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Food-Drug-Cosmetic Law JOURNAL

Agency Decision-Making: Adjudication by the Federal Trade Commission . . . . . PHILIP ELMAN

Hospital Formularies—Possible Liability Risks for Injuries to Patients . . . . . WILLIAM E. WOODS

International Food Law . . . . . by ROBERT RUARK, DR. K. DURRENMATT and RAYMOND A. IOANES

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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

About This Issue.—"May an administrative agency, which would appear to be so different an institution from a court, be depended upon to discharge the function of adjudication fairly and impartially?" This question is explored, with particular reference to the Federal Trade Commission, in an article appearing on the following page by *Philip Elman,* a Commissioner of the FTC.

The operation by a hospital of a formulary system involves risks of liability for damages for injuries to patients. The nature and extent of such risks, which are not the same for all hospital personnel, are explained in an enlightening article which begins on page 513. The author is *William E. Woods,* Assistant to the Executive Vice President of the National Pharmaceutical Council.

"The Effect of Food Legislation on the Development, Production and Utilization of Corn-Derived Sweeteners" is the title of a paper by *Robert G. Ruark,* which appears on page 530. Mr. Ruark, Vice President, Corporate Research, Corn Products Company, discussed this topic at the recent American Chemical Society Symposium on the Impact of Food Laws on International Trade.

In an article beginning on page 536, *Dr. K. Durrenmatt* points out the great variety of methods used today in food analysis, acknowledges the work already done to effect more uniformity and emphasizes the need for even further action. Dr. Durrenmatt is deputy manager in charge of worldwide new production development, Nestlé Alimentana Company, Vevey, Switzerland. This paper was also presented at the American Chemical Society's Symposium.

The administrator of the Foreign Agricultural Service of the United States Department of Agriculture discusses government programs which counteract the trade restrictive effects of foreign food laws. The paper by *Raymond A. Ioanes* appears at page 544.

B. F. Daubert, director of nutrition at General Foods Corporation, reviews the various chemical additive problems involved in food processing in an article on page 553.

In an article on page 562, *Maven J. Myers* comments on an article by Lawrence A. Coleman, "The Deep Pocket Rule and the Jumping Warranty: Strict Products Liability of Manufacturers," which appeared in the November 1963 JOURNAL. Mr. Myers believes that the theory of the Superior Risk Bearer provides a better explanation of increased products liability. Mr. Myers, a candidate for a Ph. D. degree in pharmacy, is a lecturer on jurisprudence at the Philadelphia College of Pharmacy and Science.

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Journal

Agency Decision-Making: Adjudication by the Federal Trade Commission

By PHILIP ELMAN

Mr. Elman, a Federal Trade Commissioner, Presented This Paper Before the Federal Bar Association in Washington, D. C., on September 11, 1964.

THE DISTINCTIVE CHARACTERISTIC of the administrative process is its blending of different functions and powers in a single agency. The basic duty of an administrative agency is to implement, using the wide variety of tools given it by Congress, the regulatory policies established by statute. The primary task of the Federal Trade Commission, for example, is to prevent the use in interstate commerce of unfair, deceptive, and anticompetitive business practices. The Commission has been empowered to perform this task in various ways: it can investigate; it can prosecute; it can adjudicate; it can guide and advise; it can conduct and publish economic studies; and it can issue rules and statements of policy.

This fusion of functions has raised questions as to the integrity, as well as the effectiveness, of the administrative process. I should like to explore with you, with particular reference to the Federal Trade Commission, the agency I know best, one of those questions: May an administrative agency, which would appear to be so different an institution from a court, be depended upon to discharge the function of adjudication fairly and impartially?

Administrative adjudication is a term sometimes used loosely; but the Federal Trade Commission has one function which is indisputably judicial in character. If the Commission has reason to believe that a person is violating any of the laws it administers, and if it

appears that a proceeding would be in the public interest, the Commission issues a formal complaint. The proceeding that follows before a hearing examiner is, with minor variations, similar to a court action governed by the Federal Rules of Civil Procedure. If the Commission, on review of the examiner's decision, finds that the alleged violations of law have been proved, it can (subject to judicial review of its decision) apply sanctions similar to those of a court of equity.

As in a judicial proceeding, the agency's decision must be based on the record; findings must be supported by the evidence; and the burden of proof rests upon the charging party. The basic differences between judicial and administrative adjudication are not differences of procedure; they are differences in the institutional environment in which adjudication takes place. Adjudication is the sum and substance of the judicial process, but it is only a part, and not always the largest or most important part, of the administrative process.

The judicial process is designed to ensure that the judge be a neutral and disinterested trier of facts. The ideal of the judge is a detached, even aloof, arbiter of controversies in whose outcome he has no interest other than that of applying the law fairly and even-handedly. A judge is strictly insulated from the initiation and prosecution of cases. Ordinarily, he has but limited control of his docket. And, assuming his jurisdiction is general, a judge rarely will acquire an expert's knowledge of the matters coming before him—which helps to assure that he will approach each new case with an open mind.

In comparison to judges, agency members have a more active and affirmative commitment to achieve the goals and effectuate the policies declared by Congress; and their success is measured by the results the agency achieves in striving to attain those positive objectives. Agency members, moreover, are expected to be experts, bringing to each case a specialized knowledge informed by experience. Such knowledge and experience is not, and should not be, confined to the record of a particular case.

Even if we go no further, it is apparent that the administrative process, in not shielding agency members—as judges are shielded—from responsibility for producing successful results in advancing the policies of the laws allegedly violated, complicates the task of adjudicating particular cases. But there are other stresses and strains on agency adjudication that must be noted. I do not refer to improper external pressures, conflicts of interests, *ex parte* communications, and the like. I have in mind, rather, those subtle institutional influences

which no laws, regulations, or codes of ethics can remove, and which will best be overcome if they are forthrightly recognized.

It is by no means unusual for an agency to decide that a complaint which it issued should be dismissed because the evidence or the legal theory on which it was based did not stand up under adversary attack. Of the appeals decided by the Federal Trade Commission in the past year, for example, about one-third resulted in dismissals of the complaint. Still, I think it is likely that, in general, decisions of this kind are less reluctantly made by judges than by the members of an agency. Not having issued the complaint, the judge need not concern himself with whether a subsequent dismissal will be construed as an admission that a mistake was made in issuing the complaint and that the public's (not to mention the respondent's) time and money have been wasted in a fruitless proceeding. Nor need he have any apprehension that dismissal of the case will impair staff morale. Also, a judge is not subjected to the mischievous notion that a case ought not be dismissed because judicial review is thereby precluded, or the equally mischievous notion that the success of an agency in carrying out its statutory responsibilities is measured by the number of cease and desist orders it enters.

Considerations of this sort illustrate the perils to completely fair and impartial agency adjudication. There are, however, within the existing framework of the administrative process, a number of steps that can and should be taken to assure greater fairness and impartiality.

First of all, case-by-case adjudication as a technique of administrative law enforcement should be substantially de-emphasized. As I have explained more fully elsewhere, litigation is an intolerably slow, costly, clumsy, fragmentary, and inadequate process for resolving the delicate and complex economic issues that characterize the field of trade regulation. I have therefore urged the Commission to make more use of the other regulatory tools available to it—and, in the past three years, it has been doing so with increasing frequency. The problem of adjudicative fairness could to a considerable extent be avoided altogether if the agencies utilized non-adjudicatory techniques, such as rule-making, more frequently. However, some problems yield only to the case-by-case method of inclusion and exclusion; and adjudication is the method of policy formulation that many agencies, including the Federal Trade Commission, know best.

The essential and non-delegable duty of an agency member is in the area of policy formulation. Therefore, he is helped, not hurt,

by being relieved of the responsibility for weighing specific evidence against designated persons in particular cases. Both at the complaint-issuance and appeal-deciding stages, internal delegations can do much to assure greater fairness in adjudication. I have proposed, and I propose again, that the Commission make a limited delegation of authority with respect to the issuance of complaints. Specifically, the members of the Commission should not, at the complaint-issuance stage, undertake to make their own assessment of the evidence regarding violation of law. They should limit their inquiry to considerations of law, policy, and public interest, leaving to the Bureau Directors the determination whether there is sufficient evidence of violation. If members of the Commission did not review the investigative files at the complaint-issuance stage, they would no longer be open to the charge of acting as prosecutor and judge in the same case. Instead, they would be in approximately the position of a judge who, in overruling a demurrer, finds only that the complaint states a cause of action—not that it has been proved or can probably be proved. Moreover, a Commissioner who spends much of his time reviewing investigative files at the pre-complaint stage may be disabling himself from discharging those policy-making and adjudicative responsibilities which are his alone and cannot be delegated to others.

At the appeal-deciding stage, I would accord greater deference to the findings made by hearing examiners on disputed issues of fact in which resolution depends on evaluation of the evidence rather than on the accumulated experience and special knowledge of the agency. A hearing examiner should be regarded as the agency's special master on fact questions. The independence of hearing examiners, specifically their isolation from the complaint-issuance process, is a substantial safeguard against unfairness in administrative adjudication. We strengthen that safeguard, and at the same time help the agency members concentrate on their basic law- and policy-formulation function, by attaching greater finality to examiners' findings on strictly factual or evidentiary questions. Agency members should, so far as possible, avoid inquiry into such questions. To the extent that they diminish their role of judges of the particular facts, agency members enlarge their primary role of administrators.

They should concern themselves more with general problems and broad solutions, and less with individual cases and narrow adjudications. Agencies were not created to decide issues such as "Did X do these particular acts charged against him?", but "Is it unfair and anticompetitive for companies in this industry to engage in this practice?"

The more agency members immerse themselves in the former type of question, the less able they are to deal with the latter.

Personal Standards of Agency Members

But greater delegation and other procedural reforms will themselves accomplish little. Improvements of the fairness of agency adjudication will not come until agency members frankly acknowledge, and conscientiously seek to avoid, the dangers inherent in the fusion of functions within the administrative process. A lapse from fairness in agency adjudication is more likely to derive from an unconscious yielding to institutional factors than from a cynical disregard for the duty to judge impartially. This danger could be mitigated if agency members were alert to it and determined to resist.

Beyond that, as has been said so often but not yet fully accepted, the highest standards of integrity, independence, character, and ability must govern the appointment of members of federal administrative agencies. For, as Gerard Henderson observed in his classic study of the Federal Trade Commission:

> Impartiality and fair-mindedness are personal qualities. There are men who can preserve a detached and judicial point of view, however much their relation to the controversy may draw them toward one side or another.

Why not candidly acknowledge that to judge fairly in the framework of the administrative process may be more difficult and demanding than to judge fairly as a member of a judicial tribunal, and that therefore the standards of fitness for agency appointments should be at least as high as those governing the selection of federal judges?

The questions we have explored are troublesome, and are not to be brushed aside. They troubled me when I joined the FTC three years ago, and they still trouble me. One answer—which I have rejected not because it is too drastic but because it is not responsive to the real needs of the situation—is to relieve the agencies entirely of their adjudicative function. I have not taken your time to spell out the reasons why this proposal seems to me to create more problems than it solves, and to leave the administrative process less rather than more effective. But if one believes, as I do, that the administrative process is an indispensable tool of democratic government and that the structure of the federal administrative agencies is basically sound and is likely to remain substantially unchanged in the foreseeable future, he is under greater obligation to look squarely at the perils that seem to inhere in agency adjudication. Facing realities is usually a good way to begin dealing with them. **[The End]**

Hospital Formularies — Possible Liability Risks for Injuries to Patients

By WILLIAM E. WOODS

Mr. Woods Is Assistant to the Executive Vice President of the National Pharmaceutical Council.

THE AMERICAN MEDICAL ASSOCIATION Board of Trustees and other AMA officials have stated clearly on numerous occasions that no one in a hospital should interfere with the attending physician's right to select the drug or brand of drug the physician feels is in his patient's best interest. The AMA objects to the compulsory use of hospital formularies or drug listings and to formulary prior consent provisions.

Two common procedures are used under the various formulary systems which may prevent the hospital patient from receiving the brand of drug prescribed by his physician. One is the use of prior general consent and the other is the use of imprints on hospital prescription blanks. Prior general consent refers to a hospital procedure in which a physician authorizes hospital personnel to dispense any brand of drug having the same generic name as the brand prescribed by the physician. Such authorization has been accomplished in some hospitals by requiring the physician to subscribe to hospital by-laws embodying this principle as a condition for obtaining staff privileges. Other hospitals simply require staff physicians to sign an authorization card giving the physician's consent to the hospital pharmacist to dispense a so-called "generic equivalent" drug in place of the brand of drug prescribed. In a joint release January 17, 1964, prior general consent policies under a hospital formulary system were disapproved by four national associations: the American Hospital Association, the American Medical Association, the American Pharmaceutical Association, and the American Society of Hospital Pharmacists. In the use of imprints on hospital prescription blanks, the imprints state that "generic equivalent" drugs will be dispensed unless the prescribing

physician checks a box near the imprint to indicate he is insisting that the brand prescribed be dispensed.

Should a hospital patient suffer an injury after taking a different brand of drug that has been dispensed in place of the brand actually prescribed, the resulting legal questions involve possible liability for damages arising out of operation of a formulary system. The concern of physicians and hospital personnel is whether the system entails risks which would not exist were the system not in effect.

Upon the basis of information summarized herein it would seem that the operation by a hospital of a formulary system, which permits the substitution of one brand of drug for another without the express, positive consent of the prescribing physician in each case, does entail risks of liability for damages upon the part of various persons participating in the system, which risks would not be present were the system not employed. This article deals with the nature and extent of such risks, which are not the same for all hospital personnel.

An important aspect of the liability issue centers on the safety and effectiveness of generic name (non-proprietary) drug products versus brand name (proprietary or trademarked) drug products.

THE OPERATION OF A FORMULARY SYSTEM

Characteristics and Compilation of the Formulary

The term hospital formulary generally means a listing of drugs available in the hospital pharmacy. Formularies may vary from a mimeographed list of several pages to a bound or loose-leaf book of several hundred pages. The larger books generally include discussions of pharmacological action, dosage, and common usage of the drugs. Whatever the format of the formulary listing, many hospitals have a pharmacy and therapeutics committee that is responsible for determining what drugs should be included in the hospital pharmacy inventory. If the P & T committee does not determine the specific brands to be stocked, the pharmacist may select the brand. There is no consistency as to the number of times a year a P & T committee meets nor the frequency with which formularies are revised. Some committees meet twice a month while others may not meet twice a year. Many formularies include a cross reference list which enables hospital personnel to ascertain the generic name of each trademark or brand name product prescribed. This facilitates substituting the so-called "generic equivalent" drugs. Since about one-half of the

9,000 hospitals in America do not employ a pharmacist, it is likely that not over 3,000 hospitals would have a formulary or a P & T committee. The hospital pharmacist and representatives from the hospital medical staff comprise the P & T committee, often consisting of six to twelve members. Other hospital personnel who may serve on the committee are the administrator, the purchasing agent and possibly a representative of the nursing service.

Purpose of the Formulary System

The purpose of the formulary system appears to be twofold, namely, educational and economic.

Hospital officials point out that formulary systems are educational in that they enable the medical staff to evaluate, appraise and select drugs which it desires for patient care. The ability to appraise or analyze drugs may vary from one hospital to another.

The system is or can be economic insofar as it:

(1) Tends to reduce the number of items in the pharmacy's inventory with resulting savings;

(2) Permits, encourages, or compels the distribution of generic drug products to charity patients rather than trademarked drug products prescribed by the attending physician with questionable savings to the hospital; and

(3) Permits, encourages, or compels the sale by the hospital pharmacy to the patient of generic drug products at prices which may approximate the prices charged for trademarked drugs or at prices representing a saving to the patient, if the saving is passed along to the patient. This, of course, is subject to question, for generic drugs are not cheaper than trademarked drugs simply because they have only a generic name.

Restrictions, if Any, upon the Physician

Many of the larger hospitals have even required the physician, as a condition to his staff membership, to agree in one form or another that unless he in some specified manner plainly indicates to the contrary, his prescription or order for a trademarked drug may be filled by the hospital pharmacist by supplying a product with the same generic name, and that it may or may not be the brand prescribed. Prior general consent has been disapproved by medical, pharmacy, and hospital associations.

It appears that most, if not all, hospitals make some provision in the operation of the system whereby the prescribing physician can, at least in some circumstances, obtain for his patient a specific drug product not listed in the formulary. The degree of ease or difficulty, and the added expense, if any, with which this may be done varies from hospital to hospital.

Hospital leaders prefer that physicians prescribe by generic name so that any brand of drug having the same generic name may be purchased and dispensed.

Dr. M. O. Rouse, speaker of the AMA House of Delegates, has said:

> A physician can be told many things about a drug, including its chemistry, its mode of action and to some extent, its toxic properties. But ultimately he must judge its effectiveness. To turn this responsibility over to the hospital, the pharmacist, or even a committee of the medical staff would result in poorer quality medicine and violate one of the basic principles of medicine.

Dispensing by the Pharmacist

Where a formulary system allows the physician by whatever means to require that the brand of pharmaceutical prescribed be dispensed, and the physician does so require, then, of course, the pharmacist must fill the prescription as written.

Where the system in any circumstance does not permit the hospital physician to require that the brand of pharmaceutical prescribed be dispensed or where the physician has the right to so require but does not exercise it the pharmacist can, under the system, fill the prescription or order with a so-called "generic equivalent" or with another brand of drug bearing the same generic name.

THE EQUIVALENCE OF PHARMACEUTICALS HAVING THE SAME GENERIC NAME

Ample and available medical evidence establishes that two pharmaceutical products whose principal ingredient has the same generic name may differ substantially in one or more of the following characteristics: potency, compatability, purity, period of sustained release, enteric coating, disintegration time, solubility, particle size, vehicle or base, percentage of active ingredient, allergic effects, irritation, hydrogen ion concentration, tonicity, caloric values, melting point, surface tension, viscosity, ease of application and removal, and flavor. There may be significant differences between otherwise "same" drugs attributable to quality control, packaging, storage and extent of lot

or batch controls. These data also indicate that many, if not most, of these differences can be of material significance in their effect upon the health of some patients.

A number of specific instances of "therapeutically significant differences" among "generically identical pharmaceuticals" meeting the standards of the United States Pharmacopeia, the National Formulary and the Food and Drug Administration are reported, for example, by Gerhard Levy and Eino Nelson.[1]

A dramatic example of marked potency difference involves prednisone tablets reported in 1960. The report involved prednisone tablets by two manufacturers. Both showed the same prednisone content by laboratory analysis. However, the tablet of only one of the two manufacturers gave the expected results in the patient. No discernible difference in the two makes of tablets detectable by laboratory analysis could be found. The difference in potency (which was quite real) was attributable solely to the difference in pharmaceutical formulation, which allowed the prednisone in one instance to be properly released but not in the other.

The purity of raw materials and that of the finished product must be clearly established. Sometimes an impurity introduced in the manufacturing process and not completely removed thereafter may be of great significance therapeutically.

As a case in point, a startling incident was reported in 1958 involving several children of both sexes ranging from five to ten years. While taking certain vitamin products the children experienced enlargement of the breasts and other observable physical changes of the type produced by estrogenic drugs. Through rather unusual and thorough investigation it was discovered that the vitamin capsules in this instance were contaminated with estrogens. Further checking revealed that the source of the contamination was improper cleaning of equipment used alternately for vitamin and estrogen products manufacture. Presumably the vitamin content of the product involved was satisfactory but this case history vividly demonstrates that simple analysis alone is no assurance of "equivalency."

An even more startling incident was reported in the public press on June 26, 1962 involving eight small children under treatment for

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[1] *New York State Journal of Medicine,* Vol. 61, No. 23, December 1, 1961, at pp. 4003 et seq.; *Journal of the American Medical Association,* Vol. 177, September 9, 1961, at pp. 689-691.

tuberculosis at San Francisco General Hospital. The drug being administered was INH, and an investigation was initiated when a three and one-half year old girl began to menstruate. Other children developed enlarged breasts, darkening nipples and pubic hair. Officials discovered that this drug as well as six additional products of the same manufacturer, were contaminated, probably during manufacture, with the synthetic sex hormone, diethylstilbestrol. Dr. Ellis Sox, San Francisco Health Director, was quoted as saying that the accident merely confirmed his resolution henceforth not to buy such drugs from any but the major and most reputable manufacturers and not from those submitting the lowest bid.

If "equivalent" is interpreted to mean "equal to" or "identical with," the term "generic equivalent" is deceptive and misleading. It implies that products of two different companies, each product containing an equal amount of active ingredient, are identical in their chemical composition and therapeutic action. It carries the hazardous implication that all manufacturers exercise the same amount of skill, care, testing, and technical "know-how"; employ identical equipment and trained staffs in identical factory environments; and that each of many materials necessary for drug formulation (the tablet, capsule, or form that the patient actually uses) is identical.

There is in fact no assurance that formulations which contain identical amounts of an active ingredient are actually identical, either in total chemical composition or in therapeutic value. Thus there is no such thing as an invariable "generic equivalent" of a formulated pharmaceutical product.

SCOPE OF THE LIABILITY ISSUE

By virtue of the foregoing, it is evident that a patient can sustain bodily injury, fatal or otherwise, through the operation of a formulary system when he is administered a brand of drug other than the brand prescribed or ordered by the attending physician and the difference between the brand prescribed and the brand administered is therapeutically significant to him.

In considering whether or not such injuries might result in liability for damages upon the part of persons who participate in the operation of the system when such cases occur, reference is made to the American Law Institute's Restatement of the Law of Torts. The principles stated therein are generally common to the law of all of the states of the United States, with the possible exception of

Louisiana, in the absence of specific statutes or decisions to the contrary.

Of course these principles relate only to questions of civil liability for damages and not to any question of criminal liability under any applicable penal statute.

APPLICABLE GENERAL PRINCIPLES

One who sustains bodily injury as the result of the conduct of another is entitled to recover monetary damages from that other if he can show that his injuries resulted from the other's negligence.[2] The law regards negligence as the failure to employ that degree of care which a reasonably prudent person would employ in the circumstances and the more danger there is inherent in the circumstances, the greater is the degree of care required.[3]

Where one person claims to have been injured by the negligence of another, he is required to present evidence in support of his claim before a judge and, usually, a jury. If the judge, after hearing the evidence, is of the opinion that reasonable men could differ as to whether or not the claimant, that is, the plaintiff, is entitled to recover monetary damages, the judge will submit disputed questions of fact to the jury for the jury's decision and will state to the jury the rules of law in the light of which the jury should render its verdict.[4]

The jury is thus asked to decide such questions as whether or not a thing was done or a condition existed; whether or not one thing caused or contributed to the happening of another; the nature and extent of plaintiff's alleged injuries; and the amount of monetary damages, if any, the defendant or defendants must pay. The decisions of a jury as to such questions are final and, with few limited exceptions, are not subject to review upon appeal.

Dr. F. J. L. Blasingame, Executive Vice President of the AMA, has stated that:

> [A] physician can delegate to a lay person the performance of a ministerial or nursing act, but any consent or authorization which purports to delegate medical discretion or judgment to a lay person is illegal.

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[2] American Law Institute's Restatement of the Law of Torts, Sec. 281.
[3] Work cited at footnote 2, at Secs. 282, 283, 284.
[4] Harper and James, *The Law of Torts* (1956) Vol. 2, Chap. XV, Functions of the Judge and Jury in Negligence Cases, pp. 871 et seq.

RISKS OF LIABILITY

The Attending Physician

Absent the formulary system, the pharmacist is required to fill the prescription or order as written unless he first obtains the specific permission of the physician with respect to the particular prescription or order. In such circumstances, the physician's risk of liability to a patient injured by the medicine administered is that of either (1) a claim of malpractice in negligently prescribing an unsuitable therapeutic agent [5]—a risk which is also present under the formulary system, or (2) a claim of negligence in selecting an incompetent pharmacist [6]—a risk which is also present under the formulary system.

Under the formulary system, should substitutions occur there is the additional risk, however, that a patient may claim to have suffered personal injury as a result of having been administered a pharmaceutical product other than that named by the prescribing physician upon his prescription or order where there was a therapeutic difference significant to the patient between the pharmaceutical administered and the pharmaceutical prescribed.

In such event the plaintiff would have the burden of satisfying the jury that his injuries were caused by the difference between the pharmaceutical prescribed and the pharmaceutical administered and evidence to the contrary, if any, would of course be heard from the defendant physician and his witnesses. As a practical matter, plaintiff's evidence upon this point would consist of the subject prescription or order, obtained by the pretrial discovery process, plus the pharmacist's record of the substitution also obtained by discovery, plus expert testimony as to the nature and effect upon the patient of the differences between the pharmaceutical prescribed and the pharmaceutical actually supplied by the pharmacist and administered by the nurse.

If the plaintiff failed to establish this fact to the satisfaction of the jury, its verdict should properly be returned against the plaintiff without further consideration. If the jury concluded that this con-

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[5] *Murdock v. Walker*, 43 Ill. Appl. 590 (1892).

[6] "Physicians, . . . like other persons, are subject to the law of agency . . ." *Yorston v. Pennell*, 9 NEGLIGENCE CASES (2d) 1009, 153 A. 2d 255, 397 Pa. 28 (1959) (holding surgeon liable for negligence of resident physician); American Law Institute's *Restatement of the Law of Agency* 2d Sec. 405(2), "An agent is subject to liability to the principal if, having a duty to appoint . . . other agents, he has violated his duty through lack of care or otherwise in the appointment . . . and harm thereby results to the principal in a foreseeable manner."

tention was correct, however, it would then consider whether the physician had been negligent.

The plaintiff would here contend that the physician was negligent in permitting the substitution in question by virtue of having previously given a general consent to such a practice when he knew or should have known that differences between pharmaceuticals having the same principal ingredient or ingredients can be of therapeutic significance to particular patients and that the physician either did not consider that fact in writing his prescription in this case or did consider it and reached an incorrect conclusion.

In such event the court would in all probability submit to the jury the question of whether the physician did or did not employ due care in such circumstances and that in such case there is a substantial risk that the jury would return its verdict in favor of the plaintiff.

Any prior consent given by the physician to such substitution does not avail him as a defense but to the contrary can be offered as evidence tending to establish lack of due care upon his part by, in effect, delegating the selection of a therapeutic agent to a third person unacquainted with the patient.[7]

The Pharmacist

Absent the formulary system, the pharmacist's risk of liability may be summarized as that arising from his failure to use due care (1) in the selection of his stock or (2) in the filling of prescriptions or orders as written—both of which risks are present under the formulary system.

Under the formulary system in which substitutions occur there is the additional risk, however, that a patient may claim to have suffered personal injury as a result of having been administered a pharmaceutical product other than that named by the prescribing physician upon his prescription or order where there was a therapeutic difference significant to the patient between the pharmaceutical product prescribed and the pharmaceutical product administered.

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[7] Such a contention finds strong support in the Annual Report of the Board of Trustees of the American Medical Association, which appears in the *Journal of the American Medical Association,* of October 27, 1962, Vol. 182. No. 4, pp. 363 et seq. at p. 366, which stated in part:

"Prescribing medicine for the patient is the responsibility of the individual physician and is not within the purview of the administration of the hospital."

In such event the plaintiff would have the burden of satisfying the jury that his injuries were caused by the difference between the pharmaceutical prescribed and the pharmaceutical administered. The considerations noted above with respect to the physician in this aspect of the matter are equally pertinent here.

If the jury concluded that this initial contention by plaintiff was correct, it would then consider whether the pharmacist had been negligent.

The plaintiff would here contend that the pharmacist was negligent in effecting the substitution in question when he knew, or should have known, that differences between pharmaceuticals having the same principal ingredient or ingredients can be of therapeutic significance to particular patients and that the pharmacist either did not consider that fact in making the substitution in this case or did consider it and reached an incorrect conclusion.

To this the pharmacist would no doubt reply in effect (1) that the duty of considering those matters was the duty of the prescribing physician and not his; (2) that the physician knew or should have known his patient and his patient's condition and characteristics, and knew or should have known how the formulary system operated and how the pharmacy and therapeutics committee functioned and what pharmaceuticals could be substituted for another; (3) that by giving prior consent to such substitution, the physician had in effect given notice to the pharmacist that the physician accepted exclusive responsibility for foreseeing the effects upon his patient of any possible substitutions; and (4) that the pharmacist was therefore entitled to assume that the physician would make due allowance for the possibility of substitution in this case.

To this the plaintiff would no doubt reply in effect that the complexity of the problem of writing a prescription under such a system and the inherently dangerous nature of drugs were factors which imposed upon the pharmacist the duty of anticipating that a physician in any given case might not foresee every consequence of writing a prescription under the system. In this respect the plaintiff would rely upon the principle expressed in Section 290 of the American Law Institute's Restatement of Torts which states that:

> For the purpose of determining whether the actor should recognize that his conduct involved a risk, he is assumed to know . . . the qualities and habits of human beings . . .

This principle is explained by the Restatement as follows:

Reasonable assumption as to conduct of others. The rule stated in this Section relates to the knowledge which is necessary to enable the actor as a reasonable man to recognize the existence of a risk and the extent thereof, that is, the extent of the chance that harm will be done to the interests of others. If the propensity of a small percentage of mankind to act in a manner different from that customary to the mass involves only a slight chance of trivial harm to an unimportant interest, the actor, particularly if the law regards his conduct as useful, is entitled to ignore this risk. This is generally expressed by saying that, under such circumstances, the actor is entitled to asume that others will act with normal propriety or will not be guilty of negligence or intentional misconduct, or that he is not required to anticipate and provide against such misconducts. On the other hand, if the known or knowable peculiarities of even a small percentage of human beings, or of a particular individual or class of individuals, are such as to lead the actor to realize the chance of eccentric and improper action, he is required to take this chance into account if serious harm to a legally important interest is likely to result from such eccentric action and his own conduct has not such preeminent social utility as to justify the serious character of the risk involved therein. This is often expressed by the statement that in such case the actor is bound to anticipate and provide against the negligent or intentional misconduct of the other or a third person.

The extent of the chance that harm will be done is one, but only one, of the factors which determine the magnitude of the risk with which the utility of the act is to be compared in order that its reasonable character may be ascertained, the other factors being the extent of the harm likely to be caused thereto (see Secs. 291 to 296).

It would seem that a court applying those principles in the assumed case would in all probability conclude that even granting that the risk of a physician's failure to foresee the harmful consequences of his prescription under the formulary system were slight, the magnitude of the risk involved, that is, to health or life, is such as to outweigh the social utility of the formulary system, but that in any event this too is a question to be submitted to the jury.

In the event of such a submission by the court to the jury there is of course a substantial risk in these circumstances that the jury would return a verdict in favor of the plaintiff against the pharmacist.

It may also be noted in the light of the above considerations that the extent of the care which the responsible committee or the pharmacist has exercised in making up the formulary, or their conduct in testing or not testing the drugs purchased under the system, is of no relevancy and probably would not be the subject of admissible evidence. The case would turn not on whether tests were performed but rather on a question of whether the drug product administered to the patient was therapeutically different from the brand of product prescribed.

Two quotes taken from a speech December 10, 1962 by the then AMA General Counsel, C. Joseph Stetler, are also worth considering:

Hospital pharmacists operating under the formulary system are in a precarious position and will be until meaningful standards and tests for dosage form efficacy are developed and utilized in the selection of pharmaceuticals from groups of so-called generically identical products. . . .

On the other hand, where the doctor has given prior consent to drug substitution, under the formulary system, and if he doesn't specify that only a particular brand name drug may be used in filling the prescription, it is very likely that he would also be liable for death or injury attributable to the use of a substitute drug. It goes without saying that the pharmacist and the hospital would also be liable in our assumed case.

The numerous cases in which a pharmacist has been held liable for unintentionally but negligently dispensing the wrong drug are reported in 31 A. L. R. 1336 and 44 A. L. R. 1482.

In the absence of the physician's consent to change, the pharmacist has a duty to fill the prescription with the product prescribed. Whether his breach of that duty is intentional or careless, the pharmacist is liable for the resulting injuries, usually on a negligence theory. In the case of *Hoar v. Rasmusen*,[8] a prescription called for calamine lotion with phenol. The retail pharmacist did not have the official product but instead used a similar preparation which he knew to contain also a slight amount of mercury. In other respects the compound complied with the prescription. The pharmacist did not know that the medicine was to be used by a person allergic to mercury, and there was testimony that such a condition is of very infrequent occurrence. The court in holding for plaintiff and affirming an order for a new trial said:

Although the druggist may have reason to suppose that the medicine which he supplied was just as good as what the doctor prescribed, it must be held that the risk of harm from the act of making the substitution without informing the purchaser outweighs any possible utility that the act may have had . . .[9]

It is possible that liability may be imposed not only where the patient was injured but also where no injury results. In the case of *Hammer v. Gordon*,[10] the plaintiff left three prescriptions with the defendant pharmacist. The plaintiff called for the prescriptions on the following morning. After examining them she decided they were not compounded in accordance with directions and refrained from using them. The plaintiff had the drugs checked by an analytical chemist. When the drugs proved to be other than those prescribed, she brought action against the pharmacist to recover damages for

[8] 229 Wisc. 509, 282 N. W. 652 (1939).

[9] See also, *Dunlap v. Oak Cliff Pharmacy*, 288 S. W. 236 (1926); *Adreottalo v. Gaeta*, 260 Mass. 105, 156 N. E. 731, (1927); *Laturen v. Bolten Drug Co. Limited*, 93 N. Y. S. 1035, 16 N. Y. Ann. Cas. 267 (1905).

[10] 12 N. J. M. R. 475, 172 A. 811 (1934).

willfully and maliciously filling the prescriptions with ingredients differing in kind from those set forth in the prescriptions. The judge, hearing the case without a jury, found for the plaintiff. On appeal the court held that the pharmacist's wrongful act could well be attributed to wrongful motive and therefore justified the award of damages of a penal nature.

The Nurse

Absent the formulary system, the nurse's risk of liability is that arising from any failure upon her part to administer the prescription or order as written and in case of doubt to consult with the physician.

Under the formulary system in which substitutions occur there is the additional risk, however, that a patient may claim to have suffered personal injury as a result of having been administered a pharmaceutical, by the nurse, other than the pharmaceutical named by the prescribing physician upon his prescription or order where there was a therapeutic difference significant to the patient between the pharmaceutical prescribed and the pharmaceutical administered.

What is noted above with respect to the plaintiff's burden of establishing that his injuries are due to the differences between the two pharmaceuticals is of course equally applicable here. If the jury concluded that this initial contention was correct, it would then turn to the question of whether the nurse was negligent.

The plaintiff would here contend that the nurse had been negligent in that she had knowingly administered to the patient a pharmaceutical other than that prescribed when she knew or should have known that differences between pharmaceuticals having the same principal ingredient or ingredients can be of therapeutic significance with respect to particular patients and that she either did not consider that possibility in this case or did consider it and reached an incorrect conclusion.

To this the nurse would no doubt reply that the consideration of such matters was the duty of the physician and the pharmacist, and that under the system effectuated by the hospital she was left no discretion in the matter.

With respect to the nurse particularly, opportunities for confusion and mistake arise when she is mentally changing from the brand prescribed to the nonproprietary or generic name on the ward stock bottle or on the label of the patient's individual container dispensed

on a generically labeled basis by the hospital pharmacist without any reference to the trademark of the pharmaceutical prescribed. This danger is not present when the pharmacist dispenses the brand prescribed.

Here again the plaintiff would no doubt cite and rely upon the principle expressed in Section 290 of the Restatement of Torts, contending that the nurse should have anticipated the possibility of error under these complex circumstances. There is doubt as to whether the court would apply that rule to a nurse and consequently submit the question of her negligence to the jury, and if so, whether a jury would find her negligent. Perhaps there is some risk to the nurse under these circumstances but it is less than that of the physician or pharmacist. A crucial question might be whether the nurse has a duty to contact the physician so that he may authorize administration of the product dispensed by the pharmacist or clear the matter direct with the pharmacist.

Irrespective of formularies, if the nurse negligently fails to follow the proper procedure in handling drugs she should be liable for any injury resulting.[11]

The Hospital, Its Board of Trustees, Administrator and Pharmacy and Therapeutics Committee

In considering the civil liability of hospitals for any purpose, the doctrines of governmental and charitable immunities present substantial problems. It would appear that about one half of the states impose some restriction on the liability of a charitable hospital. The extent of immunity seems to depend upon the status of the injured person. It may differ depending on whether he is an employee, a stranger, a paying patient, or a charity patient. It may differ depending upon the nature of the hospital function in the alleged negligence involved; that is, selection of personnel; instructions to employees; supplying equipment; failure to comply with statutory duty, such as injury resulting from failure to put silver nitrate in a baby's eyes when required by statute; or the commercial nature of the activity (recovery for injury in the hospital gift shop might be allowed, though recovery for injury to a patient on his floor might be denied).

In some states today, a hospital which qualifies as an eleemosynary institution cannot be held liable in damages for the negligence of its

[11] 51 A. L. R. (2d) 971.

servants, employees or agents,[12] but this immunity does not apply to hospitals operated for profit in Pennsylvania,[13] nor even to eleemosynary hospitals in a number of other states.[14] It is here assumed that the hospital does not enjoy such immunity.

In this connection it must be noted also, however, that although the hospital may have immunity, the director or administrator of a hospital may not be immune from liability for his own negligence in the conduct of the business of the hospital.

Whether or not a hospital is vicariously liable for the negligence of one of its doctors, pharmacists or nurses depends upon questions of agency law. For present purposes it is assumed that the prescribing physician is not an employee of the hospital, and in writing the subject prescription or order is not acting on behalf of the hospital. Certainly a hospital is subject to vicarious liability for negligence imputed from the actions of its employees under the doctrine of *respondeat superior* but the employer-employee relationship must exist and the conduct resulting in injury must be within the scope of employment.

Absent the formulary system, a hospital not immune from tort liability would be liable for negligence with respect to the improper administration of medicine generally only to the extent the physician, pharmacist or nurse were to be regarded as its employee. Generally, the hospital is not liable for the negligence of a private staff physician.[15]

Under the formulary system in which substitutions occur, however, the hospital, the members of its board of trustees and its administrator, are subject to the additional risk that a patient may claim to have suffered personal injury as a result of having been administered a brand of pharmaceutical other than that named by the prescribing physician upon his prescription or order where there was a therapeutic difference significant to the patient between the brand of pharmaceutical prescribed and that administered, and that such an injury was brought about by the negligence of the hospital, the members of its board of trustees and its administrator, to the extent

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[12] *Michael v. Hahnemann Medical College and Hospital of Philadelphia*, 12 NEGLIGENCE CASES (2d) 1499, 404 Pa. 424, 172 A. 2d 769 (1961).

[13] *Brown v. Moore*, 7 NEGLIGENCE CASES (2d) 152, 247 F. 2d 711 (CA-3), cert. denied, 355 U. S. 882 (1957).

[14] See *Klema v. St. Elizabeth's Hospital of Youngstown*, 11 NEGLIGENCE CASES 96, 170 Ohio 519, 166 N. E. 2d 765 (1960).

[15] *Mayers v. Litow*, 7 NEGLIGENCE CASES (2d) 686, 316 P. 2d 351 (1957).

that each participated in the institution of the formulary system which made such injury possible.

Here again the plaintiff has the burden of satisfying the jury that his injuries are in fact attributable to the difference between the pharmaceutical products and the foregoing comments with respect to this subject are equally applicable here.

If the jury is satisfied that the injuries are attributable to such differences, it then will turn to the question of whether the hospital or its board of trustees or administrators were negligent in instituting and continuing such a system.

The plaintiff will no doubt here contend that in instituting such a system these persons should have foreseen the possibility of a physician's failure either (1) to consider, in writing his prescription or order, the fact that there are differences between pharmaceuticals having the same principal ingredient or ingredients which are of therapeutic significance to particular patients or, (2) to reach a correct conclusion in a particular case even after such consideration.

Here again the plaintiff probably would cite and the court consider the applicability of the principles expressed in Section 290 of the Restatement of Torts quoted above and, in my opinion, for the reasons expressed above in the case of the pharmacist, the court probably would submit such a case to the jury by reason of those principles, in which event there is substantial risk of a verdict in favor of the plaintiff.

At the January 22, 1963 meeting of the National Drug Trade Conference, Dr. Milford O. Rouse, speaker of the AMA House of Delegates spoke on "Hospital Formularies and Prior Consent." He stated that:

> We must acknowledge, if we are going to be honest with ourselves, that hospitals are primarily for the treatment of patients. The analysis of drugs, if it is to be done properly, is so costly and intricate that most hospitals cannot afford to engage in this activity.
>
> In the final analysis, the hospital is less able than is the physician, to judge the purity or effectiveness of a particular drug. At least the physician, in observing the effect of drugs upon his patients, can often detect the fact that the product of one manufacturer seems to be more effective on his particular patient even though another manufacturer markets the same generic product. Unfortunately, if the hospital pharmacist does the ordering, he may be primarily influenced by the element of cost.

Generally the duties of the Board of Trustees include establishing hospital policy, providing adequate equipment, electing a competent administrator, and maintenance of an adequate standard of medical

care through selection and supervision of the medical staff. The Board of Trustees would seem to be responsible for establishing the particular formulary system to be used, and for selection of members of the therapeutics committee. The negligence of the Board in either respect could render the members personally liable. Negligence on the part of the Board may be difficult to establish. The Board is not in daily contact with hospital operations and should be entitled to rely on information and advice from others. Negligence of the Board having been established, the individual member could escape liability by showing that he opposed and did everything possible to reverse questionable action.[16]

In summary, therefore, it appears that the formulary system does involve risks of liability for damages for injuries to patients. Those potentially liable are the physician, pharmacist, nurse, hospital, hospital administrator and members of the hospital's board of trustees.

[The End]

FDA-FLI EIGHTH ANNUAL CONFERENCE

The Eighth Annual Educational Conference of the Food Law Institute and the Food and Drug Administration will be held on November 30, 1964, in Washington, D. C.

The conference will be called to order by Shelbey T. Grey, Acting and Deputy Director of the FDA Bureau of Education and Voluntary Compliance. Welcoming remarks will be made by Anthony J. Celebrezze, Secretary of the Department of Health, Education and Welfare. George P. Larrick, Commissioner of Food and Drugs, will present the keynote address, and Franklin M. Depew, President of the Food Law Institute, Inc., will offer a response from the Institute. Mr. Grey will then speak on "An Ounce of Prevention." Dr. Richard L. Hall, Director of Research and Development, McCormick and Company, Inc., will discuss "Self-Regulation in the Food Industry," after which Dr. Robert P. Parker, General Manager of the Lederle Laboratories Division, American Cyanamid Company, will discuss "Self-Regulation in the Drug Industry." Speaking on the topic "Science Promotes Voluntary Compliance" will be: Dr. Oral L. Kline, FDA Assistant Commissioner for Science Resources; Dr. Joseph F. Sadusk, Jr., Medical Director of the FDA Bureau of Medicine; Dr. Austin Smith, President of the Pharmaceutical Manufacturers Association; and Dr. Robert M. Schaffner, Vice-President, Libby, McNeil, and Libby. William W. Goodrich, Assistant General Counsel for the Food and Drug Division, Health, Education and Welfare Department, will then speak on "Regulations—An Aid to Voluntary Compliance." The luncheon address, "Educational Problems of Industry," will be presented by Howard Chase, President of Howard Chase Associates, Inc. "What Industry Needs from FDA for Better Compliance" will be the general subject for the afternoon panel workshops. Summations of the conference will be offered by Mr. Depew for the FLI and John L. Harvey, FDA Deputy Commissioner, for the FDA.

[16] III Fletcher Cyclopedia Corporations, Secs. 1134-1137.

The Effect of Food Legislation on the Development, Production and Utilization of Corn-Derived Sweeteners

By ROBERT G. RUARK

This Paper Was Presented at the American Chemical Society Symposium on the Impact of Food Laws on International Trade on September 3, 1964, in Chicago. Mr. Ruark Is Vice President, Corporate Research, Corn Products Company.

IN DISCUSSING THE EFFECT of food legislation on a particular series of materials, such as corn-derived sweeteners, it is difficult to be highly specific because of the wide variation in this legislation throughout the world. The subject involved is more complicated than simple food legislation since it involves the relationship between food legislation and tariff or other economic barriers. Obviously, I am not intimating that any food legislation is a simple matter. So that you may be completely cognizant of the subject matter I will try to cover, I would like to take just a few moments to discuss sweeteners in general and the changes that have taken place in the sweetener market since the turn of the century.

The History of the Sweetener Industry

Sweeteners are products coming from numerous sources. Through the years, sucrose, derived from sugar cane or sugar beets, has dominated the sweetener field, while the sucrose industry has participated in few technological changes, other than mechanization and size increase.

During the entire twentieth century, sweeteners derived principally from corn starch have entered the markets of the world through the avenues of scientific ingenuity.

In the early years of this century, hydrolyzates of various starches were commercialized all over the world. This commercialization took place particularly in America and Europe, but has now spread to practically every country on earth. During this period, crude simple sugars entered American and European markets until the work of Newkirk and others enabled industry to produce the highly pure dextrose of today. Processes for the production of corn syrups were evolved from technological discoveries which created new materials having valuable properties for food product construction—properties which gave the food technologist the ability to control not only sweetness but also consistency, mouth feel, crystallization and food protection. The development of these processes required the application of complicated chemical and biochemical paths. At the turn of the century, the corn syrup manufacturer used only simple acid hydrolysis; today multiple acid and enzyme processes provide "tailormade" syrups for specific applications. Blending of these products, either with varieties among themselves or with sucrose or sucrose syrups, gives further ability for choice based on the desired end product character.

During the years of dextrose process development and corn syrup process and product development, the sucrose industries remained substantially static except for the creation of processes for sucrose inversion. It is interesting that these processes are hydrolyses similar to those used in the production of dextrose or corn syrups and that the end point of these processes involves dextrose in substantial quantity.

Other sweeteners have evolved in the last 50 years. Levulose, from agricultural sources and by chemical transformation of dextrose, has been contemplated, but neither course has resulted in highly significant commercial success. Future developments may bring about highly significant changes in the sweetener market if levulose becomes an economic reality. Separate approaches through the synthetic chemical route have yielded saccharin and the cyclamates, but these fall into a non-nutritive character and will not be discussed further. This completes a very brief history of sweeteners and sweetener progress through this century.

Definitions

I would like next to provide precise definitions of the products involved in this discussion:

(1) Dextrose—the basic carbohydrate entity, the monomer evolved from starch by complete hydrolysis and crystallization.

(2) Corn syrup—a mixture of dextrose and polymers of dextrose evolved from the incomplete hydrolysis of starches under controlled conditions by chemical or biochemical processes.

(3) Sucrose—a disaccharide resulting principally from processing and refining sugar cane stalks or sugar beets.

A Brief Look at the Nutritive Character of These Products

Dextrose is the sugar used metabolically by the human body. Other sugars must be converted in the body by various mechanisms to dextrose before their ultimate digestion and absorption through the alimentary canal and into the blood stream. Corn syrups are polymers of dextrose and, as such, break down in the body to yield dextrose alone. The assimilation of dextrose and its polymers in the body is not a simple process, but the assimilation of other sugars is much more complex. Sucrose is broken down to yield dextrose and fructose; the first being readily absorbed into the blood stream and the latter requiring more complex metabolic mechanisms. All of these products ultimately end up in the blood stream in the form of dextrose. None of these products—dextrose, corn syrups or sucrose—have ever been proved hazardous in terms of normal human consumption. Dextrose has been used for years, in hundreds of millions of cases, for direct intravenous feeding of the sick or convalescent. Fructose has been used similarly and successfully, but negligibly due to availability and cost. Corn syrups constitute the major quantity of table syrups used throughout the world for decades. Corn syrups in liquid form and the maltodextrins in solid form mixed with milk have been and are the primary recommendations of pediatricians for infant feeding. These matters are brought to your attention to provide some index to the safety of these products. I conclude they are safe.

Caloric and Economic Value

In further discussion of the metabolism of these carbohydrates, I would like to speak about their caloric value which is a direct measure of their economic value. The caloric value of dextrose is 3.8 cal./gm. dry basis; the caloric value of sucrose is 3.9 cal./gm. dry basis; and the caloric value of corn syrups ranges from 3.8 to 3.9

cal./gm. dry basis. Thus, these materials are directly exchangeable calorically and economically.

Organoleptically, dextrose is about 70 per cent as sweet as sucrose which in turn is about 60 per cent as sweet as fructose. If sweetness were the only criterion, then levulose would be the world's primary sugar, but other factors, including economics, are pertinent. Factors mentioned previously, such as sweetness control, crystallization control and mouth feel, play a significant role, however.

Nontariff Barriers Affecting Sweeteners

Having looked at the history of the sweetener industry, the safety of nutritive sweeteners and their caloric and economic equivalence, let us look briefly at the nontariff barriers affecting their use and movement. About 100 years ago, the production of beet sugar became a practical reality. The cane sugar producer pronounced this product as an imposterous imitation, although it was chemically identical to his product. Through the years since that time, protective barriers have been erected, both in the United States and abroad, to protect local sugar producers whether they be cane or beet manufacturers. In the United States, both agricultural sources have been and are protected. Internationally, these protective measures have been by means of tariff or quota or both, and only occasionally involved the use of food laws to provide restriction.

During these same years dextrose and corn syrups entered the sweetener picture and legislation involving them was instituted and grew rapidly inside various localities using food law restrictions to effect free movement across geographic barriers. Some of these laws, obviously archaic, date back to 1890 but are still applied today. This is the use of food law to provide economic walls; to provide walls never intended in any original food law concept. For example, corn syrup is restricted by a percentage limitation in canned fruits in the United States, but may be freely used in fruit syrups and in ice cream. In West Germany glucose syrup requires special derogatory labeling for use in canned fruits, is not allowed in fruit syrups, and may be used in ice cream only in limited percentage. In Italy it is not allowed in canned fruits, must be labeled for use in fruit syrups, but may be used freely in ice cream. In contrast, Great Britain and Sweden place no restrictions on its use in these applications nor in many other applications.

An examination of 10 different classes of application in 12 countries, 11 in the European area plus the United States, shows only Great Britain and Sweden allowing unrestricted use, although Denmark follows closely, allowing 8 applications on an unrestricted basis. West Germany bans or restricts 9 uses either by label or percentage, but allows free usage in candy. Italy bans or restricts 8 uses by percentage or label and allows 2 with no restriction. France bans or restricts 8 uses. France, Italy and Germany are large producers of sugar beets with both France and Italy producing significant surpluses. Could these surpluses be a pertinent factor in the creation and enforcement of these pieces of legislation? Could reluctance to permit imports, for example canned fruits, play a role? England allows free usage, while France restricts 8 uses out of 10. One would think that the English stomach and the French stomach would perform identically, but I suppose the Frenchman would deny this to death.

Restrictions in the United States

Let us look at America for a moment. In the United States 7 of these uses are allowed, but in the case of canned fruits, chocolate, and jam and jellies, corn syrup can be used only to the extent of 25 per cent of the total sweetener. In catsup, however, 33⅓ per cent is permitted. Thus, even in America there is confusion and restriction based on reasons other than safety or deceit of the consumer.

The problem becomes more complex when nomenclature is considered. Corn syrup in America is glucose syrup in Europe. Dextrose in America is glucose in many parts of the Eastern Hemisphere. Cane sugar is cane sugar and beet sugar is beet sugar in America. Either may be called sucrose, and either can be called sugar. But dextrose cannot be called sugar. Scientifically, all of these materials are sugars and are equivalent nutritionally. Less confusion would result with nomenclature simplification using a new term such as "nutritive sweeteners."

The Principles of Food Law

Food law systems throughout the world are based on two concepts: first, protection of the consumer from materials detrimental to health or nutrition; second, protection of the consumer from deception. These principles have come through the ages. In the highly developed civilization of the Hittites about 3500 years ago, they were expressed as follows:

(1) Thou shalt not poison thy neighbors' fats.

(2) Thou shalt not cause thy neighbors' fats to be bewitched.

The *Codex Alimentarius Europaeus* affirms this principle as follows:

> The supreme law of legitimate business practice in foods is the welfare of the consumer, protecting him against dangers to health and against things misleading and deceptive. All economic and technical considerations are subordinate to this supreme law.

The principles of 3500 years ago and of today are identical and well stated. The principles of food law in America today are the same as those quoted. It is regrettable that these laws, here and abroad, are not practiced solely for their original purposes.

I believe you will agree corn syrups are safe. I think you will agree corn syrups are nutritive and provide practically equal caloric value to that provided by sucrose. Their acceptability has been determined by the food processor and confirmed by the consumer. Why then should there be any restriction on their use?

Recommendations for the Future

The food products of the future will come only when the food technologist has freedom to invent—freedom of choice. The food scientist will be the first to agree with and adhere to the concepts of any legislation relating to safety or deception. He will be the last to agree with illogical restrictive legislation and particularly with food legislation improperly used to create nationalistic trade barriers based on local economic pressures.

Therefore, let us not use food laws as a mode of protection against nonexistent hazards. Let us not restrict the use or movement of completely pure foods. Let us strive to reduce complexity by the updating of archaic laws or, where possible, let us eliminate them. Let us give freedom of choice to the technologist where the true concepts of public protection are not involved.

Most important, let us recognize that tariff protection is not desirable, but may be necessary for the economic protection of certain populations. Where this is true, let the tariff barriers be stated boldly and truthfully. Where this is true, do not prostitute food legislation to provide deceitful restriction. Let food legislation be food legislation and that alone! **[The End]**

Progress Made in the Standardization of Analytical Methods

By DR. K. DURRENMATT

The Author Presented This Paper at the American Chemical Society Symposium on the Impact of Food Laws on International Trade. The Meeting Was Held in Chicago, Illinois, on September 3, 1964. Dr. Durrenmatt Is Deputy Manager in Charge of Worldwide New Production Development, Nestlé Alimentana Company, Vevey, Switzerland.

STANDARDIZATION OF THE FOOD LAWS on an international level is facing many difficulties, which, in part, are due to differences in the concepts of national laws as well as to various consumer habits. One of the basic problems, frequently not sufficiently taken into consideration, which makes food law standardization so difficult, is the use of widely different analytical techniques. To give one pertinent example: how can one arrive at an international standard for butter fat in milk products if the analysis methods used by official chemists in different countries already give different results?

The purpose of the present paper is to draw attention to the great variety of methods used today in food analysis; secondly to acknowledge the work already done to bring about more uniformity; and thirdly to emphasize the need for even further action.

When we have good analytical methods like the Kjeldahl for nitrogen determination, or a silver titration for chlorides, methods standardization is quite simple and almost comes by itself. Difficulties arise when there are several methods available, none of which are fully satisfactory. It is this latter problem which we would like to discuss by means of some specific examples.

Some countries have reference manuals describing the routine methods used in food analysis. Among the national manuals "The Collection of Official Methods of Analysis" of the Association of Official Agricultural Chemists in the United States of America is one of the most widely used. It is distinguished by the great attention

given to details in the analytical procedures, which have been selected by collaborative studies carried out in different laboratories.

There are also international reference manuals where a similar effort has been made by international panels of well-known chemists. These manuals are limited to the analysis methods of a certain group of food products and are the work of international organizations dealing especially in these subjects.

All this makes for such an abundance of methods that the food chemist is sometimes embarrassed when selecting a particular method of analysis. To give you an idea of the complexity, we refer you to Table I, showing the most important international reference methods, as well as information about national manuals used in five different countries. Perhaps the following comments could be made:

(a) International standard methods already cover an important part of manufactured foods and raw materials. Among the foods important in international trade, without international standard methods, we mention coffee and tea, meat, some canned goods and cereal products. However, the very complete manual entitled "Cereal Laboratory Methods" compiled by the American Association of Cereal Chemists, has international standing and has already been translated into French and German.

Dairy products with their long history in international trade were one of the first to benefit from international standard methods. The earliest attempts made by the International Dairy Federation at method standardization date back to pre-World War II times.

(b) With reference to national manuals, three different situations exist:

(1) Complete manuals edited by one central organization are used in the Netherlands, Switzerland and the United States. They cover most analysis methods used for the majority of foods. In the United States and in Switzerland these manuals have been prepared by the corresponding professional chemists organizations, whereas in the Netherlands the work was carried out by the public health authorities.

(2) Less complete methods collections, dealing only with certain groups of food products, exist in Germany and in England. In general they have been prepared by the respective national chemists organizations concerned with their specialities.

TABLE I

SYNOPTIC TABLE OF OFFICIAL FOOD ANALYSIS METHODS

	INTERNATIONAL	GERMANY	NETHERLANDS	SWITZERLAND	UNITED KINGDOM	U.S.A.
Chocolate &	Int. Chocolate & Cocoa Office	----	Official Dutch Analysis Methods	Swiss Food Manual	----	Official Methods - Assc. of Official Agricultural Analysts
Confectionery & Sugars	Int. Assc. of Confectionery Manufacturers	----	----	Idem	----	Idem
Fats & Oils	Oils & Fats Division of Int. Union of Pure & Applied Chemistry	German Assc. for Fat Science	Idem	Idem	Official Methods of the Society for Analytical Chemistry	Idem
Fruit Juices	Int. Federation of Fruit Juice Manufacturers	----	----	Idem	----	----
Milk & Milk Products	Int. Dairy Federation FAO Code of Principles	Assc. of German Agricultural Analysis Stations	Idem	Idem	Idem (Milk only)	Idem, also Standard Methods of American Public Health Assc.
Soups, Bouillons & Meat Extract	Int. Assc. of Soup & Bouillon Manufacturers	----	Idem	Idem	Idem (For Meat Extract only)	Idem
Vine	International Vine Office	----	Idem	Idem	----	Idem
Vitamins	Food Division - Int. Union of Pure & Applied Chemistry	----	----	----	Idem	Idem
Trace Metals	Food Division - Int. Union of Pure & Applied Chemistry	----	----	Idem	Idem	Idem

(3) In the majority of countries, and this would include France, Italy, etc., there are no official standard methods, and the food chemists use whatever published method they think is best.

It may be interesting to compare in greater detail one particular group of food analysis methods such as those used for soups and bouillons. The manual entitled "Analytical Methods for the Soup and Bouillon Industry" was issued in 1961 by the Technical Commission of the International Association of the Soup and Bouillon Industry. It is the collaborative work of 23 industry representatives from nine European countries. Table II gives you a comparison of these international methods with those used officially in Germany, the Netherlands, Switzerland, the United Kingdom and the United States.

Again we see that the various manuals differ in the extent of coverage, that is, the variety of individual analysis methods which are standardized. Only the international methods provide a standard analysis for fat and glutamic acid. The Dutch methods include bacteriological tests whereas the American methods are very precise with reference to inorganic components and tests for the detection and determination of preservatives and anti-oxydants. This may be partially due to practical reasons since the use of anti-oxydants in foods started in the United States much earlier than in Europe.

Classification of Analytical Methods

With reference to the desirability of standardization, food analytical methods can be classified into two groups:

(a) Referee Methods.

(b) Quality Control Methods.

Referee methods are used by official and trade laboratories to determine if a merchandise complies with legal or commercial standards. For instance, one determines how much sugar is in a bar of chocolate, the fat content of a cheese and so on. Emphasis is on precision and reproducibility as the analytical results may be challenged by the trade partners or even the courts. For this reason freedom for systematic error is also important.

Uniform analysis methods are the basis for food standards, which are necessary to protect the consumers' health and pocket books. Since so much food is traded internationally, the need for international standardization is obvious, and probably best explained in the following example:

TABLE II

COMPARISON OF METHODS FOR ANALYSIS OF SOUPS, BOUILLONS & MEAT EXTRACT

	INTERNATIONAL ASSOCIATION OF SOUP & BOUILLON MANUFACTURERS	NETHERLANDS	SWITZERLAND	UNITED KINGDOM *	U.S.A.
Moisture	Atmospheric Drying	Atmospheric Drying	Atmospheric Drying	Atmospheric Drying	Vacuum Drying
Ash	Incineration	Incineration	Incineration	Incineration	Incineration
Chlorides	Silver titration	Silver titration	Silver titration	Silver titration	Silver titration or Gravimetric
Phosphorous	----	----	----	----	Molytitration or Gravimetric
Fat	Solvent Extraction	----	----	----	----
Total Nitrogen	Kjeldahl	Kjeldahl	Kjeldahl	Kjeldahl	Kjeldahl
Creatinin	Colorimetric	Colorimetric	Colorimetric	Colorimetric	Colorimetric
Glutamic Acid	Enzymatic	----	----	----	----
Colouring Matter	Chromatographic	----	----	----	----
Qualitative Tests	Antioxydants	Preservatives	Yeast Extract, Sugars, Starch, Gelatine	Gelatine	Antioxydants Preservatives
Quantitative Tests	----	----	----	----	Antioxydants & Preservatives
Bacteriological Tests	----	Coli-Aerogenes Sterility	----	----	----
Organoleptical Tests	+	-	+	-	-

* Methods apply for Meat Extract Only.

According to the International Cheese Convention of Stresa, which is adhered to by eight countries responsible for about one-half of the world cheese production, the dry matter of a so-called "full fat cheese" should contain at least 45 per cent of milk fat. If it contains less fat, the product must be designated as a "partially skimmed cheese," and sold at a lower price.

Table III gives a comparison of the methods used internationally and by various countries for the determination of fat and moisture in cheese, necessary to find out if a cheese sample complies with the full fat standard. Again we see that no fully applicable international standard has been reached. The differences in methods may seem trivial but they lead to different results. The same cheese sample would have to be considered as "full fat cheese" or "partially skimmed cheese," depending only on what analysis method was used. That such an ambiguity may lead to unfair practices, especially in international trade, is only too obvious.

There are, of course, cases where international or even national methods standardization is not necessary. This concerns the second group of food analysis methods mentioned above—the so-called "Quality Control Methods." They are widely used in food manufacture for the purpose their name implies.

Sometimes utmost precision is not necessary, since variations in the natural compositions of foods exceed by far the analytical errors. Frequently speed or simplicity determine the choice of methods. Different industry groups or even different manufacturers use methods best suited to their requirements, and we see little need for further methods standardization.

Conclusion

To summarize, uniform food standards require uniform methods of analysis. This logic has been accepted by a number of countries with reference to their national trade, and is now applied on an international basis to certain groups of food products. There is no valid objection to extending this practice to more countries and to a wider range of foods.

We therefore propose to apply the existing international methods everywhere by adjusting the various national methods. This would not require great material effort but perhaps a positive and at some times disinterested approach to the problem.

TABLE III

COMPARISON OF METHODS OF ANALYSIS OF CHEESE

	INTERNATIONAL DAIRY FEDERATION GERMANY FAO CODE OF PRINCIPLES, NETHERLANDS SWITZERLAND, UNITED KINGDOM	U. S. A. OFFICIAL METHODS A. O. A. C.
Fat	Gravimetric Acid Digestion Solvent Extraction	Gravimetric Ammonia Solubilisation Acid Digestion Solvent Extraction
Moisture	Atmospheric Drying with addition of Sand	Vacuum Drying
TYPICAL RESULT	PER CENT	PER CENT
Fat	31.51 31.50	30.45 30.39
Moisture	33.97 33.93	30.64 31.53
Fat in total Solids	47.76 47.71	43.01 43.81

Certainly the food division of the International Union of Pure and Applied Chemistry should now take the initiative and proceed along two lines:

(a) Via its nationally affiliated members, such as the American Chemical Society, it should work for universal application of existing international standard methods in all member countries.

(b) Via its Food Division, it should extend analytical methods standardization to those groups of food products not yet covered by existing international standards.

Among the various international organizations most likely to carry out such a task, the International Union of Pure and Applied Chemistry is clearly best qualified. Moreover, it has the full support of industry and trade. The task proposed is in the field of chemistry and concerns standardization of analytical methods. This is within the terms of reference of the Union. Naturally, the food division should work in close contact with other international organizations who have already studied related aspects, so as to benefit fully from existing work. **[The End]**

TIME-LIMIT EXTENDED FOR COMMENTS ON PROPOSED FRUIT DRINK REGULATIONS

The Food and Drug Administration has extended to December 1, 1964, the time in which interested persons may file comments on a series of proposed regulations establishing federal definitions and standards of identity for a number of fruit juice and fruit-flavored beverages.

Several FDA and industry proposals to standardize these popular drinks have recently been published in the *Federal Register*. On August 13, FDA published an industry proposal to standardize citrus juice beverages and at the same time published proposals of its own to establish standards for diluted fruit juice beverages and fruit-flavored noncarbonated beverages. Subsequently, at the request of industry groups, additional proposals were published in the October 1 *Federal Register*. These included republication of earlier proposals by various manufacturers to establish standards for pineapple-grapefruit juice drink and a National Canners Association proposal to standardize "Canned Fruit Nectars." The latter proposal, dealing with "spoonable" type fruit purees, had been submitted several years ago but was not published due to a misunderstanding.

The various diluted fruit-juice and fruit-flavored products now on the market differ widely in the amount of added water and in the names by which they are designated. The proposed standards would fix specific limits for added water and a standard name for each drink. They would also prescribe uniform and informative labeling.

Government Programs Which Counteract the Trade Restrictive Effects of Foreign Food Laws

By RAYMOND A. IOANES

The Author, Administrator for the Foreign Agricultural Service, United States Department of Agriculture, Presented These Remarks at the 148th Meeting of the American Chemical Society, in Chicago, on September 3, 1964.

"TRADE BARRIER" IS A TERM we usually associate with import levies, seasonal quotas, gate prices, and the like. We often overlook or don't know that food health laws and regulations also restrict agricultural trade. The current trend in the industrialized countries, which are the main cash buyers of United States farm products, is toward even more stringent food health controls.

Citrus Red No. 2

Let me tell you about the case of Citrus Red No. 2. This isn't a mystery story. It's just an illustration of the way foreign food laws and official attitudes can hamper United States agricultural exports.

Citrus Red No. 2 is a chemical used on Florida oranges to give them a bright color. The skin of some Florida oranges has a natural greenish cast, even when fully ripe, so the citrus industry uses the artificial coloring to make the fruit more attractive to consumers. Orange growers, you see, have discovered what our womenfolk have always known—that a little color here and there can help.

The Florida citrus industry practices no deception in seeking to improve the saleability of its oranges. The United States Food and Drug Administration requires that the words "color added" be stamped on each artificially colored orange. Nor is the industry using a harmful chemical. The FDA has determined through careful research that Citrus Red No. 2, as used in Florida, is safe. Furthermore, the FDA—as required by law—must first test and certify as safe each batch of the color.

Few American consumers give "color added" oranges a second thought. Actually, if they looked into the matter closely they would be pleasantly surprised. They would find that the Florida Citrus Commission, which regulates marketing of the state's oranges, demands higher quality standards for color-added than for noncolored fruit.

But what is the attitude of foreign countries to our "color-added" fruit? Although Canada and New Zealand import the artificially colored oranges, other industrialized countries—including those of Western Europe—forbid their importation. The ban is imposed despite the careful, documented research of our Food and Drug Administration. The ban is imposed even though no foreign country has developed evidence to indicate that the coloring, as used by the Florida citrus industry, is unsafe. The ban against our fruit in foreign markets has exactly the same effect that a complete economic embargo would have.

Diphenyl and Lemons

While I'm on the subject of citrus fruit, let me tell you about diphenyl and our exports of lemons.

Diphenyl is a chemical which inhibits the growth of certain fungi on citrus fruit. Our Food and Drug Administration has set the United States tolerance level of this fungistat at 110 parts per million. The United Kingdom has established the "safe" mark at 100 parts per million. West Germany and France feel that 70 parts per million is the proper tolerance. So far, so good.

West Germany, however, hasn't stopped with a low tolerance level. The new German food law, passed in 1958, prescribes that when citrus fruit is treated with the chemical, a sign must be displayed, which reads, "With diphenyl, peel unsuitable for consumption." I say, respectfully, that this wording is inaccurate and misleading. Citrus peel treated with diphenyl is perfectly safe for human ingestion when treated at the levels authorized by either West Germany or the United States. West German food chemists concur in this judgment. But the mandatory label with the damning word "unsuitable" remains. It has scared off consumers, of course. It has been a major factor in the decline of West Germany's imports of United States lemons from 1.7 million cartons in 1958 to less than 100,000 cartons in recent years.

Other United States farm products are affected by foreign health laws. Prominent on the list are fresh deciduous fruit, dried fruit, wheat flour and poultry. Still more United States commodities are

likely to be affected as foreign countries set tolerances on pesticide residues. Tolerances proposed by West Germany for residues are drastically lower than those permitted by the United States. There is some evidence that the European Economic Community as a whole, as well as the seven countries making up the European Trade Association, eventually will follow the West German lead.

All this brings me to the question: What can be done to ease the trade-hampering effects of foreign food health laws and regulations?

FIRST OBJECTIVE OF THE UNITED STATES

The first thing the United States must do is arrive at a common meeting of the minds with "customer" countries as to which laws and regulations serve a proper function and which are being misused.

Nobody can argue about general principles. All countries must safeguard the well-being of their people with effective food health laws and regulations. But in seeking what is "effective," governments display wide differences in their judgments of what is "safe," or "necessary," or "desirable." These differences in viewpoint, reflected in official actions of foreign countries, are what we need to understand —and, if we can, to reconcile.

Basic Differences in American and European Thought

Let's recognize at the outset that there are some fundamental philosophical differences between the United States and Europe with respect to the use of chemicals in food production or processing.

The United States holds to the doctrine that a chemical need not be classified as poisonous or deleterious per se. Sodium chloride—common table salt and one of the oldest food additives known to man—is a good example of what I mean. Salt is a chemical and taken in excess can be unsafe. But the mere fact that salt is a chemical should not prevent its use in safe amounts if such use can be shown to be beneficial in food processing.

The United States doesn't take the safety of agricultural chemicals for granted. Far from it. No new food additive may be used in or on food until the petitioner submits to the FDA full and convincing evidence of its safety when tested on animals. If the evidence clearly demonstrates that the material is a safe component of food under the proposed conditions of use, and if it will not promote consumer deception, the FDA issues regulations specifying how it may

be used. No pesticide residue may remain on a raw agricultural commodity if it exceeds the tolerance established by the FDA. The agency sets safe limits on the amounts of colors which may be used. All these regulations are backed up by careful labeling of chemical agents and formulations containing them, by instructions in their proper use, by regular inspections, by sampling and by analytical control. Violators are subject to legal action, including criminal prosecution.

In keeping with its regulatory attitude, the United States permits a number of different chemicals to be used in performing single general functions—such as for insecticides or antioxidants. This latitude, among other things, makes it possible for a user to select a chemical which may perform better than another when used with a particular crop or food.

Most European countries are slow to approve new chemicals. They feel that the list should be kept small—that additions to restricted lists should be granted only when they are "necessary" as well as "safe." "Necessity" is given as much weight in some countries as "safety." But "necessity" is not always defined: it could mean "essential to production"; or "important in the production of an essential of the national diet"; or, possibly, a combination of all these.

Some countries have been reluctant to expand their list of permitted food additives even in the face of a showing of necessity and safety. They want what is "naturrein"—naturally pure, that is. They want their food to come to them as unsullied as possible—a wholesome product of bright sun, sparkling rain, and organically fertilized soil. This may be a desirable objective. It might even be attained if each family produced and processed its own food. But in this modern world, where division of labor is essential, where food must pass through many hands and travel long distances on its way from producers to consumers, compromises with "naturrein" have been necessary. Most countries have accepted the inevitability of compromises. The United States feels that safe food additives are justified when they maintain the nutritional quality of a food, enhance its keeping quality, make it more acceptable, aid in its processing, or improve its nutritional value.

Recent Developments in the Food Health Area

United States preoccupation with foreign food laws is nothing new. For many years our agricultural exporters encountered prob-

lems in this area. These were handled largely on a case-by-case basis by United States agricultural attachés. Our attachés still function in this field with respect to specific cases, and will continue to do so. But the over-all scope of the food health problem, and its intensification in recent years, has called for additional measures.

Establishment of the European Economic Community in 1958 probably was the principal event bringing food health matters to a focus. The Treaty of Rome, which established the EEC, provides for a common agricultural policy—a merging of the farm economies of the six member countries. Part of this merging process is the harmonization of existing national food health regulations. Harmonization almost certainly will mean, in turn, continued tightening of the regulations, at least in the case of some EEC countries.

Let's face it—Rachel Carson's book, "Silent Spring," also has been a factor. The book had a great impact in the United States, as you know, especially on nonfarm people. Usually overlooked, however, is the fact that "Silent Spring," translated into several foreign languages, has had great popularity abroad. It undoubtedly has helped to create a climate favorable to rigid foreign food health laws and regulations.

The Department of Agriculture has kept abreast of the shift toward more stringent controls.

Between 1959 and 1963, Dr. H. L. Haller of the Department's Agricultural Research Service made a number of trips to Western Europe to check up on food health legislation, monitoring and enforcement activities, and the current thinking of foreign food scientists. Dr. Haller's excellent reports laid the foundation for much of the activity that has followed—activity in which he himself played a prominent role. He retired last month. He well deserves the leisure that retirement brings, and we wish him well, but we will sorely miss the knowledge and judgment he brought to his job.

Information Exchange—A Step Toward Understanding

More and more technical information is being exchanged between United States and foreign specialists. This exchange is bringing about the greater understanding that is our greatest need right now. Much of this work is financed, under authority of Public Law 480, with foreign currencies derived from overseas sales of United States farm products. This is an extremely constructive use of these funds.

Public Law 480 financed the trip of an American food science mission to Western Europe late in 1963. Chairman of this eminent group was William J. Darby, Vanderbilt University. Other members of the mission were Bernard L. Oser, Food and Drug Research Laboratories; Harold E. Moses, Purdue University; Walter M. Sadler, University of California; Paul E. Johnson, National Research Council; and Roy E. Willie, United States Department of Agriculture.

The mission has reported on what it saw in each country and in the European Economic Community—general provisions of food laws and regulations related to public health, the rational and scientific bases for them as viewed by foreign scientists and officials, and the nature and effectiveness of enforcement. The mission's major recommendations are aimed at promoting the improved understanding among nations that is so vital to solution of the food health-trade barrier problem.

Typical of teams that come to the United States was the group of seven West German scientists who concluded last May a four-week look at the United States food health control system. In addition to talks with Washington agencies, the team spent time in Florida, California and Kansas, where they saw chemicals being applied to crops before and after harvest, and food regulation enforcement. The visitors were especially impressed by the high United States standards of inspection and testing. It is particularly important that foreign visitors see this phase of our program. It will help to make clear to them that the setting of tolerances, or any standards for food or feed control, must be backed up by satisfactory inspection and sampling programs, and adequate laboratories for chemical control. For example, the country that sets low tolerances for pesticide residues must match its regulations with laboratories capable of making highly sophisticated chemical analyses.

U. S. Representation in Western Europe

As part of the drive for improved understanding, the Department of Agriculture has stationed a food scientist in Western Europe on a full-time basis to represent the United States in the food law field. Our official, Clinton L. Brooke, who was with Merck & Company for many years, is doing a fine job for American agriculture.

With headquarters at the "capital" of the European Economic Community, at Brussels, Mr. Brooke is raising the level of under-

standing between Western Europeans and Americans by keeping up a two-way flow of information on current food health legislative matters. He is providing technical assistance to United States agricultural attachés and cooperating trade groups abroad. He is analyzing European food laws and regulatory programs. He is maintaining contact with the foreign officials and scientists who are formulating food health regulations. He is keeping in touch with international food and health organizations.

The Department's Foreign Agricultural Service has assigned a Washington staff member, Gerald W. Shelden, to the job of food law liaison. We have long needed this focal point within the Department. Mr. Shelden works closely with FAS divisions, the Department's Agricultural Research Service, the FDA, and other agencies, groups, and individuals. He assists foreign teams visiting this country and helps to maintain a two-way flow of information between Washington, Mr. Brooke's office, and the agricultural attachés.

The United States is taking a leading role in work of the Food and Agriculture Organization and the World Health Organization to simplify and harmonize international food standards in a consolidated food code, or, more technically, a *Codex Alimentarius*. John L. Harvey, Deputy Commissioner of the FDA, has served as chairman for the first two meetings of the *Codex Alimentarius Commission*. Nathan Koenig of the United States Department of Agriculture, is chairman of the United States-FAO Interagency Subcommittee. Both have played major roles in shaping the course that this international food standards work should take.

Preparatory work on draft standards is already under way. Among the projects being carried forward is the development of draft lists of acceptable food additives, and the survey and designation, wherever possible, of proposed maximum levels of use for these additives in individual foods. Also, a world-wide Expert Committee on Pesticide Residues has the responsibility of surveying and proposing, where possible, tolerances for pesticides in individual foods.

The *Codex Alimentarius Commission* represents a new and vital influence in the realm of international food standards. This is work meriting the full support of all for the opportunity that it offers in developing equitable food standards and a means of combating the use of standards that impede or restrict international trade.

SECOND OBJECTIVE OF THE UNITED STATES

The second major objective of the United States in the food health-trade barrier area must be continued vigilance, backed up with research.

We have struck a reasonable balance in this country. We know that chemicals are essential to food production and processing. We know that with proper controls and safeguards they are not dangerous.

At the same time, we know that none of these matters must ever be considered as closed. We must be on our guard at all times and resolve all doubts on the side of safety.

Government Sponsored Research

Research is essential, of course. And prospects of expanded research are good. A Senate and House conference committee recently approved an increase of almost $26 million in the Department of Agriculture's 1965 appropriation, the new funds to be used in carrying on a stepped up program of pest control research and education.

Part of the research will be aimed at new and improved ways of insect control through sterility methods. Illustrative of what can be done in this area is the eradication in the Southeast of the screwworm, a fly pest of livestock. This, as we know, was done by raising millions of male screwworms, sterilizing them with radioactive cobalt, and releasing them to mate with native female flies.

New biological controls will be sought. The studies will involve the use of parasites and predators against insects and weeds; diseases against insects and nematodes; and vaccines against animal parasites. Efforts will be made to breed plants with built-in resistance to diseases and insects. Also to be investigated are such relatively unexplored fields of insect control as light, sound, and electromagnetic energy.

Basic research will delve deep into the biology, physiology, pathology, and nutrition of insects, plants and animals. It is hoped that out of these studies will come clues for developing new and improved pest control methods.

Research will be directed at more specific, less persistent conventional pesticides, improved methods of application, better ways of detecting and determining pesticide residues, and effects of trace levels.

It is important that our foreign friends know about this expanded program. It is a program which clearly indicates that the United

States is sparing no expense or effort to keep our foods—what we consume in this country and what we export—wholesome and safe.

Efforts to Expand American Exports

The United States is taking many steps to expand agricultural exports. We are working, through negotiations under auspices of the General Agreement on Tariffs and Trade, to lower economic trade barriers. We carry on, in cooperation with agricultural and trade groups, extensive market development activities. We operate a Food for Peace program, which is helping us—as we help less developed countries—to build permanent commercial markets for our farm products.

All this effort is paying dividends. Agricultural exports are on the uptrend and have been for several years. In the fiscal year 1963-64 we set an all-time high record when we shipped overseas $6.1 billion worth of farm products.

The food health area is one that definitely needs more work and attention for the benefit of ourselves and other countries. Greater understanding among nations with respect to food laws can do in this area what trade negotiations can do in the economic field. We know what our problems are. We have made a start toward solving them. With good will, energy, and persistence, we will solve them.

[The End]

BILL AUTHORIZING FOOD ADDITIVE EXTENSIONS BECOMES LAW

The bill (H. R. 12033) authorizing additional food additive and pesticide extensions has been signed by the President, becoming P. L. 88-625. The Secretary of Health, Education and Welfare may permit, until December 31, 1965, the continued use of uncleared food additives and pesticides which were in commercial use before January 1, 1958. Extensions may be granted only to those substances for which previous extensions were granted to June 30, 1964, and then only if the Secretary makes the following findings:

(1) A good faith action leading to a determination of the safety of the substance was begun before March 6, 1960;

(2) The good faith action was pursued with reasonable diligence after March 6, 1960;

(3) An extension is necessary to complete those investigations; and

(4) Conditions exist which necessitate the prescribing of an extension.

The texts of the amended sections of the Food Additives Amendment and the Nematocide, Plant Regulator, Defoliant and Desiccant Amendment of 1959 are located at ¶ 512 and ¶ 842.12 of Food Drug Cosmetic Law Reports.

Chemical Additive Problems in Food Processing

By B. F. DAUBERT

The Following Article Was Presented at the Chemists' Club Symposium on April 28, 1964. Dr. Daubert Is Director of Nutrition at General Foods Corporation, White Plains, New York.

UNDER THE MOMENTUM of an expanding technology, thousands of new chemicals have found their way into the air man breathes, the foods he eats, the beverages he drinks and the drugs he uses to ease his discomforts. In the last 20 years, the output of pesticides has risen from 8 to 600 million pounds; currently, some 2,200 chemicals are being added to our foods. The purpose is to preserve and protect—to add to use and availability. This they do, but they have also added a new dimension to the problem of public health, and the importance of this dimension we have only begun to apprehend within the last few decades.

Recognition by the federal government that we could no longer expect to employ, *ad libitum,* such a vast array of chemicals without legal standards formally requiring assessment and assurance of safety, is of such recent date, in fact, that the more important legislation aimed to more adequately protect the health of the consumer has all been enacted within the past seven years. I refer to the Pesticide Amendment of 1957 to the Food and Drug Act; the Food Additive Amendment of 1958, and the Color Additive Amendment of 1959.

"Permission Control" Emphasized Now

Under these new laws, the controls exercised by the federal government represent a change in emphasis from the Food and Drug Act as it existed before 1958. The emphasis now is on a licensing system, rather than policing. "Permission control," as it is termed, is entirely supported by the Food and Drug Administration. In the words of Mr. Celebrezze (Secretary of the Health, Education and Welfare Department), it involves "a shift in recent years in accordance with

changes in substantive law toward the increased establishment of specific rules in advance which guide industry toward law compliance."

These rules or regulations make it possible for the responsible individual to determine with greater assurance just what he must do to meet federal requirements, but also creates the need for a broad program of education which encourages voluntary compliance on the part of the food manufacturer.

In recognition of this need, about four months ago Secretary Celebrezze approved a reorganization of the FDA which formally established a Bureau of Education and Voluntary Compliance. The hope is that the bureau will provide better educational and informational services both to industry and to the consumer

The Food Law Institute, an organization supported by the food industry, has, on its part, instituted courses of instruction on the requirements of the Food Additive Amendment for technical, production, management, sales, and marketing personnel.

FDA Commissioner Larrick, commenting on voluntary compliance and preventive enforcement last March, told the National Association of Frozen Food Packers that to achieve maximum prevention of violation, improved controls by industry are required in all aspects of production and marketing. "Controls," he said, "could prevent regulatory actions based on illegal food additives or pesticide residues or the presence of micro-organisms."

He added that "when a regulation limits an additive in finished food to several parts per million, only good controls employed in batch after batch provide the necessary assurance that the additive present is within legal limits."

On the other hand, Commissioner Larrick warned that "the shipment of products into interstate commerce which may contain illegal additives or additives at levels above the regulated tolerance would be subject to seizure."

In this connection, fears have been expressed by some in industry that the new laws and their regulations would stifle research, dry up development of new food additives and drive small firms out of business. However, the new requirements are basically the same as those recognized and accepted for many years by responsible investigators. Most firms recognize the importance of the regulations, the need for adequate control procedures and the importance of in-house sanitation. The smaller manufacturer may lack, however, the technical

knowledge and resources to determine his specific needs in this area. It is essential, therefore, to provide reliable sources of pertinent information to which he could turn in case of need.

Understandably, industry is reluctant to reveal its difficulties to enforcement agencies. The small manufacturer often depends on advice from technical representatives of other firms which sell additives, sanitizing agents, equipment and the like. Although the contributions of the latter groups to food protection are invaluable, experience has shown that they cannot necessarily cope with the total problem. The over-all situation, then, presents a challenging opportunity for collaboration between industry and the government.

Factory Inspection

A bill—the Harris Bill—is now pending in the House of Representatives which proposes to extend the factory inspection provisions of the Food and Drug Act to cover all records, files, papers, processes, controls and facilities bearing on any violation of the Act. This would include the premises of the chemical processors of food additives, as well as of the packaging and packaging additive manufacturers.

While an inspection system has been in operation since 1938, its present purpose is mainly to supervise the sanitation and labeling of foods manufactured under Standards of Identity. The situation, according to Mr. Larrick, has changed "because of the increased responsibility in supervising the use of food additives."

The responsibility for determining, from a vast array of potentially toxic additive materials, which may be employed in food in strict compliance, is both the job of the food industry and the government. According to Mr. Larrick, the present law casts doubt on the authority of the FDA to make a complete inspection which would include examination of factory, formulas, control and dispensing additives, complaint files, and records showing that personnel are qualified to perform their assigned duties.

"It is not possible," says Mr. Larrick, "to make a sound determination as to the legality of a firm's operation simply by examining the building, its equipment, the raw materials, containers, labels and those manufacturing operations that happen to be in progress during the inspection. The inspector needs to examine the manufacturing formulas to determine that proper ingredients are being used in the proper amounts within the limits set for it."

To prevent errors, he claims, it is necessary for the food manufacturer who uses toxic chemicals as food additives to learn to employ control procedures similar to those that have been recognized as essential in the drug field. He also claims that control records are significant even if additives are not being used—for example, to determine conformance with codes and standards.

According to Commissioner Larrick, the need for examining the qualification of plant employees is self-evident. The individual responsible for determining the quantity of toxicants that go into foods must be trained to perform his operation properly.

The FDA clearly has a duty to find a way of making the present law work efficiently for the consumer and the manufacturer, or if not, to seek a better law. While much controversy has raged and opposition voiced to this proposed legislation, we may anticipate a further tightening of regulations.

Microbiological Standards for Foods

Water and milk have become virtually insignificant as sources of human illness. Advances in food technology, research and development, and the application of control techniques under the regulation of state and municipal agencies have eliminated the substantial disease hazards that these products formerly presented. Food-borne diseases, on the other hand, according to Dr. Glen G. Slocum of the Bureau of Biological and Physiological Sciences of the FDA, appear to have increased somewhat during the past two decades. Each year, some 200 to 300 outbreaks consisting of about 10,000 to 20,000 individual cases of food-borne diseases are officially reported to the United States Public Health Service. This greatly exceeds the outbreak due to milk and water. Furthermore, there is sound evidence that investigation and reporting of food-borne microbiological diseases are grossly incomplete. A moderate estimate is that 300,000 to 1 million cases occur per year. Thus the problem is formidable and represents a major challenge to industry and regulatory officials, since food poisoning must be regarded as preventable.

Food-borne salmonellosis and typhoid rose by sevenfold within the period 1948-1956—from less than 1,000 to over 6,700 cases per year. Staphylococcus, intoxication, Clostridium perfringens and botulism outbreaks are rising similarly. Two outstanding recent incidents involving smoked whitefish poisonings have virtually closed down the Lake Michigan fishing industry and a tuna fish cannery in California.

Prevention of food poisoning requires vigilant control and plant sanitation procedures, adequate reporting and development of sanitary codes.

Public Health Service's Statement on Microbiological Contamination of Food

A 1962 report of the United States Public Health Service, Committee on Environmental Health Problems, issued a statement regarding microbiological contamination of foods which it is pertinent to quote:

"The notable success of the past 50 years in controlling botulism, typhoid fever and other severe food-borne diseases has tended to create an impression that technical knowledge in this area is adequate to prevent all infections and toxications of microbial origin. However, the facts are that gastroenteric episodes continue to occur at a rate second only to respiratory infections, among short term illnesses suffered by middle class American families. Current food sanitation practices have failed to reduce the high incidence of food-borne diseases during the past 10 years.

"Concurrent outbreaks of disease in poultry, cattle, and trout in different parts of the world have focused major attention on the significance of diet contamination in the induction of cancer. Intensive research has pointed to the presence in mildewed foods of hitherto unsuspected fungal metabolites, derivatives of beta-lactone which act as powerful carcinogenic agents capable, possibly of inducing cancer in humans."

Due consideration is being given by several food manufacturers to the hazards which may be associated with mold contaminated foods and I know of at least two intensive studies now in progress on the conditions which may give rise to this state.

Determination of GRAS Status

One of the basic problems in determining conformance with Food Additive regulations is that of establishing whether an additive is generally recognized as safe. Under the law, as you probably know, the term "food additive" applies if a substance is "not generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or experience based on common food use prior to 1958) to be safe under the conditions of intended use."

The decision as to whether a substance is a food additive in the legal sense hinges solely on its safety under conditions of intended use. The decision rests not upon unilateral opinion of the FDA administration, but upon whether the substance is generally recognized as safe among qualified experts, the criterion being scientific procedures or experience in common use—the latter reserved for substances used prior to 1958.

The GRAS method of appraising safety presents difficulties unless the product can be shown to have been commonly used prior to 1958, or is the subject of a report in the scientific or technical literature. In the latter case, unless the opinion as to safety reflected in the publication are seriously questioned or refuted, they represent the prevailing view among qualified experts.

To determine whether a substance is generally recognized as safe, one may poll the experts or ask the FDA.

What is an expert? The term implies more than a person with basic skills and experience. It implies one who has considerable knowledge and familiarity with the facts involved, including the chemistry, toxicology, pharmacology, legal and food technological aspects of the problem.

One important area in which food additive assessment has taken the GRAS route is that involving flavor additives for foods and drugs. The Flavor Extract Manufacturers Association (an association supported by most of the major flavor houses) has assembled data on the use, use levels and toxicology of more than 1,200 flavor substances. They have assembled a group of qualified experts to review the findings and as a result, the majority of these substances have been declared safe. The data has been submitted to the FDA. A relatively small group of products were found to be of questionable safety and where continued interest prevailed, these were submitted for toxicological testing. On some, the petition route will be followed to seek approval for their use.

Zero Tolerance

Another area in which problems arise involves the application of zero tolerances to residues such as certain pesticides in milk and animal feed medicants. The concept of a zero tolerance to certain additives (especially those found or suspected of inducing cancer in animals) raises questions of the sensitivity of the analytical procedures and what will happen when future methods will be devised of greater sensitivity than those currently employed.

One may argue that except in mathematics, the scientist does not necessarily use "zero" in the absolute sense, but may frequently use it to indicate that nothing was detected within the sensitivity of the method employed. Whether this argument would hold up under legal scrutiny has yet to be adjudicated. Thus, what would happen when future methods will be devised of greater sensitivity than those in current use? The principle should be recognized that at some finite minimal dose any substance can be administered with reasonable certainty that no harm will result. The development of highly sensitive analytical methods that can detect parts per million of residue points out the need for the FDA to clarify what is meant by a no-residue zero tolerance.

General Food's Environmental Health Program

General Foods has operated under a basic policy supporting pre-assessment of food additive suitability since its earliest days. We at General Foods recognize the responsibility for determining which of the vast array of food additives and materials proposed for additive use can be employed in strict compliance with governmental regulations. Indeed, our management enforces this concept through a formal system of food additive clearances instituted as far back as 1951. Compliance with federal and state laws and regulations, we believe, is assured by the promulgation about a year ago of a corporate "Environmental Health" group which functions to coordinate activities dealing with all aspects of food law safety enforcement by providing counsel to each of its eight division members. In addition, the group functions to provide our International Division with current information on the status of food additive regulations in foreign countries of concern to the corporation. For this purpose, it maintains a current file on food laws and regulations for each of these countries.

Essentially, the Environmental Health group is General Foods' corporate consumer protection agency.

Services Rendered Through This Program

Specifically it renders the following service to General Foods Divisions:

(1) It provides legal counsel on food additive, color additive and pesticide regulations.

(2) It provides guides to manufacturing controls, analytical controls, record maintenance, food additive handling and dispensing procedures.

(3) It reviews new product formulations, proposed formulation changes and new processing procedures which employ additives or give rise to new food additives and provides clearance for these on the basis of existing regulations.

(4) It delineates the requirements and technical information needed to fulfill food additive petition requirements and coordinates analytical research and development, toxicological and biochemical studies, as well as other data needed for filing a petition and establishing a regulation. In this regard, it cooperates with research groups at the initial stages of food additive and process development.

(5) It acts on General Foods liaison with the FDA and related government enforcement agencies on matters dealing with regulatory and petition requirements.

(6) It provides counsel on the labeling of its products, as well as labeling of household products under the Hazardous Substance Labeling Act.

(7) It provides information on food standards.

(8) It conducts factory inspections and provides information on industrial hygiene, sanitation, air and water pollution problems.

To facilitate the operations of the Environmental Health group, each division of the corporation employs a trained environmental health representative whose duties are to define food additive and related problems, through inspection surveys and appraisal. In consultation with the corporate group, it recommends procedures to be undertaken to resolve problems in conformance with food laws and regulations.

Of particular importance are the consultation services required in dealing with potential food additives in new products, process and food additive development, provision of systems for records, controls and checklists in the dispensing and use of food additives, circularization of edited information on timely and authoritative facts and trends in food additives based on *Federal Register* and other publications, as well as information obtained from direct contact with the FDA. Periodic timely symposia on new trends and developments in important areas related to food additives are conducted, for example, on pesticides, mycotoxins (aflatoxin), color additives, etc.

To render these judgments requires the services of a team of specialists, a number of whom devote their entire time to this work. Among the disciplines represented are experts in the field of food law, analytical chemistry, toxicology, nutrition, industrial hygiene, microbiology, pesticides, sanitation engineering and, of course, food technology, whom it calls upon as consultants when required.

The tools we are employing to improve internal handling of food additive and related data retrieval has not reached the stage where automatic data processing techniques are required. However, our food additive data has been codified alphabetically, historically, and by type. We can foresee, however, a need in the future for such a system.

The food industry is making noteworthy contributions to public health, particularly in those areas in which federal food additive regulations have set a pattern. In addition, the food industry frequently supports projects in universities or its own laboratories on problems related to health, sanitary requirements, food-borne diseases, nutrition, microanalytical methods, processes engineering, chemical composition of foods, microbiological assessments, toxicology and carcinogenesis studies, and consumer acceptance studies of new products.

However great the new burden of responsibilities imposed by the food additive amendment are, we cannot relax our vigilance, nor compromise in our efforts to fulfill our obligations to the health of the consumer. **[The End]**

ADVISORY COMMITTEE ON INVESTIGATIONAL DRUGS REAPPOINTED

Reappointment of the Advisory Committee on Investigational Drugs was announced by Commissioner George P. Larrick, Food and Drug Administration, Department of Health, Education and Welfare. The Committee will report to the Medical Director of FDA, Dr. Joseph F. Sadusk, Jr.

In announcing the reappointment, Commissioner Larrick said, "This committee was established . . . to advise FDA on the implementation of the important requirements of the Kefauver-Harris Drug Amendments of 1962 covering investigational drugs. It has made a major contribution to the understanding and solution of problems faced by clinical researchers in meeting the requirements of the investigational drug regulations."

Dr. Sadusk said, "We are pleased that this outstanding group of medical scientists will continue to advise FDA's Bureau of Medicine and the Commissioner in the vital area of investigational drugs. This committee is one of a growing number of advisory groups that are contributing knowledge and experience in helping FDA deal with the complex problems surrounding the development and marketing of drugs."

The "Deep Pocket" Rule Revisited

By MAVEN J. MYERS

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AN ARTICLE in this JOURNAL describes the "Deep Pocket" Rule in the following terms:

> It is a rule of law that is jurisprudentially "radical," as it goes to the "roots" of our law; it is morally dubious, as it would rob Peter to pay Paul; it is economically oppressive, as it casts its whole burden on a single class of businessmen; and it is wrongly ordained, as it has been enacted by the courts, not our legislatures.[1]

"Deep Pocket" is an emotive phrase. It implies that, as between two parties, a financial loss should be borne by the party who has the greater financial resources. In this context, the Deep Pocket Rule does offend our moral sense of justice:

> It is assuredly a deep implicit expectation of our legal order that parties to a civil proceeding will be equally treated irrespective of their economic status. . . . [S]hall we rule for the small manufacturer when the plaintiff is a giant chain store?[2]

If this question ever arises, the answer should be a resounding NO!

Does a Deep Pocket Rule exist in our jurisprudence? In *Escola v. Coca Cola Bottling Co.*,[3] a waitress was injured when a soft drink bottle exploded in her hand. The defendant had bottled the soft drink and there was no actual proof of negligence. The court found for the waitress, applying the doctrine of *res ipsa loquitur*. In what Pound has termed an "exceptionally able concurring opinion,"[4] Mr. Justice Traynor states:

> It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury

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[1] Lawrence A. Coleman, "The Deep Pocket Rule and the Jumping Warranty: Strict Products Liability of Manufacturers," 18 FOOD DRUG COSMETIC LAW JOURNAL 654 (November 1963).

[2] Work cited at footnote 1, at p. 660.

[3] 11 NEGLIGENCE CASES 88, 24 Cal. 2d 453, 150 P. 2d 436 (1944).

[4] Pound, "The Problem of the Exploding Bottle," 40 *Boston University Law Review* 167, 172 (1960).

from defective products are unprepared to meet its consequences. . . .[T]he risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business. . . . However intermittently such injuries may occur and however haphazardly they may strike, the risk of their occurrence is a constant risk and a general one. Against such a risk there should be general and constant protection, and the manufacturer is best situated to afford such protection.[5]

Is Mr. Justice Traynor laying the groundwork for a Deep Pocket Rule, or is he reflecting what Professor Morris terms the theory of the "Superior Risk Bearer"?[6]

In the former, liability should fall on the bottler because he is wealthier than the waitress; in the latter, liability should fall on the bottler because he is better able to foresee the possibility of injury and to provide protection against the risk of loss. As Morris states:

One who should know that his activity, even though carefully prosecuted, may harm others, should treat this harm as a cost of his activity. . . . [T]his cost item will affect pricing and will be passed on to consumers, spread so thin that no one will be seriously affected. . . . Actors can normally control this cost item by getting liability insurance, which substitutes a fixed premium for the hazard of ruinous runs of bad luck.[7]

It should be noted that courts do not decide cases expressly utilizing either the Deep Pocket Rule or the theory of the Superior Risk Bearer. The express opinions of the courts consistently have attempted to fit cases into existing theories, frequently with great difficulty. Nevertheless, if one is to predict the future course of the law, one must attempt to understand the underlying social forces working to change existing law.

Both of these doctrines should be distinguished from the "Enterprise Theory of Liability." This theory posits that one who engages in an enterprise for profit should bear the losses which others incur as a result of the carrying out of this enterprise.

Is the Superior Risk Bearer theory applicable to the law of products liability? Underlying the theory is the assumption that no matter how carefully an activity is carried out, there remains the possibility that injury may result. For example, a carefully manufactured polio vaccine might contain live instead of attenuated polio virus.[8] The administration of this vaccine results in injuries. Neither the injured persons nor the vaccine manufacturer is at fault.

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[5] 11 NEGLIGENCE CASES at 92, 24 Cal. 2d at 462, 150 P. 2d at 440, 441.

[6] Morris, *Torts*, 246 ff. (1953).

[7] Work cited at footnote 6, at pp. 247, 248.

[8] *Gottsdanker v. Cutter Laboratories, Inc.*, 11 NEGLIGENCE CASES (2d) 837, 182 Cal. App. 2d 602, 6 Cal. Rep. 320 (Dist. Ct. App. 1960).

At this point the loss is borne by the injured parties. Since a social cost would be incurred in transferring this loss to someone else, the loss should remain with the injured persons unless some social good would be accomplished by transferring it.

Risk is inherent in a dynamic society. This inherent risk may be treated by minimizing, absorbing, or shifting the risk.

The vaccine manufacturer was not negligent in preparing the vaccine; presumably due care was used in selecting reputable physicians to administer the vaccine, and the physician and nurse used due care in selecting and administering the vaccine. Therefore, one must assume that risk was minimized.

Either party could absorb the risk. As a generalization, one might state that manufacturers have greater wealth than the average consumer. Under both the Deep Pocket Rule and the Enterprise Theory of Liability, the risk would be absorbed by the manufacturer rather than the consumers. To compel the manufacturer to absorb the risk under these doctrines would be to arbitrarily penalize either wealth or enterprise. Neither penalty can be supported by rational reasoning or a sense of justice.

Shifting of Risk to Insurance Companies

The third method of treating risk is to shift it. The most common method is through insurance. By paying a fixed premium, a number of people who are subject to the risk shift it to a "professional absorber," the insurance company.

Between the consumer and the manufacturer, it is the manufacturer who most economically can make the insurance payment. First, there are not as many manufacturers as there are consumers. It is less expensive from an administrative point of view for insurance companies to deal with approximately 200,000 manufacturers than with 200 million consumers.

Actuarial feasibility also favors the manufacturer. The premium to be paid should reflect the risk insured against. The most determinative factor in calculating the risk is the type of product rather than any easily classified consumer characteristic. One could posit that the risk of loss through the use of a potent vaccine is much greater than that through the use of a sponge. It is not feasible to determine one insurance premium for a consumer who seldom uses vaccines but frequently uses sponges, and a much higher premium for

a consumer who frequently uses vaccines but seldom uses sponges. However, it is feasible to establish product categories based on the probable risk of loss through the use of the product and these can be used to determine the manufacturer's insurance premium.

Although the manufacturer is the purchaser of the insurance, it should be emphasized that the risk of loss to the consumer is being shifted. It is assumed that the cost of this insurance will be passed on to the consumer in the form of higher prices.

The Superior Risk Bearer theory is not a panacea to an understanding of the law of torts or products liability. Rather, it is a concept which may be helpful in predicting the future course of these laws. The theory is subject to several limitations and objections. Some of these will be considered below.

The Theory Imposes Liability Without Fault

It should be noted that liability without fault is not a concept which is foreign to our jurisprudence. In its inception, the law of torts was not concerned with fault. As Wigmore notes:

> . . . [T]he primitive Germanic law . . . made no inquiry into negligence, and it raised no issue as to the presence or absence of intent; it did not even distinguish in its earlier phases between accidental and intentional injuries.[9]

Are we reverting to this primitive law, or are we progressing toward a rational goal of social protection?

Liability without fault exists today in several areas of the law. The doctrine of *respondeat superior* is an outstanding example; workmen's compensation statutes are another. In the field of criminal law, *mens rea* is not a prerequisite to criminal liability under many statutes.[10]

In general, however, contemporary jurisprudence is hesitant to attach liability to one not guilty of fault. Nevertheless, it cannot be overlooked that when it is in the public interest, the law has established liability without fault.

The Superior Risk Bearer theory usually operates to place strict legal liability on the manufacturer. However, when applied to an enterprise, it imposes this liability on the assumption that the manufacturer can insure against it and pass the cost of this insurance on to the consumer. Thus, to the prudent enterprise which has insured against this loss, the theory imposes liability in name only.

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[9] Wigmore, "Responsibility for Tortious Acts: Its History," 7 *Harvard Law Review* 315, 383, 441, at 316 (1894).

[10] See, *United States v. Dotterweich*, 320 U. S. 277 (1943).

The Theory Imposes Liability on a Single Class—Manufacturers

Applied to product liability, the theory generally acts to impose liability on the manufacturer. However, the theory is applicable to other areas of tort law.

For example, in *H. R. Moch Co. v. Rensselaer Water Co.*,[11] the defendant had contracted with the city to supply water service at fire hydrants. A fire broke out and because of an inadequate water supply, the fire spread and destroyed plaintiff's neighboring warehouse. The court denied recovery on a contract theory, stating that the plaintiff was only an incidental third party beneficiary of the contract. Recovery also was denied on a tort theory on what appears to be a combination of the misfeasance-nonfeasance distinction and lack of proximate cause.

The case presents a possible example of the Superior Risk Bearer theory imposing liability on someone other than a manufacturer or provider of a service. Could an insurance market exist to protect the water company against liability? The possibility of a loss occurring is difficult to establish in terms of probabilities; also, the potential extent of the loss could range from mild to catastrophic. A more predictable risk is that a certain proportion of structures will be destroyed by fires in a given period. Insurance companies tend to avoid potential catastrophic losses, preferring to assume predictable risks scattered over a wide geographic area. Most owners, whether businessmen or homeowners, are insured against fire losses.

Under these circumstances, the owner rather than the entrepreneur is the better risk bearer. It should be noted that the owner must pay for the insurance either directly, by purchasing it, or indirectly, through higher taxes or water rates.

The Theory Assumes That Cost Can Be Passed on to the Consumer

In the long run this assumption has validity. Cost sets the floor for price. If a manufacturer is to continue to exist in the long run, his prices must cover costs. Value to the consumer sets the ceiling on price. Goods cannot be sold if they are priced above what the consumer is willing to pay. Between these two limits of cost and value, actual price is determined by competition.

[11] 247 N. Y. 160, 159 N. E. 896 (1928).

The Superior Risk Bearer theory treats competitors equally. The insurance premium is a function of the potential risk of the product and the volume of sales. Since competing products can be presumed to have the same level of non-negligent risks, the unit price of the product is increased by the same increment for all competing products.

Value to the consumer also is increased by transferring the consumer's risk of loss to the manufacturer.

The major objection in this area appears to be due to a fixation on short run rather than long run effects. It is inconceivable that in the short run, the price of a 10 cent bottle of soft drink could be increased by a small fraction of a cent to reflect the cost of insurance. However, business constantly is confronted with changing costs in all areas and as noted above, in the long run these costs eventually must be passed on to the consumer. Attention should be focused on the long run. It would be folly to suggest that society is a short run phenomenon.

If the Theory Is to Be Used, It Should Be Enacted by the Legislature, Not the Courts

First, it should be reiterated that this is not a legal theory which the courts expressly apply. Rather, it is a social theory which may help determine why courts act as they do.

The line between judicial and legislative power is thin and unstable. It is not the traditional function of a court to create new aims for society. However, does this theory create new aims or does it merely enlarge on the pre-existing protection of society?

Finally, it may be noted that the law of negligence is not statutory law. As Judge Desmond stated in one of the pioneer cases establishing a right of recovery for prenatal injuries in New York:

> Negligence law is common law, and the common law has been molded and changed and brought up-to-date in many another case. Our court said long ago that it had not only the right, but the duty to reexamine a question where justice demands it. . . . Legislative action there could, of course, be; but we abdicate our own function, in a field peculiarly nonstatutory, when we refuse to reconsider an old and unsatisfactory court-made rule.[12]

Does the Consumer Want or Need This Protection?

Perhaps this is the most crucial question. By coercing a manufacturer to insure against these risks we are indirectly forcing con-

[12] *Woods v. Lancet*, 20 NEGLIGENCE CASES 180, 303 N. Y. 349, 354, 355, 102 N. E. 2d 691, 694 (1951).

sumers to pay for protection which they may neither want nor need. This is the major limitation on the theory. It is applicable only to situations in which this want and need exist or are socially desirable. Dean Pound summarized this position in the following words:

> What we shall need to do in working out our theory is to maintain a just balance between the general security and individual free activity. Each is a matter of high importance in the social and economic order. When we speak, as we do today, of spreading the loss so as to put it where it can be most justly borne, we must not put too heavy a burden upon those in no position to bear it; nor must we follow the example of the pickpocket who listened to the charity sermon and was so moved by the preacher's eloquence that he picked the pockets of all in reach and put the contents in the plate.[13]

Summary

The courts have subjected manufacturers to increased products liability through expansion of the doctrines of privity, warranty, agency, and other legal theories. If the manufacturer is to protect himself, he must understand the underlying social forces leading to this increased liability. To predict the future course of the law, one must assume that "bad" law will not be followed. A previous article has demonstrated ably that the Deep Pocket Rule is "bad" law. As such, one would predict, or at least hope, that courts will not follow it.

The thesis of this article is that the theory of the Superior Risk Bearer, as developed by Professor Morris, provides a better explanation of increased products liability. Although the theory has limitations, it should prove useful in predicting the course of the law in those cases in which it is applicable.

Neither of these theories is a rule of law. Until the courts explicitly state which, if any, of the available theories they are following, one can only study the current theories and apply that which is most reasonable. As stated in Prosser and Smith:

> Concerning this, all that can be said is that it could be true; that there is reason to doubt it; that assertion is easy, denial quite as easy, and proof impossible where the opinions themselves say nothing about it.[14] **[The End]**

[13] Work cited at footnote 4, at pp. 185, 186.

[14] Prosser and Smith, *Torts*, 705 (3d ed. 1962).

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