



Joshua Lederberg

Many 'Accepted' Additives May Be Cyclamate's Equal

HEW SECRETARY Robert H. Finch's order banning the use of cyclamate as an artificial sweetener puts a decisive period closure to a messy controversy of great potential importance to public health. My only criticism is that it was not done sooner, but this was difficult in the face of ambiguities both in the legal authority of the Food and Drug Administration and in the scientific evidence that cyclamate is a hazard in man.

We may never know the answer to this question, for it is more likely that new compounds will be discovered as alternatives to cyclamate than that cyclamate could be exonerated by further studies (even if it is essentially innocent) once it had been indicted.

Finch's decision does not answer the scientific question, although the regulatory label of "safe" or "unsafe" is often confused with a factual reality that can never be so categorical. Nor does the cyclamate affair set a satisfying precedent for the way such issues should be dealt with in the future.

OUR PRINCIPAL need, of course, is for the improvement of methods of scientific evaluation of safety. There is no particular rationale for banning an additive on the basis that it can be shown to induce tumors in some experimental animal at high doses when we know nothing of the way the additive works.

On the other hand, Dr. Marvin Legator of FDA's research laboratories had shown over a year ago that a derivative formed in the body from cyclamate, cyclohexylamine, caused chromo-

some breaks in rat germ cells when given in modest doses for short periods of time. This information was administratively ignored, perhaps because the language of the law is still innocent of any knowledge of genetic damage.

In fact, among the thousands of compounds "generally accepted as safe" or specifically licensed as food additives by the FDA, there are surely dozens which will prove to be at least as hazardous as cyclamate but have yet to reach the same kind of public attention.

Organic peroxides are proven mutagens—but are widely used for bleaching starch and maturing flour. Mustard oil is historically interesting as the first known chemical mutagen; it has, however, come to legislative attention as a cruel blistering agent for "soring" horses. Phenethyl alcohol is a synthetic perfume essence, but biochemists know it as a powerful inhibitor of DNA synthesis.

Many other additives are suspect simply on the grounds of their chemical reactivity, for they must then produce a wide and unpredictable variety of secondary products when used in foods. Many other compounds belong to classes that we do not yet recognize as having biological potency.

IF THE FDA indeed had to give adequate scientific assurance about the absolute safety of every additive, we might starve to death while the necessary research was being done, and then again when new insights into sources of peril emerged. Nevertheless, the food industry and the scien-

tific community, as well as government, should be sharpening their focus in dealing with these vital problems.

Meanwhile, we must also think of more flexible legal and regulatory approaches to these problems. Abbott Laboratories should not be charged with insincerity for having asserted its confidence that cyclamates were safe, but the main risk was being borne by millions of consumers, not the corporation. On the other hand, a government agency might be in the position of having little to lose in responding to public arousal by banning a product before all the evidence was in.

The law could provide for unconditional liability for the eventual hazard of a product when the FDA has certified a bill of particulars, for example, about bladder cancer or mutation. An Abbott Laboratories would then have to back up its confidence by sharing the risk that it was mistaken with its customers.

It might also be required to post an insurance bond. This device would help to bring in the informed businessman's judgment of a third party: the insurance underwriter who must make wise decisions about the premium to charge.

In the long run, the cost of insurance is embedded in what the consumer has to pay. But this would indirectly pay for important research on hazards and for the development of safer alternatives, as well as encourage greater discretion by the purveyors of unproven products.