

MAR 6 1970

March 4, 1970


Mr. Carrol S. Weil
Mellon Institute
4400 Fifth Avenue
Pittsburgh, Pennsylvania 15213

Dear Carrol:


After hanging up from our telephone conversation yesterday, I re-read our statement for MCA on the Delaney Clause, and concluded that your comments were well conceived. Consequently, I deleted some of the preamble and reorganized some parts of the statement and sent it on to Taylor Hanavan. He has agreed. A copy of the new version is enclosed.

Thanks for your comments, Carrol.

Sincerely,


John P. Frawley, Ph.D.
Chief Toxicologist

JPF:vvh
Enclosure

cc: Taylor Hanavan


GENERAL LEGAL

PERMANENT
TEMPORARY

ASI 00002405

Section 409 (c) (3) of the Federal Food, Drug, and Cosmetic Act states that "No such regulation shall issue if a fair evaluation of the data before the Secretary -

- (A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulations, will be safe."

There follows a proviso, the so-called Delaney Amendment, which states,

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

The Act as presently constituted imposes a per se concept so that the Secretary by statute is precluded with respect to cancer from exercising any reasonable scientific judgment on the question of toxicologically significant hazard or risk to man. Yet the legislative history of the Act and experiences thereunder demonstrate the fallacy of a per se approach to a scientific question of this type. The 1938 Act in effect imposed a per se concept that ~~a~~^{any} substance which was found harmful or deleterious at some level was prohibited from use at any level. However, experience over the years demonstrated that such a non-scientific approach was unreasonable and unnecessary. With the Food Additives Amendment of 1958, Congress recognized the need for reasonable scientific judgment in the evaluation of safety by authorizing the Secretary to establish safe limits of a substance for man even where such substance was found to cause in animals a chronic or acute toxic response at a higher level or levels. Yet in 1958, Congress reimposed the per se concept with respect to cancer; despite the fact that past experience had demonstrated it to be unworkable. ^{The pyrazolobenzimidazole case} The recent cyclamate experience confirms the unworkable nature of the Amendment, if it is interpreted in a literal or strict sense.

Because of scientific advances, the continued existence and enforcement of the Delaney Clause poses a serious threat to production of food and to the development of new products which would contribute to food technology and quality of the food supply. With today's analytical procedures, almost any substance in some quantity is capable of detection by highly refined analytical equipment and methods sensitive to parts per billion and even parts per trillion. Coupled with this is the fact that our biological scientists have developed unique toxicological testing techniques that given the right species, dosage form, timing and method of administration, almost any substance can be found to induce a tumor of some type whether benign or malignant - a result which, however meaningless, might require the Secretary to refuse approval or to ban the additive involved. Strict application of the Delaney Clause could force the Secretary to ban hundreds of food additives essential to maintaining public nutrition, especially amongst the poor.

Elimination of the Delaney Amendment automatically would not authorize the Secretary to set tolerances for carcinogens. As with any other toxic effect before any such tolerance could be established, the Secretary as a matter of scientific judgment would have to conclude from the scientific evidence available whether a threshold limit could or should be established for a suspected carcinogen. There is general agreement that in some cases it is possible to set such threshold limits. Yet the Delaney Amendment as phrased precludes any scientific judgment - the same scientific judgment which Congress entrusted to the Secretary for the safeguarding of the public health with respect to all other toxic effects which can be produced in experimental animals, including death.

There is no reasonable justification for continuing the Delaney Amendment in any form. However, it would be difficult from a legislative enactability point of view to accomplish outright repeal. For this reason, it is suggested that the Amendment be revised to restore to the Secretary the right and obligation of exercising scientific judgment in the area of carcinogenicity. To this effect, we would suggest that the semicolon and the word "or" be deleted from the last sentence of the so-called Delaney Amendment and the following language added:

" . . . unless in the opinion of the Secretary sufficient evidence exists to permit establishment of a safe or toxicologically insignificant level of intake for man of such substance so found to induce cancer."

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