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Food Drug Cosmetic Law JOURNAL

The Basis of Strict Products Liability

. . . . . REED DICKERSON

Incidental Additives to Food: Have We Made a Prudent Judgment?

. . . . . RICHARD C. NELSON

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

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REPORTS

TO THE READER

Products Liability. — Proposed Section 402A of the *Restatement of the Law of Torts, Second* would impose on each food seller coming within its terms the responsibility of strict liability and would also do away with the privity requirement at all levels of manufacturing and distribution. Professor *Reed Dickerson* of the Indiana School of Law expresses strong misgivings about some aspects of this proposed section in the article appearing at page 585.

The section would apply to all sellers of "food," which would include any product intended for ingestion by humans. The author claims that the language of the section itself fails to outline the broad area it supposedly would cover. He also takes issue with the failure of proposed Section 402A to mention implied warranty. The obligation of Section 402A has most, if not all, the characteristics of a warranty, points out Professor Dickerson. He asks, "How can merely classifying . . . a responsibility as a new tort obligation make it any less a warranty . . . ?"

However, the author finds considerable merit in the idea of strict liability of the manufacturer: "Strict liability provides an effective means of bolstering direct controls in encouraging the manufacturer to make a safe product. Experience indicates that this encouragement is an effective one and the only remaining question is whether this kind of preventive measure is necessary or desirable." Strict liability is desirable in that it arms the consumer with civil remedies designed to give him more adequate means of looking after himself, the author suggests.

Incidental Additives.—In the Food Additives Amendment of 1958, Congress gave force to the FDA judgment that a group of chemical substances—incidental food additives—should be regulated in the same manner as direct additives. Incidental additives from food packaging materials have proved to be extremely difficult to subject to the present statutory procedure. The Food and Drug Administration has been forced to expend much time and energy in investigating incidental additives, not so much because anything of concern was discovered, but simply because the number and complexity of packaging additives exceeds anyone's expectations.

This situation leads *Richard C. Nelson* to ask if we have made a prudent judgment in deciding to regulate incidental additives. The Food Additives Amendment, he says, requires that the FDA must know what, if anything, migrates to food from packaging materials. This requirement presents an analytical problem of staggering proportions. In the article beginning at page 597, Mr. Nelson puts forward a persuasive argument for asking Congress to reconsider the regulation requirements for incidental food additives. The author is a member of

the legal advisory subcommittee of the American Paper and Pulp Association.

Hazardous Substances.—On July 12, 1960, the President approved the Federal Hazardous Substances Labeling Act. Not as broad in scope as the title suggests, this Act applies to household chemical products sold in interstate commerce. If such a product is hazardous any may cause substantial injury or illness, the container must bear a warning. The article at page 615 is a report on all aspects of the Hazardous Substances Labeling Act. It was presented before the Division of Food Drug and Cosmetic Law, Section of Corporation, Banking and Business Law of the American Bar Association on August 9. The author is *George T. Scriba,* vice chairman of the Precautionary Labeling Committee of the Chemical Specialties Manufacturers Association.

Food Science and Technology.—The Imperial College of Science and Technology of London, England, will be the site of the First International Congress of Food Science and Technology next September. The program, which will run from September 18 to 21, 1962, will be divided into four sections to insure broad and comprehensive coverage of world-wide food science problems. A major item of business will be the possible formation of a continuing governing body for planning future International Congresses and other activities. Full details of the program will be announced later and published in this JOURNAL.

Agricultural Chemists Meeting.—October 30 to November 1 are the meeting dates for the annual fall gathering of the Association of Official Agricultural Chemists. Over 1,000 federal, state and local regulatory scientists and representatives of industry and colleges are expected to gather in Washington, D. C., for this meeting. The papers listed for presentation reflect the increased emphasis on the use of precision instruments for chemical and biological analysis. The new techniques of "electron capture" and microcoulometric gas chromatography have been used to analyze the composition of foods and to detect pesticide residues with increased sensitivity of results. The banquet speech will be delivered by *Dr. C. A. Morrell,* head of the Food and Drug Directorate of Canada.

Medical Literature Award.—The American Medical Writers' Association recently announced that *Dr. Charles E. Lyght* is the winner of 1961 "Distinguished Service Award," presented annually to a member of the association. The award honors a member "who has made distinguished contributions to medical literature or rendered unusual and distinguished service to the medical profession." The association is composed of nearly 1,500 medical writers and editors.

Dr. Lyght is director of medical publications the Merck, Sharp and Dohme Research Laboratories. In this capacity, he has served as editor-in-chief of the eighth, ninth and tenth editions of the *Merck Manual of Diagnosis and Therapy.*

WHO Assignment.—At the request of the World Health Organization, Dr. Mayhew Derryberry, of the U. S. Public Health Service, will serve as a special WHO consultant to the Health Ministry of Japan for six weeks. Dr. Derryberry began his assignment on October 15.

Dr. Derryberry, who heads the health education activities of the Public Health Service and is internationally known in his field, will assist Japanese health authorities in reviewing and expanding their work in health education. He will return to the United States on December 15, with a stop in Manila to report on his assignment to the WHO Western Pacific Regional Office.

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Food·Drug·Cosmetic Law
Journal

The Basis of Strict Products Liability

By REED DICKERSON

This Paper Was 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. It Is a Companion Paper to "Restatement or Reformation?" by William J. Condon, Which Appeared in the August, 1961 Issue of This Magazine. Mr. Dickerson Is Professor of Law at Indiana University and Author of *Products Liability and the Food Consumer*.

AT THE 1961 MEETING of the American Law Institute, the Reporter for the *Restatement of the Law of Torts, Second*, Dean William L. Prosser, proposed that the following new section be inserted:

Section 402A. Special Liability of Sellers of Food—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 relation with the seller.

Before turning to what I consider the solid merits of the proposed section, let me mention several reservations and the related questions that they raise. The first of these relates not so much to the text of the section as to what is claimed for it by its authors. A comment to

the section explains that the term "food" is intended to include all products for ingestion by humans, including drugs that are so consumed. On the other hand, the comment also tells us that "food" does not include clothing or hair dye. In view of the modern tendency to legislate by legislative history, this statement is generously reassuring!

Even so, the comment invites strong misgivings. If the authors mean to cover so wide an area, why should they not say so in the section itself? Moreover, the category is broadened to include ingested drugs, other problems arise. First, as the critics of the section have been quick to point out, it becomes harder to support the proposed section as a "restatement" of the law. Second, it becomes harder to find policy reasons to support a section that goes so far and no farther. Why, for example, should privity-free liability be imposed in the case of an ingested drug and not in the case of a nasal spray or a suppository? It is ironical that, according to the interpretative comments, it would include a tularemic rabbit that infected a chef who merely handled it, but exclude a surgical nail that was consumed internally.

The essential undesirability of the stopping place proposed by the official comments was so apparent that the institute voted to extend the principle expressed by the proposed section to cover all products for intimate bodily use. While this makes more consistent sense from a policy standpoint, it makes it correspondingly harder to call the proposed section a "restatement" of current law.

One of the most interesting features of the proposed section 402A is that it says nothing at all about implied warranty. The comments to the section explain that this is done for several reasons. First, warranty traditionally requires reliance on some promise or representation of the seller, which would be hard to spell out in a situation in which the consumer may not even know or care who sold the product. Second, although warranty has some of the aspects of tort, many courts insist that it is inseparable from a sale between the parties. Third, warranties are covered by the Uniform Sales Act, which has been construed by many courts to exclude warranties to anyone other than the immediate buyer. Fourth and fifth, additional problems relating respectively to damages and disclaimers integral with the concept of warranty should, of possible, be avoided. Finally, it would be anomalous to include in the restatement one kind of warranty while excluding all others. All these problems are swept aside by the simple device of not mentioning the naughty word "warranty."

This line of reasoning baffles me. How can merely classifying such a responsibility as a new tort obligation make it any less a warranty, especially when many authorities, including some courts, have long contended that breach of warranty should be treated as a tort? Moreover, the mere use or avoidance of a name has not been notably successful in preventing the courts from doing their own classifying. Courts sophisticated enough to pierce the corporate veil or to declare a statute general in form special in substance can certainly penetrate a label or, conversely, supply a missing one.

Is the obligation described in the proposed section 402A in effect a warranty? It has most, if not all, of the characteristics of a warranty: It performs the function of a warranty. It relates to the quality of the goods. It is engrafted on a sale. It affects a relationship dealt with by the Uniform Sales Act. What, then, is lacking? Certainly, the mere absence of an actual promise or representation is not significant in view of the long history of the warranty implied in law.

The problem may become largely academic in view of the apparent indifference of the courts in some states to the language of the Uniform Sales Act and in view of the replacement of that act by the Uniform Commercial Code in others.

Within the area of its coverage, the proposed section 402A would (1) do away with the privity requirement at all levels of manufacturing and distribution, and (2) impose on each seller coming within its terms the responsibility of strict liability.

In doing away with privity, would the proposed section reflect the preponderance of existing law, or would it pull itself up by its own bootstraps by purporting to reflect law that it was only creating? So far as food is concerned, a good case can be made for calling this a true restatement of at least a majority of the courts that have expressed themselves on the subject. For drugs and cosmetics and other products for intimate bodily use, on the other hand, the trend toward abolishing the privity requirement has lagged far behind. Although in this area it would seem difficult to sustain the proposed section as a "restatement," its authors contend that the great bulk of the privity cases are old ones not fully representative of current judicial thinking.

While it may be desirable for the American Law Institute not to mislabel its own products, the question of how fully the substance of section 402A reflects existing law hardly affects the merits of the rule of law that it states. Whatever difficulties there may be in rational-

izing that section as a restatement of current law, there is little occasion for extended mourning over the death of the privity requirement. For food, it is time for the funeral and, if present indications are reliable, it is only a matter of time before the privity requirement will be dead for most other products as well.

The privity requirement made a lot of sense in the kind of casual transaction that took place between two farmers in the simple sale of a horse, where the seller had no reason to be concerned in the transaction beyond his immediate buyer. If the buyer later resold the horse, that was likely to be a wholly independent and unrelated transaction. How different the pattern of mass distribution of complicated fabricated goods is today. The manufacturer knows, when he sells to a primary distributor, wholesaler, or retailer, where the goods are ultimately going, and he is equally interested with them in seeing that the goods get there. In such a climate, the factual presuppositions of the original privity doctrine seem unreal.

Some courts have begun to see that, whether or not they constitute express warranties, manufacturers' advertising appeals today are aimed primarily at the consumer, over the heads of any intervening distributors. This either makes the privity requirement a meaningless anachronism or allows us to argue, with good logic, that even if there is still a privity requirement the manufacturer and consumer comply with it because in effect they deal face to face.

One of the most persistent arguments for the retention of the privity requirement is that it gives the manufacturer a needed shield against the fraudulent claim. A high percentage of claims for products liability appears to be either downright fraudulent or, more often, valid in part but grossly exaggerated.

Although there is reason to be sympathetic with the manufacturer in his predicament, the privity requirement is for this purpose wholly unselective. It gives the manufacturer a welcome defense against the fraudulent claim, but it also lets him out when, as often happens, he is confronted with a valid one. Some manufacturers will undoubtedly answer that, as a matter of grace, they often make an appropriate settlement of an honest claim even though they are not legally accountable. Unfortunately, this leaves the consumer at the mercy of the manufacturer. I suspect that some manufacturers are not so generous.

Moreover, the manufacturer is no more vulnerable to a fraudulent warranty suit than he is to a fraudulent negligence suit. Most manu-

facturers are already stripped of privity protection in negligence suits and, if they do any direct selling, in warranty suits as well. No plaintiff can fake the defendant's negligence as such, but he can and often does fake causation. For this reason, it seems that so far as the chances of fraud are concerned there is no real difference between a products liability suit brought on the theory of negligence and one brought on the theory of warranty.

The privity requirement is an anachronism that we would do well to get rid of as soon as possible, at least in the mercantile context that we have been considering. The problem to which the legislatures and the courts must now address themselves is that of defining the kind of liability to which the manufacturer should be exposed. While manufacturer's direct liability is not necessarily strict liability, that is the likely result if he is made directly accountable to the consumer. The remainder of this discussion will therefore be directed to two general questions relating to strict liability: (1) Should the manufacturer be strictly liable to the consumer? (2) If so, what should this liability consist of?

As to the first question, it seems clear that the manufacturer should be so liable, and for the following reasons.

Strict liability provides an effective means of bolstering direct controls in encouraging the manufacturer to make a safe product. Experience indicates that this encouragement is an effective one and the only remaining question is whether this kind of preventive measure is necessary or desirable.

One basic objection to strict liability has been advanced by none less than Dean Roscoe Pound. Writing in 1950 (36 *American Bar Association Journal* 977, at p. 981), Pound attacked what Professor James and others are calling "enterprise liability" (e. g., 24 *Tennessee Law Review* 928 (1957)) as a kind of "welfare" measure better left to legislation and having even a touch of Marxism. Others have found in it part of the drift toward governmental paternalism. Although I have the profoundest respect for this great legal philosopher, it seems likely that in statements such as these he and the others have failed to take adequate account of the currents that have made it necessary and even desirable to arm the consumer civilly. Such views not only make false assumptions about the nature of strict liability but are based on an outworn view of the position that the consumer holds in the general marketing scheme.

In Adam Smith's self-regulating economy, it was assumed that buyer and seller bargained, and sellers competed, in a climate of relative equality. Compare an economy in which the goods are so complicated, manufacturers are so removed from the consumers they ultimately serve and the relative sophistication of consumer buyer and corporate seller is so disparate, that the consumer is at the mercy of those who are supposed to serve him, unless the law adds its counterweight.

As against the contention of Dean Pound made in 1950, consider the views of an equally eminent legal philosopher, writing in 1960 (40 *Boston University Law Review* 167, at pp. 183, 185):

> . . . we must break away from the idea of fault as the fundamental and exclusive ground of liability . . . Must we not seek repair of injuries incurred as incidents of what is done with no intent or purpose of causing injury, but involving in the course of carrying it on . . . great possibility of injury to others?

What eminent legal philosopher said this? Surprisingly enough, it was Dean Roscoe Pound, who in the meantime had apparently drastically revised his views. Incidentally, there is no reason to think of strict liability as some new, alien development. The retailer has long been strictly accountable to the consumer. For food, this responsibility goes back probably to the 13th century. In fact, the earliest tort liability did not even distinguish between the intentional and the accidental.

Assuming that the consumer should be protected against the overreaching manufacturer or other seller, buyer and seller can be put on a more equal basis in two ways. First, by direct governmental regulation such as the enactment of pure food laws. Second, by arming the consumer with civil remedies and defenses designed to give him more adequate means of looking after himself. As one who has spent more than 16 years as a Washington bureaucrat, I have come to look at direct government participation as a second-choice approach. In principle at least, it would seem preferable to let the consumer fight his own battles and to help him do it by giving him enough private legal weapons and factual information that he will have some chance of striking an effective blow in his own behalf. Unfortunately, in the field of food and other products for intimate bodily use, it looks as if we may need both approaches.

Prevention through civil liability normally gives the manufacturer two alternatives. He can try to improve his product to make it reasonably safe, and he can help the consumer protect himself, at little cost to the manufacturer, by including with the product adequate

warnings or directions for use. Such an approach has reduced the liability of sellers of rotary lawn mowers and, in view of the apparent feasibility of including cooking instructions with pork products, it is surprising that sellers of pork continue to complain about trichinosis judgments.

The second argument for strict liability is that it makes possible a sharing of the risk or loss among consumers generally. So far as the manufacturer is induced by civil liability to improve his product and reflect in his prices the costs of improvement, he can be said to be "spreading the risk." So far as such improvements are unsuccessful and he is induced to reflect in his prices the costs of paying injury claims, he can be said to be spreading the loss." Such price increases provide a kind of industry-wide self insurance.

What about the seller's ability to absorb or pass on to the consumer the costs of further improvements, additional precautions, increased recoveries, or product liability insurance? As I pointed out on another occasion (16 Bus. Law. 683 (1961)):

> Where the financial burden is shared by an entire industry, no problem appears to be presented, because even under highly competitive conditions the industry as a whole can adjust its general price level to reflect cost increases. A problem would appear to arise only for a manufacturer whose particular product or method of operations exposes him to risks not shared by others in the same highly competitive industry. A possible example might be carbonated drinks in glass, with its explosion hazard, as against carbonated drinks in tin, with no corresponding hazard. But even here, average costs of this kind would seem to be relatively trivial as compared to cost increments such as wage increases. So far, there is nothing to indicate that the imposition of strict liability has had an adverse affect on any seller who has taken the precaution of covering the worst of his risks with a deductible product liability policy.

One commonly met objection to strict liability for defective fabricated goods is that it expresses a kind of subversive, "deep pocket" philosophy: If someone who cannot afford the loss gets hurt, let someone who can afford to do so underwrite it; in this case, a rich manufacturer or distributor. Of course, even this interpretation of strict liability would not let the injured consumer grab at random for a rich indemnitor. It would at least limit liability to those who had a causal connection with the consumer's injury by being in the chain of manufacturing and distribution.

Here is where I believe many of the opponents of strict liability have been impliedly misrepresenting it. What do we mean by "strict liability"?

It is commonly assumed that to make out a case of strict products liability all the plaintiff has to show is that the defendant caused the plaintiff's injury. Here, we should distinguish between strict liability, on the one hand, and *strict* strict liability (what someone has recently called "liability without warranty"), on the other. By "*strict* strict liability," I refer to the kind of liability that is imposed under workmen's compensation, where all the claimant has to show is the causal relationship involved in an injury arising out of and in the course of his employment.

Under simple strict liability, on the other hand, and that is what we are considering here, it is not to be assumed that, if the courts do away with the privity requirement and expose the manufacturer to strict liability, he will automatically have to indemnify every person who is injured by one of his products. For example, the proposed section 402A does not say that the seller must pay the consumer some money if his product injures the consumer. The food must be, first, "defective" and second, "unreasonably dangerous." Not everything that causes injury or illness is either defective or unreasonably dangerous. Some of those who tend to panic in the face of possible strict liability do not fully realize that strict liability need not be so strict that the only issue is one of causation.

Although I had long thought that the question whether the product was unreasonably dangerous was simply the most reliable way to measure defectiveness, making the latter term surplusage, the word "defective" was retained in section 402A on the ground that it was needed to nail down the kind of case in which the product was improperly made, and to excuse the manufacturer of a highly dangerous article that was properly made. Apparently, it was feared that without the word "defective" a highly dangerous product might be considered to be *ipso facto* unreasonably dangerous. Under the section as it now stands, it is interesting to speculate as to what kind of situation could exist in which the product was "unreasonably dangerous" without being legally "defective."

In any event, it is important to formulate appropriate concepts of what is "defective" and what is "unreasonably dangerous." How these concepts are developed will determine the ultimate impact of doing away with the privity requirement and imposing strict liability. The appropriate development of these concepts can also furnish the key to such difficult legal problems as those involved in trichinosis,

allergies, disclaimers, and warnings. While the most provocative questions appear to be arising outside the field of food, much needs yet to be done to clarify the law relating to food.

In the traditional suit for negligence, the main problem beyond that of causation is to stigmatize the actions or omissions of the defendant. Under strict liability, on the other hand, the problem of stigmatizing the defendant is apparently removed. Even so, the plaintiff must stigmatize the product as "defective" and "unreasonably dangerous." In the usual food case, this is a simple matter. A mouse is enough to stigmatize a bottle of soft drink. Staphylococcus is enough to stigmatize a custard-filled eclair. Both are legally "defective." Both are "unreasonably dangerous."

Unfortunately, such simple and typical instances do not give us a ready key to a concept of "defectiveness" on which products liability generally should be based. Let us consider several specific problems.

In the field of food, the courts are still fighting the battle of the chicken pie. Is a chicken bone in a chicken dish enough to make it legally defective? While many courts use the test of whether the offending object is "foreign" or "natural" to the product, the most sensible test, which is adopted by many other courts, is the "reasonable expectations" test: Is the offending condition one that consumers normally anticipate and guard against? Here, a philosophy of consumer protection based on the reasonable expectations of the parties helps to supply a sensible answer.

What about trichinae in pork? Here, again, the "reasonable expectations" test seems to offer a helpful approach. Do normal consumer precautions include cooking pork to the thermal death point of trichinae? If so, trichinous pork can well be considered as not being legally defective. If this approach is correct, we cannot evaluate a product merely by looking at it or by measuring the harm that it can potentially do to a consumer. We must appraise it also in the context of what people usually expect and guard against in the kind of situation presented. The problem of defining a legal defect arises also for allergies, for which the courts are beginning to find satisfactory answers in the reasonable expectations of the parties.

The concept of defectiveness of a product depends ultimately on the concept of what the offending "product" is. This, in turn, includes the concepts of contemplated use and contemplated performance. What may be legally adequate for one purpose may be legally

inadequate for another. Thus, even within the framework of strict liability the manufacturer may have an escape hatch in the concept of contemplated or normal use. For example, in *Mannsz v. MacWhyte Co.*, 155 F. 2d 445 (CA-3, 1946), 13 NEGLIGENCE CASES 524, the defendant manufacturer of wire rope got off the legal hook, even without the help of the privity requirement, because the plaintiff's use of the rope in question, which was to support a scaffold, was one abnormal to that kind of rope.

The drug cases present problems that are hard to solve even with the help of a sophisticated philosophy of consumer protection. Part of the problem lies in the fact that for many drugs no clear concept of "normal use" has yet emerged. Chemical X may be good for curing flea bites, fair for curing eczema, and poor for curing seborrhea. What expectations have sufficiently crystallized to serve as a criterion here?

One of the strongest arguments against the extension of strict liability is that it would impede the development of new products. But, again, how serious this might be depends on how "strict" the strict liability is. Within the concepts of "defective" and "unreasonably dangerous," this ultimately depends on how the interest in protecting the reasonable expectations of consumers is balanced against the interest in not making unreasonable demands on the capacity of manufacturers to provide this protection. If the manufacturer is aware of the potential danger, normally he can either improve the product by removing or minimizing the danger or provide a suitable warning or suitable directions for use.

The crucial case, of course, is that of the new product whose benefits have fanned the expectations of consumers but whose latent dangers, which may be considerable, have not yet been revealed. Thus, the big issue in the non-food cases today is whether a product is to be considered as legally defective, even under strict liability, when it produces serious harm at a time when not even scientists are adequately aware of its potentialities. For aircraft the Electras provide a beautiful example. Some precedent exists for saying that a product is not legally defective until at least scientists know its dangers. Thus, in the allergy cases courts that permit recovery make it a condition of liability that the product have an ingredient that is known to be capable of inflicting harm on a significant, generally determinable percentage of the public.

While this approach has some judicial acceptance, fears have been expressed that a similar approach to new products not yet known by scientists to be unreasonably dangerous, by giving manufacturers one free shot at the public, make them guinea pigs for products that should have been more adequately tested before being marketed. On the other hand, even Dean Prosser, reporter for the restatement, has expressed sympathy with the objective of protecting the still ignorant manufacturer of a new drug product. That such notions can be accommodated within the concepts of "defective" and "unreasonably dangerous" should comfort those who have been thinking that all would be lost if the current assault on the citadel of privity is ultimately successful, as it most probably will be.

On this perplexing problem, it is hard to take sides. It is not even clear that what makes sense for one kind of product makes sense for another. For present purposes, the important point is that these issues can be resolved according to the best dictates of public policy within the framework of strict liability itself; that is, through the concepts of what, under the circumstances, the law is to consider "defective" and "unreasonably dangerous." It is unnecessary, therefore, to reject the advantages of strict liability to cope with this problem.

It is, indeed, a gross exaggeration to put at opposite poles what represent only modest differences in degree. On the one hand, even liability for negligence is a kind of strict liability so far as it holds a person to a general standard of conduct without regard to his peculiar idiosyncrasies. On the other hand, strict liability, despite its name, also deals with the defendant's conduct and differs only in that it substitutes what has been called in other contexts a "performance standard" for a standard that deals with specific conduct. In short, this kind of strict liability differs from negligence only in eliminating the necessity of proving specific acts of negligence.

This fact provides one more reason for supporting strict liability. What we have been calling liability based on fault in the products cases has been for the most part strict liability. The reported cases indicate that the courts have rarely been able to try a bona fide negligence issue in the field of products liability, particularly in the case of food, because the specific facts surrounding the defect are rarely known to either party. In practice, if the plaintiff can persuade the jury that the defect was in the product when it left the defendant's

plant, the inferences are usually drawn in his favor on the theoretical issue of negligence, with or without an assist from the doctrine of *res ipsa loquitur* or that of negligence per se. Because this is only paying lip service to culpability, the privity requirement has probably served only to drive strict liability into the legal underground.

Even apart from the hypocrisy involved, law suits should not be cluttered with pretended legal issues that in most cases are neither being litigated nor susceptible of being litigated. Strangely enough, the imposition of strict liability will affect the trial of products liability cases very little, beyond eliminating some of the formal legal arguments that lawyers now make. The central factual issue in a products liability case will continue to be what it has been all along: Assuming that the product that injured the plaintiff was legally "defective" and "unreasonably dangerous," can the condition be traced to the defendant's plant?

While we may feel some nostalgia for the fading issue of privity, we will do better to direct our efforts to solving the two central problems of strict liability today, those of "defectiveness" and proof of causation.

The issue of strict liability is no longer "whether" but "of what kind." [The End]

COMMISSIONER LARRICK SPEAKS ON QUACKERY

Commissioner of Food and Drugs George P. Larrick said on October 6, that consumers spend more than $1 billion a year "needlessly on falsely represented drugs, foods and cosmetics."

Speaking before the National Congress on Medical Quackery at the Sheraton-Park Hotel, Commissioner Larrick said that the cost of vitamin and so-called health food quackery alone has been "estimated conservatively at $500 million a year." The Congress was sponsored by the American Medical Association and the Food and Drug Administration.

Mr. Larrick said that there were three major kinds of quackery from the standpoint of protecting the public by both law enforcement and education—fake medical devices, pseudo science in nutrition, and false claims for drugs and cosmetics.

"From the standpoint of consumer protection the greatest harm being done by quack devices today results from continued use of individual units by local practitioners," he said. "For this reason, we are making public today a list of devices which have been outlawed by court proceedings under the Federal Food, Drug and Cosmetic Act, and which we have cause to believe are still extant and still being used.

"The most widespread and expensive type of quackery in the United States today is in the promotion of vitamin products, special dietary foods, and food supplements." Mr. Larrick appealed for help from health and nutrition educators at all levels to stem the tide of quackery.

Incidental Additives to Food: Have We Made a Prudent Judgment?

By RICHARD C. NELSON

Mr. Nelson, a Member of the California Bar, Received His LL.M. Degree From New York University as a Food Law Institute Fellow in 1953. He Has Served as an Assistant United States Attorney for the Northern District of California, and Is Presently an Attorney for Crown Zellerbach Corporation in San Francisco. Mr. Nelson Is a Member of the Legal Advisory Subcommittee of the Chemical Additives Committee of the American Paper and Pulp Association.

IT HAS BEEN SAID that men should strive for "prudence to decide what things should be feared, when they should be feared, and how much; and so a prudent judgment is involved in fearing the right things at the right time and in the right manner—neither too much nor too little." [1]

Nearly three years ago, Congress, at the behest of the Food and Drug Administration, judged that a group of chemical substances, which we will call "incidental food additives," should be regulated in the same manner as "direct additives." That judgment, expressed in the Food Additives Amendment of 1958,[2] already has resulted in the expenditure of several tens of millions of dollars, of a vast amount of precious scientific and laboratory time and of an even greater amount of less precious, but still costly, executive, administrative and legal effort—private and governmental. This paper will consider the prudence of that Congressional judgment, at least insofar as one type of incidental additive is concerned.

The first question is not whether there is some form of control which might be desirable for incidental additives, but rather whether

[1] Kenneth E. Mulford, "The Great Ideas," 16 FOOD DRUG COSMETIC LAW JOURNAL 117 (February, 1961).

[2] Public Law 85-929, September 6, 1958.

the present form of control is suitable. "Prudence" means the "provident use of resources." [3] If we are using our limited research facilities (and spending the consumer's dollar) improvidently because of an inapt statutory plan, we are being imprudent. If one of our finest regulatory agencies is drifting toward unauthorized and improper forms of regulation because of an inapt statutory plan, we are injuring our entire governmental fabric. Is the Food Additives Amendment causing these results? Is it an imprudent form of regulation for some types of incidental additives?

Definitions.—The terms "incidental [4] food additive" and "direct food additive" do not appear in the statute. They are pragmatic classifications of chemicals which fall within the statutory definition of "food additive." [5] In dealing with "food additives" within that statutory definition, the "incidental additives" are those which are used to accomplish some mechanical, chemical or physical purpose *other* than in the food. Conversely, "direct additives" are those intentionally placed in food to achieve a desired result in the food item itself.

There are many sources of incidental food additives.[6] However, incidental additives from food packaging materials have proved to be

[3] *Webster's New International Dictionary, Second Edition.*

[4] The words "indirect" and "unintentional" are used in the same sense.

[5] Section 201(s), of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 321(s), reads as follows: "The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding foods; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—(1) a pesticide chemical in or on a raw agricultural commodity; or (2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act or the Meat Inspection Act of March 4, 1907, as amended and extended."

[6] The main sources of incidental additives are: agricultural chemicals (e. g., a pesticide which leaves some residue in a finished food); animal medications (e. g., a drug which leaves a residue in milk, eggs or meat); processing chemicals (e. g., a chemical residue contributed by processing or by conveying equipment); and packaging materials (e. g., polyethylene film when a chemical component migrates).

more difficult to subject to the present statutory procedure than other types of incidental additives and are an excellent example of the problems encountered. This paper will be, for the most part, restricted to incidental packaging additives.

Unexpected Magnitude of Incidental Additive Problem

The voluminous testimony during the Congressional hearings which preceded enactment of the Food Additives Amendment did not indicate that incidental additives were a major or even a substantial hazard to health. The testimony was almost entirely directed toward direct additives. Incidental additives seem to have been included in the coverage of the Amendment primarily because the Food and Drug Administration felt that the Amendment should make no distinctions as to types or sources of additives, and that it would be in the public interest to impose the same pre-testing requirements on all sources of chemicals in food.

We find, however, that the bulk of the FDA's time and effort in the additive field is being devoted to incidental, not direct, additives.[7] Packaging additives, particularly, have absorbed a great deal of effort, not because anything of concern was discovered, but simply because the number and complexity of this type of incidental additive were far beyond anyone's expectation. As the General Counsel for Food and Drugs put it:

> The magnitude of this problem is far greater than ever anticipated. Instead of several hundred additives we thought would need clearance, there are a few thousand and seemingly, no one can sell any package or any processing equipment or the materials going into them, unless FDA has first cleared the substance for safety.[8]

Originally, FDA estimated that by March 6, 1960, 800 to 1,000 final regulations would have been issued.[9] The slow progress toward final regulations and the significance of incidental additives to the rate of progress appear from this quotation made over a year after the March 6, 1960 date:

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[7] "It is . . . the indirect additives which have been responsible for the major part of the initial confusion arising in the field, and which have absorbed a major part of the effort and time of both the administrative agencies and industry during the past year." Dr. Kenneth Morgareidge, "Food and Drug Research Laboratories," 15 FOOD DRUG COSMETIC LAW JOURNAL 672 (October, 1960).

[8] Mr. W. W. Goodrich, 16 FOOD DRUG COSMETIC LAW JOURNAL 98 (February, 1961).

[9] Deputy Commissioner John L. Harvey, 15 FOOD DRUG COSMETIC LAW JOURNAL 306 (May, 1960).

Since the enactment of this law in September, 1958, the Food and Drug Administration has responded to more than 4,200 formal inquiries dealing with food additive problems . . . there have been hundreds of discussions with industry people . . . we have received 391 petitions for food additive regulations . . . *175 were for indirect additives involving approximately 1,675 chemicals,* 216 were for direct additives involving approximately 257 chemicals . . . *we have issued 59 regulations to date* . . . we have issued extensions of the effective date of the law covering some 3,000 uses of food additives, about 1,100 (of) which are direct additives. The others[10] are in the packaging and equipment field . . .[11] (Italics added.)

Unique Problems of Packaging Additives

Why is the problem of obtaining a Food Additive Regulation more difficult where packaging additives are involved than where direct additives are the concern? The Amendment was written in terms of "any substance" and its procedures clearly are designed to deal with individual chemicals, not end products. The law is fundamentally unsuitable, in its present form, to a large number of chemical substances which are potential additives, grouped together in widely varying amounts within a single product.

Although its views may have changed, the Food and Drug Administration made it clear in the early days of the Amendment that all potential additives must be considered individually:

As we see it, there are two fundamental principles which may well have been overlooked by some in the packaging industry: The first of these is the matter of just what we should be talking about when we deal with the food-additives question. Certainly, initially we are not dealing just with the finished package. Instead, we are concerned with such of its individual components . . . which may reasonably be expected to migrate to the food. As a basic premise, therefore, it is of paramount importance to learn first just what components go into the package . . .[12]

In seeking a solution to this problem we need, first, the complete quantitative composition of the film or coating . . . and, secondly, data showing with the necessary degree of sensitivity and reliability the quantity of each component which may transfer to the food . . . Since a change in the percentage of one component of a plastic, or in the manufacturing process . . . may have a marked effect on the chemical and physical properties of the plastic, we are constrained to recommend that each formulated packaging material be individually evaluated.[13]

Inevitably, the practical problems of applying an individual component approach to highly complex end products (such as cellophane,

[10] There would be 1,900 others.

[11] Assistant FDA Commissioner J. Kenneth Kirk, 16 Food Drug Cosmetic Law Journal 284-285 (May 1961).

[12] Assistant to the FDA Commissioner J. Kenneth Kirk, 15 Food Drug Cosmetic Law Journal 264 (April, 1960).

[13] L. L. Ramsey, FDA Division of Food, 13 Food Drug Cosmetic Law Journal 789 (December, 1958).

paper, can enamels, etc.) began to appear. The major problem was the difficulty of determining the identity and quantity of each migrant. This problem normally does not face the proponent of a direct additive because he knows right from the start the identity and purity of his additive, and the quantity he proposes to introduce into the food. He has plenty of problems, to be sure, for he must determine the safety of his direct additive and this may require animal feeding tests costing hundreds of thousands of dollars and requiring several years of study. The proponents of an incidental packaging additive, however, may never be able to reach the stage of animal feeding tests because of the difficulties involved in analyzing for migrants from packaging materials. For him the question is not only whether there is enough time and money to do the job, but also whether it is scientifically possible to do it at all.

The Analytical Problem

The statute says FDA must know what—if anything—migrates to the food, and how much. Consider, for example, a packaging material (e. g., paper) where the make-up sheet for the primary product shows 20 to 30 items. Some of these items are closely related to each other (e. g., possible residual calcium from the sulphite pulping process and calcium stearate, a lubricant in starch coatings). Some items are closely related to subsequent converting chemicals which will be used (e. g., urea formaldehyde resin, used to provide wet strength in primary paper making, and formaldehyde which might be present in adhesives or coatings). Still other chemical items on the make-up sheet are proprietary mixtures known only by trade names (e. g., "Dowicide G," a slimicide, and "Nalco 71-K," a defoamer) and the composition of which may be trade secrets, if, indeed, the manufacturer knows the chemical composition with any exactness. Assume that this complex formulation of 20 or 30 items is sold for conversion into a specialty food paper (e. g., for wrapping bread) and in the conversion process is printed. (Inks are probably the most highly complicated mixtures of chemicals used in industrial processing; even a small ink maker may handle as many as fifty thousand formulations a year.[14]) In further conversion the printed paper product may be coated with a blend of several waxes, to which polyethylene may have been added. Rolls of the converted product are then shipped to food packers (e.g., bakers) who pass them over various types of wrapping

[14] "Toxicity and Printing Ink," *National Printing Ink Research Institute,* Lehigh University, Bethlehem, Pennsylvania.

equipment for the packaging of many varieties of the food (bread) at various temperatures, with the packaged food then being transported and held under varying conditions of temperature and moisture for varying lengths of time.

If we remember that the applicability of the Federal Food Additives Amendment to each one of the multitude of chemicals involved in this converted packaging product depends on whether even one molecule of one of these chemicals transfers to the packaged food under any one of the intended conditions of use, the enormous magnitude and the staggering complexity of the initial analytical problem can be grasped. However, for the sake of the example let us make a number of very unlikely assumptions. (1) Let us assume that infinite time, money and laboratory skill and facilities are available. (2) Let us assume the manufacturers of the proprietary mixtures and the inks readily can and will reveal the exact formulation of their products, either to our laboratory or to the FDA. Tests are then conducted for the presence in the food of each chemical known to have been a possible constituent of the primary product and each chemical used in the converting process. (3) Assume that where no analytical test is known to science, our hypothetical laboratory can promptly devise one. Thus each migrant and the quantity thereof becomes known.

The problems are only beginning, however. Each migrating chemical not only must be identified but its source should be known as well if it will be necessary to put any sort of limitation on its quantity. Many foods in their natural states contain substances identical with, or not capable of being distinguished from, substances which may become incidental additives. If our scientists find some fraction of a hydrocarbon in the bread, where could it have come from? The wax? Yes. From the polyethylene? Yes. From the defoamer which might have had some mineral oil in it? Yes. From the bread itself or from some direct additive to bread? Yes. Can the true source be determined? Probably not in the present state of scientific knowledge, but—back to the laboratory. (4) Sources can be pinpointed.

There are still more variables. What migrates and how much may depend on the length of time there is a contact between the packaging material (the breadwrap) and the food (bread). Not just length of time affects this determination, however; temperature, moisture, rough handling and other factors are important. And are all breads themselves of the same chemical composition? Obviously not. (5) It

is possible to establish all possible conditions of use and to evaluate their effect upon migration accurately.

Thus in the end every migrant (and its source) is identified, the quantity transferring is determined. (6) The safety of all the migrating chemicals, in those quantities, under all conditions of use, is established.[15] Our hypothetical scientists heave a sigh of relief and prepare to return to what they may consider to be more constructive endeavors. Then the manufacturer who employs them, and who has spent hundreds of thousands of dollars achieving the matters covered by our six assumptions, asks if the same converted paper product can be used for wrapping meat, candy bars, cookies, breakfast foods and ten other general categories of food. Are the same analytical tests which were devised for the bread applicable to meat? Or to candy, etc? Unfortunately not. Are the packing conditions, storage conditions, handling conditions and time of contact the same? No.

In the paper field alone, and without reference to the infinite varieties of converted products, a single manufacturer may produce more than 100 grades of primary food papers. Each grade involves several chemical differences from each other grade. Considering the variety of foods with which each grade may be used, and the variety of processing, transportation and storage conditions occurring in the case of different foods, the additive possibilities which the analytical chemist must consider are astronomical in number.

However, our weary scientists in our hypothetical laboratory are far from finished with their work when they have established the safety of all possible migrating chemicals, from all these products, to all possible packaged foods, under all possible conditions of use. Before a petition can be filed obtaining a regulation for any non-exempt chemical which is found to transfer to a food, under some possible condition of use, these scientists must develop not just an analytical technique which in their own laboratory will detect the quantity of the chemical present in the food, they must also devise a *"practical method* to determine the amount of the food additive in the . . .

[15] As previously stated, testing one chemical of unknown toxicity for safety may require several years of animal feeding tests and cost up to $500,000. The chemicals used in packaging materials are chosen for their ability to accomplish some physical effect in the package and not to make some direct contribution to the food. Thus there is less likelihood of a history of food use, or of prior animal tests, and a greater probability of having to conduct animal tests under the new law. However, since we are hypothesizing, we can dispose of this most difficult aspect of the problem with only a mention.

finished food."[16] (Italics added.) This does not mean a detection method requiring special equipment, knowledge or capability; what is envisioned is a method that can be used for practical food control purposes by any field laboratory of the government.

Here we probably ought to stop making assumptions. The requirement of such "practical" analytical methods in circumstances such as have been described is, of course, highly unrealistic. It is perhaps not beyond the range of our imagination to assume that the finest scientists in the finest laboratories can perform wonders of analytical detection given infinite time and money. It is beyond reason to think that they can translate the brilliant results of specialized laboratory research into something akin to litmus paper tests for thousands of different chemicals under thousands of different use conditions.

The foregoing example, of course, is exaggerated to make its point. It takes no account of use of the "Ramsey Solvents" which in some—but far from all—cases are enough like the food and the conditions of use to provide a satisfactory substitute for actual tests of the food. The example does not consider that in some cases a coating can be proven to be a complete barrier, thus eliminating the necessity for considering any ingredients except those in the coating itself. The example ignores the fact that in some end products (such as paper) a great many of the components are exempt from the law because of general recognition of their safety under the intended conditions of use ("GRAS"), or because they have prior sanctions,[17] in which case transfer of these substances becomes irrelevant. These helpful possibilities may lessen the magnitude of the problem, but they do not constitute a solution to it, or even offer sufficient assistance to make the law really workable. An additive pretesting law which is written in terms of the migration of any quantity, no matter how small, of individual ingredients simply is not suitable for packaging materials. It seems the Food and Drug Administration has finally come to admit this:

> Our original concept of a Food Additive Regulation was that this would specify the substance, state the purpose of its use and limit the amount which would be present in the food, and that we would, in every case, have a good method of determining whether this limitation has been met through examination of the finished food product in the laboratory. . . . When we came to the packaging field, we were faced with the problem where it was just impossible to

[16] Section 409(b)(2)(D) of the Act, 21 U. S. C. 348(b)(2)(D), and 21 C. F. R. 121.51(e), D.

[17] See footnote 5 above.

anticipate the development of methods of analysis which would enable us to examine food products and determine how much of the packaging material had migrated. . . . Also in the packaging field our first concept was a consideration of the food additive status of each substance used in making a product such as paper, for example. This would work out on the basis that if the specific substance migrated to the food we would then have a regulation for that specific substance . . . *it will, I believe, be quite apparent that approaching the problem on that basis would result in a monumental and perhaps never-ending job.*[18] (Italics added.)

Administrative Legislation—The "New" Regulations

When it became apparent that the Food Additives Amendment could not be applied to incidental additives such as packaging materials according to its terms, the Food and Drug Administration had two choices. It could return to Congress with the frank admission that the incidental additive problem had been misjudged and ask Congress to reconsider the problem; or it could develop its own methods for handling such additives and "amend" the statute by administrative interpretations. The Administration chose the latter course and came up with a number of suggested procedures for short-cutting this "monumental and perhaps never-ending job."

FDA clearly has a duty to find a way of making the present statutory plan work efficiently for the consumer (and "efficiently" means that the cost to industry—and thus to the consumer—must represent value received by the consumer in terms of safety); or, if that is not possible within the terms of the statute, FDA has a duty to return the problem to Congress for reconsideration. Apparently FDA believes that its suggested procedures, implemented by administrative "interpretation," are within the terms of the statute, and will make possible a reasonably efficient handling of incidental packaging additives. It is proper to ask, however, if these procedures are parts of a carefully studied plan by the FDA management team, including its counsel, or if they are but a succession of reactions to newly crystallized problems. Has thoughtful consideration been given to the legality and the propriety as a policy matter of imposing these procedures upon the producers and consumers of incidental additives? Has FDA thoroughly weighed the cost to the consumer of insisting on continued administration of an inapplicable statute through engrafted and inconsistent interpretations?

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[18] Deputy FDA Commissioner John Harvey, 15 FOOD DRUG COSMETIC LAW NAL 619 (October, 1960).

Regulation By Specification

Initially the suggestions offered by FDA were directed toward easing the burden of laboratory analysis. It was suggested, for example, that if the total amount of a migrating substance present in a packaging material would be safe in food, it would not be necessary to determine the actual amount migrating.[19] Another suggestion was that if a given quantity of a migrating chemical would be safe in the food, the analytical test method would not have to be sensitive to amounts below the safe level. Thus, the regulation could specify a test method of limited sensitivity and if the test showed zero, use of the substance would be in conformity with the regulation.[20]

If a packaging product were to be approved because the total amount of a particular migrant present in the product would be safe in food, even if it all migrated, it would be necessary to establish specifications for that particular product so that it would not be manufactured later with a greater amount of the particular migrant in it. If specifications were to be established for one ingredient of an end product, FDA soon came to the view that it might be useful to establish specifications for the entire end product. This would have the advantage of permitting, in some cases, an analytical control test of the end product as a whole, and from the point of view of an ardent regulator, of course, it would have the advantage of placing an entire line of commerce under control instead of only one, small, raw material ingredient.

The "Blanket Regulation"

The specification approach, which is exemplified by the polypropylene and polyethylene regulations,[21] led to another form of regulation which has come to be called the "blanket regulation." Although it has been much discussed, only one regulation in this form has been issued.[22] In the author's opinion, this form of regulation is outside the bounds of the regulatory plan set up by the Food Additives Amendment and its use creates legal and policy problems which FDA has not adequately considered.

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[19] A. A. Checchi, Assistant to the Deputy FDA Commissioner, 14 Food Drug Cosmetic Law Journal 593 (September, 1959).

[20] Source cited at footnote 19, at pp. 593-594.

[21] 21 C. F. R. 121.2501 (Polypropylene) and 21 C. F. R. 121.2510 (Polyethylene).

[22] For Cellophane, 21 C. F. R. 121.2507.

The blanket regulation was initially described this way:

> . . . Our people have been discussing with industry representatives the possibility of some sort of blanket regulation for specific types of packaging materials which will list the various components which themselves may be food additives and which may be used provided the packaging material meets certain extraction tests of an exaggerated character using various solvent materials.[23]

As described, the regulation would be similar to the polypropylene-polyethylene technique, involving an extractability test for the end product. It would differ in that only some of the components would be listed and there would be no over-all specification. In due course, however, it was suggested that a "blanket regulation" might not necessarily involve specific products and might not necessarily involve an extractability test. Instead, it was suggested, a blanket regulation might constitute a listing of all the chemicals involved in all the end products made of one primary material (e. g. paper, paperboard, cellophane, etc.) with the chemical components grouped according to whether or not they were generally recognized as safe (GRAS), covered by a prior sanction, not reasonably expected to transfer, or covered by an issued, or to-be-issued regulation.[24]

Such a blanket regulation would be an ineffective general description accomplishing nothing positive in and of itself. However, such a blanket regulation raises more serious legal and policy questions. For example, it is hard to find the legal authority to list in a Food Additive Regulation purportedly issued under Section 409(c) of the statute, many chemical substances which are admittedly completely exempt from regulation under Section 409 because they are exempt from the definition of "food additive" contained in Section 201(s).

The same question frequently has been raised with reference to Regulatiton 21 C. F. R. 121.101 in which, by regulation, FDA purports to establish those substances which are GRAS.[25] GRAS substances, by definition, are not food additives and are totally exempt from regulation as food additives. It is beyond question that FDA is not the authority designated to determine whether any substance is GRAS. Congress set the standard for determining that question, and any

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[23] Source cited at footnote 18, at p. 620.

[24] This suggestion has been made to representatives of the American Paper and Pulp Association, the National Paperboard Association, the Paper Shipping Sack Manufacturers Association the Glassine and Greaseproof Manufacturers Association.

[25] ". . . generally recognized, among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown . . . to be safe . . ." See footnote 5 above.

manufacturer is entitled to apply it to his own situation. FDA has a duty to reach a judgment on the GRAS statute of any suspect substance, and if FDA determines that substance is not GRAS, FDA should continue its inquiry to see if an unlicensed food additive is involved. However, when FDA finds that a substance is GRAS, in FDA's opinion, then that substance, so far as FDA is then concerned, is exempt from the law and from FDA's control or jurisdiction under the Food Additive Amendment.

FDA's practice of issuing regulations stating which substances are GRAS encourages the impression that no substance is GRAS unless FDA, by regulation, makes it so. Customers become very uninterested in having a supplier tell them that a given migrant is exempt because it is GRAS unless FDA has included that migrant on one of its published lists. The net result in the commercial world in many product areas has been to preclude individual determinations of GRAS status and to give FDA nearly as much control over exempt substances as it has over those which Congress placed under FDA jurisdiction. Fortunately this trend has been somewhat slowed by the establishment of expert panels in some fields to establish GRAS lists without reference to FDA's views.[26] It would be reassuring if FDA would re-examine, as a policy matter, the entire concept of issuing regulations which to the commercial world appear to be Section 409(c) Food Additive Regulations, but which are partially or wholly devoted to exempt substances.

FDA's apparent intention to regulate that which Congress has not subjected to regulation appears again in FDA's expressed desire to write regulations for entire industries and all their products (e. g., paper and paperboard), under a statute which covers only a few of the raw material ingredients used. There is no evidence that Congress ever intended the FDA should write regulations stating how paper, paperboard, cellophane, etc. were to be manufactured. Such a prospect was never considered in all the years of hearings on the Food Additive Amendment and most lawyers would agree the statute would need be very clear before such a drastic degree of regulation could be authorized. Something akin to the authority to standardize foods, so carefully established by Congress in Sections 401 and 701(e) of the

[26] See the description of the Flavoring Extract Manufacturers Association panel and its work, given by Franklin M. Depew, President of the Food La Institute, 16 FOOD DRUG COSMETIC JOURNAL 257 (May, 1961).

Act, would be required before FDA would have the power to standardize food papers, food cellophanes, etc. Yet if the Food Additive Regulation itself is written in terms of vast groups of end products and purports to list all the chemicals which may be present in the end product (including large groups of chemicals *not* covered by the law as well as those which *are* subject to it), the same drastic result is achieved without statutory authority.

Lastly and perhaps most important, under the proposed blanket regulation procedure there seems to be no requirement that petitions contain reports of toxicological investigations and a description of a practical means for enforcing the regulation, that is, of readily determining whether or not the product or products to be controlled comply with the regulation. As previously indicated, it is difficult if not impossible to apply these provisions to incidental additives but these requirements are not merely administrative requests to be waived at FDA's pleasure. The statute itself requires the petition for a Food Additive Regulation to contain "a description of practicable methods for determining the quantity of such additive in or on food . . ." and ". . . full reports of investigations made with respect to the safety for use of such additives . . ."[27] A blanket regulation issued in a form ignoring these statutory requirements is of very questionable value, for such a regulation would appear to be voidable at any time for failure to conform to the statute; and—if FDA should seek to cure the regulation's voidable nature—its proponents might at any time be subjected to demands for the missing scientific data or have their industry subjected to a form of control they never anticipated.

Factory Inspection: The "Food-Additives-Are-Food" Theory

There may be an explanation for the absence of a control method from some of the FDA descriptions of the blanket regulation. FDA believes it has or should have, very comprehensive factory inspection powers. The polypropylene regulation seems to assume that there will be inspections by FDA of plants producing this material. Factory inspection may be the implied method for assuring compliance with other blanket regulations now contemplated.[28]

[27] Sections 409(b)(2)(D) and (E) of the Act, 21 USC 384(b)(2)(D) and (E).

[28] "Plant inspection can augment laboratory testing to insure compliance with such requirements. It is on this philosophical footing that we have constructed our regulations for polypropylene and the nylons, and are considering

(*Continued on following page*)

Here again serious legal questions arise. The statute contains a power to inspect. Section 704(a) of the Act[29] states in part that for purposes of enforcement, duly designated employees are authorized:

> (1) To enter, at reasonable times, any factory, warehouse, or establishment in which *food,* drugs, devices or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction . . . and (2) To inspect . . . such factory . . . and all pertinent equipment, finished and unfinished materials, containers and labeling therein. (Italics added.)

So far as packaging additives are concerned, the key word in the above quotation is "food." There is no explicit authority to inspect factories, warehouses, etc., where food *additives* are manufactured, etc., nor to inspect such establishments where food *containers* are manufactured, etc. Congress never considered, let alone authorized, FDA inspection of industrial chemical factories, packaging plants and other non-food establishments. When the Food Additive Amendment was passed, no change was made in the authority granted by Section 704(a).

FDA claims to find authority for such inspections in the theory that a "food additive" is a "food" and these two terms are interchangeable throughout the statute. This equation of words arises from the definition of food in Section 201(f) of the Act, which includes "articles used for components" of food and the definition of food additive in Section 201(s) which refers to substances which may reasonably be expected to become components of food.

FDA has used this same argument as one support for its claimed power to seize unlicensed food additives before they are are used with food. (The statute authorizes the seizure of adulterated *food,* for instance where a food is adulterated because it bears or contains an unlicensed food additive,[30] but it does not authorize seizures of unlicensed food *additives* capable of some day causing a food to be adulterated.) The theory in this application has been well analyzed —and rejected—by at least one well qualified writer.[31]

(Footnote 28 continued)
those for can enamels and similar substances." L. M. Beacham, FDA Division of Food, 16 FOOD DRUG COSMETIC LAW JOURNAL 264 (May, 1961).

[29] 21 U. S. C. 374(a).

[30] Section 304(a) of the Act, 21 U. S. C. 334(a) reads: "Any article of food . . . that is adulterated . . .shall be liable to be proceeded against . . . on libel of information and condemned . . . " Section 402(a)(2)(C), 21 U. S. C. 342(a)(2)(C) reads: "A food shall be deemed to be adulterated . . . (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of Section 409. . . " Section 409 equates

In answer to questions about the statutory authority for factory inspection and seizing empty containers (which might be unlicensed food additives) FDA's General Counsel stated the FDA position as follows:

As far as I'm concerned, it is true that "food additives" were not specifically made "food" by definition when the Food Additives Amendment was passed. The Congress' explanation for that was: "It was unnecessary to do so." . . . If any container has a poisonous[32] substance in it that is reasonably expected to migrate to food and the container is being shipped to, or is in the possession of, a food processor, we would not hestitate to attempt to take regulatory action to prevent its use before food was packaged in it, thereby rendering the food adulterated. We think the law is ample on that point.[33]

The question of inspecting these places[34] has not come up. As you know, our inspection authority is supported by a criminal statute and of course it likely to be strictly construed. I must say, however, that if anyone will look at the polypropylene food additive regulation he'll see that it is established in terms of what was used in preparing that substance.

As a practical matter, we're not going to be able to issue regulations for some packaging material without doing it on the basis of specifications for the packaging material. In order to make those regulations effective there will have to be an adequate inspection power. I don't anticipate any difficulty on this nor am I here suggesting that when we bring our first criminal case to get a reliable interpretation of the factory inspection authority, we go into some can company to start. The statutory basis for authority to inspect would have to be that the food additive is a food because it is intended for use which results in its becoming a component of food. . .[35]

Packaging additives are not "used for components of food" even though they may "become components of food," and no amount of semantical acrobatics will change that fact. Also, there is no evidence, as has been said, that Congress intended the word "food" in the factory inspection section of the Act to authorize inspections of metal, paper and plastics packaging plants. In addition to these points, we should note another problem with the "food-additives-are-food" theory: the application of the food labeling provisions of the Act to all food additives. If FDA accepts this theory—and the gains in terms of expanded factory inspections and seizure powers suggest that

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(*Footnote 30 continued*)
"unsafe" to unlicensed, that is, a use not in conformity with an issued regulation.

[31] John G. Kuniholm, "Are Empty Containers Food," 15 Food Drug Cosmetic Law Journal 637 (October, 1960).

[32] Since the Food Additives Amendment is completely antithetical to the concept of "poisons," this reference should be to an "unlicensed food additive."

[33] Mr. W. W. Goodrich, 16 Food Drug Cosmetic Law Journal 51 (January, 1961).

[34] Plants producing food-packaging materials.

[35] Source cited at footnote 33, at p. 57.

FDA will push the theory—then why does FDA do nothing about all the "misbranded foods" (that is, food additives) being shipped every day?

The answer is that FDA recognizes that food additives don't need to be labeled as foods, in many cases could not be so labeled, and that Congress never said they should be so labeled. FDA has said: "We do not believe that an empty can [36] requires labeling as a food." [37] Then, in the same breath, FDA says: "We believe that can manufacturing plants are subject to inspection to detect possible violations of the food-additives amendment." [38] From this it appears that while FDA may want some of the benefits of its "food-additives-are-food" theory, it will not apply that theory consistently across the board. If Congress intended that all uses of the word "food" in the statute should include "food additives," FDA would have no such choice. Perhaps even FDA has some reservations about the validity of this theory.

A Short-Cut Procedure

The FDA originally wanted to hold all additive clearance techniques closely in line with the statute:

> . . . we have been asked if we do not recognize that we should take the position that the incidental additive from packaging materials be classed as *"de minimus"* or of "pharmacological insignificance." While these are nice sounding terms, the fact remains that we just are not in a position to solve our food-additives problems on the basis of semantics.
>
> When you come right down to fundamentals, the proponents of this idea are really asking that we deal with these incidental additives on a basis clearly different from that contemplated by the law. They are saying that we should, in effect, set tolerances for incidental additives by a sort of short-cut procedure—just because the additives are present in quite small quantities. [39]

In lieu of solving the problem with "nice sounding terms," FDA now suggests we solve it with "the blanket regulation." This is a solution "clearly different from that contemplated by the law" for it amounts to a proposal (1) to issue regulations covering chemicals which are totally exempt from control under the enabling statute; (2) to issue regulations controlling entire industries and the manufacture of their end products under a statute clearly written to deal with only certain chemical ingredients of such end products; and (3) to institute

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[36] In the context, this reference is to an empty can containing a food additive.

[37] "FDA Answers to Questions," 15 FOOD DRUG COSMETIC LAW JOURNAL 232 (April, 1960).

[38] Source cited at footnote 37.

[39] Assistant Commissioner J. Kenneth Kirk, 15 FOOD DRUG COSMETIC LAW JOURNAL 264-265 (April, 1960).

factory inspections of non-food plants (and seizures of non-food items) on the basis of a highly questionable statutory construction, inconsistently applied.

This sort of "administrative legislation" does no credit to FDA. Congress always has provided regulatory power where FDA could demonstrate the need. FDA is not overstaffed or short of useful work to do. Thus it is hard to understand why FDA should be so quick to claim additional power beyond that granted by Congress. The blanket regulation, inspection of non-food factories and seizures of non-food items may be only reactions to what FDA believes is a regulatory need, but this does not justify proceeding without statutory authority. These activities ought to be closely reviewed by the FDA Commissioner and his policy-making superiors.

A Prudent Judgment?

We have been trying to assess the prudence of the judgment that incidental packaging additives should be regulated in the same manner as direct food additives. We have seen the enormous difficulties involved in subjecting packaging additives to the present statutory procedure and we have seen how this has led the FDA toward forms of regulation, and methods of enforcement, not sanctioned by the statute. The other results of this judgment cannot be measured with great accuracy but they are beginning to be clear.

First, so far as the author can determine, the huge expenditures and intensive studies of the last three years have not produced any evidence that any old or new packaging material would have been a serious hazard to health if the Food Additives Amendment had not been enacted. Some specifications have been set for new materials, and some limitations have been placed on the usage of components of older materials. However, no major health hazards from packaging materials have been identified, and it is likely that similar specifications and limitations would have been established by the manufacturers involved without governmental fiat—and without the great expense which attended the issuance of formal regulations.

Second, FDA has not concentrated its efforts on direct additives but has diverted the bulk of its all-too-limited resources to handling incidental additives and particularly packaging additives. If the direct additive problem is as serious as FDA told Congress it was prior to 1958, it is wasteful (and perhaps even dangerous) to divert effort from that field to incidental additives.

Third, there has been a sharp reduction in research on, and the development of, new products and new methods. The number of research workers and facilities available in industry is limited. If these workers and facilities must be devoted to solving difficult and lengthy analytical problems involving existing products, they cannot be serving the consumer at the same time with the development of better and cheaper new products.[40] When the work they must do on old products is enormously expensive, the loss to the consumer in new products is very great.

Fourth, the aggregate cost of the scientific determinations required by the present law for incidental additives is tremendous. That cost is a cost to the consumer. Is the consuming public paying this tremendous cost for a negligible (if any) increase in the safety of what is already by far the world's finest food supply? The foregoing strongly suggests that this is true, and if it is, we are indeed being "improvident in the use of our resources." [41]

Congressional Reconsideration

If, as the author believes, the present regulatory plan is imprudent when applied to incidental packaging additives, Congress ought to be asked to reconsider it. If some form of control is necessary, an appropriate method of achieving it at a reasonable cost to the consumer can be devised. Or it may be that the evidence will show rather clearly that there are no hazards from packaging additives which justify any form of regulation. In either case, the enormous waste, cost and the administrative aberrations resulting from the present inapplicable statutory plan will be remedied.

A vigorous effort should be made to enlist FDA's support for Congressional reconsideration, but the effort must come soon, before the ill-considered regulatory policy exemplified by the blanket regulation becomes so well established that the FDA will not be willing, as a policy matter, to change its direction. Few governmental agencies have so consistently demonstrated their fair-minded objectiveness over the years, and it is certainly reasonable to expect that FDA's top-level administrators, if they can somehow be caused to take the time to thoughtfully consider the problem, will recognize the need for a special legislative solution and will cooperate in seeking it. **[The End]**

[40] For a discussion of related adverse effects on research in animal drugs and agricultural chemicals, see Charles F. Hagan, 15 FOOD DRUG COSMETIC LAW JOURNAL 118 (February, 1960) and Adrien L. Ringuette, 15 FOOD DRUG COSMETIC LAW JOURNAL 334 (May, 1960).

[41] Source cited at footnote 3.

The Federal Hazardous Substances Labeling Act

By GEORGE T. SCRIBA

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THE FEDERAL HAZARDOUS SUBSTANCES LABELING ACT[1] was approved by the President on July 12, 1960. It provided that it should take effect on February 1, 1961, subject to the power of the Secretary of Health, Education and Welfare, who administers it, to prescribe a subsequent date no later than February 1, 1962. The Secretary has prescribed first, August 1, 1961, and later February 1, 1962, as the effective date for the penalty and condemnation provisions of the Act, except as to "flammable", "highly flammable" and "highly toxic substances."[2] As to those three exceptions the Act became fully effective on February 1, 1961.

The title by which the Act may be cited is the "Federal Hazardous Substances Labeling Act." The scope of the statute is not as broad as this title would suggest. A more accurate title would be "Federal Hazardous Household Substances Labeling Act."

Perhaps the simplest and clearest title would be "Federal Hazardous Household Chemical Products Precautionary Labeling Act" if, as appears probable, the Act applies only to chemical products. The statute relates to the precautionary labeling of "hazardous substance(s) or mixture(s) of substances." It relates to them when they are "in a container intended or suitable for household use."

If one were required to state the gist of the new statute in a single sentence it would not be far wrong to say that where the common law

[1] 74 Stat. 372, 30 U. S. C. 1261-1273.

[2] 26 *Federal Register* 937, 26 *Federal Register* 6544.

imposes liability for personal injury for failure to warn of the hazards of a product covered, the Act now imposes criminal penalties.

If one were allowed a paragraph one could reasonably say—The Act applies to household chemical products sold in interstate commerce. If such a product is hazardous, and may cause substantial injury or illness, the container must bear a warning. The statutory standard for determining whether a product is hazardous is the standard used by the courts in civil liability cases. The duty to warn is the same under the common law rule and under the rule of this Act.[3] The Act specifies the basic elements of a warning label; a signal word **(DANGER, WARNING OR CAUTION)**; a statement of the hazard; and advice on precautionary and first aid measures. In addition to the warning, the label must identify the hazardous ingredients for the doctor in case of an accident and must give the name and address of the responsible seller. All of this must be "located prominently . . . in conspicuous and legible type." The Act requires the word "poison" on a highly toxic product which comes within the traditional pharmacists' definition of a poison, and the Act also empowers the Secretary to require the word "poison" on any less toxic product which he finds is nevertheless highly hazardous. The Act generally empowers the Secretary to require more, or less, precautionary labeling where the relative hazard makes this necessary or sensible. Products whose precautionary labeling is regulated by certain other statutes are exempt. The Federal Caustic Poisons Act[4] is repealed and products formerly subject to it are subject to the standards established by this Act.[5]

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[3] It would seem that the Act imposes a duty to know the toxic, flammable and other hazardous characteristics of the product. If so, it may be in advance of the common law of negligence in some jurisdictions.

[4] 44 Stat. 1406, 15 U. S. C. 401-411.

[5] This one paragraph summary of the Act may be compared with its basic provisions. They read: Sec. 4—"The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any misbranded package of a hazardous substance." Sec. 2(p)—"The term 'misbranded package' or 'misbranded package of a hazardous substance' means a hazardous substance in a container intended or suitable for household use which, except as otherwise provided by or pursuant to section 3, fails to bear a label—

"(1) which states conspicuously (a) the name and place of business of the manufacturer, packer, distributor or seller; (b) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Secretary by regulation permits or requires the use of a recognized generic name; (c) the signal word 'danger' on substances which are extremely flammable, corrosive, or highly toxic; (d) the signal word 'warning' or 'caution' on all other

The substitution above of the word "product" for the word "substance" has been natural and deliberate. People commonly talk of "consumer products" and of "products for household use." The word "substance" is awkward for anyone but a chemist. The questions which may arise on a first reading of the Act are quite simply: What products are covered by it? What is the meaning of the word "substance" as used in it?

What Does the Word "Substance" Mean?—Does the word "substance" mean a chemical or mixture of chemicals? Or does its meaning include an article, a thing, a device?

Is a child's bed painted with toxic lead paint subject to the Act? Does a flammable celluloid toy come under it? If cigarettes are cancer-producing are they hazardous substances under this Act? If they will injure the small child who eats them are they subject to it? Are paper and matches subject to it? The stronger view would seem to be that none of these come within its scope. It relates to chemical products.

The word "substance" is not defined in the Act. The definition of a "hazardous substance" in Section 2(f) begins—"any substance or mixture of substances . . . ." A standard dictionary definition of "substance" is—"*Chemistry.* Any particular kind of matter, whether ele-

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(*Footnote 5 continued*)
hazardous substances; (e) an affirmative statement of the principal hazard or hazards, such as 'Flammable,' 'Vapor Harmful,' 'Causes Burns,' 'Absorbed Through Skin,' or similar wording descriptive of the hazard; (f) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Secretary pursuant to section 3; (g) instruction, when necessary or appropriate, for first aid treatment; (h) the word 'poison' for any hazardous substance which is defined as 'highly toxic' by subsectioin (h); (i) instructions for handling and storage of packages which require special care in handling or storage; and (j) the statement 'Keep out of the reach of children,' or its practical equivalent, and (2) on which any statements required under subparagraph (1) of this paragraph are located prominently and are in English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label."

Sec. 3(b)—"If the Secretary finds that the requirements of section 2(p)(1) are not adequate for the protection of the public health and safety in view of the special hazard presented by any particular hazardous substance, he may by regulation establish such reasonable variations or additional label requirements as he finds necessary for the protection of the public health and safety; and any container of such hazardous substance, intended or suitable for household use, which fails to bear a label in accordance with such regulations shall be deemed to be a misbranded package of a hazardous substance."

Sec. 2(f)—"The term 'hazardous substance' means: 1. (a) Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is

(*Continued on following page*)

ment, compound, or mixture."[6] This seems to be the sense in which the Act uses the word.

Thus Section 2(f) also provides that the term "hazardous substance" does not apply to "economic poisons", whose labeling is regulated under the Federal Insecticide, Fungicide and Rodenticide Act, nor to "foods, drugs, and cosmetics" whose precautionary labeling is governed by the Federal Food, Drug, and Cosmetic Act, but says nothing about the "devices" which are subject to these two Acts. It would seem that if "devices" had been thought to come within the definition they also would have been excluded.

Section 4(a) prohibits the introduction into interstate commerce of "any misbranded *package* of a hazardous substance." It does not prohibit the introduction of unpackaged misbranded substances. A "misbranded *package* of a hazardous substance" is defined in Section 2(p) as "a hazardous substance *in a container* intended or suitable for household use which . . . fails to bear a label which states . . ." Section 2(n) defines a "label" as a "display of written, printed or graphic matter *upon the* immediate *container* of any substance." Throughout the Act the provisions speak of the container and the label on the container. Nowhere is any mention made of warning labels on "substances" as such. The intent can hardly have been to require warnings on hazardous articles and things when they are packaged, but not when they are unpackaged; to require a warning on a packaged flammable toy, but not on an unpackaged one; on packaged stationery or tissue paper, but not on unpackaged paper. The reasonable conclusion must be that the Act applies to chemical prod-

(*Footnote 5 continued*)
flammable, or (vi) generates pressure through decomposition, heat, or other means, if 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."

[6] *Webster's New Collegiate Dictionary, 1958.* The seven definitions given there are: "1. That which underlies all outward manifestations; real, unchanging essence or nature of a thing; that in which qualities inhere; that which constitutes anything what it is. 2. Essential element or elements; characteristic components; as, the ideas are the same in substance. 3 Essential import: gist; as, the substance of what he said. 4. Material of which a thing is made; hence, solidity, body; as, to test the substance of concrete; also, a material object, as distinguished from something visionary or shadowy. 5. Material possessions; estate; property; resources, as, to waste one's substance. 6. *Chem. Any particular kind of matter, whether element, compound, or mixture; any chemical material of which bodies (sense 6) are composed.* 7. Christian Science. Spirit." (Italics added.)

ucts which cannot be sold unpackaged, which from their very nature must be in a container in order to be handled or used.[7]

Section 2(f) incorporates in the definition of a hazardous substance the ways in which such a substance can injure. It confines the definition to substances which are toxic, corrosive irritant, sensitizing, flammable and pressure generating. Taken collectively these adjectives are characteristic of chemicals and mixtures of chemicals, rather than of articles and things.

Thus, the Act contains these and other clear indications that the word "substance" is used in its dictionary meaning.

This view is strongly substantiated when we look at the origins of basic provisions in the Act and when we look at the legislative history.

Important parts of the language and requirements of the Act are adopted from the now classic chemical labeling manual first published in 1945 by the Manufacturing Chemists' Association, identified as "Manual L-1" and entitled *Warning Labels. A Guide for the Preparation of Warning Labels for Hazardous Chemicals.* The definitions of "highly toxic," "corrosive," "irritant," "strong sensitizer," "extremely flammable" and "flammable" Section 2(h), (i), (j), (k) and (l) use, in varying degrees, the language of the definitions in the manual. The specifications for precautionary labeling under the Act, Section 2(p), are taken directly from pages 10-13 of the 1956 edition (fourth revision) of the manual. Here again is evidence that the Act is specifically designed to cover the labeling of chemical products.

The Senate Committee Report and the House Committee Report speak only of chemicals.[8]

The House Committee Report says on page 3:

> In recent years rapid advances have been made in the field of applied *chemistry,* and these advances, although generally beneficial to the public at large, have posed new problems which can adequately be dealt with only through public education and Government regulation.
>
> Modern developments have increased the possibilities of physical injury from the careless handling of *household chemical compounds.* At the time of passage of the Federal Caustic Poison Act in 1927 the number of *household chemical compounds* in use was extremely limited. The Act called for the labeling

[7] See also Section 4(f) which forbids the introduction into interstate commerce of a hazardous substance "in a reused food, drug, or cosmetic container or in a container which though not a reused container, is identifiable as a food, drug or cosmetic container by its labeling or by other identification."

[8] Senate Report No. 1158, 86th Congress. House Report No. 1861, 86th Congress, 2d Session.

of only 12 caustic and corrosive alkalis and acids. Other laws—the Federal Food, Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act—include requirements for certain descriptive labeling, but, in the aggregate, the scope of these acts is not sufficient today. There are numerous *hazardous chemicals* used in the household which are not subject to any of the above-mentioned laws. (Italics added.)

The examples mentioned in the House Committee Report are silver polishes containing cyanide, dry cleaning preparations containing carbon tetrachloride and "numerous other chemicals not covered by the Federal Caustic Poison Act (page 3 also)."

The Senate Committee Report contains similar general language confined to chemical products (pages 1 and 2) and similar examples of chemical products only (pages 1, 4 and 6).

Both Reports indicate that the principle evil to which the Act is directed is the accidental ingestion of chemical products by children. (House Committee Report, pages 3, 6; Senate Committee Report, pages 1, 3, 4, 5, 6, 7, 10.)

Similarly, at the Hearings before the House Subcommittee, the oral testimony and the written statements filed speak only of chemicals. The numerous examples of hazardous substances cited are all examples of chemical products.[9]

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[9] Records of Hearing before a subcommittee of the Committee of Interstate Commerce on H. R. 5260, 86th Congress, Second Session. March 14, 1960. The definition of a substance was approached only once at the hearings. The Commissioner of Food and Drugs in answer to a question expressed the opinion that a plastic bag "would not come under this Act". That opinion might well have been based on the fact that a plastic bag is not toxic; that it is not corrosive or irritating or a sensitizer; that it is not flammable or pressure generating. The possible hazard it presents is suffocation. But the context of the testimony indicates that both the Congressman and the Commissioner were thinking along broader lines and that, at least at the time, both of them felt this Act applied only to chemical substances. Here are the questions and the answers:

"Mr. Roberts: Dr. Larrick, I am sure that this has had the attention of the Food and Drug people, and I know I am not speaking of anything new, but I am wondering if some type of label can be extended to the use of plastic bags?

"Mr. Larrick: Plastic bags?

"Mr. Roberts: Yes, sir.

"Mr. Larrick: Yes, it could be. Plastic bags that are in the nature of laundry bags and articles of that sort are not normally the type of commodity that we work with, but I am sure that this Congress could do anything they wanted to along that line. I would like to think about it.

"Mr. Roberts: It is considered a chemical substance?

"Mr. Larrick: It would not be a drug. It would not come under the Pure Food and Drug Law, and it would not come under this act, in my opinion.

"Mr. Roberts: It would not come under this act. Again I want to thank you for your statement. Are there any questions, gentlemen?"

It would seem that the word "substance" was used advisedly in this Act in its dictionary sense and means only chemicals and compounds and mixtures of them, packaged, handled and used as such.

We must now consider which of them are subject to the Act. What standards does the Act establish for the requirement of warning labeling? Or for determining whether a chemical product carries a hazard of which the consumer should be warned?

What is a "hazardous substance"?—The definition in Section 2(f)(1)(A), foreshortened for clarity, reads:

> The term "hazardous substance" means any substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable or generates pressure, if 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.

This is common law language and the Senate Committee Report says on page 2:

> The standards established in this bill for determining whether a substance is or is not a hazardous substance are those which are generally recognized at common law in civil liability cases relating to the seller's duty to warn users of the hazards of his products.[10]

This section represents an important breakthrough in the field of household product labeling statutes in several ways.[11]

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[10] The Senate Committee Report also says at page 10: "It is also intended by these definitions to draw as clear a line of distinction as possible between the substances covered by this bill and the substances which are unaffected by it, employing the language of the common law of civil liability in drawing such a line." and at page 12: "It is intended in making such a finding that he (the Secretary) will be guided by principles of the common law with respect to the duty owed by a seller to warn of the hazards of his products." The House Committee Report says at page 6: "Judicial decisions relating to the duty of manufacturers, distributors, or sellers to warn of the hazards of products may also, to the extent that they are consistent with the above discussion, be resorted to for further light on the meaning of the 'if' clause of the definition of 'hazardous substance' in section 2(f)(1)(A) of the bill, it being the committee's view that, in the event of conflict among such decisions, those decisions will be more in consonance with the legislative intent which are more liberal in recognizing the foreseeability of accidental handling or misuse of a hazardous household substance in the absence of adequate warning."

(The "above discussion" relates to the fact that the Act applies only to toxic, corrosive, etc. substances; to the meaning of the word "substantial" in modifying "injury" and "illness"; and to the fact that swallowing or handling by children is often reasonably foreseeable.)

[11] Similar broad household "hazardous substances" labeling laws representing a comparable breakthrough at the state level have been recently enacted in California, Colorado, Connecticut, Illinois, Indiana, Kansas, Massachusetts, Minnesota, Ohio, Texas and Vermont. Similar broad measures are embodied in the New York State Sanitary Code and in the New York City Health Code.

(a) The older federal, state and municipal labeling laws, ordinances and regulations which have accumulated in the books over the years relate only to a few specifically named chemicals.[12] This Act encompasses all hazardous chemicals.

(b) Traditionally, a labeling law has only been enacted after the event; after a number of people have died. This Act is anticipatory as well as experience-minded. Where the hazards are known or are reasonably foreseeable today, warnings are required. Where they become known or reasonably foreseeable tomorrow, warnings will then be automatically required. When new products are introduced, we need not wait for experience. If knowledge or tests indicate that they present reasonably foreseeable hazards, warnings are required.

(c) Again, traditional labeling laws have dealt only with poisons (and with "flammable" products); only with the few products which are "highly toxic" and meet the traditional definition of a poison, or with the fewer less toxic products which have caused numerous deaths and have proven themselves highly hazardous. Limited only by the common law rule this broad Act covers all toxic, corrosive, irritating and sensitizing products which may cause "substantial" injury or illness. The words toxic, etc. are not limited in degree.[13] The discussions of the word "substantial" in the Senate Committee Report and in the House Committee Report indicate that death or incapacitating injury is by no means all that Congress was thinking of.

(d) Labeling laws in the past have adopted a rough and ready, per se, approach. A particular product consisting of a particular chemical causes serious injury and death. A labeling law is passed. It requires a warning (almost invariably "Poison") on the chemical alone or on all products containing that chemical in any proportion, whether or not a particular product containing it actually presents a hazard.[14] And, of course, the product may not. Other ingredients

[12] Many of these will be found in the "Compilation of Laws Affecting Proprietary Drug and Allied Industries", 1960 Edition, published by The Proprietary Association, Washington, D. C.

[13] The definition of "toxic" in Section 2(g) reads: "The term 'toxic' shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface". It would seem that any further definition of "toxic" in terms of an LD_{50} can serve only to limit the scope of the Act.

[14] For example, the New Hampshire Wood Alcohol Law, which dates back to 1915, provides "No person shall sell . . . methyl alcohol . . . whether in concentrated or diluted form, unless the container . . . shall bear a label or tag with the following conspicuously printed in red thereon, viz. . . ." N. H. Rev. Stat. 1955, Ch. 339, Sec. 399.48.

may neutralize or reduce the toxicity of the chemical named. The kind of package used may eliminate the hazard. (For example, liquid of a given degree of toxicity by ingestion may present a serious hazard when packaged in a bottle and none when packaged in an aerosol.) The physical form of the product may be such that there is no hazard. (Thus, a liquid or an aerosol containing a chemical which causes eye injury will be hazardous, where a solid product containing the same chemical is not hazardous.) And in general, the foreseeable handling and use of a particular product containing the black-listed chemical may be such that it presents no hazard of substantial injury. The common law and this Act take all such factors into account in determining whether a product should bear a warning. This Act rejects the "per se" doctrine for chemicals in household products in much the fashion the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act rejected it for chemicals in foods. Warning labeling under this Act is based on the foreseeable hazard or lack of hazard presented when the product itself is actually handled and used in the home—not solely upon the degree of toxicity, corrosiveness, etc. of the different ingredients or of the product itself in the laboratory.

(e) A basic element of the common law standard is that there is no duty to warn where the hazard is known to the user or handler. There is no duty to remind him of something he already knows. "When a dangerous condition is fully obvious and generally appreciated, nothing of value is added by a warning. The sharpness of knives and axes . . . is so notorious that a warning could be expected to add nothing useful to . . . the knowledge common to all men." [15]

There is good reason behind the adoption of this rule as the rule of this Act. Throughout both the Senate Committee Report and the House Committee Report emphasis is put on the fact that unnecessary warnings will tend to defeat the purposes of the law. The House Committee says on page 6—"It is not intended to impose . . . self-defeating requirement(s)" and speaks of "inviting indifference to precautionary statements." The Senate says on page 11 that—

> It is the purpose of this bill to require precautionary labeling which is meaningful and will be observed by the user, but not to require labeling on so many of the things that go into a household as to invite carelessness and the ignoring of precautionary statements.

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[15] 2 Harper and James, *The Law of Torts*, (1956), p. 1542 and p. 1546. Par. 28.5 and Par. 28.7.

While these quotations are taken from portions of the Reports commenting on the use of the words "substantial injury" and "substantial illness" in the definition of a hazardous substance, their relevance and application to the present point are obvious. Unnecessary warnings of hazards known to everyone weaken the impact of necessary warnings of unknown hazards.

To a degree, most chemical products carry their own warning "to all men." Users and parents are generally aware that chemicals are bad to drink, or to breathe or to get in one's eyes. People need warnings where the hazards are greater than they suspect. If, in general, warnings merely elaborate the obvious, the user and parent have no way of recognizing those that should have their attention.

(f) The Act provides clear and simple regulatory procedures for determining and announcing whether a particular product is a "hazardous substance" under the common law rule and under the Act. While the bill was pending, the Secretary of Health, Education and Welfare wrote the two Congressional Committees (House Committee Report, page 24; Senate Report, page 25) as follows:

> It is apparent, that . . . the application . . . of the basic definition of "hazardous substance" in the bill is so largely dependent on judgmental factors—what is "reasonably foreseeable"—that it will lead to considerable uncertainty and much costly litigation, with different courts and juries reaching different results, unless some mechanism for authoritatively resolving this uncertainty short of litigation is devised. We realize that, on the one hand, in view of the broad sweep of the bill, and because of the constant development of new useful but hazardous substances suitable for household use, the inclusion of a statutory list of covered substances (in analogy to the list in the Federal Caustic Poison Act) or the limitation of coverage to substances listed by regulation would not be feasible. And while, on the other hand, we would prefer elimination of the "if" clause altogether from the point of facility of enforcement, we recognize that the inclusion of some such clause can be justified.
>
> It is feasible, however, and we strongly urge, that the committee include in the bill provisions deeming a substance to be hazardous where the secretary by regulation declares it to be such upon the basis of a finding that it meets the requirements of the bill's basic definition of "hazardous" substance. . . .

This suggestion resulted in the addition of Section 3(a). The basic provisions of this section read:

> 1. Whenever in the judgment of the Secretary such action will promote the objectives of this Act by avoiding or resolving uncertainty as to its application, the Secretary may by regulation declare to be a hazardous substance, for the purposes of this Act, any substance or mixture of substances which he finds meets the requirements of subparagraph (1)(A) of Section 2(f).

Proceedings for the issuance of a regulation are "in all respects governed by Section 701(e), (f) and (g) of the Federal Food, Drug,

and Cosmetic Act." Under Section 701(e) "any action for the issuance of any regulation . . . shall be begun by a proposal made—(a) by the Secretary on his own initiative or —(b) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary." Thus the way would seem clear for either the Secretary or any manufacturer or packager interested in any particular product or classification of products to propose the issuance of a regulation declaring the product or the classification to be a hazardous substance, upon a finding that it is within the definition of that term in the Act. The Senate Committee Report states at page 2—"It is intended in making such a finding that he (the Secretary) will be guided by principles of the common law with respect to the duty owed by a seller to warn of the hazards of his products." The interests of other persons are protected. Section 701(e) provides for the publication of the proposed regulation and an opportunity for objections and a hearing.

It would seem that in finding whether a particular product or classification of products is hazardous, the Secretary will necessarily consider the degree of hazard and that the regulation when issued can indicate the degree; and that it can most effectively do so by describing suitable warnings for the containers. The manufacturer or packager who recognizes that his product is hazardous may well want to resolve uncertainty as to the adequacy of his warning, or his trade association may want to encourage a uniform warning for a common product packaged in a common fashion. It is in cases like these that petitions by industry for regulations are envisaged.

(g) However, it would seem that the difficulties which a manufacturer faces in the absence of such a regulation in deciding whether a product is a hazardous product have been exaggerated. The Act requires him to know the toxicity, flammability, etc. of his product and knowing these facts, he will be able to estimate without much difficulty whether a jury will hold him liable in a civil lawsuit if he fails to warn. Responsible packagers (and claims-conscious packagers) of household products have been doing this for years. Experienced counsel accustomed to putting a dollar value on a negligence suit can do so with considerable confidence.

For many common products a comparison of the number of containers which reach the home with the accident records kept by federal and state government agencies will be useful in evaluating hazards. The National Clearing House for Poison Control Centers

consolidates the information available from state and local poison control centers. The National Office of Vital Statistics consolidates reports of the causes of death. Both are under the Department of Health, Education and Welfare.

Where a product has been marketed in quantity for a number of years, the reports of accidents which the manufacturer or packager has received will be indicative of its hazards. They must, of course, be multiplied by some reasonable factor for he cannot expect to hear of all accidents. And if claims for damages have been notable by their absence, this fact will be highly indicative that the hazards are known and that there is no duty to warn. Surely the most strongly motivated critics of the absence of a warning are the injured persons and their lawyers. If by their silence over the years they have recognized that no duty to warn existed, it would seem most unlikely that there is one. By the same token, if they have pressed their claims and the courts have held them valid, there can be no doubt of the duty to warn under this Act.

(h) To ask for a code of regulations under this Act which will clearly differentiate each hazardous product from each non-hazardous one is to ask the impossible. General rules along such lines can only be rough and ready. The cry for certainty will turn quickly into a cry of outrage when any such rule is proposed. Even limited rules which seem to elaborate the obvious and to cover only the clearly hazardous products will still be subject to exceptions. It is conceivable that even a "highly toxic" product, or a product with a flashpoint of less than 80° F, may be so packaged or its hazards may be so universally known that it is not a hazardous substance.

On the other hand, guideposts can be developed and will develop of themselves. The Food and Drug Administration will sooner or later be in court. The decisions which its activity produces will be highly valuable, whether it wins or loses. In the course of time, experience will suggest products and limited groups and classifications of products which lend themselves to declaratory regulations under Section 3(a); regulations perhaps which provide for specific exceptions and for future exceptions. The packagers themselves, individually, or through their trade associations, may propose such regulations.

What Warnings and Other Information Does the Act Generally Require on Packages Containing Hazardous Substances?—The pattern of precautionary labeling required by the Act is set forth in Section 2(p).

It will be clearer to describe this pattern in terms of a specific example of a specific product. The warning and precautionary labeling for ethylene glycol antifreeze recommended by the Chemical Specialties Manufacturers Associations contains all of the elements named in the Act, and there is the advantage that the speaker is familiar with its development. It reads:

WARNING

HARMFUL OR FATAL IF SWALLOWED.

Do Not Drink Antifreeze or Solution.
If Swallowed, Induce Vomiting Immediately.
Call a Physician. Ethylene Glycol Base.
Do Not Store in Open or Unlabeled Containers.

KEEP OUT OF REACH OF CHILDREN.

The first requirement of Section 2(p) is a signal word—**DANGER, WARNING** or **CAUTION.** The signal word "Danger" is mandatory for products which are "corrosive," "highly toxic" or "highly flammable," as defined for the purpose in Section 2. This product is none of these.

The second requirement is an affirmative statement of hazard. The statement used here is "Harmful or Fatal if Swallowed." The only stronger statement which the English language provides is "Fatal if Swallowed." Less strong statements available are "Harmful if Swallowed" and "May be Harmful if Swallowed." The product reaches the garage but not the kitchen; it is liquid; it is drinkable; what is not immediately used is sometimes stored. Available statistics show very few instances of accidental ingestion by children or by adults, whether or not the tremendous number of cans that reach the home annually is taken into account. This is a product which toxicologists rate as "moderately toxic".[16] If it were not "antifreeze", a lesser warning would be indicated. But a few people drink antifreeze deliberately and in quantity. While it can reasonably be said that the danger is known "to all men" (there are literally no claims or lawsuits), the stronger statement of hazard is intelligent.

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[16] "Ethylene Glycol. Toxicity rating of 3 (moderately toxic) is based on clinical data. In guinea pigs, rats and mice the rating is 2 (slightly toxic)." Gleason, Gosselin and Hodge. *Clinical Toxicology of Commercial Products.* 1957 at p. 56.

The third requirement is a statement of the precautionary measures to be followed or avoided. The Act suggests that the Secretary may modify this requirement, presumably where it is superfluous. Perhaps this is so here. The statement "Harmful or Fatal if Swallowed" clearly implies the Precautionary Measure "Do Not Drink Antifreeze or Solution". The only doubt would be about the words "or Solution."

The Act requires first aid instructions "where necessary or appropriate." Those given here are "If Swallowed, Induce Vomiting Immediately. Call a Physician."

For the information of the physician in case of an accident [17] the Act requires the name of the hazardous ingredient. This label states "ethylene glycol base", rather than "contains ethylene glycol," to meet the requirements of state antifreeze registration statutes.

The Act next requires instructions for handling and storage "of packages which require special care in handling or storage." Antifreeze is commonly packed in containers without replaceable closures and experience has shown that people sometimes transfer it to bottles and store it for as long as a year. Hence the feeling that special care is needed. And hence the statement, "Do Not Store in Open or Unlabeled Containers."

The Act makes mandatory the statement **"keep out of reach of children"** or its practical equivalent. Hence this statement.

The Act also requires that the label bear the name and address of the manufacturer, packer, producer or seller.

The pattern of labeling now incorporated in Section 2(p) of the Act is derived directly from the chemical labeling manual first published sixteen years ago by the Manufacturing Chemists' Association.[18]

Since the MCA manual represents responsible industry practice over a period of years, and since the statutory pattern of warning labeling is so obviously derived from it, there is reason to believe that the manual will be useful and used in the interpretation of Section

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[17] Both the Senate Committee Report and the House Committee Report state that the purpose of requiring the name of the ingredient contributing to the hazard (or of several ingredients if several of them contribute) is to provide the doctor with information in case of an accident. See pages 1, 3 and 7 of the Senate Report. See pages 2 and 4 of the House Report.

[18] "Warning Labels. A Guide for the Preparation of Warning Labels for Hazardous Chemicals" (Manual L-1; Fourth Revision: 1956), Manufacturing Chemists' Association, Inc., Washington, D. C.

2(p). The manual elaborates on the elements of a warning and gives reasons for them.

Regarding the signal word it says, for example:

> This word is intended to draw attention to the presence of hazard and to indicate the degree of severity. The signal words recommended are, in order of diminishing severity of hazard:
>
> DANGER, WARNING, CAUTION.
>
> Degree of severity can be expressed only in relative terms. "Danger" is the strongest of the three words and should be used for those products presenting the most serious hazards. "Caution" is recommended for those compounds presenting the least serious hazards. "Warning" is intermediate between "Danger" and "Caution."

The general principles it enunciates have much to do with the selection and writing of a statement of hazard. These principles include, among others:

> All statements on warning labels should be brief, accurate, and expressed in simple easily understood terms.
>
> On labels for different products, uniformity in language to indicate the same hazards and same degree of hazard is most desirable in order to gain greater understanding through standardization.

These two principles are basic. The statement of hazard (and the precautionary labeling as a whole) must be accurate and must fit the hazard of the product. If so, they will enable the user and handler of the product to differentiate its particular hazards from those of products which are less, or more hazardous. The differentiation is important to the prevention of injury. Suppose all products which it is reasonably foreseeable may cause "substantial" skin irritation in varying degrees of severity are labeled "Causes Skin Irritation." A man or woman after exposure to four or five which barely require a warning will ignore the warning on the sixth one which may cause an incapacitating reaction. Statements of hazard which vary with the degree of hazard are required. In this case they might be: "Causes Severe Skin Irritation," "Causes Skin Irritation," "May Cause Skin Irritation." [19]

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[19] Similarly where it is reasonably foreseeable that liquid products will be ingested, the statements of hazard will vary along the lines indicated in the text. For example, one can expect that if they are all products containing a single chemical which is toxic by ingestion, and if that chemical is "highly toxic," the applicable warning will vary according to the percentage of that chemical along the following lines: Less than U percent—No warning; from U percent to V percent—May be Harmful if Swallowed; from V percent to W percent—Harmful if Swallowed; from W percent to X percent—Harmful or Fatal if Swallowed; from X percent to Y percent—Fatal if Swallowed; from Y percent to Z percent (100 percent)—POISON. Fatal if Swallowed.

The clear corollary of the principle that the warning must be accurate and must vary with the degree of hazard, is the principle that products presenting comparable hazards must bear comparable statements of hazards. Thus, where a group of hazardous products are kept under the kitchen sink, in comparable containers, and are equally palatable and drinkable and lack emetic or other distinguishing qualities, so that the risk or chance of ingestion is comparable, those having the same degree of toxicity by ingestion will, ideally, bear the same statement of hazard since they carry the same degree of risk of the same degree of injury.[20]

The beauty of this Act is that it permits and requires observance of these two principles. Unlike the traditional labeling laws it does not require "poison" on all products which may injure, regardless of the degree of hazard. It requires an accurate statement of the individual hazard of each and, by the same token, it requires equivalent statements of hazard on products which present equivalent hazards.[21]

Regarding precautionary measures, the manual makes one suggestion which differs from the requirements of the Act. The statement is made—"A minor hazard may frequently be covered clearly and briefly by an appropriate precautionary statement alone." This suggests, in effect, that instead of the statement of hazard "May be Harmful if Swallowed," the label might say simply "Do Not Take Internally." Or in lieu of "Breathing of Vapors Harmful," the label might substitute "Avoid Breathing of Vapors." The Act does not envisage this reliance upon an implied statement of hazard.

On the other hand, the manual also points out that the statement of hazard sometimes clearly implies the precautionary measure. The manual suggests that it is seldom necessary to follow the statement of hazard "Fatal if Swallowed" with the admonition "Do Not Take Internally." Section 2(p) of the Act seems to suggest that the Secretary may find this sound doctrine.

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[20] Possible variations of statements of relative hazard are indicated in footnote 20. The stronger the statement, apparently the more rarely will it be used. Of approximately 400 common household and farm formulations (other than insecticides, etc.) listed in Gleason, Gosselin and Hodge (book cited), about 35 are rated as "relatively non-toxic" by ingestion; about 100 as "slightly toxic" about 160 as "moderately toxic"; about 80 as "very toxic"; and about 14 or 15 as "highly toxic."

[21] Here again this Act represents an important breakthrough, when compared with earlier statutes. For example, the Federal Caustic Poison Act required "poison" indiscriminately on products containing from 5 percent to 20 percent caustic (depending upon the particular chemical) to 100 percent caustic. This Act repeals it.

As to first aid instructions, the manual opens with the medically suggestive statement (the italics are its own and apparently a doctor's):

> The purpose of a warning label is to prevent injury or damage. However, instructions in case of contact or exposure may be included in those instances where the results of contact or exposure are severe and immediate treatment is highly desirable and where simple remedial measures may be taken safely by nonprofessional persons before medical assistance is available

This may be of value in interpreting the statutory requirement which reads: "Instruction, when necessary or appropriate, for first aid treatment." The manual includes the flat statement:

> Because of serious and lasting effects that may result from eye injuries, a recommendation to get medical attention should accompany any specific instructions directed to treatment of the eyes.

The manual includes full warning texts for well over 150 individual chemicals. It is important to note they are described as "Illustrative Warning Labels for Industrial Chemicals." It will frequently be necessary to modify their warning when the same chemicals or products containing them in important proportions are packaged for household use. The hazards to the industrial worker in the plant and to the child in the household are different. For example, the MCA labels reflect the absence of the hazard of ingestion in the factory. They concentrate on the hazards of inhalation, of skin contact and of eye contact. In the household, ingestion by small children is a principal hazard and must be given equal and frequently greater weight.

On What Products Does the Act Require the Word POISON?—As we have just seen, Section 2(p) provides a pattern of warning labeling under which the statement of hazard will automatically be required to fit the hazard of the particular product and under which the supplementary statements and information required will be in balance with it.

It is thus apparent that the general requirements of Section 2(p) will provide effective warnings for substantially all hazardous products.

However, the Act intelligently provides in Section 3(b) that if the Secretary finds that more is needed and useful on the container of "any particular hazardous substance" he may by regulation require more. It is difficult to envisage any more that might be required, with one exception. That exception is the traditional addition of the word "poison" on containers of highly hazardous products, even where they are only moderately toxic.

While, as we will see in a moment, the Act requires the word "poison" on the containers of hazardous products which are "highly toxic," the word has also long been used on a few products which al-

though not "highly toxic" present special hazards and have actually caused numerous deaths. It may make sense to continue that practice under this Act for the time being where a product is in fact highly hazardous and is not being labeled on a per se basis. It may or may not make sense, as time goes on and we see how effective the Section 2(p) pattern is, to continue the practice. It is obvious that "Danger. Fatal if swallowed" carries a very strong warning indeed. It may be more intelligent to reserve the word "poison" for "highly toxic" products which need to be equated in the public mind with cyanides, arsenic compounds and strychnine.

The Act requires "poison" on containers of hazardous products which are "highly toxic." The term "highly toxic" is defined for this purpose in Section 2(h). Pharmacists tell us that it is a translation, in modern language, of the traditional definition of a poison. It is written in terms of the now familiar LD_{50}, in terms of the grams per kilogram of body weight that kill half of a group of test animals. Specific dosages and concentrations are stated for ingestion, inhalation and skin absorption. If human data are available which indicate what the LD_{50} to humans is at those dosages or concentrations, the human data take precedence. Section 2(h)(2) reads:

> If the Secretary finds that available data on human experience with any substance indicate results different from those obtained on animals in the above named dosages or concentrations, the human data shall take precedence.

This represents a residual bit of the per se doctrine. If a hazardous substance is "highly toxic" its container must be labeled "poison" regardless of the degree of hazard presented by the product as packaged, handled and used. (If, as packaged, it presents no hazard, of course it requires no warning.)

It is because of this per se aspect of Section 2(h) that it is important that when a product which is not "highly toxic" presents a special hazard and requires "poison" labeling, the requirement be made under Section 3(b) where the hazard will be evaluated and not under Section 2(h) where it will not be.

It also seems important to deal with highly hazardous products under Section 3(b) from the point of view of good order. It would surely be regrettable to say that Section 2(h) calls methanol "highly toxic" when the literature classifies it as "moderately toxic."

It is clear that the language of Section 2(h)(2) does not require or permit this distortion. The section is couched in toxicological terms. The "data on human experience" referred to are toxicological

data. The "results different from those on animals" which are to "take precedence" are results "in the above named dosages or concentrations." The comparison to be made in determining whether they are "different" is a comparison of human toxicological data with animal toxicological data. It is not a comparison of the number of accidents to humans on the one hand, with the LD_{50} to rats on the other. These two figures present nothing to compare; nothing to find "different" or similar.

The language of Section 2(h)(2) is taken almost verbatim from the Manufacturing Chemists' Association Manual. It seems apparent that both the manual and Section 2(h)(2) mean:

> If the Secretary finds that available data on human experience with any substance indicate *that the results obtained on humans would be different from those obtained on animals if they could be tested on humans* in the above named dosages or concentrations, the human data shall take precedence. (Italics added.)

In summary, the Act presently requires "poison" on hazardous products which are "highly toxic," which fall within the cyanide, arsenic compound, and strychnine range; and under Section 3(b) the Secretary is empowered to require it also on products which are highly hazardous.

How Does the Act Require that Warning Labeling be Displayed?— Section 2(n) requires that the warning be displayed on the immediate container; on any outside container or wrapper; and on all accompanying literature where there are directions for use.

The Act specifies neither location nor type size nor color. As to location, the key word used is "prominently." As to size of type, the key words are "conspicuous and legible." As to general conspicuousness and color, the key words are "in contrast by typography, layout or color."

The exact language of Section 2(p), abbreviated for present purposes, is:

> The term "misbranded package" means a hazardous substance in a container intended or suitable for household use, which fails to bear a label:
>
> (1) which states conspicuously (signal word, statement of hazard, etc.);
>
> (2) on which any statements required are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

It is obvious that what is intended is a rule of reason; that Congress recognized that given the infinite variety of modern packaging design and the extensive use of color and typography and space to

achieve it, what is prominent and conspicuous on one label will be concealed and unnoticeable on another.

It would also seem reasonable to conclude that Congress felt that the display of the warning, (as well as its wording) should be commensurate with and should vary with the degree of the hazard.

Again the Act eschews the rough and ready type size and color rules of the emergency *ad hoc* statutes of the past. Again it sets reasonable standards on which it is difficult to generalize, but which present little difficulty in specific cases. Artists and printers have no trouble in making the elements of a label prominent and conspicuous. The business man and lawyer, with a jury in mind, will have little difficulty in judging the label when they look at it.

Any general rules are likely to mean overlabeling on many products, a conspicuousness and a prominence out of all proportion to the hazard, remembering the broad scope of the Act; remembering the fact that this is not a "flammable" or "poison" law; that most of the products it covers are of relatively low toxicity; that most of the warnings will read "May be Harmful if Swallowed" or "May Cause Skin Irritation" or "Prolonged or Repeated Breathing of Vapors May be Harmful."

What Has Been Omitted?—1. The definition of "hazardous substances" includes radioactive materials, under some circumstances; excludes household fuels, under some circumstances; and excludes materials subject to the Atomic Energy Act.

2. The definitions of "toxic," "corrosive," etc. which appear in Section 2(g) through (m) of the Act are either self-explanatory or technical. It would seem that any further definition of "toxic" in terms of an LD_{50} or otherwise can serve only to limit the scope of the Act; it cannot modify the common law definition of a hazardous substance or create a per se rule.

3. The supplementary prohibitions, the penalty and seizure and other enforcement provisions, the guarantee provisions, the factory inspection and record inspection provisions, the publicity provisions and the import provisions, resemble those in the Federal Food, Drug, and Cosmetic Act, but have been modified in some respects to meet particular aspects of this Act.

In Conclusion.—This paper has put its emphasis on those provisions of the Act which seem to be, at once, of long term general interest and most under current discussion. It is a topical report on

a statute which is not yet in effect, except as to certain relatively simple and clear matters. It is necessarily a report of one man's thoughts as of today.

It is a report by an enthusiast. This statute covers broadly and intelligently matters which have been dealt with in the past by piecemeal and rough and ready measures. It provides a federal law which establishes a pattern for state legislation, making for uniformity in a field where uniformity makes sense. Above all, it puts its weight on the individual consideration of the individual case. By its common law approach, its disregard for per se rules, and its emphasis on the hazards of individual chemical products as packaged, handled and sold, it permits and requires an intelligent attack on the evils which it seeks to alleviate without exaggerating or minimizing them. It is pleasant to jump from the 17th to the 20th century. **[The End]**

THE WONDERFUL WORLD OF CRYSTALS

Modern "wonder" drugs and chemicals photographed under the microscope—revealing patterns and color that rival the imagination of today's nonobjective artists—were placed on display on October 16, at the Kodak Exhibit Center in Grand Central Station, New York City.

The sixty color photomicrographs comprising the exhibit are the work of photographer Jack Kath. The subjects he "paints" with his camera are primarily drugs and chemicals, including such research discoveries as cortisone and hydrocortisone, vitamin B_{12}, chlorothiazide, conservatively at 3500 million a year." The Congress was sponsored several sulfa drugs and many others.

Kath aids scientists in their research by photographing compounds at enlargements up to 600 times. In the course of this work Kath noted the unusual beauty of the magnified crystals. He began to experiment by changing the position of the slide in the microscope and by introducing polarized light to heighten color effects. The photomicrographs on exhibit are magnified 120 times.

Crystals of these compounds offer an infinite variety of size, shape and character. In fact, it is virtually impossible to duplicate the crystallization pattern of a single compound on two slides.

The exhibit, entitled "The Wonderful World of Crystals," will continue through November 5.

Kath, a graduate of Thomas Jefferson High School in Elizabeth, New Jersey, became interested in photography in 1938. He has been working with the photography of drugs and chemicals since 1941, with the exception of four years he spent as a cameraman in the Air Force during World War II. His department has grown into a staff of four, three photographers and one graphic artist. In addition to medical and scientific photography, this group prepares illustrative material for scientific papers.

Kath attended Rutgers University, the School of Modern Photography in New York City and the New York Institute of Photography.

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

First National Congress on Medical Quackery.—Eliminating medical quackery as a major health problem in the United States was the objective of the National Congress on Medical Quackery which convened in Washington, October 6 and 7.

The meeting, under joint sponsorship of the American Medical Association and the Food and Drug Administration, discussed all phases of the quackery problem, which were broadly defined to include misinformation and illegal practices of all kinds which are detrimental to health.

Abraham Ribicoff, Secretary of Health, Education and Welfare, and Dr. Leonard W. Larson, M. D., President of the American Medical Association, spoke at the conference. Commenting on the meeting Secretary Ribicoff said, "It is highly appropriate for organized medicine and government agencies to work together on this problem. Quackery is a menace to public health. It is a kind of criminal activity that deserves close attention."

Joining Secretary Ribicoff in the opening session was Postmaster General J. Edward Day who defined the work of the Post Office Department in enforcing the postal laws against mail frauds in the health field.

Herbert J. Miller, Assistant Attorney General in charge of the criminal division, outlined the role of the Department of Justice in enforcing statutes against quackery.

Paul Rand Dixon, Chairman of the Federal Trade Commission, discussed the problem of quackery in advertising.

The Food and Drug Administration was represented by Commissioner George P. Larrick, Assistant General Counsel William W. Goodrich, and Dr. William H. Kessenich, Director, Bureau of Medicine. Dr. Kessenich presided over the afternoon session, October 6, during which representatives of major private organizations discussed specific types of quackery and means of dealing with them. Speakers at that session included Dr. L. Henry Garland, M. D., San Francisco, who represented the American Cancer Society; Dr. R. W. Lamont-Havers, M. D., who is the medical director of the Arthritis and Rheumatism Foundation; Miss Maye A. Russ, the Vice President of the National Better Business Bureau and Oliver Field, director of the Department of Investigation of the American Medical Association.

Authorities on other fields of quackery spoke Saturday morning, October 7, in a program moderated by Dr. Lemont-Havers. Quackery in the field of nutrition was discussed by Dr. Fredrick J. Stare, M. D., of the Harvard School of Public Health. State law enforcement against quackery was the subject of the speech by Milton P. Duffy, Chief of the Bureau of Food and Drug Inspections, California Department of Public Health. A report from the Federation of State Medical Boards was presented by Dr. Harold E. Jervey, M. D., the immediate past president. Public education against quackery was discussed by Dr. Morris Fishbein, M. D., representing science writers and editors.

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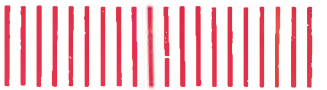

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