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Food Drug Cosmetic Law JOURNAL

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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REPORTS

TO THE READER

IDIP and Citation Hearings—Rights, Responsibilities and Opportunities.—Beginning on page 404, *Tobias G. Klinger* investigates the so-called citation or informational hearings under Section 305 of the Food, Drug, and Cosmetic Act. Mr. Klinger deals not only with the opportunities afforded the manufacturer to discuss the alleged violation with the government accuser and to prepare and present the facts and his views, but also the responsibility that FDA has toward the manufacturer in instituting an intensified inspection. Mr. Klinger is a partner in the law firm of Klinger and Leevan.

The New Citadel: Enterprise Liability for Inherently Dangerous Products.—This article was written by *André L. Philpot*, who is employed in the Ontario Attorney General's office, and is soon to be associated with Kings College, London. Mr. Philpot questions whether the war on enterprise liability should be pursued, and speculates on the cost if it is. The areas of Mr. Philpot's concern are the legal controls over products not known to be inherently dangerous at time of purchase, and control of products known to be unavoidably dangerous. The article begins on page 414.

Problems in the Administration and Enforcement of Food Laws.—The problems in administration and enforcement of food laws are extensively discussed by *Michael F. Markel* in an article presented at SOS/70, Third International Congress of Food Science and Technology, Washington, D. C. The suggestions for instituting mandatory standards "having the force and effect of law" and "fixing nutritional values for certain classes of foods" are examined. Mr. Markel also examines the scientists' responsibility and "moral obligation" to help solve the problems of enforcement of food laws, especially with respect to evaluation of all available scientific information and data. Concern is also expressed for the adverse effects of unwarranted publicity given to administrative and enforcement activities. This publicity has not only confused the consuming public, but has, directly and indirectly, eroded the independence of the Food and Drug Administration. Mr. Markel, whose article begins on page 429, is a partner in the Washington, D. C. law firm of Markel, Hill & Byerley.

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IDIP and Citation Hearings—Rights, Responsibilities and Opportunities

By TOBIAS G. KLINGER

Mr. Klinger Is a Partner in the Law Firm of Klinger and Leevan, Los Angeles, California.

MUCH HAS ALREADY BEEN WRITTEN and spoken about the Intensified Drug Inspection Program (IDIP) both from the Government and industry points of view, describing its purposes and objectives, its legal foundation and suggestions as to how they should be approached and handled both from a legal and practical point of view.[1]

On the other hand, very little has been written or spoken about the so-called citation or informational hearings under Section 305 of the Act. Yet it is a procedure used with considerable frequency by the Food and Drug Administration (FDA) and relates to matters which are potentially of the most serious concern. The FDA considers them an important part of the Act, providing a most useful and worthwhile method both to educate industry (or at least individual mem-

[1] See, Kushen, *Intensified Drug Inspection As Industry Sees It*, FOOD DRUG COSMETIC LAW JOURNAL, February, 1969, p. 78; Frediani, *FDA's Intensified Drug Inspection Program*, FOOD DRUG COSMETIC LAW JOURNAL, March, 1970, p. 131; Whyte, *Intensified Drug Inspection Program*, FOOD DRUG COSMETIC LAW JOURNAL, April, 1970, p. 197; Kleinfeld, *Intensified Inspections—A Rule of Reasonableness*, FOOD DRUG COSMETIC LAW JOURNAL, April, 1969, p. 210; Barnard, *FDA's Intensified Drug Inspection Program (IDIP)*, FOOD DRUG COSMETIC LAW JOURNAL, May, 1969, p. 220.

bers of it) and to implement its regulatory program. From an industry point of view, such hearings, while far from an unmixed blessing, represent an opportunity which, whenever possible, should be responsibly seized and responsibly utilized.

There is—or may be—a connection between intensified drug inspections and citation or informational hearings, so that combining them in a single topic or subject is not so far-fetched as it may at first blush appear. Intensified inspections may very well lead to the consideration by the FDA of criminal action, and in that event the citation hearing will come into play. I do not know as of now whether any IDI has led to a citation hearing—they have led to injunctive proceedings—but there is no question that they can, just as the regular or normal factory inspections have and do.

Objectives of the Inspection

Government sources have made it plain that the fundamental purpose of the IDIP is to achieve compliance "or taking the necessary regulatory steps to keep the firm's products from reaching the patient."[2] One way of discouraging the production of illegal or non-complying drugs is, of course, criminal prosecution of those responsible.

With respect to the IDIP, suffice it for present purposes to say that the FDA has certain definite responsibilities to industry which it is fair to say it is attempting to fulfill. Fundamentally, the Government's responsibility is to undertake these inspections after the full and complete discussion and explanation of them to management, to use them primarily for the purpose of making an in-depth study of the operations of the particular drug manufacturer involved, and to seek the voluntary correction of any significant deviation from good manufacturing practice disclosed by the inspection. Since these inspections are conducted under the legal authority of the Factory Inspection sections of the Federal Food, Drug, and Cosmetic Act, the Government has the responsibility to see to it that they are conducted reasonably as to time, manner and scope. They should not be a disguised inquisition resulting in the submission by the Inspector of a long series of observations which are trivial and nit-picking in the extreme and only create antagonism and a feeling of persecution.

It is well, and the manufacturer has the right, at the so-called pre-inspection conference or briefing, to discuss and make as concrete

[2] Berch, *FDA's Intensified Drug Inspection Program,* Feb. 1970, Food Drug Cosmetic Law Journal, p. 101, at 102.

as possible the objectives of the proposed IDI. Notes should be taken at the conference and can be reduced to writing so that specific guidelines are established for the inspection. This is not to straightjacket the inspection or unduly to limit or restrict the Government. Rather, a clear and definite understanding at the outset will make for a better inspection, for better and more willing cooperation, and achieve better results. The Government has the responsibility, once these guidelines are properly established, to keep its inspection within the guidelines laid down. If, under these circumstances, during the inspection the Inspector deviates substantially from the defined purposes, the manufacturer certainly has the right to, and should, communicate such deviations to the District Director, or the other FDA representative in over-all charge, so that such variations and such misunderstandings —if they are misunderstandings—may be straightened out and corrected. For example, if the inspection is to concern itself with prescription items only, and this is understood at the outset, then for the inspection, once it is in progress, to start getting into over-the-counter drugs, or food supplements, or labeling matters, should not be permitted unless there is further agreement that one or more of these matters may be added to the originally-stated objectives of the inspection.

Maintaining Appropriate Balance

There is one procedure we have followed in connection with IDI's that is, or should be, useful both to the manufacturer and to the Government. Although IDI's may be handled somewhat differently in the different regions and by different inspectors, what is generally done is that intensified inspections are conducted in various phases or segments covering different aspects of the pharmaceutical manufacturing process. At the completion of each segment of such intensified inspection, the inspector prepares and submits to the manufacturer a list of his drug inspectional observations which sets forth, frequently in considerable detail, everything which he saw, heard or discovered which might possibly affect the quality of the drugs being manufactured. It is not an exaggeration to say that a supertechnical inspector, who may quite humanly believe that the longer the list of his observations the better the report will appear to his superiors, can find numerous things to report even in the finest and most modern plant. The intensified inspection is not limited at all to the discovery of drugs which are actually adulterated or which deviate substantially from their claimed potency or are otherwise improperly manufactured or prepared, but includes the observation and reporting of conditions

which *might,* however remotely, cause difficulty. Some observations noted may, by any standard, be trivial in the extreme.

Frequently during the inspection, some condition or other in the plant or in the conduct of an employee is noted, and when brought to the attention of management is immediately corrected. Nevertheless, the inspector's report will list the condition or conduct noted without any reference to the fact that it was promptly corrected by management. Perhaps most significantly, from a reading of the inspector's drug inspectional observations, one frequently cannot determine whether a particular observation represents an isolated instance posing no real problem, or constitutes a practice which may create a real problem.

For these reasons, we have found it useful that at the completion of each phase of an IDI, when the inspector's drug inspectional observations are received, they are carefully and fully reviewed and a detailed statement in writing is prepared covering and discussing each item in the inspector's list which is submitted to the District Director or the Supervisory Inspector to be made a part of the record. The written statement thus made should be very carefully prepared so as to be as accurate and complete as possible. There is nothing worse than having a Reviewing Officer in Washington or in the FDA Regional Office read several lists of 20, 30 or 40 drug inspectional observations all pointing to or suggesting operational and other deficiencies, unrelieved by anything in the same record explaining or clarifying many of the items and showing what management has done and is doing with respect to them. Such a detailed statement serves the salutary purpose of putting the inspector's observations and the entire inspection in proper perspective.

Lawyers would understand that it is somewhat like a lawsuit where first you hear the plaintiff's case and witness after witness testifies for the plaintiff so that the plaintiff's case appears overwhelming. Then when the defendant presents his case and his witnesses, some appropriate balance is restored and a fairer and truer picture of the facts is obtained and a closer approximation of the truth achieved.

So it is with the written response to the drug inspectional observations. It cannot be emphasized too strongly, however, that care should be exercised in the preparation of the response so that the response is fair, measured and accurate. It should not be peevish or belligerent, but if there are instances in which the inspector is in error, or misunderstood a particular situation, the error should be

pointed out and the misunderstanding clarified. Such a response is not only helpful and useful to the manufacturer for the reasons indicated, but should be of value to the Government as well, since it describes what the manufacturer is doing and how he is responding to the intensified inspection.

Notice of Hearing Procedure

If, as a result of an intensified drug inspection, or as the result of a normal factory inspection, or as the result of information coming to the FDA in any other way, a violation or violations of the Act of sufficient seriousness to warrant the consideration of criminal prosecution are found, the FDA will issue a Notice of Hearing pursuant to Section 305 of the Act to the firm and/or individuals deemed responsible.

What is it, and what should be done about it?

What it is, in blunt terms, is a notice that the FDA considers the named respondent responsible for certain violations of the Act described in an accompanying charge sheet, and is considering referring the matter to the Department of Justice for criminal prosecution.

What to do about it is to take full advantage of the opportunity offered to convince the FDA that criminal prosecution is unwarranted or unnecessary and should not be undertaken. What must *not* be done is to ignore it or treat it in some off-hand or cavalier fashion. It is a serious matter and should be treated in a serious way.

If it is not done before, and if it is at all possible, steps should be taken at once to cure or correct—or to start curing or correcting—the matters upon which the charges are based.

If it is a matter of labeling, further shipments of the misbranded items should be halted and the labeling corrected.

If it is a matter of drug potency, further manufacture and further shipment of such drug should be stopped, and the practices and procedures reviewed to determine the reason therefor and to correct it.

If it is a matter of sanitation, procedures should be adopted to correct and clean up the plant, including inspections, extermination programs, improvement of plant and equipment, and other appropriate measures.

These things should be done so that when the respondent attends the hearing, the FDA may be advised of the affirmative and constructive steps which have been taken and are being taken. This type of conduct is not only proper from a public and self-interest point of view, but is the most important evidence one can present at the

hearing showing respondent's concern and good-faith desire to operate in compliance with law. If what has been done is appropriate and meaningful, it will go far toward persuading the FDA not to institute criminal proceedings.

The Notice of Hearing is not unlike an order to show cause, which is a familiar procedural device in our courts. In substance, it says that we—the FDA— have evidence that you—the manufacturer —are probably responsible for a violation of the Act which may result in criminal proceedings against you, and we are giving you an opportunity to come in and present your views orally or in writing, or both, with respect to the matters charged. It sets a date for the hearing, includes a so-called Information Sheet explaining the purpose and nature of the hearing, and informs the respondent that if no response is received on or before the date set, the decision on whether to refer the matter to the Department of Justice for prosecution will be based on the evidence at hand.

What is offered is an opportunity to explain voluntarily any circumstances in connection with the preparation, handling, shipment or sale of the particular articles involved in the charges described in the accompanying Charge Sheet which would indicate that criminal action should not be taken. The respondent is specifically informed that he may, but is not compelled, to answer.

Statutory Basis

The statutory basis for this procedure is found in Section 305 of the Act, which declares that "before any violation of this Chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with respect to such contemplated proceeding."

Although the statute uses the mandatory "shall," the courts have determined that the affording of such a hearing is not a prerequisite or a condition precedent to a criminal prosecution.[3] It is considered an "administrative direction" to the Administrator rather than a "jurisdictional requirement" for criminal proceedings. Be that as it may, and while it appears from some of these cases that such a hearing has not always been held prior to criminal prosecution, it is my understanding that except in a situation of some extreme

[3] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

emergency where speed in the institution of criminal prosecution is of the essence, it is the invariable practice to hold such a hearing.

As a matter of legal right it has been determined that once such a hearing is held, the facts and views presented must be considered by the Government before criminal prosecution is undertaken. This, on the reasoning that the statement is given under the implied understanding or promise that it would be considered before a decision to prosecute was made.[4] How one can tell whether it has been considered is hard to tell, unless the criminal prosecution follows so closely upon the hearing that as a physical matter it could not possibly have been considered. Nevertheless, such consideration is a requirement and in my experience the FDA has observed it, and one can be quite certain will continue to conform to it. The remedy, if it is not so considered, is not to prevent the criminal prosecution but to permit the suppression of the statement in the criminal prosecution so that the Government may not use anything in it against the defendant.

Section 305 Hearing Procedures

This brings us to a consideration of the possible adverse legal consequences of attending a Section 305 hearing and making a statement, written or oral. It is plain that if at such a hearing admissions are made, they can be used by the Government in a subsequent criminal prosecution to the extent that they are material and relevant. For that matter, they could be used as evidence in a contested seizure action or a civil action for an injunction. Nor is the Government required to warn the respondent that a civil action for an injunction is being contemplated.[5] Similarly, in a criminal prosecution the Government can pretty well use use pertinent evidence and admissions obtained by way of interrogatories in a prior or contemporaneous civil proceeding.[6] The same rule would apply to evidence or leads obtained in depositions[7] or by requests for admissions. Analysis of the *Kordel* case and its implications could very well be the subject of a 10- or 15-minute talk itself. But the general rule it lays down is that except in the rare situation where it can be shown that no individual can answer interrogatories addressed to a corporation without subjecting himself to a real and appreciable risk of self-incrimination, or where the

[4] *U. S. v. Andreadis* (D. C. N. Y. 1964), 234 F. Supp. 341.

[5] *U. S. v. Ellis Research Laboratories, Inc.* (C. A. 1962), 300 F. 2d 550; cert. denied 370 U. S. 918.

[6] *U. S. v. Kordel.* (U. S. Supreme Court, Feb. 24, 1970).

[7] *U. S. v. Andreadis, supra.*

Government has brought the civil action solely to obtain evidence for its criminal prosecution, interrogatories directed against a corporate defendant in the ordinary course of a civil proceeding will have to be answered, and the evidence or leads thus obtained can be used in a subsequent or simultaneous criminal prosecution.

However, with respect to the statements and information given at a Section 305 hearing, the fact is that by the time a Notice of Hearing is sent, the Government is beyond the point of looking for evidence with which to support a criminal prosecution. The Government by that time generally has the evidence which it deems necessary to support a criminal prosecution if it should decide to go forward with one, and is ready to proceed unless it is persuaded or convinced to the contrary. Thus, while it is not suggested that Russian-style confessions of guilt be made in such statements, it is my own judgment that the properly-prepared statement will not increase the respondent's jeopardy.

In the *Kordel* case, the court points out quite correctly that service of the statutory notice on a respondent does not necessarily mean that a criminal prosecution will follow, and the opinion refers to testimony before the District Court that fewer than 10% of the matters involving a Section 305 notice reach the state of either indictment or information. Since the FDA has been using the warning letter permitted by Section 306 of the Act more frequently than it did in the past, and reserving the Notice of Hearing procedure for what are considered the more serious violations, it may be that this percentage has increased, or will increase. But even if criminal prosecution followed in only 10% of the cases, that would be ample reason to prepare fully and completely for the hearing and to present to the Hearing Officer data and information of a specific and concrete nature which will tend to establish that criminal prosecution should not follow.

Precise Statement of Facts

Generally, citation hearings are not taken with a stenographer or court reporter present, and there is no transcript of the proceedings, although there have been times in the past when statements have been transcribed. Objection should be made to a transcription of any oral statement by the respondent given off-the-cuff, as it were, at the hearing because of the very real risk that such a statement will be incomplete or not clearly or precisely composed. What we prefer to do in nearly every case is to prepare a detailed written

statement to be made a part of the record. Such a written statement, supplemented with exhibits attached of copies of pertinent letters, memoranda, guaranties, shipping documents, analyses, etc., is permitted by the rules governing the hearing and is welcomed, although not demanded nor insisted upon. The preparation of a written statement to be submitted in triplicate at the hearing permits the careful and precise statement of the facts which the respondent wishes to present and makes that statement a part of the permanent record. This is far better than any summary of notes taken by the Hearing Officer, even though the summary or Record of Hearing, as it is called, is submitted to the respondent afterwards for review and correction. Hearing Officers tell me that oral statements alone are often composed of generalities, whereas what the Hearing Officer is looking for is specifics, both as to explanations, factors in mitigation, and actions taken to correct any deficiencies and prevent their recurrence.

Moreover, it is my view that the preparation and submission of such a complete and detailed written statement is more impressive and more persuasive than an oral statement alone. It demonstrates to the Hearing Officer and to any Reviewing Officer in Washington that the respondent not only considers the matter serious and is concerned about it, but is prepared to make a written commitment on the record. Of course, no commitment should be made which cannot or will not be kept, for you may be sure that the FDA in due course will be checking on the performance of any pledge, promise or commitment. It is far better to make no commitment at all than to make one for the temporary postponement of a criminal prosecution which will ultimately be instituted, perhaps with redoubled energy, when the falsity of the commitment is exposed. The written statement can, and generally should, be orally supplemented and amplified at the hearing, and various points made in the written statement may usefully be emphasized orally.

Decisions, Consequences and Opportunities

At the conclusion of a hearing, the Hearing Officer or the Regional Office decides upon a recommendation to be made in the particular case. One of three decisions is possible.

A decision to prosecute may be recommended. This recommendation is referred to Washington for review. I have been told that the recommendation made from the field is followed in at least 99% of the cases.

The decision may be not to prosecute and to put the matter into what is sometimes termed *permanent abeyance.* This is ordinarily the end of the matter, although on occasion the Regional Office may request a review of such a decision by Washington.

A third alternative, frequently used, is a decision to put the matter in what has been called *temporary abeyance.* This simply means that the respondent is going to be given another chance, to be put on probation, as it were. The matter is not finally terminated, but no immediate prosecution is to be undertaken. Later inspections or investigations will be made to determine whether the particular violations involved persist. If they are then found, the matter placed in temporary abeyance is resurrected and, together with the new violations found, may form the basis of a prosecution. If later inspections disclose no serious or continuing violations, the matter held in temporary abeyance will ultimately be put in permanent abeyance.

One further point. At the conclusion of the hearing, most Hearing Officers do not announce their recommendation, although occasionally if the matter is to be placed in temporary abeyance he will so advise the respondent. What happens, when no decision as to recommendation is announced, is that the respondent must simply wait. As a rule of thumb, after six to twelve months pass without any criminal prosecution being instituted, it can probably be concluded that a decision not to prosecute criminally was made.

Section 305 hearings afford the particular respondent or respondents a unique opportunity, rarely found in criminal law, to discuss the alleged violation with the government accuser and to prepare and present in a relatively informal way the facts and his views as to why criminal prosecution should not be undertaken in his case.

In my experience the FDA has lived up fully to its responsibility in affording the respondent a full opportunity to present his views, and to give them fair and even sympathetic consideration. Industry, in these matters, should fully exercise its right to such a hearing and fulfill its parallel responsibility to present fairly and in good faith the facts and circumstances which establish that enforcement of the Act and obtaining compliance therewith do not require the institution of criminal prosecution. The Government will thereby be in a better position to make an informed, fair and reasonable decision in each case, and, at the same time, both the public interest and the legitimate interests of industry will be better served. **[The End]**

The New Citadel: Enterprise Liability for Inherently Dangerous Products

By ANDRÉ L. PHILPOT

Mr. Philpot Is With the Attorney General's Office in Ontario, and Is Soon To Be Associated with Kings College, London.

THE CITADEL HAS FALLEN, or at least so we are told.[1] The battle is won, but how far should the war be pursued, and at what cost?

One of the last frontiers in assigning liability to the manufacturer lies virtually untouched, perhaps rightly so. Retrospectively the justification for the assault on the citadel seems obvious, inevitable. The memory of the citadel seems amazing, even absurd. That a manufacturer should pay for the damage caused by rodents in his beverages, toes in his tobacco, poisons in his foods and so forth appears almost undeniably just, even if it may be sometimes challenged as an impractical solution. But what is to be done with the cases on the new fringe of Enterprise Liability law? What do we do when the bottle does not explode, implode, crack or contain foreign pollutants? What do we do when it merely contains what it claims to contain, pure and in no way adulterated, but that contents brings injury? Whether the dangerous propensities of the contents be known or unknown, there is no facile or obvious answer to the problem of assigning liability to the manufacturers of inherently dangerous products.

While the control of products, which are improper either by reason of error attributable to the manufacturer, or by unmarketability by reason of some unknown cause, has been created by the

[1] Prosser, "The Fall of the Citadel" 50 *Minn. L. R.* 791.

interpretive at least, extravagant at most, imaginations of the judges, we will very seriously question the propriety of judicial action in the sphere of controlling inherently dangerous products. The decision that the manufacturer of a product which is unavoidably dangerous, or which turns out to be dangerous despite the informed prediction of modern science to the contrary, is to pay for the inevitable losses, is better reached by representatives of contemporary opinion, the legislatures, than by arbitrators charged with upholding legal maxims. The cases show, however, that the judges have not seen their duties to be so limited.

In summarizing the legal control over inherently dangerous products, I will deal firstly with products that the consumer buys under the erroneous but reasonable belief that they are by nature harmless; secondly, those which he knows to be harmful but purchases anyway. Although these categories are of some significance from the point of law-making in reference to social policy, the products do not always slip into them easily. When a successful suit is brought, the product involved has already, in experience, proven dangerous. Such products as cigarettes and birth control pills were at first not considered dangerous and now are deemed under suspicion. Other products dwell on the borderline; we have always rather suspected that such things as pesticides and food additives, if not inherently dangerous, at least should be suspect, being creators of frighteningly drastic ecological and biological changes. These products cannot be assigned easily to either category.

A. Legal Controls Over Products Not Known To Be Inherently Dangerous at Time of Purchase

The alarming regularity with which products considered harmless to human health are being exposed as causes of substantial harm, warrants a serious consideration of the extension of liability to the manufacturer who markets the product. For a great many years it was not popularly believed that there was a real link between cigarettes and cancer diseases; the early purchasers of such notorious drugs as thalidomide had no grounds for suspecting it to be teratogenic; food additives,[2] pesticides[3] and oral contraceptives, all con-

[2] In Canada a phased withdrawal of cyclamates will end by Sept. 1st, 1970, so that none will be on grocery shelves; permissible levels of brominated oils in soft drinks have also recently been lowered; *Globe and Mail*, April 15th, 1970, p. 11.

[3] See next page for text of footnote.

sidered of great worth until a few years ago, are under the scrutiny of health officers of today.

(1) Drug Products

The whole pharmacopoeia is filled with drugs that are not safe, even when they are properly made and properly use.[4]

No products are more liable to be labelled as a benefit one day and a curse the next than are drugs. The very nature of the therapeutic action sought inevitably creates a substantial risk of injurious side-effects:

We may generalize that many poisons may be drugs, and many, possibly all, drugs may be poisons. Therapeutic effects are in fact for the most part specific toxic actions. The utility of a drug depends on the margin between the desired toxic action and that which is an embarrassment, and also on the nature of the less desirable manifestations of its toxicity.[5]

The unpredictable adverse effects of new drugs may be of three kinds: (1) therapeutic side-effects, where the desired action of the drug works to excess and interferes with regular physiological functioning of the body; (2) allergic reactions to the drugs displayed by individuals demonstrably different from the normal population; (3) "Toxic reactions not predictable from the therapeutic effect and not involving an idiosyncratic reaction to the drug."[6]

The U. S. Public Health Service estimate of 1.3 million drug reactions per year, requiring medical attention or resulting in loss of work, include adverse effects of the three kinds mentioned above and reactions to blood transfusions and vaccinations.[7]

It is generally recognized that therapeutic side-effects, the exaggerated therapeutic action of a new drug, is rare and usually transitory.[8] A greater problem exists, however, in reference to allergic reactions. Often, no amount of testing can eliminate the possibility that adverse effects may be the result of use of a new compound by susceptible customers. Thus the injury a plaintiff user of the new drug sues on is often totally unpredictable by science. The legal consequence of this has been that the court, unable to stretch tort law or foreseeability

[3] A recent example being the suspected teratogenic effect of the herbicide 2, 4, 5-T, a weed killer for which interstate sales have now been prohibited; *Globe and Mail*, April 16th, 1970, p. 4.

[4] Prosser, footnote 1, supra, p. 808.

[5] G. E. Paget, "The Safety of New Drugs," 1 *Medicine, Science and Law* (1961) 153.

[6] After Paget, footnote 5, supra, p. 154.

[7] See *Drug News Weekly*, Jan. 30, 1968, p. 8, col. 2.

[8] Paget, footnote 5, supra.

under contract to cover the situation, has generally concluded that the patient, turned victim, has no grounds for recovery either for negligence or for breach of warranty, where he as buyer was unusually susceptible to injury from the product reasonably considered by the manufacturer to be harmless.[9] As we shall see, however, failure to adequately warn of known dangers, even to a minority of consumers, or to test for unknown ones, may form the basis for an action in negligence.[10]

The third possible kind of adverse effect of new drugs, unpredictable toxic reactions, has been the object both of public interest and of substantial litigation. The most notorious instance of injury resulting from a new drug was the thalidomide affair. Thalidomide was a sleeping pill developed by a German manufacturer and marketed in many other countries. Its effect upon the unborn child of its users came as a very major shock to the public on both sides of the Atlantic. There were very few incidents of injury in North America, but the drug seriously handicapped between two and three thousand babies in West Germany. On their behalf the West German government has brought suit against the Chemie-Gruenenthal company, which in turn has had a settlement offer of $27,300,000, or between $13,000 and $19,000 for each child, refused.[11] In rejecting a motion for dismissal of the suit, the presiding judge in the twenty-month trial has ruled that the proof of causal connection which must be presented for the plaintiffs is not absolute scientific and mathematical certainty,[12] but legal proof.[13] Seven executives of Chemie-Gruenenthal also face charges of causing bodily harm through neglect and with intent, negligent killing and violating West German drug laws.[14]

In the United Kingdom, thalidomide went on sale in 1958 and was withdrawn in 1961. In a series of sixty-two awards to date,[15] the distributors of the drug in Britain have paid approximately $50,000 average for each instance of malformation caused by the drug. The latest award was handed down in High Court against Distillers Co.

[9] See 26 A. L. R. (2d) 966. Note there are decisions to the contrary of this dicta; in *Briggs v. National Industries*, knowledge of the potential harmful effect of a product on a minority, gives rise to a duty to warn but no liability will lie without knowledge. 92 Cal. App. (2d) 542 (1949), 207 P. (2d) 110.

[10] See P. D. Rheingold, "Product Liability—The Ethical Drug Manufacturer's Liability," 18 *Rutgers Law Review*, 947.

[11] *Time*, Feb. 9, 1970, p. 40.

[12] Challenged as unverifiable by Nobel Prize-winning scientist; *Globe and Mail*, April 3rd, 1970, p. 9.

[13] See footnote 12, supra, this term is not clearly defined.

[14] See footnote 12, supra.

[15] April 23, 1970.

(Biochemicals) Ltd. in an agreed settlement of damages of $961,243.40 for eighteen children.[16] No suits have yet been litigated in North America.

The thalidomide cases are, however, the easier cases to decide in favor of enterprise liability. There is substantial evidence available that the company was negligent in failing to test its product, even in violating existing drug laws; as well there are allegations of marketing with knowledge of possible dangers.[17] It is an established principle that negligence in testing or in failure to warn of known dangers may well found a cause of action in tort.

Regulation of New Drugs

The thalidomide episode became a public issue in the late summer of 1962, and had a great effect on the Congressional considerations of drug law amendments before Congress at that time.[18] A sweeping revision of the Federal laws in this area, for the first time in twenty-five years,[19] became effective in October of 1962.[20] Of prime interest are the provisions made in regard to the introduction of new drugs. Before the 1962 amendments it was possible, in admittedly specialized circumstances, that a drug could be legally released without the express approval of the Food and Drug Administration (FDA). Now by Section 104(a) and (b) of the amendments, no drug may be released until the FDA has affirmatively determined that its use is both positively efficacious and safe, as far as predictable by elaborate tests.

Testing unfortunately is far from a complete answer to the problem of toxic reactions to new drugs, since it is a far-from-perfect screening mechanism. In many cases the species on which a new drug is tested will be either more or less susceptible to toxic reactions than are the drug's future human users. In one test of an antibacterial substance of some promise, under investigation for a United Kingdom manufacturer,[21] the compound was administered in proportionately large doses to rats, dogs and mice with no harmful reactions. Some small effect was noted in rabbits, and a trivial change occurred in monkeys given the drug. Startlingly, however, in guinea pigs the

[16] *Globe and Mail*, March 24, 1970.

[17] *Globe and Mail*, April 3, 1970, p. 9.

[18] See note: "Drug Amendments of 1962: How Much Regulation?" 18 *Rutgers Law Review*, 101 at 113-115.

[19] Of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938).

[20] As law S. 1552, 76 Stat. 780 (1862), 21 U. S. C. §§ 301-92 (Supp. 10, 1962) called the Kefauver-Harris Drug Amendments of 1962.

[21] Paget, footnote 5, supra, p. 156.

eyes became opaque due to rapidly occurring changes in both lens and cornea, giving rise to widespread and irreversible derangement of the ocular structures. Needless to say, the drug was abandoned.

The other side of the coin is obviously that demonstrations showing that such products as cyclamates or brominated vegetable oils can cause bladder cancer and heart lesions respectively,[22] in rats, does not mean that they do so when consumed in beverages by humans. Toxic reactions are simply not universal to all species, so that it remains possible for a drug to harbor unknown hazards to its consumers even if it be fully tested to the limit of legal duty and scientific knowledge.[23] Risk of harm from unpredictable toxic reactions to new drugs can only be minimized, not eliminated, by testing.

Bases of Liability

The legal problem thus will remain; under what conditions will the manufacturer or distributor of a new drug erroneously considered to be free of harmful effects be held liable for the injuries which result from its normal use? One basis of liability, inadequate testing, has been stretched by the courts to allow recovery in cases where negligence has been minimal. Thus in *Stromsodt v. Parke-Davis and Co.*,[24] the defendant manufacturer of "Quardrigen" antigen against diptheria, perterssis, tetanus, and poliomyelitis, was held liable for the toxic reaction suffered by an infant treated with the product. The defendant was said to be liable in negligence for inadequately testing the drug before marketing it, notwithstanding that the drug satisfied the minimum standards set by the Federal Government. Two other recent cases, concerned with injuries from toxic reactions associated with the use of a drug by the name of MER/29, came to very different conclusions. In Oregon,[25] it was held that the drug, properly tested, labelled with appropriate warnings of known dangers approved by the FDA, and marketed properly under federal regulations was, as a matter of law, reasonably safe, and in consequence no action would lie with the injured user unless some flaw of the particular batch of the product could be shown. In California,[26] it was held

[22] *Globe and Mail*, April 15, 1970, p. 11.

[23] The contention that dangers inherent in new drugs could be avoided by a detailed biochemical analysis, (see J. M. Barnes and Dentz, F. A., 1954, "Experimental Methods Used in Determining Chronic Toxicity," *Pharmacol. Rev.* 5, 191) is impractical as we simply lack the detailed knowledge needed for such analysis in most cases.

[24] (D. C. N. D.) 257 F. Supp. 991 (applying North Dakota law).

[25] *Lewis v. Baker*, 243 Or. 317, 413 P. 2d 400.

[26] *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 *Cal. Rptr.* 398.

that the same drug was not tested with ordinary care before marketing and that the defendant was liable in negligence, evidenced as well by breach of the reporting requirements of the Federal Food, Drug, and Cosmetic Act.

In many instances, a drug which has proven itself to be harmless, not only to the satisfaction of the FDA, but also under the best scientific techniques, may turn out to be unpredictably harmful. Where the manufacturer has produced a drug, perfect in the commercial sense, and the plaintiff's suit results from injury by toxic reaction to that drug, which no available scientific knowledge could predict, the general course is to deny recovery.[27] The only justification for a contrary jurisprudence, that is, holding the manufacturer liable, would be, it is maintained, on economic grounds with an aim to best distributing the losses of the unpredictable injury. To use this justification as a general rule would create more absurdity and injustice than it would alleviate.

A drug of unknown harmful effects does not only harm one petitioner, it may harm thousands or millions of users. As the injury is unpredictable, the manufacturer cannot plan his price on the basis of distributing foreseeable losses before they occur. If the drug is popular and measurably injurious, the suits would eliminate even the most substantial manufacturer, providing neither justice for the drugs' victims who sue too late, nor equity to the manufacturer who through no fault of his own is driven from business. The law would not serve society in putting out of business the manufacturers who by mere misfortune cause such injuries, nor would it provide any assistance for the bulk of the users of a dangerous product; it would be a law merely for the few users who happened to sue a solvent company early enough. As such, it is a law to be condemned as arbitrary and useless in solving the main issues the problem area raises.

Even should absolute liability of drug manufacturers whose products cause unforeseeable harm be advocated, the decision to impose it should be a legislative one, not a judicial one. The considera-

[27] See *O'Hara v. Merck & Co.* (C. A. 8 Minn.) 381 F. 2d 286 where the injury was intestinal lesions from the use of "Diuril K a-50," but the action failed as no negligence in testing was shown; see also *Fritz v. Parke Davis & Co.*, 277 Minn. 210, 152 NW 2d 129 (affirming judgment for defendant); by analogy see the "cigarette cases" *Lastigue v. L. J. Reynolds Tobacco Co.*, 317 F. 2d 19 (5th Cir.) 1963 and *Ross v. Phillip Morris & Co.*, 328 F. 2d 3 (8th Cir.) 1964, which both held that strict liability did not extend to dangers "which no skill or knowledge thus far existing could avoid;" this proposition is admittedly not settled; I avoid here any discussion of warranty suits.

tions involved in formulating such a solution are basically economical, the factors being the effect such a move would have, not only on the industry as it is today, but also on the future degree of medical innovation the industry would dare. Even to advocate strict liability with compulsory manufacturer's liability insurance, which would serve to protect the consumer, would be to place a premium on the industry even in the course of prudent operation. What would be the insurance rate for the unpredictable incidence of liability on an unpredictable scale? What would be, for instance, the extra cost for marketing the oral contraceptive pill? Would such products be released? Even if these obstacles could be met, they are best dealt with by a legislative body rather than a judicial one, who have only the tools of the past with which to work on a basically new problem.

Judicial Over-Reaching

Such judicial over-reaching has been displayed in some cases which seek to extend the law of warranty to make liable the manufacturer of a product which turns out, despite scientific belief to the contrary, to be dangerous. For example, at the Third Circuit Federal Court level in *Pritchard v. Liggett and Myers Tobacco Co.*,[28] it was concluded that there was both an express, by advertising, and an implied warranty that cigarettes were safe to smoke. I am not here concerned with arguing whether or not that court has misinterpreted the law of warranty; that is, whether the manufacturer has a duty in law to provide a merchantable cigarette or a merchantable and safe "product,"[29] for the consideration of the result of such an interpretation is more important. Tobacco products allegedly cause 125,000 deaths a year in the United States alone.[30] Is the industry to pay for this by itself? Even supposing that the industry could stand such a blow, should it be delivered by the judicial interpretation of a legal maxim, or by the reasoned legislative consideration of economic realities? What pleasure the layman might receive from watching the slaughter of an industry of demonstrably minimal utility must not be made a temptation to perform an action with such economic and social repercussions. If we wish to eliminate either the tobacco or the innovative drug enterprises, we should do so through legislative action, not through the extension of judicially-imposed liability.

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[28] 295 F. 2d 292 (3rd Circuit) 1961.

[29] *Pritchard v. Liggett* is opposed by *Lastique v. L. J. Reynolds* as well as *Ross v. Phillip Morris & Co.*, see footnote 27, supra.

[30] "Health Consequences" 1967, 33-36, 39.

Returning to a direct analysis of the possibility of a plaintiff, injured by an unpredictably dangerous drug, recovering his losses, it has been suggested that a suit may lie against the FDA.[31] That body, having been set up as the arbitrator of the merchantability of new drug products, it is contended, is guaranteeing the safety of proper use of any approved drug. While such a conclusion may be more desirable than manufacturers' liability in this sphere, the law renders it impossible to reason with it. Statutory enactment,[32] in effect, means that the Government may be sued only where the harm has arisen from lack of due care, and not from misrepresentation. Where both the manufacturer and the FDA have been negligent in testing the product, however, it may be conceivable to enjoin the Government agency in the suit and thereby eliminate the possibility of insolvency.

(2) Other Products

While new drug products contain in them an inevitable risk of unknown harmful effects, they are the most obvious, not the only example, of such inherently dangerous products. Recent recalls by the FDA of products deemed for one reason or another to be harmful include 334,000 pounds of popcorn, 24,000 strawberry pies, 80,000 pizzas, 13,900,000 packages of soup and 2,000 cases of candies.[33] Various chemicals, including cyclamates and brominated vegetable oils used in soft drinks, have been suspected of being inherently dangerous, and their sale has been limited or terminated.[34] Monosodium glutamate, a staple additive for the recipes set out in Canada's Centennial Cookbook[35] in 1967, was in 1969 the object of grave suspicions. Coca-Cola until 1904 contained coca, a drug related to cocaine and one which since that time, has been considered so inherently dangerous as to be declared a narcotic.[36] Now caffeine, as well as chemicals in tea and hot chocolate, have been found mildly additive and if not actually harmful, certainly suspect.[37] Dairy products, milk,

[31] See note on 1962 Drug Amendments, 18 *Rutgers Law Review*, 101 at pp. 135-40.

[32] Whether sounding in tort or in contract, suit will lie against the United States only insofar as the Government has waived its sovereign immunity. *People v. U. S.* 307, F. 2d, 941, 943 (9th Cir.) 1962; modified, as explained in text, by Federal Torts Claim Act (1958) 28 U. S. C. 1291, 1346(b), 1042(b) etc.

[33] See *Globe and Mail*, April 23, 1970, W 7; in some cases cited, although it is not yet clear, the recalls may have been due to dangers not inherent in the components but due to error in the preparation of the batch.

[34] *Globe and Mail*, April 15, 1970, p. 11.

[35] P. Berton, published Toronto, 1967.

[36] See N. Taylor, *Narcotics, Nature's Dangerous Gifts, Dell*, U. S. A., 1966 at p. 64.

[37] See footnote 36, supra, pp. 173-196.

butter and cheese, as well as eggs, have been causally linked to hardening of the arteries. Fears have arisen over the potential hazards of such formerly praised products as amine aerosol asthma stimulants,[38] various cold remedies, oral contraceptives and so on.

As our scientific and medical knowledge progresses, it is inevitable that we will find that certain products accelerate or cause certain physical ailments. Once a product is exposed as harmful there must be a decision made to limit or ban its use or, because of some overriding utility, to regulate but permit its use. The industry must of course be discouraged from marketing such new products as drugs and food additives unless they are shown to have been fully tested and are of proven benefit. In the introduction of new products for human consumption, the risk of harm to the consumers is never extinguishable. The product then is to be basically suspect and should not be marketed until it is shown not only to be safe, as far as medical science can predict, but also effective in the sense of being a reasonable preparation to fulfill the purpose for which it is sold. This philosophy underlies the clause relating to acceptance by the FDA of new drugs for marketing; they must be "efficacious."[39] In Canada, the director-general of the Food and Drug Directorate has suggested such a criteria for the release of food additives, saying that in the future the government may well demand that the product significantly increase the quality, quantity or nutritive value of the food to which it is added.[40] These types of legislatively-created regulations will, it is contended, better control the release of new products, which have an inevitable possibility that they will eventually be deemed harmful, than would any attempt to impose liability on the non-negligent manufacturer.

B. Control of Products Known To Be Unavoidably Dangerous

Even when a product is known to have injurious effects on its user, it may still be considered of sufficient value to warrant its continued consumption. When such a product, be it tobacco products, whiskey, rabies vaccine or drugs known to be dangerous, is offered, certain judicial and now legislative controls encumber its marketing.

There clearly lies upon the manufacturer, distributor or seller of a product known to be injurious, a duty to warn of the nature and

[38] Telegram, April 1, 1970, p. 29, a warning now required to accompany product.

[39] See footnote 20, supra.

[40] *Globe and Mail*, April 15, 1970, p. 11.

extent of the risk of injurious effect which may be unknown to the consumer. No doubt a product sold without such a warning is to be regarded as deficient, and the manufacturer of it should be liable on the grounds of either negligence[41] or possibly for breach of implied warranty, created by the absence of the warning that there are no known dangers.

A popular example in this area of product liability is the rabies vaccine.[42] To avoid almost certain and excruciating death from the disease itself, the patient must submit to a series of vaccinations which science can render neither comfortable nor free from possible toxic reaction. In *Carmen v. Eli Lilly & Co.*[43] the patient died, but the court refused his estate's action on the finding that sufficient warning had been given to him prior to the treatment. A pamphlet which was given to him mentioned that in 100,000 treatments, forty cases of paralysis and two deaths had been recorded. While restating perhaps more mildly this warning, the deceased's doctor had referred to the drug as "harmless." If the court finds, as they did here, that the consumer was warned of the potential dangers, then it will permit the damages to lie where they have fallen.

While I have no quarrel with this decision, which is naturally appealing in its application to a product of such utility, it is interesting to note that as far as achieving the ends at which the general law of product liabiilty aims, the imposition of liability in this case would have been successful. If liability had been established, the result would have been the distribution of losses among the vaccine's users through price readjustment. As the incidence of injury resulting from this product appears both low and reasonably stable, the industry would not be eliminated. Instead of having the loss fall on the shoulders of the single unfortunate, as it does now, it would be shared by those who find themselves in the same situation.

This solution would be a better answer to the problem of injuries from rabies vaccine, but it could not be used in reference to other products known to be dangerous. In the United States alone, the excess deaths attributable to consumption of tobacco products exceeds

[41] Eg., *Canifax v. Hercules Powder Co.*, 46 *Cal. Reptr.* 552, dynamite with inadequate warning; recent cases include four suits against the manufacturers of the drug Aralen; *Krug v. Sterling Drug, Inc.* (Mo.) 416 SW 2d 143; *Bine v. Sterling Drug, Inc.* (Mo.) 422 SW 2d 623; *Yanow v. Sterling Drug, Inc.* (D. C. S. D.) 263 F. Supp. 159; *Sterling Drug Inc. v. Cornish* (C. A. 8 Mo.) 370 F. 2d 82.

[42] Prosser, footnote 1, supra, at p. 808.

[43] *Carmen v. Eli Lilly & Co.* (1941) 109 Ind. App. 72, 32 N. E. 2d 729.

the combined total fatalities resulting from automobile accidents, the Vietnam war and homicide.[44] The only apparent utility of the industry appears to be the employment of 700,000 families in the cultivation of a crop worth annually $1.2 billion.[45] The industry spends 6.1% of its total receipts in advertising, more than any other industry. The result has been that annual per capita consumption of cigarettes has risen from 138 in 1910 to 4,290 in 1966.

The somewhat abortive judicial attempts to charge the tobacco industry for the injuries suffered by its customers were terminated by the removal of their alleged basis in law, implied warranty, by the discovery and publication of their hazardous nature. As far as the informed consumer is concerned, he indulges his habit despite, not in ignorance of, its deleterious effects. While this fact is almost undoubtedly sufficient to remove the last bit of legal foundation from the shaky cases supporting cigarette manufacturers' liability, it is often in reality true that the knowledge in the consumer that he is indulging in a potentially fatal habit is not a deterrent. The fact that 50% of American teenagers consider themselves to be regular smokers by the age of eighteen, and have probably become so under the influence of variant social pressures has, in one commentator's mind,[46] rendered the implied assumption of risk theory, "pure fiction." The weight of this observation is increased by the fact that both cigarettes and the other most widespread dangerous product in use, alcohol, are habit-forming and continue in use for this reason, rather than as a result of a rational benefit-detriment decision.

In particular reference to products whose ill effects are well-known, an intriguing argument has been advanced against the application of enterprise liability.[47] The argument in capsule form proposes that the political decision has been made to allow the marketing of products such as whiskey and cigarettes; that this decision means that the legislature has made a pronouncement to the effect that such products, although dangerous, are still reasonably safe; this in turn is interpreted to mean that a court may not later declare them to be otherwise; that is, it cannot be found that the manufacturer is in

[44] A. A. White, "Strict Liability of Cigarette Manufacturers and Assumption of Risk," (1969) 29 *L. L. R.* 589 at p. 597 .

[45] All figures from 1966 date see White, footnote 44, supra.

[46] A. A. White, footnote 44, supra, p. 602, note 43.

[47] See Fleming James, "The Untoward Effects of Cigarettes and Drugs; Some Reflections on Enterprise Liability," 54 *Cal. L. Rev.* (1966) 1550 at p. 1552.

breach of any warranty of merchantability. The argument is particularly strong when applied to the control of alcohol. During prohibition, it may be said that the legislature considered alcoholic beverages to be unreasonably dangerous to health and morals. The revocation of prohibition amounts to a declaration of the legislature's opinion that although whiskey may be dangerous, it is not unreasonably so.

The weakness of this form of analysis is that it attributes to the legislatures an omniscience they rarely exercise. It is difficult enough to interpret legislative pronouncements without being put upon to interpret their silence. In reference to products about which the legislature has had nothing to say, for it has had much to say about alcohol and cigarettes, the proper interpretation of legislative silence is even more difficult. Usually, of course, silence indicates merely that the problem has not been considered, not that it has been considered and dismissed. Thus the analysis is too facile, it does not ring of truth. This is of course not to discount its aim, the exclusion of enterprise liability from this area, which I have supported on other grounds above.

General Modes of Control

Far from being generally silent, the legislatures have begun to act to reduce the possible damage caused by the various known dangerous products. Various general modes of control, other than enterprise liability, may be pointed out.

1) The required use of warnings has been adopted as a measure of assuring that consumers of many dangerous products will be made fully aware of possible complications, and thus be made able to make an informed decision as to whether or not to purchase them, as well as to be able to recognize complications. Recent legislative action in Canada requires special warnings not only on asthma stimulants,[48] but also on common aspirins.[49] In the United States, public controversy concerning the safety of the oral birth control pill has resulted in a required one-hundred word warning. Also in the U. S., as of January 1, 1971, each package of cigarettes must bear the following warning: "The Surgeon-General says cigaret smoking is dangerous to your health."[50]

[48] Telegram, April 1, 1970, p. 29.

[49] Labels will be required to bear "a red octagonal symbol on a white background" and state "This bottle contains sufficient drug to seriously harm a child. Always store out of the reach of child." *Globe and Mail*, April 26, 1970.

[50] *Globe and Mail*, April 2, 1970, p. 1.

2) The legislature has also moved to discourage, by limiting advertising, the sale of products known to be dangerous and of low utility. Thus, the U. S. Federal Communications Commission invoked the so-called fairness doctrine to offset the effect of cigarette advertising. When faced with the objection from the industry that a dangerous precedent was being set to be applied to other products, the commission replied that it knew of no other "advertised product whose normal use has been found by the Congress and the government to represent a serious potential hazard to public health."[51]

3) A third mode of controlling the sale of dangerous products has been to limit the market by simply prohibiting sales to certain persons. Thus in Ontario, liquor sales must be made only to those who are twenty-one years old, and until recently, not to Indians. Similar provisions have been enacted in many jurisdictions to control liquor, cigarettes or drugs by prescription.

4) When the dangerous element in the product may be severed from the rest, the legislatures have sought to limit the amount of the harmful chemical used in the composition of the product. This has been done or contemplated in Canada to control the degree of harm from phosphates in detergents, cyclamate sweeteners and brominated vegetable oils in soft drinks and pesticide components.

Inevitable Risks

These sorts of legislative efforts will, it is contended, result in a more realistic and consistent control over dangerous products than would the imposition of product liability. The arguments against judicially-imposed product liability for the manufacturers of inherently dangerous products have been argued on economic and social grounds, but there is something repugnant about the idea which is not from these sources. As Prosser put it:

> Is the maker of good whiskey—as distinguished from whiskey full of fusel oil, strychnine or old cigar studs—to be held liable, without negligence and without privity of contract, for all the harm that may result from its consumption? In other words, is the maker who has supplied a popular demand to be held responsible for the drinking habits of the American public?[52]

[51] Gimlin, "Regulation of the Cigarette Industry" 2 *Editorial Research Rep.* 867 (1967).

[52] Prosser, footnote 1, supra, p. 807.

The damage is the result of an enterprise, true, but of what enterprise? When a drug manufacturer without the slightest reproachable error on his part, and fully according to law, produces a compound we later discover to be harmful, is the relevant enterprise the drug business; or is it really the enterprise of living in an era of scientific progress—an enterprise in which we are all involved? Is the damage attributable to one man's business, or to the inevitable risks of the business of all—progress? Likewise, when a person complains that he has suffered from the normal use of a product known to be inherently dangerous, is the harm on the conscience of the manufacturer? Is it not rather the realization of the inevitable risks of life in a basically free society, in which the consumer may choose to buy all but the most dangerous products, and may therefore choose to ignore the dangers involved in such purchases?

It is too easy merely to point the finger at the manufacturer and say "but for him this would not have happened, let him pay," when it is more relevant to say "but for our system this would not have happened," and usually, "with it, the occurrence is inevitable." To choose a system of progress is to choose a system in which false steps will inevitably occur to the injury of some. To choose a system of freedom is to choose a system in which men will inevitably make choices to their detriment. Such injuries may never be eliminated, they may only be minimized. Perhaps it is at this kind of loss we should end the assault on the manufacturers' citadel and let them produce in peace. **[The End]**

NOTICE

The Joint Educational Conference of The Food and Drug Law Institute, Inc. and the Food and Drug Administration will be held at the Marriott Twin Bridges Motor Hotel, adjacent to the National Airport in Washington, D. C. on Thursday and Friday, December 10th and 11th, 1970. The theme of this year's conference will be "Nutrition, Health and Safety." All interested persons are cordially invited to attend. If further information is desired, write to Franklin M. Depew, President of The Food and Drug Law Institute, Inc., 205 East 42nd Street, New York, New York 10017.

Problems in the Administration and Enforcement of Food Laws

By MICHAEL F. MARKEL

This Article Was Presented at SOS/70, Third International Congress of Food Science and Technology, Washington, D. C., on August 10, 1970. Mr. Markel Is a Partner in the Washington, D. C. Law Firm of Markel, Hill & Byerley.

"PROBLEMS IN THE ADMINISTRATION and enforcement of Food Laws" is my *assigned* and *not* my *selected* subject. When contemplating its discussion before an international group of eminent scientists such as are expected in this audience, I have felt frustrated as never before. Where does one begin? And how does one end such a discussion? The problems are, in the term of bacteriologists, "TNC" —"to numerous to count." Therefore, discussion necessarily needs to be general, with emphasis on the more vexing problems currently confronting both regulatory officials and the regulated industry.

Discussion of the assigned subject invites, first, examination of the source of the problems, the food laws; and secondly, the causes which give rise to them during the course of their administration and enforcement.

While food laws of the various countries and, indeed, the various states here in the United States, may appear to differ in many respects, they are basically the same. All are based on identical, and relatively narrow and well-defined, legislative objectives, namely, the protection of the consumer's health and purse. To that end, all food laws declare as outlaws of commerce, and exclude from the channels of commerce, foods which are *unsafe* for human consumption; those *unfit* for human consumption by reason of the presence of filth or having been exposed to filth in the preparation under unsanitary conditions; and those which are *fraudulently* presented to consumers.

The differences which are found in the various food laws are not in their provisions, which establish the indicated legislative

objectives, but rather in their implementing provisions, calculated to assure effective administration and enforcement so as to achieve these objectives. In this respect, food laws can remain deficient to a point where the objective prescribed by the legislative body cannot practicably be achieved.

For example, the United States Food, Drug, and Cosmetic Act, as enacted in 1938, was considered to be sophisticated and advanced. Yet, as a matter of practical enforcement, the statutory objective of food safety could not be achieved effectively. The reason was that the Government had the burden of proving, by scientific information and data qualifying as court proof, that a questioned food was likely to be dangerous to health. Under modern conditions of production and distribution of foods, regulatory officials were confronted with an impossible task. The food safety provisions of the law simply could not be enforced effectively under these conditions.

This has now been corrected in the United States by suitable amendments to that law. The law now forecloses the channels of commerce to all foods, or substances intended to be added to foods, which are not "generally recognized as safe," until such time when their safety has been established, by administrative regulation, with required proof of safety submitted by the one wishing to market such food products. To the extent of my familiarity with other laws, this is now the law in most, if not all, jurisdictions where more modern food laws have been adopted. Thus, the legislative objective of food safety is much more readily achievable.

Mandatory Standards

I have alluded to this, not as a problem, because it has been resolved as indicated, but for the purpose of pointing up a new parallel problem which presently looms on the regulatory horizon. The problem stems from the suggestion, currently widely discussed among nutritionists, that mandatory standards having the force and effect of law be promulgated, establishing and fixing minimum nutritional values for certain classes of foods. Such, I believe, are the recommendations of the White House Conference. Also, the Chairman of a Senate Committee concerned with nutritional values of foods stated recently that his Committee expects to discuss this subject with officials of the Food and Drug Administration.

Our Federal food law does not include, however, direct legislative authority for promulgating nutritional standards for a food or classes of food which would serve to foreclose, *unconditionally*, the channels of commerce to all foods of that class not meeting that

standard. Our regulations dealing with enriched foods derive from the branding provisions of our law. This includes, of course, Section 401, which authorizes promulgation of regulations establishing standards of quality for any food or class of food. This statutory authority includes the authority to issue regulations fixing nutritional standards when the administrator of the law has concluded, on the basis of supporting evidence, that consumers may be confused and deceived in purchasing a food represented as nutritionally improved; that is, "enriched" or "fortified," unless the added nutrients are of the kind and are present in such amounts that their presence in the designated food can be regarded as a nutritionally significant improvement of that food. Thus, a regulation establishing the group of nutrients which are required, and those which may be added to a given food, and prescribing maxima and minima for the added nutrients, has been upheld by our Supreme Court.

However, enrichment of foods remains on a voluntary basis. Bread, for example, *may*, but *need not*, be enriched. Indeed, many bakery products being marketed today which nutritionists believe should be enriched, are not enriched. Thus, if the problem of nutritional sufficiency of certain foods is to he resolved by issuing nutritional standards having the force and effect of law, which would *unconditionally* close the channels of commerce to any food of the standardized class which does not meet that standard, our law would have to be amended so as to spell this out as an additional legislative objective.

I understand, however, that nutritional standards regulated within the current statutory authority are proposed. As I understand it, the thought is to establish minimum nutritional value for a food or class of food by issuing a standard of quality. While this concept was not considered when the present law, authorizing promulgation of standards of quality, was enacted, one can hardly argue that improvement of nutritional value of a food is not a standard of quality authorized by Section 401.

Presumably, the present law is intended to fix nutritional values and prescribe authorized label statements for given foods or classes of food. The law is not intended, however, to foreclose the channels of commerce completely to foods of that class which do not meet the standards. Such foods could still be marketed by some sort of crepe label which would be adequate to inform consumers that the food did not meet the nutritional standards prescribed by regulation. It is believed that competitive pressures of the marketplace would

be such that, in effect, all foods of a class for which such a regulation had been prescribed would have to be fortified as a matter of economic survival. Such indirect economic coercion is a novel and intriguing approach to achieving voluntary compliance. It remains to be seen how well it will work. Past efforts to induce voluntary compliance have not proven very successful.

I believe such a regulation will, no doubt, be sustained by our courts. They have gone far, indeed, to sustain regulations where the end result is deemed justified. However, this appears to me to be backing into the solution of the problem by extending the misbranding provisions to an area of regulation not specifically intended as a legislative objective when the law was passed. It would seem that legislative guidelines, based on Congressional evaluation of the problem, would be preferred, if not essential, in resolving this problem.

The only other notable problem which stems from the law is the recent much-publicized administrative action taken with respect to cyclamates. This action stems from a provision in our law which, when considered by the Congress, was fairly generally branded by the scientific community as unscientific, since it would impede the exercise of sound scientific judgment in evaluating the safety of food additives.

The law provides, in essence, that no food 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. . . ." This language has been construed to mean that if tumors can be induced under whatever extreme conditions, the law applies and is to be enforced accordingly.

One of the investigations undertaken in testing the safety of cyclamates included high-level feeding of cyclamates to rats. The autopsy revealed tumors in the bladder, agreed to be malignant by scientists who examined them. It was concluded, therefore, that the use of cyclamates in foods was a violation of this law and had to be discontinued. Top regulatory officials stressed that there was *no evidence* before them indicating that quantities of cyclamates consumed under normal conditions of use presented any hazard to health. Yet, the law requires that the channels of commerce be closed to such a substance.

It would seem that administrative discretion implied in the law to assure effective, yet fair, enforcement might have allowed some leave for phasing out a practice so long and so widely followed with-

out any evidence of harmful effect. An amendment to the law granting this discretionary power would go a long way in softening its impact. It would then be possible to phase out an operation on a showing, to the satisfaction of qualified scientists and the administrator, that doing so did not involve a health hazard.

Aside from specific handling of food additives under this provision of our law, it is bound to confront both the scientist and the regulated industry with a continuing serious problem. *Food Chemical News,* a respected trade publication, in its July 13, 1970 issue, page 17, quotes from a paper presented by Dr. Leon Golberg at a recent "Symposium on Chemical Contaminants in Foods" sponsored by Canadian Food and Drug Directorate, as follows:

Current attempts to find that food additives and other chemicals are carcinogens, mutagens, or teratogens, at any level, and through any mode of administration, were criticized by Dr. Leon Golberg, of the Institute of Experimental Pathology and Toxicology at the Albany Medical College. "As the crowning pediment of the entire structure of hypothetical hazards, we have the thesis that the phenomena of mutagenesis, carcinogenesis, and teratogenesis are so closely linked that a positive result in any one of these areas automatically renders the compound suspect on all three counts," Golberg said. He added, "on the other hand, should it happen that a chemical agent turns out to be negative in all tests applied, it remains under suspicion until such time as someone, somewhere, can discover an organism, devise a route of administration or achieve a sufficiently heroic dose to produce some positive biological results, however bizarre."

Thus, the scientific community has a particularly important and special responsibility in publishing results of investigations calculated to determine the safety of food additives. Results obtained by unusual or novel procedures, not generally accepted or understood by the scientific community, should be subject to restricted and restrained publication designed to determine their validity by appropriate verification by experts in the field.

Not many problems, however, derive directly from the law itself. As noted, the legislative objectives are rather narrow in scope. None can find fault with them. Certainly, no one of the regulated industry can afford to market unsafe or filthy foods. Marketing foods fraudulently is usually not long-lived. However, the ramifications in the practical administration and enforcement of the law to achieve their objectives are very broad indeed. Therefore, administrative organization and administrative action, or inaction, can give rise to some of the most vexing problems.

The Scientists' Responsibility

The scientific community has great responsibility in its contribution to the administration and enforcement of the food laws. Every

determination of the administrative action deemed necessary to achieve the indicated legislative objective must necessarily be based on the evaluation of the pertinent available scientific information and data. Marshaling such data, undertaking indicated new investigations, evaluating all available relevant data, are indispensable to the administration and enforcement of the law if this is to be achieved effectively yet fairly.

These are the functions and responsibilities of the scientists. Therefore, scientists in all fields, particularly in those fields which deal with the science of survival as related to foods, have a moral obligation to help solve the problems of administration and enforcement of food laws. These laws are, of necessity, very general in language. Their precise application must be left in the hands of their administrators. The policies and decisions of these administrators should, however, always square with sound scientific knowledge, tested in the time-honored ways of scientists. All scientists, whether in government, industry, or the groves of academy, should submit their findings and opinions to the scientific community for confirmation or rejection. If proven correct, they should be courageous enough to make them heard, no matter what the effects may be. When rejected, or seriously questioned by substantial numbers of the scientific community, especially by those having special knowledge in the field, they should be confined to continued scientific scrutiny prior to publication.

Administrators have a right to expect this integrity from the scientific community. Consumers and the regulated industry, in turn, have a right to expect that enforcement actions be based on, and square with, scientific conclusions reached from such a responsible evaluation by qualified scientists of all available scientific information and data.

Of course, the results of such evaluations are hardly ever, if ever, either all white or all black. They are usually gray. Therefore, a line of demarcation has to be drawn by someone. This is the function of the administrator of the law. He is the one best capable to balance consumer interests against recognized impact on food production and distribution. He must, therefore, draw the line, always within the gray area, however, which, in *his* judgment, resolves the question most equitably. Such balancing of equities does not, I submit, mean sacrificing consumer protection in favor of alleviation of industry burdens, as is irresponsibly charged at times. If within the gray area, consumer protection is adequately assured. This part in

the process of reaching conclusions for required administrative action is not a scientific, but an administrative function. The administrator has a right to have his ultimate decisions respected by the scientific community so long as his decisions fall within these defined scientific limits.

Unfortunately, such has not been the experience in the recent past. It seems that the urge for headline recognition, presumably motivated by the desire for self-glorification, by members of all classes, including administrative officials and members of the scientific community, I regret to say, has brought about conditions where administrative action has not always been founded on such scientific evaluations and advice. Pressures of all sorts, particularly those resulting from lay press publicity based on reports of investigations designed to determine food safety, have had their impact on administrative decisions—and indecisions.

I shall digress for a moment, at the risk of appearing immodest, to point up some of my qualifications to discuss and express judgment on the subject to which I have alluded.

I have been privileged to serve on the team of one of the administrators of our food laws who, in my judgment, and in the judgment of all who have served under him, has been a truly great administrator. I refer to Walter G. Campbell, who was the chief administrative official directly responsible for the administration and enforcement of our food laws from about 1927 to 1945. During his tenure as Chief of the Food and Drug Administration, that organization achieved a public image which was the envy of many other governmental agencies. It enjoyed full confidence and was highly respected by consumers, the members of Congress, and even members of the regulated industry, although some thought he was overly-strict on occasions. Regrettably, this cannot be said today. "What has happened to the Food and Drug Administration?" is a question frequently asked by many. One could, no doubt, pick out any number of past mistakes which contributed to this loss of confidence. That mistakes have been made cannot be denied.

Unwarranted Publicity

In my judgment, however, the principal cause is unwarranted publicity given to administrative and enforcement activities, which has served only to confuse and result in loss of confidence in the regulatory agency. This, in turn, has, directly and indirectly, resulted in the loss of independence of the Food and Drug Administration, previously enjoyed, and the consequent digression into activities not directly related to the administration and enforcement of the law.

Mr. Campbell foresaw these dangers and took all precautions possible to avoid them. Particularly pertinent is an admonition expressed on the occasion of a discussion of proposed regulation involving nutritional and food technology issues. Mr. Campbell said:

> Gentlemen, we in this agency must be careful at all times to avoid publicity. We must neither seek it nor perform our functions in a manner so as to invite it, except where imminent danger to health requires this, because once the headline potential of our work becomes known, it will be a sad day for both this organization and for the consumer.

How prophetic this has proved to be!

There is neither the need nor the time to take note of all of the publicity which, in my judgment, has proven detrimental to both the regulatory agency and the regulated industry, and has resulted in unwarranted scares and confusion of the consuming public. Nor need there be any discussion of justification for so-called "trial by lay press," other than to point out that some of the most damaging publicity in the lay press has usually been based on publication of scientific articles which have not been subjected to our suggested scientific evaluation before publishing. It will suffice to note briefly two recent headline producers of this character.

One of these articles, entitled "Cataracts Produced in Rats by Yogurt" was published in the June 12, 1970 issue of *Science* magazine. The purpose of the investigation was to determine the effects of yogurt on paroxysmal peritonitis. The investigators decided to determine whether the symptoms of the illness and periodic recurrences of them could be produced experimentally in rats. Results of the experiment, according to the authors, suggested "that yogurt probably plays no role in the etiology of benign paroxysmal peritonitis."

An examination of the test animals, however, showed that all of the rats fed high levels of yogurt had developed cataracts. While the article did not say so in so many words, some of the wording could lend itself to at least suggesting inferentially that these results were projectable to humans. This, in turn, led to headlines in the lay press which, I am informed, had an unusually severe adverse impact on that industry. Economic losses are reported to have been severe.

On the other hand, scientists have informed me that it is safe to say that this article does not contribute anything to scientific literature. This phenomenon was reported by Mitchell and Dodge in 1935 and published in the *Journal of Nutrition*, volume 9, page 37. Thereafter, the phenomenon was further investigated and it was definitely established that rats were peculiarly susceptible to high-lactose diets and that these results were, however, not projectable to

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other animals and to humans. It would seem, therefore, that responsible reporting should at least have included a suitable footnote alerting the reader that this was merely a confirmation of a long and well-established phenomenon not projectable to humans.

The other instance of a similar character of which special note should be taken, particularly at this time, is published reports on the effects of monosodium glutamate (MSG) on the developing brain of newborn mice and one newborn monkey. The first article appeared in *Science* magazine for the May 9, 1969 issue, reporting that subcutaneous injections of monosodium glutamate induced acute neuronal necrosis in several regions of the developing brain of newborn mice. The same author later performed a like experiment on one rhesus monkey and reported that brain damage resulted from subcutaneous injection of monosodium glutamate. This article appeared in the *Science* magazine issue for October 17, 1969.

The impact of these articles was explosive. The principal producers in U. S. of monosodium glutamate found it necessary to suspend production of monosodium glutamate for months, with resultant loss of jobs by all of the employees of this plant and severe economic losses to the industry.

Furthermore, the Food and Drug Administration found it necessary to refer this substance for investigation by a special committee of qualified scientists of the National Research Council of the National Academy of Sciences. All evidence on the subject of the safety and function of MSG in the diet of humans was collected and submitted to this Committee for review, including the foregoing identified articles.

According to reports, this Committee not only studied the written material submitted to it, but heard various experts knowledgeable in this field, including the author of the two identified articles. The Committee's report to the Food and Drug Administration was released on August 7, 1970.

The Committee's conclusions are summarized as follows in its official summary of the report:

> Thus, the Committee concludes that the risk associated with using MSG in foods for infants is extremely small. The Committee cannot find, however, that the usage confers *any* benefit to the child and therefore recommends that MSG not be added to foods specifically designated for infants.
>
> The Committee found no evidence of hazard from the reasonable use of MSG in foods for older children and adults, except for those who are individually sensitive to the substance. The flavor-enhancing property of MSG is considered to be beneficial to the general consumer in these age groups. The Committee therefore recommends that use of MSG be permitted in processed

foods for these groups and that such foods be clearly labeled to indicate the presence of added MSG for the information of those who wish to avoid it. Sale of MSG in packages for institutional and home consumer use need not be curtailed.

Other similar examples no doubt come to mind. It is not for me to suggest a remedy for this situation. Somehow, somewhere, the scientific community should find ways of assuring reporting of investigations in this area of the science which will not have such devastating impact on the regulated industry as well as the regulatory agency. In the last example, the Government was put to a considerable expense to have an independent committee establish what its own scientists already knew and understood. Both examples are in an area where even a casual inquiry, if not by the authors, then at least by the referees or the editors of the publication, would have revealed facts on the basis of which these particular articles should either have been rejected or at least characterized by suitable editorial comment so as to minimize, if not avoid, their severe impact. The lay-press reporters are entitled to this.

FDA's Eroded Independence

The other source of rather vexing problems here in the United States has been the fact that the Food and Drug Administration's independence has been severely eroded. This may also be attributed, both directly and possibly indirectly, to the headline potential implicit in the administration and enforcement of food laws. Time will not permit going into details which would lend support to this charge. In my opinion, however, past experiences do support it. Whatever the cause, it must be stressed that an independent Food and Drug Administration is essential to effective administration and enforcement of food laws if the indicated legislative objectives are to be achieved. Commissioner Edwards has given assurance to a Congressional committee that he will insist on such independence. He allowed that there was some need for someone from the Secretary's office to "look over my shoulder—but not too much," because the Administration is, of course, a bureau for which the Secretary is responsible. It seems, however, that the Secretary's primary responsibility is best discharged by appointing a Commissioner to whom he can entrust the administration and enforcement of the food laws completely.

It appears to me to be a self-evident truth that both budgetary and personnel resources should be conserved by restricting the activities to areas required for the effective enforcement of the law. I

again cite the late Commissioner Campbell as authority for this statement. He was appointed as the chief administrative officer of food law about 1927. One of the problems which he then had to resolve was differences existing among scientists regarding enforcement of food laws. For example, there had been established the so-called "Poison Squad," consisting of a group of volunteers for investigating the likely harmful effects of sodium benzoate on humans. Mr. Campbell's first report to the Secretary in 1928 included the following, in alluding to the reorganization which he had undertaken:

> The year's work has demonstrated the advantages of the reorganization, the principal purpose of which was to set up a law-enforcement machinery divorced from research activities having no regulatory bearing. The new arrangement makes it possible for the Washington force and the field force to proceed with a single objective, unhampered by the demands of unrelated research, which, of necessity, slow down regulatory operations, and at the same time to carry on investigations that bear on regulatory activities and are necessary for effective law enforcement.

The present Commissioner is confronted with a similar situation. He is entitled to the best scientific advice available to him that relates to issues requiring to be resolved in enforcing the food law. It is important also that scientific evaluations, which may have to qualify as court proof to support the administrative action taken, be made by scientists fully aware of legislative objectives required to be achieved and sensitive to the wide ramifications and impacts of these decisions on consumers and the regulated industry.

Free and full discussions between scientists of the regulated industry and the investigators with the scientists of the regulatory agency is essential, in my opinion, to a full and fair evaluation of scientific data and information pertinent to the scientific question under review. The Administrator is entitled to and needs scientific evaluations and conclusions determined by free and full discussions among all scientists who have a responsibility in the matter, in order to pick out his administrative line of demarcation in any gray area fairly. Complaints are heard from time to time that such open discussions are not always available.

In this connection, I may also direct attention to like complaints of the regulated industry which have come to my attention regarding the Joint FAO/WHO Expert Committee. I want to stress that I am merely reporting on complaints I have heard. There is no intention to be critical of the Secretariat, whom I have found to be most cooperative. The established procedure is being criticized.

This Committee's whole operation is kept completely confidential to the extent possible. Thus, in principle at least, the identity of

members of the Expert Committee is not to be known and none of its deliberations are to be revealed until its recommendations are published in the form of a monograph. There have been occasions in the past where the results of the deliberations by that Committee and the conclusions reached are at variance with the conclusions reached by regulatory officials who made their decision on virtually the identical evidence. Confidentiality of the Committee's proceedings may well account for this.

Critics suggest that the procedure of the Expert Committee be revised so as to make full and free discussion possible. If the investigators whose work is being reviewed and the qualified scientists of the industry directly affected by the results are not allowed to participate as members of the Committee, they should, at least, be afforded an opportunity to appear before the Committee.

This is deemed important even though the Committee is not a government-to-government committee in its organization, because governments rely on these monographs. Therefore, if not in organization, in fact, the impact of the Committee's conclusions is not unlike that of the scientists advising the administrators of food laws.

The Report of the Food Additives and Contaminants Committee to the Ministry of Agriculture, Fisheries and Foods of the United Kingdom will serve as an example of this. A review of its 1970 report indicates that the monographs of the Expert Committee are cited and relied on rather extensively. Thus, one may well question whether the criticism of lack of adequate communication does not also carry over to administrative actions taken by the regulatory officials who rely on the work of the Expert Committee.

The reported criticism, if valid, points to problems of administration and enforcement of an international scope. If valid, it might well be desirable that the whole matter be re-examined with a view of doing what may appear necessary to minimize such problems.

Conclusion

I trust that this summary of some of the problems in the administration and enforcement of the food laws, and the examples cited, will serve to point up the great responsibility which all who are involved in the science of survival as related to the production and distribution of foods, have in carrying on and reporting the results of their investigations. A well-disciplined scientific community, one which will support merit wherever needed, but will also be heard and decry irresponsibility, is indispensible if "trial by press" is to be restrained to fair and accurate reporting. [The End]

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