Delaney Clause: Defended against an Uncertain Threat of Change

Anything that causes cancer in man or in animals should not be added to food. Certainly that proposition sounds reasonable enough. In 1958, it sounded so reasonable to Congress that it became law—a provision of the Food, Drug, and Cosmetic Act that is known as the Delaney amendment, or more correctly, the Delaney clause. The provision has been an object of considerable controversy ever since.

The many, and often passionate feelings people have about this anticancer clause were most recently on display during a 2-day workshop on "The scientific basis for the Delaney amendment" sponsored by the New York Academy of Sciences. Approximately 125 scientists and lawyers of various persuasions, food industry representatives, and consumer advocates engaged in heated debate in a moderate-sized room that barely contained them. Their encounter was as political as it was scientific (underneath, at least), and it quickly became apparent that the real issue was not whether there is a scientific basis *for* the Delaney clause, but whether there is a scientific basis for changing it. For all practical purposes, the Delaney clause states that no substance can be added to food if it causes cancer in any animal at any dosage. Critics of the amendment as it is written argue that it is so definitive, so black and white, it leaves no room for scientific judgment. Its proponents do not accept this point of view.

A number of those who showed up for the New York workshop arrived convinced that the law might be changed during this session of Congress. Although organizers were loath to admit it for the record, the workshop, which was hastily arranged as far as New York Academy meetings go, was put together to head off at the pass any move to soften the anticancer clause. It probably succeeded, at least for the present.

Ardent defenders of the present law had two reasons for anticipating a heated battle in Congress this year. They believe that the food industry is planning a major campaign to convince congressmen that the Delaney clause is too stringent. Even though many industry representatives at the meeting called such suspicions nonsense, the pro-Delaney group leaned on the anticipated boom in the food industry to add a touch of cold logic to its argument. According to economic forecasters, including Richard L. Hughes of Arthur D. Little, Inc., the demand for food additives is rising sharply as the market for processed convenience foods expands. Hughes, a year ago, estimated that food additives comprise a $500 million per year business. By 1980, he predicts, food additive sales will reach $756 million.

According to Senator Gaylord Nelson (D–Wis.), the industry itself estimates that "the average American eats 5 pounds of additives every year."

There is no question that the tests which must be performed to demonstrate the safety of food additives are costly and time-consuming for industry. Certainly, many persons in industry would like to see the law toned down to permit certain chemicals in such small doses that they might be presumed to be harmless. But industry people persistently denied suggestions that they have been trying to pressure Congress into seeing it their way. Delaney supporters simply do not believe this. They may have reason.

Food Lawyers Favor Status Quo

Although the food industry appears to recognize defeat for now, there is evidence that it has not given the matter up for good. Earl I. Lambert, an attorney with Covington and Burling, a leading Washington law firm that represents many major food industry associations and food companies, summed things up when he said at the conclusion of the meeting, "On the basis of the evidence presented, I don't see any practical basis for a change in the Delaney clause at this time."

Against the possibility of a change in the status quo in a couple of years, one of the leading food industry trade groups has formed a subcommittee to gather all the data it can on the Delaney clause and potentially related scientific advances. The group, whose identity has been successfully concealed thus far, is said to be afraid that the public will misunderstand its intent if word gets out about what it is doing.

As if the veiled threat from industry were not enough, advocates of the present law recently found their stance challenged by no one less than Charles C. Edwards, commissioner of the Food and Drug Administration (FDA), which administers the law. (Edwards is expected to leave the FDA soon to become assistant secretary for health in the Department of Health, Education, and Welfare.) Edwards has made no secret of the fact that he thinks there should be some thought given to an eventual change in the law. Essentially, he has said that science has "outstripped" the law in that it is now possible to detect minute quantities of potentially harmful substances in food but it is not possible to actually say whether these amounts are, in fact, dangerous.

Acknowledging that it would be politically foolhardy for the FDA to initiate changes in the law, Edwards has called for an international conference to review the scientific merits of the case.

The academy workshop beat him to it. Edwards was invited to participate in the New York meeting. Organizers, including Irving J. Selikoff, an authority on environmental carcinogenesis at Mount Sinai School of Medicine in New York and a governor of the academy, say that he was invited "repeatedly" to come himself or to send a surrogate. Although there were a couple of FDA employees at the meeting, apparently neither was officially representing the agency.

Edwards denies that either he or his aides were boycotting the academy workshop. On the basis of what he heard at second hand about it, he said, "I think it probably was a pretty good meeting for a first." But Edwards thinks that the whole issue of risk versus benefit needs to be debated more—"not just in the New York Academy of Sciences." He is hoping that some large, nonprofit foundations can be convinced to sponsor a long-term study of the question as it applies to food additives and drugs and to devices and procedures, such as coronary artery grafts.

Edwards personally thinks that the FDA will have to establish a dose-response curve for food additives even-

tually, but he is not "pushing" for the present. "I really don't know how Delaney should be changed," he says.

The question of "how" seems to be the crux of the matter. A significant number of scientists believe that the Delaney clause is too rigid, that it is not really scientifically defensible. But when it comes to proposing an acceptable alternative, they are stuck with the fact that that means establishing some kind of threshold. There is general consensus that the state of the art is not up to that at the moment. Establishing a threshold is a no-win issue. As one investigator put it, "I feel, in a biological sense, that there must be a threshold." But it is hard to translate that into specific experimental procedures and limits for analysis. He astutely calls the Delaney clause "scientifically hard to live with but morally hard to argue with."

—BARBARA J. CULLITON

Arms Control: White House Whittles Down Peace Agency

The White House apparatus for enlisting outside advice on arms control and defense matters has been thrown into a state of flux and the shape of the rescue effort, if there is to be one at all, is far from clear. The Arms Control and Disarmament Agency (ACDA) has recently been dealt two body blows, which, although less than fatal, suggest a sudden coolness in the White House's affection for the agency. The President's Science Advisory Council (PSAC), formerly a source of arms control advice, has long been moribund and awaits only a decent burial. Apart from the considerable expertise available to the intelligence agencies, it may be that the main channel for independent scientific advice to reach the White House will be via Henry Kissinger's private brain trust.

ACDA's two misfortunes are a 33 percent cut in its new budget and loss of the chairmanship of the U.S. delegation to the strategic arms limitation talks (SALT). White House spokesmen deny that the agency is being downgraded.

The savings made in ACDA's budget, which Senator William Proxmire (D–Wis.) points out will amount to about a third of the price of a single F-14 airplane, will fall chiefly on the agency's external research program, and there will also be a small loss of staff.

More serious in terms of influence is ACDA's apparently reduced role in the SALT talks. Until his resignation last month, Gerard C. Smith was both head of ACDA and chairman of the American delegation to the SALT talks. The White House has now decided to separate the two jobs, on the grounds that the SALT negotiator is too often abroad to be able to run ACDA as well. The new negotiator, Under Secretary of State U. Alexis Johnson, is considered likely to be a temporary appointment because of his age (64) and relative inexperience in dealing with arms control issues. It is not yet known who will be head of ACDA or whether the top staff, who have turned in their resignations, will be replaced. A report current in Washington is that the agency was offered to Harold Agnew, director of the Los Alamos Scientific Laboratory where nuclear warheads are designed. Agnew, who is said to have refused the offer, declined to comment.

While it is too early to tell the White House's intentions for ACDA—much will depend on who the new director is—the present prognosis is gloomy. The possibility of further moves against the agency seems to have at least been discussed within the White House. One hypothesis is that Nixon is downgrading ACDA as a sop to the conservatives. Another conjecture is that he wishes to have all advice on arms control matters concentrated within the White House.

If ACDA is to be dissolved, whether outright or in practice, relatively more importance may be attached to certain informal channels of advice. Although PSAC is just about over with, the National Security Council has received advice on arms control matters from various PSAC panels, although not on an institutionalized basis, and from selected individuals. A group of Cambridge scientists and others, which serves as a kind of private brain trust to presidential adviser Henry Kissinger, has been active in the past and may be so again.

The brain trust is chaired by Paul M. Doty, professor of chemistry at Harvard, and apparently evolved out of another Cambridge-based organization, the Soviet-American Study Group. The study group, which is affiliated with the American Academy of Arts and Sciences, meets once every 6 weeks and, about once a year, meets with a counterpart group in the Soviet Union. Its purpose is to discuss long-range problems of arms control, rather than day-to-day negotiating positions.*

Kissinger is a former member of the study group but resigned on joining the Administration. There is no formal relationship between the study group and the Kissinger brain trust other than an overlap of membership. The brain trust is said to have been concerned almost exclusively with matters arising out of the SALT negotiations.

In recent weeks, Kissinger has been preoccupied with Vietnam, and arms control matters have hung fire. Whatever machinery emerges for handling the second round of SALT talks, proponents of arms control are anxious for ACDA to continue to play a front-line role. The agency played a crucial part, as they see it, in helping the first round of SALT talks to fruition. Many of the significant papers in the first round were drafted jointly by ACDA and the Office of the Secretary of Defense. The agency formed a necessary counterbalance to the military, both in providing analysis and in the interagency discussions—part of the Kissinger system for educating the bureaucracy in arms control positions (such as the SALT concession allowing the Soviets 62 missile submarines to the United States' 44).

Most of the relevant material is classified, hence without a group such

* Present members of the Soviet-American Study Group include Paul Doty, chairman, Benjamin Brown (Harvard), executive secretary, Richard Garwin (IBM), Carl Kaysen (Princeton), Franklin A. Long (Cornell), Wolfgang Panofsky (Stanford), George Rathjens (M.I.T.), Jack Ruina (M.I.T.), Marshal Shulman (Columbia), Louis Sohn (Harvard), Jerome Wiesner (M.I.T.), and Cyrus Vance, former U.S. negotiator at the Paris peace talks.