VOL. 16, NO. 8 AUGUST 1961

Food-Drug-Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

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.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $20 per year. Single copies are $2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

August, 1951

Volume 16 • Number 8

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . August, 1961

VOLUME 16 NUMBER 8

REPORTS

TO THE READER

Manufacturers' Liability.—Last May, the American Law Institute adopted a new Section 402A of the *Restatement of Torts Second.* This section defines a completely new tort liability, making a food seller subject to liability for bodily harm *even though* he has exercised all possible care in the preparation and sale of the food and *even though* the consumer has not bought the food from or entered into any contractual relationship with the seller.

This section gives a broad definition of the word "food," encompassing all articles intended for human consumption internally and intimate externally. Author *William J. Condon* points out that the language of the new section calls for liability without fault and negates the requirement of privity. In the article appearing at page 473, the author mounts an argument against strict liability of the type proposed in Section 402A. This section, he says, typifies "a philosophy which seeks to remove all risks of living from all people in the country."

Mr. Condon is an attorney for Swift & Company. The article is a paper delivered before the annual meeting of the American Bar Association in St. Louis this month.

FDA and Enforcement.—In another paper from the American Bar Association meeting, the Food and Drug Administration's Deputy Commissioner, *John L. Harvey,* discusses the Federal Hazardous Substances Labeling Act and other administrative problems of enforcement now facing the FDA. He also analyzes the significant *Delson Thin Mints* and *Pinocchio Blended Oil* cases in this paper, which begins at page 484.

The author reports on his agency's recent experience with the drug counterfeiting racket. He urges that retail pharmacists need only buy from reputable sources in order to stamp out this spurious operation.

Mr. Harvey also has a second article in this issue, beginning at page 493. This is an address before the Fourth International Congress on Canned Foods, held in Berlin last May. It presents in capsule form a short history of pure food and drug legislation in the United States and some problems under the present Federal Food, Drug, and Cosmetic Act.

FDA Rule Making.—The article which appears at page 500 traces the development of the rule-making concept in food and drug administration. The first rule-making powers were given to FDA by the Food, Drug, and Cosmetic Act of 1938. In that piece of legislation, Congress required the Food and Drug Administration to certify new drugs as safe under proposed conditions of use. Rule-making powers have since been expanded by passage of the 1941 insulin amendment, the 1945 penicillin amendment, the 1954

Miller Pesticide Amendment, the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960.

The author of this article is *Franklin D. Clark,* Assistant to the Deputy Commissioner of the Food and Drug Administration.

How to Control Weight.—Violations of the law involving incorrect and inconspicuous declarations of the quantity of contents of food, drug and cosmetics packages attract a great deal of attention from the FDA. "A New Approach to Weights and Measures Control," at page 508, details new investigative methods employed by the Food and Drug Administration to detect such misstatements of quantity.

The author, *George P. Larrick,* also comments on the *Delson* case. He points out that (1) the consumer has a right to expect that a nontransparent container of food is reasonably full, (2) the size of the container should be a reliable index to the amount of food in the package, and (3) the package should not be filled with excessive padding. A favorable ruling in the *Delson* case would be a long step forward in consumer protection, claims Mr. Larrick. He is Commissioner of Food and Drugs, U. S. Department of Health, Education and Welfare.

Common or Usual Name.—Section 403(i) of the Federal Food, Drug, and Cosmetic Act provides that the label of a food which has not been standardized by the FDA must bear the common or usual name of the food "if any there be." *Vincent A. Kleinfeld* notes in the article at page 513 that this provision is honored more in the breach than the observance.

Scientists' Forum.—*Dr. Bernard L. Oser* has edited a montage of criticism against FDA regulations which were published April 29. The Forum this month is composed of extensive quotations of testimony by five leading industrial scientists before an FDA public hearing in July. Scientific Editor Oser entitles the discussion, "Toxicologists' Views of Regulations Under the Hazardous Substances Labeling Act."

Veterinary Food-Hygienists. — Proceedings of the Second Symposium of the International Association of Veterinary Food-Hygienists are available to interested parties. The Proceedings of the Symposium, which was held in Basle, Switzerland, on May 15-21, 1960, comprise a book of 400 pages. It may be obtained by sending a check, payable to the secretary-treasurer of the I. A. V. F. H., to the bank Vlaer & Kol, Utrecht, the Netherlands.

Food Additives and Cancer.—Last December, the Joint Expert Committee on Food Additives of the Food and Agriculture Organization and the World Health Organization of the United Nations met in Geneva, Switzerland, to evaluate the carcinogenic hazards of food additives. The collective views of this expert panel have been gathered in WHO Technical Report No. 220, which is available in the United States through the Columbia University Press.

Wiley Award.—The Association of Official Agricultural Chemists has announced that the 1961 Harvey W. Wiley Award goes to *Paul A. Clifford.* Mr. Clifford was formerly on the staff of the Bureau of Biological and Physical Sciences, Department of Health, Education and Welfare, and is now consulting editor of the Association. The Wiley Award was established in 1956 to honor the founder of the original food and drug law and of the AOAC. It carries with it a monetary award of $500, presented annually to a food and drug scientist.

Controlled Drugs. — The Canadian Parliament has amended the Food and Drugs Act to provide for more effective control of amphetamine, barbituric acid and methamphetamine and their salts and derivatives. These drugs now require a license and are known as "Controlled Drugs."

Vol. 16, No. 8 August, 1961

Food·Drug·Cosmetic Law
Journal

Restatement or Reformation?

By WILLIAM J. CONDON

This Article Was Originally Presented Before the Division of Food Drug Cosmetic Law, Section of Corporation, Banking and Business Law of the American Bar Association at the Annual Meeting in St. Louis, August 9. The Author, an Attorney for Swift & Company, Criticizes Section 402A of the Forthcoming *Restatement of Torts Second* of the American Law Institute. This Section Proposes Strict Liability Without Fault for Food Sellers.

ACCORDING TO THE OFFICIAL PROGRAM of this American Bar Association meeting, my function here today is to give a conservative point of view of tort liability of food and drug manufacturers. This I propose to do, but in the time-honored custom of speakers everywhere, I shall depart somewhat from the bare bones of that concept.

This discussion was brought about by a dramatic, if unheralded, development which occurred in Washington last May. At that time, the American Law Institute adopted a new Section 402A of the *Restatement of Torts Second,* which is now in the process of development. I call this dramatic because Section 402A defines a completely new tort liability, hitherto unknown to the law. This section, as presented to the Institute by the Reporter in tentative draft Number 6, read as follows:

> One engaged in the business of selling food for human consumption who sells such food in a defective condition unreasonably dangerous to the consumer is subject to liability for bodily harm thereby caused to one who consumes it, even though (a) the seller has exercised all possible care in the preparation and sale of the food, and (b) the consumer has not bought the food from or entered into any contractual relationship with the seller.

Comment C to this Section states:

> The word "food," as it is used in this Section, includes all products intended for internal human consumption whether or not they have nutritional value. Rather than repeat a lengthy list, the one word is used in the Section and throughout these comments. Food includes beverages, candy, chewing gum or Chewing tobacco, snuff and raw materials such as unground coffee beans from which the consumer or some intermediate party is expected to prepare the food ultimately to be consumed. It also includes drugs which are to be taken internally.

At the meeting in May, it is reported that the Institute tentatively adopted an amendment to this section which would extend the rule to products intended for intimate external bodily use. This would include hair dyes, cosmetics, permanent wave lotions, soap, cigarettes, cigars, vaccines and linaments, to name a few. Presumably, it would also include articles of wearing apparel and devices for use upon the human body, such as hearing aids, eye glasses, crutches and the like.

At this point, let me call your attention to the object of the *Restatement* of the law as defined by the American Law Institute in the introduction to the original *Restatement*. It said:

> The object of the Institute in preparing the Restatement is to present an orderly statement of the general common law of the United States, including in that term not only the law developed solely by judicial decision, but also the law that has grown from the application by the courts of statutes that have been generally enacted and have been in force for many years.

It went on to say that the sections of the *Restatement* "may be regarded both as the product of expert opinion and as the expression of the law by the legal profession."

From this, I presume that one has a right to infer that the sections will reflect expert opinion as to the state of the law at the time of the promulgation of the *Restatement*. I presume further that one has a right to infer that the *Restatement* is not meant to be either a prediction of what the law will be nor a reflection of what the Reporter or the members of the American Law Institute think it should be.

At the outset, there are three things to be especially noted about Section 402A. The first is that it is confined to food, which is defined to include all articles intended for human consumption internal and intimate external. The second thing to be noted is that the section defines a liability in tort, which is to attach even though the seller has exercised all possible care in the preparation and sale of the food. This, of course, is the language of liability without fault. The third point which I wish to call especially to your mind is that this liability is to attach even though the consumer has not bought the food from or entered into any contractual relationship with the seller. This, of

course, is the language designed to negate the requirement of privity. We all know that, even before the famous case of *McPherson v. Buick Motor Car Company*[1] in New York, privity of contract was not necessary in order to maintain an action in negligence against the seller or manufacturer of food. Why, then, should it be necessary to insert this privity negation in a section of this type in the *Restatement of Torts?* The answer to this question, as well as the reason for bringing these other points to your mind at this time will be apparent from a review of the cases relied upon to support this statement of the law.

In a note to the Institute, appearing immediately after the Section 402A, the Reporter listed 24 jurisdictions where the principle of strict liability in food cases had been accepted. He also listed 14 jurisdictions which have rejected strict liability and 14 more where there appears to be no definite law as to food. Of the 24 which have adopted strict liability in food cases, five have reached that result under statutes, which provide or are construed to provide for strict liability as to food. Of the remaining 19 jurisdictions in this category, nearly all the cases are food cases and all of the cases involve breach of implied warranty. In other words, the Reporter has construed the abolition of the privity requirement in breach of warranty cases to be an acceptance of the doctrine of strict liability with respect to food. Conversely, in those 14 jurisdictions where strict liability has been rejected, it has been by way of a refusal of the courts to permit a direct action for breach of implied warranty where the requirement of privity was lacking. In other words, the language negating a privity of contract requirement is in this tort section because the cases relied upon to support it are all warranty cases. The heavy preponderance of food cases in the list would be more than sufficient to justify confining the application of the section to food cases, if in fact it were so confined. But, unfortunately, the section is not so confined. Food is used as a convenient expression to include a host of other products, cases for whose justification are either scant or entirely lacking. A whole paper could be, and indeed should be, prepared by someone better acquanted with the industry than I concerning the impropriety of including drugs in this list. The only drug case cited, and the only one which has come to my attention, wherein direct action for breach of warranty in the absence of privity of contract has been allowed, is the well-known *Cutter* case in California.[2] The peculiar nature of this

[1] 217 N. Y. 382, 111 N. E. 1050 (1916).

[2] *Gottsdanker v. Cutter Laboratories,* 6 Cal. Rptr. 320 (Cal. App., 1960), 11 NEGLIGENCE CASES (2d) 837.

case renders its reliability as a precedent somewhat questionable. It will be recalled that the problem in that case was that the poliomyelitis vaccine was claimed to have caused the very illness which it was designed to prevent. No weight of authority stands behind the inclusion of the other products for internal human consumption or for intimate external bodily use in this section.

One final note on the coverage of Section 402A: It will be seen that the liability described in this section applies to anyone engaged in the business of selling food for human consumption. It is, therefore, broad enough to include anyone in the chain of distribution of the food product. With regard to middlemen, cases have been noted in only six of those jurisdictions where direct action has been permitted against the manufacturer. Of those six states, three have permitted direct action against the wholesaler [3] and three require privity of contract in such a situation.[4] It is thus evident that the inclusion of the middleman in the sweep of this section does not rest upon any trend in the law with respect to them nor upon any great weight of current cases.

In view of the fact that all of the cases relied upon to support this section are warranty cases, why does the section speak of strict liability in tort rather than warranty? The answer to this is found in the Reporter's note to the Institute. He points out that warranty carries with it technical limitations which will make it more difficult for some courts to accept the liability. Among these are the traditional requirement that warranty suggests reliance by the plaintiff on the defendant; many courts insist that a warranty is inseparable from a sale or at least a contract relation between the parties; warranties are covered by the Uniform Sales Act and many courts construe the words buyer and seller in that act to mean the immediate buyer and the immediate seller; the Uniform Sales Act requires notice to the seller of breach of warranty; the contract approach to warranty may prevent the recovery of some damages not within the scope of breach of contract; warranties are traditionally subject to disclaimer by the seller; if the section were stated in warranty, it would be difficult to explain why

[3] Kansas: *Swengel v. F & E Wholesale Grocery Co.*, 147 Kan. 555, 77 P. 2d 930 (1938); Washington: *Nelson v. West Coast Dairy Co.*, 5 Wash. 2d 284, 105 P. 2d 76 (1940), 4 NEGLIGENCE CASES 488; Florida: *Hoskins v. Jackson Grain Co.*, 63 So. 2d 514 (Fla., 1953), *dictum*.

[4] Mississippi: *Elmore v. Grenada Grocery Co.*, 189 Miss. 370, 197 So. 761 (1940), 4 NEGLIGENCE CASES 500; Missouri: *Degouveia v. H. D. Lee Mercantile Co.*, 231 Mo. App. 447, 100 S. W. 2d 336 (1936); Texas: *Bowman Buiscuit Co. v. Hines*, 151 Tex. 370, 251 S. W 2d 153 (1952).

other warranties, all of which have some tort aspects, were not also treated in the Restatement. The obvious purpose of the section is to create a strict tort liability, clean and free from any limitations, technicalities or defenses. The difficulties ascribed to warranties which have just been listed, obviously are regarded as archaic anachronisms which merely will stand in the way of plaintiff's recovery and which are mere technicalities through which defendants may escape deserved liability. One may argue, I expect, that many of these so-called difficulties have their roots deep in the law, and that at least some of them are founded upon principles of fairness and justice. In this connection, let us pause for a moment and consider the requirement in warranty that the seller be given notice of a breach within a reasonable time after its discovery. In discussing this difficulty, the Reporter quotes the well-known language from the old case of *Ketterer v. Armour & Company*,[5] "the remedies of injured consumers ought not to be made to depend upon the intricacies of the law of sales." It is perhaps too well-known to require repetition that the *Ketterer* case did not involve warranties, but that the court in making this statement was concerned solely with the ancient requirement of privity of contract in order for a plaintiff to maintain an action for negligence.

An excellent example of the real importance of the notice requirement is to be found in the case of *Henningsen v. Bloomfield Motors*.[6] You will recognize this as the landmark decision in 1960 wherein the New Jersey Supreme Court for the first time abolished the privity requirement in warranty cases. Its landmark character arises from the fact that New Jersey had not previously abandoned this requirement in food cases and the *Henningsen* case involved an automobile. Plaintiff there was driving a new automobile when, suddenly, something snapped in the front end, the car crashed into a wall, and plaintiff was injured. Plaintiff's proof as to the defect in the automobile was given by an adjuster appraiser for an insurance company who had had experience as an automobile mechanic for eleven years. He testified that the front end of the car was so badly damaged in the accident that it was impossible for him to tell what had gone wrong. However, on the basis of what plaintiff had said about the accident, he gave as his opinion that something definitely went "wrong from the steering wheel down to the front wheels." This evidence was of great weight in persuading the tryer of facts that there was something wrong with

[5] 200 Fed. 322 (S. D. N. Y., 1912).

[6] 33 N. J. 358, 164 A. 2d 69 (1960), 19 AUTOMOBILE CASES (2d) 610.

the automobile. The Chrysler Corporation, which was a defendant, made no examination of this car. Why? Because the Chrysler Corporation never knew that a claim was to be made based upon a defective part or some defective mechanism. By the time the lawsuit was brought, the car had been long since disposed of. I cite this example, not for the proposition that New Jersey does not require notice, but rather to show that the requirement of notice is more than a mere technicality. The ordinary principles of fair play would seem to dictate that the defendant in such a situation should be given an opportunity to determine for himself whether or not the alleged defect in its product was there.

On its face, Section 402A clearly represents an extension of liability in food products cases. It is pertinent to inquire why this is felt to be necessary or desirable. What is there about food products liability that seems to call for extended liability? Is it because the present law is such as to constitute too heavy a burden for the plaintiff? Quite the contrary is true. Dean Prosser, who, incidentally, is the Reporter for the *Restatement of Torts Second,* points out that the plaintiff's burden will be little different under this strict tort liability than it is today.[7] Even in negligence cases, he notes, the courts have so limited the requirements of proof of negligence that the plaintiff has a rather simple job of establishing a *prima facie* case. He notes further that in very, very few cases are the issues determined on the basis that the defendant was found not to have been negligent. Under a strict tort liability, as under present law, the plaintiff must prove a defect in the product and he must trace that defect to the defendant. If he can do that and prove that the defect caused his injury, he will have made out his case under either system of law. Yet, we are told that public interest demands this extension.

Our courts say that the public interest in human life, health and safety requires a strict accountability of the manufacturer of food. Again they say that since the manufacturer or seller of food creates the demand for his product, public interest requires that he be strictly accountable for injuries resulting from its use. Finally, courts will tell us that public interest requires that the needless and expensive circuity of action be avoided. Throughout all of these points runs the thread of public interest.

---

[7] Prosser, "The Assault upon the Citadel," 69 *Yale Law Journal* 1099 (1960).

The essence of this public interest argument seems to be that since food is so vital to human life and health, extended liability is necessary in order to protect the public. In answer to this, one might make two points:

1. Our food supply in this country is the most abundant, most nutritious and safest food supply in the history of the world.

2. A proper enforcement of the Food, Drug, and Cosmetic Act and state food and drug laws is a far more effective method of protecting the public in its food supply than any extension of civil liability by the courts could hope to be.

In addition, the public interest argument ignores the fact that plaintiff has adequate redress under the present law without the necessity of any extension of liability. There is one further factor which is necessary to consider in connection with this demand of public interest. This is the essential nature of the injuries which are present in the ordinary food case. As one advocate of strict liability says: "One is struck by the essential triviality of most of them." [8] It is extremely unusual to find a food case which involves substantial injuries. Virtually all of them are involved with minor injuries caused by foreign substances or with gastro-intestinal upsets lasting from two to three days. While I don't recommend these experiences to anyone, nevertheless, they don't compare with the severity of injuries with the attendant sequelae that are to be found in other areas of personal injury litigation. Rarely is a food plaintiff faced with a calamitous economic loss either in earnings or in medical expenses. Recoveries are almost invariably small. In short, they are not the type of injuries that would give rise to any public clamor. Indeed, I have never been made aware of any public clamor in connection with food products liability.

The clamor, such as there is, has come from the organized plaintiffs' bar and from numerous learned commentators writing in the field. May I be so bold as to suggest that to the organized plaintiffs' bar, food products liability cases as a class are more trouble than they are worth. In my experience, I have yet to meet any plaintiffs' attorney with a successful practice who was anxious to spend the time and effort involved in a food products liability case. The return to be expected from such effort simply wouldn't justify his time. Why then, one might ask, is the plaintiffs' bar interested in products lia-

[8] James, "General Products—Should Manufacturers Be Liable Without Negligence?" 24 *Tennessee Law Review* 923 (1957), at p. 926.

bility? Why does all the activity center around food products liability and the liability of related products? The answer suggests itself and is really very simple. Food products liability is regarded merely as a wedge, a foot in the door which will create the opening through which strict liability for all manufactured products will eventually flow. This is the real goal.

Until recently, the only cases in which the privity requirement was abrogated in warranty actions were cases involving food. In 1958, the Michigan Supreme Court allowed a direct action in warranty in a case involving cinder building blocks.[9] Unfortunately, it is difficult to rely on this case as establishing much of anything because the court seemed to hold that in Michigan, breach of warranty is bottomed on negligence and since the record disclosed that the manufacturer had been negligent, recovery could be had. Nevertheless, the case is widely cited for the proposition that a direct action in warranty may be brought in the absence of privity of contract in Michigan. It is not entirely clear what the Michigan court would have done if there were no evidence of the manufacturer's negligence. No such cloud surrounds the *Henningsen* decision in New Jersey. There the court clearly abolished the privity requirement in actions for breach of implied warranty in the State of New Jersey.

The New Jersey court relied heavily upon food products cases in order to reach this result. The food cases, drawing heavily upon the public interest, now form a wellspring for the imposition of strict liability on manufacturers of other types of products. The justification for this seems to lie in the tort aspects of warranty, referred to by the Reporter. Section 402A carries this concept to its logical extreme, creating as it does a strict tort liability with no mention of warranty whatsoever.

This brings us logically to the question of why strict liability is an unsatisfactory doctrine. Perhaps, in the best of all possible worlds, strict liability might be a very good rule. It might likewise be said that collectivism would be a good social system in such a world. The trouble is that this is not the best of all possible worlds. Litigants, lawyers, judges and jurors are all people with human frailties. Many of the restrictions and limitations in our law have the effect of nullifying or at least modifying the effectiveness of some of the weaker or baser human tendencies. The charge is frequently made that any

[9] *Spence v. Three Rivers Builders & Masonry Supply, Inc.*, 353 Mich. 120, 90 N. W. 2d 873 (1958), 8 NEGLIGENCE CASES (2d) 457.

extension of strict liability will lead to an avalanche of fraudulent claims, to which the response is usually made that fraudulent claims exist today and can readily be made out under today's rules of law. And this response is true, as far as it goes. As long as we have people with enough nerve and ingenuity to rob big city banks, we can expect lesser lights with enough nerve and ingenuity to bring fraudulent claims. However, it is nonetheless true that, if the safeguards were reduced in the big city banks we would have more robberies and, by the same token, if the safeguards are removed from products liability law, we can expect more fraudulent claims. In the real world of commerce, the menace of the fraudulent claim is a very real and costly proposition.

However, the possibility of increased worthless claims is hardly the basic objection to the concept of strict liability. Far more fundamental is the objection to the underlying philosophy which cradled the doctrine. As James points out,[10] what is desired is to place the loss in these cases on the one in the economic community who is best situated to spread it around. The result to be sought by this is that the losses will be reflected in the prices charged and, eventually, the cost will be borne equally by all in the community. It is not my intention to discuss at this time the economic difficulties with this theory, with the attendant problems of the ability to pass these costs along in the form of increased prices, or the disastrous effects that such losses might have on the small and marginal producers in any industry. It is better that we content ourselves at this time with the discussion of the philosophical aspects of this position. Prosser recognizes it for what it is, because he points out that he would not shrink from "a spot of socialism in our law when the public interest demands it."[11] This frank and accurate description of what the "spreading the risk" concept really encompasses suggests several difficulties. First of all, who is to determine that the public interest demands a spot of socialism? What public interest is to be considered? Will it be a broad or a narrow public interest? Will it be a long-range or a short-term public interest? Obviously, under this proposal, these questions will be left to the determination of one or a small group of judges. Without intending any reflection on our judiciary, it is necessary to point out that, by and large, judges are not politically responsible. It is, therefore, a violation of the principles of representative

[10] Source cited at footnote 8.

[11] Source cited at footnote 7.

government to endow judges with the power to make such a fundamental change in the political philosophy and the direction of our country.

Another difficulty which I have with this whole approach is what I conceive to be its underlying morality. It will make of our courts a band of Robin Hoods taking from the rich and giving to the poor. And like that legendary bandit of Sherwood Forest, the courts in so doing will be cloaked with the mantle of righteousness. The proponents of this philosophy are in a very comfortable position, because they stand as the champions of the sick, the lame and the halt, the poor and the down-trodden, against the wealthy, the rich and the powerful. Anyone who would oppose is placed in a bad light indeed.

Yet, it seems necessary to speak out against the approach because of its insidious nature. Today, it's food products; tomorrow, all products. After that we might expect strict liability for the drivers of automobiles and so on until finally all of our law could get to the point where the determination of any given case would depend upon the concept of one judge as to where the public interest happened to lie.

On other platforms it has frequently been suggested to me that strict liability is not a new concept, but rather has found expression and complete acceptance in the common law doctrine of *respondeat superior* and in the statutory system of workmen's compensation. I don't believe that either supports the argument for which they have been cited.

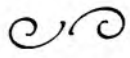
The doctrine of *respondeat superior* does not impose a liability without fault. It is true that the vicarious liability placed upon the superior is not the result of the superior's fault but it cannot be imposed without the finding of fault on the part of an agent, servant or employee of the superior.

Workmen's compensation, on the other hand, is unquestionably a system imposing upon employers an obsolute responsibility for injuries received by their employees during the course of the latters' employment. The system was designed, admittedly, to spread the risks of our industrial civilization to a certain extent and to remove or mitigate at least some of the effects of human frailties. But workmen's compensation is not judge-made law. In each state where it exists it has been enacted by a legislature responsive to the will of the electorate. Moreover, workmen's compensation, while imposing absolute liability, places limits upon the sums recoverable by means of schedules of awards. Contrasted to this, the strict liability doctrine

proposed by Section 402A of the *Restatement of Torts Second* in essence constitutes a judicially imposed system of compulsory insurance with no limitation on awards and no specification of the manner or degree in which the cost of that system is to be borne. To my way of thinking, these two concepts are "entirely different animals."

I suggest that the logical conclusion to be reached from the arguments in support of strict liability is one of two alternatives. The first might be a government-controlled fund, raised by compulsory levies upon all citizens, from which payments could be made to successful plaintiffs in products liability cases. The alternative would be a system resembling workmen's compensation wherein awards would be made by administrators which would be paid directly from a fund comprising compulsory contributions from manufacturers which contributions are determined on an experience basis. Both of these programs would require legislative action in accordance with the accepted principles of representative government. Determinations as to wherein lies the public interest or to what extent we wish "a spot of socialism" in our law would be made by those responsible to the people. I must make it clear at this point that I do not recommend either of these programs. They represent the natural consequences of a philosophy which seeks to remove all risks of living from all people in the country.

Professor Seavey once said that at any given time and place the law is the resultant of the conflict between the basic concepts of security and freedom of action.[12] The ascendancy of the basic concept of freedom of action has made this country great and, within reasonable limits, its continued ascendancy will keep it great. We must keep moving to stay where we are. This applies with equal force in the law as in all other phases of our economic and political life. **[The End]**



[12] Seavey, "Principles of Torts," 56 *Harvard Law Review* 73 (1942).

Current Administrative Developments

By JOHN L. HARVEY

This Paper Was Prepared for the Eighty-Fourth Annual Meeting of the American Bar Association in St. Louis, August 9. Mr. Harvey Is Deputy Commissioner of the Food and Drug Administration.

IT IS AGAIN A GREAT PLEASURE for me to have this opportunity of meeting with you for a discussion of subjects of current interest from the standpoint of the agency enforcing the Federal Food, Drug, and Cosmetic Act and its affiliated laws. It has usually been my custom to deal with one or two subjects that were deemed to be of particular concern or importance at the moment and I am sure that ordinarily such approaches are more useful than a more random discussion of what has happened recently.

As a matter of fact, before the preparation of a paper for this meeting I had contemplated devoting the time allotted me primarily to a discussion of the Federal Hazardous Substances Labeling Act and since I have been immersed in the developments in this area I anticipated no great material search in the preparation of the paper. Our distinguished but absent Chairman, Mr. Markel, had in conversation indicated essentially that I could select my own topic. I neglected, however, to inquire of him as to topics selected by or assigned to others so that upon receipt of the program I found that the topic I contemplated using had been assigned to our good friend Mr. Scriba. I am sure this is all to the good and I look forward with much interest to Mr. Scriba's discussion of this interesting topic. I hope that I can avoid intruding upon his subject in any way such as to interfere with it.

During the last week much of my time was devoted to participation in the writing of the final regulations under the Federal Hazardous Substances Labeling Act and, if anticipated schedules are followed, these regulations should be published in the *Federal Register* some time this week.

This act, designed to require that labels for hazardous substances used in the household bear adequate information as to potential hazards involved in their misuse, provided for the promulgation of the usual interpretive regulations and, to a limited extent, regulations that will have the force and effect of law. The latter of course may be subject to judicial review. The act provided that it should become effective upon enactment, which occurred July 12, 1960. It further provided, however, that penalties or condemnations under the act should not be imposed for a period of six months from the date of enactment, and that this provision could be extended up to 18 months by the Secretary of Health, Education and Welfare on the basis of a finding that conditions exist that necessitate the prescribing of such an additional period.

No extension was granted beyond the first six months' period for the provisions relating to substances defined as "highly toxic," "extremely flammable" and "flammable." Orders were issued extending the effective date for other categories until August 1, 1961, and subsequently on July 14 further order was issued extending the effective date for these products until February 1, 1962, the maximum extension allowed by statute.

The regulations have been in the course of preparation for many months and on April 29, 1961, the proposed regulations were published in the *Federal Register* with an invitation for written comment thereon. This resulted in well over 400 documents being filed with the hearing clerk, a few of which recommended promulgation of the proposals as final. Most of the filings, however, objected to many of the proposed provisions.

In early July an open meeting was held which afforded opportunity for all concerned to make oral statements with regard to their views on these proposed regulations. Every viewpoint, every objection and every criticism made orally or in writing has been considered and taken into account. Many of the comments, criticisms and suggestions have been adopted. A few have not.

The implementing regulations under this act, while final in character, are not necessarily immutable but can be changed whenever convincing evidence is available to persuade us that a change is needed. We shall, of course, as always keep in mind the purpose as well as the provisions of the law itself.

I have been most impressed with the volume and to some extent the heat of the objectives raised. It has distressed me that so many representatives of industry fail to or refuse to recognize the sincerity of the FDA in treating the proposed regulations as tentative proposals with every intention of giving the fullest possible consideration to the objections raised. I trust that the final regulations will evidence our sincerity. I should like to emphasize to this group, unnecessarily I would hope, that whenever the Food and Drug Administration publishes a proposal and invites comment and suggestions, we are fully prepared to treat all serious recommendations and suggestions with the fullest consideration and that any assumption that we are wedded to the proposal in such manner and fashion that we are impervious to recommendations for change is in error. I think the record of the years will bear this out. Perhaps the seeming skepticism, which I may exaggerate, among those interested in the Federal Hazardous Substances Labeling Act regulations arises because many will be affected thereby who have not hitherto had experience with government procedures involving regulations under the Federal Food, Drug, and Cosmetic Act, and therefore have had little contract or experience with our enforcement agency.

I must say that I have also been somewhat surprised at the insistence of some representatives of industry that they should as a matter of right participate in the writing of the final regulations, and this despite the fact that plenty of opportunity has been granted for the presenation of their views.

I am sure that I have already infringed upon the talk which is to follow and I apologize to the next speaker for my presumption.

Among the activities of the Food and Drug Administration during the past year has been an intensive study and application of the resources existing in the present law for dealing with the many questions that have been raised about the safety and efficacy of the nation's drug supply. I do not intend to go over the whole subject and I am sure that many of you are as familiar with the publicity that has arisen largely if not wholly from hearings conducted by the Senate Com-

mittee as I am. I should emphasize that whatever may be our personal concern with regard to the cost of drugs to patients and users, we do not to any degree consider the Federal Food, Drug, and Cosmetic Act as an instrument for price control or for the regulation of prices charged to consumers of drugs. We recognize that there are many costs in research and elsewhere in the development of drugs and few should know better than we the time and money involved in pharmacological and clinical studies which are essential to the production of new drugs.

While it may be that the economies of drug production and merchandising has attracted the headlines to a greater extent than the safety and efficacy of the drug supply, it is still true that the latter points are of great concern not only to us but to the public generally. It will continue to be our purpose to enforce the existing law as far as it goes, doing everything possible to insure that the drug supply is safe when used as directed and is capable of accomplishing what the manufacturer claims for it. I do not believe that this is either the time or the place for me to elaborate upon the legislative remedies for the present shortcomings that we find in the food and drug law as it relates to drugs. I should say that we are of the opinion that some fairly substantial improvements should be made to clearly provide for authority to make such inspections as have any bearing on adulterations or misbrandings and to otherwise strengthen provisions requiring full disclosure to physicians of the attendant risks as well as the therapeutic virtues attached to the drugs which they use.

We found what is best described as a counterfeit drug market in existence in which marginal manufacturers produced dosage forms of drugs to look like, feel like and taste like some of the expensive, well-known drugs produced by large companies. For the most part these drugs contained the ingredients in the genuine articles, although this was not always true. Because these counterfeiters had no investment in research and development and no costs relative to a new drug application, they could and did sell their output much cheaper than the legitimate article. Apparently they found no difficulty in finding an outlet for their wares. Our investigations disclosed the spurious products in retail drug stores where their inevitable use was as a substitution in the prescription for some patient. It is apparent that there are trademark and patent issues involved here which are not a part of our interest although undoubtedly closely allied with it. As part of our investigation our inspectors purchased prescriptions from stores all

over the country. Drugs chosen for purchase on the basis of prior history and cost were Miltown and Equanil, well known tranquilizers; Diuril and Hydrodiuril, diuretics; Esidrex and Serpasil, blood pressure depressants; Tedral, an anti-asthma drug; and Meticorten, a multi-purpose drug. In very special techniques in our laboratories we were able to determine whether these drugs purchased were legitimate or counterfeit. For example, among 2,700 samples collected at 900 drug stores in February and March, nine samples from nine different stores were found to be counterfeit. In certain geographical areas where we knew a distributor of counterfeits was operating, this percentage would be higher. This is not a simple matter of pure economic gain. It is a very definite and potentially explosive health problem. The drug industry for the most part maintains, and the new drug provisions demand, rigid controls that minimize dangers of ingredient mix-ups, mislabeling and variations in potency. These protections to the consuming public were completely lacking in the counterfeit operations we uncovered. Legal actions were taken and are continuing. We intend to bring the full force of the food and drug law against this evil.

The solution to this problem is not difficult and we have made several statements pointing it out. Retail pharmacists need only to buy from reputable sources. This counterfeit racket and other illegal operations have to be, in order to exist, paper sack and under-the-counter types of transaction.

We are at present involved in another facet of drug investigation against a similar threat to the public health. The drug industry has, as part of its system of merchandising, developed a public relations program involving free samples of drugs. The manufacturers distribute these as "physician samples" and you may have had the experience of your doctor handing you such a sample bottle. Such bottles usually have "Physician's Sample" plainly marked on them. We have no objections to such a procedure, assuming of course that the sample drugs are legally labeled and are produced under the same conditions and care as the regular drug. The fact that they cost the doctor and you nothing is just a dividend. It seems, however, that the volume of free samples to physicians has reached the point where it becomes profitable for individuals or fly-by-night firms to establish routes which include physicians as customers. They seek out those physicians who do not want all of the free drugs they receive and are willing to give them away or exchange them for other merchandise. The accumulators of such drugs then proceed to assemble them into the various

kinds, dump them in bulk containers and sell them. Again we have the situation where the drug seller does not have the testing and development costs and therefore can merchandise the bulk product at a price considerably below the regular wholesale price. This also becomes a sub-rosa paper sack operation and is subject to the same hazards as in the case of the counterfeiter, with the possibility of additional ones. Repacking drugs from one container to another and affixing the proper labels may be classed as a simple operation; but where several different drugs of several different potencies are involved, unless proper controls are maintained, mix-ups will occur. In the drug field this can be fatal. Some of the firms we found engaged in this operation were completely devoid of facilities and training that would equip them to handle such operations. Through legal actions and publicity we hope we have contributed to the elimination of this hazardous operation. Our investigations are continuing. Associations representing the drug industry, the medical profession and retail pharmacists have expressed their deep concern over the problem and their willingness to cooperate wherever possible. Again, if pharmacists confine their drug purchases to established channels known to be legitimate, the use of mixed-up samples can be avoided.

Passing now to one of our activities in the cosmetic field, I would like to discuss briefly our actions against eyebrow pencils which were given some publicity earlier this year.

What was involved here was the use of coal-tar colors which had been properly certified for general drug and cosmetic use under the provisions of the Food, Drug, and Cosmetic Act. Such certification procedures for colors requires testing of each batch of manufactured color for purity and conformance with specification. Under the provisions of the act and its regulations it is made plain that certification of a batch of coal-tar color does not mean that it can be used in cosmetics for application in the area of the eye. The reason for this rule was and is that safety for general cosmetic use does not necessarily make the colors safe for use in this very sensitive orbital area. Because non-coal-tar colors were available, the required effort was not made to develop coal-tar colors that could be demonstrated to be safe for this use. No critical situation developed for many years and we still are not exactly sure what happened, but our investigations in April of this year showed that eyebrow pencil leads included coal-tar colors. Because of the prohibition in the law these eyebrow pencils were seized and stocks containing such colors were removed from the market.

We believe that ladies need not be concerned now. The eyebrow pencil industry, being a rather close-knit one, has now evolved formulations which do not include coal-tar colors.

In this connection it is worthy of mention that under the provisions of the Color Additive Amendments of 1960 it will be necessary within the next 18 months for all colors of coal-tar derivation and all others which are used in food, drug and cosmetic products to be demonstrated safe for their intended use. We are now in the "transitional" or "provisional" period under the Color Additive Amendments. This period essentially maintains the status quo and unless a color additive is shown to be harmful, it can continue to be used. However, on January 12, 1963, the permanent provisions take over and all color additives must be listed for their uses. Such listing requires certain protocols in prescribed form and a positive showing of safety for their intended use. Those of you with clients affected by these amendments might well see that necessary steps are taken.

Also, I would like to mention a charge that is being hurled at the Food and Drug Administration alleging that we have been making offers to physicians, at $50 per performance, asking them to record by tape recorders or other recording devices their conversations with detail men, which is the trade nomenclature for drug salesmen. It is alleged that these recordings are for the purpose of prosecuting drug salesmen for their statements. For some mysterious reason this alleged activity has been called un-American, illegal, immoral and unethical. We have been asked from many sources whether such a horrible thing can be true. We have answered that the charge of our offering to pay physicians $50 to assist in making recordings is false. We have made no such offers and do not intend to. We do maintain, however, that if evidence reaches us that drugs are being misrepresented or misbranded by drug salesmen either on a personal basis to increase sales or as a policy of the company he represents we would certainly take every step necessary to document such information.

Usually at the meetings of this Section, Billy Goodrich tells us about the important cases that have been decided during the preceding 12 months. I will take the liberty of pinch hitting in a small way for Bill since it was not possible for him to be here.

The two most significant court decisions of the past year were in the *Delson Thin Mints* case and the *Pinocchio Blended Oil* case.

Delson involved a product which we believed was seriously slack-filled. The candy box had hollow dividers and end pieces which made the container somewhat longer than necessary. We offered evidence that single thickness dividers were just as effective and much less deceptive. The case was tried in the district of New Jersey. The court ruled that the package was not slack-filled.

The court of appeals reversed, finding that there was substantial uncontradicted evidence that the container was so filled as to be misleading. The court said, however, that the claimant could justify this circumstantial deception by proof that this kind of packaging was necessary to safeguard the product. The announced rule is that before the slack-fill can be justified, the district court has to find "that the container's efficacy outweighs the deceptive quality and that the available alternative efficacious means are not less deceptive than those actually employed."

On the remand, the district court again ruled against us. The findings were that the package was not so filled as to be misleading and that the hollow divider packaging was reasonably necessary to protect the contents and no more deceptive than other packaging methods reasonably available. We will, of course, plan to take this case back to the court of appeals as soon as a final judgment is entered.

Despite our two setbacks in the district court, the opinion of the court of appeals is a definite plus. It announces a very satisfactory principle for the enforcement of the slack-filled provision. It is that the government must show that the package is deceptive, and having shown this, the claimant may justify the deception by proof that it was necessary and that no reasonable alternate exists.

The *Pinocchio* case in the second circuit was concerned with a blended oil prepared and sold in New York from ingredients which had moved in interstate commerce. The district court held that the blended oil was a "new" product that had not been in interstate commerce, and was thus beyond the reach of the Federal Food, Drug, and Cosmetic Act.

The court of appeals reversed this decision, holding that the local blending of the interstate oils did not make them immune to seizure. All the components of this food had been shipped interstate and the article offered for sale to the public was the same kind of a product, salad oil, as the ingredients comprising it.

The case does not necessarily decide whether if some, but not all, of the ingredients have moved interstate, the product would be subject to seizure. Nonetheless, this case, together with an opinion by the district court for the Eastern District of Michigan, clearly indicates that where all of the ingredients, or where the most important ingredients, have been shipped interstate, the protective features of the law can be brought to bear to prevent misbranding and adulteration of the end product fabricated from the interstate components. The *Pinocchio* case is pending on petition for a writ of certiorari. [The End]

HAZARDOUS SUBSTANCES LABELING

The effective date of the penalty provisions of the Federal Hazardous Substances Labeling Act has been extended until February 1, 1962, by the Food and Drug Administration in FDA Order No. 2. All substances other than highly toxic, extremely flammable and flammable substances are covered by the extension, reported full text in FOOD DRUG COSMETIC LAW REPORTS, at ¶ 6830.

[Order No. 2, 21 CFR, Chap. 1, published at 26 F. R. 6544, July 21, 1961.]

On January 31, 1961, Order No. 1 extended the penalty and condemnation provisions of the Federal Hazardous Substances Labeling Act until August 1, 1961, as applied to all hazardous substances defined in the act, except "highly toxic," "extremely flammable," and "flammable."

On April 29, 1961, proposed regulations were published in the FEDERAL REGISTER and comments were requested thereon. Numerous comments were received from associations, firms, and individuals during the 60 days specified for submitting comments. In addition, an open meeting was held on July 13 and 14, 1961, at which time oral statements were received. Time will be required to consider all the comments received and to issue final regulations.

Therefore, pursuant to the provisions of the act (sec. 16(b), 74 Stat. 380; 15 U. S. C. 1261 (note)) and under the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (25 F. R. 8625), *It is ordered*, That the provisions of section 5 and 6 of the Federal Hazardous Substances Labeling Act shall be further suspended until February 1, 1962, for all hazardous substances as defined in section 2, other than "highly toxic," "extremely flammable," and "flammable."

The Federal Caustic Poison Act remains in full force and effect during the period of this extension for any article affected thereby.

Effective date. This order shall be effective on the date of signature, July 17, 1961.

(Sec. 16(b), 74 Stat. 380; 15 U. S. C. 1261 (note).)

Legislation– Trends and Actual Problems in the United States

By JOHN L. HARVEY

Deputy Commissioner Harvey of the FDA Delivered This Address Before the Fourth International Congress on Canned Foods, Which Was held in Berlin, Germany, on May 18, 1961.

THE FEDERAL FOOD, Drug, and Cosmetic Act regulates the quality and integrity of many canned foods through the application of the principle of "food standards" which consist of reasonable specifications which can be achieved through good manufacturing and labeling practices and which are generally familiar to the discerning housewife. This concept did not emerge full blown in the form in which it now exists, but has developed through an evolutionary process which can be traced to a practical beginning shortly before the turn of the century.

In 1897 the Association of Official Agricultural Chemists, which is an organization whose membership at that time primarily consisted of state chemists, since it was before the federal pure food law was enacted, appointed a committee of experts to consider the general problem of writing standards for various kinds of foods. In 1900, based on the recommendation of this committee, the association adopted tentative definitions and standards of identity for certain foods, among which were lards, jams, jellies, syrups, milk and certain milk products. These standards were of no direct legal significance, but they did represent progress from the standpoint of having a group of experts who agreed upon the composition of the named food articles.

The next evolutionary step was a recognition by the Congress of the United States that the standardization of food products was in the interest of consumers and a reasonable function of government. Beginning in 1902 and extending until 1906, the Congress granted

funds to the Department of Agriculture to continue the process of food standardization with the pronounced purpose of guidance to enforcement officials and to courts of law.

In 1906 the Federal Food and Drugs Act was passed in recognition of the overriding interest and obligation of the federal government in the consumer welfare in the food and drug field. This statute prohibited adulteration and misbranding, but did not include any standard making procedures, nor did it define any criteria for arriving at the normal composition of foods. The Secretary of Agriculture continued to use the advisory standards which had already been developed and proceeded to formulate others, but found that these advisory standards, having no specific authorization in law, were difficult, if not impossible, to enforce. In bringing action in federal court in an effort to prove that undeclared variations were not expected by consumers or sanctioned by good trade practices, it was found that judges and juries brought in conflicting decisions on essentially the same facts. Thus, manufacturers could not be certain of their obligation, nor could consumers always depend upon labels to describe the contents of a can or package.

In the area of canned foods the canning industry themselves became quite concerned, fearing deterioration of consumer confidence in their products unless reasonable standards could be enforced against low-grade and slack-filled products. They offered an amendment to the Food and Drugs Act of 1906 which was called the McNary-Mapes Amendment, which passed in 1930, and which required a substandard declaration on the label of canned fruits and vegetables falling below standards prescribed by the Secretary of the Department of Agriculture.

Other segments of the food industry recognized the validity of the McNary-Mapes Amendment approach, started movements towards standardization in other areas such as jams, jellies and preserves. There had been no fruition of such efforts, however, when in 1938 Congress passed the Federal Food, Drug, and Cosmetic Act, which made rather sweeping changes in food and drug enforcement and included an entirely new concept of food standardization. The 1938 Act clearly recognized as a function of government the establishment of reasonable and enforceable standards for foods.

The general provision for definitions and standards for foods are contained in Section 401 of the Act, which is:

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided,* That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and the need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

Other sections of the Act specify the legal status for foods so standardized and for procedures to be followed in establishing the standards. Statutory provisions were made for a public hearing before any standards were set, at which time all interested parties who had relevant information were afforded an opportunity to be heard. Facts developed and presented at the hearing, and the standards arrived at were published in the *Federal Register,* a government publication which contains material from all government agencies which is for the guidance or information of industry and the public. Parties adversely affected by a published standard are further protected by an appeal procedure to the middle court of the three stage judiciary of the United States—the United States Court of Appeals—with the possibility of final review by the highest federal court—the Supreme Court of the United States. The end product is a standard or standards with the full force and effect of law. Several standards have been appealed to the courts, some reaching the Supreme Court. The rulings in these cases have demonstrated a strong judicial support for consumer protection, thus increasing our belief in the inherent rightness of the concept of food standards.

Of the three types of standards provided in Section 401, the "Definitions and Standards of Identity" were most needed to stabilize the food situation. When a housewife has not prepared the product herself and cannot see through the container, she must depend upon the label of a can to tell her what is inside. It is important to her to

know exactly what to expect when she opens the can. If she wants peach halves, she would be disappointed to find the product to be sliced or diced peaches.

The standards of *identity* list and describe those ingredients that must be present, and those which may be included at the manufacturer's option. No other ingredients may be added; no other foods may be marketed under that name after a standard of identity is promulgated. The Act declares a food misbranded which fails to comply with the standard established for it. It also deems the food misbranded if it fails to conform to labeling requirements of the standard—the name of the food as specified and the common names of the optional ingredients which are required by the standard to be declared. Among the optional ingredients for canned peaches, for example, are whole, half, or sliced peaches and packing media which may vary from water to extra heavy peach juice syrup.

The standards of *quality* for peaches, as an example, relate to their tenderness, adequate peeling, uniformity of the size of the pieces and similar factors. The standards of quality under the Food, Drug, and Cosmetic Act are minimum standards and do not recognize grades such as "Fancy" or "Grade A." Such designations are recognized as marketing factors by the canning trade in general and by a sister agency in the U. S. Government—the United States Department of Agriculture. When such grade designations are used, then the contents must live up to whatever quality is thereby promised—minimum quality is no longer sufficient. Canned products for which there are standards of quality are not illegal if they fall below such standards but are still good food provided they bear specified substandard labeling which, in some instances, gives the reasons why the standard has not been met, such as "Not well peeled; unevenly trimmed."

Standards of *fill of container*, in general, require packages to contain the maximum quantity of food that can be filled in the container and processed without damaging the food.

Standards of identiy have been promulgated for some breads and rolls; over sixty different kinds of cheese; various chocolate and cocoa products; dressings for foods; liquid, frozen and dried eggs; a large variety of fruit butters, jams, and jellies; alimentary pastes; some dairy products, margarine; and over 30 kinds of wheat and corn flour and cereal products.

Canned fruits and fruit products for which standards of identity, quality and fill of container have been promulgated are peaches, apricots, pears, cherries, pineapples and pineapple juice, fruit cocktail, plums, seedless grapes, dried prunes, and 11 kinds of berries. Additional identity standards allowing the addition of rum and for artificial sweetening have also been promulgated for some fruits, as have identity standards for prune juice, canned figs and frozen concentrate for lemonade.

Canned vegetables and vegetable products for which standards of identity and quality have been promulgated include peas, green and wax beans, sweet and field corn, and tomatoes. Standards for fill of container have been set for canned peas, canned corn, and canned mushrooms, and standards of identity have been set forth for all vegetables normally canned and for the various comminuted tomato products such as catsup, puree and sauce.

Canned tuna fish and canned oysters have standards of identity and fill of container and canned shrimp has standards of fill of containers.

Hearings are in process on controversial points of proposed standards for orange juice and orange juice products. At issue are matters of selecting names for the various products and their precise meanings, such as "pasteurized orange juice" or "concentrated orange juice"; of determining whether such things as tangerine juice or orange pulp should be permitted as ingredients; and the proper Brix-acid ratio for the various orange juice products.

Another series of standards for which all problems have not been resolved are those for ice cream and related frozen desserts. In this instance, final orders after extensive hearings have issued and industry has appealed to the courts for a resolution of the differences still remaining. Points of controversy in this instance are provisions of the standards limiting the use of whey, provisions setting out the labeling required for declaration of flavors and the failure of the standards to permit the use of milk alkalies capable of neutralizing developed acids in the milk product ingredients.

The first step of standard making procedure, that of a public hearing, raised one problem which became rather serious. The hearing procedure required that any regulation made pursuant to the hearing had to be based solely upon findings of fact developed from evidence which had been adduced at the public hearing. This meant

that all elements of the standard, whether controversial or not, had to be supported by evidence in the record of hearing. This resulted in a number of protracted hearings with voluminous records which had to be reviewed and studied before the standards could be promulgated. Numerous scientific and legal experts suggested that this part of the standard making procedure could be effectively shortened. Their recommendations resulted in the passage in 1954 of an amendment to the Food, Drug, and Cosmetic Act—the Hale Amendment—which simplified the standard making procedure to the extent that hearings are required only when objections are filed to published proposals and then only on the actual points in controversy. The provision for appellate court review was retained.

A valid objection was voiced by industry that strict standardization of food tended to stifle progress unless exceptions could be granted for experimental marketing studies of foods deviating in some respects from the requirements of the applicable standard. This was handled administratively with the instigation of a permit system which provides for temporary permits exempting experimental packs from full compliance with the standard requirements for the purpose of performing legitimate market testing.

Not all canned foods have as yet been standardized. Those which are not fall under the general provisions of the Federal Food, Drug, and Cosmetic Act which requires the contents to be free from adulteration and to be informatively labeled. The label must bear, in addition to the name and place of business of the manufacturer, packer or distributor and an accurate statement of the quantity of contents, the common or usual name of the food if any there be. In case the food is fabricated from two or more ingredients, the common or usual name of each such ingredient must be listed in the order of its predominance in the food. Spices, flavorings and colorings, other than those sold as such, may be designated as spices, flavoring or coloring without naming them.

Recent legislation also has had an impact on canned foods. I have reference to two amendments to the Food, Drug, and Cosmetic Act whose aim and content are evident from their titles which are "The Food Additives Amendment of 1958" and the "Color Additive Amendments of 1960." Both statutes grew out of the world-wide interest and concern engendered by the increased use of emulsifiers, antioxidants, sequesterants, buffers and the like, without thorough

investigation of their toxicity. Following lengthy hearings before a Select Committee of the United States Congress, the Food Additives Amendment was enacted which has, as a keystone, demonstrated safety for the intended use. If a chemical additive is safe, it may be used. If limitations are necessary for such safe use, they are specified.

The Color Additive Amendments continue this philosophy to articles that contribute color, whether the historical "coal-tar color" or of some other origin. Again, safety for the intended use is the test, but for color additives the addition of a certification precedure, wherein each production batch is sampled and examined by the FDA laboratories before it may be distributed, is included where such is necessary for the protection of the public health. Color additive legislation covers drugs and cosmetics as well as food. Both the food additives and color additive amendments declare as unsafe the use of any additive if it has been found to induce cancer when ingested by man or animal, or if it has been found to induce cancer in man or animal by tests which are deemed appropriate.

Additives can get into foods directly—by intended addition as part of the process or through one of the ingredients; or indirectly through a leaching process from the container or from processing equipment. Thus, if a canner wanted to test market a canned food already standardized to which he desired to add a food additive, he would need not only a permit to deviate from the standards, but a regulation which would provide for the safe use of the additive. Coloring materials used in canned foods, standardized and unstandardized, now have to undergo testing for safety and be included on special lists before they may be used. **[The End]**

FASTER CHEMICAL DOCUMENTATION

A record breaking total of 75,000 new chemical compounds was reported by the world's chemists in 1960. Approximately one-fourth of the new chemicals, 19,000, were made by American scientists. Iron Curtain chemists reported approximately 9,000 new chemicals, while the Japanese accounted for almost 7,000 compounds. Other top chemical-producing countries include England and Germany.

The first cumulative index of the *Index Chemicus* published by the Institute for Scientific Information, Philadelphia, Pennsylvania, marks the first time that this vital information has been reported so promptly. The *Index Chemicus* was prepared by electronic computing equipment in the record-breaking time of two months—an historic achievement in chemical documentation.

Index Chemicus contains listings of chemical names, structural diagrams and molecular formulas; as well as complete bibliographical information, including article titles, authors, institutions, addresses and original journal references.

The Regulatory Functions of the Food and Drug Administration

By FRANKLIN D. CLARK

This Article Reviews Federal Food, Drug and Cosmetic Legislation from the Food and Drugs Act of 1906 to the Present. The Author, Who Is Assistant to the Deputy Commissioner of the Food and Drug Administration, Delivered this Address to the American Management Association in New York, June 1, 1961.

IT IS INDEED a pleasure and privilege to meet with you today. I bring you regards from Mr. John L. Harvey, the Deputy Commissioner of the Food and Drug Administration, who could not be present because of a conflict with a trip abroad. He asked that I bring his greetings to his many friends in your organization.

Your Program Chairman granted me considerable latitude in the particular aspect of the regulatory activities of the Food and Drug Administration to be discussed. I have chosen the development of the rule-making concept and the several variations of this procedure in the present Food, Drug, and Cosmetic Act, including its most recent amendments.

It would seem appropriate in presenting this problem to at least briefly trace the historical evolution of our organization and of the principal legislation we enforce.

The Food and Drugs Act of 1906 was the direct result of the crusading zeal of Harvey W. Wiley and of public indignation at some of the practices of the food industry which had been widely publicized. The law came at a time when food production and preservation were changing from the home kitchen to a factory operation, thus making the consumer dependent upon others to harvest, prepare and process

much of his food supply. Some of the primitive practices in the early food industry were indeed shocking. Although the primary purpose of the 1906 Act was to protect the consumer, it did have the very important effect of benefiting the honest and conscientious manufacturer by discouraging competition from those who would produce a debased food. This was not immediately recognized, but as the enforcement pattern and its results became apparent, endorsement by the more responsible segments of industry was attained.

Let us skip now to the early 1930s by which time some of the deficiencies in the 1906 Act had been demonstrated and technological advances had outstripped some of the provisions which were adequate in 1906. The production of new and wondrously potent drugs was starting to create problems which could not be handled under the existing statute. Vitamins and other foods for special dietary uses were entering the market. More subtle food fabrication and sophistication had been invented and the cosmetic industry had started its phenomenal growth.

The Food, Drug, and Cosmetic Act of 1938 was finally enacted after five stormy years. This Act was an extension of the 1906 statute and yet contained some radically new concepts. One in particular developed on the eve of the Act's passage as a result of a tragedy that underlined the necessity for pretesting of new drugs or new formulations of old drugs. A drug manufacturer conceived the idea that sulfanilamide in a liquid dosage form would be more acceptable to some patients than would a tablet or capsule. To prepare this elixir the manufacturer mixed the drug with a highly toxic vehicle, diethylene gycol. The simplest and most abbreviated toxicological test would have shown this mixture to be lethal, but no such advance precautions were legally necessary and none were taken. Over 100 deaths occurred. Congress therefore added to the pending bill a brand new administrative procedure designed to prevent further occurrences such as this.

Fundamentally, what is required for new drugs is that the promoter of such a drug not generally recognized as safe by qualified experts, must prove it will be safe under the conditions of its proposed use before it is placed on the interstate market. The government makes no charge for its part in this preclearance operation and in fact is under definite time limitations for considering the application. This control, which was so vigorously attacked as needless meddling with private enterprise, has come to be recognized as perhaps the

greatest influencing factor in the development of rational therapeutics during the past two decades. It is estimated that 90 per cent of the drugs prescribed today were unknown in 1938. About 13,000 new drug applications have been processed to date. Many drugs have not been allowed to enter the market, but many have. Thus, the first of a number of new administrative procedures was introduced into our food and drug laws.

Another new administrative concept was added in the 1938 Act. Besides broad authority to prescribe general procedural and definitive regulations there is authority which provides for the establishment of rules to explain what is required by particular sections of the statute and to describe the conduct and the activities that will be considered violative. For example, the Act gives authority to issue regulations specifying fully informative labeling for foods for special dietary use; to establish definitions and standards of identity and reasonable standards of quality and fill of container for most foods; and to describe in considerable detail the labeling that must be applied to drugs to insure that they will be safe for their intended uses. These regulations are promulgated and published in the *Federal Register* in proposed form and comments from all interested parties are solicited. After thorough consideration of the various viewpoints, they are subsequently issued in final form with the full force and effect of law.

The next rule-making development occurred in 1941 with the addition of the insulin amendment, requiring each batch of this life-saving drug to be certified by the government as to its strength, quality and purity before it could be marketed in interstate commerce.

In 1945 a really substantial step in the same direction was taken with passage of an amendment requiring pretesting and certification of each batch of penicillin and certain of its derivatives before marketing. Here in contrast to a preclearance procedure as for new drugs on the basis of a showing of safety by protocols and scientific data, we have a system where each batch of a particular drug product is examined and certified by the government on a fee basis for potency, safety and efficacy before it is allowed to be placed upon the market. Regulations are issued for acceptable dosage forms, potencies, labeling and packages. Since the original requirement to certify each batch of penicillin, four other antibiotic drugs have been added to the list by subsequent amendments.

Another evolutionary development in the rule-making procedure took place in the area of pesticide chemicals used in the growing and

marketing of agricultural crops. Most such chemicals are highly toxic, or they could not do their prescribed job. If they are toxic to pests in most cases they are also toxic to humans. The role they play in a modern agricultural economy is, however, such that they cannot be ignored but must be dealt with if possible. Indeed, if they can be used to raise better crops and not result in unsafe residues, we cannot object to such uses. Having recognized their toxicity and their usefulness, machinery was necessary to assure their safe use. The answer was the Miller Pesticide Amendment passed by the Congress in 1954. The problem was to establish what chemicals are needed to control a variety of agricultural pests; to determine how poisonous each of these chemicals actually was; to learn just how much of it is needed to control the pests and how much remains in what foods; and to arrive at how much of the toxic materials man can safely consume over his lifespan, and thus what a safe tolerance would be for the pesticide on the several foods consumed by man in his daily diet. As you can see from a statement of the problem its solution required estimations in entomology, food composition and consumption, and in toxicology. The 1954 statute is patterned in some respects after the new-drug controls, but in addition contains the unique feature of a tolerance. After the Department of Agriculture has assured us that a particular pesticide is useful and that its use in effective amounts and in effective ways results in certain residues on the agricultural crop, we require the manufacturer to demonstrate to us that there are adequate methods for determining and measuring such residues and also to submit to us pharmacological data demonstrating that such residues are safe. Unless residues remaining are safe, the pesticide may not be used, no matter how useful it might be. This service operates on money from fees which are set on a cost basis.

A raw agricultural product may have tolerances for several pesticide chemicals and a pesticide chemical may of course have tolerances for several different agricultural crops. If a tolerance for a particular pesticide on a particular crop is not found in the regulations, the tolerance is zero.

The Food Additives Amendment of 1958 is an extension of the same rule-making philosophy just discussed. Modern technology resulted in the development of food ingredients, some of which were in themselves toxic substances, but which could be used in safe amounts and accomplish their intended purposes, be it a smoother product, a more stable product, or one with other more desirable characteristics.

Therefore, this amendment requires that those who want to sell or use any additives for food must furnish safety data and analytical methods to the Food and Drug Administration before such additives can be used. Regulations are issued setting forth permissible conditions of use, including specifications of purity and tolerances when necessary. The amendment covers not only substances directly added to food, such as emulsifiers and anti-oxidants, but also those that may migrate to the food from processing equipment, packaging materials and the like. Again, if a safe use cannot be described, the substance cannot be used.

A special provision of the Food Additives Amendment is the so-called Delaney Clause which forbids food additives that cause cancer when ingested by laboratory animals or are found to be carcinogens by other suitable tests. This applies not only to foods for human use but also to feeds for food-producing animals.

No one in the United States had a full understanding of what was going on in food and packaging chemistry before the enactment of the Food Additives Amendment. Knowledgeable people in industry knew, of course, what new chemicals they were using. They probably had a pretty good idea what their competitors were using. But they did not have a full picture as applied to the entire food and packaging industry. Neither did we in the Food and Drug Administration fully realize the extent of the use of new chemical substances in connection with food production and handling. We knew, of course, the use of additives was substantial, but we were just not prepared for the volume which was encountered.

The truth is that a complete revolution in food and packaging technology has been taking place in the past few years and is continuing. Especially in the paper, packaging and plastic industries, the amendment stimulated the new awareness of the necessity for checking all substances that come in contact with food from using them. The reason is, of course, not solely the enactment of the Food Additives Amendment. The food industries have always wanted assurance that their packaging materials are safe. But now they are insisting that the substances they use in food and food packages be cleared with the government for safety.

The Color Additive Amendments were enacted on July 12, 1960. Until that date, coal-tar colors for use in foods, drugs and cosmetics were subject to government certification where it could be shown that

they were harmless. Other colors in or on foods were subject to the safety provisions of the Food Additives Amendment. The old coal-tar color provisions did not contain authority for limiting the amount of the color used.

When some of the colors formerly thought to be suitable for use were found by modern-day pharmacological tests not to be harmless, it was necessary to remove them from the lists of colors certificable for food use. These investigations followed instances of illness of many children after eating highly colored novelty foods. Similar action was taken in the case of certain drug and cosmetic colors when investigations showed that they could no longer be regarded as harmless.

The Color Additive Amendments, although based on the same fundamental concept of safety-for-intended-use as is present in the Pesticide and Food Additive Amendments, contain provisions for variations in the rule-making procedures. In this statute, the Secretary is authorized to prepare and publish lists of acceptable color additives for use in or on foods, in or on drugs and in or on cosmetics. He may designate any restrictions on the use of such listed colors that are necessary for their safe use; and he may require batch by batch certification for purity if such is necessary to protect the public health.

If a color additive, and this definition now includes all colors whether or not coal-tar colors, is not listed for a particular kind of use, it is illegal if so used. Its lack of listing may be because it has been demonstrated unsafe or that it has not been adequately tested. Listing will only be made upon a positive showing of safety for its intended use.

The Color Additive Amendments also contain the Delaney Clause, which prohibits the listing of color additives which cause cancer when ingested by laboratory animals, or, if the substance is not one which is ingested, if it is found to be carcinogenic by other appropriate tests.

We can now look back from the vantage point of today and see a philosophy of a changing concept of food and drug law drafting. First, we can see a trend towards preventive enforcement rather than punitive. Emphasis is placed upon government preclearance, pretesting, or pre-approval. Secondly, the laws enacted by the Congress still are expressed in considerable generality, but the Congress is relying more and more upon the administrative agency to interpret the statute and pinpoint the actions that will be and will not be tolerated

through the administrative rule-making process. For example, a new drug may be marketed legally only after evidence concerning its safety has been submitted to and accepted by the Food and Drug Administration. There is, therefore, little if any room for confusion on the part of the would-be manufacturer of a new drug. Insulin and the certifiable antibiotics may be marketed only in accordance with regulations that set forth in detail conditions that must be met and only after a sample from the batch in question has been examined by the Food and Drug Administration and found acceptable. The pesticide regulations set forth in detail the allowable quantities of permitted pesticides that may remain in or on crops when they are marketed so that all one has to do to determine whether his crop is legal from the standpoint of pesticide residues is to make an appropriate analysis. Normally, even this is not necessary. When the labeled directions of the insecticide have been carefully followed, with reference to the crop and to the time and amount of application, no illegal residues will remain. In food and color additives we determine upon request or petition the conditions under which the additive may safely and legally be employed and we issue a regulation stating these conditions for all interested parties.

The net result is that law compliance is becoming easier for the individual who wishes to abide by the law. He doesn't have to wonder whether a product that he is going to market will be interpreted by the courts as meeting the requirements of the Food, Drug, and Cosmetic Act in those numerous cases where, following the administrative rule-making process, we have established by regulation the exact conditions that will constitute law compliance.

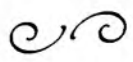
The bulk of our efforts in the administrative and legal fields are likewise being devoted to this rule-making process that has become so important today. Between 1938 and 1954, we established by the old rule-making procedures one formal tolerance for a poisonous substance in food. This was the tolerance for flourine on apples and pears which was later declared invalid by the courts. We had a very few informal tolerances, for example for lead and arsenic on apples and pears, which were not fully effective as regulatory tools. Since the enactment of the Pesticide Chemicals Amendment in 1954, we have established more than 2,000 individual tolerances for well over 100 pesticide chemicals for a variety of crops. It is quite apparent that there will be a similar flow of regulations for food additives.

Last year a very large proportion of the time of the top management of the FDA was spent on regulations and problems that arise from the rule-making procedures. It is a matter of some satisfaction to us that we have been finding it possible to increase the consumer protection available under the Food, Drug, and Cosmetic Act by rule-making through which the requirements can be made clear to all who wish to comply. I do not mean to imply at all that the conventional legal actions in the federal courts are coming to an end. The crucial phase of this new look in the food law field will come as we proceed with the enforcement of the regulations we are issuing. There will be some firms that fail to abide by the new rules, and there will be continuing necessity for legal actions because of such non compliance.

The Pesticide, Food Additive and Color Additives Amendments, all enacted in the last six years, present a serious challenge. We are assigned the heavy task of so restricting the use of additives that directly or indirectly enter our foods that no harm can come.

We can meet this challenge, and thus protect the public health, only to the extent that we have good scientific appraisals of good scientific data to help us in drafting the rules for permissible use of additives, that we have good inspectional techniques to detect any misuse of additives and that we have means of enforcing the established rules. We must have all of these things, if this new approach to food safety is to succeed.

It is important for us to all realize that the facilities must be available to provide the three essential steps in regulation through administrative rule. We must have enough technical and other factual information, we must study and soundly evaluate this and formulate the rule, and we must systematically enforce the rule on a basis that gives adequate assurance to all that the rule is being followed—and not disregarded. **[The End]**



A New Approach to Weights and Measures Control

By GEORGE P. LARRICK

This Paper Was Delivered at the 46th National Conference on Weights and Measures, Held at Washington, D. C., on June 15, 1961. Mr. Larrick Is Commissioner of Food and Drugs, U. S. Department of Health, Education, and Welfare.

IT IS A PLEASURE to be with you again and to have the opportunity of considering matters of mutual interest with you.

Mr. Bussey has told me of your interest in what is being done, and what more can be done, working in cooperation with you to correct violations of the law involving incorrect and inconspicuous declarations of the quantity of contents of packages of foods, drugs, and cosmetics. At your meeting last year we reported on a nationwide survey made specifically to obtain information on this subject and we supplied to all who were interested a tabulation of our findings. This involved 106,695 food packages in 35 different commodity groupings.

This special survey differed from our normal and usual approach which involves the routine checking on quantity of contents on samples collected for examination for any other violation plus follow-up on any specific complaint received from the trade, consumers or cooperating law enforcement officials. For the purpose of giving you up-to-date facts on the results of such routine activities, we reviewed our file for a 12-month period from April, 1960, to April, 1961. During this period our laboratories routinely examined all samples for quantity of contents. We found serious shortages that required seizure of 14 shipments of foods, such as: coffee, bakery products, honey, confectionery and seafood.

In addition, we have under consideration several other samples where there were shortages. A criminal prosecution case filed some-

what earlier and based on spices adulterated with buckwheat hulls and packaged short weight was terminated late in 1960 with a fine of $1,000.

In our routine enforcement actions (as well as in some flagrant cases which are handled separately), we are on the alert for violations of the provisions of the law calling for conspicuous declaration of required information including quantity of contents statements. Canada recently amended its regulations to require such declarations to appear in boldface type of specified size for each of four different defined total label areas and the statement is to appear on the main panel of the label "Or any panel other than the bottom of the package." This will, of course, affect many firms in this country shipping their products to Canada. Our regulations do not carry this specific requirement, but as you know, we have continued to advise inquirers that, to insure compliance with our law, mandatory information should appear conspicuously on the principal display panel of the label. Firms that elect not to follow such advice do so on their own responsibility and under such circumstances it is necessary to make a determination on the basis of the facts in each particular instance as to whether we believe we can establish that the law has been violated.

Frequently we uncover serious economic cheats that do not fall in the weight shortage area but rather in the weight or volume increase area—for example, due to the addition of water—one of the oldest and most profitable forms of adulteration. After a two-week trial in Texas last month the Court found a Houston firm and those responsible for its operation guilty of shipping watered and sweetened orange juice labeled as fresh orange juice as nature made it, with nothing added. The product was actually only about one-half orange juice. The convictions resulted from long and painstaking work by our inspectors, who used field glasses and cameras to get evidence on the surreptitious operation after laboratory tests indicated that the product was being adulterated. Whenever inspectors made regular inspections the hidden sugar could not be located and the plant always promptly started packing pure orange juice. From a nearby rented apartment they later observed an unmarked truck delivering sugar to a shed toward the back of the firm's premises, from which it was carried by bucket brigade into the plant. Still later evidence was uncovered showing cash purchases of over 750,000 pounds of sugar by employees who were permitted to carry no identification. Total fines assessed by the court amounted to $20,000 and in addition the firm's

officials received prison sentences which were suspended except for one official who must serve six months. These officials also have yet to stand trial for perjury during testimony in their own behalf and an injunction order was signed in May to stop further violations.

At your June meeting last year, Mr. Hubble of our Bureau of Enforcement related some of the difficulties we have been having in enforcing the prohibitions of the law against deceptively packaged foods, drugs and cosmetics, and described the Delson Candy Company chocolate covered thin mints case that had been contested by the owner of the goods. You may recall that it involved a rectangular package with hollow ends and hollow dividers on which there was an accurate net weight statement, but in which the candy occupied only 34% of the cubic content. It contained only 30 mints whereas the package could have held 41 except for the hollow ends and dividers.

The lower court decision, which was unfavorable to the Government, was appealed to the Third Circuit Court of Appeals. The unanimous ruling of the three-judge court in effect states that food cartons may not be larger than reasonably necessary to protect the contents from damage, taking into account the alternative methods of protection available. Three principal concepts are developed in its opinion:

(1) That the consumer has a right to expect that a nontransparent container of food is reasonably full; (2) That the size of the container is a reliable index to the amount of food in the package; and (3) That the package is not filled with excessive padding.

The case has been remanded to the district court judge for reconsideration and findings consistent with the law and the facts. We propose to step up our regulatory activity against deceptive packaging if the matter is finally adjudicated favorably to the Government. This, of course, will be a long step forward in consumer protection.

All of us are anxious to see both the federal and the state or local laws with respect to weights and measures enforced as effectively as possible.

From the facts in our possession, despite the number of legal actions we have taken since 1959, there are indications that there are still too many occasions in which a manufacturer produces and markets foods that are short of the declared weight or volume. We

note that a number of you have also reached the conclusion that something more needs to be done to give adequate consumer protection.

I wish I were in a position to tell you that the Food and Drug Administration is prepared to increase many-fold the effort it will put in to investigation of short-weight practices during the coming year. I cannot give you this assurance. We still have many health problems that require attention. The funds under which we are operating this year and the funds that we have requested for the following year do not provide for sufficient increase in weights and measures work to give any degree of assurance that we will begin to control the problem adequately with resources available to the federal government.

We know that you also are limited in the amount of attention that you give to the problem.

So the question now is: "What can we do with our limited resources to increase significantly the protection that the consumer gets in the weights and measures field?" We have a suggestion for your consideration which may yield real benefit. And it is based upon experience that we have had in another field—the animal feed area.

Over a period of years we have had insufficient manpower to do as much work in checking the accuracy of label claims for protein, fat and other components of animal feeds as might be desired. Many states had good programs.

But a state, acting under its laws, often was unable to force a manufacturer in another state to make fundamental correction of bad practices. So we commissioned many state feed control officials as agents of the Food and Drug Administration for the purpose of collecting and examining samples of foods originating outside their states. When such examinations have shown significant shortages in feed nutrients, the states have forwarded the facts to us and we have been able to bring action, either seizure or prosecution, under the federal law for the violations detected. We have been unable to reimburse the states for their time and expense in this endeavor but I believe they are satisfied that the benefit to their citizens far outweighs the relatively minor expense of the cooperative effort in which they have engaged.

In several states the principal officials responsible for weights and measures enforcement work already hold similar commissions from us. We would welcome requests for such commissions from other officials responsible for this type of work in other states. We

would like to see a concerted nationwide effort by the state officials and the Food and Drug Administration to stamp out the shipment of short-weight merchandise. If you can help us by detecting the cheats that are being perpetrated within your state borders by firms who escape your jurisdiction because they are located in another state, we can help you by bringing legal actions where indicated.

We should add one precautionary note: Under the federal law we may take action against products that are short weight when shipped. In many instances simple net weight determinations at point of sale will be enough to establish a violation.

If you think well of the idea, perhaps you will wish to name representatives to help work out the details of a joint program. We hope you will look with favor upon our proposal and that our coordinated efforts will result in a substantial reduction in short-weight and short-volume foods in the American market place. **[The End]**

FDA REPORTS RECENT SEIZURES

The Food and Drug Administration announced recently that, from July 10 to August 3, 43 seizure actions were filed in federal courts in a nationwide campaign against foods it charges to be short weight or otherwise improperly labeled. FDA has asked U. S. Attorneys to institute 24 additional seizure actions.

The agency said "improper labeling" includes failure to declare required information such as ingredients and net contents as prominently and conspicuously as required by the Federal Food, Drug and Cosmetic Act.

The law states that:

"A food shall be deemed to be misbranded . . . if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

Commenting on the drive, Commissioner of Food and Drugs George P. Larrick said: "For several years we have not been able to give adequate attention to honest packing and prominent labeling in the food field because of the pressure of other duties.

"Through educational efforts and a limited number of regulatory actions, we have tried to keep industry aware of its responsibilities," the Commissioner continued. "However, from several sources we have reports of continued abuses, and these are being borne out by the survey now under way.

"These abuses must be corrected. However, I would like to point out that most foods are not short weight. Although there has been a variety of foods seized, the abuses obviously do not involve the whole food industry."

Mr. Larrick said that "a total of 4,436 samples representing our general food supply have been examined in the recent survey."

"Common or Usual Name"— Its Meaning, if Any

By VINCENT A. KLEINFELD

This Paper Was Presented Before the Technical Symposium, Food Additive Session, of the Flavoring Extract Manufacturers' Association Convention, Held in New York City, May 16, 1961.

ONE PROVISION of the Federal Food, Drug, and Cosmetic Act which is probably honored more in its breach than its observance is the section [403(i)] dealing with the naming of ingredients on the labels of food products. The reason for the fact that the labels of many foods do not comply with the section, at least as it is generally but not invariably construed or interpreted by the Food and Drug Administration, is that it frequently does not make sense to set forth what some persons, either in government or industry, consider to be the "common or usual name" of each ingredient. In addition, of course, no manufacturer is anxious to employ on the label of a food a formidable appearing list of complicated and esoteric chemical names.

The section provides generally that the label of a food which has not been standardized by the Food and Drug Administration must bear the common or usual name of the food "if any there be." If the food is fabricated by two or more ingredients, the label must bear the common or usual name of each ingredient, except that spices, flavorings and colorings "other than those sold as such," may be designated as spices, flavorings and colorings without naming each. It is interesting to note that, with respect to a food which does not have more than one ingredient, the common or usual name must be employed "if any there be." This avenue of escape is not used where there are two or more ingredients. Why the same escape clause was not used in the latter situation is by no means clear.

Why did Congress require the listing of ingredients by their common or usual names? There were two reasons. One reason, as a Congressional Committee put it, was "to discourage the practice of

coining a fanciful, high-sounding name for a product composed largely of cheap ingredients, which could not be extensively marketed at the exorbitant prices charged except by cloaking its identity under such a name." The second reason, again as the Committee explained it, was that "a surprisingly large proportion of our people are made ill—some violently so—by common ingredients of food which most people consume with impunity. That large group of unfortunates can protect themselves from the consumption of foods to which they are allergic by the information made available to them" by the requirement that the label of the food set forth the common or usual name of each ingredient. In ascertaining how the section has been interpreted and administered, it is interesting to keep in mind at all times these reasons for the inclusion in the Federal Food, Drug, and Cosmetic Act of the food ingredient labeling provisions.

The section contains a proviso which could make the requirement a more resilient, practical one rather than what it has turned out to be in numerous instances—a meaningless, even misleading, provision which has little if any bearing on the Congressional reasons for the enactment of the section. The section contains a proviso that to the extent that compliance with the labeling of ingredients "is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary." I do not know whether, in all the years since the passage of the Act in 1938, any exemptions have been granted because the revealing of the ingredients might result in deception, for example. Yet, the frequent administrative holding in some instances that the "common or usual name" provision necessitates the use of a lengthy, mysterious, and often unpronounceable chemical name can be said with some reason to mislead the consumer rather than help him. Certainly it conveys no useful information to him.

Upon the passage of the Act in 1938, various industries, such as the soft drink industry, were told that until definitions and standards of identity were promulgated the common or usual names of the ingredients would not have to bet set forth on the labels. This type of exemption is still in effect in some instances. But the government does not appear to have utilized the exemption in particular situations to permit the use of some generic terms, such as "emulsifier," which has at least some meaning to the consumer, rather than some chemical name which has no significance to him. And it must always be kept in mind, as the government has always strenuously and clearly held,

that it is the consumer and not chemists or experts whom the law is primarily designed to protect.

The Food and Drug Administration may at long last be beginning to accept this concept. In January of this year the Agency announced a proposal to establish a definition and standard of identity for fat preservative, fat antioxidant, added to fats or to foods containing fats to retard the development of rancidity. The food can be prepared from any of ten ingredients, with names such as butylated hydroxyanisole, nordihydroguaiaretic acid, and monoisoproply citrate or combinations of these ingredients. The Food and Drug Administration proposes to permit the use of the terms "fat preservative" or "fat antioxidant" instead of the non-informative chemical names of the ingredients. The proposed regulation states that:

> When a fat preservative, fat antioxidant, is present in a fabricated food as an ingredient, it may be declared as such without reference to the name or names of the optional ingredients present in the fat preservative, fat antioxidant.

In announcing this proposal of the Food and Drug Administration, the Commissioner stated that it would clarify consumer understanding.

What is a "common or usual name?" It seems to me not to be an oversimplification to say that we, as well as the government, should first look at the dictionaries. "Common" is defined as "generally or probably known," "notorious," "widespread," "general," "ordinary," "familiar," "usual," etc. "Usual" is defined as "habitual or customary," "such as is commonly met with or observed in experience," "ordinary," etc. Again, considering the acknowledged fact, enunciated by the government and approved by the courts without exception, that it is the consumer whom the law is designed to protect, can a requirement that esoteric and meaningless chemical names be employed he said to make sense or even to be in compliance with the Act? Would not a generic term, in many instances, be more informative to the consumer?

The government's position has not been an entirely consistent one. For example, only a few months ago a government official, at an administrative hearing to standardize a food product, testified that in his opinion a common or usual name "is the name by which the product is known when it is being seriously and accurately described. What I might call the colloquial term applied to the product which is readily understood by those who hear it, is not necessarily the common or usual name I feel in terms of a legal standard. We all use inaccuracies in our speech, and those who hear us recognize and

make allowances for those inaccuracies." Yet "colloquial," again according to the dictionary, means "characteristic of or familiar to ordinary or familiar conversation rather than formal speech or writing," and is often mistakenly used with a connotation of disapproval, as if it meant vulgar or incorrect usage, whereas it is merely a familiar style used in speaking rather than in writing. The official further testified, with regard to the name to be given to the food involved, that "there is no common or usual name in the sense that the housewife has a term which she commonly uses and which accurately and adequately describes the product." Here he apparently is saying that the common or usual name concept is not enough, notwithstanding the use of the expression in various sections of the law, and that in his view the term must be what the government believes is "accurate" and "adequate." But these are not the terms which Congress chose to employ.

And a United States Court of Appeals has held that the name of a drug as it appears in a pharmacopoeia is not necessarily the common or usual name of the drug. The Court said:

> What did Congress mean when it made use of the phrase "common or usual name?" The adjective "common" has a multiplicity of definitions, but the first and usual definition is "Belonging or pertaining to the community at large . . . habitual or notorious . . ." The adjective "usual" is ordinarily deemed to be synonymous with the adjective "common." We think, therefore, that Congress intended that drugs should be labeled with the name by which they are known to the community at large.

It seems to me that this does not include a name which is meaningless to the consumer; in fact meaningless even to many in industry. In line with this, there is no doubt but that if a drug manufacturer calls his product "acetylsalicylic acid" instead of "aspirin," the government will take the position that he is violating the law.

There are instances where the position taken by the government has been a most reasonable one—where the government has simply said, in order to reach a sensible result, that a generic term may be used even where the common or usual name might have at least some sense. For example, the government has held that the oil or shortening in which potato chips and sticks are prepared need not be declared by its specific name, and that the term "vegetable oil" or "vegetable shortening" might be used. And the baking industry was advised that, in view of the impracticability of always anticipating the particular shortening which might be utilized at any given time, the term "shortening" would be regarded as substantial compliance.

The government has also stated that ordinarily it would be a substantial compliance with law to indicate the presence of resinous glaze in confectionery by the term "resinous glaze." The government has permitted small quantities of excipients and fillers to be described as "excipients and fillers," ordinary masticatory ingredients of chewing gum to be labeled as "masticatory substance" or "gum base," and ingredients in gum which affect plasticity to be designated as "plasticizing ingredients," "plasticizers," "softening ingredients" or "softeners." It was held, further, that since oils in food had been subjected to hydrogenation, which had the effect of changing the identity of the ingredients, terms such as "hydrogenated vegetable oil" "made exclusively from hardened vegetable oils," etc. could be used. In connection with monosodium glutamate, the government has permitted the use of either "monosodium glutamate, an artificial flavor," or a more general term "vegetable protein derivative, an artificial flavor." On the other hand, in numerous other instances, the government has insisted that complicated chemical names be employed, rather than generic terms which conveyed at least some valuable information to the consumer. Thus, in connection with drugs, where the same general concept as to "common or usual names" holds true, the government stated that Mercurochrome was a trademark, not a common name, and that the chemical term "dibromoxymercurifluorescein sodium" should be used in the ingredient statement.

As a matter of law, flavorings do not differ from other food ingredients except with respect to the situation where a flavoring is used in a food with other ingredients. In such a situation, the Federal Food, Drug, and Cosmetic Act provides that flavorings (as well as spices and colorings) may be designated as such. It is clear that Congress realized that because of the many and complex ingredients found in flavorings, it would be extremely difficult, and would serve no really useful purpose, to compel the common or usual name of each ingredient found in a flavoring to be set forth on the label of a food in which the flavoring is employed. It would seem that a plea might be made to Congress that the reasons applicable to a food in which a flavoring is utilized are equally applicable to the labeling of the flavorings themselves. This would have to be accomplished by Congressional action for the Food and Drug Administration has held, although perhaps it did not have to do so, that flavors which were not standardized and which were fabricated from two or more ingredients had to be labeled with the "common or usual name" of each ingredient. The Agency has stated that the ingredients should be listed in the

order in which they contribute flavor, followed by the specific name of the vegetable gum and other ingredients. Of course, water must be listed when present.

As far back as 1941, the Food and Drug Administration held that the terms "extract" and "flavor" are not synonymous; that "extract" implies an alcoholic product; and that flavoring products prepared with vehicles other than alcohol should be labeled with the term "flavor." If a flavoring, as in the case of any food, is defined and standardized by the Food and Drug Administration, there would be no necessity under the Act for designating, on the label of the flavoring, the names of the ingredients of the flavoring. As you probably know, the Federal Food, Drug, and Cosmetic Act provides that whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of the consumer, he is authorized to promulgate regulations fixing and establishing for any food, under its common or usual name as far as practicable, a reasonable definition and standard of identity. When the definition and standard of identity is promulgated, the names of the ingredients need not be specified on the label; only such optional ingredients must be named as are specifically so required by the Secretary in order to promote honesty and fair dealing in the interest of consumers.

The rule of reason has sometimes been used in connection with flavorings as with respect to other food ingredients. In 1940, the government held that, in connection with imitation flavors, group names of ingredients of the flavors could be used although at least one member of each group should be specifically named. For example, names such as "benzaldehyde and other aldehydes," "ethyl acetate and other esters" were approved.

It can be seen that "common or usual name" can be considered to be an elastic term. Certainly the government has not in every situation insisted that the apparent letter of the law be observed. This may well be because it can be held with reason that long and complicated chemical names do not necessarily constitute "common or usual names," and that generic terms more clearly, in many instances, fall within the statutory definition as reasonably interpreted.

[The End]

The Scientists' Forum

Toxicologists' Views of Regulations Under the Hazardous Substances Labeling Act

By BERNARD L. OSER

President and Director, Food and Drug Research Laboratories, Inc.

Dr. Oser, Scientific Editor of this Journal, Presents a Montage of Criticism Against FDA Regulations Which Were Published April 29. This Article Includes Extensive Quotations of Testimony by Five Leading Industrial Scientists, Including Dr. Oser, at a Public Hearing Held by the FDA in July.

FOLLOWING PUBLICATION in the *Federal Register* of April 29, 1961, of the Proposed Definitions and Procedural and Interpretative Regulations under the Federal Hazardous Substances Labeling Act, many critical comments were expressed, both publicly and privately, by toxicologists. These were directed principally toward the policy of "freezing" toxicological test procedures into the regulations. Exception was also taken, however, to the details of many of the proposed procedures, particularly with respect to the criteria and methods for determining whether or not household products are toxic or irritant. On July 13 and 14, the Food and Drug Administration held a public hearing in Washington at which an opportunity was afforded to present testimony in support of these objections. Among the witnesses who testified were a number of industrial scientists with long experience in the assessment of the toxicity of chemical substances, who are charged with the responsibility of evaluating potential hazards and advising with respect to handling and precautionary labeling.

In order to give expression to the views of these toxicologists, The Scientist's Forum presents herewith a composite series of excerpts from their statements, each of which is attributed to its author, as indicated by his initials. Selections have been made from the presentations of the following individuals:

Horace W. Gerarde, M. D., Ph. D., Esso Research and Engineering Company; Bernard L. Oser, Ph. D., Food and Drug Research Laboratories, Inc.; Verald K. Rowe, M. S., The Dow Chemical Company; C. Boyd Shaffer, Ph. D., American Cyanamid Company; Henry F. Smyth, Jr., Ph. D., Mellon Institute (Union Carbide Corporation); John A. Zapp, Jr., Ph. D., E. I. duPont de Nemours and Company.

It is not intended to imply that these were the only scientists among the several hundred persons who either submitted statements to the Food and Drug Administration or testified at the hearing. The excerpts quoted are to some extent repetitious but by no means do they cover all the points raised by the toxicologists. Furthermore, no reference is made in this article to testimony of these or other witnesses relative to such matters as the definition of containers, the placement and typography of label statements or similar subjects of a non-toxicological nature.

In the final order establishing the regulations, which appeared in the *Federal Register* of August 12, 1961, cognizance is taken of some, but not all, of the recommendations of these toxicologists. These regulations are reported to have been predicated also on the recommendations of two advisory panels designated by the Food and Drug Administration, composed, respectively, of dermatologists and toxicologists (nonindustrial, it may be added). Hence this article will conclude by referring to certain of the changes made in the initially proposed regulations. It is hoped that the views of the toxicologists expressed here will be of interest to members of the legal profession concerned with the testing and labeling problems created by the new labeling law.

Introductory Comment

Although the death rate in the United States due to accidental poisoning by solids and liquid substances is less than 0.1 per cent of deaths from all causes, the annual total of approximately 1400 deaths in recent years is quite significant. In the context of this particular hearing it should be pointed out that approximately two-thirds of these accidental deaths resulted from the misuse of drugs, while the remainder arose from ingestion of, or contact with, petroleum products, heavy metals, corrosives, solvents, etc. However, among young children these

ratios are reversed (cf. reports from the U. S. National Office of Vital Statistics). To the extent that legislation can reduce this number, all efforts should be made to enforce it in the most effective manner possible.

A recent analysis of nearly 12,000 cases of accidental poisoning over a period of years, showed that in about two-thirds of the cases the causative agent was not in its customary place in the home and in one-third of the cases it was not even in its original container (Cann, H. M. and Verhulst, H. L., Journal of the American Medical Association, *168,* 717 (1958)). In 85 per cent of the cases involving children there was said to be parental supervision. We should be under no illusion therefore that precautionary labeling will provide complete protection against accidental poisoning. However, it can not be denied that such labeling can warn of hazards where none are reasonably foreseen and may establish an attitude of respect for the proper storage and use of household products. Nevertheless regulations leading to the excessive, non-essential use of "poison" or "warning" labels could conceivably defeat its very purpose.

Toxicity has been defined as the "*capacity* of a substance to produce injury" whereas hazard is the "probability that injury will result from use of a substance in a proposed quantity and manner" (National Academy of Sciences-National Research Council Publication 750, (1960)).

In the Act a hazardous substance is defined in terms of two criteria, first, the type of hazard (viz., toxic, corrosive, irritant, etc.) and second, "the probability that such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use including reasonably foreseeable ingestion by children." Thus cognizance is taken of the distinction between toxic and hazardous substances, and in this way Congress, with great foresight, established two separate but equal requirements by ascertaining whether a substance is hazardous to the extent of requiring precautionary labeling. In other words, a non-hazardous substance may be one that is either non-toxic, non-corrosive, etc., or one that is toxic, corrosive, etc., but is unlikely to cause substantial injury or illness under conditions of use.

If these distinctions are clearly understood the tendency toward excessive use of precautionary labeling could be avoided without sacrifice of the important public safety advantages to be derived from the proper use of such labeling. I feel it is necessary to emphasize this point because many individuals and companies in the regulated industries are assuming that every product must be subjected to animal tests for toxicity, irritancy, etc., irrespective of the conditions of use and whether the history of use, which in many cases represents millions of packages over long periods of time, suggests the probability that substantial injury or illness may reasonably be expected to result. This is not to belittle the necessity for appropriate testing when such likelihood exists. **(B. L. O.)**

Evaluation of Human Experience

The second but equally important requirement of substantial injury or illness, contained in the statutory definition of hazardous substance, should be reflected in a statement in the regulations. The food additive regulations provide "in reaching a decision on any petition . . . the Commissioner will give due weight to the anticipated levels and patterns of consumption of the additive specified or reasonably inferable." Similar considerations are, in my opinion, applicable to foreseeable conditions of use relating to the evaluation of the potential hazard of household substances. Among these would be the size of the container, the

material of which it is composed, the type of closure, the viscosity and physical state of the contents (i. e., whether liquid, solid or semi-solid), its taste or odor, its emetic properties, and the history and experience in the use of household products. . . . Section 191.2 gives "reliable data on human experience" precedence over animal data in classifying a substance as hazardous. As now worded however this appears to be a one-way street since the inference is that greater weight is given to human experience only if it indicates the substance to be more hazardous than is suggested by the animal tests. It would seem reasonable that it work both ways especially in view of the highly exaggerated conditions under which animal tests are conducted compared with actual or reasonably foreseeable conditions of handling or use. **(B. L. O.)**

. . . the regulations should specify the weight to be attached to previous experience with use of a substance, or of related substances, by consumers, and how this experience is to be ascertained and verified. The Proposed Regulations give no legal, experimental, or investigative test by which one wishing to comply with the Act can determine if a substance "may cause . . . injury . . . during . . . reasonably foreseeable . . . use," yet such a determination is the crux of the Act. Instead they set forth much toxicological detail, which is speciously presumed to run parallel to hazard. **(H. F. S.)**

Objections to "Freezing" Tests

Toxicologists generally prefer to have some degree of latitude in applying test procedures. They prefer to exercise a reasonable degree of choice of procedures when alternatives permit equally sound or possibly even more reliable conclusions, and to employ test procedures which simulate to some degree the conditions of use or exposure. This principle has been recognized in the regulations under the food and color additive sections of the Federal Food, Drug and Cosmetic Act which provide that the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated (or provided) in current publications of the National Academy of Sciences-National Research Council. However they further declare that petitions will not be denied if they are based on procedures other than those outlined in these publications provided they give equally reliable results. **(B. L. O.)**

. . . I feel strongly that it is not in the interests of the public or of industry or government to fix procedures by which toxicological investigation must be done. By this I do not wish to imply that the methods as described will not give useful information but rather to point out that those methods given are not the only methods which will give useful, adequate and reliable information by which a competent investigator can assess the hazards of chemicals . . . the detail is unimportant in the hands of the competent investigator. It is the objective one must keep in mind and the route is immaterial. . . . I feel confident that other persons doing this type of work have their methods which also yield satisfactory information . . . if specific methods become a part of regulations, they will be the *only* methods recognized as fulfilling the requirements of the Act. . . . I suggest that a general statement be made in the regulation to the effect that the classification of materials under section 191.1(e), (f), (g), (h) and (i) shall be made by a qualified investigator. The investigator then would be allowed whatever methods he deems appropriate so that he may reach conclusions which will

fulfill both the requirements and the intent of the Act and upon which he is willing to risk his good name and reputation. **(V. K. R.)**

. . . The representative of our Legal Department who sits on our Label Committee tells me that failure to comply with the regulations in explicit detail would constitute *prima facie* evidence of negligence in the event of a lawsuit for alleged injury from one of our products, even though the product was properly labeled.

I do not think that it is the intent of the Food and Drug Administration to interfere with the judgment of qualified investigators, nor hinder their development of new and improved techniques. However, unless the specification of test procedures in detail is eliminated from the final regulations, I will have no choice but to alter all of our pertinent scientific procedures in order to fulfill my responsibility to my company's interest.

. . . In the last analysis, an experimental observation is of little value until it has been interpreted, and, if it is assumed that interpretation will be done by qualified persons, I feel we may safely leave to their judgment the precise steps by which the observation was obtained. **(C. B. S.)**

. . . We question whether the regulatory pattern should be frozen to one type of test. By way of illustration, we note that the test methods described for the evaluation of skin absorption toxicity, skin irritation, and eye irritation are those currently used by Dr. Draize of the Food and Drug Administration. Du Pont at its Haskell Laboratory for Toxicology and Industrial Medicine evaluates skin absorption toxicity, skin irritation and eye irritation by procedures similar to, but not identical with, those of Dr. Draize. We believe our results are just as valid as those obtained by the Draize tests. **(J. A. Z.)**

. . . The situation here is different from the question of flash point, where the American Society for Testing Materials has long specified authoritative methods which are generally accepted. No professional scientific body has proposed standard methods for the determination of acute toxicity, irritation, and eye injury. No authoritative methods exist. . . . If the Administration wishes to cite its own laboratory methods as helpful guidance to the inexperienced toxicologist, a descriptive booklet would be helpful. **(H. F. S.)**

. . . neither the definitions for highly toxic substances contained in the statute nor those for toxic substances in the proposed regulations take into account such pertinent factors as the sex of the test animals; whether or not they are to be fasted prior to dosage and for how long; whether or not a diluent is to be used in administering the test dose, particularly if it is a solid or semi-solid material, and if so, what it should be; the rate of air flow or number of animals per unit volume in the test chamber in an inhalation toxicity test, etc. Apparently any conditions would be suitable so long as they conform to "good pharmacological practice". Would it not be desirable therefore instead of attempting to define the details of these tests by regulation, to provide only that they are conducted by competent toxicologists and conform to good pharmacological practice or to some recommended procedure such as those described in the Food and Drug Administration's handbook "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics", or to any other procedures which yield equally reliable results. **(B. L. O.)**

"Highly Toxic" and "Toxic" Substances

. . . the listing of certain solvents as "highly toxic on the basis of available data on human experience" raises the question of whether this means mixtures of these solvents alone, or mixtures or compositions containing any amount of any of them. If the latter is implied it should be pointed out that the accidental ingestion of low concentrations of these solvents can be without significant effect. As a matter of fact methanol, for example, is a normal constituent of certain alcoholic beverages, turpentine is present in certain drugs, and some of the other solvents may occur as minor residues in food ingredients or as migrants from equipment or packaging materials. Whether or not they are highly toxic would depend entirely upon the concentration or amount ingested . . . . **(B. L. O.)**

. . . 191.4, listing substances declared to be highly toxic on the basis of human experience, is totally without foundation. The Act defines "highly toxic" as having an acute oral rat LD_{50} of 50 mg. per kg. or less, rabbit dermal LD_{50} of 200 mg. per kg. or less, and one hour rat LC_{50} [by inhalation] of 200 PPM or 2 mg. per liter. The only substances listed for which the human LD_{50} is approximately known are ethylene [glycol] and diethylene gylcol, of the general order of 1000 mg. per kg. for humans. This is a human toxicity greater than that for rats, but far less toxic than the Act's definition of highly toxic. Section 2(h)(2) of the Act empowers the Secretary to rely upon the human data on "the above-named dosages or concentrations," when that is known, in determining that substances are highly toxic. The human data on ethylene [glycol] and diethylene glycol show that the LD_{50} is far greater than 50 mg. per kg., hence they cannot be highly toxic under the Act. Specific substances containing the six named components can be required to carry appropriate labeling under 191.1(r), without debasing the concept of highly toxic. Human experience with these six materials is that they are of such a physical nature, or have such uses, that they are likely to be handled hazardously, not that they are highly toxic to humans. **(H. F. S.)**

I appear here today to present my views regarding the proposed regulation to label kerosine [sic] or a mixture containing kerosine as a highly toxic substance on the basis of human experience. The human experience refers to the accidental ingestion of kerosine by children. The record clearly shows that the majority of these unfortunate accidents is due to carelessness of parents who created a hazard where none existed by having the kerosine in an open container commonly used for drinking purposes such as a glass, a cup, or a bottle. These children develop a chemical pneumonitis as a result of the aspiration or entry of liquid kerosine into the lungs and not from the absorption of kerosine from the stomach or intestine. Animal experiments show that the direct entry of a few drops of kerosine into the lungs can cause more lung injury than a stomach full of kerosine. In fact, the oral LD_{50} of kerosine is of the same order of magnitude as that of glycerol which is regarded as a food.

Preparations such as asphalts, roof cements, paints, lotions, emulsions, or gels may contain high concentrations of kerosine but present little or no hazard of causing chemical pneumonitis because their viscosity and/or surface tension preclude aspiration. It is inconceivable that these mixtures should be labeled as highly toxic substances. **(H. W. G.)**

Ethylene glycol would not be considered "highly toxic" under the LD_{50} test in Section 2(h)(1) of the Act. However, use of ethylene glycol as an anti-freeze does raise a serious hazard question because of the unfortunate and erroneous association in the minds of many that anti-freeze is primarily a substitute for potable alcohol and can be drunk in quantity with the same non-fatal results. Presumably, the serious injuries that have resulted from this type of deliberate consumption in quantity of ethylene glycol constitute the basis in "human experience" for the proposed ruling that ethylene glycol is "highly toxic." This experience with ethylene glycol anti-freeze might justify its classification as a hazardous substance. Yet, it is not the kind of experience which should have any bearing on a determination that a single accidental exposure is "highly toxic." The listing of ethylene glycol as a highly toxic hazardous substance in 191.4 should be deleted.

[Section 191.1(f)(1)] defines a toxic substance as "any substance . . . that produces death . . . at a single dose of more than 50 milligrams per kilogram but not more than 5 grams per kilogram of body weight. . . ." The Du Pont Company questions whether the imposition of this 5 gram level readily serves the objectives of the Act.

Most substances which may be toxic as this level would not appear in household products subject to the Act in quantity necessary to achieve a toxic effect. Yet, application of the 5 gram standard, in effect, brings within the jurisdiction of the Act a wide range of household products which heretofore have not been questioned as a source of serious household injury or death.

This raises a serious practical problem. The 5 gram requirement will result in so many relatively harmless products being labeled in accordance with the Act that the warnings on more dangerous products may lose ther significance.

It is suggested that the more reasonable limit of approximately 2.5 grams per kilogram be established. **(J. A. Z.)**

. . . an oral dose as high as 5 gm. per kg. body weight, corresponding to a dose of 5 ounces for a 65 pound child or 12 ounces for a 154 pound man, is not only so extreme as to present the likelihood of excessive use of warning labels, but it raises a significant scientific question as applied to the laboratory animal specified in the regulation. This size dose of a household product, even if it could be swallowed by man, would in most cases be vomited and hence result in no substantial injury. However, in the case of the rat, which does not possess a vomiting reflex, such a dose might prove extremely lethal. Thus two criteria are called into question, namely the validity of using the rat and the magnitude of the critical dose. For this reason, and because it is better pharmacological practice, it would be preferable to leave the choice of animal to the judgment of the pharmacologist and to determine, not the lethality of a single arbitrary dose, but the approximate LD_{50} or the dose which would be calculated to kill half of a group of test animals. This determination can be made with an estimate of its confidence limits, that is, its degree of statistical validity.

. . . I would recommend establishing a 10-fold dosage ratio between highly toxic and toxic substances, that is to say a critical dose of 50 mg. per kg. for the former and 500 mg. per kg. (or at most 1 gm. per kg.) for the latter. If the past or future experience of Poison Control Centers should indicate the toxic dose limit to be too low the regulations can readily be amended to increase the critical dose. **(B. L. O.)**

Section 191.6 of the proposed regulations states that the Commissioner of Food and Drugs has found that epoxy resin systems have a significant potential for causing hypersensitivity and that, therefore, all such products are strong sensitizers under Section 2(k) of the Act. It is submitted that the Commissioner cannot have considered frequency and severity of reactions as to each and every epoxy resin system on the market today since data supporting a contrary finding exist for some systems. Certain epoxy systems have been found not to produce hypersensitivity even after use beyond the lengthy period of many continuous working days' exposure required to produce significant hypersensitivity by known sensitizers. It is therefore unreasonable to infer that all epoxy resin systems are strong sensitizers. This problem can only be resolved on a case-by-case basis. **(J. A. Z.)**

Comment on Details of Proposed Tests

Typical of the difficulties that may be encountered in establishing test procedures by fiat is the provision concerning the size of groups of experimental animals, viz. "the number of animals tested shall be sufficient to give statistically significant results and be in conformity with good pharmacological practice." The basic statute requires the use of groups of 10 or more animals in tests for highly toxic substances. This [coincides] with the recommendations of the American Medical Association, the Manufacturing Chemists Association, the Chemical Specialties Manufacturing Association and the New York City Sanitary Code. (It should be noted, however, that the regulations omit reference to the statutory minimum of 10 animals per test group.)

Statistical significance is usually determined at some specified degree of probability such as 95 per cent (p-0. 05) or 99 per cent (p-0. 01). Depending upon the circumstances or the purpose of the toxicological tests these or even higher degrees of significance may be justified. However a group of 10 animals is barely sufficient to yield a statistically significant result even at the lowest level of probability usually expected in pharmacological practice (p-0. 05). For this degree of significance, in an LD_{50} estimation, for example, it would require that the entire group either live or die. The best that can be said for such a test is that it serves a screening function; to this end it may have validity for the purpose of these regulations. However it would be more consistent to employ the same statistical yardstick for both highly toxic and toxic substances rather than to set a new, vaguely defined, criterion for the latter. **(B. L. O.)**

Specific points of difference are: (1) while we use rabbits for skin absorption toxicity studies, we seldom have found it necessary to use the rubber sleeve or to immobilize rabbits in a stock for more than a few hours; (2) we use guinea pigs, not rabbits, for skin irritation studies and believe that the results obtained are as valid as those obtained with rabbits; (3) we seldom cover patches, in an irritancy test, with an impermeable overwrap because common solvents such as diesel fuel and ethyl acetate would produce severe skin damage; (4) we do not believe it possible to keep a rabbit "comfortable but immobilized" for 24 hours; and (5) when testing for eye irritation, we wash some rabbit eyes 20 seconds after application of the test material and leave others unwashed. Some materials, like soap, are immediately irritating but harmless if washed out promptly. Others are so damaging that washing may be of little benefit. It would seem important to distinguish between such materials in precautionary labeling. **(J. A. Z.)**

In 191.10(c), Procedures for Testing, it is noted that the animals must be immobilized in a multiple animal holder. In the first place I do not believe that this is at all necessary. Why multiple? Furthermore we have been studying skin absorption in rabbits for many years and have developed a method whereby we are able to confine materials to the skin for 24 hours and allow the animal the complete freedom of his cage. . . .

Under paragraph 191.10(d), Procedures for Testing Unctuous Materials, it is specified that a 20-mesh wire screen may be employed instead of a rubber sleeve. We see no reason for the use of a screen or a sleeve made of rubber. The objective in such studies is to assure intimate contact between the skin and the test material over a prolonged period of time and this can be done by other means at least equally as well, as by the method described. Later on in this section it is stated that the volume of unabsorbed material, if any, must be measured. Why? I doubt that this is important unless the investigator wishes the information for his own purposes. Further it is difficult to measure recovered powders and solids volumetrically, the method specified . . . .

Under paragraph 191.11, Method of Testing Primary Irritating Substances, it is my personal opinion that a minimum of six animals is rarely if ever needed to determine whether a material is an irritant or not. Three animals in our experience would provide highly accurate results and if there are discrepancies noted between the responses of these animals, then certainly it would be appropriate to add more, but the investigator should be competent to take such action as required to obtain an answer to the question . . . .

In paragraph 191.12, Tests for Eye Irritants, my experience would indicate that the requirement that six rabbits be used is unnecessary. Here again two or three animals usually will give reliable results and if marked differences are noted then, of course, additional animals should be used. . . . The methods we described and used ten, yes, even two years ago, are not exactly the same as those in use today. We must be free to constantly improve our methodology. We must realize that the specification of methods in a regulation could very conceivably result in "do-it-yourself" testing by untrained and incompetent workers. Toxicological investigation should be done only by properly trained persons. **(V. K. R.)**

While the rabbit has been widely used as a subject for testing eye irritants, certain limitations must be recognized in the use of this species as an alternative to the human. The anatomical and physiological features of the rabbit eye tend to exaggerate to an excessive degree the responses which might be expected in man. While this may have some merit for predictive purposes it should be recognized that under certain circumstances the results might be quite different. For example, the nature of the lacrimatory secretion in rabbits is such that foreign substances are not diluted or removed to the same extent as in man. This would be true not only of soaps but of mists or dusts which might be subjected to this type of testing. In the experience of the soap industry an ordinary toilet soap would be classified as an irritant by this test. It would seem appropriate to provide for observation of effects induced in the rabbit eye when the test material is flushed out promptly after its administration in simulation of what might take place as a result of accidental exposure. Provision is made for this variation in procedure in the Food and Drug Administration's handbook referred to above. **(B. L. O.)**

The definition of a toxic substance in relation to inhalation is completely unrealistic [191.1(f)(2)]. I know of no organic vapors other than some olefins and fluorohydrocarbons which are so unirritating to the eyes or nose that a person would willingly breathe a concentration of 20,000 PPM for one hour. Furthermore, 200 milligrams of mist or dust per liter of air is not a concentration equivalent to 20,000 PPM, nor is it one which can be maintained for one hour in the laboratory. I know of no equipment which can produce and maintain such a miasma for animals to breathe, nor can such a concentration be "encountered by man" except for a brief period following the accidental bursting of a bag of cement, for instance. A more appropriate definition would specify 4,000 PPM of vapor, or 20 milligrams of mist or dust per liter. **(H. F. S.)**

The Final Order

On the basis of his review of the comments received in writing and at the public hearing, as well as "other relevant material" including the advice of the panels of dermatologists and toxicologists, the Commissioner issued the final order setting forth the regulations under the Act on August 12, 1961 (26 F. R. 7333). With respect to the major points raised by the toxicologists, as quoted herein, these regulations embody the following conclusions:

1. The requirement that toxicity tests be carried out on a "sufficient" number of animals to yield statistically significant results has remained unchanged, leaving the actual number, and degree of statistical significance quite indefinite. (Section 191.1(e)(3) and (f)(3).

2. The dosage limit of 5.0 gm. per kg. body weight for orally toxic substances has not been reduced. However recognition was taken of other conditions affecting the potential hazard of toxic substances by the addition of the following provisions (Section 191.1(f)(1)):

> Substances falling in the toxicity range between 500 milligrams and 5 grams per kilogram of body weight will be considered for exemption from some or all of the labeling requirements of the act, under section 191.62, upon a showing that, because of the physical form of the substances (solid, a thick plastic, emulsion, etc.), the size or closure of the container, human experience with the article, or any other relevant factors, such labeling is not needed.

3. Human experience with respect to toxic, irritant or corrosive substances is to take precedence over animal data not only when it indicates the article to be more hazardous but also when it shows it to be *less* so. (Section 191.2.)

4. The list of "strong sensitizers" includes not only parapheny enediamine, powdered orris root, formaldehyde and oil of bergamot but also products containing them. However in the latter two cases the critical concentrations have been specified as 1 per cent and 2 per

cent, respectively. In the case of epoxy resin systems the category was limited to those containing "ethylenediamine, diethylenetriamine and diglycidyl ethers of molecular weight of less than 200, irrespective of concentration. (Section 191.6.)

5. The substances (solvents) "or mixtures of any of them" previously listed as "highly toxic," are now considered separately, with concentration being taken into account except in the case of carbon tetrachloride. Regardless of its concentration in mixtures, this substance will require the signal words "Danger" and "Poison" and the skull and crossbones symbol, as well as the statement "May be fatal if inhaled or swallowed" and "Avoid contact with flame or hot surface." Different precautionary statements are required for methyl alcohol including mixtures containing 4 per cent or more by weight. The concentration limits above by which other specified solvents are considered hazardous and thus subject to special labeling (but not including the skull and crossbones symbol) are as follows: Ethylene or diethylene glycol, 10 per cent; Turpentine (defined to include gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine and, destructively distilled wood turpentine), 10 per cent; and Petroleum distillates (defined to include kerosene, mineral seal oil, naphtha, gasoline, benzine, mineral spirits, paint thinner, Stoddard solvent and related petroleum distillates), 10 per cent. (Section 191.7.)

6. No concession was made in response to the recommendation of toxicologists for greater latitude in the choice of test procedures although changes were made in a few details. For example, in the test for acute dermal toxicity in rabbits, the use of "other impervious material" is permitted as an alternative to rubber dams; elimination of the size mesh of wire screen used in the testing of unctuous materials; dropping the requirement for measuring the volume of unabsorbed material following skin application; but rabbits are still required to be placed in a "comfortable but immobilized position in a multiple animal holder" notwithstanding the objections of industrial toxicologists. The dosage levels to be employed in the rabbit exposures are not specified, as they were originally, but are adjusted to permit calculation of the dermal LD_{50} (Section 191.10). No changes were made in the procedures specified for testing primary irritant substances or eye irritants (Section 191.11 and Section 191.12).

In conclusion, it may be pointed out again that no attempt has been made in this article to discuss, except incidentally, the regulatory

requirements for labeling information and the prominence with which it must be displayed. However, because of the imminence of the effective date of the statute, February 1, 1962, "manufacturers and shippers" of hazardous substances which come under the Act are permitted to apply stick-on labels, tags or similar devices for providing the necessary information, in lieu of complete relabeling. **[The End]**

FOOD ADDITIVES POLICY

[The following features of the administrative policy of the FDA, in reference to the Food Additives Amendment, were enumerated in a recent speech by L. M. Beacham of the FDA.]

A few of the salient features of the policy developed so far perhaps merit mentioning:

(1) In evaluating a food additive, we must have convincing evidence of its safety; we cannot gamble or speculate on that all-important point. We have urged those who have problems involving pharmacology in their solution to discuss with our Division of Pharmacology the work they plan before they start it. It is true our people sometimes advise that the program is not sufficiently comprehensive, but there are other times as well when they are able to conclude that not all of the proposed work is necessary, or to advise other more promising approaches.

(2) A substance to be "generally recognized as safe among experts qualified to evaluate its safety" must be just that. It is not enough that the manufacturer have data that shows him it is safe, or even that convinces our experts. If from reasons of trade secrecy or for some other cause, little or nothing is known about it in the scientific community, it cannot be "generally recognized as safe." Such a substance is a food additive and requires a regulation to authorize its use, but if its safety can be convincingly demonstrated, there should be no difficulty in developing such a regulation.

(3) The law exempts from the definition of food additives those products which had been given approval—or as the statute terms it, "prior sanction"—by either FDA or the Meat Inspection Division or the Poultry Inspection Division of USDA before the enactment of the Amendment. We have held that these prior sanctions are applicable only to the specific usage of the product for which they were granted. Any different usage does not come under the exemption. However, a prior sanction granted one firm for a specific use of a substance applies equally to all others using the same product in the same way.

(4) An ideal food additive regulation defines the substance, describes its use, limits the allowable amount, and provides a proper analytical method for determining whether the limitation has been met. In the case of many direct food additives it is our policy to require this as a sound minimum objective, but in some instances limitations on the maximum amount permissible have been found unnecessary and, accordingly, the analytical method need not have the precision that is necessary when tolerance limitations have been set. With indirect additives, the need for suitable analytical methods constitutes one of our current problems.

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

July Report of Food Seizures.—Eight hundred and eighty-one tons of contaminated food were seized in 52 court actions during the month of June.

Of this total, wheat contaminated by rodents accounted for the largest tonnage (459 tons), but a sizable amount (44 tons) became subject to seizure because of contamination with seed wheat treated with a poisonous chemical used to prevent rotting of the seed in the ground before sprouting.

Over 69 tons of food became contaminated or decomposed in warehouses where it was stored after shipment in interstate commerce. Included were 45 tons of green coffee beans, 8.4 tons of nonfat dry milk and five tons of cane sugar.

Approximately 50 tons of food seized in 18 federal court actions were found to be economic cheats. Canned cat food accounted for 17 tons; it was labeled as "Chicken Dinner with the taste appeal of plump, country-fresh roasted chicken," but actually consisted of chicken viscera, backs, necks, fish and cereals. Six tons of canned peaches were below fill of container standards. "Butter Cake" was found to have other fat substituted for the butter. Butter mints "made of pure creamery butter" were found artificially butter-flavored; butter was found low in butter fat; blind Swiss cheese had artificial holes cut to conceal its inferiority; grouper fillets were sold under the name of "Snapper Fillets"; vanillin was substituted for vanila extract; oregano and garlic powder were short weight; canned "whole apricots" contained mixed pieces of irregular sizes and shapes; canned tomatoes were below the minimum quality standard because of excess peel; and cottonseed was partly substituted for corn oil.

Eight seizures involved vitamin-mineral food supplements, containing food additives, such as folic acid and boron, for which no tolerances have been established under the Food Additives Amendment of 1958.

Drug and Device Seizures.—Sixty-two federal court actions were taken against drugs and devices during the month of June. Thirty of these actions were based on charges of false and misleading therapeutic claims. Twelve actions involved substandard products. These included: sulfanilamide, substituted in part for sulfacetamide; a vitamin tonic found 42 per cent deficient in riboflavin; a vitamin-mineral with only 60 per cent of the declared vitamin D; and a medicated feed, labeled as "Chlortetracycline HCL (Aureomycin) 25 grams per pound," but containing little or none of the antibiotic.

Eight actions charged inadequate directions for use or inadequate warnings on the labels; three involved over-the-counter products containing more folic acid than permitted in such products. Five actions involved repackaged physicians' samples; two, counterfeit drugs; one, failure to bear the Rx legend; and one, a drug for which government certification is required but was not in compliance with that requirement.

One manufacturer in Pennsylvania offered his various powders, tablets and formulas in glowing terms as treatment for a veritably limitless array of diseases such as cancer, diabetes, obesity, insomnia, colitis, skin diseases, arthritis, rheumatic diathesis vascular lesions

of the central nervous system, virus infections and pneumonia.

Herbal tablets were charged to be misbranded by labeling claims of value for liver and gallstone conditions, nerve spasm, rheumatism, hypertension, ringworm, dropsy and numerous other conditions.

A New Jersey manufacturer recommended his products for treatment of habitual abortion, ovarian failure, and muscular dystrophy, among other conditions.

In a continuing campaign, another seizure was made of sea water, promoted as a "chemical smorgasbord" for body glands, claiming to provide proper function of pancreas, liver, spleen, bone marrow, thyroid, adrenals, and suggesting its use as a treatment of prevention of cancer, leukemia, multiple sclerosis, sterility and other conditions.

Cosmetic Seizures.—Eye make-up preparations, such as eyebrow pencils and eye liners, containing coal-tar colors, not permitted for use in the area of the eye, accounted for ten actions.

Voluntary Actions by Industry.—The largest tonnage in a single voluntary action involved 750 truckloads—each consisting of 17 tons—of a variety of food items which were badly damaged in a Rochester, New York, warehouse fire. When it became obvious that salvage operations would be unsuccessful, the entire load was voluntarily destroyed under state inspector surveillance.

In Iowa, 750 tons of flood-damaged soy beans were taken to the city dump and buried.

Over 13,600 tons of food, including vegetables, fish and poultry unfit for human consumption were either destroyed or converted to animal feed in 75 voluntary actions by the industry.

Approximately 13 tons of decomposed liquid egg whites were voluntarily denatured with red dye to prevent use for human food.

More than five tons of rotten strawberries were voluntarily removed from the market by dumping the load at Lake City, Arkansas.

Two tons of dog food deficient in fat and protein and also short weight were turned over to Utah State Prison for use as animal feed.

Voluntary plant improvements totaled $14,557 in eight actions.

Investigation of Short Weight Food Products.—The Food and Drug Administration is pressing a national investigation and enforcement campaign against what it describes as a widespread practice of short-weighting food products, and has so far announced a total of 99 seizure actions. In commenting on the seizure actions the Commissioner emphasized that there are hundreds of thousands of food items in the country which are correctly labeled, but at the same time expressed shock that some manufacturers have failed to give the consumer full measure. Seizure actions are being brought where the average weight is below the net weight declared after allowance is made for moisture loss and other unavoidable variations.

Among recent actions of the FDA is the securing of a temporary restraining order against a large candy manufacturer enjoining the shipment of its candy bar product in interstate commerce because it is short weight. FDA charges that the firm's multipack carton containing six individually wrapped bars of candy is labeled as containing nine ounces, but actually weights 8¼ ounces. The complaint also charges that the packages of the candy intended for use in vending machines were under the declared net weights of 1¼ and 1¾ ounces.

Hazardous Substances Act.—In announcing that the number of poison-control centers had reached a new high of 460, the FDA commented that when the Hazardous Substances Labeling Act is in full operation it should lighten the work of these control centers. The law is now fully enforceable with regard to highly toxic and flammable substances, and requirements for labeling other hazardous articles are scheduled to go into effect February 1, 1962.

A COMMERCE CLEARING HOUSE PUBLICATION

REQUEST CARD

Mail today for full information.

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

BUSINESS REPLY MAIL
NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY—

COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

REQUEST CARD

Mail This Card Today

CCH®

COMMERCE CLEARING HOUSE, INC.

4025 W. Peterson Ave., Chicago 46, Ill.

Please send further details about CCH's complete Reporter covering government regulation of foods, drugs and cosmetics—FOOD DRUG COSMETIC LAW REPORTS—no obligation, of course. We understand there will be special help on the Hazardous Substances Labeling Act and the Final Regulations under it.

Signature & Title .....

Firm .....

Attention .....

Street Address .....

080—807

City, Zone & State .....