

February 20, 1974

Mrs. Betty Rae Stevick
Chairman
Health Task Group
Arlington Branch
American Association of University Women
Arlington, Virginia

Dear Mrs. Stevick,

Thank you for your letter of February 14th.

The position I have taken on the Delaney Amendment is that, for the time being, its practical advantages as a deterrent to the introduction of potentially dangerous additives far outweighs the technical criticisms that can be lodged against it. The statement that was quoted in your letter from the subcommittee hearings is perhaps derived from the language of my talk at the Forum, a few pages of which are enclosed, but is unfortunately susceptible to being read out of context. As you will see from my remarks about cycloamates, I have for a long time tried to increase public vigilance about food additives; however, I have also believed it essential that we develop the technical insight that is required to justify long-range policy on careful, measured, quantitative considerations. It is clear that a great many compounds have the potential of some low level of carcinogenic effect -- undoubtedly including natural metabolites -- and I fear that concerns about food additives will be discredited if we take an arbitrary position rather than one that seeks to examine and to balance benefits and risks. As far as I am concerned, this is still a hypothetical problem and I have no quarrel with any of the regulatory actions on food additives that the FDA has undertaken to date. It is also true that Mr. Hutt believes that the Delaney Amendment is relatively unimportant but its existence on the statute books is undoubtedly a significant reminder to an agency that has not always been so responsive to these needs. I agree, that at least as far as I am aware, that as quoted in your letter no instances of extraordinary justification have yet been presented or documented, although it is hard to understand how tobacco can be exempted from regulatory control except under such a doctrine.

I am not sure whether the Delaney Amendment does or does not apply to natural products. The very first entry in the food chemicals codex, and a typical member of the so-called GRAS group, is acacia, or gum arabic. There are of course hundreds of other vegetable products of this kind that could be regarded either as foods or as food additives, and I suspect would be embraced by the Delaney Amendment if they presented a clear hazard under its terms. If you have other legal advice to the contrary, I would be interested to see it.

One specific example of a food stuff which contains a highly suspect constituent is horse raddish. I do not mean to suggest that horse raddish or mustard necessarily present significant hazards to human health in the quantities ordinarily consumed. The critical constituent, allyl isothiocyanate, has been reported to be carcinogenic when applied to the skin, but I know of no studies upon which one could rely for its safety or toxicity when fed to any animal. I would be surprised if this compound were not carcinogenic, albeit at probably a rather low level, if fed, and were this to be pursued I suspect that FDA would have a dilemma with regard to allowing the sale of synthetic mustard oil. This would then raise an interesting question with respect to allowing natural sources of the same material to continue to be marketed.

Aflatoxin presents a very similar question and I would be interested indeed in whether the legal doctrine has been tested that peanuts used as inputs to food processing applications might be obliged to carry a zero tolerance for the presence of moldy peanuts, a condition that would be impossible to verify in practice if the term is taken literally. Perhaps indeed a legal technical distinction will be sustained as between a raw agricultural product, and specific chemical constituents obtained therefrom; this would hardly seem to be a very rational way to make policy distinctions. However, I say this from a very different vantage point than the one that is attributed to me by implication of wanting to overturn the Delaney Amendment. Certainly it should not be disturbed until we have still more effective means of technical control to take its place and these are not now in sight.

Most of my discussion at the Forum was concerned with drugs rather than with food additives. However, I enclose some of my other writings on the subject. If you will read them in chronological order, I think you will have a fair idea of my present day viewpoint.

Sincerely yours,

Joshua Lederberg
Professor of Genetics

JL/rr
Enclosures