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Food Drug Cosmetic Law JOURNAL

Federal Law and Patient Consent

. . . . . HERBERT L. LEY, JR.

Papers Presented at the American Bar Association Meeting on Food, Drug and Cosmetic Law

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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

Federal Law and Patient Consent.—Beginning on page 520, *Dr. Herbert L. Ley, Jr.* outlines the FDA's regulations concerning patient consent, and notes the difficulties encountered in translating ethics into law. Dr. Ley, the FDA's Commissioner of Food and Drugs, delivered his paper before a Conference on New Dimensions in Legal and Ethical Concepts for Human Research at the New York Academy of Sciences.

1969 Meeting of the Food, Drug and Cosmetic Division of the Corporate, Banking and Business Law Section of the A. B. A.—Two of the papers presented at this meeting of the American Bar Association are published in this issue of the JOURNAL. Additional papers read at the meeting, which was held in Houston, Texas, on August 13, 1969, will appear in a later issue.

The article by *William R. Pendergast* reveals the recommendations of a special committee which investigated FDA hearing procedures. The article which begins on page 527, is entitled: "The Nature of Section 701 Hearings and Suggestions for Improving the Procedures for the Conduct of Such Hearings." Mr. Pendergast is a partner in Condon, McMurray and Pendergast, a Washington, D. C. law firm.

"A Perspective Concerning Fault and 'Strict Liability in Tort,'" by *John A. Maher*, a member of the New York and District of Columbia Bars, begins on page 537. Mr. Maher is convinced that in the field of product liability, a lawyer's maximum energy should be devoted to the job of counseling manufacturing clients as to their duties and responsibilities, rather than diverting energy to bewailing the origin of today's law.

The Deve'opment and Use of National Voluntary Standards.—The article beginning on page 550 is by *Donald R. Mackay*, Chief of the Office of Engineering Standards Services of the Institute for Applied Technology, National Bureau of Standards. He presented his paper at the 54th National Conference on Weights and Measures for the dual purpose of explaining the development of national voluntary standards by NBS, and of encouraging weights and measures officials to participate in its activities.

Industry Associations and Self-Regulation.—This article tells what the trade associations have done and can do to assure the production of better food and drugs. Its authors, *Fred J. Delmore* and *Kermit V. Sloan*, are both members of the FDA. Mr. Delmore is Acting Associate Director, Bureau of Compliance; and Mr. Sloan is Project Leader, Hazardous Substances and Cosmetics, Division of Industry Services. Their paper, which begins on page 557, originally appeared in the September issue of *FDA Papers*.

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Journal

Federal Law and Patient Consent

By HERBERT L. LEY, JR., M.D.

Dr. Ley, Commissioner of Food and Drugs for the Food and Drug Administration, Presented This Paper at a Conference on New Dimensions in Legal and Ethical Concepts for Human Research, New York Academy of Sciences, New York, New York, on May 21, 1969.

THE PROCESS WHEREBY ETHICS BECOME LAW is very familiar. In these days it is a vast and continuous operation—as legislators translate and apply age-old principles of morality to the complex circumstances of modern life. But a law is not usually enacted simply because someone says there ought to be one. A demonstrated need must exist—some social, economic or technological problem that demands an equitable solution. And sometimes, unfortunately, a catastrophe of some kind must occur to dramatize the issue before action is possible.

The history of thalidomide is so well known that it hardly needs repeating. But there are some aspects of the story which are pertinent to the subject before us. While the Food and Drug Administration (FDA) had received the impression that all clinical investigators had been warned of the apparent effects of the drug on developing offspring when the U. S. licensee first heard of them in November 1961, it was learned some months later that notice had gone only to some sixty or seventy investigators who participated in the initial trial of the drug, and not to approximately 1,000 others who had received the drug at a time when the company believed it would soon be released for marketing. In the summer of 1962, therefore, FDA inspectors visited all physicians in their respective districts who had been

supplied with the drug to inquire about such matters as observations of side effects, whether they had signed Investigator Forms, or had received warning of adverse effects, and whether all remaining materials had been destroyed or returned to the company. It was learned that considerable quantities of the drug were unaccounted for, and that at least eleven cases of birth deformities had occurred in this country as a result of use for investigational purposes. An additional seven cases were found to be related to use of thalidomide obtained from abroad.

Public interest in all these developments focused intense scrutiny on every phase of drug research and marketing, a subject which had already been under very thorough consideration by Senator Kefauver's Anti-trust and Monopoly Committee for approximately two years. A bill, S. 1552, was awaiting action in the Senate. But this bill contained no provision regarding patient consent. The record shows it was first proposed by Senator Jacob Javits when the Senate was debating the bill on August 23, 1962. Senator Javits reported that a survey by the Library of Congress had shown there were no state laws on the subject—in itself an indication of the newness of the idea as a legal requirement and the difficulties it presented. But the Congress was confronted with the fact that thousands of consumers in the United States had received thalidomide without being advised that it was an experimental drug—a fact that was highly persuasive. On the same day the press reported the results of the FDA's canvass of the physicians who had given thalidomide to their patients.

Several important amendments were made in S. 1552 while it was being debated. One of these is designed to insure that people who receive an experimental drug are generally informed of the nature of the experiment and give their consent.

The Patient Consent Provision

Under Federal law (The Food, Drug, and Cosmetic Act), a new drug may be shipped across State lines only after the Department of Health, Education, and Welfare has approved its proposed use as safe and effective. However, the Secretary is directed to issue exempting regulations stating conditions under which drugs may be shipped for experimental use for purposes in which they have not yet been proved safe and effective. (The authority to perform this and most other functions under the law has been delegated to the Commissioner of Food and Drugs.) Among other things the law states:

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human being to whom such drugs, or any controls used in connection therewith, are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this sub-section shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

Although it was new as a matter of statutory law, patient consent certainly was not new as an ethical concept. The ethical and moral principles had been stated with great force in the Nuremberg Code of 1947. The indictment of 23 Nazi physicians for crimes against humanity had shocked the world. The tribunal in its decision had seen the need for a code for medical experimentation involving human subjects. The first of its 10 commandments read as follows:

The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

In considering the amendment to the United States law, the Senators were quite aware of the difficulties involved in requiring patient notification and consent, while not placing insurmountable obstacles to research and permitting the physician to fully exercise his judgment in fulfilling his other ethical obligations to the patient. The terminal cancer patients, the child patient, the emergency patient, the mentally incompetent and the patient in a coma, were all mentioned. And the Senators also took the malpractice law into consideration. As Senator Carroll put it:

I am confident that doctors will read this (Congressional) Record. The legislative history we are making will be transmitted to them. I warn them—and I am now speaking as a lawyer—that the use of drugs for experimental purposes, without the knowledge of their patients, is a hazardous step to take. I am now talking about the law which protects patients—the malpractice law.

The FDA regulations to carry out the Congressional mandate are based on the law itself and its legislative history. However, they also reflect principles that have been recognized and accepted by leaders in the field of medicine for many years.

Explicit Standards Required

The Nuremberg Code, the thalidomide experience, the enactment of the 1962 Drug Amendments in the United States and a rapid expansion of clinical investigation throughout the world after World War II, created a need for the more explicit standards which were adopted at Helsinki by the World Medical Association in 1964. In regard to patient consent the Declaration states, and I quote:

> In the treatment of the sick person the doctor must be free to use a new therapeutic measure if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering.
>
> If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.
>
> The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.
>
> In the purely scientific application of clinical research carried out on a human being it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.
>
> The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.
>
> Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured.
>
> The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.
>
> Consent should as a rule be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject, even after consent is obtained.
>
> The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.
>
> At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued. The investigator or the investigating team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual.

The American Medical Association endorsed the ethical principles set forth in the Declaration of Helsinki and accepted them as an accurate expression of fundamental concepts previously published in its "Principles of Medical Ethics."

"Ethical Guidelines"

The "Ethical Guidelines for Clinical Investigation" adopted by the House of Delegates of the American Medical Association in 1966 enlarged upon those fundamental concepts. Generally speaking, a doctor may participate in clinical investigations only as part of a systematic program employing accepted standards of scientific research calculated to produce valid and significant scientific data. The investigator must demonstrate the same concern and caution for the welfare, safety, and comfort of the person involved as is required of a physician attending a patient independent of any clinical investigation.

The "Ethical Guidelines" emphasize that *in a clinical investigation primarily for treatment,* the physician is expected to exercise his professional judgment and skill in the best interest of his patient. Voluntary consent must be obtained from the patient or his legal representative if necessary. This consent should be obtained only after the physician discloses that he intends to use an investigational drug or experimental procedure, and explains the nature of the drug or procedure to be used as well as the risks involved and the possible therapeutic benefits. An offer to answer any inquiries should be made and the disclosure of alternative drugs or procedures should be explained. Ordinarily, this consent should be in writing. An exception is made where the physician deems it necessary because of the particular circumstances to rely upon consent in other than a written form. The assumption of consent is permissible only where the patient in an emergency situation is incapable of giving consent and there is no one available who has the authority to act on his behalf. It is also deemed appropriate in exceptional circumstances to withhold requesting consent from the patient where such disclosure would be detrimental to the best interests of the patient. In such circumstances this information must be disclosed to a responsible relative or friend of the patient when possible.

In a clinical investigation primarily for the accumulation of scientific knowledge, adequate safeguards must be provided for the welfare, safety, and comfort of the subject. In this instance, consent must be in writing from the subject or his legally authorized representative and again only after disclosure that an investigational drug or procedure is being used, with an explanation of the procedure and risks involved, as well as an offer to answer any inquiries on the drug or procedure. No person may be used as a subject against his will. Minors or mentally incompetent people may be used as subjects when

the nature of the investigation requires their particular participation and consent in writing is given by a legally authorized representative acting in circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.

In 1962 and 1963 the Food and Drug Administration published its answers to numerous questions regarding the new law, including the patient consent provision. The Investigator's Form 1572 called on him to certify that he would "inform any patients or any persons used as controls, or their representatives, except where this is not feasible, or, in the investigator's professional judgment, is contrary to the best interests of the subjects."

Interpretative Regulations

By 1966 it was evident that specific guidelines were needed on how consent was to be obtained, and what exceptions were allowed. Indeed, such guidelines had by then been developed by the medical profession and it was feasible to codify them in the form of interpretative regulations.

On August 29, 1966 the FDA published regulations requiring consent to be obtained in writing except, as provided in the law, when this is deemed not feasible, or "contrary to the best interests of such human beings."

On March 10, 1967 the requirement for written consent was revised so that physicians using investigational drugs under conditions of medical practice (the final "Phase III" stage of clinical investigations) could use their own judgment as to whether consent should be obtained orally or in writing.

The FDA regulations require consent to be obtained in writing from patients, or their representatives, in all cases where investigational drugs are administered *primarily to acquire scientific knowledge,* such as study of drug behavior, body processes, or the course of disease. Where such drugs are being used *primarily for treatment,* consent is required in all but exceptional cases.

"Treatment" includes use for diagnostic, therapeutic, or other purposes involving medical judgment.

"Exceptional cases" means those relatively rare cases in which it is not feasible to obtain the patient's consent or the consent of his representative because of inability to communicate; for example, when

the patient is in a coma, or his representative cannot be reached, and it is imperative to administer the drug without delay.

"Contrary to the best interests of such human beings" is defined by the regulation to apply when communication to obtain consent would seriously affect the patient's well-being and the physician has made a professional judgment that the patient's best interests would suffer if consent were sought.

"Consent" means that the person has legal capacity to give consent, is able to exercise free power of choice, and is provided with a fair explanation concerning the nature and purpose of the drug, the method and duration of its use, the hazards involved, the existence of alternative therapy, if any, and the beneficial effects that may result from its use.

As previously pointed out, patient consent in writing is required for the first phases of investigation. When, in Phase III investigations, the physician decides that *oral* consent is necessary or preferable, he is required to record it in the medical record of the patient.

It will be noted that this leaves open the question of any record being made in those instances where consent is *not* required because it is not feasible or contrary to the best interests of patients. We are presently discussing with representatives of the medical profession an amendment to close this gap by requiring a notation in the patient's record where consent has not been obtained because it is not required. The reaction to this proposal has thus far been generally favorable, and we expect to publish it shortly, as a proposal.

Translation of Ethics into Law

Quite a few physicians joined in a hue and cry in 1962 and 1963 against the patient consent provisions of Federal law. With the passage of time, most doctors seem to accept this provision as a reasonable reflection of standards developed by the medical profession itself. We in FDA agree with this view. There have been instances in which we have had to deny an investigator the privilege of receiving investigational drugs in interstate commerce. But the instances have been few and, in each case, the abuses that required the action (termination of the exemption) have ben flagrant. Certainly the physician investigator who follows the guides established by his own peers can be assured that he is meeting the Federal requirements which are based on these very guides. **[The End]**

The Nature of Section 701 Hearings and Suggestions for Improving the Procedures for the Conduct of Such Hearings

By WILLIAM R. PENDERGAST

This Article and the One Following Were Presented at the 1969 Meeting of the Food, Drug and Cosmetic Division of the Corporate, Banking and Business Law Section of the American Bar Association, Held in Houston, Texas, on August 13, 1969. Mr. Pendergast Is a Partner in Condon, McMurray and Pendergast, a Washington, D. C. Law Firm.

LAST WINTER, Frank Depew of the Corporation, Banking and Business Law Section and Charles Whitmore of the Administrative Law Section appointed a special committee to investigate Food and Drug Administration (FDA) hearing procedures and selected me as chairman. At that time, there was a considerable discussion in the Bar that the procedures by which these hearings have been conducted have not adequately provided a means of control to insure that the hearings were, on the one hand, completely fair to all parties, while, at the same time, sufficiently expeditious to insure that proper regulations could become effective as soon as possible. Many people experienced with these hearings published articles discussing the various problems which seemed to be occurring, but there had been, until then, no concerted effort to arrive at any solution.[1]

[1] Just a few are: Selma M. Levine, "Separation of Functions in FDA Administrative Hearings," 23 FOOD DRUG COSMETIC LAW JOURNAL 132 (March, 1968); Spiker & Stafford, "A Look at FDA's New Rules of Practice—And Problems Still Unresolved," 21 *The Business Lawyer* 1069 (1966); William W. Goodrich, "The Food and Drug Administration's View on Procedural Rules," 23 FOOD DRUG COSMETIC LAW

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This committee was given a broad mandate to make whatever recommendations seemed indicated, even including legislative reforms, if necessary, in order to improve the situation.

Very early in our discussions, however, it became apparent that recommendations should be made as early as possible, and that they should be recommendations which could be implemented without going to Congress. We felt that an attempt should be made to devise regulatory improvements which could be put into effect at once, for we recognized that a return to Congress for new legislation would inevitably delay any improvements in the hearings. The situation, as we found it, with many hearings scheduled and more in the offing, compelled us to take this expedient course of action. Therefore, the problem which faced us was to devise recommendations for improving the hearing procedures under present laws; to limit our recommendations as much as possible to absolute essentials; and finally, to make recommendations which would be sufficiently self-evident that their early enactment by the FDA could be anticipated.

Determining the Proper Methods

In doing this, I found that in the field of administrative law there is nothing so baffling or so complex as determining the proper method, within the principles of the Administrative Procedure Act, for conducting an administrative hearing for a particular agency under a particular statute. There exists a veritable mountain of articles and treatises discussing administrative hearings, criticizing how they are done, recommending improvements, and, very often, condemning them out of hand. These articles and treatises, referring to the Administrative Procedure Act, abound in such broad terms as rulemaking and adjudication, and discuss with easy authority what is an "adjudicative" fact or what is a "rulemaking" fact, and one author actually uses the term "general fact."[2]

But it seems to me that any attempt to draw specific conclusions from such general statements, and to devise from these conclusions a scheme for the conduct of hearings at a particular agency under a particular statute is an attempt which is foredoomed to failure. Every agency has its own fact issues to consider, and most agencies have their own unique statutes with which they must comply. Generaliza-

(Footnote 1 continued.)
JOURNAL, 481 (October, 1968); Joel E. Hoffman, "Some Suggestions for Improvements in the Hearing and Rulemaking Procedures of the Food and Drug Administration," 23 FOOD DRUG COSMETIC LAW JOURNAL 465 (September, 1968).

[2] 1 Davis, *Administrative Law Treatise*, Sec. 6.05, p. 378.

tions about hearings, be they rulemaking or adjudicative, are always true, just as all generalizations are always true.

For instance, the statement by the Department of Justice opposing the proposed American Bar Association (ABA) code of the conduct for administrative hearings on the ground that the proposal represented a tendency toward further judicialization which might increase delay and inefficiency[3] is true, as is the statement by Professor Gellhorn that "one of our country's gravest administrative deficiencies stems from lawyer-induced over-reliance on courtroom methods to cope with problems for which they are unsuited."[4] Too much judicialization *might* cause delay in the enactment of needed regulations. Too much reliance on courtroom methods, whatever they are, *could* be an abuse of the administrative system. But such statements are too general and, if they stay too much in the forefront of our thinking, prevent us from resolving our concrete problems. Professor Davis has stated the only generalization which can accurately be made about these problems. He says that the "best answer to the overall question of whether we want more judicialization or less is probably that we need more in some contexts and less in other contexts."[5]

Our committee approached the FDA hearing procedures as specific problems to be studied first by reference to the statutes involved, then to the types of fact issues usually presented at these FDA hearings, and finally, by an understanding of the real position of the parties who appear in these hearings and the way in which present statutes require them to present their cases. This has not been an easy task, but the Committee consists of attorneys who have personally appeared in certainly the vast majority of all the hearings ever held at FDA. They are: Vincent A. Kleinfeld, Alan Kaplan, Walter E. Byerley, Michael F. Markel, Rodney R. Munsey, Daniel Marcus, H. Thomas Austern, Selma Levine, and myself.

The Scope of the Recommendations

To begin with, in our deliberations we confined ourselves to the hearings required by Section 701 of the Food and Drug Act.[6] Other sections of the Food and Drug Act such as 505 and 507 also provide for hearings, but the 701 hearings have been most frequently held

[3] Reported in 1 Davis, *Administrative Law Treatise*, Sec. 104 (1965 Supplement), p. 40.

[4] Gellhorn, "Administrative Procedure Reform: Hardy Perennial," 48 *American Bar Association Journal* 243 (1962).

[5] Davis, footnote 3 above.

[6] 21 U. S. C. 371.

and they are the ones which have resulted in the most confusion.[7] Also, if these could be reformed by new procedural regulations, such regulations would constitute a logical starting point for any changes in hearing procedures under the other statutes.

Section 701 hearings have been referred to by the courts and elsewhere as rulemaking proceedings,[8] an appellation which offers more heat than light because it leads us to generalizations made about other agency rulemaking hearings which may or may not be applicable here. Actually, partially as a result of the Hale Amendments,[9] hearings under Section 701 appear to be a separate class, partaking of the qualities of both rulemaking and adjudicative proceedings, with a greater tendency toward the latter. The promulgation of regulations under this Section involves a two-step hearing procedure. The FDA announces new regulations by a proposal affording all interested parties an opportunity to present their views "orally or in writing."[10] This preliminary hearing thus can, in fact, be an oral hearing, if the FDA so chooses, and, in fact, the Federal Trade Commission (FTC), in its Fair Packaging Regulations, which also rely upon Section 701 of the Food and Drug Act,[11] does permit the use of an oral hearing which is very informal.[12]

Sec. 701(e) then goes on to require that after this first hearing, the FDA shall enter a final order to become effective on a date certain, but providing that any person who is adversely affected by such order may file objections to it, and, if he states reasonable grounds, he is entitled to a hearing. The statute provides that this second hearing shall be a public hearing for the purpose of receiving evidence relevant to the objections made, and that any interested person may be heard. After the hearing, an order issues which must be based "only on substantial evidence of record at such hearing."[13] It is this second 701(e) hearing with which we are concerned.

Determining the Nature of Regulations

It is readily apparent from this description of the statutory scheme that, in this second hearing, the Food and Drug Administra-

[7] For a discussion of the many possible hearings see Walter E. Byerley, "Some Common and Uncommon Hearing Procedures Under the Federal Food, Drug, and Cosmetic Act," 23 FOOD DRUG COSMETIC LAW JOURNAL 457 (September, 1968).

[8] *Pharmaceutical Manufacturers Assn. v. Gardner*, 381 F. 2d 271, 275 (CA D of C, 1967); William W. Goodrich, "Patchwork on a Crazy Quilt of Administrative Procedures," 10 FOOD DRUG COSMETIC LAW JOURNAL 604 (September, 1955).

[9] 68 Stat. 55 (Aug. 15, 1954); 70 Stat. 919 (Aug. 1, 1956).

[10] 21 U. S. C. 371(e)(1).

[11] 15 U. S. C. 1455(b).

[12] 16 CFR 1.16(c).

[13] 21 U. S. C. 371(e)(3).

tion is not taking evidence in an attempt to ascertain the factual basis for regulations which it is considering, nor is it holding a public meeting for the purpose of receiving public comments or facts about regulations under consideration. All that has already been done. These hearings are held only after FDA has published a final order which would have gone into effect had not valid objections been filed to it. Then and only then does a hearing take place.

With this statutory setup, we find another reality which we must face. These hearings are not held to present evidence which would be new to the FDA. The reality is that long prior to the hearing the FDA understands full well the position of the objecting parties and the factual basis for it. Similarly, the objecting parties know the factual basis for the FDA's position, at least in general terms. The hearings are held because the FDA has disagreed with the objectors' interpretations of these facts and the conclusions to be drawn from them. At the hearing, the FDA introduces evidence to support its position and to nullify the position taken by opponents, while the opponents reply in a similar fashion. This is what actually occurs no matter what theories may be espoused in the textbooks. Certainly it demonstrates the true adversary nature of these proceedings. It is abundantly clear that the purpose of these hearings is not to develop new facts for consideration by the agency. That is and always would be done on a far more informal basis. Instead, the purpose of these hearings is to provide a public record of the positions of the FDA and the objecting parties and a record which will constitute the four corners of any order resulting from the hearing. Why Congress would require such a mechanism is manifest, for it provides any party who disagrees with the agency an opportunity to force the agency to establish a record of such clarity and completeness that a Court of Appeals can properly review the agency's action. This scheme thus provides the industries regulated by the FDA with a means for obtaining independent judicial review of the agency's position to determine if there was substantial evidence for the agency's action.

It is pertinent, in determining the true nature of 701(e) hearings, to note that the FTC, which promulgates regulations under Section 701(e) for the Fair Packaging and Labeling Act,[14] specifically declares that the second hearing is an adjudicative hearing with all the trappings for adjudication at that agency,[15] while the FDA, in its regu-

[14] See footnote 11.

[15] 16 CFR 3.2. The FTC Rules for such adjudicative hearings provide for pleadings, discovery, motions, interlocutory appeals and subpoenas, 16 CFR 3.11 through 3.46.

lations under the same Act, which are also governed by Section 701(e), chooses to regard the same hearings as rulemaking,[16] and does not utilize its own adjudicatory regulations.[17] Someone has to be wrong.

Interpretation of Purpose

Viewing Section 701 as I have described it, it is obvious that every opportunity must be taken to insure that the hearing record which is developed is the best record possible; that the record contains the position of all the parties involved; that the record reveals that the parties had ample opportunity to test the accuracy of FDA's position; and that it is abundantly clear that every scientific or economic factor relevant to the issues was adequately considered. If the record does not meet these high standards, then the Court of Appeals cannot properly exercise its duty of independent review, and the entire Congressional purpose is frustrated. Concededly, these are high standards, perhaps higher even than some other agencies must follow, but I believe that Section 701 imposes these high standards, and I am also confident that Congress, when it enacted the 1938 version of Section 701, well prior to the Hale Amendments, was even then insistent that FDA provide the best sort of hearing.[18]

The special committee has, therefore, recommended a series of improvements which view 701 proceedings with a sense of reality as to the true nature of participation in these hearings, and with an appreciation that Section 701 requires something more than might be thought of as usual in a traditional rulemaking proceeding—that the hearings partake of adjudicatory hearings where "trial-type" procedures can play a role.[19]

Pre-Hearing Recommendations

We have therefore recommended that the hearing examiner be given greater authority and control over the conduct of pre-hearing

[16] "[The] Procedure for the issuance . . . of regulations under . . . sections 4 and 5 of the Fair Packaging and Labeling Act is described in Section 701(e)(1) [and the] . . . Public hearings . . . arise only through the rule making provisions . . .". 21 CFR 2.48.

[17] 21 CFR 130.14 through 130.26.

[18] 83 Cong. Rec. 11, 830-835 (June 13, 1938).

[19] "Whenever particular issues become crystallized and are likely to be hard-fought, so that contradictory testimony is probable, the convenient method, if the issues are sufficiently important, is the method of trial, so that each party will have unabridged opportunity for cross-examination and for submission of rebuttal evidence." 1 Davis, *Administrative Law Treatise*, Sec. 7.06, p. 431.

conferences and over the use of discovery mechanisms.[20] Perhaps one of the greatest problems one faces in an FDA hearing is the lack of precision as to what factual issues will be litigated. This is often coupled with a lack of understanding as to who opposes what issues, who supports them, and how they are going to do it. Therefore, it seemed to our Committee to be necessary to develop techniques which would eliminate this confusion.

One possibility is the greater use of depositions prior to hearing. Any regulations providing for such depositions would have to be drawn with care so that they are not abused and the examiner must have complete control at all times. If they are properly controlled, the intelligent use of depositions can go far toward eliminating unnecessary contentiousness at the actual hearing. But the use of depositions is of no value unless the examiner has the power to enforce his orders regarding such discovery. Under current law at FDA, the examiner has no subpoenae power and therefore cannot compel the attendance of witnesses at depositions or anywhere else. The Committee has concluded that the only way the examiner can control depositions or discovery and make them work is to give him the authority to exclude from the actual hearing any witness who refuses to appear for a deposition the examiner has ordered, or, in a proper case, to exclude a party from further participation in the hearing until the examiner's orders are obeyed. We believe the FDA can grant this authority to the examiner and that it should be done.

Pre-hearing conferences at FDA have been relatively unsuccessful. The Committee recommends that the examiners should apply much greater effort to these conferences than in the past, and that the FDA should, by regulation, encourage them to do so. As a matter of policy, it seems to me that the FDA, as soon as it appoints an examiner to a proceeding, should turn over to him the various preliminary Federal Register statements, together with objections to the preliminary regulations and the objections which brought about the hearing. The examiner should then be directed, and given sufficient time, to become thoroughly familiar with this material so that when he appears to conduct a pre-hearing conference he will be able to make the parties sit down, head to head, and discuss the factual issues, hopefully with candor; to concede that which they know they ultimately must concede; to determine, as far as possible, the

[20] Gallagher, "Use of Pre-trial as a Means of Overcoming Undue and Unnecessary Delay in Administrative Hearings," 12 *Administrative Law Bulletin* 44 (1959-1960); Kintner, "Discovery in Administrative Adjudicatory Proceedings," 16 *Administrative Law Rev.* 223 (1964).

qualifications of the proposed witnesses and the authenticity of documents; and to determine if there are areas which are not controversial, or if there are areas in which too much repetitious testimony is contemplated. If he is so prepared and does conduct such a meaningful pre-hearing conference, the examiner can then enter a pre-hearing order which would narrow the issues and rule on many peripheral issues, all to the end of shortening the conduct of the hearing itself.

Recommendations on the Hearing

As for the hearing, the Committee recommends that all direct testimony be submitted in written form prior to the appearance of the witness for cross-examination. This has been tried in the ongoing vitamin hearing, and while it had many problems there, I think most of those problems were the result of a failure to initiate the procedure soon enough.

The Committee recommends that all witnesses, be they industry or government, who appear in a 701 hearing should be required to produce the relevant portions of their prior written statements, as well as other documentary material specifically relied upon by them. The Committee recommends that appropriate safeguards be promulgated to insure that trade secrets and confidential government documents, if any, are adequately protected. This, of course, is the Jencks Act situation. Many agencies have adopted Jencks Act regulations for the conduct of their hearings, and the American Bar Association's special committee to develop a code of rules of evidence has proposed a similar rule for use in District Courts, which I believe states the appropriate rules in the briefest possible terms.[21] With such rules embodied in regulations, the parties will know what is expected of them, will be fully protected, and it will be unnecessary to chance the ad hoc procedures currently in force.

Limitation of Participation

The Committee has also recommended that no employee of the Department of Health, Education and Welfare (HEW) or FDA who participates in the investigation and conduct of such hearings should be allowed to participate in the decision process. To me, this includes participation in the decision of any matters, procedural or substantive, affecting the rights of a participant in a hearing. We think this

[21] Rule 6-12, Draft of Proposed Rules of Evidence for the United States District Courts and Magistrates, 46 FRD 161, 306; See also *Great Lakes Airlines v. CAB*, 291 F. 2d 354 (9 Cir., 1961), cert. den. 368 U. S. 890 and 29 CFR 102.118 as amended by 33 Fed. Reg. 9819 (July 9, 1968).

is just elemental fairness which is more and more the rule today, and that a regulation or announcement from FDA that it accepts these principles is essential.

The Committee also recommends that the current regulations governing ex parte contact be revised to make it clear that all ex parte communications to employees of HEW or FDA concerning the issues raised at such a hearing are prohibited unless made a part of the public record. This part is very similar to the current regulation[22] and attempts to make it clear that the prohibition goes only to issues raised at the hearing, not to other matters dealing with products which may also be affected by the hearing. Our proposal goes one step further and recommends that this prohibition include all communications made by employees of FDA or HEW when made to any official of FDA or HEW who is or who reasonably may be expected to be participating in the decision process. This proposal would permit FDA employees to discuss the hearing proceedings freely among themselves, so long as they do not discuss them with the Commissioner or the Commissioner's Office. We see no reason why employees of the FDA should have any contact with the Commissioner's Office regarding the substantive matters of a hearing in progress.

The Testimony of Experts

Our final recommendation brings us back full circle to the realities of FDA 701 hearings. As I have said, there is no subpoenae power at FDA, and furthermore the issues in these hearings are, or at least should be, of a specific scientific or economic nature. These hearings thus result in the sort of evidence offered by experts who appear and present expert opinion testimony. Very often there are relatively few real experts in the field and their testimony is thus all the more crucial to the outcome of the proceeding. For these reasons, our Committee recommends that these expert witnesses be presented by the proponents, usually the FDA, in a candid manner, with the hearing examiner permitting cross-examination to extend to the witness's entire field of competence so long as the testimony is relevant to the issues at hand, is material—that is, of some consequence—and is not unduly repetitious.[23]

[22] 21 CFR 2.104. Other agencies impose even greater restrictions, 14 CFR 300.2 (CAB); Appendix C, Ex Parte Communications, 49 CFR 1100.247 (ICC).

[23] The view that a fact is "material" if it is of consequence to the determination of the action is found in the Draft of Proposed Rules of Evidence, footnote 21 above, pp. 220-222.

Our Committee recommends that no witness should be foreclosed from presenting his entire views by reason of any limitation placed on the choice of his direct examination. The Congressional purpose in providing for such hearings is completely frustrated if an expert in a particular field of science or medicine is presented at a hearing and then asked questions on direct examination about only a small area of his expertise, with the result that, on cross-examination, it is impossible to develop this expert's opinions on relevant issues within his sphere of competence. Because of the absence of subpoenae power, there is no way participants in these hearings can demand that such an expert return at a later time. If this expert's relevant opinions are not obtained while he is on the stand, there is the real possibility that they will not be obtained at all.

To me, this recommendation will do more than anything else to insure that all the issues are fully explored in these hearings. It ill-behooves the FDA to bring in a leader in any field of science or any other intellectual discipline and then attempt to foreclose him from presenting his views on the regulations in issue by the technical device of asking just a few direct questions directed at a point FDA wishes to make. The FDA above all should encourage experts who testify to give free rein to their opinions—even where they disagree with FDA.

The Impact of the Recommendations

True enough, the examiners will have a real task of insuring that such cross-examination will stay within the bounds of relevancy, materiality, and non-repetitiousness, but if they do so, this procedure, far from lengthening the proceeding, should actually shorten it. For I would think that, in most cases, the entire views of a few genuine experts are far more valuable than bits and pieces from many experts fitted together into a complex jigsaw puzzle.

These are the recommendations of the Special Committee, recommendations which have been made to the Administrative Law Section and to the Corporation, Banking and Business Law Section, and we leave them to your thoughtful consideration. I wish to assure the FDA that the members of this Committee stand ready to sit down and work out any details to make these recommendations work.

[The End]

A Perspective Concerning Fault and "Strict Liability in Tort"

By JOHN A. MAHER

Mr. Maher Is a Member of the New York and District of Columbia Bars.

I DON'T PRETEND TO BE A FAN of that wrought by Dean Prosser[1] and Justice Traynor.[2] Neither do I regard "strict liability in tort" as intrinsically evil. While I supported those *advocates* who fought its rise and—more particularly—its premature embodiment in the Restatement of Torts,[3] I fear that their greatest—and perhaps only—success was in the nature of rhetorical overkill. Witness the following extract from a speech by an institutional buyer of insurance:

> . . . a multitude of products case histories . . . bear witness even to a layman that juries and jurists have grown to espouse a concern for providing a remedy where a plaintiff can show injury, an involvement with a product, and a possible connection between the two. I can remember, and so can you, when a defect sufficient to cause a deleterious effect had to be proven.[4]

This gentleman has been led to believe that not only is absolute liability in vogue, but that causation is no longer an element of proof.

Consider this "definition" from a leading loose-leaf service: "Strict liability is the imposition of liability without fault upon sellers of defective products."[5]

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[1] Prosser, *Torts* 692 (Hornbook Scries, 1941); Prosser, "The Assault Upon the Citadel" (Strict Liability to the Consumer), 69 *Yale Law Journal* 1099 (1960).

[2] *Escola v. Coca Cola Bottling Co. of Fresno*, CCH PRODUCTS LIABILITY REPORTS, ¶ 4506, 24 Cal. 2d 453, 150 P. 2nd 436 (1944) (concurring); *Greenman v. Yuba Power Products, Inc.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 4510, 59 Cal. 2d 57, 377 P. 2d 897, 27 Cal. Rptr. 697 (1963); Traynor, "The Ways and Meanings of Defective Products and Strict Liability," 32 *Tennessee Law Review* 363 (1965).

[3] Restatement of Torts, Second, Section 402A.

[4] Damon, "Claims Problems," *The National Insurance Buyer*, July 1967, p. 3.

[5] CCH PRODUCTS LIABILITY REPORTS, ¶ 4010.

Don't the "without fault" and "defective products" phrases sound a little like a cat chasing its tail? Does every product "defect" give rise to liability?

A study of the leading cases does not give rise to a ringing affirmative. Further, despite one or two strange decisions,[6] causation is very much part of plaintiff's case.

My view is not that of Pollyanna.[7] Our society is *not* treating manufacturers kindly. My plea is that, rather than fostering a generation of Miniver Cheevies[8] who grow lean while they assail the seasons, we devote maximum energy to the job of counseling manufacturing clients as to their duties and responsibilities, rather than diverting energy to bewailing the origin of today's law. This will do far more to control costs than wailing about "liability without fault" can ever do. Such counseling does *not* entail abandonment of the field to the plaintiffs' bar; it *does* entail making sure that they win only deserved victories. They wouldn't have it any other way.[9]

There is no magic formula. The secret is spelled—as it ever was—homework.

Pre-History of Products Liability

Before proceeding to "strict liability" and its pre-history, I must restate the all-too-obvious fact that domestic manufacturers—and this is particularly true of those which produce "consumer goods"—operate in an environment of "consumerism" marked by competition—often frantic—among governmental agencies to "get a piece of the action."[10] Whether today's resulting fragmentation of effort serves—or serves to confuse—the consumer, I won't remark. The fact is that manufacturing and marketing organizations are actually or potentially affected by a confusing complex of rule-making, publicity without recourse, well-intentioned investigations concerning product liability and safety,—and should shape their courses accordingly.

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[6] *Dement v. Olin-Mathieson Chemical Corp.*, 282 F. 2d 76 (5th Cir. 1960).

[7] Porter, *Pollyanna.*

[8] Thompson, (Ed.), "Miniver Cheevy," *Tilbury Town—Selected Poems of Edwin Arlington Robinson,* Macmillan, 1953, p. 6.

[9] "First, we declare it to be the duty of every advocate to do everything possible within the framework of the law to promote his client's best interests," "Code of Ethics, American Trial Lawyers Association," *Trial,* June/July 1969, p. 19.

[10] Witness the appointment of "Special Assistant to the President for Consumer Affairs" in both the Johnson and Nixon administrations, the Justice Department's appointment of a "Consumer Counsel" in 1968, HEW's appointment of a "Coordinator of Consumer Education" in 1968, erection of the National Commission on Product Safety in 1968, F. T. C.'s commencement of a series of public hearings on "National Consumer Protection" in November 1968 over and above the traditional roles of F. D. A., F. T. C., U. S. D. A., etc.

That endorsement of consumers' "rights" is a politically safe move does not require statement.[11] That limiting exposure, in terms of both civil liability and a public black eye, is a problem cutting across traditional line and staff responsibilities of a manufacturing enterprise may require statement, although it shouldn't. For example, the National Commission on Product Safety has explicitly declared that—on its unilateral determination of a household product's ". . . unreasonable risk of hazard to the consumer"—the public will be "warned" of danger.[12]

Thus, the stage is set for another cranberry disaster. How many household products manufacturers have caused their public relations people to get together with their manufacturing and marketing brethren, not to mention counsel, in light of the commission's clear and unambiguous warning? How many have weighed what the threatened "public" warning can do to their marketing effort?

Concern for "products liability" is somewhat wasted if it is entertained in a vacuum. In this day and age, "products liability" in the traditional sense is but a part of a total spectrum in which talents other than product development, manufacturing, marketing and legal must be coordinated. "Government relations" and public relations people are very definitely part of today's team as are those who (hopefully) keep a jaundiced eye on copywriters' artful prose and depictions. To the degree that effective communications among these people are lacking, their employer is exposed.

Now, back to that segment of the spectrum which concerns us today and, more particularly, its sub-part known as "strict liability

[11] See, for example, bills proposing a federal Consumers' "Class Action Jurisdiction Act" to confer jurisdiction on federal district courts—*without* regard to diversity of citizenship or amount in controversy—to entertain class actions to remedy ". . . violation of consumers' rights under state or federal statutory or decisional law . . ." so long as interstate or foreign commerce is affected. H. R. 11656 (Eckhardt) and S. 1980 (Tydings), 91st Cong., 1st Sess. (1969). These bills include undifferentiated incorporation of decisional and statutory "state law" into "federal law" and award of attorneys' fees at a minimum level of 10% if plaintiffs are awarded actual or punitive damages. Sponsor's statements make repeated reference to consumer frauds and the undoubted fact that dollar damages attributable to many specific consumer complaints are too small to permit economic prosecution of individual claims. However, the "cure" proposed by early bills is far broader than the bill alleged. For example, "consumer" is not defined. Is not U. S. Steel a "consumer?" Does it need the contemplated relief? "Consumer Class Action" proposals are neither lacking in merit nor without support. Sanford, *"Giving the Consumers 'Class'" The New Republic*, June 26, 1969, p. 15. However, early bills are awesome in their sweep which, I submit, relates more to unsophisticated draftsmanship than to malevolence.

[12] National Commission on Product Safety, News Release, September 20, 1968.

in tort." What is strict liability? I've flagged my own discontent with the "liability without fault" jargon. Imagine how charmed I was by a May 1969 decision of the Illinois Supreme Court in which the court said that "Strict liability in tort"

> . . . is *not*, . . . a doctrine of absolute liability entitling any person harmed in using a product to recover from any member of the production and distribution group. It *does not* make a manufacturer . . . an insurer of the consumer's safety. It *is* liability without negligence but it is *not* liability without fault. There must be a defect in the product, it must be established as existing at the time of leaving defendant's control, and it must be such as renders the product unreasonably dangerous to the consumer.[13]

I hasten to note that these words were *not* necessary to the court's decision which went to plaintiff's burden to plead and prove freedom from contributory negligence. In any event, I thank Justice Underwood for the most succinct statement of what strict liability is—and is not—I've encountered. Not having read counsels' briefs, I am quite ignorant of whether this "setting the record straight" was predicated by argument in the case or a revulsion to the rhetoric of overkill to which I referred earlier.

Let's put things in context. New York's Court of Appeals recently held that one who engages in blasting as part of his business must assume responsibility, and be liable without fault, for injury caused to neighboring property.[14] *That's absolute liability.* Even here, causation is still in the picture.

Modern History of Products Liability

Still pursuing that context, let's reflect on the modern history of products liability. We've all been taught that *Winterbottom v. Wright*[15] held that, in the absence of privity with the injured party, a contractor or manufacturer could not be held liable for damage caused by his neglect in manufacture. Quickly-developed exceptions to this all-embracing "privity" doctrine related to "inherently dangerous" articles intended for human consumption or use.[16] However, the general rule led to the anomaly in which those enjoying privity could recover in warranty for damage caused by defective products

[13] *Williams v. Brown Mfg. Co.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 6193 at pages 9321 and 9322 (dictum), 93 Ill. App. 2d 334, 236 N. E. 2d 125 (1969).

[14] *Spano v. Perini Corporation; Davis v. Perini Corporation*, — N. Y. 2d — (June 5, 1969).

[15] [1842] 10 Meeson & Welsby 109, 152 Eng. Rep. 402.

[16] *Davis v. Guarnieri*, 45 O. St. 470, 15 N. E. 350 (1887); *Thomas v. Winchester*, CCH PRODUCTS LIABILITY REPORTS, ¶ 4502, 6 N. Y. 397 (1852).

—quite without reference to how the defect came to be[17]—while those injured by another's demonstrable neglect but lacking privity were precluded. *Macpherson v. Buick*[18] expanded the "inherently dangerous" exception from *Winterbottom v. Wright* to include all manufactured items which, when made imperfectly, involve unreasonable risk of physical harm subject, of course, to proof of the defendant's ability to foresee such harm in terms of the product's intended use and his failure to exercise reasonable care to avoid the imperfection in question.

Even after *MacPherson,* plaintiff's road was not an easy one. Ingenious attorneys sought to avoid the very real burden of showing the *"whyness"* or *"howness"* of defects and various courts abetted these efforts. Under the "warranty" heading, we find decisions by which the actual purchaser was held to be the injured consumer's "agent" under circumstances which some might regard as somewhat tenuous,[19] others by which third party beneficiary contracts were deduced,[20] and yet others in which covenants were found to run with the product.[21]

On the tort side of the proposition, *res ipsa loquitor* was strained —at least—to the breaking point in order to assist plaintiffs in carrying the negligence burden. *"Res ipsa . . ."*, as originally borrowed by the courts from logicians, relieved plaintiff from going forward when he established a mandatory inference as to an identified defendant's responsibility. Don't confuse my use of "mandatory inference." That which is a mandatory inference from one state of facts may be rebutted by attacking these facts. Traditional *"res ipsa . . ."* merely meant that a rebuttable presumption of negligence arose from proof that the instrumentality causing injury was in defendant's exclusive control *and* that which caused injury ordinarily does not occur absent negligence.[22]

A breaking point, in my mind, occurs when a court places the burden of tracing product history on two or more manufacturer-defendants because plaintiff can establish a permissive—as opposed to mandatory—inference that at least one defendant, otherwise un-

[17] *Ryan v. Progressive Grocery Stores,* CCH PRODUCTS LIABILITY REPORTS, 4505, 255 N. Y. 388, 175 NE 105, 74 ALR 339 (1931).

[18] 217 N. Y. 382 (1916).

[19] For example, *Ryan v. Progressive Grocery Stores,* footnote 17; *Wisdom v. Morris Hardware,* 151 Wash. 86 (1929); *Gimiwez v. Great A. & P. Tea Co.,* 264 N. Y. 390, 191 NE 27 (1934).

[20] For example, *Ward Baking v. Trizzino,* 27 O. App. 475, 161 N. E. 557 (1928).

[21] For example, *Coca-Cola Bottling Works v. Lyons,* 145 Miss. 876 111 So 305 (1927).

[22] Black's Law Dictionary (Third Ed., 1933).

identified, was negligently responsible for an ultimate assembly's defect. This was epitomized by a fifth circuit decision known as *Dement v. Olin Mathieson, et al.*[23] Truly, in such a situation, I must admit that causation is virtually out of the picture. This "multiple agency" theory, by blithely ignoring the traditional "exclusive control" concept, destroys any basis in logic for a presumption. But, this problem exists without necessary reference to "strict liability."

A less offensive stretch of *"res ipsa . . ."* (which is not unfamiliar to the Food and Drug Bar generally) has been stressed recently in Illinois in terms of products liability generally. Dealing with an allegedly negligently manufactured rope which had spent a limited time in a retailer's stock, the court held it possible ". . . to determine from the nature of the defective instrumentality and the surrounding circumstances whether the inference of defendant's negligence is *strong enough* to survive the fact that, between defendant's control and plaintiff's injury, another possession intervened . . . ."[24] Plaintiff needn't trace product history to exclude ". . . every alternative hypothesis suggesting a cause than negligence . . . [of defendant] . . . in order to recover."[25] This approach, which turns on recognizing a mere *probability* that a limited time lapse—or restricted handling—while product was in the hands of an intermediary didn't preclude manufacturer's neglect,[26] is far from satisfying in terms of analytical rigor. However, it is far more respectable than *Dement's* boot-strapping.

This brief treatment has not exhausted the modern progression of products liability theories. An obvious omission is the development of warranty by advertising theories[27] which, until they became somewhat old hat while still in their youth,[28] were provocative of philosophic dispute as to whether they constituted exceptions from the privity requirement, *or* contracts between advertiser and reader, *or* simple misrepresentation.

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[23] *Dement v. Olin Mathieson,* footnote 6.

[24] *May v. Columbian Rope,* CCH PRODUCTS LIABILITY REPORTS, ¶ 5027, 40 Ill. App. 2d 264, 189 NE 2nd 394 (1963).

[25] See footnote 24, at 273.

[26] *Bustamante v. Carborundum Co.,* CCH PRODUCTS LIABILITY REPORTS, ¶ 5724, 375 F. 2d 688 (CA-7 Ill. 1967). See also, *American Motors v. Mosier,* CCH PRODUCTS LIABILITY REPORTS, ¶ 6202, — F. 2d — (CA-5 Tex. 1969).

[27] *Randy Knitwear, Inc. v. American Cyanamid Co.,* 11 N. Y. 2d 5, 226 N. Y. S. 2d 363, 181 N. E. 2d 399 (1962); *Burr v. Sherwin-Williams Co.,* 42 Cal. 2d 682, 286 P. 2d 1041 (1954) (dictum); *Rogers v. Toni Home Permanent Co.,* CCH PRODUCTS LIABILITY REPORTS, ¶ 4507, 167 O. St. 244, 147 N. E. 2d 612 (1958); *Lane v. C. A. Swanson & Sons,* 130 Cal. App. 2d 210, 278 P. 2d 723 (1955); Restatement of Torts, Second, Section 402B.

[28] But see, "Advertising Claims Negate Warnings on Products' Warranty," Trial, August/September 1967.

Key Cases

One could almost view "strict liability in tort" as a breath of fresh air after far too many years of contrived answers in far too many jurisdictions. From the manufacturers' perspective, the key cases are four in number: New Jersey's *Henningsen v. Bloomfield Motors*[29] and *Santor v. A &M Karaghensian, Inc.*,[30] California's *Greenman v. Yuba Power Products*[31] and *Seeley v. White Motor Co.*[32]

Mrs. Henningsen sustained *personal injuries* when her car, *purchased and given to her by her husband from an independent dealer*, collided with a wall. Alleging a defect in the auto's steering mechanism, she sued the car's manufacturer for breach of warranty. Stressing ". . . justice to the consumer . . .",[33] Jersey's Supreme Court shook traditionalists by upholding a nonbuyer's right to recover in warranty from a remote manufacturer when a product defect causes injury. There was more to the *Henningsen* case but its essential holding was an *implicit* recognition of what we now call "strict liability in tort."

Explicit use of the "strict liability in tort" label[34] was a hallmark of the *Greenman* case in 1963. Dealing with a fact pattern remarkably similar to *Henningsen*, the *Greenman* decision involved a gentleman injured by a defectively designed power tool which had been purchased by his wife from a retailer. The newly defined standard looked to a manufacturer's liability ". . . when an article he places on the market, *knowing that it is to be used without inspection for defects*, proves to have a defect that *causes* injury to a human being."[35]

By the *Santor* decision, New Jersey extended *Henningsen*'s implied warranty to a situation not involving personal injury. Plaintiff was unhappy with a carpet purchased as top-grade from a retailer and sought damages from the manufacturer. Holding for plaintiff, the court admitted that ". . . the greater appeal of the personal injury claim . . ." had predicated the *Henningsen* rule but, with considerable logic, observed that ". . . once in existence, the field of operation of the remedy should not be fenced in by such a factor."[36]

Plaintiff in California's *Seeley* case sought not only recovery from the manufacturer of the purchase price paid a retailer for what proved to be a defective truck, but also profits lost because of inability

[29] 32 N. J. 358 (1960).
[30] 44 N. J. 52 (1965).
[31] 59 Cal. 2d 57 (1963).
[32] 63 Cal. 2d 9, 45 Cal. Rptr. 17 (1965).
[33] See footnote 29.
[34] See footnote 31, at page 62.
[35] See footnote 31.

to use the truck normally and property damage for an upset of the vehicle alleged to have resulted from "the" defect. Although plaintiff was allowed to recover the economic losses on a somewhat curious theory of express warranty, Justice Traynor rejected application of the *Greenman* approach to economic loss. His theory: the "distinct problem of physical injuries . . ."—as opposed to "business needs" or "economic expectations"[37]—is handled in the law of torts while the law of sales governs ". . . the economic relations between suppliers and consumers . . . ."[38] While the property damage count in *Seeley* lost out because of a *failure in proof* of *causation,* it was stated that "property damage" is within the scope of "strict liability."[39]

Parenthetically, Justice Traynor chose to avoid a conflict with New Jersey's *Santor* by characterizing it as *another* "express warranty" case,[40] which doesn't quite square with the New Jersey holding which patently faced the concept of applying *Henningsen* to "economic loss."[41] It may have been this semantic exercise which caused some to infer that *Seeley* excluded "property damage" (in place of "economic loss") from "strict liability."[42] In any event, the "economic loss" question is not resolved. It will not be easily put to bed and will provide fodder for many law review articles.[43]

The now famed Section 402A of the Restatement of Torts boils down to manufacturers being liable, quite without reference to the care exercised in "preparation" of a product for market, to ultimate users or consumers for physical injury to person or property (1) caused by a (2) product defect (3) which existed when the product left the manufacturer's hands (4) *if,* by reason of the defect itself, the product was "unreasonably dangerous."[44] *Greenman* explicitly teaches that (a) there must be a defect in design or manufacture which renders a product unsafe for its intended use, and (b) plaintiff, when injured, must have been using the product in an intended

[36] See footnote 30, at page 60.

[37] See footnote 32, 45 Cal. Rptr. at pages 22 and 23.

[38] See footnote 32, at page 21.

[39] See footnote 32, at page 24 (dictum).

[40] See footnote 32, at page 23.

[41] See footnote 30, at page 63; however, the New Jersey Court did say placing goods on the market is a ". . . representation that they are suitable and safe for the intended use." See also pages 64 and 65.

[42] For example, Kroner, Pontaleoni, Koerner & Mutterperl, "Symptoms and Decisions," *Trial,* June/July 1967 at page 32.

[43] For example, note, "Economic Loss in Products Liability Jurisprudence," 66 *Columbia Law Review* 917 (1966); Note, "Manufacturer's Strict Tort Liability to Consumers for Economic Loss," 41 *St. John's Law Review* 401 (1967).

[44] Restatement of Torts, Second, § 402A.

way.[45] The restatement's "unreasonably dangerous" language seems to provide the context for "intended use" rather nicely.[46]

Definitions

What, however, is a "defect" or a "defective condition"? A dictionary equates "defect" with "imperfection" and "fault."[47] This "fault," of course, being in the product as opposed to the producer. "Defect" has a plain meaning if we look at a bobsled with a cracked kingpin in the steering assembly *or* we encounter a product which fails to comply with its maker's published specifications *or,* in the very simplest terms quite unrelated to *how* the condition came to be, a newly acquired product "doesn't work." But what of the product which precisely conforms to specifications? For example, the combination power tool in *Greenman*?

In the *Seeley* case, we were told that manufactured goods can be required "to match a *standard of safety* defined in terms of conditions . . ." which don't create unreasonable risk of harm.[48] Very nice. What then of this "standard of safety"? Is comparison with similar products the answer?

How does one compare a 1967 Rolls-Royce with a 1962 Volkswagen? One foreign auto-maker's ads, I believe, boast that 80 or 90% of the cars they've sold in the U. S. in the last ten years or so are on the road. If such comparisons are permissible, how does one quantify deviations from the average in order to set a line beyond which is "defect"? One can not. If you'll permit a somewhat stretched analogy from the trial of negligence actions, custom or customary practice does not establish the standard of due care, although it may be admissible as evidence of a standard.

If such comparisons are not permissible to *fix* the standard, do we probe instead for risks implicit in most manufactured items in order to identify those which are "unreasonable" a la the restatement? Doing so must involve a weighing of the consumer's awareness of danger. Again referring to *Greenman* and its reference to a manufacturer's knowledge that his product ". . . is to be used without inspection for defects, . . ." [49] This approach excludes plaintiffs injured while using the product in *either* a way other than intended

[45] See footnote 31, at page 64.

[46] For example, *Erickson v. Sears, Roebuck & Co.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 5539, 240 C. A. 2d 793, 50 Cal. Rptr. 143 (Cal. Dist. Ct. of App. 1966).

[47] For example, *Webster's Unified Dictionary & Encyclopedia*, Stuttman, 1959.

[48] See footnote 32, 63 Cal. 2d at page 18.

[49] See footnote 31, page 62.

or a manner inconsistent with clear instructions as to precautions to be taken in normal uses.

Use of a phrase such as "unreasonably dangerous" is a clear recognition that nothing can be made safe for *all* uses. Comments in the restatement look to danger ". . . to an extent beyond that . . . contemplated by the ordinary consumer . . . with the ordinary knowledge common to the community . . ." of a product's characteristics *and* exclude the "defective" concept when a product ". . . is safe for normal handling and consumption."[50]

Policy for Manufacturers

If a manufacturer recognizes that a specific use of his product would involve great risk of harm and that such a use is not improbable, it would seem consistent that the failure to warn would itself constitute a defect. How far can one push this? Does a failure to warn against speeding on rain-slicked city streets become a defect? Reason rebels at such a notion. Those consequences of reckless conduct which are "common sense" surely aren't within the manufacturer's *duty* to warn. Suddenly, we're talking of *duty*. How like good old-fashioned negligence. Doesn't this *duty* bring us right back to "foreseeability"? Even the Fifth Circuit thinks so.[51] In a hair dye case, it held that it was *not* foreseeable that a consumer would blithely ignore warnings and instructions.

Before passing from what the law *is* to what those counseling manufacturers should consider, let me touch upon causation again. Each of the cases I've cited makes the point that causation is still with us. The restatement makes the point. Decisions are written on causation.[52] While some sloppy demonstrations have been allowed,[53] this cannot be put at the door of "strict liability."

What can our clients do?

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[50] See footnote 31, at page 45, comments h and i. See also, *Evans v. General Motors Corp.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 5544, 359 F. 2d 822 (C. A.-7 Ind., 1966) and contrast it with the hopefully unique holding in *Larsen v. General Motors Corp.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 5939, 391 F. 2d 495 (C. A.-8 Minn., 1968).

[51] *Helene Curtis Industries, Inc. v. Pruitt*, CCH PRODUCTS LIABILITY REPORTS, ¶ 5851, 385 F. 2d 841 (C. A.-5 Tex. 1967.) See also, Robb & Rosen, "Warnings Aren't Enough," *Trial*, June/-July 1969.

[52] For example, *Mathews v. Clairol*, 371 F. 2d 337 (3d Cir. 1967).

[53] *Savage v. Peterson Distributing Co., Inc.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 5791, 150 N. W. 2d 804, (Mich. S. Ct. 1967); *Helene Curtis v. Pruitt*, see footnote 51; *Dement v. Olin Mathieson Chemical Corp.*, see footnote 6. See also the curious *Larsen* holding, cited at footnote 50.

Sophisticated ones are not in business to hurt people or property. They want repeat sales and abhor a reputation for other than thoroughness. However, it is conceivable that some levels don't get the word.

Earlier, I indicated that there should be an in-house medium for interdisciplinary communication. I won't rehash obeying public law, being active to insure that formal industry standards are realistic, avoiding over-representation in ad copy by having not only lawyers, but also technicians review it, etc.[54]

Manufacturing clients must be made to understand that controls against production errors are not the end-all and be-all. How to communicate the design defect problem? How about a reference to the coverage distinction underwriters wish to make between "management error" and "production error"?[55] Having succeeded in communicating that there is a "design defect" problem, what then?

Presumably, design follows identification of needs—uses. Having then established *"why?,"* one proceeds to the other classic questions of journalism: *Who? What? When? Where? How?* The answers to these questions establish parameters for what the product will be intended to do in a given environment as well as provide a reliability index. Selection of materials and definition of manufacturing techniques follow. At this point, the classic trade-offs of cost against quality become mandatory. Quality is a big word which embraces both safety and dependability. In an ideal world, neither would be sacrificed but, so long as buyers comparison shop, we won't have an ideal world.

Safety should not be part of the manufacturer's quality vis-a-vis cost trade-offs. This does not mean that every product should be fool-proof. Rather, it should be designed for safe operation in normal conditions. This process should include not only preparation of coherent use instructions when method of use is not patent but also identification of misuses and, at least as to those misuses which can cause danger but are not obvious, preparation of a coherent warning. Coherent to *whom* is a key question.[56] If we're talking of complicated gear purchased by sophisticates, a statement of product limitations

[54] Maher, "Reduction of Products Liability Exposure," *Business Lawyer* 577, 582-588 (April 1967).

[55] Fire Casualty & Surety Bulletins, The National Underwriter Company, Public Liability A-37 (April 1966).

[56] *Restatement of Torts, Second*, § 388. See also, *Oakes v. Geigy Agricultural Chemicals et al.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 6206, (Cal. Ct. App. 3d Dist., 1969).

may be a sufficient warning. The less sophisticated the intended user, the bolder and simpler the warning.[57]

Design of production processes—manufacturing techniques—involves a recognition that many human and environmental factors will induce variability in the usual operation. The degree and type of quality control required will relate directly to such variability and its potential impact on both reliability and safety. Its effectiveness relates to specification of the outer limits of permissible variations (formulation or adoption of objective standards), availability of instrumentation, and men. I needn't say that effectiveness of men relates not only to state of training but also *attitude*.

One very specific bit of advice to give a client who is proud of his quality control or "zero defects" program is to be quite sure that, when references of production "defects" for rework are recorded, the "cure" also should be recorded. Otherwise, in a tactical sense, your good clients may be hard put to give a sensible answer to the "how do you know . . ." question when—and if—they are privileged to testify.

The raw material manufacturer who is inclined to permit use of his trademarks by fabricator-customers would do well to take steps against advertising or labels which, to the public, imply that the trademark-owner and the fabricator are either one or equally involved in the fabrication.[58]

In this effort, I have not dealt with the Uniform Commercial Code or stressed "classic" warranty and negligence. They still exist.

Warranty and Negligence

Some suggest that there must be a "showdown" of sorts between "strict liability" and the Code's Section 2-318—extension of warranties to third party beneficiaries in the "household."[59] As to this, I presently defer to others.

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[57] A very special puzzle for drug manufacturers is posed by *Davis v. Wyeth Laboratories, Inc.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 5908, 399 F. 2d 121 (C. A.-9 Idaho 1968).

[58] *E. I. Du Pont de Nemours & Co. v. McCain*, CCH PRODUCTS LIABILITY REPORTS, ¶ 6209, 455 P. 2d 587, (C. A.-5 Tex. 1969).

[59] For example, Franklin, "When Worlds Collide: Liability Theories and Disclaimers in Defective Product Cases," 18 *Stanford Law Review* 974, 993-994 (1966). But also note that it has been said that the Code ". . . wallows in definition that does not define and the definition that misleads—definition for the sake of forgotten definition. It includes many ways of saying the same thing, and many ways of saying nothing." Mellinkoff, "The Language of the Uniform Commercial Code," 77 *Yale Law Journal* 185 (1967).

But, as to warranty and negligence, I must urge that your clients not be so educated as to "strict liability" and its unspecified terrors that consciousness of the more traditional causes of action fade into the woodwork.[60] This, I sometimes think, is a communication error which lawyers may commit. Is it possible that "management" can be so stirred with gory details of the latest horror perpetuated by the courts or threatened by government that, being human, they sublimate the more clearly defined but less "popular" sins?

I suggest that good plaintiff's attorneys would much rather try a negligence case, if your manufacturer client will obligingly provide the ammunition. If the "whyness" of the defect is potentially exciting to the jury, why be content with mere "defect"? **[The End]**

STATE COURTS HOLD MANUFACTURERS NOT LIABLE

State courts have denied claims of liability in two recent cases, one against a manufacturer of cosmetics, and the other against a drug manufacturer.

In the first case, a judgment in favor of the purchaser of an oxidation-type hair tint was reversed in an action to recover for a condition diagnosed as allergic contact dermatitis caused by use of the tint. Plaintiff in *Alberto-Culver Co. v. Morgan* alleged negligence and misrepresentation, but the Texas Court of Civil Appeals treated the action as one based on the strict liability doctrine. The court said that the plaintiff had to either negate evidence as to allergy or hypersensitivity, or show that she was one of an appreciable class or number of persons who could have been reasonably foreseen to be subject to harm. This she failed to do. (CCH PRODUCTS LIABILITY REPORTS ¶ 6249.)

The New Mexico Supreme Court has held that a physician found liable for malpractice was properly denied recovery in a cross-claim against a drug manufacturer. A jury found that the physician injected tranquilizer into an artery, causing his patient to develop dry gangrene and to lose part of the functions of her hand and arm. The physician claimed that the manufacturer was strictly liable because of its failure to warn of the danger of intravenous injections, but the court refused to set aside the trial court's finding that a "direction circular" accompanying the drug gave adequate precautions for intravenous injections. (*Schrib v. Seidenberg,* CCH PRODUCTS LIABILITY REPORTS ¶ 6252.)

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[60] See, for example, *Neville Chemical Co. v. Union Carbide Corp.,* CCH PRODUCTS LIABILITY REPORTS, ¶ 6121, 294 F. Supp. 649 (D. C. Pa. 1968), in which, as between merchants, effect was denied stereotypical warranty disclaimers and damage limitations appearing in a contract for sale of chemicals. Read it not so much for what the law is as for the circumstances which effect its administration. "Hard cases make. . . ."

The Development and Use of National Voluntary Standards

By DONALD R. MACKAY

Mr. Mackay Is Chief of the Office of Engineering Standards Services of the Institute for Applied Technology, National Bureau of Standards. He Delivered This Paper on June 11, 1969, at the 54th National Conference on Weights and Measures, Washington, D. C.

IT IS A PLEASURE TO HAVE THIS OPPORTUNITY to speak about the Commerce Department's voluntary Product Standards program. This program is a responsibility of the National Bureau of Standards (NBS) Office of Engineering Standards Services.

The Managing Director of the U. S. Standards Institute has already discussed a little of the history of standards, and has explained the need for standards as well as the benefits of standardization activities. After hearing Mr. Peyton's description of the functions and activities of the largest private standardization organization in the U. S., you may be wondering why a government program exists, and where it fits into the national standards structure. In addition to answering these questions, I would like to explain our function and how we assist in the formation of standards.

Let me begin by mentioning the requirements which must be met before the Department participates in the development of a standard. First, the proposed standard must not be contrary to the public interest. In this requirement are three essential words which are the key to the purpose of our program. The words are: "the public interest." The Government's program is first and foremost a service to the public, to the producers of the products standardized, as well as to the distributors and users of these products. Secondly, a proposed standard, to be considered, must have potential national effect or implication. Our program is not concerned with local or regional problems. Thirdly, a standard must have apparent industry-wide interest or endorsement; otherwise, it might be foolish to initiate the development of a standard. And finally, the standard must be such

that it cannot be processed according to the *needs* or *desires* of the industry by a nationally-recognized, private standardizing body. In other words, we are not in competition with private groups. Instead, we exist to complement their activities, and to serve the public interest.

Development of Voluntary Standards

The Government's voluntary standards activities began during World War I. At that time, industry-government cooperation was essential to the war effort. The Conservation Division of the War Industries Board was created to see that the largest possible amounts of labor, capital, materials and equipment were released for the war effort. The government-industry program was established to conserve materials and eliminate waste through standardization and simplification of varieties and sizes of commonly used, mass-produced items.

But when the war ended, so did compulsory standardization, and many manufacturers quickly returned to the old uneconomic conditions of over-variety. The situation was aggravated in 1921 when a delayed post-war depression struck and manufacturers felt they had to offer variety to obtain more sales. Herbert Hoover, as a prominent engineer and later as Secretary of Commerce, was one individual who was so concerned about this situation that he sought to rid industry of waste through the establishment of standardization programs.

Herbert Hoover's personal philosophy about government and industry goals and their interaction in what is known as "society" is just as appropriate today as it was nearly 50 years ago. This philosophy was summed up by Hoover in the following quotation:

> The primary duty of organized society is to enlarge the lives and increase the standards of living of all the people. The whole basis of an increased standard of living, of better human relations, of national progress—indeed, of the advancement of civilization—is the continuous improvement in production and distribution.

In 1921, while he was President of the American Engineering Societies, Hoover appointed a committee to study the existing conditions of waste in industry and to make suggestions as to possible remedies. The committee studied six typical industries and found that preventable waste of labor and materials averaged almost 50% in those industries. The committee's report entitled "Waste in Industry" estimated that ten billion dollars a year—1921 dollars—could be saved through standardization and simplification alone.

The committee's report suggested that the Government should play an active part in the formation of industry standardization committees. When he became Secretary of Commerce, Herbert Hoover

had the opportunity to implement this recommendation. He established, within the Department of Commerce, a Division of Simplified Practice. This Division played a major role in promoting the development of voluntary industry standards. Its publications, entitled "Simplified Practice Recommendations," provided for the voluntary reduction of the number of sizes and varieties of many products. For a time, it led a massive national drive for standardization. In 1927, the scope of the government's activities was broadened to include a Commercial Standards Unit which developed, cooperatively with industry groups, standards establishing quality requirements for specific products. Through the years, the program has been assigned to different offices within the Department of Commerce and the National Bureau of Standards. It has changed names several times, and it has experienced consolidation—the Simplified Practice Division and the Commercial Standards Division were merged into the Commodity Standards Division within the Department of Commerce.

In 1963, a reorganization resulted in the work being transferred back to the National Bureau of Standards. At this time, it was decided that instead of two publications, Commercial Standards and Simplified Practice Recommendations, only one publication series would be issued—to be called "Products Standards." These standards could include quality requirements as well as simplification practices. The one thing that has not changed with time is the goal of the program: to aid industry in the development of standards which are deemed to be in the *public interest.*

Procedures

Our procedures, revised in December of 1965 and amended May of 1968, reflect the emphasis on this goal. I would now like to summarize those procedures for you. The process begins when an interested group, whether made up of producers, distributors, consumers or users, testing laboratories, or representatives from a Government agency, asks the Bureau to participate in the development of a voluntary standard. The Bureau then determines whether the request is feasible and if it conforms to the requirements I mentioned previously, including: Is it in the public interest?

When the request is approved, a specific proposal is developed in consultation with interested trade groups and interested Government agencies. This proposal is then subjected to an impartial technical review by an appropriate Government agency or by several agencies interested in the standard. If it is appropriate, the technical

review may be accomplished by an unbiased group outside the Federal Government. A draft of the proposal is then circulated for consideration and comment to interested groups, including consumers and users.

At this point, a Standard Review Committee is established to review the amended draft, which incorporates the suggestions received from all segments of the industry. The procedures specify that the Standard Review Committee must be representative of all groups interested in the product for which the standard is sought. It is also our policy to see that small business, as well as big business, is represented on the committee. Once the committee approves the proposal, it is distributed to known producers and a representative sampling of distributors, users, consumers and general interest groups for final consideration and acceptance. Any objections received from these groups are carefully considered by NBS. If there are no significant objections and if the proposal is supported by a "consensus," the Bureau announces the approval of the proposal as a Product Standard.

Finally, prior to the printing of a Product Standard, a Standing Committee is named to review the standard within five years of its issuance, to consider any proposals to revise or amend the standard, and to provide such interpretations as may be required. This committee is essentially identical to the Standard Review Committee as to membership and procedures.

A standard, then, is submitted once to an impartial group for technical review, once to a special committee made up of representatives from the interested groups and twice to the general industry for consideration. It should be noted that any individual or company is at liberty to comment during either distribution to the industry. Generally, a press release is issued when the proposed standard is distributed for initial comments, and always when the recommended standard is distributed for acceptance.

At this point, let me explain what is meant by "consensus." The latest amendment to our procedures established a specific definition of consensus in terms of the *numerical* percentages. It is now required that a standard be supported by at least 70% of those responding to the distribution of the recommended standard in the production segment, in the distributor segment, and in the user or consumer segment of the industry. Furthermore, the procedures require that the average percentage of acceptance for each of the three

segments be not less than 75%. The amended procedures also provide a second definition for consensus which involves lower percentages. This alternative definition is implemented for standards which are considered to be in the public interest, but which did not receive the percentages of acceptance previously mentioned. Under this second procedure, the minimum acceptability in any segment of the industry must be not less than 60% and the average of the three segments must be not less than 66⅔%. This procedure also involves the holding of a public hearing to allow the Department to substantiate the importance of the standard to the public.

Responsibilities of NBS

I now would like to enumerate the specific responsibilities of the National Bureau of Standards and of the group proposing the standard. The Bureau assists in the formation of a voluntary standard through the following: It acts as an unbiased coordinator in the development of the standard; it provides editorial assistance in the preparation of the standard; it supplies such assistance and review as is required to assure the technical soundness of the standard; it sees that the standard is representative of the views of producers, distributors, users and consumers; it seeks satisfactory adjustment of valid points of disagreement; and finally, it publishes the standard.

The group proposing the standard, and the industry which is affected by it, have the responsibility of initiating and participating in the development of a standard, providing technical counsel, and promoting the support for and use of the standard.

Our voluntary standards may cover definitions, classes, sizes, dimensions, capacities, quality levels, performance criteria, testing equipment, and test procedures. They may vary in scope from the most complex requirements for precision instruments to size standards for the simplest of items such as two-by-four lumber. At present, we have only a few published Product Standards that are of interest to weights and measures officials. These include, among others, Commercial Standard CS 1-52, "Clinical Thermometers," and CS 8-61, "Gage Blanks." In the Simplified Practice Recommendation series we have SPR 252-60, "Standard Sizes of Pint, Quart and Half-Gallon Rectangular Ice Cream Cartons and Molds," R 155-49, "Cans for Fruits and Vegetables (Names, Dimensions, Capacities, and Designated Use)," and R 253-54, "Retail Container Sizes for Frozen Fruits and Vegetables." I would like to note at this point that the Scale Manufacturers Association has requested Bureau assistance and

cooperation in the development of voluntary standards for concrete batching scales, for bathroom scales, and for the installation of motor truck scales. We look forward to working with the scale industry in the development of these standards and hope that this initial effort will encourage others in the weights and measures field to consider the possibilities of utilizing our procedures, our facilities, and our services to alleviate, if not to eliminate, their problems through the development of voluntary standards.

One of the primary purposes of a standard is to provide a means of communication between individuals—whether they be producers and users, buyers and sellers, or industry representatives and government officials. If we, through the development and publication of a voluntary Product Standard, can provide a better understanding of the characteristics of that product and, at the same time, improve the quality of that product, we will have made a contribution to the society in which we live. Weights and measures officials can assist us materially in our efforts to develop good standards that are in the public interest.

The Role of Weights and Measures Officials

Previously, I mentioned two committees that play important roles in our standards program—the Standard Review Committee and the Standing Committee. These committees are made up of representatives of producers, distributors, consumers or users, and general interest groups. In all cases we attempt to seek out and appoint individuals who are knowledgeable and well-qualified to represent the views of a particular segment of the industry, and, at the same time, honor and uphold the public interest. I don't know of a better group to represent consumers and users than weights and measures officials. This is particularly true in areas in which these people have responsibilities, such as in the packaging and labeling of consumer commodities.

At the present time we are processing four packaging and labeling standards through Standard Review Committees which have, as consumer representatives, various weights and measures officials. Don Konsoer from the State of Wisconsin is serving on our committee for the packaging and labeling of instant non-fat dry milk; Dick Thompson from the State of Maryland serves on our committee for green olives; Earl Prideaux of Colorado is concerned with our standard for instant mashed potatoes; and Matt Jennings of Tennessee is concerned with package sizes of toothpaste.

I personally feel that weights and measures officials make good representatives of consumers and users. They are knowledgeable, fair, objective and interested. It is our intent to rely more and more on people such as these to assist us in the development of standards and to serve on our committees. I hope that when called upon, they will serve without hesitation—and indeed without compensation, except for the knowledge that they have served the people of our great nation.

In closing, let me say that I have had two prime objectives today—one was to enlighten you about our standards program, and the second was to encourage participation in the development of voluntary Product Standards. I hope I have been able to accomplish these objectives. **[The End]**

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION

(Act of October 23, 1962; Section 4369, Title 39, United States Code)

1. Date of filing: Oct. 1, 1969. 2. Title of publication: Food Drug Cosmetic Law Journal. 3. Frequency of issue: Monthly.

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7. Owner: Commerce Clearing House, Inc., Chicago, Illinois 60646. Names and addresses of stockholders owning or holding 1 percent or more of total amount of stock: CT Corporation System, Wilmington, Delaware; The Corporation Trust Company (Del.), Wilmington, Delaware; The Corporation Trust Company (N. J.), Jersey City, New Jersey; The Corporation Trust Company (N. Y.), New York, New York; Eddy and Co., New York, New York; Ince and Co., New York, New York; Kelly and Co., New York, New York; Meth and Co., Denver, Colorado; The Millbrook Tribute Garden, Inc., Millbrook, New York; Perc and Co., Minneapolis, Minnesota; Pitt and Co., New York, New York; Reing and Co., New York, New York; Justus L. Schlichting, Toms River, New Jersey; Stuart and Co., New York, New York; Bertha Palmer Thorne, Bar Harbor, Maine; George T. Whalen, as Trustee under the will of Oakleigh Thorne, Millbrook, New York.

8. Known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages or other securities: None.

9. For completion by nonprofit organizations authorized to mail at special rates: Not applicable.

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Industry Associations and Self-Regulation

By FRED J. DELMORE AND KERMIT V. SLOAN

The Co-Authors Are Both Members of the FDA: Fred J. Delmore Is Acting Associate Director, Bureau of Compliance, and Kermit V. Sloan Is Project Leader, Hazardous Substances and Cosmetics, Division of Industry Services.

THERE HAS BEEN MUCH DISCUSSION in recent times concerning self-regulation by the food, drug, and other industries subject to the laws administered by the Food and Drug Administration (FDA).

This is not a new concept. For many years there has been a considerable degree of self-regulation among the more enlightened and progressive elements of these regulated industries. If there had not been, FDA's job of administering the consumer protection laws would have been well nigh impossible.

However, the enormous increase in production and processing of foods in this era of technological revolution, the manufacture of more and more sophisticated drugs, and the proliferation of cosmetics and household chemical products have made it highly important that the producers, distributors, and marketers of these consumer essentials largely regulate themselves. Government enforcement of laws and regulations cannot alone provide the protection consumers demand and must have in our modern society.

Within the last few years it has become increasingly apparent that assurance that the consumer protection laws are complied with must be a responsibility shared by the regulated industries, state food and drug control authorities, FDA and other federal agencies. FDA has officially recognized this important fact; first, by a major reorganization in 1964 to place more emphasis on education, information, and voluntary compliance programs in cooperation with industry;

second, by moving formally within the last year to set up a state-federal "partnership" to share inspection and other regulatory responsibilities; and, third, by promoting the concept of self-certification through voluntary agreements between FDA and qualified firms.

The term "self-regulation" by industry in this connotation means (1) self-inspection of plant, materials, and production procedures; (2) the adoption and maintenance of good manufacturing practices; and (3) all other actions necessary to achieve full compliance with the law and regulations for assuring consumer protection.

Large segments of the regulated industries have in past years adopted various measures of self-regulation. But there is a pressing need for more activities on an industrywide basis to assure the safety and effectiveness of drugs and the wholesomeness and purity of food. The federal and state governments, by pooling their resources, can be more effective in enforcement activities against violators of the law. By more self-regulation, industry can reduce violations and help in the overall consumer protection effort. In a shared "partnership," government and industry can make consumer protection a reality.

Historically, the industry trade associations have played a prominent role in fostering and promoting self-regulation and voluntary compliance by their member firms. A number of effective programs for improving sanitation standards, manufacturing practices, and product quality, for example, have been initiated by trade associations, both alone and in cooperation with FDA. Among the various functions of associations and services provided for their constituent companies, none are more important or valuable to consumers than those which aid in the protection of the public health and safety.

Throughout the years, FDA has recognized the importance of this role of associations and has been greatly assisted in the performance of its mission of consumer protection by their activities. There are a number of outstanding examples of association cooperation with FDA in programs to improve sanitation standards and product quality in the food industries.

Among such self-regulation pacts is the Better Salmon Control Program. This program was originated in 1937 as a cooperative effort on the part of FDA, the salmon canners, and the National Canners Association to improve the quality of salmon and to keep from the market any portion of the pack considered unmerchantable for any

reason. For many years this program in its original form served its purposes very well. However, in 1967 it was revised and strengthened. It is now known as the Canned Salmon Control Plan of 1967 and has the same objectives as the original pact—self-regulation to improve the quality of salmon and to keep from the market any of the product that is contaminated or unmerchantable for any reason.

The National Canners Association also is active in research to improve food quality and has a number of other programs for promoting voluntary compliance and improving consumer protection.

Another example is The Dried Fruit Association of California Program. This association has been designated by the U. S. Department of Agriculture as the official inspection agency for the marketing of California figs, almonds, walnuts, and prunes. Upon request of individual packers, the association also inspects dried-cut fruits—peaches, pears, and apricots.

Still other outstanding examples of self-regulation are the baking industry self-inspection programs. The American Baking Institute in 1946 initiated an effective program covering plant inspection, training of personnel, and standardization of equipment designed in the interest of improved sanitation. This program and a voluntary inspection program carried on by the Quality Bakers of America cover some eighty percent of the Nation's baked goods production. These programs have helped raise the average standards of the baking industry to a point where it is only infrequently that FDA finds it necessary to take legal action.

Although there are no industrywide self-regulatory programs as such in the drug area, many individual drug manufacturers have self-inspection programs and a number of companies have adopted "zero defects" or error-free production programs.

In addition to information and research programs for its member companies, the Pharmaceutical Manufacturers Association (PMA) has cooperated extensively with FDA and leading universities in sponsoring seminars on quality controls in drug production. PMA recently entered into a major contract to set up a programmed learning course for packaging mechanics in drug plants. This course, it is understood, will be available to the entire industry.

The Proprietary Association and the National Association of Pharmaceutical Manufacturers similarly have participated with FDA in conferences on manufacturing controls and various drug production problems.

These are by no means all of the self-regulatory activities of associations and individual firms in the regulated industries. But they do exemplify what can and should be done to a greater extent by organized industry groups.

FDA's Voluntary Compliance Program

For its part in promoting and assisting voluntary compliance, FDA, in the 1964 reorganization, grouped and expanded its activities in these areas and mounted a major program to provide information and advisory assistance for industry. Initially, the new program was developed in two principal areas: (1) advisory assistance to individual firms on such compliance problems as labeling of products, suitability of ingredients, application of the law to particular situations; and (2) dissemination of information for industry generally on requirements of the law and regulations.

The latter program includes the preparation and distribution of a variety of information materials, such as booklets, speeches, articles, fact sheets, posters, motion pictures, and exhibits. In addition, a large number of copies of *Federal Register* reprints of regulations and orders are distributed.

A special information and educational service initiated within the last two years is a series of drug recall case studies. These studies, without disclosing the identities of the firms involved, show the production and other errors which led to the recall of various drugs. These case studies, based on FDA's and the firms' own investigations of what went wrong, have proved to be very valuable to the industry generally in assessing its operations to prevent similar errors. (See *FDA Papers,* June 1968.)

The overall purpose of the FDA information and educational program is to make available to industry (a) an explanation of how laws and regulations affect it; (b) results of FDA's scientific research and improved analytical methodology; (c) recommendations for controlling bacterial contamination and adopting good manufacturing practices, and (d) advice and support in adopting self-regulation, self-inspection, and error-free production programs.

A collateral activity that quickly became, and still is, a leading part of FDA's voluntary compliance effort is a program of conferences, seminars, and workshops. These are intended not only to brief members of industry on the requirements of the law and regulations

but also to provide a two-way communication on industry problems and their solutions.

This program was begun in fiscal year 1966 with a modest schedule of six workshops. With increasing industry interest and support, a heavy schedule of national and regional conferences and District workshops was developed thereafter. From its inception up to the present, the program has included an aggregate of 325 workshops and 40 national and regional conferences and seminars. More than 34,000 industry officials and supervisory and production personnel representing nearly 16,000 individual firms have attended these meetings.

The various conferences and workshops have covered subject matter in the entire range of FDA regulatory jurisdiction. They have dealt not only with specific legal requirements but with a variety of problems, such as bacterial and chemical contamination of foods. Some of the major national conferences have explored technical and scientific problems, such as small particles of foreign matter in large volume parenteral (injectable) drug solutions, indirect additives entering food through processing equipment or packaging, sterile packaging of devices, and stability of drugs.

Various associations in each of the regulated industries have been active in sponsoring and participating in the many conferences and workshops. Drug associations, as previously mentioned, have sponsored seminars on good manufacturing practices and quality controls. Food associations have participated with FDA in national conferences and in workshops on various contamination problems. Feed industry associations have sponsored a long series of workshops on manufacturing practice regulations for medicated feeds, reaching many thousands of individuals and firms in this industry.

The Toilet Goods Association has sponsored a national joint conference on cosmetic sciences and has taken other steps to help solve microbiological contamination problems in the cosmetic industry.

The Chemical Specialties Manufacturers Association and the National Paint, Varnish and Lacquer Association have been quite active in promoting self-regulation and voluntary compliance with requirements for labeling hazardous household chemical products and paints under the Federal Hazardous Substances Act. Over the last year they have initiated and cooperated with FDA in sponsoring

one national conference and six regional seminars in major cities across the Nation.

All these workshops, conferences, and seminars have had a common objective—to help give the industries a better understanding of the law and regulations, to make available the benefits of FDA research and methodology to help solve contamination and other problems, and to encourage maximum self-regulation

Associations that have initiated voluntary compliance programs and have participated with FDA in a cooperative effort to promote industry self-regulation can rightfully take pride in their contributions to consumer protection. FDA continues to welcome their cooperation, and earnestly solicits a greater effort by all trade groups in the regulated industries to achieve full compliance with the consumer protection laws.

Present and Future Opportunities

Right now, associations in the food and drug industries have an excellent opportunity to provide an essential service for their members and at the same time perform an important public service in the interest of consumer protection. They can do so by developing educational and information programs to instruct and train food and drug plant employees at all levels in good manufacturing practices and sanitation standards. Industrywide programs of in-plant training together with aids such as booklets, posters, slides, exhibits, and perhaps motion pictures would greatly aid the cause of voluntary compliance with legal requirements as well as help assure safe and effective drugs and pure and wholesome food. Many of the human errors that lead to recall of defective and unsafe drugs and to contamination of foods can be eliminated by such programs.

FDA's Good Manufacturing Practice regulations (GMP's) for drugs and its "umbrella" GMP regulations for the food industry provide the basis for association-sponsored programs of this kind.

The PMA-FDA-university regional seminars on quality controls in drug production and the FDA-industry workshop conferences on good manufacturing practices have done much to explain the drug GMP's to top and middle management of individual drug firms. But education in GMP's should be carried to employees all down the line. It is here that associations can perform their most valuable service—

by developing industrywide programs for training employees in GMP's and providing incentives for error-free production. FDA can be counted on to provide whatever assistance it can in the development and conduct of such programs. As Food and Drug Commissioner Herbert L. Ley, Jr., said a few months ago: "It is industry's responsibility to comply with the law and regulations voluntarily. FDA has a responsibility to provide the kind of information and education that will help industry to comply."

FDA's new umbrella food GMP's and the necessity of developing specific GMP appendices for particular foods similarly provides food associations with the opportunity to perform one of their most important and responsible functions as representatives of their industries.

The umbrella regulations are so designated because they cover the food industries generally and the practices which should be followed by all the food industries to maintain good sanitation.

To supplement the umbrella regulations, FDA now is undertaking to develop a series of appendices spelling out current good manufacturing practices for specific food industries. In this task it hopes to draw on the expertise and cooperation of the industries involved.

FDA invites and urges food associations to draft proposed GMP appendices for their particular industries. With their superior knowledge of the food technology of the particular products involved and of current good manufacturing practices in their fields, they are in a far better position than FDA to prepare GMP appendices. And they, too, can develop programs and aids to instruct and train plant employees in following these regulations.

FDA experts in food science and technology are available to counsel with industry groups in the development of such guidelines, whether or not these are formally promulgated as appendices to the umbrella GMP's.

Some associations already have drafted current good manufacturing practice appendices to supplement the umbrella regulations, and others are in process of doing so. The National Pecan Shellers and Processors Association, in cooperation with FDA, has prepared and distributed a set of specific good manufacturing guidelines for the pecan shelling industry. The National Shrimp Breaders Associ-

ation has worked closely with FDA in developing a GMP appendix containing regulations for the industry. The National Association of Frozen Food Packers has prepared and issued to its member companies specific guidelines, including in-plant test procedure and steps for controlling bacterial buildup.

The primary and most important reason for developing GMP regulations and guidelines, of course, is to improve consumer protection against adulterated foods. Another important reason is to provide standards by which compliance or noncompliance with the law can be better judged by enforcement officials and industry itself.

GMP's provide an internal standard by which FDA itself can judge conditions in various manufacturing plants and avoid possible inconsistencies in evaluating and acting on borderline findings by different inspectors and administrative reviewers of inspection reports.

GMP's for specific foods also will provide the industries with knowledge of the yardstick by which they are being judged, as well as a basis for appraising their own performances. Top management will have a standard against which it can measure the performance of individual staff members responsible for plant sanitation. Industry, furthermore, will be provided the means by which specific sanitation programs can be developed, planned, and budgeted with a clearer understanding of what the current regulatory demands are with respect to its particular operations.

Food GMP's also will provide state and local enforcement authorities with a clear picture of the standards being applied by FDA in the sanitation area. This will permit more effective joint planning and uniform enforcement under the cooperative state-federal program mentioned earlier. And GMP's will provide a basis for understanding what does and does not constitute violative conduct by food plants.

FDA applauds the initiative and cooperative activities of trade groups in the GMP area as well as in the fields of education and information to promote voluntary compliance and self-regulation. And it urges an even greater effort in these respects by all associations in each of the regulated industries. Through their leadership, associations can assure that their industries increasingly share responsibility with regulatory authorities for providing protection in today's society. **[The End]**

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