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"Beyond this, we have totally streamlined FDA's organization and, through the Office of the Assistant Secretary for Health and Scientific Affairs, made it directly responsible to the Secretary."

See also comments
of Delaney, 5/18/70
Food Chem News
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FINCH WEIGHING SIX "OPTIONS" ON THE DELANEY CLAUSE

Health, Education and Welfare Secretary Finch is weighing six alternative "options" - - not necessarily mutually exclusive - - in his approach to doing something about the Delaney Clause of the Food Additive Law which bars clearance for substances which may cause cancer in man or laboratory animals.

But regardless of what decisions are made on the six possible approaches, Finch told the Pharmaceutical Manufacturers Association in Boca Raton, Fla., on April 10 that his Department will seek some kind of modification of the Delaney Clause.

Most of his speech was devoted to the Delaney Clause, and he summed up his argument for modification of the provision, as follows:

" . . . where a carcinogen is unavoidable in the food supply or is essential in the diet, we must be in the position - - if responsible scientists say it can be done - - to establish a level for the substance in the diet that, on the best available evidence, is judged to be without hazard to man. And to exercise that careful and informed discretion, we must have new legislation."

The Secretary invited all interested parties to participate in selection between the six options which he presented. The options are:

"(1) We could hold to the present law and continue to deal administratively with cancer-producers that unavoidably get into food."

"(2) We could propose that the Delaney Clause be extended, to apply to irreversible effects in addition to carcinogenesis - - to liver, brain, and heart damage, for example, and to mutagenesis and teratogenesis. And, as a sub-option, we could propose that HEW might be permitted to set tolerance-levels for all these substances when there is a compelling reason to do so."

"(3) We could apply the principle of the Delaney Clause to all foods - - not just to additives but also to substances naturally present. And by recognizing that certain carcinogens are unavoidable and some essential to human health and nutrition, we could accept these facts of life and surround them with most stringent safeguards."

"(4) Legislation could provide for periods of limited approval of additives, during which time the effects on man would be carefully tested and closely scrutinized. Any significant doubt as to safety would terminate the limited approval."

"(5) We could require that any additive be proved useful to the consuming public before approving its use."

"(6) We could provide, by law or administrative action, for a periodic review of detailed test procedures - - the updating of minimum standards to be applied in establishing the safety of food additives."

Stressing his determination, Finch said, "Make no mistake about it: we definitely intend to work with the Congress to improve and to strengthen and update the Delaney Clause." He invited PMA's "responsible participation . . . from the very start of the decision-making process." Noting the cyclamate controversy, the Secretary said, ". . . by inviting every interested group and every expertise to climb aboard at the take-off, we intend to minimize the risk of crash-landings."

Stressing that "we are going to introduce legislation," Finch said he will choose between the options "based in overriding concern for the public health and safety." He emphasized that "the final choices have not yet been made," adding: ". . . as we sense the mood of the Congress, there will be no tolerance on the Hill for proposals that do not measure up to the best of our present scientific capabilities . . . and to an abiding concern for human health and welfare."

Despite his desire to revise the Delaney Clause, Finch endorsed "the fundamental principle of the Delaney Clause," which, he said, is "that it is rational to bar substances that cause cancer in test animals, if there are acceptable alternatives . . ." Thus, he made it clear he wants discretion to clear potential carcinogens only if they are unavoidable or essential.

Recalling the cranberry incident during the Eisenhower Administration, when HEW Secretary Flemming took action against cranberries containing amino-triazole under the Delaney Clause, Finch said the question is whether Flemming's "options (should) have been so limited as to preclude any response between the extremes of 'all yes' or 'all no.'" Finch asked, "Should there be room also for degrees and gradations of judgment . . . for calculations of risks weighed against benefits?"

The Secretary continued that, ". . . we simply do not know what precise amount of a chemical that produces cancer in test animals will produce cancer in man - - nor, indeed, do we know whether it will produce cancer or any other serious disease or illness." He added:

"But the state of the art has advanced in quantum leaps during the decade - - and so have refinements in test procedures and thus our capability to weigh risks and benefits. We now know that there are chemicals in the environment and in our food supply that, in certain concentrations, can be hazardous to health. There are unavoidable carcinogens so widely spread that we cannot eliminate all traces of them and still have an adequate food supply - - substances like selenium in wheat, arsenic in shrimp, and benzopyrene in some smoked and broiled

foods. Some unavoidable carcinogens may even be essential to human health, in the right amounts and concentrations."

Finch attempted to "eradicate" two "public myths" about "food chemicals." He said these are (1) "the public myth that food chemicals can be grouped, in some simple way, as 'toxic' and 'non-toxic' - - apart from the circumstances of their use;" and (2) "the equally mythical distinctions between natural substances and chemical substances - - because, of course, foods are nothing but chemicals."

Regarding the "option" of retaining the Delaney Clause as it stands, Finch raised the objection that "we are fast approaching the time when we can find traces in foods of many chemicals that are present in the environment, even though not directly applied to foods." Handling the matter of unavoidable carcinogens administratively, the Secretary said, would face HEW "with a succession of crises and crash-decisions - - whenever these trace substances were found to cause cancer when fed to test animals." This, he said, would lead to "public apprehension, hurried and ad hoc governmental response, and severe market dislocations . . ."

Regarding a possible extension of the Delaney Clause to other hazards in addition to carcinogenesis, with tolerance-setting powers, Finch said this would give "greater administrative flexibility - - where, for example, minute traces of teratogens were found to be present in foods." This broadening of the Clause, he said, "would broaden and strengthen present law" and "proceeds from the premise that potential victims of more than just cancer should also be protected . . ."

Discussing the option of applying the Delaney Clause principle to "foods," including natural substances, Finch said this would recognize "that the effects of natural substances and additives may be identical - - and that some substances present in foods may be simultaneously hazardous and essential to human well-being." As an adjunct to this approach, the Secretary said, "the law could be framed to permit and indeed to mandate the convening of panels of experts - - with stringent safeguards against conflicts of interest - - to give authoritative advice about the substance in question." Finch explained:

"Such a panel . . . would first advise whether a non-hazardous level could in fact be established for a particular substance. Then, if he judged it in the public interest, the HEW Secretary might set such a level - - as close to zero as possible, and if the substance were unavoidably present. He would be dealing rationally and authoritatively in situations that predictably will arise in the years ahead. Scientists are not now capable of setting precise levels, of course, above which teratogenesis and mutagenesis will occur and below which they will not. But in some situations - - with appropriate dose-response curves and a threshold