sweeteners.¹

Advisory reports can be suppressed when their results are unwelcome or they can be commissioned as alternatives to facing up to unpleasant decisions, but at least the reports themselves are potentially useful if they get into the right hands—or are they? The case of the Medical Advisory Committee on Cyclamates illustrates dramatically that the advisory system itself can easily be corrupted. In this case, a government official who apparently wanted to give a political decision the appearance of technical legitimacy put together a committee of "experts" who obediently found reasons to tell him—and the public—what he wanted to hear.

Cyclamates were first used commercially as an artificial sweetener of foods in the early 1950s—primarily in special diets for the treatment of such conditions as diabetes. But in the 1960s their use became much more widespread, as the food industry conducted massive TV advertising campaigns extolling "diet" foods and soft drinks while panning over the contours of beautiful slim women.

On October 18, 1969, this commercial success story was suddenly jeopardized. Robert Finch, Secretary of Health, Education, and Welfare, called a press conference and announced:

I am today ordering that the artificial sweetener, cyclamate, be removed from the list of substances generally recognized as safe for use in foods.

Recent experiments conducted on laboratory animals disclosed the presence of malignant bladder tumors after these animals had been subjected to strong dose levels of cyclamates for long periods.

The findings of these experiments form the basis of my action.²

But Finch added that cyclamate-sweetened foods nevertheless would still be available.

My order does not require the total disappearance from the marketplace of soft drinks, foods, and nonprescription drugs containing cyclamates.

These products will continue to be available to persons whose health depends upon them, such as those under medical care for such conditions as diabetes and obesity.

I expect that in the future these products will be labeled as drugs to be consumed on the advice of a physician.³

The facts seem clear from the Secretary's statement: a new and unexpected danger had been discovered, and the government had moved decisively to protect the public from that danger. The government was just doing its job protecting the wholesomeness of the Nation's food supply. A look at the regulatory history of cyclamates both before and after Secretary Finch's announcement tells a much more complex story, however. In this chapter we investigate the role played by outside advisors in the process which (1) led the responsible federal agency, the Food and Drug Administration, to classify cyclamates as "Generally Recognized as Safe" during the period 1958-1969; (2) prompted Secretary Finch to conclude in 1969 that the benefits to "persons whose health depends upon them" outweighed the risks; and (3) led the Department of Health, Education, and Welfare (HEW) to reverse this decision a year later, finally banning cyclamates entirely after most of the cyclamate-sweetened food already on store shelves and in warehouses in October 1969 had been sold.

The Food and Drug Administration and the National Academy of Sciences

The use of cyclamates as a food additive became established in an era when such chemicals were given the benefit of the doubt. In the early fifties the burden was on the Food and Drug Administration (FDA) to prove that food additives were unsafe in order to force their withdrawal from use. But the agency was not

looking for fights with the food industry. Unless there were blatant adverse health effects from a food additive, the FDA was inclined to look the other way. This is what happened with cyclamates.

In 1958, with passage of the Food Additives Amendment to the Federal Food, Drug, and Cosmetics Act, manufacturers of food additives were required to prove to the FDA that their products were safe—unless a food additive was

generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in foods) to be safe under the conditions of its intended use.⁴

This exemption led to the compilation by the FDA of a "Generally Recognized as Safe" (GRAS) list of food additives.

The advice that the FDA had received from the Food and Nutrition Board of the National Academy of Sciences' National Research Council (NAS-NRC) would not appear to imply that cyclamates were generally recognized as safe. The Board's 1954 advisory report concludes:

The Board is impressed with the fact that cyclamate has physiologic activity in addition to its sweetening effect, that there is no prolonged experience with its use, and that little is known of the results of its continued ingestion in large amounts in a variety of situations in individuals of all ages and states of health. The priority of public welfare over all other considerations precludes, therefore, the uncontrolled distribution of foodstuffs containing cyclamate.⁵

But the FDA decided that a careful look at the health effects of cyclamates was not required and included cyclamates on the "Generally Recognized as Safe" (GRAS) list along with several hundred other food additives and common household seasonings.

The food industry had a strong economic incentive to maximize its use of cyclamates: cyclamates provide sweetening power at about one-tenth the price of sugar, and the label "diet drink" or "diet food" had obvious appeal to weight-conscious Americans. The FDA's action in placing cyclamates in the same category of safety as sugar, salt, and cornstarch was understood by the industry as permission to go full speed ahead. The advertising men were unleashed, and national consumption of cyclamates skyrocketed from about 1 million pounds in 1958 to about 17 million pounds in 1968.⁶

The FDA was somewhat taken aback by this tremendous increase in the use of cyclamates. In 1962 the NAS-NRC Food and Nutrition Board was asked to look once again into the safety of cyclamates. The conclusion of its report was the same as before.

The priority of public welfare over all other considerations precludes, therefore, the uncontrolled distribution of foodstuffs containing cyclamate.⁷

The report added:

It is emphasized strongly that the availability and consumption of artificially sweetened foodstuffs have no direct influence on body weight, nor are the foodstuffs in question of any importance in weight reducing programs except as they are used in feeding regimens in which the total energy intake is supervised and controlled.⁸

This statement reflected evidence that cyclamates may actually be an appetite stimulant⁹ and, of course, directly contradicted the claims then being made in the massive advertising campaigns promoting the consumption of cyclamate-sweetened foods and drinks.

Although the new NAS-NRC report did not cause the FDA to remove cyclamates from the GRAS list, it has been credited with stimulating research into the possible adverse effects of cyclamates.¹⁰ As the 1960s went on, this research turned up increasing evidence for a long list of serious side effects associated with cyclamates use, ranging from major changes in the actions of drugs in the presence of cyclamates to growth retardation, liver damage, chromosomal damage, and birth defects.¹¹

In 1968 the FDA repeated its ritual of asking the NAS-NRC for a review of the safety of cyclamates. Once again the ritual response came back that "totally unrestricted use of the cyclamates is not warranted at this time."¹² It was now fourteen years since the FDA had first received this warning, and the scientific evidence for adverse effects had mounted to the extent where there was considerable concern about cyclamates in the medical and scientific divisions of the FDA. Congressional staffers investigating in 1970 turned up a number of internal memoranda dating from late 1968 urging higher-ups to take cyclamates off of the GRAS list.¹³ Foods and drinks containing cyclamates had become a billion-dollar-a-year business,¹⁴ however, and the FDA brass apparently relished less than ever the prospect of the bruising confrontation with industry which would have developed if an attempt had been made at that time to remove cyclamates from the GRAS list. As one internal FDA memorandum stated in September 1967:

We cannot say today that the cyclamates are generally recognized as safe; however, removing them from the GRAS List and establishing tolerances in soft drinks, *et cetera*, will produce difficult problems.¹⁵

The Congressional subcommittee which in 1970 investigated the handling of the cyclamates affair summarized the situation as it stood before October 1969 as follows:

It was evident at least as early as 1966 that there was a genuine difference of opinion among qualified experts as to the safety of cyclamate sweeteners. Consequently, FDA had an obligation at that time to remove cyclamates from the GRAS List, to declare them to be a "food additive" within the statutory definition, and to ban their use until industry had established their safety. But despite the mounting evidence in the ensuing years, FDA did not act.¹⁶

The Sugar Research Foundation and the Delaney Amendment

Action was finally forced in October 1969 by an initiative from within the food industry itself. The sugar industry had not enjoyed seeing cyclamates taking over its market and had funded research on the side effects of this food additive through its Sugar Research Foundation. The research eventually led to the conclusion that cyclamates produce bladder cancer in rats.¹⁷ This discovery activated a section of the Food Additives Amendment, the "Delaney Clause," which specifies

that no additive shall be deemed to be safe if it is found to produce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.¹⁸

In other words the FDA now had no choice but to ban cyclamates as a food additive.

Thus followed the October 1969 announcement made by HEW Secretary Finch (within whose Department the FDA resides). Finch, a long-term political associate of President Nixon, anticipated the cries of anguish from the food industry and did the best he could to soften the blow. He promised that cyclamate-sweetened foods and drinks could continue to be sold if they were relabeled as "nonprescription drugs" and moved to appropriate supermarket shelves. He also promptly accepted the suggestion by the fruit canning industry, which had just completed its canning season in his home state of California, that the deadline for removing foods containing cyclamates from the market be postponed seven months.¹⁹ He even went so far as to initiate efforts to repeal the Delaney clause.²⁰

Secretary Finch's Medical Advisory Committee on Cyclamates

Having publicly promised that cyclamate-sweetened foods would remain available as nonprescription drugs, Finch found himself in an uncomfortable position. The FDA—which was legally responsible for the registration of new drugs—pointed out that registering these products as drugs would probably be illegal, for drugs are required by law to have been shown by their manufacturer to be safe and to be effective against some disease. But in the words of an internal FDA position paper:

We are aware of no evidence that cyclamate-containing foods are safe or effective in the treatment of obesity or diabetes. Under the principles we

strongly adhere to in permitting drugs to be marketed, these products should not be allowed on the market. To approve a New Drug Application for these products is not supportable medically or legally.²¹

Finch was committed, however. If he couldn't get the FDA's blessing, then he would find other experts. The Secretary's Medical Advisory Committee on Cyclamates was duly set up, made up in almost equal numbers of HEW administrators (Finch's subordinates) and outside specialists.²² And after due consideration of the evidence submitted to it by the FDA, the committee gave Finch the advice he wanted:

Although the use of cyclamates is not absolutely necessary in any disease, it can be useful in the medical management of individuals with diabetes or patients in whom weight reduction and control are essential to health. Particularly in juvenile patients who have diabetes, where sweets and soft drinks are a special problem, non-nutritive sweetened foods may be an essential part of preventative therapy.²³

The advisory committee also gratuitously informed the Secretary of their support on another point. They advised that foods and drinks containing cyclamates remain available "on a non-prescription drug-labeled basis to be used only on the advice of a physician."²⁴

Unfortunately for the committee—and the Secretary—this recommendation was to cause trouble. Not only did it violate common sense to put a medicine which was "to be used only on the advice of a physician" into the category of nonprescription drugs, it also violated the specific requirements of the Federal Food, Drug, and Cosmetics Act which defines a prescription drug as

a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, other methods of its use, or other collateral measures necessary for its use, is not safe for use except under the practitioner licensed by law to administer such drug.²⁵

It is puzzling why a committee made up entirely of M.D.s took a position that it must have known was indefensible. The only obvious advantage from such a recommendation would accrue to the distributors of cyclamate-sweetened foodstuffs, who would be able to continue to deal with their customary grocery store outlets.²⁶ But most people would agree that such considerations are outside the province of a medical advisory committee.

The Congressional Investigation

If it had not been for a group of "Nader's raiders," the story might have ended here. In early 1970, a report of a Ralph Nader summer study group on the FDA was released: *The Chemical Feast* by James S. Turner. A study of the background of Secretary Finch's cyclamates decision was the book's featured

attraction—Chapter One. The discussion quoted extensively from the FDA's files and was based also on interviews with FDA personnel. An excerpt will indicate the message:

The dramatic removal of cyclamates from the marketplace was necessary because the FDA failed to do its job. It did not heed the frequent early warnings against the general use of cyclamates made by the scientific community. It did not periodically and systematically review the safety of substances on its GRAS list. It dismissed or distorted the warnings of its own scientists. Secretary Finch compounded these failures by ignoring the accumulated doubts about cyclamates and minimizing the importance of removing the chemical from the market rapidly. He did not connect this removal with the legal requirement that all chemicals must be proved safe before being added to food. He never mentioned evidence that birth defects and genetic damage that were related to cyclamates in tests on laboratory animals are a more serious danger than cancer. And he denied the importance of free scientific inquiry, expression, and interchange between scientists and the public. . . . By attempting to avoid, then delaying and finally distorting the ban on cyclamates, the FDA and Secretary Finch undermined confidence in the American Food supply and left the impression that neither government nor industry is primarily concerned with protecting the public interest.

The impression is quite accurate.²⁷

The charges contained in *The Chemical Feast* helped bring about a Congressional investigation of the FDA's handling of the cyclamates affair by the Intergovernmental Relations Subcommittee of the House Committee on Government Operations. The subcommittee is headed by conservative North Carolina Democratic Representative L. H. Fountain. The staff of Fountain's subcommittee did a thorough study of the FDA's records relating to the matter and explored a number of aspects of the affair which the Nader report had failed to develop—the role of the Secretary's Medical Advisory Committee on Cyclamates in particular.

When newly appointed FDA Commissioner Edwards came before the subcommittee, Congressman Fountain did not mince words:

I believe that this subcommittee can, within the limitations of time and staff, render a public service in reminding you, Dr. Edwards, and your associates, that the role of FDA is to enforce the [Food, Drug, and Cosmetic] act fully and effectively. All of the sections of the law are important, and Congress did not, and I believe does not now want any of them to be put in limbo, as I am sure some people would like.²⁸

This opening statement was then followed by relentless questioning of Edwards and his subordinate administrators by Fountain and two members of his subcommittee staff, Gilbert Goldhammer and Dr. Delphis Goldberg. Memorandum after memorandum from the FDA files and addressed by FDA's medical and scientific staff to its administration were introduced. In these memoranda the adverse health effects of cyclamates were repeatedly set forth as a basis for removing cyclamates from the GRAS list. As the documents piled up, Edwards

and his staff offered an ever weaker defense of the FDA's record, until finally Fountain squeezed this admission from Edwards:

I think without any question the cyclamates could have been removed from the GRAS list earlier than they were. I am not prepared, Mr. Chairman, to say specifically when, but I think it could have been done considerably sooner than it was.²⁹

The FDA officials *did* defend Finch's decision to relabel cyclamate-sweetened foods as nonprescription drugs, but Fountain's subcommittee was not persuaded. In a report to the House based on the hearing record, Finch's role in the cyclamates affair was described as follows:

The Secretary of Health, Education, and Welfare announced on October 18, 1969, that prohibition of further marketing of cyclamate-containing products as foods was required by the Delaney Clause. The Secretary announced at the same time that continued marketing of cyclamate-containing products as non-prescription drugs would be permitted. FDA was then called upon to implement this decision, which the agency sought to do through *illegal regulations and procedures*. The basic cyclamate decisions were made in the Secretary's office despite the fact that responsibility for enforcing the Federal Food, Drug, and Cosmetic Act had been delegated to the FDA Commissioner. [Emphasis added.]³⁰

The Medical Advisory Committee Meets Again

Just before the June 1970 Congressional hearing, Finch was replaced as HEW Secretary and appointed Counselor to President Nixon, a position in which he quickly faded into well-deserved obscurity. And with Finch out of the way, HEW moved to extract itself from its increasingly untenable position on cyclamates. The way in which this was done was true to form. HEW reconvened the Medical Advisory Committee and asked it to reconsider the safety and effectiveness of cyclamates. The response to this request was dramatic to say the least: the committee reversed itself completely. It explained its change of mind by citing "new information" on the production of bladder tumors in rats with doses of cyclamates comparable (relative to body weight) to those consumed by heavy cyclamate users. The committee added that

the literature provided to the group does not contain acceptable evidence that cyclamate has been demonstrated to be efficacious in the treatment or control of diabetes or obesity.³¹

The committee offered no explanation for this direct contradiction of its previous assertion that cyclamate-sweetened foods may be an essential part of preventative therapy with juvenile diabetics. Cyclamates were thereupon totally banned.

Representative Fountain was not through, however. His subcommittee staff

investigated the matter again and established that the evidence which had been cited by the Medical Advisory Committee as "new" had in fact already been referred to in its original report.³² Indeed, little had changed in the interval between the Committee's two meetings other than the political pressures on HEW generated by the Fountain subcommittee hearings. The subcommittee's final report did not conceal its disdain at the way in which HEW had used its Medical Advisory Committee:

HEW used an outside advisory body to make recommendations on matters which had already been decided, involving a basic issue which the advisory body was not qualified to decide.

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 FDA's medical staff in reaching a contrary conclusion. The advisory group, moreover, was not qualified to determine the real issue—whether the law permitted implementation of the Department's announced decision to permit continued marketing of cyclamates.

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. The evidence on which the panel reversed its earlier recommendations was known and available to the group when it was originally convened.³³

HEW responded in kind by issuing a press release which claimed to rebut the Congressional report and concluded by stating that "its [the subcommittee report's] interpretation of the facts and the law in this instance are erroneous."³⁴ When Fountain requested Dr. Edwards to explain in person to the subcommittee the error in its interpretation, however, Edwards put on a rather pathetic performance.³⁵

The prostitution of the advisory committee system in this case is obvious and needs no further comment. Another point worth noting, however, is the remarkable ineffectuality of the NAS-NRC Food and Nutrition Board in its fourteen years of advising on the cyclamates issue. It makes one wonder why such advisors keep coming quietly back.

NOTES

1. Quoted by R. J. Bazell, "Cyclamates: House Report Charges Administrative Alchemy at HEW," *Science* 170 (1970): 419.

2. Quoted in U.S. Congress, House, Committee on Government Operations, *Cyclamate Sweeteners*, 91st Congress, 2nd Session, June 10, 1970. p. 27.

3. *Ibid.*
4. Quoted in U.S. Congress, House, Committee on Government Operations Report, *Regulation of Cyclamate Sweeteners*, 91st Congress, 2nd Session, House Report No. 91-1585, October 8, 1970, p. 3.
5. National Academy of Sciences-National Research Council Food and Nutrition Board, *Policy Statement on Artificial Sweeteners* (Washington, D.C.: National Academy of Sciences, November, 1954), pp. 7-8.
6. U.S. Department of Agriculture figures, reprinted in *Cyclamate Sweeteners*, p. 63. The price relative to sugar is quoted on p. 6.
7. NAS-NRC Food and Nutrition Board, *Policy Statement on Artificial Sweeteners* (Washington, D.C.: National Academy of Sciences, revised April 1962), p. 7.
8. *Ibid.*, p. 4.
9. A study by M. B. McCann, et al., *Journal of the American Dietetic Association* 32 (1956): 327, found "no significant difference . . . when the weight loss of users and nonusers of these products [artificial sweeteners] was compared." A later controlled experiment with rats by L. M. Dalderup and W. Visser, "Effects of Sodium Cyclamate on the Growth of Rats Compared With Other Variations in the Diet", *Nature* 221 (1969): 91, found that "sodium cyclamates in the quantity given [replacement for sugar in ordinary diet] seems to stimulate appetite, and thus a rise in weight. It is surprising that the food efficiency [weight gained per calorie consumed] is also higher." Both articles are quoted in *Cyclamates Sweeteners*, pp. 64-68.
10. Report by John J. Schrogie, M.D., October 1969, reprinted in *Cyclamate Sweeteners*, pp. 4-5.
11. See e.g., the FDA reports reproduced in *Cyclamate Sweeteners*, pp. 18-21 and 82-84.
12. Quoted in FDA memorandum reproduced in *Cyclamate Sweeteners*, pp. 18-21.
13. Quoted in *ibid.*, pp. 17-21.
14. *New York Times*, October 19, 1961, p. 1.
15. Quoted in *Cyclamate Sweeteners*, p. 22.
16. *Regulation of Cyclamate Sweeteners*, p. 5.
17. The sequence of events which led to this conclusion is recounted in a letter to Representative L. H. Fountain (D.-N.C.) from R. W. Kasperon, vice-president of Abbot Laboratories, a manufacturer of cyclamates. The latter is reproduced in *Cyclamate Sweeteners*, pp. 98-103.
18. Quoted in *Regulation of Cyclamate Sweeteners*, p. 4.
19. James S. Turner, *The Chemical Feast: Ralph Nader Study Group Report on Food Protection and the Food and Drug Administration* (New York: Grossman Publishers, 1970) p. 19. See also *New York Times*, October 23, 1969, p. 36.
20. See the story by G. C. Thelen, Jr., *Washington Post*, June 10, 1970, reproduced in *Cyclamate Sweeteners*, pp. 35-36, and the discussion there (pp. 34-36) between Representative Fountain and FDA Commissioner Edwards concerning the allegations in the article. See also *New York Times*, November 6, 1969, p. 5.
21. Quoted in *Cyclamate Sweeteners*, pp. 68-69. See also the discussion following p. 69.
22. The membership of the Medical Advisory Committee is given in *ibid.*, p. 40.
23. Quoted in *ibid.*, p. 89. The entire first report of the Medical Advisory Committee is reprinted in *ibid.*, pp. 86-90.
24. Quoted in *ibid.*, p. 87.
25. Federal Food, Drug, and Cosmetics Act, Section 503(b)(1)(B) (21 U.S.C. 353(b)(1)(B)). Quoted in *ibid.*, p. 91.
26. See the discussion on this point between Representative Fountain and FDA spokesmen quoted in *ibid.*, pp. 91-93.
27. Turner, *The Chemical Feast*, p. 29.
28. *Cyclamate Sweeteners*, p. 1.
29. *Ibid.*, p. 24.
30. *Regulation of Cyclamate Sweeteners*, p. 15.

31. The second report of the Medical Advisory Committee on Cyclamates is reprinted in U.S. Congress, House, Committee on Government Operations, *The Safety and Effectiveness of New Drugs (Market Withdrawal of Drugs Containing Cyclamates)*, 92nd Congress, 1st Session, May 3, 1971, pp. 20-27. This reference is hereafter referred to as *Safety and Effectiveness of New Drugs*. The lines quoted appear on p. 21.
32. *Regulation of Cyclamate Sweeteners*, pp. 12-13.
33. *Ibid.*, p. 16.
34. U.S. Department of Health, Education, and Welfare, *HEW Position Paper*, reprinted in *Safety and Effectiveness of New Drugs*, p. 17.
35. *Ibid.*, p. 15ff.