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Volume 9
Issue 3 *Psychiatry and Law (A Symposium)*

Article

1960

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Recommended Citation

Robert E. S. Post, Food Additives: Legal Recognition of a Scientific Problem, 9 Clev.-Marshall L. Rev. 503 (1960)

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Food Additives: Legal Recognition of a Scientific Problem

*Robert E. Post**

FOOD ADDITIVES COULD CREATE one of the nicest legal problems that courts have ever had to face. We are not concerned with theories of negligence, warranty, privity, or statutory interpretation as it applies to any of these three concepts. The real problem is twofold: establishment of harm arising from the presence of an additive or additives; and establishment of a judicial policy to contemplate the fact that, if and when such harm does befall someone, it will happen in spite of the utmost good faith on the part of the manufacturer, and in the face of legislative and administrative authorization of the use of such additives.

Product liability in general has been well treated in this law review and elsewhere.¹ Liberal treatment by the courts of implied warranty of merchantable quality² and disregard of privity³ make the supplier and manufacturer liable for anything the jury may find wrong with the product that makes it unfit for the general purpose intended. Such a finding is almost automatic in the case of a harmful ingredient in food. Hence the importance of a substantial basis for establishing cause and effect.

If, notwithstanding the best efforts of manufacturers and governmental agencies, it should turn out that some common, supposedly innocuous food additive has been poisoning people for many years, an economic explosion could result under the liberal holdings in implied warranty. It would seem that we need some legal ground rules now to guide all concerned. Otherwise, instead of resolving the problem so as to serve the ends of justice rationally and nobly, we may hopelessly bungle things with confused decisions resting on vindictiveness, hindsight or defensive subterfuge.

Evidence of cause and effect is related to the technological and scientific aspects of the problem. But science and technology are also fundamentally necessary in establishing a reasonable

* B.E. in Chemical Engineering, Yale University; M.S. in Chemical Engineering, University of Wisconsin; Ph.D. in Physical Chemistry, University of Illinois; second year student at Cleveland-Marshall Law School. The writer's experience with statistical inference arises in connection with work in viscose rayon where the problems are much like those of food additives in principle.

¹ See for example *Advertised-Product Liability*, 8 Clev-Mar. L. R. 1.

² *Ryan v. Progressive Grocery Stores, Inc.*, 255 N. Y. 388, 175 N. E. 105, 74 A. L. R. 339 (1931).

³ *Jacob E. Decker & Sons, Inc. v. Capps*, 139 Tex. 609, 164 S. W. 2nd 828, 142 A. L. R. 1479 (1942).

policy. Unfortunately, science is not so exact as it is supposed to be, and it is unlikely that sufficiently complete agreement will ever be found among scientists to serve as a useful guide in truly borderline matters. The doubtful areas are the crux of the present food additives problem. Here only long periods of time and large amounts of data will suffice to provide anything approaching a conclusive answer. In the meantime we must depend on scientific reasoning and conjecture. Whatever the popular conception of scientists may be, they do take their prejudices into their laboratories. Yet it is fortunate that they do, for many important discoveries are the outcome of the pursuit of a course of action founded only on the scientist's faith in his own convictions—convictions not shared by his contemporaries, nor supported by available data. All of which is to say that the facts of life are not much changed by scientific discipline. A prejudice may be "right" or "wrong." Ultimately it may be "good" or "bad." A nation of eccentrics would destroy itself in internal chaos. A nation of reasonable men would vegetate. The true wisdom, so essential to a solution to the problem which will best serve the nation, is no easier to locate in connection with food additives than it is with affairs of state. The label of scientist is only a rudimentary qualification.

The concepts of sufficient data and a best course of action to follow in absence of it are fundamental to scientific inquiry. With sufficient data, a statistical evaluation can be made from which quantitative conclusions can be drawn. Otherwise we proceed through hypothesis and inference applied to experiments whose outcome can be determined with satisfying certainty. It is the general contrast of induction and deduction.

The result obtained from statistical evaluation of data is a statement of the probability that the outcome observed could have occurred by chance. It is here the old adage that figures don't lie but liars figure is especially appropriate. It must also be emphasized that statistics only reveal an association—never cause and effect. Cause and effect must be inferred with more or less justification as the case may be. The justification is usually quite adequate when a certain result is strongly associated with an applied treatment and coincidence is eliminated. The statistical method is necessary when it is either impossible or too impractical to control all conditions adequately. Usually adequate control is obtainable only with highly restricted laboratory experiments, and even then, if the subject has inherent variability, such control may be impossible on any scale no matter how restricted. Fortunately many avenues of research are available that lead to unequivocal results. That is to say the results are unequivocal, although their interpretation may not be. Arguments over interpretation lead to additional experiments to confirm or refute various interpretations until some interpretation becomes generally accepted. Often, as in the case of drugs, clinical tests are required as a final evaluation. It is to the credit of

the laboratory workers that ultimate failures on the mass scale are virtually unknown. Hence we may be encouraged by the knowledge that, although mass data on the effects of food additives are not readily available for the purpose required, there is an abundant fund of good chemistry available to provide guidance in the selection or rejection of chemicals that find their way into our food supply.

In what has preceded, we have defined the scope of the food additives problem for the purposes of this article, and we have attempted to introduce in a general way the place of science and scientists in relation to the problem. We will proceed to consider further the matter of statistical inference, particularly as it bears relation to evidence of cause and effect. We will take a look at judicial and legislative policy as reflected in Supreme Court decisions, legislative history of the Food, Drug and Cosmetic Act, and a few of the leading case-book cases on liability in implied warranty. Finally we will review science and law and common sense with a view to suggesting a suitable course to follow.

Statistical Inference

The application of statistical methods is only one part of the overall concept of an experiment or population study. The first step is the proper design of the experiment. The design is important whether or not statistical methods are to be used. In the first place coincidental factors must be eliminated or accounted for, otherwise there could be a multiplicity of possible causes assigned to any given effect. Secondly, an experiment should be designed to be as efficient as possible; that is to yield as much useful data for a given amount of work, time and expense as ingenuity can accomplish. With the increased application of statistical methods to analyze data, this matter of efficiency has become both more important and more apparent, particularly when interactions of factors must be determined. A third and very important consideration is sampling. Proper sampling is essential to controlled experiments, and absolutely indispensable to population studies, the best known examples of which are the political polls.

Needless to say, the actual performance of an experiment or survey of the population is an important part of the whole, but the requirements involved are more of technique than principle. Given an adequate design and proper performance, one will obtain certain results or data, and these results or data will be subject to more or less error because of the impossibility of obtaining absolute precision. The province of statistics is to evaluate quantitatively the significance of the results. However, this evaluation of significance is relevant only to the internal relations of the experiment. Effects of coincidence or systematic errors in measurement will not be revealed. Interpretation of the results is anything but automatic. Obtaining the correct interpretation

depends not only on faultless design and accurate data, but also on the objectivity of the interpreter. This is so even in physical experiments where the data are often so precise as not to require statistical analysis.

Since the element of interpretation is so basic to the problem at hand, we will pursue it a bit further into the field of "exact" sciences before we consider some practical applications in the fields of physiology and biochemistry. The interpretation of certain astronomical phenomena escaped astronomers and physicists for many years. The data simply did not fit existing theory; and the discrepancy might have been attributed to experimental error, although, to be sure, scientists were reluctant to do so. It remained for Einstein's theory of relativity to provide a satisfying explanation. In this case the data were more precise than the theory, and interpretation depended on a better theory, which, indeed, brought about a revolution in scientific thought, as is well known. As another example, the relations of various forms of energy are summarized in the mathematically precise science of thermodynamics, but through thermodynamics' half-brother, statistical mechanics, we find that this precision exists only because the probability of things being otherwise is so small as to be inconsequential. This state of affairs comes about only because we deal with numbers of molecules far exceeding the pennies in the national debt. There are not enough people, guinea pigs or even insects in the world to enable us to approach this precision in the life sciences. A final illustration of the importance of the nature of the system is a contribution of the atomic and nuclear physicists. It has been found, *a priori*, that when dealing with the order of magnitude of atoms and nuclei that it is impossible both to determine the position of a particle on this scale and also to determine its velocity, even though precision is unlimited as to either alone. Fortunately this effect is vanishingly small on the familiar scale; otherwise a batter, if he had any idea at all how fast the pitcher was throwing the ball, might just as well swing with his eyes closed. Now, this digression from the immediate statistical field may seem superfluous. However, its purpose is to emphasize and reemphasize the objective limitations of physical sciences. When we add to these the subjective limitations of scientists, and consider that food additives lie in a field far removed in precision from those mentioned, and one that is furthermore far less amenable to *a priori* analysis, it is abundantly apparent that much work and experience lies ahead before any reliable conclusions can be drawn.

A popular text on the subject of statistics is *Statistics, A New Approach*⁴. This particular text is especially useful because it sets out the problem in many concrete examples. One of these is quite pertinent in that it involves the effect of vitamin supplements in the diet of soldiers on their performance in the field.

⁴ The Free Press, Glencoe, Ill. (1956).

The handling of this study is illuminating, and although we cannot go into it here in great detail, some of the factors can be listed by way of illustration of the general discussion given above.

This was an expensive experiment. It was performed because there was reason to believe from studies on rats and to a lesser extent on humans that vitamins might enable soldiers better to withstand extreme cold. But to begin with, combat activity could not be simulated and a substitute had to be devised. Then too, it was desirable to have a quantitative measure of effect, hence the vagaries of actual combat would almost necessarily be precluded. The limited number of men placed a limitation on how much could be investigated. As a result it was decided to study the combined effects of vitamins B and C. The effect of either alone or their interaction with each other had to be left out. The sampling could not be done at random for administrative reasons, so the risk had to be run that coincidence might arise from the choice of volunteers from a particular group.

However, once this group was formed, it was divided into two groups randomly, one of which received the vitamins and the other constituted a control group. To eliminate psychological factors both groups received capsules, but only one received vitamins in their capsules. The effect of the vitamins was measured as a relative score on physical fitness tests before and after the experiment; thus we have a control group as to vitamins and a control reference as to performance. There were many psychological features to be circumvented. Chief reliance was placed on interplatoon competition as an offsetting factor.

In conducting the experiment records were kept of food intake, physical performance and incidental observations. The menu, barracks conditions, uniforms and activities all had to be according to plan.

The results before analysis showed that both groups actually improved considerably in spite of limited diet and hard work. Since it was by no means obvious that vitamins were helpful, a statistical evaluation had to be made. As was mentioned before statistics measures the probability of the observed difference in average scores happening by chance. In other words, if a group similar to the group that received no vitamins in the actual experiment were to be put through the same experiment, one would not expect to obtain the same average score. From the distribution of scores making up the average, the probability of obtaining any given different score, including the score actually obtained by the group receiving vitamins in the experiment, can be estimated. In this experiment the probability turned out to be 17 times in 100—about 1 in 6, or the probability of throwing a one-spot on a die. Now, one does not have to be trained in any science to make a judgment on this basis. If for example, you want to determine if a die is loaded, you might throw it once and get a two. If on the second throw, you get another two, the odds being 1 in 6 that this will happen by chance, will you conclude

the die is loaded? You will probably want to throw it at least once more, when the odds will be 1 in 36, before drawing any conclusion.

In this test, some associations obtained from the data were considered significant, but on the whole a beneficial effect of vitamins was not established. Furthermore the effect of vitamins in relation to combat *inactivity* with its manifest psychological implications could not be estimated at all, because it was not included in the original design. However there is some indication of benefit, and it could be that the real benefit would be to enable the weakest to survive. About this we can only conjecture.

These authors also discuss the association between smoking and lung cancer. A survey showed a lung cancer death rate about nine times as great for pack-a-day or more smokers as for non smokers. However analysis of the data also showed a 30% lower death rate in the sample as a whole than that for the United States generally, the death rate for heavy smokers even being below the national rate. Such results suggest selectivity in the sample. A possible explanation would be that the sample consisted of a smaller proportion of those on the verge of death than the national average, and, in the portion destined to be the survivors, a lower proportion of smokers than the national average. Some would say that this is far fetched, especially since other smaller scale studies seem to confirm the association. But it is pointed out that such selectivity could very likely be common to all the surveys.⁵ At any rate, this is still only an association, strong as it may be. It is still possible that heavy smoking and lung cancer are common effects from the same cause. To suppress the possible influence of coincidence it would be necessary to select two groups at random and cause one to smoke at least a pack a day while preventing the other from smoking at all. This truly verges on the ludicrous, at least in our society. While the experts argue this matter pro and con, it is well for the rest of us to keep in mind the vast areas of uncertainty involved and to realize that no one can be expected to view such a personal subject without some prejudice.

Judicial and Legislative Policy

Recent litigation in the Federal Courts over the coloring of oranges⁶ brings the food additive situation sharply into focus because it concerns the *economic necessity* of applying a *non-harmless coal tar* color to the *skins* of oranges in the *absence of any scientific evidence of the likelihood of injury to man*. Also such oranges are stamped "*color added*". Note that there is something

⁵ The original data was reported by Hammond and Horn, *The Relation between Human Smoking Habits and Death Rates*, 155 J. A. M. A. 1316 (1954). The analysis as to selectivity was by Berkson, *The Statistical Study of Association between Smoking and Lung Cancer*, 30 Proc. Staff Mtgs. Mayo Clinic 319 (1955).

⁶ *Fleming v. Florida Citrus Exchange*, 79 S. Ct. 160, 358 U. S. 153 (1958).

special about coal tar colors. Being "unnatural", they are especially suspect when it comes to their use in food. We also note that the issue of economic necessity arises here, which would be shocking to consider at all in connection with possible poisons in food—except that there is no evidence that man is likely to be poisoned in this case. Furthermore, the color is in the skin, and the consumer is given notice that color has been added. This can hardly be called an insidious deception practiced on the helpless consumer.

The treatment of this problem by Congress and the Federal Courts is perhaps the best source of enlightenment as to public policy on the matter of food additives. Recall that we here confine our consideration of food additives to what may be called legitimate or bona fide uses. We avoid the general subject, which includes the use of additives to deceive as to quality or the negligent or willful use of known dangerous chemicals in known harmful amounts. We do generalize however as to the meaning of additive and include all chemicals that may enter food, from those used agriculturally to those emanating from the wrapper or container. Oppenheim, in this law review,⁷ and the U. S. Department of Health Education and Welfare, in a pamphlet for consumers,⁸ have set out many of the uses and sources of food additives.

The original Food and Drug Act⁹ prohibited and defined adulteration of food. In *United States v. Lexington Mill & Elevator Co.*¹⁰ it became necessary for the Supreme Court to construe Sec. 7, fifth subdivision which read as follows (the italics are the Supreme Court's):

Fifth. If it contains any added poisonous or other added deleterious ingredient *which may render such article injurious to health.*

In this case flour bleached with nitrogen peroxide gas had been seized in shipment in interstate commerce. The flour contained residual nitrogen peroxide and various reaction products of a poisonous nature. The trial court charged the jury

. . . that the government need not prove that this flour, or foodstuffs made by the use of it, would injure the health of any consumer. It is the character—not the quantity—of the added substance, if any, which is to determine this case.

The Supreme Court applied the rules of construction that (1) the province of construction lies wholly within the domain of

⁷ Oppenheim, Food Additive Law and Practice, 8 Clev-Mar. L. R. 516 (1959).

⁸ Leaflet No. 10, U. S. Dept of Health, Education, and Welfare, FDA, Wash. 25, D. C.

⁹ 34 Stat. 768 (1906).

¹⁰ 34 S. Ct. 337, 232 U. S. 399 (1914).

ambiguity and (2) significance and effect shall, if possible, be accorded to every word. It found that the charge of the trial court in effect omitted the import of the italicized words above. The court then held that this placed the burden of proving possible injury to health on the government. However it construed the word "may" broadly so as to contemplate any use of the food and any person using it. The court quoted Senator Heyburn,¹² chairman of the Senate committee, who expressed the point of view that "poisonous" is a matter of quantity and combination.

The Federal Food, Drug, and Cosmetic Act of 1938,¹³ in the light of experience, codified the practice under the 1906 Act and introduced more specific matter as well as some new provisions on procedure for establishing tolerances. Use of coal tar colors was forbidden unless the color was from a batch certified on the basis of being *harmless* and suitable for use in food by the Secretary of Agriculture.¹⁴ The practice of strictness as to coal tar colors had developed in administration of the 1906 Act. However, the Secretary was given the power of determining the safe limits as to other additives, if they were required in manufacture or could not be avoided.¹⁵ Compliance avoided liability under the issue of the *Lexington Mill* case¹⁶ as to possible injury to health. A procedure for establishment of regulations¹⁷ and review of controversial orders by the Secretary¹⁸ was set up. When the coal tar color litigation over Red 32 began in 1956, the 1938 act was still the law, although the Food and Drug Administration had been transferred to the Department of Health, Education, and Welfare. Before it was to end, a special temporary law and an extension of time to it had been passed, and the 1938 act had been substantially amended, although not as to coal tar colors.

The litigation over the use of coal tar colors on oranges arose when FD and C Red No. 32, among others, was delisted November 10, 1955, effective February 10, 1956. The delisting had been done after appropriate hearings on the basis that these colors were no longer considered harmless, and when various interested parties petitioned for a rehearing, it was denied by the Secretary of Health, Education, and Welfare. Two cases reached Federal Courts of Appeals, and the petitioners were successful in getting a bill introduced into Congress to permit temporarily continued use of Red 32.

¹¹ *Id.* at 339.

¹² 40 Cong. Rec. Pt. 2, 1131.

¹³ 52 Stat. 1040, 21 U. S. C. A. Secs. 301-392.

¹⁴ Adulteration prohibited in 52 Stat. 1042, 21 U. S. C. A. Sec. 331 (b). Coal tar color adulteration defined in 52 Stat. 1046, 21 U. S. C. A. Sec. 342 (c). Coal tar color certification directions in 52 Stat. 1049, 21 U. S. C. A. Sec. 346 (b).

¹⁵ 52 Stat. 1049, 21 U. S. C. A. Sec. 346 (a).

¹⁶ *Supra* note 10.

¹⁷ 52 Stat. 1055, 21 U. S. C. A. Sec. 371 (e).

¹⁸ *Id.* Sec. 371 (f).

The facts before the courts and before Congress are in general as indicated at the beginning of this section on Judicial and Legislative Policy. More specifically, as to being not harmless, the evidence showed that ill effects were produced in dogs at a feeding level of 100 ppm. (parts per million) in their diet, and that 196 persons had become acutely ill after eating popcorn colored with Red 32. The FDA found that man appears to be more susceptible than test animals to the effects of such materials, and that there was no evidence of a safe level for human use. Actually the FDA had not attempted to determine such a safe level, but on the other hand, the petitioners had not contributed anything either. In this connection an important fact to consider is that such coloring materials can enter the diet from many sources other than oranges.

As to economic necessity, there was little doubt that uncolored oranges would meet with strong consumer resistances.

As to the matter of there being no evidence of likelihood of harm to man, there was the fact that coloring of oranges had been practiced since the early 1930's with no known ill effects. The maximum rate of human consumption of Red 32 would be through eating candied orange peel containing 7.4 ppm., which would be only a relatively small part of the diet in contrast to the continuous feeding of 100 ppm. in the total diet of the test dogs. In orange juice the coloring is present only as a fractional part per million. Furthermore, petitioners testified that the only use of Red 32 at that time was in the coloring of oranges.

The findings of the FDA were not contested by the petitioners, nor did the Secretary take any issue with the evidence introduced as to economic necessity or absence of proven harmfulness. The issues resolved to ones of statutory construction as to (1) the sense in which the word "harmless" was to be interpreted and (2) the discretionary powers of the secretary in the event of a finding of harmfulness, in whatever sense the court finds it should be interpreted.

Pending the outcome of the litigation, Congress concluded it would not be dangerous to the health of the nation to permit the continued use of Red 32 under limited circumstances.¹⁹ The limitations were (1) a three year time limit during which it was expected a harmless color could be found; (2) use restricted to oranges mature and not intended for processing; (3) oranges so colored to be stamped "color added" so that the buying public would be fully apprised of the fact. The reason was plainly and admittedly that Congress felt the risk was negligible compared to the economic necessity involved.

In the Second Circuit the order of the Secretary was appealed by a group of dye manufacturers in *Certified Color*

¹⁹ 70 Stat. 512, 21 U. S. C. A. Sec. 342 (c) 2nd proviso. For legislative history see 2 U. S. Code, Cong., and Adm. News 3055 (1956).

Industry Committee v. Secretary of Health, Education, and Welfare.²⁰ In the Fifth Circuit it was appealed by a group of citrus fruit growers and the holder of a patent on the coloring process in *Florida Citrus Exchange v. Folsom*.²¹ Judgment was for respondents in the Second Circuit and for petitioners in the Fifth. While it is possible to find distinguishing features in these cases, largely related to the nature of the petitioners, the Supreme Court, on certiorari from the Fifth Circuit, found for the Government without reservation.²²

In *Certified Color Industry Committee* the Color Industry argued that the word "harmless" should relate back to the clause construed in the *Lexington Mill* case, since this clause was carried over into the 1938 Act. They further argued for a less strict interpretation for which they cited *Wood Manufacturing Co. v. United States*²³ where the words "... as ordinarily used ..." appeared. Thus they would have the statute interpreted so that harmless would mean such as may render injurious as ordinarily used. In support of this the Color Industry urged that Congress being aware of the toxicity of coal tar colors must have realized that the authorized use would have some relation to quantity, and they pointed out that salt and vinegar are harmful if taken in sufficient quantity. They felt that the authorization of limited amounts of poisonous substances when necessary or unavoidable in good manufacturing procedure should be permitted in the case of coal tar colors—that coal tar colors were not to be excepted from this provision; hence by somewhat circuitous reasoning, "harmless" should be interpreted as it would be for any other substance.

The Secretary argued for recognition of coal tar colors as a separate subject of that act—that coal tar colors were to be definitely excepted from all provisions not specifically mentioning them. He submitted that the use of "harmless" instead of the more familiar statutory language was evidence of Congressional intent to provide an absolute standard for coal tar colors.

The court reviewed legislative history and analyzed the whole act in an endeavor to extract the legislative intent. It was noted that by the terms of the act a substance not added to food will not render the food adulterated if it does not ordinarily render the food injurious to health. An added substance constitutes adulteration if it may render the food injurious

²⁰ 236 F. 2nd 866 (2nd Cir. 1956).

²¹ 246 F. 2nd 850 (5th Cir. 1957).

²² *Supra* note 6.

²³ 286 F. 84 (7th Cir. 1923). The court spoke of "... when diluted as it is ordinarily used ..." in contemplation of possible injury to health. However, from the opinion it is evident that the court did not overlook the possible uses of the coloring material involved any more than the court in the *Lexington Mill* case overlooked the possible uses of flour.

to health.²⁴ A coal tar color is permitted only if it is from a listed batch, and a batch may be listed only when the color is found harmless and suitable for use in food. However, the court did not overlook the provision for the Secretary to set up tolerances for added poisonous or deleterious substances which are necessary to or cannot be avoided in good manufacturing practice. It decided that "harmless" could not stand alone, but must have some relation back to the above mentioned concepts of adulteration. But the court rejected the point of view of the Color Industry, observing that whatever might have been the significance of the holding in the *Wood* case as to the concept of ordinary use, Congress definitely distinguished the test of ordinary use from that of possibility in the 1938 Act. The court reflected on the fact that under the 1906 Act the FDA had recognized the necessity for special treatment of coal tar colors, and certified only those colors satisfying its specifications. This history, the strictness implied in the 1938 Act in requiring certification of batches, and the wording of the statute led the court to find that under the agreed facts the delisted coal tar colors were not harmless. The court apparently applied the *Lexington Mill* test in its holding.

In the *Florida Citrus Exchange* case the Citrus Exchange argued for an interpretation of "harmless" as applied to use according to appropriate regulations of the Secretary; that is a substance is to be considered harmless if it can be rendered harmless in a relative sense. The Secretary held to an absolute standard.

The court purported to look to the entire act, with its declared object and policy to protect the public health, in the light of certain rules of statutory interpretation which the court set up as appropriate. These rules were (1) to avoid incongruous or absurd results, (2) to avoid an interpretation occasioning inconvenience or producing inequality or injustice in favor of a more reasonable one, and (3) to examine statutes *in pari materia*. On this basis the court concluded that not to construe "harmless" in relation to use would be discrimination against the orange industry. Again the clause in the statute providing for limited use of poisonous substances necessary to good manufacturing practice was introduced in support of interpretation of "harmless" as a word of relation. This court cited the *Certified Color Industry Committee* case as supporting the *Lexington Mill* doctrine, and evidently found even less suggestion in the statute of a unique standard for coal tar colors than that court did. At least it reported no finding on whether the delisted colors were harmless or not. (In the dissenting opinion by Hutcheson, C.J., it was pointed out that in the *Lexington Mill* case an entirely different statute was construed.)

²⁴ 52 Stat. 1046, 21 U. S. C. A. Sec. 342 (a).

The Supreme Court considered the *Lexington Mill* doctrine (and incidentally cited the *Wood* case as applying it). It then examined the statute for evidence of legislative intent much as had the courts below. The Supreme Court, however, was struck by the distinctions in the treatment of coal tar colors. While the language involved in the *Lexington Mill* case survived generally in the 1938 Act, a separate test was provided for coal tar colors. The Supreme Court conceived that it was competent for Congress in the light of recognized problems to health to adopt a rule of caution. It was taken that Congress intended that the Secretary address himself to the harmless character of the substance first, and thus relieved him of the burden of proof as in the *Lexington Mill* case. This would circumvent the argument of not-proven which seemed to have great weight in the *Florida Citrus Exchange* case in the court below. To the Supreme Court it appeared that Congress had turned its back on procedures of analyzing the uses made of a substance and duplicating the proportions experimentally. It held that "harmless" was to be construed relative to tests such as were actually conducted on the colors in question.

On the second issue as to the Secretary's discretionary powers, the courts displayed a similar diversity of reasoning. In the *Certified Color Industry Committee* case, the Color Industry had argued for an interpretation of "harmless" such as would permit the Secretary to issue regulations for limited use. The court found the substance not harmless, and thereby was able to narrow the issue somewhat. As to the Secretary's authority to permit limited use, the court said that that question need not be answered. The only question that needed to be answered was whether, in any case, the petitioners could require him to establish tolerances. The answer became a matter of review of the Secretary's findings. The court observed that there was nothing in the record as to a safe level for humans, that the petitioners had contributed nothing, and that the Secretary's decision was reasonable. In fact the court declared that it would be unconscionable to require the Secretary to permit the use of the delisted colors without the clearest and most uncompromising evidence of a safe level of usage. It held that the Secretary's findings should be accepted. The point was raised that the danger would be reduced substantially if the Secretary were to limit the use to a single food. The Secretary claimed no authority to do this, to which the court seemed to agree, and held that the Secretary had acted within his discretion. The court submitted that this was a problem distinct from that before Congress in amending the statute for a temporary specific use.

This decision was duly recognized in the *Florida Citrus Exchange* case, where in fact the court seized upon the observation about Congress and specific use and interpreted it to apply to the distinction between specific and general uses. (The

dissent held that the distinction should have been between legislation and litigation.) This court thus proceeded on the basis of a narrower problem than that of the Color Industry. Not having placed any construction on the word "harmless" that would by itself prevent the Secretary from certifying a color for use, the court concentrated on examination of the factors involved in establishing a safe level of use. To the argument that there was a variety of possible uses, the court replied that this did not seem to be a problem with other poisonous substances of equal or greater toxicity, but be that as it may, the Secretary could limit the use to oranges. The Secretary contended that he did not have such authority, but the court merely noted that while there was no such specific authority, there was no specific prohibition either, and, indeed, the use of a class of colors known as lakes had at one time been permitted for use on egg shells only. Thus this court construed the 1938 Act as requiring the Secretary to determine if the color was required, and where required to determine the quantity that can be tolerated in that application and to regulate the use accordingly. (Actually it would appear that restriction to specific uses is automatic whenever necessity is a requirement.) The court expressed accord with the view of the court in the *Certified Color Industry Committee* case as to a requirement of clear evidence, and suggested resumption of tests, but unquestionably placed the burden on the Secretary to produce some evidence of harmfulness to humans at any level of use that might serve the purpose of coloring oranges. The order of the Secretary was set aside, and the court directed him to restrict the use to oranges and continue certification of batches. However, nothing was to be deemed to restrict the Secretary from determining a safe level. In the eyes of this court no further legislation was required. (The dissent concluded that this decision was judicial legislation.)

The Supreme Court made short work of the issue of requiring the Secretary to establish tolerances even though the color was found to be harmless. The court said that the command of the statute is plain. Where the color is not harmless, it is not to be certified. Where it is not certified, it is not to be used at all. The court summed up by asserting that the benefits of visual appeal do not outweigh the risk to public health. It is the duty of the Secretary to give effect to the distinction from other added poisonous materials.

It is clear that there is a difference of opinion among our courts. It would seem to be more than a difference in political, social or economic views. It would seem to be associated with a perhaps unrecognized viewpoint on probability. The court in the *Certified Color Industry Committee* case appeared to be much more concerned with possible harm than did the court in the *Florida Citrus Exchange* case. The Supreme Court avoided

weighing the probabilities by concluding that it was competent for Congress to adopt a rule of caution.

There also seemed to be a tendency in both lower courts to construe the statute strictly, apparently as being in derogation of the common law as set forth in the *Lexington Mill* doctrine. Perhaps we shouldn't call this common law, but in any case prior decisions had more weight than the apparent abrupt change in statutory expression. The Supreme Court, though, did not hesitate to accept the Secretary's argument based on the inclusion of special paragraphs for coal tar colors and the use of an unusual word, "harmless."

In the light of these decisions, it can be taken that national policy according to the Supreme Court is to leave the weighing of probabilities as much as possible to Congress and the administrative agencies. That is that economic necessity shall not be set off against even a small risk, if the statute can be interpreted otherwise.

The Food, Drug, and Cosmetic Act was amended in 1958 to prohibit the use in food of additives which have not been adequately tested to establish their safety.²⁵ It also permits the use in foods of additives that would not have been permitted in the 1938 Act, provided the proposed usages are in amounts accepted by FDA as safe. We have a reversal of the *Lexington Mill* doctrine. The burden of proof is now on the user rather than the government, but food additives no longer come under the test of possible injury to health. Instead, a new section has been added setting out in detail the procedure to establish safety.²⁶

The 1958 amendment culminated six years of extensive hearings.²⁷ In the process Congress evolved a concept of safety derived from the testimony of many scientists. At the same time it became apparent that there existed considerable diversity in scientific opinion or judgment factors. (The great responsibility imposed on the Commissioner of Food and Drugs was also recognized by an increase in his salary from \$17,500 to \$20,000 per year.)

As to the concept of safety, in general, proof of reasonable certainty that no harm will result is the criterion. It is recognized that complete certainty of harmlessness is not attainable. The Secretary is required to consider probable consumption, direct or indirect, of the additive or by-products; cumulative effect including effects produced by related substances, and safety factors applied to the translation to human use of data obtained from animal experimentation.²⁸

²⁵ 72 Stat. 1784, 3 U. S. Code, Cong., and Adm. News 5300 (1958).

²⁶ 72 Stat. 1785, 21 U. S. C. A. Sec. 348.

²⁷ The matter of color additives, however, is still pending at this writing, although it appears that the law will be essentially similar to the food additives amendments.

²⁸ 21 U. S. C. A. Sec. 348 (c) (5).

The Congress, in the light of the contradictory views of the eminently qualified scientists who testified, concluded that a "fair evaluation" of the entire record must be set as the new standard of judicial review.²⁹ This replaces "substantial evidence," and the reason is that Congress felt that the testimony of any one of the scientists would be substantial evidence, but it was obviously not enough. This was urged by manufacturers who feared one-sided decisions by the Secretary, based predominantly on the convictions of scientists within the Department.

"Food additives" covers a wide variety of things including radiation, but excludes such accidental contaminants as paint or cleaning fluid which would be covered by the general provisions of the 1938 Act. In deciding on tolerance levels no additive shall be deemed safe if found to induce cancer.³⁰ This so-called Delaney Amendment seems to fall in the same class of statutes as the coal tar colors. It reads:

(3) No such regulation [prescribing conditions under which an additive may be safely used] 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 regulation, will be safe: *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 the safety of food additives, to induce cancer in man or animal. . . .

In the Senate Committee report³¹ it is stated:

We applaud Congressman Delaney for having taken this, as he has every other opportunity, to focus our attention on the cancer producing potentialities of various substances, but we want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which reasonable people would expect to produce, not just cancer, but any disease or disability. In short we believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration.

This no-cancer clause has actually turned out to be as strict as it appears to be. The "cranberry incident" of the 1959 holiday season³² arose because of the discovery of very slight residues of a carcinogenic substance. Indeed, the attitude of Secretary Arthur Fleming has been thoroughly against permission of any amount of a carcinogen in food, quite the contrary to the idea that the

²⁹ *Id.* at Secs. 348 (f) (2) and 348 (g) (3).

³⁰ *Id.* at Sec. 348 (c) (3) (A).

³¹ Senate Report No. 2422, Aug. 18, 1958, 3 U. S. Code, Cong., and Adm. News 5301, 5309.

³² See 255 Food, Drug, Cosm. L. R. 1 (Nov. 16, 1959).

statute would read the same without the clause. The clause has brought objections not only from industry,³³ but also from the Department of Agriculture.³⁴ Both are concerned with the possibility of losing large sums of money on research in chemicals which by some superfine test of the future may show up in food and be banned because they are carcinogenic when fed in large quantities to rats. It is a matter of degree, and opponents of the clause argue that carcinogens should be treated as any other toxic substance. The Secretary does not believe that a little bit of cancer is all right, and he is supported by cancer experts at the National Institutes of Health. He has gone only so far as to ask for modification of the Delaney Amendment to the extent of permitting cancer-causing agents such as stilbestrol (widely used for fattening cattle) on animal feeds where *no* residue appears in the meat. It is said that without such fattening agents the price of meat might increase 10%.³⁵

The President asked for the creation of a special board to help in evaluating scientific evidence.³⁶ This is in keeping with the fair evaluation standard provided by Congress.

Pending a new color additive law, Congress has enacted special legislation permitting a new coal tar color, Citrus Red No. 2, to be used on oranges until September 1, 1961.³⁷

The policy indicated by Congress, except for the Delaney Amendment, is one of liberalizing the use of additives—by placing the big decisions in the hands of the Department of Health, Education, and Welfare. Under the President's proposal this would finally be a decision by a board of scientists. On the whole this is a reasonable way of handling a very difficult problem. It should result in decisions uninfluenced by political, social or economic views, but it is hard to imagine that such decisions will be free from personal probability judgments. If such judgments are adverse to important groups in the future, will it result in more special legislation of the kind obtained by the citrus fruit industry?

Warranty Cases

We now consider briefly some theories of warranty expressed by courts "case book" cases. These cases serve an important purpose in demonstrating the reasoning of the courts; hence they appear in case books. We will narrow the consideration to implied warranty. If a vendor wishes to make an express warranty as to the harmlessness of his product, that is his privilege. On the other hand, where negligence exists, no one would deny liability, in principle at least. But in the field of implied warranty, im-

³³ 86 No. 9 Chemical Week 21 (Feb. 27, 1960).

³⁴ 86 No. 14 Id. at 15 (Apr. 2, 1960).

³⁵ 86 No. 8 Id. at 44 (Feb. 20, 1960).

³⁶ This release appeared nationally in newspapers May 15, 1960.

³⁷ 73 Stat. 3, 21 U. S. C. A. Sec. 342 (c) 3rd proviso.

posed by law, there is much of policy considerations, and it is of some interest to inquire as to what this could lead to. Development of the law along these and other lines has been thoroughly examined elsewhere.³⁸ We propose only to examine some of the reasoning.

In *Ryan v. Progressive Grocery Stores, Inc.*,³⁹ the court found that loaves baked with pins in them are not merchantable quality—a wholly reasonable conclusion. However in this case liability attached to the immediate seller who was not responsible. Furthermore, the customer had asked for the bread by its trade name. This liberal construction of the Uniform Sales Act was defended in part by suggesting that this seller could recover in turn from the manufacturer; but unless this holding is really based on the desire to provide a remedy where direct action is barred against the manufacturer because of privity considerations, the recovery-in-turn principle is rather tenuous. If the holding stands on its own, it would mean that a food processor whose product contained an approved additive would be liable for any untoward consequences arising from its use. There is one possible distinguishing feature, and that is as to when the product becomes unmerchantable. Bread with pins baked in it would not in general have been merchantable at any time. However, food containing an additive which turns out to be harmful in spite of all precautions, does not become unmerchantable until it is found to be harmful. Until such time it will pass in the market under its general description.

Another theory is simple public policy not to permit unwholesome food to be sold. Such was the case in *Jacob E. Decker & Sons, Inc. v. Capps*.⁴⁰ In a jurisdiction which accepts the policy of the Federal Government as its own public policy, it would appear that no liability would be incurred by the use of an approved food additive. (Of course continued use after knowledge of defect would be negligence.)

Where public policy or a theory of implied warranty based on reliance of the buyer on the seller is applied one might ask: On whom does the buyer rely? Is it actually the seller or is it the United States Government? But who put the stuff in the food in the first place? Actually the government serves primarily to protect the public, not to recommend additives. (This point is immediately complicated by the fact that the Department of Agriculture is actually recommending substances that find their way into food.)

The whole question is complicated still further by the presence of public demand direct or indirect for at least the end result of food additive utilization. That is to say, that many of

³⁸ See Holdridge, *Law of Manufacturer's Liability*, 8 Clev-Mar. L. R. 14 (1959).

³⁹ *Supra* note 2.

⁴⁰ *Supra* note 3.

today's foods that are put up in a form for easy preparation would not be available without food additives. And of course we should not forget the problem of the citrus industry to sell uncolored oranges. It does not appear that present theories of implied warranty are well enough developed to work justice in the case we have contemplated here.

Science, Law, and Common Sense

In the light of the foregoing discussion of the scientific problem and of judicial and legislative policy, we now turn to the question of what is the best course to follow. We continue to break down the subject into evidence of cause and effect on the one hand and policy considerations on the other.

The point that was made in the section on statistical inference was that any considered opinion must take into account the design of the experiment or survey, and must ultimately rest on some statement of the probability of the observed result happening by chance alone. Now, while the mathematics of statistics may be difficult, and while the elements of experimental design are often subtle, when the results are properly presented they are not beyond the comprehension of ordinary man. Nor would contention over significance of design elements be especially likely to confuse him. And certainly he is as well qualified as any expert to weigh the odds. Hence we submit that the jury should not be permitted to draw any conclusions based on expert opinion alone when statistically derived results are available. Let the forum consider the propriety of the design and the weight of the probabilities rather than the credibility of the witness.

In the absence of such results the only question we can consider is whether there is any possibility of a cause and effect relation. Any opinion as to the strength of the possibility is improper because it does not meet the test of statistical inference. The situation is analogous to testimony in a personal injury suit. It is not really science. When the situation comes to this, should opinion evidence be allowed at all when entire industries and millions of people are involved? In a recent case the court directed a verdict for the defendant where the plaintiff alleged that he had contracted lung cancer from smoking defendant's cigarettes.⁴¹ This case typifies the problem we have considered here. The opinions and further development on appeal should be highly enlightening.

The attitudes involved in policy considerations are demonstrated in a journalistic debate appearing in *Chemical Processing Magazine*.⁴² Here Gordon Weyermuller set out to answer an article by columnist Jack Mabley entitled *A Poison Death for All*

⁴¹ *Pritchard v. Liggett & Myers Tobacco Co.*, Pittsburgh Fed. Distr. Ct., May 4, 1960 (A. P. dispatch).

⁴² Weyermuller, C. P. I. Must 'Break Silence', *Chemical Processing* 22 (May 1960).

of *Us*?⁴³ Mabley observed that chemicals are present in our food, and that we really do not know what their cumulative effect over a period of years will be. This is a point well taken. Weyermuller replied that Mabley, not being a chemist, lacked understanding of the complex subject of his article. But does Weyermuller fully understand it himself? He remarks that food itself is a chemical (a banality) and that many natural ingredients of food would be poisonous by themselves. However, this brings out an important distinction between natural ingredients and unnatural ones. Mankind has had countless generations in which to develop immunity to the natural constituents of his diet in the amounts in which they ordinarily occur.

Mabley was disturbed by the chemicals in water. Weyermuller pointed out that they are put there to prevent the scourge of impure water. This reason is hard to challenge.

Mabley was impressed by the fact that in America, life expectancy at birth is near the top, but at 40 it is near the bottom. A logical explanation for this is not hard to find. In other societies for the most part only the hardiest babies survive. However, neither this explanation nor one which places the blame on food additives is warranted except as a hypothesis. Similarly, Mabley notes that an increase in the cancer death rate and a progressive deterioration of the national health coincides with the introduction of chemical poisons into the food supply, but he never pauses to weigh the consequences of eliminating these so-called poisons. He makes another good point, though, in bringing out the variation in effect on different people. Furthermore, there is little opportunity for people who simply want to avoid modified food to do so, and in fact it may be difficult even to determine whether a certain material has been added or not. It would seem that in the interests of good faith and self protection manufacturers ought to list all ingredients. In any case, until all effects of a food additive are known, and in the absence of an effective system of notice, the only wise policy is clearly to protect the most susceptible. A large factor of safety in setting tolerances is indicated.

Weyermuller countered Mabley's somewhat alarmist observations with the statement that only one death has been definitely attributed to a food additive, and it was clearly misused. He naturally enough considers the consequences of eliminating chemicals from food. He feels that thousands of lives have been saved through the use of chemicals in processing food. In fact he says that it is certainly known that it would be extremely harmful to bar chemicals from food. He offers as a lone example the use of chemical sanitizers to keep milk germ free from milking parlor to consumer's table. He does not defend his statement as to the countless other food additives in common use. Weyermuller is chiefly concerned about the reputation of the chemical

⁴³ Chicago Daily News, March 18, 1960.

industry, and in that context he goes on to remind the reader of the great benefits to life which that industry has contributed. However, this only diverts attention away from the real problem raised by Mabley. Weyermuller points with pride to the exhaustive tests conducted in industry laboratories to check the safety of chemicals—to which we simply say they had better!

There are certain other aspects of the problem which should not be overlooked. Consider for example that fats and cholesterol have been indicted as a cause of heart and arterial disease. These are perfectly natural foods. It is said that part of America's poor national health picture arises from a high standard of living which permits of more rich living. These associations are as justified as those made with food additives and national health.

It must be admitted that food additives have become popular in convenience foods, and in a sense are demanded although indirectly where they reduce costs. It may be that there is a national assumption of risk, which can perhaps best be illustrated by an analogy. Consider the great care taken in maintaining and operating the President's private plane. If this care were extended to commercial aircraft, it is likely that aircraft fatalities would be reduced. It appears that we accept something less in the interests of economy and convenience.

Probably the best ground on which to judge an additive is its purpose. If it is used primarily to cut manufacturers' costs without any material benefit in kind to the consumer, it is not justifiable. If there is a non-essential benefit to the consumer such as a matter of texture or convenience, it should at least be possible to avoid it. If there is a benefit connected with safety as is the case with preservatives and water treatment, the use is justified in that the benefit outweighs the risk, but even so this does not mean that research to find something better is unnecessary.

It was in connection with research that Mabley made his most telling point. The FDA has a research budget of \$2.9 million to protect the safety of America. The Department of Agriculture research budget runs to some \$139 million mostly for economic purposes. Does this reveal our national policy?

The conclusion is inescapable that our best protection lies in a vastly increased amount of research on food additives. This would undoubtedly also yield valuable incidental benefits. Those who are most concerned about food additives could hardly do better than to work for an increase in this much needed research.