PUBLIC INTEREST GROUPS*

A. KARIM AHMED, Ph.D.
Staff Scientiest, The Natural Resources Defense Council
New York, New York

THE historical basis for the Delaney clause in the Food, Drug, Cosmetic Act is really a long one. The first legal regulation of harmful substances in food goes back to 1906 with the passage of the Pure Food Act, then under the jurisdiction of the Department of Agriculture. It was not until 1938 that the so-called Food, Drug, Cosmetic Act of 1938 addressed the question of premarket testing, in this instance of new drug products to be placed on the market. During the 1950s there were a series of hearings that dealt with the problems of food additives and food contaminants present in many products. New products proliferated back in the 1950s and 1960s, and assessment of risk with respect to carcinogens was heatedly debated.

There is a long story behind how the Delaney amendment was included in the 1958 Amendments to the Food, Drug, Cosmetic Act. Congressman Delaney felt that the hearing record clearly addressed a public policy question, namely, whether for a given carcinogen one can establish a so-called safe level or what people now refer to as a "threshold." This concept comes from traditional public health toxicology, where one assesses acute toxicity or subacute toxicity to establish thresholds. At the time of the hearing, certainly no evidence indicated a so-called threshold for a carcinogen, because carcinogens behave differently from most other toxic substances in that they affect one cell of the body, theoretically speaking, which could then clone and multiply to cause a malignant tumor. Obviously, baseline defense mechanisms exist in the body, but this is still a debatable issue. We do not have much information that would have indicated the establishment of a safety level for a carcinogen.

The Delaney clause states:

A food additive shall be deemed unsafe and shall not be listed for any use which will or may result in ingestion of all or part of such additive if the additive is found by the

*Presented in a panel, Public Policy and Regulation, as part of *Cancer Epidemic? A Symposium on Carcinogens* held by Blue Cross and Blue Shield of Greater New York at the New York Academy of Medicine May 25, 1977.

Secretary, [in this case H.E.W.] to induce cancer when ingested by man or animal or if it is found by the Secretary after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animals.

There are two basic segments of the Delaney clause, and people tend to mix the two. First, one has to determine whether a given substance causes cancer, a scientific question that relies upon scientific experimentation and judgment. The second question is one of public policy, a legislative question. That is a decision that has already been made by Congress, and suggests the following: we cannot establish a safe level for a given carcinogen. No scientist will unequivocally argue that any data support the establishment for any given carcinogen of a so-called safe or threshold level. We have indications, perhaps, about a threshold from epidemiologic data, but that is at best extremely equivocal. The Food and Drug Administration (FDA) has the authority to regulate other substances, noncarcinogenic substances, to establish so-called tolerance or safe levels. But for a carcinogen, the legislative intent of Congress was that the agency in question should not be given the discretion to develop a safe level for a carcinogen. Consequently, once the scientific question has been resolved to the satisfaction of the agency's scientists that a particular substance may cause cancer, there are no "ands, ifs, and buts" about whether one should leave it on the market or whether one can develop a benefit-risk ratio. The legislative mandate is that one cannot establish such a level and cannot therefore give an agency that discretion.

We must separate the question of scientific judgment from questions of public policy because very often one hears an attack on the Delaney clause as unscientific. It is asserted that there is no room for scientific judgment or no room for a scientist to judge the validity of the experiment in the first place. Was it done according to the right kind of protocols? Was it done in a manner which a peer-review group would consider correct? These questions always precede the regulatory decision. The Delaney clause has been invoked by the FDA only a very few times. They have authority, but are very careful in using it, and only rarely have they invoked it because the scientific burden is rather large.

It is very likely that we shall have to continue "grandfathering" existing chemicals on the market by placing the burden on the agency to show that it is unsafe before it is removed from the market, the Delaney clause being one of the handles. However, in the future, under the Toxic Substances Control Act and the Food, Drug, Cosmetic Act with respect to new food

additives, drugs and pesticides and in some cases chemicals in the work place, we must use exhaustive premarket testing. Here some very interesting possibilities exist—the environmental organizations, industrial scientists, the academic community, and the unions all can develop a significant program of implementation of premarket-testing regulations. One hopes that as this debate continues a desire will grow for more exchange of information based on what we know today and how we can develop meaningful regulations in this area.