VOL. 21, NO. 11 NOVEMBER 1966

Food Drug Cosmetic Law JOURNAL

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

November, 1966
Volume 21 • Number 11

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

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The Food and Drug Administration and the Economic Adulteration of Foods

By WESLEY E. FORTE

This Article Is Reprinted from the Indiana Law Journal (Vol. 41, No. 3, Spring 1966) with the Permission of the Indiana University School of Law and of the Author. The First Part of This Article Appeared in the October Issue of the Food Drug Cosmetic Law Journal. Mr. Forte Is a Member of the Pennsylvania Bar.

Part II: The Standards Used to Determine Economic Adulteration

A. Introduction

Section 402 (b) of the Federal Food, Drug and Cosmetic Act begins by stating, "A food shall be deemed to be adulterated" and then defines in individual subsections the conditions which may result in the economic adulteration of a food.[53] Sections 402 (b) (1) and (2) provide that a food is adulterated if any valuable constituent of the food is removed or omitted, or if any substance is substituted in whole or in part therefore.[54] Sections 402 (b) (3) and (4) provide that a food is adulterated if damage or inferiority is concealed in the food, or if any substance has been packed with the food to increase its bulk or weight, reduce its quality or strength or make it appear better or of greater value than it is.[55] "Food" is defined in the act as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[56] This general definition is satisfactory for most purposes but it offers little help in the interpretation of section 402 (b).

The word "food" in section 402 (b) can be given either of two different interpretations. One interpretation is that "food" means a familiar recognizable food; the other interpretation is that "food" means the allegedly adulterated food itself.[57] For example, assume

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a product called "Bred Spred" is made in semblance of jam but with only one-half the fruit content of jam.[58] If the court defined "food" as the familiar recognizable food, Bred Spred would be an economically adulterated jam. However, if the court defined "food" as the allegedly adulterated product, Bred Spred would be an economically adulterated food when compared to jam. Both interpretations seem equally acceptable so long as the only standard against which Bred Spred can be judged is that of the familiar recognizable food, "jam."[59] However, if Bred Spred may be economically adulterated by comparison with some standard other than jam, "food" in section 402 (b) cannot be interpreted consistently as the familiar recognizable food.[60] "Food" must then mean the allegedly adulterated product itself in at least some cases[61] and the courts can look beyond the standard of the familiar recognizable food in these cases in determining economic adulteration. This is the important issue—whether the ambit of consumer protection is limited to confusion with a familiar recognizable food. The issue is completely obscured if the standard of the familiar recognizable food is read into the statute through the word "food."

B. The Proper Interpretation of *Bireley's*: Economic Adulteration Standards Must Be Reasonably Definite and Precise

United States v. 88 Cases of Bireley's Orange Beverage[62] is considered the leading economic adulteration case both on the interpretation of the word "food" in section 402 (b) and on the standards which are to be applied in determining whether a food is adulterated under that section. The *Bireley's* case involved an orange beverage which consisted of 6% orange juice, 2% lemon juice, 87% water, and small quantities of other harmless substances, including artificial coloring. The government's theory was that the jury could examine the beverage and decide the percentage of orange juice which the beverage appeared to contain. If that percentage exceeded 6%, the government argued the beverage was adulterated because it appeared better than it was.[63] The government therefore wanted to judge Bireley's Orange Beverage by its own appearance rather than by comparison with a familiar recognizable food.[64]

The claimant argued the precise opposite. The claimant's position was that food in section 402 (b) meant a familiar recognizable food and that this was the only standard which could be used in economic adulteration cases.[65] The government prevailed in the lower court but the Third Circuit Court of Appeals reversed.[66] The opinion of the Court of Appeals is notable in several respects. The court first held

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that the interpretation of food in section 402 (b) depends upon the facts of each individual case. In a prior case, the court noted that food had been interpreted as the allegedly adulterated food itself and the court reasoned that this could not be considered an improper or surprising conclusion in relation to the facts involved. Conversely, the court reasoned that food might also mean a recognized food rather than the allegedly adulterated product if different facts were presented.[67]

The court had more difficulty determining the standard to be applied in *Bireley's* case. The standard urged by the government, the per cent of orange juice which appeared to be in the allegedly adulterated beverage, was considered by the court to be vague, speculative and whimsical.[68] The court therefore accepted the claimant's argument that Bireley's Orange Beverage should be compared against a defined, familiar and superior food. The only relevant food was undiluted orange juice and the court remanded the case to the lower court for a trial on the issue of whether Bireley's Orange Beverage would be confused with undiluted orange juice by the ordinary consumer. The court stated, "The difficulty with this entire approach [the approach urged by the government] is that the 'adulterated' food is made to serve as its own only standard. . . . Without a finding that a marketable inferior product is likely to be confused with a specified superior counterpart, we think there can be no appearing 'better than it is' within the scope of disapproval of a section patently concerned only with confusion."[69]

This dicta must be viewed in the context of the facts of the *Bireley's* case. In *Bireley's* the court was faced with a choice between two standards. One (the per cent of orange juice which appeared to be in the drink) was speculative while the other (undiluted orange juice) was concrete. Under these circumstances the court quite correctly chose the concrete standard.

Despite the contrary assumption by one court,[70] *Bireley's* does not necessarily exclude from economic adulteration law a standard which is both derived from the allegedly adulterated food and is also definite and concrete. No such standard was before the court in *Bireley's* and the court's dicta cannot be considered as binding on that issue.[71] To determine whether that type of standard is permissible, it is necessary to consider the nature of economic adulteration.

The essence of economic adulteration is sale of a food which appears to be superior to its actual composition.[72] The deceptive appearance of the food is analogous to a misrepresentation[73] or a fraudulent concealment of material facts in a sales transaction.[74] However, the

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remedy chosen by Congress to correct economic adulteration was, in general, not limited to a disclosure of the actual facts through labeling.[75] On the contrary, with the possible exception of labels prominently identifying the food as an imitation, truthful labeling is at most only one of many considerations in determining whether a food is economically adulterated.[76]

Truthful labeling was rejected as a complete defense to economic adulteration charges for two reasons: first, because many purchasers purchase food by its general appearance without reading the detailed information on the label,[77] and, second, because truthful labeling could be separated from the food at some later point in the distribution system and the adulterated food then passed off on unsuspecting purchasers.[78] The burden was therefore placed upon sellers to refrain from creating and selling foods which have a deceptive appearance.[79]

The classic economic adulteration cases involve the issue of whether the food appears to the ordinary purchaser and consumer to be a superior food.[80] Such cases rest upon a comparison of the appearance of the allegedly adulterated food with the appearance of a food which is both familiar and recognizable to the ordinary purchaser and consumer.[81] If the labeling of the allegedly adulterated food suggests that it is a familiar recognizable food, the case is easier. In such cases, the possibility of passing-off is immediate rather than remote and the courts will have little difficulty in declaring the food adulterated by comparison with the standard of the familiar recognizable food.[82]

Other economic adulteration cases have involved a comparison of the allegedly adulterated food with a standard set by the allegedly adulterated food itself. Usually such cases have involved ingredient statements which suggest the food is better than it is—for example a label stating that the food contains 25% olive oil when in fact it contains almost no olive oil[83]—but there is also reason to believe that, under certain circumstances, an allegedly adulterated food may be judged by a standard it has set through secondary meaning[84] or through its natural composition.[85] The ingredient cases alone are numerous enough to make it clear that, contrary to the dicta in *Bireley's,* allegedly adulterated foods can set their own standards and may be judged by these standards in economic adulteration cases.[86] *Bireley's* must therefore be read as merely requiring that the standards applied in economic adulteration cases be reasonably definite and precise.[87]

Both standards set by the allegedly adulterated food itself and standards set by a familiar recognizable food are reviewed below.

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C. The Standards Used to Determine Economic Adulteration and the Evidence Required to Prove Each Standard.

1. The Familiar Recognizable Food:

The familiar recognizable food is the standard which has been applied most frequently in economic adulteration cases.[88] The standard consists of a single superior food which is both known ("familiar") to retail purchasers and identifiable ("recognizable") by them.[89] The food must not only be identifiable under ordinary conditions of purchase and use; it must also be identifiable generally in its composition.[90] The composition of the familiar recognizable food is defined according to the common understanding of retail purchasers and consumers.[91]

The familiar recognizable food is a generic food. It may be either a standardized or unstandardized food, a natural or fabricated food.[92] The standard is usually applied without comment or discussion by the courts and consequently there is little understanding of the standard. It seems likely that the common understanding of retail purchasers and consumers is not a monolithic standard but that, on the contrary, a food which purports to be a familiar recognizable food may arouse diverse and conflicting expectations among substantial numbers of retail purchasers and consumers. If this is so, a food which appears to be a familiar recognizable food but which falls short of the expectations of almost all purchasers ought to be considered economically adulterated even if there is a diversity of opinion concerning the usual composition of the food. This was apparently the situation in *United States v. 36 Drums of Pop'N Oil.*[93] In the *Pop'N Oil* case, the government seized drums of artificially-colored mineral oil intended for use as popped corn seasoning. The court held the mineral oil was economically adulterated because it was inferior to all of the oils (cottonseed, coconut and soyabean) which had previously been applied to popped corn.[94]

More subtle questions arise when the food complies with the expectations of some of the purchasers and consumers concerning familiar recognizable foods but falls short of the expectations of others. In theory it would seem that a manufacturer who has created a food with an appearance which may deceive any substantial number of purchasers and consumers should not be able to defend an economic adulteration charge by showing that other purchasers and consumers are not deceived.[95] However, the application of this principle to economic adulteration cases would yield startling results. Foods which complied with the expectations of most purchasers and consumers could be outlawed

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or required to be labeled imitation and, quite apart from the economic consequences to manufacturers, more confusion than enlightenment would probably result from such a situation.[96] Therefore, it is likely that the courts will hold that where a difference of opinion exists concerning the composition of the familiar recognized food, the allegedly adulterated food is not adulterated so long as a substantial number of ordinary purchasers and consumers consider it within the definition of the familiar recognizable food.[97] Protection of purchasers and consumers with higher expectations will be limited to the misbranding sections of the act, although this may require that they read ingredient statements until the government promulgates standards of identity defining the food.[98] The standards of identity end the controversy concerning the proper composition of the food, so far as the misbranding sections of the act are concerned.[99] The effect of standards of identity upon economic adulteration cases is, however, more dubious and this and other evidentiary problems are reviewed below.

(a) Standards of Identity

Under section 401 of the act, the Secretary is authorized to promulgate reasonable definitions and standards of identity and quality for all foods.[100] This provision was inserted in the Federal Food, Drug and Cosmetic Act because of the government's difficulties in proving the composition of the familiar recognizable food in cases under the 1906 Act.[101] However, Congress did not provide in the Federal Food, Drug and Cosmetic Act that a food which failed to comply with a standard of identity or quality was economically adulterated; instead Congress provided that such a food was misbranded.[102] This left open the question of the effect of a standard of identity in an economic adulteration case.

In *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,*[103] the government seized claimant's "fruit spread" because it was economically adulterated and because it violated the standards of identity for jam. The evidence showed that claimant's product was being passed off as jam and that ordinary purchasers would consider it as jam but that claimant's product contained approximately 10% fruit rather than the approximate 40% fruit required by the jam standards. The court concluded that the product was both economically adulterated and misbranded because it was represented to be and purported to be jam but failed to conform to the standards of identity for jam.

In *United States v. 716 Cases of Del Comida Brand Tomatoes,*[104] the government seized canned tomatoes because they were economically adulterated and because they failed to conform to the standard of quality

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for canned tomatoes. Both charges were based upon the fact that the tomatoes had been diluted with water. The trial court held that the canned tomatoes were misbranded but not economically adulterated. The Circuit Court reversed, holding that the tomatoes were economically adulterated since the Act was intended to provide protection against the substitution of less expensive ingredients, in whole or in part, for the more expensive ingredients of familiar recognizable foods.[105] The standard of quality was accepted as proof of the proper composition of canned tomatoes.

In neither the *Leader Brand Strawberry Fruit Spread* case nor the *Del Comida Tomatoes* case did the courts discuss the effect of a standard of identity or quality on an economic adulteration case. In these cases involving obvious and deliberate frauds, the courts simply accepted the standard as proof of the familiar recognizable food. The claimants apparently did not contest either the admissibility of the standard or the weight given to it.

A later case, *United States v. Cudahy Packing Company*,[106] involved a contest of both questions. In the *Cudahy* case, the government brought criminal charges against a corporation for shipping oleomargarine which failed to contain the 80% fat required by the standards of identity. The deficiency in the fat content of defendant's oleomargarine was slight and inadvertent and the court concluded that the oleomargarine was misbranded but not economically adulterated. The court reasoned that economic adulteration consists of skimping upon expensive ingredients and enlarging cheaper ingredients, and that this offense had not been proved in the *Cudahy* case because there was no evidence of the relative cost of the ingredients involved.[107] The government's contention that standards of identity can be used to support an economic adulteration charge was rejected. The court held that since the adulteration sections of the act do not refer to the standards of identity as canons or tests, the standards are irrelevant to adulteration cases.[108]

It is difficult to accept either the position that standards of identity are conclusive upon, or irrelevant to, an economic adulteration case. Since Congress provided for misbranding penalties for failure to comply with the standards, it seems unlikely that the same offense was intended to be an adulteration.[109] However, proof of the ordinary or usual composition of a food is usually admitted in economic adulteration cases and a standard of identity seems at least as good evidence of that composition as the custom of the trade.[110] The

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proper approach is probably to accept the standard as evidence and let the courts determine according to the facts of each individual case whether additional evidence of consumer expectations is required. If the facts indicate that the deficiency from the standard involves a major or important ingredient, the courts may well decide that purchasers would expect the omitted or reduced ingredient in the food.[111] Conversely, if the facts show that the deficiency from the standard of identity is minor both nutritionally and financially, the courts may decide that more evidence is required to infer that purchasers expected to receive the omitted or reduced ingredient in the food.[112] This type of analysis would reconcile the apparently conflicting decisions in the *Leader Brand*, *Del Comida*, and *Cudahy* cases.[113]

(b) Custom of the Trade

In cases involving unstandardized foods, proof of the ordinary or usual composition of a food is made through the testimony of competing food processors or chemical analyses of their products rather than proof of a standard identity.[114] The evidence secured from the processors or chemical analyses indicates the custom of the trade and is relevant to, but not determinative of, the composition of the familiar recognizable food. As one court said, "The standard set by the statute is not what is customarily done by manufacturers but what is properly done by them. . . ."[115] The custom of the trade is probably most apt to be rejected when the evidence indicates that manufacturers are diluting foods to secure competitive advantage, rather than when evidence indicates that the variation in ingredients has resulted from competing manufacturers' attempts to make the food more nutritious or acceptable to retail purchasers and consumers.[116] In general, however, the custom of the trade has been given great weight in economic adulteration cases and the government has usually found it necessary to prove that foods are outside ordinary trade standards to secure judgments in economic adulteration cases involving the standard of the familiar recognizable food.[117]

(c) Opinion Surveys and Expert Testimony

Since the composition of the familiar recognizable food depends upon the common understanding of retail purchasers and consumers, opinion surveys and expert testimony concerning purchasers' and consumers' expectations are often used in economic adulteration cases.[118]

The government has relied upon opinion surveys in economic adulteration cases since at least 1911. In *United States v. One Carload*

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of Corno Horse and Mule Feed,[119] the government introduced evidence of an opinion survey intended to prove that "oat feed" was generally interpreted as ground oats rather than oat by-products. The court decided that the survey deserved little weight because it purported to show evidence of the opinion of the general public rather than of the ordinary purchasers of the product.[120] Since the product in question, mule feed, had a rather specialized and limited market, the court's conclusion was probably correct.

A more fundamental objection was raised to the government's opinion survey in *United States v. 88 Cases of Bireley's Orange Beverage.*[121] The claimant objected to the government's survey as hearsay and the court concluded that the survey was admissible since it was offered to prove the reactions of the persons surveyed rather than the truth of their opinions.[122] The survey was of the opinion of householders and the public generally but the court did not indicate that this affected the weight given to the survey, probably because Bireley's Orange Beverage was a food which appealed to householders and the public in general.[123]

Opinion surveys, if properly conducted, may be invaluable in cases involving basic adulteration questions (for example, whether the flavoring ingredient in popped corn is mineral oil, oleomargarine or butter), but in more complex cases involving, for example, the percentages of ingredients in a food, a survey of ordinary purchasers and consumers is likely to produce no intelligible results.[124] In such cases, it would seem more fruitful to introduce expert testimony concerning the understanding of purchasers and consumers concerning the composition of a food.[125] Among the many experts who may shed light on this subject are nutritionists and dieticians; food brokers, wholesalers and retailers; restaurant proprietors and chefs; food processors and representatives of trade associations of food processors, and housewives.[126] These witnesses may be cross-examined and asked their opinion concerning statements of the composition of the food found in common reference books such as recipe books, dictionaries, and encyclopedias.[127] From the expert testimony, the fact-finder may be able to construct the standard of the familiar recognizable food. The resulting standard will reflect the consensus of informed opinion rather than an understanding that is common to retail purchasers and consumers and hence will be highly artificial. However, it is a workable and fair standard and probably the best possible in the absence of a standard of identity.[128]

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2. The Natural Composition of the Natural Food:

The natural foods, when sold as such, are subject to a standard which may be more stringent than the standard of the familiar recognizable food.[129] This standard is based upon the natural composition of the particular lot of food involved and it prevents the deliberate dilution of that lot to the level of the general average of that food.[130] Assume, for example, that Farmer X's cows consistently produce milk with more than the average percent of butterfat. If Farmer X abstracts the "extra" butterfat, reducing his milk to the general average of milk sold, he may be held guilty of economic adulteration.[131] Or, assume that Farmer X's fields consistently produce oats with less weeds, dust and chaff than the general average of oats sold. If Farmer X adds additional weeds, dust and chaff to his oats, reducing his oats to the level generally sold, he may be held guilty of economic adulteration.[132] Even more surprising, Farmer X's milk and oats which have been made exactly equivalent to the general average of the food in the market may be seized because they are economically adulterated.[133]

This reasoning which seems paradoxical on its face takes on more logic when viewed in the light of the history and purposes of the act. Both the 1906 Act and the Federal Food, Drug and Cosmetic Act of 1938 were intended to prevent tampering with and debasement of foods.[134] There is no social good to be achieved from the purposeful debasement of superior natural foods to the level of the general average.[135] Indeed, if every producer of superior foods reduced his foods to average, then either the government would have to seize all below-average foods or the average would be constantly falling and the consumer constantly receiving less quality in his foods.[136] The government therefore applies standards based on the natural composition of each lot of the food, thus making deliberate debasement illegal per se and giving the greatest possible protection to purchasers and consumers.

3. Statements on the Label:

Some foods set their own standard through representations made on their labels. For example, a food called "Pinocchio Oil" which is labeled "25 per cent pure olive oil" or a food which is labeled "Figlia Mia Brand, a Blend Consisting of 90% Vegetable Oils, Choice Cottonseed, Corn and Peanut Oils, Plus 10% Pure Olive Oil," may be judged by these statements in economic adulteration cases.[137] The use of the label as a standard in economic adulteration cases is well-supported by

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precedent at least so far as ingredient statements are concerned.[138] One recent decision has, however, rejected that approach entirely, relying upon the dictum in *Bireley's* that a food cannot set its own standard.[139] Another recent decision took precisely the opposite approach.[140] It accepted the label as the standard for the food and looked beyond the ingredient statement to the "selling copy" for the standard. Both decisions deserve detailed review.

In *United States v. Fabro, Inc.*,[141] the government brought a criminal action for economic adulteration and the defendant filed a motion to dismiss. The government's action was based on section 402(b)(1) of the act and the government charged that defendant's pet food was adulterated because it was labeled "Guaranteed Analysis Crude Protein . . . . (Min.) . . . . 11.00%" while the protein content was actually less. The court dismissed the action stating, "The only standard shown by the information or by the statute upon which it is based is that the dog food showed upon its label that it contained 11% protein when in fact it contained less. Thus, it attempts to make the product serve as its own standard, and this the said product cannot be made to do."[142]

In support of this reasoning, the court cited *Bireley's*. *Bireley's*, however, involved a situation in which the government attempted to make the appearance of the product serve as the standard and the court rightly rejected this approach as "speculative" or even "whimsical."[143] The label in *Fabro* set a definite and specific standard and, it is submitted, the court in *Fabro* erred when it failed to follow cases prior to and after *Bireley's* which have accepted such a standard in economic adulteration cases.[144]

Approximately a year and a half after the *Fabro* decision, another district court decided an economic adulteration case based on a label statement. This case, *United States v. Food Products Labs., Inc.*,[145] was also a criminal action and the government brought economic adulteration charges because the defendants shipped in interstate commerce certain vitamin D enrichment wafers which were labeled as "stable" and having a "long shelf life" when in fact the wafers were unstable and had a short shelf life. The court ignored the *Bireley's* decision and looked to the label of the food for the standard against which the food could be judged. The defendants argued that the words "stable" and "long shelf life" were not used in the absolute sense; that they were relative words which should not form the basis of a criminal charge. The court rejected that argument, stating, "We

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cannot accept defendants' argument that the offenses here charged could be committed only if words of absolute meaning were used. In cases involving relative words there are, of course, areas within the center of the spectrum that may involve difficulty but the tests of particular products here involved reveal conditions that rise above or fall below any high or low water marks that could be said to be encompassed within any doubtful area toward the center of the concept of relativity."[146] The defendants were found guilty.

Thus, in contrast to *Fabro,* which would not accept an absolute statement on the label as the standard in an economic adulteration case, the *Food Products* case held that even relative statements on the label could be used as the standard.[147] The *Fabro* court cited *Bireley's* while the *Food Products* court ignored it. Yet *Bireley's* was concerned with the fatal vagueness of the standard, a problem which was more present in *Food Products* than in *Fabro.*[148] It could be argued that the apparent orange juice content of a beverage is no more vague a standard than the words "stable" and "long shelf life."[149] If this is so, both cases were wrong; *Fabro* because it failed to recognize that label statements could provide the standard and *Food Products* because it failed to recognize that the standard provided by the label must be definite and precise. Such an interpretation would return the law to its approximate state prior to these cases.[150]

Part III: The Individual Subsections of Section 402(b)

A. Introduction.

After the proper standard has been identified, there must be a comparison of the allegedly adulterated food with the standard and a determination whether the differences constitute economic adulteration. Not all deviations from the standard are prohibited. For the government to prevail, it must prove both a proper standard and a deviation from that standard which falls within one of the individual subsections of section 402 (b). The problems encountered under each subsection are described below.

B. "(b) (1) If Any Valuable Constituent Has Been in Whole or in Part Omitted or Abstracted Therefrom":

Section 402 (b) (1) provides a food is adulterated if any valuable constituent is in whole or in part omitted or abstracted therefrom.[151] The key word in this subsection is "valuable," for it describes those constituents which cannot be omitted or removed from the food without adulteration. Every constituent of a food presumably has some

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value but Congress apparently intended to distinguish between constituents of greater and lesser value by the use of the word "valuable." The distinction could be based upon the cost of the constituent ("financial value"); the amount of calories or energy provided by the constituent ("food value"), or the total nutritive contribution made by the constituent ("nutritive value").[152] Different results will be reached in economic adulteration cases, depending upon which value is adopted.

Assume, for example, a quart of milk is labeled "Enriched with 1500 Units of Vitamin A" and the Vitamin A is in part omitted. If the label sets the standard for the food, it can be argued that, so far as section 402 (b) (1) is concerned, (a) there is no economic adulteration because "valuable" means "financial value" and Vitamin A is relatively inexpensive, or, (b) there is no economic adulteration because "valuable" means "food value" and Vitamin A supplies no calories or energy, or, (c) there is economic adulteration because "valuable" means "nutritive value" and Vitamin A is an important element in nutrition. Valuable is thus inherently ambiguous in this context and the statute contains no definition of this highly ambiguous word.[153]

The ambiguity implicit in "valuable" has not been clarified by court decisions. The predecessor 1906 statute prohibited merely the abstracting of a valuable constituent.[154] This seemed to imply a removal of an ingredient from a pre-existing food rather than a failure to put a usual ingredient into a food[155] and this is probably the reason why there were so few cases involving adulteration under this subsection of the 1906 Act. The 1906 Act cases relating to this subsection seemed to involve primarily economic cheapening of foods accompanied occasionally by a reduction in food or nutritive value as well.[156]

The Federal Food, Drug and Cosmetic Act of 1938 prohibited the omission as well as the abstraction of valuable constituents and there has been a slight increase in litigation under the act. In general, however, the courts have avoided any attempt to define or interpret "valuable," although holdings of economic adulteration usually occur in cases involving pecuniary and nutritive frauds on the public.[157] One of the few cases involving food value was *United States v. 70 Gross Bottles of Quenchies*.[158] In the *Quenchies* case, the government seized a base for soft drinks which had been sweetened by saccharin instead of sugar. The government contended that the beverage base was economically adulterated because saccharin contributed no calories or

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energy and had no food value. One of the government's witnesses testified that she gave her children soft drinks for energy and that when a soft drink was labeled "sweetened," she expected it to contain sugar.[159] Claimant's position was that many purchasers wanted a beverage base without sugar. The court issued a judgment for claimant, noting that the very absence of calories and food value made the food valuable to some purchasers.[160]

The most recent reported case under section 402 (b) (1) is *United States v. Fabro, Inc.*[161] In that case, the defendant shipped a dog and cat food in interstate commerce. The pet food was labeled with a guaranteed analysis stating the minimum percentages of protein and fat therein. In fact, the pet food did not contain the minimum protein and fat stated in the guaranteed analysis and the government brought criminal charges against the defendant under section 402 (b) (1). The court dismissed the charges on two grounds: first, because the statute is too vague and indefinite to be sanctioned as a penal statute and second, because the product cannot serve as its own standard.[162]

The court's reasoning concerning the vagueness of section 402 (b) (1) was based on the difficulties involved in determining the meaning of "valuable constituent." The court noted, "The statute furnishes no definition of what constitutes a 'valuable constituent,' nor can a satisfactory definition be found in the words themselves. The word 'valuable' is a relative term susceptible to many interpretations and of no definite or absolute meaning."[163] The latest decision under section 402 (b) (1) therefore holds that section 402 (b) (1) is too vague to be enforced in criminal actions and, with this precedent, it is likely that the government will have increased difficulties in cases under this section in the future.[164]

C. "(b) (2) If Any Substance Has Been Substituted Wholly or in Part Therefor":

Section 402 (b) (2) is the broadest section of our economic adulteration statute. This section provides that a food is adulterated if any substance has been substituted wholly or in part therefor.[165] An almost identical provision was contained in the 1906 Food and Drugs Act.[166]

The statute makes no distinction as to whether the substance substituted is better or worse than the original ingredient.[167] Substitution of an ingredient is per se sufficient to adulterate a food under the literal

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language of the statute.[168] Most improvements in fabricated foods involve a change in the identity or proportion of the ingredients commonly used in these foods. There is thus a substitution of one substance for another which is literally prohibited by section 402 (b) (2).

Because of the sweeping nature of section 402 (b) (2), it has been relied upon by the FDA in a multiplicity of cases.[169] Many of these cases have involved obvious economic frauds and there can be little quarrel with the results of the cases although the basic objections to the statute itself remain. The statute was obviously designed to permit purchasers to purchase recognized foods with confidence that they will receive the food they desire.[170] The theory of the statute is analogous to the FTC decisions which hold that the consumer is prejudiced, if upon giving an order for one thing he is supplied with something else, even if his choice is dictated by caprice, fashion or ignorance.[171] Analogous situations under FTC law are resolved by truthful labeling and it might be argued analogously that truthful labeling should be accepted as a defense under section 402 (b) (2), even if the labeling is not a defense under the other adulteration sections of the statute.

The applicability of a truthful labeling defense to a economic adulteration charge under section 402 (b) (2) was presented squarely in *United States v. 716 Cases of Del Comida Brand Tomatoes.*[172] The FDA seized the claimant's tomatoes because water had been added to them. Although economic adulteration charges might have been alleged under other sections of the statute, the government relied upon section 402 (b) (2), contending that a product containing water was substituted wholly or in part for the canned tomatoes. The trial court held that the tomatoes were misbranded but not adulterated and provided in its decree that the tomatoes be released to the claimant for the purpose of truthful labeling. The Circuit Court reversed, holding that the tomatoes were economically adulterated and could not be sold in interstate commerce even if they were truthfully labeled.[173] While the facts in the case were certainly unfavorable to the claimant, the case stands as a precedent for rejecting truthful labeling as a defense to a section 402 (b) (2) charge, with apparently only one district court opinion, which is not generally reported, to the contrary.[174]

A more recent attempt to limit the all-inclusive language of section 402 (b) (2) was made by the Fifth Circuit Court of Appeals in *Van Liew v. United States.*[175] Defendants were convicted of conspiring to sell

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and selling an economically adulterated orange drink in interstate commerce. The government's theory was apparently that the orange drink would be confused with orange juice. The court reversed the conviction on a number of grounds, one of which was a unique interpretation of section 402 (b) (2).[176] The court reasoned that section 402 (b) (2) must be construed in conjunction with section 402 (b) (1). The substitution which is prohibited according to the court is the substitution of an ingredient for a valuable constituent of the food.

The validity of this interpretation seems dubious.[177] Under the court's interpretation, there would have to be an omission or abstraction which violated section 402 (b) (1) before there could be a substitution which violated section 402 (b) (2).[178] Section 402 (b) (2) would thus add nothing to section 402 (b) 1) and the *Van Liew* case makes sense only if Congress intended to prohibit the same offense twice.[179]

If, as seems likely, the *Van Liew* case is not the law, the limitations, if any, on section 402 (b) (2) are not found in the statute itself. A possible solution is to look to the purpose of the statute. Congress was clearly trying to prevent fraud and confusion in section 402 (b)(2), and when the substitution results in either economic fraud or a nutritionally deficient food, the courts will probably find economic adulteration.[180] The substantiality of the deception and the producer's intent are probably also relevant.[181] Labeling, while not a defense to a section 402 (b) (2) charge, may be an indication of the producer's intent since those who intend fraud do not usually publish the changes they have made in foods. Consideration of these factors would reconcile most of the cases which have been decided under section 402 (b) (2).[182] Although the same type of interpretation was rejected in the *Filled Milk Act* case, it was rejected in very different circumstances.[183] Even if this interpretation were adopted, the uncertainty which pervades the statute would, however, remain. Uncertainty seems highly inappropriate since criminal liability can be imposed for violations committed without criminal intent under the Federal Food, Drug and Cosmetic Act.[184]

D. "(b) (3) If Damage or Inferiority Has Been Concealed in Any Manner":

Of the four subsections of section 403 (b) only subsection 403 (b) (3) is passably well drafted. This subsection provides that a food is adulterated if damage or inferiority has been concealed in any man-

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ner.[185] The corresponding subsection in the 1906 Food and Drugs Act provided that a food was adulterated if it was mixed, colored, powdered, coated or stained in a manner whereby damage or inferiority was concealed.[186]

The statute therefore requires proof that the food, when compared to a proper standard, has either been damaged or is inferior and that the damage or inferiority has been concealed. Damage and inferiority are two different concepts. Damage means that the food has deteriorated or been injured or suffered a loss of strength or quality.[187] Inferiority means that the food was originally of low grade or quality.[188] Inferiority is present if the appearance, texture, composition, digestibility, or nutritive qualities of the food are of low grade and quality.[189] Foods may also be economically inferior, depending upon the values of the marketplace.[190] Concealment of the damage or inferiority is also essential. It is not illegal under this subsection to sell a damaged or inferior food so long as the damage or inferiority is apparent.

Most of the cases brought by the government under the 1906 Food and Drugs Act involved foods which had been artificially colored to look like superior foods. These cases included cases involving artificially colored vanillin which simulated vanilla extract,[191] artificially colored lemon oil and alcohol which simulated lemon flavor,[192] artificially colored derivative of wild cherry bark which simulated cherry juice,[193] and artificially colored macaroni which simulated macaroni composed of superior wheat.[194] One classic series of cases involved flour which had been bleached white. In the *Lexington Mills* case[195] which ultimately went to the Supreme Court, the jury returned a verdict of adulteration and the Circuit Court reversed the verdict because the color of the flour was at best an uncertain index of quality and because the color of the bleached flour was distinct from the color of the nonbleached superior flour. The United States Supreme Court affirmed the Circuit Court without deciding the economic adulteration issue since the case was to be retried to a jury.[196]

Probably the most well known case arising under this subdivision of the 1906 Food and Drug Act was *United States v. Nesbitt Fruit Products, Inc.*[197] The claimant sold a syrup consisting of orange juice, orange peel flavoring, sugar, and acid in interstate commerce. The government alleged that the inferiority of this product had been concealed because it resembled orange juice. The evidence showed that the color of the syrup itself was far deeper than orange juice and that

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the syrup could not possibly be mistaken for orange juice. When an orange juice drink was prepared, the syrup was diluted by water and the diluted beverage simulated the color and taste of orange juice. However, the evidence showed that the dilution was made in the presence of the consumer, and it was obvious to the consumer that the orange drink was not orange juice. The Circuit Court therefore held that the inferiority, if any, of the claimant's product had not been concealed.

The government occasionally tried concealed inferiority cases under the 1906 Act involving concealment of inferiority by means other than artificial coloring. These cases included alleged concealment of inferior wheat by mixing it with superior wheat;[198] alleged concealment of wild oats, weed seeds and chaff by mixing them with cultivated oats,[199] and alleged concealment of wheat by-products by powdering them.[200] However, the government had very little success in such cases and, in general, the government's victories in reported cases under this subsection of the 1906 Act almost universally involved artificially colored foods.

Although the Food, Drug and Cosmetic Act of 1938 substantially broadened this subsection, most of the government's cases have continued to involve artificially colored products. The two classic cases under this section of the Federal Food, Drug and Cosmetic Act are *United States v. Two Bags of Poppy Seeds*[201] and *United States v. 36 Drums of Pop'N Oil.*[202] In the *Poppy Seed* case the seeds had been artificially colored to resemble more expensive seeds. In the *Pop'N Oil* case, mineral oil had been artificially colored to resemble butter or vegetable oils. In both cases the government alleged that the coloring concealed the inferiority of the foods and in both cases, although the products were truthfully labeled, the government was successful. In the *Poppy Seed* case it was proved that despite the artificial coloring, the inferiority would be obvious to the dealers who purchased the poppy seeds although consumers would be deceived by artificial coloring. In the *Pop'N Oil* case, the dealers who purchased the oil recognized that it was not butter or vegetable oil but consumers of the popped corn would have been deceived by the use of the oil in place of butter or vegetable oils. In both cases, the courts held that inferiority was concealed if consumers would be defrauded. In neither the *Poppy Seed* nor the *Pop'N Oil* case was the product deceiving anyone at the time of its seizure. Instead, both courts rested their decision on

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the ground that the artificially colored product would deceive consumers in the future.

Despite the fact that most judgments of economic adulteration under this subsection have involved artificially colored products, the prohibition is broader than this. The FDA's *Trade Correspondence* suggests that if a chemical preservative conceals the age of a product or if an imitation flavoring conceals the inferior taste of a product, the foods may be adulterated, although FDA has brought no such cases yet.[203] Similarly, inferior foods which are artificially prepared to have the texture or consistency or even odor of superior foods may be held to violate this subsection.[204] The outer limits of subsection 402 (b) (3) are still to be discovered but, in contrast to the two preceding subsections of the statute, subsection 402 (b) (3) seems at least to be a relatively straightforward, well-drafted prohibition against economic and nutritional fraud.[205]

E. "(b) (4) If Any Substance Has Been Added Thereto or Mixed or Packed Therewtih So As to Increase Its Bulk or Weight, or Reduce Its Quality or Strength, or Make It Appear Better or of Greater Value Than It Is":

Section 402 (b) (4) provides that a food is adulterated if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength; or make it appear greater or of better value than it is.[206] The corresponding section in the 1906 Act prohibited the mixing or packing of a substance which reduced the quality and strength of a food but did not prohibit the addition of substances which increased the bulk or weight of a food, or made the food appear greater or of better value than it is.[207] This subsection was therefore both lengthened and broadened in the passage of the Federal Food, Drug and Cosmetic Act.

Under the 1906 Act, the government had to prove both that a substance was mixed or packed with the food and that the added substance reduced, lowered, or injuriously affected the quality and strength of the food. The latter element was sometimes supplied by inference. For example, in the early case of *United States v. Griebler*[208] involving watered milk, the court charged the jury, "It is sufficient if you believe he delivered the milk for shipment, or shipped it, and that there was water in it, and that the water was mixed therewith so as to reduce or lower or injuriously affect its quality or strength; and as

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to that question you know as much as any witness. It is not a matter for an expert. It is a matter of everyday knowledge as to whether water in the milk would reduce or lower its strength. Everybody knows that it does. So if you believe from the evidence that there was water in the milk you will convict the defendant."[209] Similarly in cases in which alcohol was added to lemon oil,[210] pepper shells were added to pepper,[211] and cottonseed oil was added to olive oil,[212] the courts did not seem to require direct evidence indicating that the quality and strength of the food was reduced.

Other cases under the 1906 Act were more complex and evidence was apparently required to prove that the quality and strength of the food was reduced. For example, when nitrates were added to flour, the government proved that the flour did not improve with age as ordinary flour would have.[213] Since the effect of nitrates upon flour was not common knowledge, such evidence was probably necessary to prove a violation of the statute.

Under the Federal Food, Drug and Cosmetic Act three separate offenses are prohibited by section 402 (b) (4). These offenses are mixing or packing a substance with the food, which (i) increases its bulk or weight; (ii) reduces its quality or strength; or (iii) makes it appear better or of greater value than it is.[214] The last prohibition is the broadest of the subsections and, as one would anticipate, the FDA has concentrated almost exclusively in its enforcement upon it.

FDA's early victories under section 402 (b) (4) involved poppy seeds which had been artificially colored to simulate more expensive poppy seeds[215] and mineral oil which had been artificially colored to simulate butter or vegetable oils.[216] Since the artificially colored foods appeared to retail purchasers and consumers to be more expensive foods, the courts concluded that they were made to appear better or of greater value than they were.

In the leading *Bireley's* case,[217] the government alleged that claimant's orange beverage appeared to be better than it was because it appeared to be composed entirely or in large part of orange juice while it only contained 6% orange juice. The trial court had charged the jury that the product was adulterated if any part of the public including the ignorant, the unthinking, the credulous and those who do not stop to analyze in making a purchase would be misled.[218] The Circuit Court reversed, holding, "The correct standard was the reaction of the ordinary consumer, under such circumstances as attended retail distribution of this product. When a statute leaves such a matter as

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this without specification the normal inference is that the legislature contemplated the reaction of the ordinary person who is neither savant nor dolt, who lacks special competency with reference to the matter at hand but has and exercises a normal measure of the layman's common sense and judgment."[219]

Despite the holding of the *Bireley's* case, the questions to whom the food must appear better than it is, and how it is to be determined whether the food appears better than it is, seem far from settled. In *Bireley's,* the government tried for a broad FTC-type standard and was defeated.[220] In future cases, the attempts to lower the intelligence level will probably be more subtle. The *Bireley's* case does not bar the government from proving by market research that particular foods appeal to children and the less educated and less sophisticated portion of the population and this type of evidence will probably present a much closer question. This evidence would certainly fall within the *Bireley's* rule that "all circumstances of retail acquisition and consumption are relevant."[221] The closest authority in point, however, seems to be a misleading packaging case and the court there rejected the government's argument that "the question is whether the package is so filled as to mislead an average five-year-old child who might expect the box to be filled to overflowing," accepting instead an ordinary person standard.[222]

One of the interesting questions raised by *Bireley's* is whether proof that restaurant patrons will be deceived by the food is sufficient to cause the food to be considered as economically adulterated. If so, the packaging and labeling of the food would be irrelevant since they would not ordinarily be seen by restaurant customers. The *Bireley's* court held that the packaging and labeling were relevant in the absence of proof that some considerable part of the retail trade acquired the food without the packaging.[223] The court cited in support of the holding the Circuit Court's opinion in *United States v. 62 Cases of Jam*[224] in which the Circuit Court held that imitation jam violated section 403 (g) because it was served to restaurant customers as the standardized food jam without disclosure that it was an imitation. The Circuit Court's opinion in the *Jam* case was later reversed by the United States Supreme Court which held that the prominent disclosure of the word "imitation" on the label was sufficient to warrant a judgment for the claimant.[225] The United States Supreme Court has thus indirectly strengthened the argument for consideration of packaging and labeling in section 402 (b) (4) cases. The realities of

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the marketplace also strengthen the argument. If the possibility of a restaurant passing off an imitation for a superior food were all that were required for economic adulteration, many common and useful foods such as oleomargarine, vegetable whipping bases, and powdered milk, and all imitation and substandard foods could be considered economically adulterated. It seems likely therefore that the courts will continue to regard packaging and labeling as one consideration in determining whether foods appear better than they are except when the evidence indicates either that there is a considerable amount of palming-off of the food in restaurants or the food is actually designed for palming off in restaurants and other situations.[226]

Probably the most difficult question concerning to whom the food must appear "better than it is" was presented in *United States v. Antonio Corrao Corp.*[227] In the *Corrao* case the defendants sold in interstate commerce a blend of oils marked 80% peanut oil and 20% olive oil. The government seized the blend of oils as economically adulterated, alleging that it contained little olive oil and had been made to appear better than it was by the addition of artificial flavoring which simulated the flavor of olive oil and squalene which simulated the chemical properties of olive oil. The interesting legal question arose because of the presence of the squalene.

Squalene is an odorless, colorless substance which cannot be detected by the consumer. However, squalene is a natural component of olive oil and the government therefore tests for squalene content when it attempts to determine whether olive oil has been omitted or removed from a food. To frustrate the government's tests, the defendants added squalene artificially to the blend of oils. The district court concluded that the blend of oils actually contained the 20% olive oil stated on the label but that the blend of oils was adulterated under section 402 (b) (4) because the added squalene made the blend appear better than it was to the government officials who tested it—that is, the blend appeared to contain more than 20% olive oil to the government's officers.[228]

On appeal, the Circuit Court reversed, holding that since the natural squalene content of olive oil varies and there was no indication of the amount of squalene added, it could not be said that the added squalene was sufficient to deceive the government's officers. The Circuit Court therefore never reached the question of whether a food is economically adulterated if it is made to appear "better than

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it is" to the government, but not to ordinary purchasers and consumers.[229]

This type of case can be approached as an agency situation. It could be reasoned that the ordinary purchasers and consumers have, through their legislators, appointed government officials as their agents to make certain that the foods sold to them comply with the law. The fraud, if any, in the *Corrao* situation was on the governmental agents rather than on the ordinary purchaser-principal. Since the purchaser-principal received exactly what was specified, the fraud would seem immaterial, and since the Federal Food, Drug and Cosmetic Act was intended to protect purchaser-principals rather than governmental agents, there would be no adulteration.

Because section 402 (b) (4) was changed so significantly from its predecessor section of the 1906 Act, there are probably even more unresolved questions concerning this subsection than exist concerning the other subsections of the act. The *Bireley's* and *Corrao* cases illustrate the interesting and complex questions which can arise concerning to whom the food must appear better than it is. Other questions will probably arise concerning how the food can appear better than it is. *Bireley's* says flavor can be considered, so "appear" does not seem to be limited to visual impressions of the food.[230] The FDA's *Trade Correspondence* suggests if water is added to poultry,[231] if silver nitrate is added to fish,[232] if artificial coloring is added to baked goods,[233] and if artificial flavor is added to food,[234] these foods may appear better than they are. The government therefore views this portion of the statute as applying to many varied situations.

There has been very little reported litigation in connection with that portion of subsection (b) (4) which prohibits packing a substance with food to increase its bulk or weight. In *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,*[235] the court held that adding water, sugar and corn syrup to a purported jam violated this section of the statute and in other cases the government has contended that adding excess water to canned oysters[236] and adding water and sugar to orange juice is a violation,[237] but the first case was lost on the facts and the second through faulty pleading. FDA's *Trade Correspondence* also suggests that soaking poultry in water is a violation of this portion of the statute.[238] Most violations of this prohibition and the prohibition against adding substances which reduce the quality and strength of a food are also violations of that portion of the subsection which prohibits packing a substance with the food which

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makes it appear better or of greater value than it is, and this probably explains the scarcity of reported cases under the first two portions of subsection 402 (b) (4).

Part IV: Conclusion

Congress in the 1906 Food and Drugs Act enacted our first comprehensive legislation prohibiting the economic adulteration of foods. The government secured judgments in both criminal and civil cases under the 1906 Act and, in general, the act was sufficient to eliminate blatant economic cheats.[239] However, the more subtle economic cheats remained,[240] and the government under the 1906 Act was unable to prevent the sale of economically debased foods which were sold as compounds or blends or labeled with distinctive names.

The Federal Food, Drug and Cosmetic Act was designed to eliminate the loopholes in the 1906 Act. Although the Federal Food, Drug and Cosmetic Act was actually enacted in 1938, the roots of the statute lie in the early 1930's.[241] As in another noted depression era statute, the Robinson-Patman Act,[242] drastic action rather than precision of language was the foremost consideration of proponents of the law.[243]

The Federal Food, Drug and Cosmetic Act's economic adulteration provisions suffer from two significant defects. First is the failure to describe precisely the standards against which the allegedly adulterated food is to be judged.[244] Second is the failure to describe precisely the types of deficiencies from the standard which constitute economic adulteration.[245] The combination of these two deficiencies have confounded the courts which have issued diverse and conflicting opinions.[246] While the trend seems to be to refuse to apply economic adulteration sanctions at all, except in the clearest of cases,[247] in at least one recent case economic adulteration sanctions were applied under very dubious circumstances.[248] Economic adulteration law therefore resembles a type of national lottery in which the odds are that the defendant will go free although he may not if he happens to draw the wrong judge.

When criminal liability can be imposed without intent, it would seem that the legislature, the governmental agency which administers the law, and the courts have a responsibility to issue precise and definite guidelines which will permit persons to predict in advance the consequences of their conduct. Yet all of these have abdicated this responsibility in relation to our economic adulteration laws and chaos

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has resulted. There is a patent and immediate need for a revised economic adulteration statute. In the interim, the FDA should by interpretative regulations define and explain what constitutes a violation of the present act.[249] **[The End]**

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[53] 52 Stat. 1046 (1938), 21 U. S. C. § 342(b) (1958).

[54] 52 Stat. 1046 (1938), 21 U. S. C. § 342(b)(1) and (2) (1958).

[55] 52 Stat. 1046 (1938), 21 U. S. C. § 342(b)(3) and (4) (1958).

[56] 52 Stat. 1041 (1938), 21 U. S. C. § 321(f) (1958).

[57] In *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951), the claimant argued that under § 402(b), the court either had to conclude that the seized product was a familiar recognizable food which was adulterated or a new and original food which was unadulterated. The claimant reasoned that § 402(b)(4) said a food was adulterated if any substance was "mixed or packed therewith" etc., and that the prohibition must mean that a basic and identifiable article of food had been adulterated through the introduction of some additive. The court rejected that argument citing prior cases in which "food" had been interpreted as the allegedly adulterated product rather than as a familiar recognizable food. The court concluded that § 402(b)(4) applied ". . . . whether a recognized food is altered or sundry ingredients are combined or compounded to make what is essentially a new article of manufacture." Cited at 970. There was thus a recognition in the court's opinion that food could either mean the "familiar recognizable food" or the "allegedly adulterated food." *Cf.* Kushen, "The Significance of Section 402(b)," 10 Food Drug Cosmetic Law Journal 829, 843 (1955).

[58] "Bred Spred" is generally considered the classic example of economic adulteration although the product was exonerated in the three reported cases under the 1906 Act. See text accompanying footnote 33 [21 Food Drug Cosmetic Law Journal 544 (1966)]. *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,* 93 F. Supp. 764 (S. D. Iowa 1950), involved a product similar to Bred Spred called "Leader Brand Strawberry Fruit Spread" and the product was held economically adulterated under the Federal Food, Drug and Cosmetic Act. While the court's opinion is somewhat unclear, it seemed to be grounded on the theory that the product was an adulterated jam.

[59] Defining food as the familiar recognizable food is the easiest and most grammatically precise interpretation of § 402(b). Using this interpretation, the statute would be neither familiar nor recognizable. See 52 Stat. 1041 (1938), 21 U. S. C. § 321(f) would provide that the familiar recognizable food is adulterated if a valuable constituent has been removed from the familiar recognizable food, or any substance has been substituted for the familiar recognizable food, or if damage or inferiority has been concealed in the familiar recognizable food, or any substance has been added to the familiar recognizable food to increase its bulk or reduce its quantity or strength, or make it appear better than it is.

Defining "food" as the allegedly adulterated food provides a less graceful interpretation of the statute. Using this interpretation, the statute would provide that an allegedly adulterated food is adulterated if a valuable constituent has been removed from the allegedly adulterated food, or any substance has been substituted for the allegedly adulterated food, or if damage or inferiority has been concealed in the allegedly adulterated food, or any substance has been added to the allegedly adulterated food to increase its bulk, or reduce its quality

(Footnote continued on next page.)

(Footnote 59 continued.)
or strength, or make it appear better or of greater value than it is, when the allegedly adulterated food is compared with any proper standard.

The basic difference between the two interpretations is that in the former the standard of the familiar recognizable food is read into the statute whereas in the latter the courts must look outside the statute to find the standards used to determine adulteration.

[60] The only reason to interpret food as the familiar recognizable food is to provide a standard for determining economic adulteration. The reason for such an interpretation therefore disappears if a standard other than the standard of the familiar recognizable food is applicable in economic adulteration cases.

[61] Both the word "food" in § 402(b) and the definition of food in § 201(f) are inherently broader than familiar recognizable foods. The word and definition include all foods, whether familiar or new, and all ingredients of such foods, many of which would be neither familiar nor recognizable. See 52 Stat. 1041 (1938), 21 U. S. C. § 321(f) (1958). Additionally, the interpretation of food as the allegedly adulterated product rather than the familiar recognizable food is more consistent with the other adulteration prohibitions in § 402(a) and (c). These sections provide a food is adulterated if it bears poisonous substances, unsafe food or color additives or if it consists of filthy or putrid substances or is prepared, packed, or held under insanitary conditions or is the product of a diseased animal. 52 Stat. 1046 (1938), as amended, 21 U. S. C. § 342(a) and (c) (1958). Congress clearly intended that these basic prohibitions against dangerous foods were to apply to all allegedly adulterated foods whether or not they were familiar recognizable foods. It seems likely that the word "food" was intended to have the same broad meaning throughout § 402.

[62] 187 F. 2d 967 (3d Cir.) *cert. denied,* 342 U. S. 861 (1951). The *Bireley's* case was reviewed at 100 *University of Pennsylvania Law Review* 139-41 (1951).

[63] The trial court's charge to the jury is reported at 2 Kleinfeld 128-37. The trial court charged the jury at the request of the government, "It is for you to decide, upon all of the evidence, first: whether the yellow coal-tar dyes make the article look like a product composed entirely or in large part of a fresh orange juice." Cited at 134. The portion of the charge permitting the jury to conclude the product was adulterated if it appeared to be in large part orange juice was reversible error. See Nelson, "What Standard For the Non-standardized Food?—The Bireley's Case," 8 FOOD DRUG COSMETIC LAW JOURNAL 425, 435 (1953).

[64] The claimant contended that if the government were right and the jury could speculate whether the product was in large part orange juice, the statute was unconstitutionally vague. The court never reached that issue because it rejected the government's interpretation. Nelson, cited at footnote 63 at 434.

[65] See footnote 57 above.

[66] *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951).

[67] Cited at footnote 66 at 970-71.

[68] Cited at footnote 66 at 972.

[69] Cited at footnote 68.

[70] See *United States v. Fabro, Inc.,* 206 F. Supp. 523, 526 (M.D. Ga. 1962) which is reviewed in more detail in text accompanying footnotes 141-44.

[71] The material allegations of the government's libel in the *Bireley's* decision were that the beverage appeared to be composed entirely or in large part of fresh orange juice. See *United States v. 88 Cases of Bireley's Orange Beverage,* 2 Kleinfeld 128, 130 (D. N. J. 1949), *reversed,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951). When the court decided that adulteration could not result from the beverage appearing to be composed in large part of orange juice, the only issue remaining was whether the beverage appeared

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(Footnote 71 continued.)
to be composed entirely of orange juice and the court ordered a trial on that issue.

[72] No food can be adulterated except by comparison with some standard. See *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951); *United States v. Goodman,* White & Gates 484 (E.D. N. Y. 1913). In general, a standard becomes relevant to an economic adulteration charge because the allegedly adulterated food by its appearance expressly or impliedly represents that it complies with the standard. *Cf. United States v. Nesbitt Fruit Products, Inc.,* 96 F. 2d 972 (5th Cir. 1938). The one exception involves situations in which natural foods, sold as such, have been diluted. Courts then hold that the dilution constitutes economic adulteration not because the food fails to equal the standard set by its appearance; but simply because, contrary to the expectations of purchasers and consumers, the food has been diluted. See text accompanying footnotes 129-36.

[73] The misrepresentation analogy is most obvious in cases involving false ingredient statements. However, implied misrepresentations are probably present when a food appears to be a familiar recognizable food or appears to be equal to its former composition, or appears to be a natural undiluted food, and the contrary is true.

[74] A fraudulent concealment of material facts probably occurs when a seller, by altering the composition of a recognized food or by intentionally creating a new food in the appearance of a recognized food, conceals the inferiority of his product. *Cf.* Restatement, Torts, § 550 (1938); Prosser, Torts 532-33 (2d ed. 1955). Similarly a fraudulent concealment of material facts probably occurs if a seller debases his own familiar proprietary and conceals the inferiority by offering it in its former container and with its former name and label. *Royal Baking Powder Co. v. FTC,* 281 Fed. 744 (2d Cir. 1922). There is more than nondisclosure in such situations; there is affirmative action designed to prevent the purchaser from discovering the inferiority of the new products. It is as if the seller falsely stated, "Here is the familiar recognizable food" or "Here is my familiar proprietary food."

[75] *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947); *United States v. Two Bags of Poppy Seeds,* 147 F. 2d 123 (6th Cir. 1945); see also *United States v. 716 Cases of Del Comida Brand Tomatoes,* 179 F. 2d 174 (10th Cir. 1950); *cf. Federal Security Adm'r v. Quaker Oats Co.,* 318 U. S. 218 (1943); *United States v. Carolene Products Co.,* 304 U. S. 144 (1938); Willis, "Preventing Economic Adulteration of Food, 1 FOOD DRUG COSMETIC LAW QUARTERLY 20, 25 (1946): "It is clear from the cases that where a food product is inherently deceptive so that it may tend to mislead or confuse the ultimate consumer, label statements may not be relied upon to correct its deceptive character."

[76] See footnote 75. Labeling may be a defense to an economic adulteration charge if it is adequate and effective notice that the food is an imitation or a different generic product. While it is difficult to cite precedent for this proposition other than the analogous *62 Cases of Jam v. United States,* 340 U. S. 108 (1951) (which involved § 403(g) rather than § 402(b) of the act), it is apparent that a number of foods are now sold under such labeling without challenge by the government and have been for some time. Consider, for example, soft drinks with artificial sweeteners, non-dairy coffee lighteners, and vegetable whipping bases. All of these foods would be economically adulterated except for labeling which distinguishes them as different generic products from their more traditional counterparts and the government, by permitting their widespread sale, has in fact accepted such labeling as sufficient. If the labeling does not identify the food as a different generic product, the labeling is only one consideration in deciding whether the food is adulterated.

[77] *Cf.* "Experience had shown that truthful labeling of a product was no protection to the bulk of the consuming public; if a product gave the appearance of being a certain food, the public assumed that it contained only those ingredients which were commonly associated with that food and the label was never consulted." *United States v. 306 Cases of Sandford Tomato Catsup with Preservative,* 55 F. Supp. 725, 726 (E. D. N. Y. 1944), *aff'd,* 148 F.2d 71 (2d Cir. 1945).

[78] *Cf. United States v. 36 Drums of Pop'N Oil,* 164 F.2d 250 (5th Cir. 1947), in which the court noted that the popped corn with oil on it was not accompanied by any ingredient statement. As H. Thomas Austern has stated, "Except on camping trips, food is seldom served in the original container. Very often it is so happily prepared that one hasn't the vaguest notion of the identity of what he is eating.

It is this apprehension which leads to the idea of things being inherently deceptive: the assumption that a manufacturer who departs from a prescribed composition in an identity standard may have in mind creating an opportunity for a restauranteur, the proprietor of a boarding house, or the operator of a logging camp to pass off the different product on his unsuspecting patrons or employees. Even if he isn't, he is hanged by the possibility. The producer of the food may be acting honestly and labeling forthrightly, but he is restricted because of the venality of others." Austern, "Section 403(g) Revisited," 6 Food Drug Cosmetic Law Journal 181, 187-88 (1951). However, the courts have not generally held that the possibility of passing off by restaurants to their customers is enough. See text accompanying footnotes 223-26.

[79] This type of restriction is not unique or unconstitutional. *United States v. Carolene Products Co.,* 304 U. S. 144 (1938), involved a compound of condensed skimmed milk and coconut oil which was banned from interstate commerce under the Filled Milk Act. The district court sustained a demurrer and the United States Supreme Court reversed, holding that the statute was constitutional and that it was for the legislature to determine whether the public would be adequately protected by a prohibition of false labels or whether it was necessary to go further and prohibit entirely the sale of substitute food-products which were inferior to and indistinguishable from, natural milk. See also *Hebe Co. v. Shaw,* 248 U. S. 297 (1919) (opinion by Holmes, J. upholding the constitutionality of an Ohio statute prohibiting the sale of condensed skimmed milk from which cream was removed); *Powell v. Pennsylvania,* 127 U. S. 678 (1888) (upholding a Pennsylvania statute prohibiting the sale of substitutes for butter made from animal fats). All of these cases involved wholesome foods which were prohibited despite truthful labeling.

Perhaps the most difficult constitutional case was *Carolene Products Co. v. United States,* 323 U. S. 18 (1944), in which the seller sold a product consisting of skimmed milk plus cottonseed or coconut oil and added vitamins. The product was as nutritious as milk; was honestly labeled, and was sold in its natural color which was indistinguishable from milk. The defendant argued that (1) the legislative history of the Filled Milk Act indicated it was directed at foods which were nutritionally inferior to milk and that therefore his product was outside the act; and (2) the Filled Milk Act was directed at foods which were artificially prepared to simulate milk and that he had not altered the natural appearance of his food. The Court held that in the Filled Milk Act Congress was concerned with confusion, and defendant's product must be banned because, whatever its nutritional qualities might be, it would be confused with milk. The Court also held that the Filled Milk Act was directed at all mixtures which simulate milk whether or not they were conscious and purposeful simulations.

[80] See cases cited at footnote 88. These cases are called classic economic

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adulteration because they are similar to the "Bred Spred" case and the other adulteration cases which were in large part responsible for the passage of the economic adulteration sections of the Federal Food, Drug and Cosmetic Act.

[81] See footnote 72 above.

[82] Most of the cases have involved labeling which falsely suggested that the product complied with a standard of identity rather than economic adulteration cases involving familiar recognizable foods. See *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,* 93 F. Supp. 764 (S. D. Iowa 1950); *cf. United States v. 306 Cases of Sandford Tomato Catsup with Preservative,* 55 F. Supp. 725 (E. D. N. Y. 1944), *aff'd,* 148 F.2d 71 (2d Cir. 1945), holding that claimant's designation "Tomato Catsup With Preservative," was not an arbitrary or fanciful name but a designation which suggested what the food really was—tomato catsup; *United States v. 20 Cases of Buitoni 20% Protein Spaghetti,* 130 F. Supp. 715 (D. Del. 1954), *aff'd,* 228 F.2d 912 (3d Cir. 1956) (per curiam); *United States v. Omar Inc.,* 91 F. Supp. 121 (D. Neb. 1950), holding that the distinction between "vitamin rich farina" and "enriched farina" is a very thin line to draw if the consumer is to receive any protection from standards of identity. Logic and one Supreme Court case suggest the courts will reach the same results in economic adulteration cases. See *United States v. Schider,* 246 U. S. 519, 521-22 (1918), holding, "The obvious and undisputed purpose and effect of the label was to declare the bottled article a compound essence of grade. . . . Within the statute's general terms the article must be deemed adulterated since some other substance had been substituted wholly for the one indicated by the label. . . ."

[83] See *United States v. 40 Cases of Pinocchio Brand Oil,* 289 F.2d 343 (2d Cir.), *cert. denied,* 368 U. S. 831 (1961), and cases cited at footnote 138.

[84] *Cf. United States v. 70½ Dozen Bottles of 666,* 1 Kleinfeld 89 (M. D. Ga. 1944); *Royal Baking Powder Co. v. FTC,* 281 Fed. 744 (2d Cir. 1922).

United States v. 70½ Dozen Bottles of 666 involved a drug called "666" which had been known and sold to the public for many years as a drug containing iron and quinine. The manufacturer eliminated the iron and quinine and sold the drug under the same name and in the same style packages to the public. The drug was held misbranded.

Similarly, in *Royal Baking Powder Co. v. FTC* the respondent had manufactured and sold a baking powder with cream of tartar called "Dr. Price's Cream Baking Powder" for many years. When the cost of the cream of tartar increased, respondent changed the composition of its product from a cream of tartar powder to a phosphate powder, selling the new product under the same name and in the same style package and the FTC brought an action under § 5 of the FTC Act. The FTC ordered respondent to cease and desist selling a phosphate baking powder under the name of "Dr. Price's" or "Price's" unless the word "Cream" was omitted and the word "Phosphate" was incorporated in the label. Respondent was also ordered to cease and desist using any label simulating or resembling in coloration, design or general appearance the labels formerly used on its cream of tartar powder. The court affirmed the FTC's order holding that ". . . . petitioner in the use of its labels and otherwise, ... did deceive the public, into buying a phosphate baking powder believing it was Dr. Price's Baking Powder which had been well known for 60 years as a cream of tartar powder, concealing and obscuring the fact that it was a radically different powder." Cited at 753.

In both cases the fraud related to the composition of the product and the Government might have succeeded had it brought economic adulteration charges.

[85] See cases cited at footnote 130.

[86] See cases cited at footnotes 137-38.

[87] One court has rejected an ingredient statement as the standard in an economic adulteration case, basing its de-

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cision on *Bireley's. United States v. Fabro,* 206 F. Supp. 523 (M. D. Ga. 1962). However, the weight of authority is to the contrary. See *United States v. 40 Cases of Pinocchio Brand Oil,* 289 F.2d 343 (2d Cir.), *cert. denied,* 368 U. S. 831 (1961); *United States v. Food Products Labs., Inc.,* 6 Kleinfeld 123 (W. D. Mo. 1963). *Cf.* Nelson, "What Standards For the Nonstandardized Food?—The Bireley's Case," 8 FOOD DRUG COSMETIC LAW JOURNAL 425, 438 (1953); "Developments in the Law—The Federal Food Drug and Cosmetic Act," 67 *Harvard Law Review* 632, 648 (1954): "[I]nsofar as the decision [*Bireley*] immunizes from adulteration charges a certain product which, though deceptive in appearance, could not be confused with an identified superior, it would seem to deny the consumer the full protection the act intended."

[83] Cases involving alleged economic adulteration by comparison of the food with a familiar recognizable food are almost infinite in number and numerous cases are collected in this footnote. With few exceptions, however, the decisions in these cases rest upon simple findings of fact or points of law having little relevance to economic adulteration charges. Many of the 1906 Act cases, for example, turn upon the interpretation of the provisos relating to distinctive names and compounds (which were abolished in the 1938 Act) and many of the later cases were actually decided on misbranding charges rather than the economic adulteration charges. The principal value of the list is therefore to enable members of the profession to find cases involving particular foods easily and quickly. The cases are: *United States v. Schider,* 246 U. S. 519 (1918) (grape essence); *Van Liew v. United States,* 321 F.2d 664 (5th Cir. 1963) (orange juice); *United States v. Treffinger,* 224 F.2d 855 (2d Cir. 1955) (horseradish); *United States v. 716 Cases of Del Comida Brand Tomatoes,* 179 F.2d 174 (10th Cir. 1950) (canned tomatoes); *United States v. 36 Drums of Pop'N Oil,* 164 F.2d 250 (5th Cir. 1947) (popped corn flavoring); *United States v. Two Bags of Poppy Seeds,* 147 F.2d 123 (6th Cir. 1945) (poppy seeds); *United States v. 800 Sacks Barley Mixed Oats,* 64 F.2d 678 (5th Cir. 1933) (oats); *United States v. Centralia Dairy Co.,* 60 F.2d 141 (W. D. Wash. 1932) (butter); *W. B. Wood Mfg. Co. v. United States,* 286 Fed. 84 (7th Cir. 1923) (food colors); *F. B. Washburn v. United States,* 224 Fed. 395 (1st Cir. 1915) (macaroons); *Libby, McNeill & Libby v. United States,* 210 Fed. 148 (4th Cir. 1913) (condensed skimmed milk); *Lexington Mill & Elevator Co. v. United States,* 202 Fed. 615 (8th Cir. 1913), *aff'd,* 232 U. S. 399 (1914) (flour); *Hall-Baker Grain Co. v. United States,* 198 Fed. 614 (8th Cir. 1912) (No. 2 wheat); *William Henning & Co. v. United States,* 193 Fed. 52 (5th Cir. 1912) (tomato catsup); *United States v. W. F. Morgan,* 155 F. Supp. 40 (E. D. Va. 1957) and 155 F. Supp. 847 (E. D. Va. 1957) (canned oysters); *United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955) (oleomargarine); *United States v. 149 Cans of Black Eyed Peas,* 4 Kleinfeld 27 (D. Colo. 1953) (canned peas); *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S. D. Ohio 1952) (soft drink base); *United States v. Midfield Packers,* 3 Kleinfeld 157 (W. D. Wash. 1947) (frozen fruit); *United States v. Beck,* 2 Kleinfeld 197 (S. D. Iowa 1948) (salad dressing); *United States v. 55 Cases of Popped Corn,* 62 F. Supp. 843 (D. Idaho 1943) (popped corn); *United States v. South Peacham Creamery Co.,* White & Gates 1266 (D. Vt. 1931) (butter); *United States v. Morehouse,* White & Gates 1210 (N. D. Cal. 1928) (mustard seed); *United States v. 4½ Cases of Creme De Menthe,* White & Gates 1191 (E. D. Mo. 1926) (creme de menthe); *United States v. 200 Sacks of Wheat Middlings,* White & Gates 1189 (E. D. Mich. 1926) (powdered wheat middlings); *United States v. 24⅞ Gallons of Smack,* White & Gates 1181 (E. D. Wis. 1926) (grape juice); *United States v. 37 One-Pound Packages of Colors,* White & Gates 1165 (E. D. Pa. 1925) (food colors); *United States v. Mar-*

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marelli, White & Gates 1122 (S. D. N. Y. 1924) (olive oil); *United States v. Krumm*, 269 Fed. 848 (E. D. Pa. 1921) (macaroni); *United States v. Alban*, White & Gates 1014 (S. D. N. Y. 1921) (olive oil); *United States v. 100 Cases of Canned Red Kidney Beans*, White & Gates 982 (W. D. Ky. 1920) (kidney beans); *United States v. 6 Barrels of Ground Pepper*, White & Gates 817 (S. D. N. Y. 1917) (pepper); *United States v. Shucart*, White & Gates 693 (E. D. Mo. 1915) (cider); *United States v. 60 Barrels of Wine*, 225 Fed. 846 (W. D. Mo. 1915) (claret wine); *United States v. 6 Cases of Honey*, White & Gates 543 (E. D. Pa. 1913) (honey); *United States v. Goodman*, White & Gates 484 (E. D. N. Y. 1913) (nonalcoholic cordial); *United States v. German American Specialty Co.*, White & Gates 459 (S. D. N. Y. 1913) (eggs); *United States v. Huyler's*, White & Gates 455 (Police Ct. D. C. 1913) (maple sugar); *United States v. Dunham Mfg. Co.*, White & Gates 440 (E. D. N. Y. 1913) (shredded coconut); *United States v. 30 Cases of Grenadine Syrup*, 199 Fed. 932 (D. Mass. 1912) (grenadine syrup); *United States v. Auerbach & Sons*, White & Gates 357 (S. D. N. Y. 1912) (milk chocolate); *United States v. 75 Boxes of Alleged Pepper*, 198 Fed. 934 (D. N. J. 1912) (pepper); *United States v. 100 Barrels of Vinegar*, 188 Fed. 471 (D. Minn. 1911) (vinegar); *United States v. Heide*, White & Gates 325 (S. D. N. Y. 1911) (almond paste); *United States v. Rinchini*, White & Gates 318 (D. Ariz. 1911) (ice cream); *United States v. 100 Barrels of Calcium Acid Phosphate*, White & Gates 58 (N. D. Cal. 1909) (calcium and phosphate).

[89] The leading economic adulteration case, *United States v. 88 Cases of Bireley's Orange Beverage*, 187 F.2d 967 (2d Cir.), *cert. denied*, 342 U. S. 861 (1951), refers to the standard as a "defined and familiar food." The food certainly must be familiar to purchasers (or else there can be no deception), but the use of the word "defined" is somewhat misleading. The test is not whether the food is defined in standards of identity or by the trade; the test is whether the food is recognized by the ordinary purchaser or consumer as a food containing certain ingredients (or a certain proportion of ingredients) which the allegedly adulterated product does not have. Thus there may be no complete definition of the food anywhere. *Cf. United States v. 4½ Cases of Creme De Menthe*, White & Gates 1191 (E. D. Mo. 1926) in which the only issue was whether creme de menthe was recognized as containing caffeine. It seems more precise therefore to refer to the standard as the "familiar recognizable food."

[90] *United States v. 88 Cases of Bireley's Orange Beverage*, cited at footnote 89; *United States v. Midfield Packers*, 3 Kleinfeld 157 (W. D. Wash. 1952); *United States v. 70 Gross Bottles of Quenchies*, 3 Kleinfeld 141 (S. D. Ohio 1952); *United States v. 55 Cases of Popped Corn*, 62 F. Supp. 843 (D. Idaho 1943); *United States v. 30 Cases of Grenadine Syrup*, 199 Fed. 932 (D. Mass. 1912). *Cf. United States v. Swift & Co.*, White & Gates 1146 (D. Ore. 1925); *United States v. Krumm*, 269 Fed. 848 (E. D. Pa. 1921); *United States v. 154 Cases of Tomatoes*, White & Gates 967 (W. D. Pa. 1920); *United States v. Rinchini*, White & Gates 318 (D. Ariz. 1911), are examples of cases in which the government was defeated because it failed to plead or prove the composition of a familiar recognizable food which differed from the composition of the allegedly adulterated product.

[91] See *United States v. 4½ Cases of Creme De Menthe*, White & Gates 1191 (E. D. Mo. 1926); *United States v. F. B. Washburn & Co.*, White & Gates 434 (D. Mass. 1913), *rev'd on other grounds*, 224 Fed. 395 (1st Cir. 1915); *United States v. Auerbach & Sons*, White & Gates 357 (S. D. N. Y. 1912); *United States v. 30 Cases of Grenadine Syrup*, 199 Fed. 932 (D. Mass. 1912); *United States v. 75 Boxes of Alleged Pepper*, 198 Fed. 934 (D. N. J. 1912); *United States v. Bettman-Johnson Co.*, White & Gates 299 (S. D. Ohio 1911); *cf. Libby, McNeill & Libby v. United States*, 210 Fed. 148 (4th Cir. 1913).

[92] See cases cited at footnote 88.

[93] 164 F.2d 250 (5th Cir. 1947).

[94] In *United States v. 55 Cases of Popped Corn,* 62 F. Supp. 843 (D. Idaho 1943) the government had seized popped corn flavored with mineral oil because of economic adulteration and the court had dismissed the seizure because there was no established formula for the preparation of popped corn. The *Pop'N Oil* case, cited at footnote 93, only four years later, then held that variances in the formula were irrelevant since all of the oils used had more food value than mineral oil. The different results in the two cases probably rest upon different evaluations of mineral oil by the two courts. In the *Popped Corn* case, the court did not know whether mineral oil had been used before but knew of no reason why mineral oil should not be used. In the *Pop'N Oil* case, the court recognized mineral oil as new and inferior to all other oils formerly used for flavoring popped corn. Therefore, regardless of whether mineral oil was deleterious, its use on popped corn was deceptive to purchasers and consumers and the court correctly found economic adulteration.

[95] Certainly if the same manufacturer deceived a substantial number of purchasers and consumers by a false or misleading advertisement of the composition of the food, he could be subject to a cease and desist order issued by the FTC. See 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(a)(6) (1964); Millstein, "The Federal Trade Commission and False Advertising," 64 *Columbia Law Review* 439, 457-62 (1964). The fact that other customers were satisfied or not deceived would be no defense to the cease and desist proceeding if the advertisement had the capacity to deceive. *Cf. Erickson v. FTC,* 272 F.2d 318 (7th Cir. 1959), *cert. denied,* 362 U. S. 940 (1960); *Independent Directory Corp. v. FTC,* 188 F.2d 468 (2d Cir. 1951). It can be argued that the manufacturer should also be liable under economic adulteration law if instead of publishing a deceptive advertisement, he creates an inferior food having an appearance which will deceive a substantial number of purchasers.

The distinction probably lies in the two statutes. The FTC Act is very flexible and the FTC can fashion orders to individual cases so that the deception is ended and the manufacturer is able to continue to sell his products. The Federal Food, Drug & Cosmetic Act gives no comparable power to the FDA and therefore if the food is considered economically adulterated, it must be either labeled imitation or removed from sale.

[96] The economic adulteration sections of the Federal Food, Drug & Cosmetic Act are constructed on the premise that there is only one genuine version of each familiar recognizable food. These sections therefore require the seller to either label any other version as an imitation or refrain from selling it. *Cf. United States v. 62 Cases of Jam,* 340 U. S. 593 (1951).

When it becomes apparent that there are several versions of the familiar recognizable food, all of which vary in quality and all of which are regarded as genuine by some members of the public, the law becomes totally inadequate. In such circumstances, the courts must either force the manufacturers to label as imitation a food which some purchasers and consumers regard as genuine, or, the courts must simply not apply the economic adulteration laws to the various versions of the food and leave the purchaser to protect himself by reading the ingredient statement. The courts have usually handled such situations by holding that the standard is too indefinite to hold any of the versions of the food economically adulterated. See cases cited at footnote 97. The purchasers are thus left to rely upon labeling although the judicial consensus seems to be that labeling is inadequate protection for purchasers. *Cf. Federal Security Adm'r v. Quaker Oats Co.,* 318 U. S. 218 (1943); *United States v. 306 Cases of Sandford Tomato Catsup With Preservative,* 55 F. Supp. 725 (E. D. N. Y. 1944), *aff'd,* 148 F. 2d 71 (2d Cir. 1945). How-

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ever, in at least one analogous situation, a federal agency tried the "imitation" labeling route and this was found equally inadequate. See *Armour & Co. v. Freeman*, 304 F. 2d 404 (D. C. Cir.), *cert. denied*, 370 U. S. 920 (1962) in which it was regarded as deceptive to label ham with added water as imitation ham.

[97] Probably the two most recent relevant authorities are *United States v. 70 Gross Bottles of Quenchies*, 3 Kleinfeld 141 (S. D. Ohio 1952) and *United States v. 55 Cases of Popped Corn*, 62 F. Supp. 843 (D. Idaho 1943). In the former case there was apparently a difference of opinion whether soft drink bases should be sweetened with sugar or saccharin while in the latter case there was a difference of opinion whether popped corn should be flavored with butter, vegetable oils or mineral oils. In both cases the court concluded the products were not adulterated. However, the same approach is inherent in those cases which define the familiar recognizable food according to the *common* understanding of purchasers and consumers, *cf.* authorities cited at footnote 97, since it can be argued, there is no *common* understanding when substantial groups of purchasers and consumers dissent.

[98] Establishing a standard of identity is probably the best approach when differences of opinion exist concerning the proper composition of the food. The procedure for establishing a standard of identity is set forth in § 701 of the act and, briefly, it consists of a proposal for a standard initiated by the Secretary of HEW or by any interested person, publication of the proposal and an opportunity to file written objections and request a public hearing, a public hearing at which evidence may be presented, and publication of a final order subject to court review. 52 Stat. 1055 (1938), as amended, 21 U. S. C. § 371(e)-(f) (1958). While this procedure is time-consuming, it provides an opportunity for all interested persons to voice their opinion concerning the proper composition of the food, and provides the basis for establishing a reasonable standard of identity which will "promote honesty and fair dealing in the interest of consumers." See 52 Stat. 1046 (1938), as amended, 21 U. S. C. § 341 (1958). The public hearing and the publicity concerning the controversy over the proper composition of the food may also make a small contribution to the education of some purchasers and consumers. *Cf.* "The Second Citizens Advisory Committee Report on the Food and Drug Administration," 17 FOOD DRUG COSMETIC LAW JOURNAL 587, 597-99 (1962), wherein the committee stressed the need for education rather than just prosecution. Ultimately, if it were decided that there was more than one legitimate version of the familiar recognizable food, the standard of identity could provide for optional ingredients, thus preserving the sellers' rights to sell both versions of the food.

[99] 52 Stat. 1047 (1938), as amended, 21 U. S. C. § 343(g)(1) (1958).

[100] 52 Stat. 1046 (1938), as amended, 21 U. S. C. § 341 (1958).

[101] On June 12, 1933, Senator Copeland introduced a bill which would have completely revised the 1906 Food and Drugs Act; the revision, in amended form, was ultimately enacted on June 25, 1938. See *Dunn*, Federal Food, Drug and Cosmetic Act 24-30 (1938). The authority to promulgate standards of identity for foods was part of the original bill providing for the revision of the 1906 Act. See S. 1944, 73d Cong., 1st Sess. § 11 (1933). The early Senate Reports of the bills providing for the proposed revision of the 1906 Food and Drugs Act made it clear that the standards of identity were intended to apply in economic adulteration cases. See S. Rep. No. 493, 73d Cong., 2d Sess. § 7 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. § 302 (1935); S. Rep. No. 646, 74th Cong., 1st Sess. § 302 (1935). (These reports are reprinted in *Dunn*, cited at 110-32, 237-66, and 477-90 respectively.) For example, S. Rep. No. 646 stated: "Paragraph (g) overcomes a serious deficiency of the

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present law which makes no provision for definitions and standards of identity for food, with the exception of one enacted by Congress defining butter. The absence of such authority has seriously handicapped effective enforcement. The provisions of the law, as well as those of this bill, dealing with so-called 'economic adulteration' that is, the cheapening of foods either through lessening the quantities of valuable constituents or through the substitution of cheaper constituents, require definitions and standards whereby the article can be judged. For example, under the law and under the bill, a food is defined as adulterated if any substance has been mixed or packed with it so as to reduce its quality or strength, or if any substance has been substituted wholly or in part therefor. These provisions in themselves imply the existence of definitions and standards of identity, since no one can tell when an article is adulterated under them without first determining definitely what constitutes the unadulterated product." *Dunn,* cited at 480.

However, later legislative reports concerning the proposed revision of the 1906 Food and Drugs Act did not contain the same type of language, see H. R. Rep. No. 2755, 74th Cong., 2d Sess. (1935) (*Dunn,* cited at 550-65); S. Rep. No. 91, 75th Cong., 1st Sess. (1937) (*Dunn,* cited at 675-81); S. Rep. No. 152, 75th Cong., 1st Sess. (1937) (*Dunn,* cited at 686-92); and H. R. Rep. No. 2139, 75th Cong., 3d Sess. (1938) (*Dunn,* cited at 815-33), although H. R. Rep. No. 152, for example, did note the Government's difficulties in dealing with cheapened jams and that the standards of identity would prevent this debasement in the future. (*Dunn,* cited at 819.)

It seems plain therefore that Congress originally intended the standards of identity to apply in economic adulteration cases but it is not clear whether Congress later retreated from that position, intending the misbranding remedy alone to govern.

[102] Foods which fail to conform to a standard of identity are misbranded (unless labeled imitation); foods which fail to conform to a standard of quality are misbranded unless labeled that they fall below the standard. 52 Stat. 1047 (1938), as amended, 21 U. S. C. § 343-(g)(h) (1958).

[103] 93 F. Supp. 764 (S. D. Iowa 1950).

[104] 179 F. 2d 174 (10th Cir. 1950).

[105] See footnote 104.

[106] 4 Kleinfeld 138 (D. Neb. 1955).

[107] In the *Cudahy* case, cited at footnote 106, the defendant had apparently increased the percentage of whole milk and decreased the percentage of cottonseed oil in the oleomargarine. No evidence was introduced concerning the relative cost of these ingredients, and, unlike the *Del Comida* case, cited at footnote 104, involving watered tomatoes, the court could not take judicial notice of the cost differential.

[108] The court said "Another obstacle to conviction under Count I arises because it assumes that resort may be had in support of a charge under Title 21 U. S. C. A., Section 342(b)(2) to 21 CFR Section 45.0(a) [the standard of identity for oleomargarine]. . . . Unlike the section of the statute defining misbranding, (Title 21 U. S. C. A., Section 343(g)) the section within which Count I was framed does not refer to such regulatory definition or standard as a canon or test of adulteration," cited at footnote 106 at 147. The court cited *Bruce's Juices, Inc. v. United States,* 194 F. 2d 935 (5th Cir. 1952) in support of this reasoning. In *Bruce's Juices* cans of blended pineapple and grapefruit juice were seized because the juices were decomposed. The claimant argued that the condemnation was improper because no standards of identity had been promulgated for the product and the court correctly concluded standards of identity were irrelevant to the adulteration charge. The court in *Cudahy* thus traveled far afield to find support for its reasoning.

[109] If Congress intended to make the failure to conform to the standards an adulteration, it would have been easy enough to do so expressly. Instead, and in contrast to the previously adopted

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laws and regulations of a number of states, Congress chose the misbranding route. See Callaway, "Current Problems in Formulating Food Standards," 2 FOOD DRUG COSMETIC LAW QUARTERLY 124, 128 (1947). Violations of the Butter Act, 42 Stat. 1500 (1923), as amended, 15 U. S. C. § 321(a) (1958), which requires 80 per cent milk fat in butter have always been considered economic adulterations. See, for example, *United States v. Centralia Dairy Co.*, 60 F. 2d 141 (W. D. Wash. 1932); *United States v. South Hero Creamery Ass'n*, White & Gates 1142 (D. Vt. 1925). However, the Butter Act was enacted in 1923 (before Congress enacted the Federal Food, Drug & Cosmetic Act providing for misbranding penalties for failure to conform to a standard of identity) and hence is only analogous precedent for the argument that the failure to conform to a standard of identity is an economic adulteration.

[110] See text accompanying footnotes 114-117. The standard of identity would seem better evidence than the custom of the trade since there is less deviation from it.

[111] This is simply an issue of fact for the trial court. If, for example, the standards require 40% fruit in jam and the allegedly adulterated food only contains 10% fruit, the deficiency is sufficient so that consumer expectations have probably been violated. *Cf. United States v. 30 Cases of Leader Brand Strawberry Fruit Spread*, 93 F. Supp. 764 (S. D. Iowa 1950); Markel, "Federal Food Standards," 1 FOOD DRUG COSMETIC LAW QUARTERLY 28, 42 (1946) in which the author suggests that the nature of the deficiency of the food when compared to the standard will determine whether it is economically adulterated.

[112] In the *Cudahy* case, cited at footnote 106, defendant's margarine contained at least 73% fat and averaged 79.8% fat as compared with an 80% standard. The deficiency was apparently filled largely with nonfat dried milk. Neither substantial economic nor nutritional inferiority was therefore shown.

[113] In the *Del Comida*, cited at footnote 104, and *Leader Brand Strawberry Fruit Spread*, cited at footnote 103, cases, both elements were present: (1) substantial nutritional inferiority of the adulterated food as compared with the familiar recognizable food and (2) substantial economic inferiority of the adulterated food as compared with the familiar recognizable food. Both of the same elements were missing in the *Cudahy* case.

[114] In cases involving unstandardized foods fabricated from two or more ingredients or natural foods packed or preserved with another ingredient, the government usually proves the composition of the familiar recognizable food in part at least by evidence of the custom of the trade. See, for example, *United States v. 36 Drums of Pop'N Oil*, 164 F. 2d 250 (5th Cir. 1947) (custom of the trade was to use butter or vegetable oils rather than mineral oil to flavor popped corn); *United States v. Two Bags of Poppy Seeds*, 147 F. 2d 123 (6th Cir. 1945) (custom of the trade was to use Dutch and Turkish rather than British India poppy seeds to decorate baked goods); *United States v. 149 Cases of Black Eyed Peas*, 4 Kleinfeld 27 (D. Colo. 1953) (custom of the trade was to use less water than claimant in canned peas); *United States v. 154 Cases of Tomatoes*, White & Gates 967 (W. D. Pa. 1920) (libel dismissed because government failed to allege that custom of the trade was to exclude tomato pulp from canned tomatoes); *United States v. 60 Barrels of Wine*, 225 Fed. 846 (W. D. Mo. 1915) (custom of the trade was to make claret wine from the entire grape rather than the grape residue remaining after extraction of the juice); *United States v. Golden & Co.*, White & Gates 1033 (Police Ct. D. C. 1922) (custom of the trade was to use less water than claimant in canned oysters); *United States v. Krumm*, 269 Fed. 848 (E. D. Pa. 1921) (libel dismissed, in part, because government failed to allege that custom of the trade was to manufacture macaroni solely from semolina rather than flour); *cf. United States v. 30 Cases of Grenadine Syrup*, 199 Fed. 932 (D. Mass. 1912); *United States v. Bettman-John-*

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son Co., White & Gates 299 (S. D. Ohio 1911). But see *W. B. Wood Mfg. Co. v. United States*, 292 Fed. 133 (8th Cir. 1923) in which the court would not permit evidence of the custom of the trade.

Cases involving unstandardized natural foods not packed or preserved with another ingredient are handled a little differently. The composition of unstandardized natural foods is apt to be a matter of common knowledge and, when foreign ingredients are introduced in the food, it is usually unnecessary to prove the composition of the natural food. For example, olive oil is generally recognized as an oil extracted from olives and when cottonseed oil is found in a container of olive oil, the debasement is clear. See *United States v. Germack*, White & Gates 1178 (S. D. N. Y. 1925); *United States v. Marmarelli*, White & Gates 1122 (S. D. N. Y. 1924); *United States v. Alban*, White & Gates 1014 (S. D. N. Y. 1921); *United States v. Monahos*, White & Gates 935 (S. D. N. Y. 1919); *United States v. Paraskevopolus*, White & Gates 925 (S. D. N. Y. 1913). In some situations, occur when horseradish is adulterated with parsnip, see *United States v. Treffinger*, 224 F. 2d 855 (2d Cir. 1955), or, eggs are adulterated with skimmed milk, see *United States v. German American Specialty Co.*, White & Gates 459 (S. D. N. Y. 1913). In some situations, however, the composition of the natural food is not obvious and in such cases the custom of the trade becomes relevant. See *United States v. 75 Boxes of Alleged Pepper*, 198 Fed. 934 (D. N. J. 1912), in which the dispute was whether the familiar recognizable food "pepper" properly consisted of black pepper or long pepper.

Additionally, unstandardized natural foods are sometimes adulterated by increasing the cheaper ingredients which occur naturally in the food and decreasing the more valuable natural ingredients. If such foods fall below the consumers' expectations, they could be considered adulterated under the standard of the familiar recognizable food and evidence of the usual quantitative composition of such foods as sold by the trade would be relevant if the government applied the standard of the familiar recognizable food to such cases. As a practical matter, however, the standard of the familiar recognizable food is not applied to such cases. Another more stringent standard based upon the natural composition of these foods is applied and this standard makes the dilution of the food illegal per se. See text accompanying footnotes 129-36.

[115] *W. B. Wood Mfg. Co. v. United States*, 292 Fed. 133, 134 (8th Cir. 1923). See also *United States v. 4½ Cases of Creme De Menthe*, White & Gates 1191, 1197 (E. D. Mo. 1926): "It is not a question of what Tom, Dick or Harry put in there, because Tom, Dick or Harry may be violating the law themselves, but the question is, whether it is a standard formula and whether this conforms to it."

[116] See *United States v. W. B. Wood Mfg. Co.*, White & Gates 1002 (E. D. Mo. 1921), *aff'd*, 292 Fed. 133 (8th Cir. 1923) in which the government charged that a red food color was being diluted by salt. The defendant wanted to prove that it was customary to dilute food colors with salt and the court excluded this testimony, reasoning that the standard was not what was customarily done by manufacturers but what was properly done by them.

[117] The FDA in its 1933 report to the Department of Agriculture summarized the situation as follows: "To prove that a product sold within the jurisdiction of the Food and Drugs Act and that fails to comply with the advisory standard is adulterated or misbranded, it is necessary for the Department to present to the court and jury convincing evidence that the advisory standard does represent the actual composition of the product expected by the consumer and recognized by the majority of the trade." Dunbar, *Federal Food Drug and Cosmetic Law Reports 1907-1949*. 800 (1951). The government can now promulgate legally binding standards of identity, but in cases involving unstandardized foods, the same type of evidence seems required today as was required in 1933.

[118] *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951); *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S. D. Ohio 1952); *United States v. One Carload of Corno Horse and Mule Feed,* 188 Fed. 453 (M. D. Ala. 1911). Analogous situations involving such evidence include *United States v. 174 Cases of Delson Thin Mints,* 195 F. Supp. 326 (D. N. J. 1961), *aff'd,* 302 F. 2d 724 (3d Cir. 1962) (misleading packaging); *United States v. 254 Cases of Baby Brand Tomato Sauce,* 63 F. Supp. 916 (E. D. Ark. 1945) (false and misleading labeling); and *Rhodes Pharmacal Co. v. FTC,* 208 F. 2d 382 (7th Cir. 1953), *rev'd on other grounds,* 348 U. S. 940 (1955) (F. T. C. deceptive advertising case).

[119] 188 Fed. 453 (M. D. Ala. 1911).

[120] See footnote 119 at 462.

[121] 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951).

[122] See footnote 121 at 974.

[123] In comparing the *Corno* case, cited at footnote 119, and the *Bireley's* case, cited at footnote 121, it should be remembered that the public in general is a potential purchaser and consumer of orange beverages while the public in general is not, to the same degree, a potential purchaser of mule feed.

[124] For example, in *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947) in which the issue was whether mineral oil was a proper flavoring for popped corn, consumer surveys would probably have been helpful but in *United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955) in which the issue was whether oleomargarine should contain 79% or 80% fat, the survey would probably have produced no intelligible results.

[125] One commentator has summarized the identity factors of a food as follows:

> The identity factors of any food are (1) composition, and (2) resulting organoleptically determinable physical characteristics. These, in turn, are subdivided into—

(1) Composition	(a) Qualitative (b) Quantitative
(2) Resulting organoleptically determinable physical characteristics	(a) Taste (b) Color (c) Odor (d) Texture or consistency, ranging from liquid to solid

See Markel, "The Law on Imitation Food," 5 Food Drug Cosmetic Law Journal 145, 166 (1950). The expert can compare the qualitative and quantitative composition of the familiar recognizable food and the allegedly adulterated product and describe the differences in the organoleptically determinable physical characteristics of the two foods which result from the differences in their composition. This type of testimony will better enable the jury to understand the issues of the case and their importance. See *United States v. 4½ Cases of Creme De Menthe,* White & Gates 1191 (E. D. Mo. 1926) for this type of approach.

[126] In *United States v. 254 Cases of Baby Brand Tomato Sauce,* 63 F. Supp. 916 (E. D. Ark. 1945), a misbranding case in which the principal issue was the proper composition of tomato sauce, the witnesses included chemists employed by FDA and competitors, a plant manager employed by a competitor, a buyer and sales manager of a food wholesaler, a housewife, a chef, a restaurant manager, a partner of the defendant canning company, the owner of a competing cannery, and two food brokers. *Cf.* The nutritionists' testimony concerning the proper composition of farina in *Federal Security Adm'r v. Quaker Oats Co.,* 318 U. S. 218 (1943) (appeal from a standard of identity). In addition to experts on food in general, witnesses may testify who are authorities on the particular food involved in the suit. Perhaps the best examples of this type of testimony were the wine experts who testified concerning the proper composition of claret wine in *United States v. 60 Barrels of Wine,* 225 Fed. 846 (W. D. Mo. 1915), basing their testimony upon the taste and smell of claimant's product.

[127] See *United States v. 254 Cases of Baby Brand Tomato Sauce,* 63 F. Supp.

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916 (E. D. Ark. 1945) for this type of cross-examination. In at least one older case, *United States v. 30 Cases of Grenadine Syrup,* 199 Fed. 932 (D. Mass. 1912), dictionaries seem to have been used directly as evidence of the proper composition of the food, but this practice may raise hearsay problems. *Cf.* McCormick, *Evidence* 620-21 (1954).

[128] The definition of the familiar recognizable food could be derived from three different sources—the government, the trade, or the purchasers and consumers of the food. When the government has failed to promulgate standards, either the custom of the trade or the expectations of purchasers and consumers must govern. Since the trade in general could be deliberately debasing food for economic advantage, the expectations of purchaser and consumers, difficult as they may be to define, seem the best possible test.

[129] The standard of the familiar recognizable food reflects the common understanding of purchasers and consumers. See cases cited in footnote 91. Where there is a difference in expectations among purchasers, the food is probably not adulterated unless it falls outside the expectations of all substantial groups of purchasers. See text accompanying footnotes 95-97. It thus follows that if water were added to milk, the milk would probably not be adulterated under the familiar recognizable food standard unless it contained considerably more water than all substantial groups of purchasers and consumers would ordinarily anticipate. This is in contrast to the standard described in text accompanying footnotes 129-36 which makes the addition of any water to milk illegal.

[130] *United States v. 154 Sacks of Oats,* 283 Fed. 985 (W. D. Va. 1922), *modified,* 294 Fed. 340 (W. D. Va. 1923); *United States v. Heimann,* White & Gates 840 (E. D. Ill. 1917) are the cases which best illustrate this rule. However, support can also be derived for this rule from *Union Dairy Co. v. United States,* 250 Fed. 231 (7th Cir. 1918); *United States v. Tetz,* White & Gates 917 (W. D. Wash. 1919); *United States v. Taylor,* White & Gates 839 (S. D. Ill. 1917); and *United States v. Griebler,* White & Gates 29 (E. D. Ill. 1908). In these cases the courts treated the addition of water to milk as illegal per se. *Cf. United States v. Six Barrels of Ground Pepper,* White & Gates 817 (S. D. N. Y. 1917) in which the claimant had intermixed pepper shells with pepper. Although the claimant's product still met the United States Department of Agriculture's chemical standards for pepper, the deliberate dilution of the product with pepper shells was illegal.

[131] *Cf. United States v. Heimann,* White & Gates 840, 841 (E. D. Ill. 1917) in which the court said: "The evidence shows that not all cows are uniform in the amount of butterfat which their milk contains—whatever it does contain, that the shipper should ship the whole milk without any abstraction of any part of it."

[132] See *United States v. 154 Sacks of Oats,* 283 Fed. 985 (W. D. Va. 1922), *modified,* 294 Fed. 340, (W. D. Va. 1923), in which claimant deliberately added weed seeds, chaff and dust to his oats until the product just met the standard for oats provided by the Grain Standards Act.

[133] In both *United States v. Six Barrels of Ground Pepper,* White & Gates 817 (S. D. N. Y. 1917) (pepper adulterated by pepper shells); and *United States v. 154 Sacks of Oats,* cited in footnote 132, the condemned products met the minimum standards for such foods established by the government. *Cf. United States v. 3998 Cases of Canned Tomatoes,* White & Gates 1213 (D. Del. 1928).

[134] See text Part I, Wesley E. Forte, "The Food and Drug Administration and the Economic Adulteration of Foods," 21 Food Drug Cosmetic Law Journal 533 (October 1966).

[135] More tampering is permitted in foods which are fabricated from a combination of ingredients and sold under distinctive names because the manufacturer may be producing and selling a new and desirable food. See *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert.*

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denied, 342 U. S. 861 (1951); *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S. D. Ohio 1952). Society has no comparable interest in permitting the sale of a natural food, as such, which has been reduced to the average prevailing in the market.

[136] There is also a possibility that producers permitted to reduce superior natural foods to average might reduce these foods below average on occasion.

[137] See *United States v. 40 Cases of Pinocchio Brand Oil,* 289 F. 2d 343 (2d Cir.), *cert. denied,* 368 U. S. 831 (1961); *United States v. 5 Cases of Figlia Mia Brand,* 179 F. 2d 519 (2d Cir.), *cert. denied,* 339 U. S. 963 (1950).

[138] See cases cited in footnote 137 and *United States v. Antonio Corrao Corp.,* 185 F. 2d 372 (2d Cir. 1950); *Barnes v. United States,* 142 F. 2d 648 (9th Cir. 1944); *United States v. Fabro, Inc.,* 206 F. Supp. 523 (M. D. Ga. 1962); *United States v. Germack,* White & Gates 1178 (S. D. N. Y. 1925); *United States v. One Carload of Corno Horse & Mule Feed,* 188 Fed. 453 (M. D. Ala. 1911). See also *United States v. Food Products Labs., Inc.,* 6 Kleinfeld 123 (W. D. Mo. 1963); *United States v. Beck,* 2 Kleinfeld 197 (S. D. Iowa 1949).

[139] See *United States v. Fabro, Inc.,* 206 F. Supp. 523 (M. D. Ga. 1962).

[140] See *United States v. Food Products Labs., Inc.,* 6 Kleinfeld 123 (W. D. Mo. 1963).

[141] 206 F. Supp. 523 (M. D. Ga. 1962).

[142] See footnote 141 at 526.

[143] *United States v. 80 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951).

[144] See cases cited at footnotes 137-38.

[145] 6 Kleinfeld 123 (W. D. Mo. 1963).

[146] See footnote 145 at 124.

[147] The distinction between absolute and relative statements is perhaps more often described as the distinction between facts and puffery. Merchants have traditionally been given wide latitude in expressing their opinions or evaluations of the intangible qualities of their products although the FTC has decreased that latitude somewhat in more recent years. See Millstein, "The Federal Trade Commission and False Advertising," 64 *Columbia Law Review* 439, 469-70 (1964). *The Food Products* decision suggests that if the puffery on the label relates to the composition of the food and is too extravagant, liability may be imposed under economic adulteration law.

[148] *Fabro,* cited at footnote 139, raised for the first time the question whether *Bireley's* really barred all standards derived from the food itself from economic adulteration law, and, contrary to the opinion of the author of this article, answered the question in the affirmative. Both the question and the answer were unnecessary in *Fabro* since the court had other more substantial grounds (which it also relied upon) for finding for the defendant. See text accompanying footnotes 161-64.

[149] In *Bireley's,* cited at footnote 143, the court refused to let the jury speculate whether the apparent orange juice content of the beverage was more than 6%. Presumably the jury had both beverages—Bireley's and natural orange juice—as exhibits. In *Food Products,* cited at footnote 140, the court sitting without a jury, decided that vitamin enrichment wafers labeled "stable" and "long shelf life" were adulterated and misbranded because they could not retain the vitamins "over any significant period of time." Both questions seem vague. Assume, however, that the court's conclusion that the vitamin enrichment wafers were misbranded was correct, would it necessarily follow that they were economically adulterated? It could be argued that when it comes to puffery at least, the courts ought to regard this as the exclusive province of the misbranding section of the Federal Food, Drug and Cosmetics Act, reserving economic adulteration penalties for factual misrepresentations concerning the composition of the food. There is no indication that the defendant raised this argument in the *Food Products* case.

[150] Before *Fabro,* cited at footnote, 139, and *Food Products,* cited at footnote 140, there were no reported cases in which a court had ever refused to apply a

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definite standard derived from the food in an economic adulteration case or in which a court had ever applied puffery as the standard in an economic adulteration case.

[151] 52 Stat. 1046 (1938), 21 U.S.C. § 342(b)(1) (1958).

[152] These definitions do not appear as such in economic adulteration cases. However, a comparison of FDA's economic adulteration cases and its trade correspondence illustrates that these values are considered by both FDA and the courts. Compare, for example, *United States v. Two Bags of Poppy Seeds,* 147 F. 2d 123 (6th Cir. 1945) where the holding of economic adulteration was based solely on financial value with *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947) where the holding of economic adulteration was based primarily on food value, although the product was also economically inferior. See also *FDA Trade Correspondence* 311, August 20, 1940 (1 Kleinfeld 691), and 8A, April 4, 1946 (1 Kleinfeld 752) for examples of FDA's concern about food values. *Cf. United States v. Newton Tea & Spice Co.,* 275 Fed. 394 (S. D. Ohio 1920), *aff'd,* 288 Fed. 475 (6th Cir. 1923) a misbranding case in which the court was concerned with the food and nutritive values of a product labeled as a substitute for eggs.

[153] *Cf. United States v. Fabro, Inc.,* 206 F. Supp. 523 (M. D. Ga. 1962).

[154] Act of June 30, 1906, ch. 3915, 34 Stat. 768, § 7, *repealed,* 52 Stat. 1059 (1938).

[155] *Cf. United States v. One Carload of Corno Horse and Mule Feed,* 188 Fed. 453, 456-57 (M. D. Ala. 1911): "There is no charge or proof of removal of any part of the contents of the package as originally put up." But see *United States v. Golden & Co.,* White & Gates 1033 (Police Ct. D. C. 1922) (involving canned oysters with excess water in which the court apparently considered it sufficient if the valuable constituent (oysters) was in part omitted rather than removed.)

[156] See *United States v. Schider,* 246 U. S. 519 (1918); *United States v. Hall-Baker Grain Co.,* White & Gates 291 (W. D. Mo. 1911), *rev'd,* because there was insufficient evidence, 198 Fed. 614 (8th Cir. 1912) (inferior wheat allegedly packed with No. 2 wheat, reducing its quality); *United States v. Rinchini,* White & Gates 318 (D. Ariz. 1911) (ice cream allegedly deficient in butterfat); *United States v. One Carload of Corno Horse & Mule Feed,* cited at footnote 155 (oat byproducts allegedly reduced quality of feed when substituted for ground oats); *United States v. Heimann,* White & Gates 840 (E.D. Ill. 1917) (butterfat allegedly abstracted from milk, reducing its quality); and *United States v. Golden,* cited at footnote 155 (excess water allegedly put in canned oysters reducing their quality).

[157] See *United States v. 5 Cases of Figlia Mia Brand,* 179 F. 2d 519 (2d Cir.), *cert. denied,* 339 U.S. 963 (1950) (olive oil omitted from blend of oils); *Barnes v. United States,* 142 F. 2d 648 (9th Cir. 1944) (vitamin deficiency in vitamin tablets); *United States v. Fabro, Inc.,* 206 F. Supp. 523 (M.D. Ga. 1962) (protein omitted from dog food); *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S.D. Ohio 1952) (sugar allegedly omitted from soft drink base); *United States v. Midfield Packers,* 3 Kleinfeld 157 (W.D. Wash. 1952) (fruit in part allegedly omitted from frozen fruit); *United States v. Antonio Corrao Corp.,* 2 Kleinfeld 206 (E.D.N.Y.), *rev'd,* 185 F.2d 372 (2d Cir. 1950) (olive oil allegedly omitted from blend of oils); *United States v. 55 Cases of Popped Corn,* 62 F. Supp. 843 (D. Idaho 1943) (butter and vegetable oils allegedly omitted from popped corn).

[158] 3 Kleinfeld 141 (S.D. Ohio 1952).

[159] See footnote 143.

[160] "Saccharin is allegedly non-nutritious. Unlike sugar it does not build calories. It merely sweetens. But this very characteristic is a quality that is much desired and sought by many who fear that their waist line may unduly expand with the use of sugar."

[161] 206 F. Supp. 523 (M.D. Ga. 1962).

[162] The court also dismissed the case because under its interpretation of *Bireley's* the product could not set its own standard. But see text accompanying footnotes 141-44 for a review of the fallacies of that theory.

[163] See footnote 161 at 526.

[164] The government had not been particularly successful in either civil or criminal cases prior to *Fabro,* cited at footnote 161. Of the seven cases under § 402(b)(1) listed in footnote 157, the government won two and lost five. The government is now in a situation in which its indifferent prior record under §402(b)(1) is coupled with a patently recognizable and recognized ambiguity in the statute. Since the government could not convince the *Fabro* court that protein was a valuable constituent of dog food, other courts will probably be hesitant to declare any constituent as "valuable."

[165] 52 Stat. 1046 (1938), 21 USC § 342(b) (2) (1958).

[166] See Act of June 30, 1906, ch. 3915, 34 Stat. 768, § 7, repealed, 52 Stat. 1059 (1938).

[167] See CCH Food Drug Cosmetic Law Reporter ¶ 50,087.

[168] See footnote 167.

[169] See, for example, *United States v. Schider,* 246 U.S. 519 (1918); *Van Liew v. United States,* 321 F. 2d 664 (5th Cir. 1963); *United States v. Treffinger,* 224 F. 2d 855 (2d Cir. 1955); *United States v. 716 Cases of Del Comida Brand Tomatoes,* 179 F. 2d 174 (10th Cir. 1950); *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947); *Libby, McNeill & Libby v. United States,* 210 Fed. 148 (4th Cir. 1913); *Hall-Baker Grain Co. v. United States,* 198 Fed. 614 (8th Cir. 1912); *United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955); *United States v. 149 Cases of Black Eyed Peas,* 4 Kleinfeld 27 (D. Colo. 1953); *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S.D. Ohio 1952); *United States v. Beck,* 2 Kleinfeld 197 (S.D. Iowa 1946); *United States v. 254 Cases of Baby Brand Tomato Sauce,* 63 F. Supp. 916 (E.D. Ark. 1945); *United States v. 55 Cases of Popped Corn,* 62 F. Supp. 843 (D. Idaho 1943).

[170] *Cf. United States v. Paraskevopolus,* White & Gates 925, 926 (S.D.N.Y. 1919); *United States v. Shucart,* White & Gates 693, 694 (E.D. Mo. 1915); *United States v. 58 Sacks of Corn Meal,* White & Gates 322, 323 (D. S.C. 1911) (misbranding) ("As a matter of law I charge you that a man when he purchases an article, has a right to buy whatever he pays his money for; it may be a pure fancy on his part, and it may be the veriest whim on his part, but if he stipulates in the contract that he is to buy certain specified articles, or an article prepared in a certain specified way, and that is the contract and the agreement, and he pays for it, then he is entitled to have it, although the result may be that he chooses to buy an inferior article at a higher price. . . .")

[171] See, for example, *FTC v. Algoma Lumber Co.,* 291 U. S. 67 (1934).

[172] 179 F. 2d 174 (10th Cir. 1950).

[173] See footnote 172.

[174] See *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S.D. Ohio 1952). The court said, "Thus, the generally recognized rule that no illegal substitution occurs where a replacement is made, in whole or in part, with another substance not injurious or deleterious to health, provided the name of the substance substituted appears on the label, governs in these proceedings. And we are not confusing adulteration with misbranding. *United States v. 36 Drums of Pop'N Oil.*"

The *Pop'N Oil* case, 164 F. 2d 250 (5th Cir. 1947), involved artificially colored mineral oil which had been prepared as a flavoring for popped corn. The government alleged adulteration under § 402(b)(2), (3), and (4) and the Circuit Court only considered the latter two subsections. No reason is cited by the Circuit Court for not considering the § 402(b)(2) claim and the District Court opinion is unreported. However, the Circuit Court states that the District Court dismissed the libel because truthful labeling was, in the ab-

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(Footnote 174 continued.)

sence of a standard of identity, sufficient to comply with the act. The court in the *Quenchies* case, may have assumed that the failure of the Circuit Court to reverse the dismissal of the § 402(b)(2) was a defense to this section of the statute. Alternatively, the court in *Quenchies* may only have been citing the *Pop'N Oil* case for the proposition that adulteration should not be confused with misbranding.

[175] 321 F. 2d 664 (5th Cir. 1963).

[176] The court stated, "For there to be a crime under (2), there must be the substitution of any substance for some valuable constituent of the food. Unless there is a valuable constituent plus a substitution of any substance for it, there is simply no crime." See footnote 175 at 670.

[177] The 1906 Act provided: "That for the purposes of this Act an article shall be deemed to be adulterated: . . . .

First. . . .

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted. . . . "

There is thus no possible construction of the 1906 Act whereby it can be logically concluded that the substance had to be substituted for a "valuable constituent." The economic adulteration provisions of the Federal Food, Drug and Cosmetic Act were intended to be broader than the corresponding provisions of the 1906 Act. It is therefore inconsistent with the history and purpose of the Federal Food, Drug and Cosmetic Act to conclude that the revised statute was intended to limit § 402(b)(2) to the substitution of substances for a valuable constituent. None of the prior cases have so limited it. See, for example, cases cited in footnote 169.

[178] Before a substance can be substituted for a valuable constituent, the valuable constituent must be omitted or abstracted. The omission or abstraction of valuable constituents is prohibited by § 402(b)(1). See 52 Stat. 1046 (1938), 21 USC § 342(b)(1) (1958).

[179] See footnote 178.

[180] See, for example, *United States v. 40 Cases of Pinocchio Brand Oil,* 289 F. 2d 343 (2d Cir.), *cert. denied,* 368 U. S. 831 (1961) (cheaper oils substituted for olive oil); *United States v. 716 Cases of Del Comida Brand Tomatoes* 179 F. 2d 174 (10th Cir. 1950) (water substituted for tomatoes); *United States v. 149 Cases of Black Eyed Peas,* 4 Kleinfeld 27 (D. Colo. 1953) (brine substituted for peas); *United States v. Beck,* 2 Kleinfeld 197 (S.D. Iowa 1948) (mineral oil and other substances substituted for butter and cream), all of which were decided in favor of the government.

[181] Compare *United States v. 716 Cases of Del Comida Brand Tomatoes,* 179 F. 2d 174 (10th Cir. 1950) and *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,* 93 F. Supp. 764 (S.D. Iowa 1950) with *United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955). In the former two cases the violation was substantial and deliberate while in the latter the alleged adulteration was minor and inadvertent. Economic adulteration was held in the *Del Comida* case and the *Leader Brand* case but not in the *Cudahy* case.

[182] *Compare* the cases cited in footnote 180 with the following cases in which the claimant (or defendant) prevailed: *United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955) (minor and inadvertent shortage of fat in oleomargarine); *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S.D. Ohio 1952); *United States v. 55 Cases of Popped Corn,* 62 F. Supp. 843 (D. Idaho 1943).

In general, when the government has prevailed under § 402(b)(2), it has been in factual situations where there was economic and nutritional fraud, where the deception was substantial and deliberate, and where there was no labeling indicating the substitution. Conversely, the claimant (or defendant) has usually prevailed when it was selling

(Footnote continued on next page.)

(Footnote 182 continued.)

a useful and accurately labeled food with changed ingredients, see *Quenchies,* above, when the substitution was an unintentional error, see *Cudahy,* above, or when the court saw no reason why the substitution should not be made. See *Popped Corn,* above.

[183] The Filled Milk Act specifically prohibits interstate sale of any milk containing fats or oil other than milk fat or which has been made in imitation or semblance of milk. 42 Stat. 1486 (1923), 21 USC §§ 61-63 (1958). The statute is therefore much more specific than the economic adulteration statute. Additionally, the United States Supreme Court cases have involved foods which were made in imitation of milk but which were much less costly. See *Carolene Products Co. v. United States,* 323 U. S. 18 (1944) and *United States v. Carolene Products Co.,* 304 U. S. 144 (1938). It is one thing for the Supreme Court to prohibit the sale of a food consisting of skimmed milk and coconut oil which is in semblance of milk, or a food which consists of milk and cottonseed or coconut oil which is in semblance of milk, when there is a specific statute and the food offers an obvious opportunity for economic fraud. Quite a different case is presented if, for example, the courts are operating under a general statute such as § 402(h)(2) and the food involved consists of the ordinary ingredients plus an added ingredient which is more expensive and improves the nutritive qualities of the food. There may be a substitution of one substance for another but the courts are likely to approach the substitution much more sympathetically. *Cf. United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955) and *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S.D. Ohio 1952) for less favorable situations in which the courts decided in favor of the manufacturer.

[184] See *Van Liew v. United States,* 321 F. 2d 664 (5th Cir. 1963).

[185] 52 Stat. 1046 (1938), 21 USC § 342(b)(3) (1958).

[186] Act of June 30, 1906, ch. 3915, § 7, 34 Stat. 768, repealed, 52 Stat. 1059 (1938).

[187] *United States v. Ten Cases of Bred Spred,* 49 F. 2d 87 (8th Cir. 1931).

[188] See footnote 187.

[189] See *United States v. 200 Sacks of Wheat Middlings,* White & Gates 1189 (E.D. Mich. 1926).

[190] See *United States v. Atlantic Macaroni Co.,* White & Gates 793, 804 (E.D. N.Y. 1917); see also *United States v. Two Bags of Poppy Seeds,* 147 F. 2d 123 (6th Cir. 1945) and *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947).

[191] *United States v. Hudson Mfg. Co.,* White & Gates 462 (N.D. Ill. 1913).

[192] *United States v. Edward Weston Tea & Spice Co.,* White & Gates 69 (E.D. Mo. 1909).

[193] See *Weeks v. United States,* 224 Fed. 64 (2d Cir. 1915), *aff'd on other grounds,* 245 U. S. 618 (1918). The government was unsuccessful in the *Weeks* case because the food was labeled "compound."

[194] *United States v. Atlantic Macaroni Co.,* White & Gates 793 (E.D.N.Y. 1917). The macaroni had been colored yellow to simulate the appearance of macaroni made from semolina flour prepared from durum wheat but was actually prepared from flour made from inferior wheat.

[195] See *United States v. 625 Sacks of Flour,* White & Gates 129 (W.D. Mo. 1910), *rev'd, sub. nom. Lexington Mill & Elevator Co. v. United States,* 202 Fed. 615 (8th Cir. 1913), *aff'd,* 232 U. S. 399 (1914).

[196] *United States v. Lexington Mill & Elevator Co.,* 232 U. S. 399 (1914).

[197] *United States v. Nesbitt Fruit Products, Inc.,* 96 F. 2d 972 (5th Cir. 1938).

[198] *United States v. Hall-Baker Grain Co.,* White & Gates 291 (W.D. Mo. 1911), *rev'd,* 198 Fed. 614 (8th Cir. 1912).

[199] *United States v. 154 Sacks of Oats,* 283 Fed. 985 (W.D. Va. 1922), *modified,* 294 Fed. 340 (W.D. Va. 1923).

[200] *United States v. 200 Sacks of Wheat Middlings,* White & Gates 1189 (E.D. Mich. 1926).

[201] *United States v. Two Bags of Poppy Seeds,* 147 F. 2d 123 (6th Cir. 1945).

[202] *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947).

[203] *FDA Trade Correspondence* 49, February 12, 1940 (1 Kleinfeld 589). See also *FDA Trade Correspondence* 213, March 21, 1940 (1 Kleinfeld 652).

[204] *FDA Trade Correspondence* 233, April 11, 1940 (1 Kleinfeld 660); see also *FDA Trade Correspondence* 340, September 17, 1940 (1 Kleinfeld 703).

[205] If, for example, diluted jam is made to appear to have the consistency of ordinary jam, it would seem to violate § 402(b)(4). *Cf. United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,* 93 F. Supp. 764 (S.D. Iowa 1950); *FDA Trade Correspondence* 185, March 15, 1940 (1 Kleinfeld 641).

[206] 52 Stat. 1046 (1938), 21 USC § 342(b)(4).

[207] Act of June 30, 1906, ch. 3915, § 7, 34 Stat. 768, repealed, 52 Stat. 1059 (1938).

[208] White & Gates 29 (E.D. Ill. 1908).

[209] See footnote 208 at 30.

[210] See *United States v. Edward Westen Tea & Spice Co.,* White & Gates 69 (E.D. Mo. 1909).

[211] See *United States v. Six Barrels of Ground Pepper,* White & Gates 817 (S.D.N.Y. 1917).

[212] See *United States v. Alban,* White & Gates 1014 (S.D.N.Y. 1921); *United States v. Monahos,* White & Gates 935 (S.D.N.Y. 1919).

[213] *United States v. 625 Sacks of Flour,* White & Gates 129 (W.D. Mo. 1910), *rev'd on other grounds, sub. nom. Lexington Mill & Elevator Co. v. United States,* 202 Fed. 615 (8th Cir. 1913), *aff'd,* 232 U. S. 399 (1914).

[214] See *Van Liew v. United States,* 321 F. 2d 664 (5th Cir. 1963).

[215] *United States v. Two Bags of Poppy Seeds,* 147 F. 2d 123 (6th Cir. 1945).

[216] *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947).

[217] *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951).

[218] See footnote 217.

[219] See footnote 217 at 971.

[220] FDA's extreme position in *Bireley's* was apparently derived from *Aronberg v. FTC,* 132 F. 2d 165, 167 (7th Cir. 1942). See "Developments in the Law—The Federal Food Drug and Cosmetic Act," 67 *Harvard Law Review* 632, 648 at n. 118 (1954).

The charge of the trial court is also very similar to the standard applied in *Charles of the Ritz Distribs. Corp. v. FTC,* 143 F. 2d 676, 679 (2d Cir. 1944). *Cf.* Millstein, "The Federal Trade Commission and False Advertising," 64 *Columbia Law Review* 439, 457-62 (1964) for a review of the standard usually applied in FTC advertising cases. Under the Federal Food, Drug and Cosmetic Act, the courts have usually applied an ordinary purchaser standard. See Nelson, "What Standard For The Nonstandardized Food? The Bireley's Case," 8 FOOD DRUG COSMETIC LAW JOURNAL 425, 433 (1953); see also Forte, "The Food and Drug Administration, the Federal Trade Commission and the Deceptive Packaging of Foods," 21 FOOD DRUG COSMETIC LAW JOURNAL 205, 248 (April, May 1966). This may be because the ordinary purchaser standard is implied under § 403(f) of the act. 52 Stat. 1047 (1938), 21 USC § 343(f) (1958). *Cf. United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951) relying upon § 403(f) as authority for the ordinary purchaser standard.

[221] *United States v. 88 Cases of Bireley's Orange Beverage,* cited at footnote 217. See Forte, "The Food and Drug Administration, the Federal Trade Commission and the Deceptive Packaging of Foods," 21 FOOD DRUG COSMETIC LAW JOURNAL 205, 248 (April, May 1966) for the author's views on the limitations of market research in defining the ordinary purchaser.

[222] *United States v. 116 Boxes of Arden's Assorted Candy Drops,* 80 F. Supp. 911 (D. Mass. 1948). Apparently the FDA believes the same type of rule will apply in economic adulteration cases. See

(Footnote continued on next page.)

(Footnote 222 continued.)
testimony of George Larrick, then Commissioner of the FDA, before a *Special Subcommittee of the Committee on Labor and Public Welfare of United States Senate* on S. 1839 and H.R. 7042, 89th Cong. 1st Sess., p. 10 (1965).

[223] See *United States v. 88 Cases of Bireley's Orange Beverage,* cited at footnote 217; *United States v. 306 Cases of Sandford Tomato Catsup with Preservative,* 55 F. Supp. 725 (E.D.N.Y. 1944), *aff'd. sub nom. Libby, McNeill & Libby v. United States,* 148 F. 2d 71 (2d Cir. 1945) (in which the court noted in passing the problems raised by restaurant consumption of a food which simulated a standardized food).

[224] 183 F. 2d 1014 (10th Cir. 1950), *rev'd,* 340 U. S. 593 (1951).

[225] *62 Cases of Jam v. United States,* 340 U. S. 593 (1951).

[226] *Cf.* footnote 76. The artificially colored mineral oil in the *Pop'N Oil* case and the artificially colored poppy seeds in the *Poppy Seed* case were foods which were actually designed for "palming-off" and the courts therefore disregarded the labeling of these foods. See *United States v. 36 Drums of Pop'N Oil,* 164 F. 2d 250 (5th Cir. 1947) and *United States v. Two Bags of Poppy Seeds,* 147 F. 2d 123 (6th Cir. 1945).

[227] 185 F. 2d 372 (2d Cir. 1950).

[228] The district court's opinion is reported at 2 Kleinfeld 206 (E.D.N.Y. 1950).

[229] The Circuit Court said, "It is suggested, however, that indirect deception, in violation of the statute, occurred if the added squalene, on an ordinary squalene test, led the officers to believe that the blend contained a larger percentage of olive oil than it did contain, even if the actual percentage was 20%, that is, the percentage represented to the consumer. It may be urged that such a construction of the statute is untenable because, unless there is less olive oil than that stated on the label, the consumer, who knows nothing of the squalene content, cannot be disadvantaged economically since he receives what he thinks he is buying. But we need not decide whether the suggested construction of the statute is correct. . . ." *United States v. Antonio Corrao Corp.,* 185 F. 2d 372, 376 (2d Cir. 1950).

[230] See *United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967, 971 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951).

[231] *FDA Trade Correspondence* 154, March 7, 1940 (1 Kleinfeld 629).

[232] *FDA Trade Correspondence* 213, March 21, 1940 (1 Kleinfeld 652).

[233] *FDA Trade Correspondence* 218, March 21, 1940 (1 Kleinfeld 654).

[234] *FDA Trade Correspondence* 233, April 11, 1940 (1 Kleinfeld 660).

[235] 93 F. Supp. 764 (S. D. Iowa 1950).

[236] See *United States v. W. F. Morgan,* 155 F. Supp. 847 (E.D. Va. 1957).

[237] *Van Liew v. United States,* 321 F. 2d 664 (5th Cir. 1963).

[238] *FDA Trade Correspondence* 154, March 7, 1940 (1 Kleinfeld 629).

[239] The passage of the 1906 Food and Drugs Act had an almost immediate effect upon economic adulteration. As early as 1917 the Bureau of Chemistry noted in its report to the Department of Agriculture: "The best evidence that many of the abuses formerly occurring in the food industry have ceased, is to be found in the fact that the violations of the Food and Drugs Act observed today are hardly comparable with those obtained during the first few years of the past decade. Most of the staple food products now found in violation are either of a higher grade than formerly, or are products of the clever adulterator, that is, of those who have more or less anticipated the ordinary means of detection by so manipulating their products so that not infrequently the adulteration can be detected only by the most detailed and painstaking chemical analysis coupled with factory inspection." 1917 *Report of the Bureau of Chemistry* 14, Dunbar, *Federal Food Drug & Cosmetic Law—Administrative Reports 1907-1949,* 368 (1951). In 1926, the Bureau reported,

(Footnote continued on next page.)

(Footnote 239 continued.)

"The enactment and the enforcement of the Federal and State food legislation has restored the confidence of the public in the purity and wholesomeness of the food supply of the Nation." Cited at 635.

[240] See 1931 *Report of the Food and Drug Administration 5,* Dunbar, *Federal Food Drug & Cosmetic Law—Administrative Reports 1907-1949,* 743 (1951) and footnote 239 above.

[241] The proposed revision of the 1906 Food and Drugs Act was introduced on June 12, 1933, and enacted on June 25, 1938. See Dunn, *Federal Food, Drug and Cosmetic Act 29-30,* 1015 (1938). Although the public was apparently complacent in 1926, by 1930 there was evidence of renewed public interest in the measures taken by the government to insure wholesome, pure, and honest food. See *Annual Reports of Food and Drug Administration for 1926,* at 19, and 1930, at 2 reprinted at Dunbar, cited at footnote 239 at 635 and 714. Consumers' groups thought the new law was not tough enough and urged Roosevelt to veto it. See Young, "The Government and the Consumer: Evolution of Food and Drug Laws—The 1938 Food, Drug and Cosmetic Act," 13 *Journal of Public Law* 197, 203 (1964).

[242] 49 Stat. 1526 (1936), 15 USC § 13 (1958).

[243] Both the FDA and the muckrakers sought a revision of the 1906 Food and Drugs Act. The muckrakers were represented in large part by an organization called Consumers Research and this organization's suggestions were considered even by FDA as "too extreme to be practicable." Young, cited at footnote 241 at 200.

[244] These standards appear to be (1) a familiar recognizable food, (2) the natural composition of a natural food, (3) label statements and (4) possibly the standards set by secondary meaning of a food. See Text Part II and footnote 84. However, these standards are not set forth in the statute or any regulations and, if the author's interpretation of "food" in § 402(b) and the *Bireley's* case, is correct, other standards could also be used provided they were reasonably definite and precise. See Part II.

[245] See Text Part III. This is the most vital defect in the current law.

[246] Compare *United States v. Fabro, Inc.,* 206 F. Supp. 523 (M.D. Ga. 1962) (holding that the label cannot set the standard in an economic adulteration case) with *United States v. Food Products Labs., Inc.,* 6 Kleinfeld 123 (W.D. Mo. 1963) (holding the contrary). Or compare *United States v. 716 Cases of Del Comida Brand Tomatoes,* 179 F. 2d 174 (10th Cir. 1950) (holding proper labeling is not a defense to an economic adulteration charge under § 402 (b)(2)) with *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141, 144 (S.D. Ohio 1952) (which cites the "generally recognized rule that labeling is such a defense.") Or, compare *United States v. 716 Cases of Del Comida Brand Tomatoes* and *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,* 93 F. Supp. 764 (S.D. Iowa 1950) (which seem to accept standards of quality and identity as conclusive proof of the standard in economic adulteration cases) with *United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955) (holding that such standards are totally irrelevant).

[247] See *Van Liew v. United States,* 321 F. 2d 664 (5th Cir. 1963); *United States v. Fabro, Inc.,* 206 F. Supp. 523 (M.D. Ga. 1962); *United States v. Cudahy Packing Co.,* 4 Kleinfeld 138 (D. Neb. 1955); *United States v. Midfield Packers,* 3 Kleinfeld 157 (W.D. Wash. 1952); *United States v. 70 Gross Bottles of Quenchies,* 3 Kleinfeld 141 (S.D. Ohio 1952); *cf. United States v. 88 Cases of Bireley's Orange Beverage,* 187 F. 2d 967 (3d Cir.), *cert. denied,* 342 U. S. 861 (1951).

[248] See *United States v. Food Products Labs., Inc.,* 6 Kleinfeld 123 (W.D. Mo. 1963) wherein relative (or puffery) statements furnished the standard against which the food was judged.

[249] In another context, Judge Friendly has advanced the thesis that the success of the administrative process is dependent upon the development of more definite standards. See Friendly, "The Federal Administrative Agencies: The Need For Better Definition of Standards," 75 *Harvard Law Review* 863 (1962). Judge Friendly suggests that precise standards are necessary to require like treatment under like circumstances; to permit security of business transactions; to make the standards for administrative action known and therefore amenable to change; to maintain the independence of administrative agencies from improper lobbying and political influences; and to inform and educate the staff of the administrative agency. Cited at 878-82. Therefore, even if the Federal Food, Drug & Cosmetic Act only provided for civil penalties, the vagueness of the present statute, unclarified by interpretative regulations, would still be highly undesirable.

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION (Act of October 23, 1962; Section 4369, Title 39, United States Code)

1. Date of filing: Oct. 1, 1966. 2. Title of publication: Food Drug Cosmetic Law Journal. 3. Frequency of issue: Weekly. 4. Location of known office of publication: 4025 W. Peterson Ave., Chicago, Cook, Illinois 60646. 5. Location of the headquarters or general business offices of the publishers: Chicago, Illinois 60646.

6. Names and addresses of publisher, editor, and managing editor: publisher: Commerce Clearing House, Inc., Chicago, Ill. 60646; editor: Henry L. Stewart, Chicago, Ill. 60646; managing editor: George H. Harris, Chicago, Ill. 60646.

7. Owner: Commerce Clearing House, Inc., Chicago, Illinois 60646. Names and addresses of stockholders owning or holding 1 percent or more of total amount of stock: C. T. Corporation System, Wilmington, Delaware; The Corporation Trust Company, (Del.), Wilmington, Delaware; The Corporation Trust Company, (N. J.), Jersey City, New Jersey; The Corporation Trust Company, (N. Y.), New York, New York; Eddy & Company, New York, New York; Egger & Co., New York, New York; Hurley & Company, New York, New York; Kelly & Co., New York, New York; The Millbrook Tribute Garden, Inc., Millbrook, New York; Reing & Company, New York, New York; Justus L. Schlichting, Toms River, New Jersey; Stuart & Company, New York, New York; Bertha Palmer Thorne, Bar Harbor, Maine; George T. Whalen, as Trustee under the will of Oakleigh Thorne, Millbrook, New York. 8. Known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages or other securities: None.

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D. Free distribution (*including samples*) by mail, carrier or other means	21	21
E. Total distribution (*Sum of C and D*)	1,007	1,010
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I certify that the statements made by me above are correct and complete:

(Signed) Henry L. Stewart

Prescription or Ethical Drugs: Fallacies as to Warranties, Failure to Warn, and Strict Liability in Tort

By WARREN FREEDMAN

Mr. Freedman Is a New York Attorney.

BY DEFINITION, A PRESCRIPTION OR ETHICAL DRUG IS a product which is purchased and used pursuant to prescription of a licensed physician.[1] Under Section 503 (b) of the Federal Food, Drug and Cosmetic Act a drug which is "habit-forming,"[2] or which "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug," is a prescription drug which can only be dispensed upon a written prescription.[3] It is definitely not a consumer product, nor is it intended to be sold "over the counter" to a consumer, except to that particular person who is the patient of a particular doctor who has given the patient a specific written prescription for his use of that particular drug.[4] The

[1] In contrast to the prescription or ethical drug is the proprietary or patent drug which is sold *over the counter.* Under Section 201 (g) of the Federal Food Drug and Cosmetic Act the term "drug" includes *both* prescription and proprietary drugs.

[2] See Section 502 (d) for list of habit-forming drugs which can be dispensed on prescription only. Their habit-forming derivatives are listed in regulations, 21 CFR 165.1.

[3] 52 Stat. 1050 (1938), 21 U. S. C. § 353 (b).

[4] Dispensing a prescription drug without a written prescription of a practitioner licensed by law to administer such a drug is an act which results in the drug being "misbranded" while held for sale and subjects the product to seizure under Section 304 (a). Sale of the drug *without* prescription, if done after shipment in interstate commerce, is also prohibited by Section 301 (k) and subjects the responsible person to criminal penalties and to an injunction suit.

manufacturer of the ethical or prescription drug (as well as statutory law in all jurisdictions) does not intend that the product should fall into the hands of the consumer. This drug is a "physicians' product,"[5] in the same sense as a scalpel, an electro-cardiogram, a hypodermic needle, or, in fact, any other "tool" of the medical profession purchased from the manufacturer for use by the doctor in the practice of medicine.

Prescription drug advertisements which are found only in medical and trade journals (as opposed to consumer magazines) are expressly regulated by the Food and Drug Administration (FDA) under Section 502 (n) of the Federal Food, Drug and Cosmetic Act. The established name of the prescription drug must be included in the advertisements and other descriptive printed matter; it must be printed prominently and in type at least half as large as that used for trade or brand name. The formula of the prescription drug must also be included in all advertisements and other descriptive printed matter.[6] Such drugs must bear "the directions for use and cautionary statements, if any, contained in such prescription" by the terms of Section 503 (b) (2). Furthermore, prescription drugs under Section 503 (b) (4) must be labeled: "Caution: Federal law prohibits dispensing without prescription." In addition, such prescription drugs must bear name and address of dispenser, serial number and date of prescription or of its filling, name of prescribing physician, and name of patient.[7] The label must also contain the quantity of active ingredients.[8]

Accordingly, it is submitted that the rules of products liability law generally applicable to consumer products cannot be made and indeed are *not* applicable to prescription or ethical drugs which are

[5] The Federal Food Drug and Cosmetic Act under Section 503 (b) stresses the responsibility of the physician for dispensing prescription drugs. There have been innumerable criminal convictions of physicians for selling prescription drugs *without* prescription. In *Brown v. United States* [250 F. 2d 745, CA 5, 1958] the physician was found not to have prepared or given any prescription, had not physically examined either of the recipients of the drugs, had not questioned them or prescribed a dosage, nor otherwise attempted to acquaint himself with either the physical condition or medical needs of the recipients. The Court found that the doctor-patient relationship did not exist.

Also, see *Cox v. Laws*, 244 Miss. 696, 145 So. 2d 703 [1962] to the effect that the sale of the drug without prescription was in violation of the Act.

[6] Detailed FDA regulations over the ethical drug industry have resulted from the sweeping changes made by the Kefauver-Harris Drug Amendments of 1962 [76 Stat. 780, 21 U. S. C. §§ 301-92, Supp. IV, 1963].

[7] Section 503 (b) (2).

[8] Section 502 (e).

sui generis.[9] However, the one common ingredient of the lawsuit against the product manufacturer of either the consumer product or the prescription or ethical drug, whether the action sounds in negligence or in breach of warranty, is proof of a specific defect in the product.[10]

Warranty

In *Magee v. Wyeth Laboratories, Inc.*[11] the California District Court of Appeals tersely stated the principle of warranty law applicable to prescription drugs: "A person not reasonably expected to *use* the manufacturer's drug (or product) is not one to whom the warranty runs . . ." Judge Ashburn delineated "use" by ruling that "the contemplated *use* was that of administration to a patient by or under the direction of a physician and by no other persons and in no other manner." Therefore, one who is passively enjoying the benefit of the product as in the case of a passenger in an airplane or automobile is *not* a "user" in this sense of the term as applicable to the prescription drug. The doctor's patient does not "use" the prescription drug because the patient is administered the drug by his physician, and he has not, *by personal choice,* selected the drug for his use. Representations in labeling of the product (or in the medical literature) made by the manufacturer are directed solely to the medical profession. The product manufacturer does not actually, nor even by implication, make known to a patient the purpose for which the prescription drug is to be used. No product warranty is therefore intended by the manufacturer to run in favor of a patient.

Promotion of the ethical drug product does not involve any advertising to the public, which factor the New Jersey Appellate Division in

[9] Ethical or prescription drugs, once conceived by the manufacturer, involve the expediture of vast sums of money for research and development. Before marketing these drugs are subjected to vigorous testing procedures including (a) synthesis by chemists; (b) screening tests by pharmacologists; (c) laboratory tests upon animals or human tissue in vitro to determine toxicity and therapeutics as well as human dosages and tolerances; (d) clinical tests on humans to establish values of absorption, elimination, and toxicity; (e) tests in hospitals and other institutions on the efficacy of the drug in patients suffering from a specific disease or illness, emphasis being placed upon side effects and contra-indications; and (f) field tests by physicians in private practice. See generally Paul D. Rheingold, "Products Liability-The Ethical Drug Manufacturer's Liability," 20 FOOD DRUG COSMETIC LAW JOURNAL 328, 372 (June, July 1965).

[10] See Warren Freedman "Defect in the Product: The Necessary Basis for Products Liability in Tort and in Warranty" in Winter 1966, *Tennessee Law Review.* Also, 79 A. L. R. 2d 335.

[11] 214 Cal. App. 2d 361, 29 Cal. Rptr. 322 (1963).

Kaspirowitz v. Schering Corporation[12] opined "casts doubt on the very existence of an implied warranty of merchantability running from the defendant (manufacturer) to the plaintiff (patient)." In fact, the patient, under most circumstances, is not even aware of the identity of the particular drug-product which is administered by his physician. A manufacturer's warranty, whether express or implied, can only exist in favor of a person when it has been made with that person in mind. In the *Kaspirowitz* case, where no warranty was held to exist in favor of the user of a prescription drug, the Court specifically found "no such inducement by the defendant manufacturer . . . (which) motivated plaintiff's purchase and use of Sebizon." A prescription drug, by definition, does not imply any invitation by the manufacturer for the patient to use the product, except under a doctor's direction. A prescription drug cannot reasonably be expected to be used by a patient without a doctor's prescription.

The overwhelming majority of courts have steadfastly refused to consider the treating physician as the *agent* of the patient in receiving such warranties or representations concerning the product.[13] The medical profession cannot accept any interpretation of law holding the doctor to be a mere agent of the patient. The physician is a trained, independent contractor; he is not an agent of any patient, nor is he a principal answerable by an agent. Obviously, in the doctor-patient relationship there is no opportunity for affirmation of fact by a product manufacturer to a patient with respect to a prescription drug, which the doctor must prescribe for the patient. There can be no affirmation of fact tending to induce *sale* of the product insofar as the patient is concerned.[14] Accordingly, there is no logical nor legal basis for a warranty, whether express or implied, to run from the manufacturer in favor of the patient.[15]

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[12] 70 N. J. Super. 397, 175 A. 2d 658 (1961).

[13] See *Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154, 169 N. W. 541 (1918); *Krom v. Sharp & Dohme Inc.*, 7 AD 2d 761, 180 N. Y. S. 2d 99 (1958); and *Marcus v. Specific Pharmaceuticals, Inc.*, 191 Misc. 285, 77 N. Y. S. 2d 508 (1948).

[14] The pharmacist dispensing a prescription drug has been held not liable for breach of warranty, *McLeod v. W. S. Merrell Co.*, 167 So. 2d 901 [Fla. 1964]. The Florida appellate court relied upon *Whitely v. Webb's City*, 55 So. 2d 730 (1951): "In the case at bar we are concerned with a drug product sold on doctor's prescription. It could not be sold until approved by the pure food and drug administration in compliance with Federal Law. None of these conditions are negatived by the declaration, and being so, even if the doctrine of implied warranty was applicable, to apply it in this case would go far beyond the doctrine in *Sencer v. Carl's Markets, Inc.*" [55 So. 2d at 732].

[15] Furthermore, proof of *defect* in the product is essential to a cause of action in warranty. In the *Magee* case,

(Footnote continued on next page.)

Another essential element of a cause of action for warranty is reliance upon that warranty by the person seeking recovery for breach of that warranty.[16] Since a patient has no voluntary part in the selection or the use of the drug, the patient has no opportunity for reliance upon any warranty. (The patient may not even know the identity of the product until after injury has occurred!) In *Oppenheimer v. Sterling Drug, Inc.*[17] the Ohio Court of Appeals affirmed judgment in favor of the product manufacturer of a prescription medicine which allegedly caused a skin disorder to the plaintiff. The Court found no "breach of warranty, either express or implied, as to this plaintiff," because

> The record fails to disclose any *reliance* by the plaintiff upon anything published or said by the defendant . . . (T)he record is completely silent as to any *reliance* upon the part of the plaintiff . . .

The Court also emphasized that there was no "affirmation of fact by the seller as to a product or commodity to induce the purchase thereof. . . ." Interestingly, the Ohio Court also found "nothing to indicate that the doctor *relied* upon any information furnished by the defendant in prescribing Aralen for his patient. . . . It can hardly be said that he *relied* upon anything produced by the defendant or found in the general literature." Accordingly, without the opportunity to rely upon the warranty, no reliance can, in fact, exist.[18]

(Footnote 15 continued.)
see footnote 11, the California court's instruction to the jury on the drug "Sparine" precluded any verdict that the drug was defective: "There is no evidence in the record from which it can be inferred that Sparine was not reasonably fit for human consumption or that the injections received . . . . were not up to Sparine standard."

[16] See 79 A. L. R. 2d 333: "In accordance with well-settled rules of the law of implied warranties, there can be no recovery against such a seller on the ground of breach of implied warranty of fitness where the buyer has not relied upon the seller's skill or judgment; there can be no recovery against such a seller for breach of an implied warranty of fitness where the drug or medicine was bought under its patent or trade name; and there can be no recovery against such a seller on the ground of breach of the implied warranty of merchantability which accompanies goods bought by prescription where it does not appear that the drug or medicine in question was actually bought by prescription."

[17] Ohio Court of Appeals, Franklin County, December 29, 1964.

[18] It has even been urged that doctors themselves do *not* rely upon the manufacturer's product data. In the February 1966 issue of *Journal of Marketing Research,* the authors Raymond A. Bauer and Lawrence H. Wortzel, in their article entitled "Doctor's Choice, The Physician, and His Sources of Information about Drugs," indicate that today's physician is neither the helpless dupe of a drug company nor a man of science who keeps totally aloof from trade journal advertising: —"The doctor uses all sources of information on drugs—but he is discriminating." The more serious an illness, the less likely is the treating doctor to trust commercial sources alone for his drug product information.

Warranty arises out of the *sale* of a product, and in the case of the prescription drug, there can be no sale of the product to the patient. The initial sale of the ethical drug to the distributor or retailer is not sufficient to create a warranty in favor of the patient. The patient is not an agent of these vendees nor is he in privity with them. Furthermore, the manufacturer does not intend that the product be freely sold over the counter to a patient. Warranty cannot arise from the "service"[19] of the treating physician during which "service" a prescription drug chosen by the doctor is administered to the patient. A physician cannot be considered an agent of the patient so as to bridge the gap and give rise to warranty in favor of the patient.[20] In *Ravetz v. Upjohn Co.*[21] the federal court in Pennsylvania expressly found that the plaintiff-patients were not protected by warranties under the Uniform Sales Act because they were not "buyers" within the meaning of that Act[22] since they received the injections from the doctor who had purchased the penicillin from the defendant.

Warranty also demands proof that the product is "defective". Official Comment "i" to the *Restatement of Torts Second,* Section 402A examines the question of "defect" in the product by defining "unreasonably dangerous" as "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases . . . (the product) with the ordinary knowledge common to the community as to its characteristics." [See *Jakubowski v. Minnesota M. & M. Co.*,[23] which reversed the lower court because the product was *not* unreasonably dangerous for its intended use.] Thus, a product which is "unreasonably dangerous" is deemed to be defective without further proof of "defect." Admittedly, such proof is difficult, for a product manufacturer simply does not knowingly market a product that can

[19] See *Perlmutter v. Beth David Hospital,* 308 N. Y. 100, 123 N. E. 2d 792 (1954), and *Sloneker v. St. Joseph's Hospital,* 233 F. Supp. 105 [D. C. Colo. 1964]. Also note *Koenig v. Milwaukee Blood Center, Inc.,* 23 Wis. 2d 324, 127 N. W. 2d 50 (1964); *Dibblee v. Groves,* 12 Utah 2d 241, 364 P. 2d 1085 (1961); *Merck & Co. v. Kidd,* 242 F. 2d 592 [CA 6, 1957]; and *Gile v. Kennewick Public Hospital District,* 48 Wash. 2d 774, 296 P. 2d 662 (1956).

[20] See *Krom v. Sharp & Dohme Inc.,* footnote 13: —"It does not follow from the *Perlmutter* decision that the transaction which the court refused to recognize as a "sale" renders the doctor an "agent" as to his patients. None of the ordinary elements of agency are present here. The patient, who allegedly would be the principal, had no right of control as to the result or the means to be used. *Currie v. International Magazine Co.,* 256 N. Y. 106, 175 N. E. 530; *Delisa v. Arthur F. Schmidt, Inc.,* 285 N. Y. 314, 34 N. E. 2d 336."

[21] 138 F. Supp. 66 [DCED Pa., 1955].

[22] Note also that Section 2-103 (a) of the Uniform Commercial Code defines "buyer" as a person who buys or contracts to buy goods.

[23] 42 N. J. 177, 199 A. 2d 826 (1964).

truthfully be characterized as "unreasonably dangerous." In *Dalton v. Pioneer Sand & Gravel Co.*[24] plaintiffs claimed damages for burns received from handling cement, but the court opined that the product was not defective because the product was indeed not unreasonably dangerous but was reasonably suitable for the purpose for which it was produced. The New Jersey Supreme Court in the *Jakubowski* case[25] directed that proof of a defect must be shown by "direct evidence," and reminded bench and bar that "the necessity for such proof is implicit in the opinion of this Court in *Henningsen v. Bloomfield Motors, Inc.*"[26] Comment "i" of the *Restatement* also points out that "many products cannot possibly be made safe for all consumption," citing the fact that any product necessarily involves some risk of harm, that is, a food or drug "from over-consumption," or even sugar which is "a deadly poison to diabetics." These products are not "unreasonably dangerous," and hence are not defective. In *Hopkins v. E. I. duPont de Nemours & Co.*,[27] the court ruled that "the dynamite was not defective," although plaintiff was killed when a charge was detonated in a borehole by heat from drilling. Similarly, cigarette lighter fluid was held to be a product in common use and not "inherently dangerous," *Traynor v. United Whelan Stores Corp.*[28] No reported case has been found in which a prescription drug was termed "unreasonably dangerous."

The prescription or ethical drug must also be viewed from the viewpoint of "unavoidably unsafe products" (Official Comment "k" to *Restatement of Torts Second,* Section 402A), as delineated hereinafter under "Failure to Warn."

Failure to Warn

Since by definition a prescription drug is not intended for sale to a consumer nor intended for use by a consumer without a doctor's prescription, any warning in the labeling of the product or in the medical literature cannot become the basis for an action in negligence for failure to warn by the patient against the drug manufacturer.[29] Factually, the warning is intended only for the medical profession, not for the patient nor for any consumer. In the *Magee* case[30] Judge Ashburn concluded that a "reasonable warning in the case of a drug

[24] 37 Wash. 2d 946, 227 P. 2d 173 (1951).

[25] See footnote 23.

[26] 32 N. J. 358, 161 A. 2d 69 (1960).

[27] 212 F. 2d 623 (CA 3, 1954).

[28] 274 A. D. 800, 79 N. Y. S. 2d 329 (1948).

[29] See generally *Ball v. Mallinkrodt Chemical Works,* 381 S. W. 2d 563 (Tenn. 1964).

[30] See footnote 11.

which is manufactured for use of doctors and distributed primarily to them and for their use" cannot be judged adequate or inadequate by the patient. The California court expressly found that the pharmaceutical manufacturer did not owe a duty to warn the patient directly. In *76 A. L. R. 2d 25* (cited by Judge Ashburn) the applicability of a prescription drug manufacturer's negligence in failing to warn is limited to "his immediate vendee," to wit, the physician. Indeed, "there can be no recovery on such basis by one other than the immediate vendee where adequate warning was given the immediate vendee." In *Harper v. Remington Arms Co.*[31] the New York court delineated the duty to warn:

> In selling these shells exclusively to arms manufacturers or dealers in shells, the defendant's liability ceased at the time of yielding control of these shells to the vendee ..... The plaintiff was not a person to whom the defendant could contemplate these shells would pass, and the defendant owed no duty to anyone other than those whom it expected rightfully and properly to use these shells (to wit, the arms manufacturer or dealer in shells).[32]

Duty devolves upon the manufacturer to warn physicians of all known dangers in the administration of the prescription or ethical drug. Such duty to warn raises a question of fact as to adequacy only in terms of reference to the immediate vendee or treating physician.[33] In *Love v. Wolf*[34] the California court spelled out the duty of the product manufacturer "to warn the doctor who prescribes the drug. This would be the only effective means by which a warning could help the patient." Any effort by a product manufacturer to warn patients is, ipso facto, futile, unreasonable, and veritably impossible. No such warning to the public is necessary, as stated in *Stottlemire v. Cawood;*[35] U. S. District Court Judge Holtzoff directed a verdict in favor of the prescription drug manufacturer who had fulfilled its obligation by warning the physicians against possible dangers from the use of the product. Since Chloromycetin is a prescription drug, Judge Holtzoff ruled that Parke, Davis Co. had neither a duty, nor an opportunity to warn the public:

> As to Parke, Davis Company, the claim against it is predicated on the contention that it failed to warn the public generally of alleged dangerous characteristics of this drug. It must be borne in mind that this was a pre-

[31] 156 Misc. 53, 280 N. Y. S. 862; 248 A. D. 713, 290 N. Y. S. 130; and 272 N. Y. 675 ( ).

[32] To the same effect, *Pedroli v. Russell,* 157 Cal. App. 2d 281, 320 P. 2d 873 (1958).

[33] On adequacy of warning generally, see *Gielskie v. State,* 10 A. D. 2d 471, 200 N. Y. S. 2d 691 (1960); *Webb v. Sandoz Chemical Works,* 85 Ga. App. 405, 69 S. E. 2d 689 (1952); and *Carmen v. Eli Lilly & Co.,* 109 Ind. App. 76, 32 N. E. 2d 729 (1941).

[34] 226 Cal. App. 2d 378, 38 Cal. Rptr. 378 (1964).

[35] 213 F. Supp. 897 (D. D. C. 1963).

scription drug. It could not be obtained by anyone except on a doctor's prescription, presented at a drugstore. Consequently, there was no reason why there should be a warning of any dangerous possibilities given to the general public. This was held in *Parker v. State,* 201 Misc. 416, 105 N. Y. S. 2d 735, 741.

Judge Ashburn, in the *Magee* case[36] cited *Holmes v. Ashford,*[37] an English case holding that the manufacturer of a hair dye was *not* liable to one injured when the dye had been applied to her hair by a beauty parlor operator to whom the manufacturer had sold the hair dye; the hair dye manufacturer had enclosed instructions warning the beauty parlor operator of the necessity of the requisite preliminary patch or skin test for hypersensitivity. Accordingly, the English court held that the product manufacturer had given a warning which was

> sufficient to intimate to the beauty parlor operator the potential dangers of the substance with which he was going to deal, and that is all that can be expected; and *it would be unreasonable and impossible to expect that they should give warning in such form that it must come to the knowledge of the particular customer who is going to be treated.* (Italics added.)

The analogy of the patron of the licensed beauty salon to the patient of the licensed physician indeed rings true! The physician (like the beautician) is not a mere *conduit* for the distribution of the product, but is a professional "administrator" or user of the product. He has an independent duty to evaluate the risks and to exercise professional discretion and professional judgment.[38] In the *Stottlemire* case[39] the federal court specifically refuted the patient's contention that the manufacturer was negligent in not warning the public of Chloromycetin's dangerous characteristics: "There was no reason why there should be a warning . . . . given to the general public." In *Marcus v. Specific Pharmaceuticals, Inc.*[40] the New York Court specifically indicated that there was no duty to warn the public so long as the manufacturer had given adequate warning to the medical profession. The court regarded the doctor as the only proper defendant in the case.[41]

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[36] See footnote 11.

[37] 2 All Eng. 76 [C. A. 1950].

[38] See *Kapp v. E. I. du Pont de Nemours & Co.,* 57 F. Supp. 32 [D. C. Mich. 1944]; *Willey v. Fryogas Co.,* 363 Mo. 406, 251 S. W. 2d 635 (1952); and *Stout v. Madden,* 208 Ore. 294, 300 P. 2d 461 (1965).

[39] See footnote 35.

[40] 191 Misc. 285, 77 N. Y. S. 2d 508 (1948).

[41] See *Marcus* case, footnote 40, at p. 287: "It made no representation to plaintiff, nor did it hold out its product to plaintiff as having any properties whatsoever. To physicians it did make representations . . . . The sole claim is not misrepresentation or even concealment, but a negligent failure to give adequate information, and in some instances a failure to use adequate means to call attention to the information given. It may be safely conceded that these allegations would be sufficient if the product were sold to the public generally as a drug for which no physician's prescription was neces-

(Footnote continued on next page.)

Indeed, medical ethics as well as medical practice dictate that the physician exercise independent judgment over the choice and the administration of the particular ethical drug, unaffected by the manufacturer's control.[42] The patient, even if he were given the highly technical information and warnings associated with the use of the drug, would not be competent to make an evaluation; due to his lack of knowledge the patient might conceivably object to the use of the drug and thereby jeopardize his life! From a practical point of view no drug manufacturer could be certain that he could reach the patient by labeling and by advertisements.[43] The California District Court of Appeal in *Love v. Wolf*[44] restated the principle for prescription drugs:

> If adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.

To give the patient the benefit of a cause of action in negligence for failure to warn (when the manufacturer's duty to warn runs only to the physician) there must be some overriding consideration which does not obviously exist.[45] Granted that the injured patient may have a cause of action against the doctor for malpractice, and that the doctor may have a cause of action against the product manufacturer for failure to warn—nevertheless, the injured patient does not have a cause of action against the manufacturer for failure

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(Footnote 41 continued.)
sary. The situation alleged is materially different. There is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer. Nor is there any reason to expect that if a doctor did choose to rely on the information given by the manufacturer he would prescribe without knowing what that information was. In the absence of any such grounds for belief there would be no negligence."

It should also be noted that the physician takes control over the drug-product, and may himself be negligent in the selection and in the administration of the ethical drug to his patient.

[42] The Ohio Court of Appeals in *Oppenheimer v. Sterling Drug, Inc.*, footnote 17, specifically held that the patient's physician should have known through the manufacturer's literature and the "Physicians' Desk Reference" that the drug sometimes caused visual disturbances calling for withdrawal or reduction of dosage of the drug.

[43] Druggists commonly repack prescription drugs in their own packaging and destroy or cover over the original label.

[44] See footnote 34.

[45] Whether the doctor has a duty to warn the patient about the possible dangers of the drug product has been answered by *Mitchell v. Robinson*, 334 S. W. 2d 11, motion for rehearing denied 360 S. W. 2d 673 (1960). The Missouri Supreme Court ruled at page 19 that "the doctors owed their patient in possession of his faculties the duty to inform him generally of the possible serious collateral hazards" of insulin treatment.

to warn. All parties can be joined in the single lawsuit but the issues must be properly separated; of course, the injured patient would always have a *direct* cause of action against the product manufacturer for negligence in manufacture of the product, that is, an adulterated, contaminated or defective product.[46]

Strict Liability in Tort

Recent decisions under the jurisdiction of the Texas Court of Civil Appeals[47] and the Oregon Supreme Court[48] point up the fact that prescription drug manufacturers are not liable to patients or users simply upon proof of injury. Indeed, there is not a single appellate court case imposing Strict Liability in Tort upon the manufacturer of a prescription drug where the drug was not adulterated, contaminated, or defective. In *Love v. Wolf*[49] the Court opined:

> No rule of strict liability (whether expressed in terms of breach of an implied warranty or in terms of a breach of a duty of care in tort) has been applied to a failure adequately to warn of the dangers inherent in the use of the drug.

Simply because the prescription drug product may have caused injury does not make it legally defective, nor bring into sway the doctrine of Strict Liability in Tort. Furthermore, it has been widely accepted

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[46] Under Section 402 A of the *Restatement of Torts Second,* a product is not "in a defective condition" if proper or adequate warning is given. The seller may reasonably assume that the warning will be read and heeded; indeed, "a product bearing such a warning which is safe for use if the warning is heeded is not in a defective condition, nor is it unreasonably dangerous" [Comment "j" thereunder]. Obvious or patent dangers, as well as unknown or latent risks from the use of the product, do not require warnings; hence, absence of warning in such instances does not make the product defective. See *Love v. Wolf,* footnote 34, specifically holding that failure to adequately warn of the known side effects of the drug did not make the product "defective." Comment "j" of the *Restatement* also points out "the seller may reasonably assume that those with common allergies . . . . will be aware of them, and he is not required to warn against them."

Radium paint just 50 years ago was not recognized as likely to cause poisoning; and in *LaPorte v. U. S. Radium Corp.,* 13 F. Supp. 263 [DCNJ 1935] it was held that no warning on the product could *then* have been given, and hence the product was not defective. On the other hand, fifty odd years later in 1966, provided that the dangers or potentialities of danger in the use of a product are generally known and recognized, "the seller is not required to warn" [Comment "j"].

[47] *Cudmore v. Richardson-Merrell, Inc.,* —Tex. App. —, 398 S. W. 2d 640 (December 17, 1965). Chief Judge Dixon ruled that the manufacturer "should be liable on the grounds of implied warranty for injurious results only when such results . . . ought reasonably to have been foreseen by a person of ordinary care in an appreciable number of persons in light of attending circumstances." (Rehearing denied Jan. 28, 1966.)

[48] *Cochran v. Brooke,* — Ore. —, 409 P. 2d 904 (1966).

[49] See footnote 34.

that Contributory Negligence of the claimant is a valid defense to Strict Liability in Tort; most recently the New Jersey Supreme Court opined:

> Where a plaintiff acts or fails to act as a reasonably prudent man in connection with use of a warranted product *or one which comes into his hands under circumstances imposing strict liability on the maker or vendor or lessor,* and such conduct proximately contributes to his injury, he cannot recover.[50] (Italics added.)

The authoritative *Restatement (Second) Torts*, Section 402A, "Special Liability of Seller of Product for Physical Harm to User

[50] *Maiorino v. Weco Products Co.*, 45 N. J. 570, 214 A. 2d 18 (1965). Here the plaintiff allegedly suffered a lacerated left wrist while undertaking to open a glass container in which a new toothbrush was packaged. Plaintiff's sister had purchased the product almost three years before the date suit was commenced, although plaintiff had endeavored to use the product approximately two weeks after date of purchase. The retailer was sued for breach of implied warranties and negligence in the handling and sale of the product; the manufacturer was sued for breach of warranties and for negligence in packaging the toothbrush. After trial the jury returned a no cause of action as to the retailer on warranty and as to the manufacturer of both issues of negligence and warranty. The New Jersey Supreme Court refused to disturb the verdict which was based upon submission to the jury of the issue of plaintiff's contributory negligence on the warranty cause of action. According to the Court: "The question whether contributory negligence may be utilized as a defense in breach of warranty cases is no longer open. We concluded recently in *Cintrone v. Hertz Truck Leasing, etc.*, 45 N. J. 434, 457-459 (1965), that such defense may be raised and if established, it constitutes a bar to plaintiff's recovery . . . The defensive concept has been expressed at times in terms of assumption of risk, that a party cannot recover for a loss that he could have averted by the exercise of due care, and by contributory negligence. See *Dallison v. Sears, Roebuck & Co.*, 313 F. 2d 343 [6 Cir. 1962]; *Barefield v. La Salle Coca Cola Bottling Co.*, 370 Mich. 1, 120 N. W. 2d 786 (1963); *Gardiner v. Coca Cola Bottling Company of Minnesota*, 267 Minn. 505, 127 N. W. 2d 557 (1964); *Nelson v. Anderson*, 245 Minn. 445, 72 N. W. 2d 861 (1955); *Fredendall v. Abraham & Straus*, 279 N. Y. 146, 18 N. E. 2d 11 (1938); *Natale v. Pepsi-Cola Co.*, 7 App. Div. 2d 282, 182 N. Y. S. 2d 404 (1959); *Razey v. J. B. Colt Co.*, 106 App. Div. 103, 94 N. Y. Supp. 59 (1905); *Nationwide Mutual Ins. Co. v. Don Allen Chevrolet Co.*, 253 N. C. 243, 116 S. E. 2d 708 (1960). When considering the problem of effect of plaintiff's own conduct we became convinced that in the concept of liability in warranty or strict liability cases there is nothing to justify holding the defendant responsible for the consequences of plaintiff's own proximate contributory carelessness. If such carelessness cannot be separated from the consequences of defendant's breach of warranty or breach of the duty which gives rise to strict liability, in justice plaintiff cannot be permitted to recover for his personal injury and sequential damages . . . . A manufacturer or seller is entitled to expect a normal use of his product. The reach of the doctrine of strict liability in tort in favor of the consumer should not be extended so as to negate that expectation."

In an exchange of letters with the author, dated March 22 and March 30, 1966, Professor Fleming James, Jr. stated: "As for the plaintiff's conduct, I agree that this too may be an important consideration under the rule of strict liability . . . ."

or Consumer," described by its official reporter as one of "the most radical and spectacular developments in tort law during this century" specifically conditions liability upon the finding of a *defect*[51] in the product:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user . . . is subject to liability for physical harm thereby caused to the ultimate user . . . .

Official Comment "k" entitled "Unavoidably Unsafe Products," which is an explanation dealing with prescription or ethical drug products, reveals the drafters' (and implicitly the courts') recognition of the invaluable service performed by the manufacturers of prescription and ethical drugs, and the need for special rules with reference to such products:

> k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of the lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable danger.

The "unavoidably unsafe product" is illustrated by the blood transfusion, during which homologous serum hepatitis may appear. It is admittedly impossible to detect or prevent the disease (despite the most careful selection of blood donors), and the disease is commonly accepted as an inherent risk of all blood transfusions.[52] No court

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[51] See generally Warren Freedman, "Defect in the Product: The Necessary Basis for Products Liability in Tort and in Warranty", in the Winter 1966 issue of *Tennessee Law Review.*

[52] Should a product involve *unexpected dangers* in its use, such as the cancer-producing possibilities from smoking tobacco, the product is not "defective." In 1966, despite abundant public discussion and statistical knowledge of carcinogenic effects, the cigarette is still not a "defective" product because the danger is expected, although in *Ross v. Philip Morris Co.*, 328 F. 2d 3 [C. A. 8, 1964], the manufacturer was deemed not to be an insurer

(Footnote continued on next page.)

has seen fit to attach liability to the "unavoidably unsafe product," or to the impure blood which is but part of the "service" of the blood transfusion. The Arizona Supreme Court in *Whitehurst v. The American National Red Cross*[53] affirmed summary judgment in favor of the defendant blood supplier; having supplied the market with "an apparently useful and desirable product,"[54] the manufacturer of the prescription or ethical drug is liable only for an "unreasonably dangerous defective condition" of his product.[55] [See discussion hereinbefore under "Warranty".]

The above *Restatement* view was recently relied upon by the Supreme Court of Oregon in *Cochran v. Brooke*[56] a case in which plaintiff became blind after using the prescriptive drug, Aralen (chloroquine), which is widely used in combating the effects of arthritis. While this ethical drug was known to have some adverse effect upon the vision, the extreme reaction suffered by the plaintiff was extremely uncommon. There was no evidence that the drug was impure, adulterated, or not reasonably fit to combat arthritis.[57] The trial court accordingly directed a verdict in favor of both the defendant doctor and the manufacturer on all issues of negligence (including manufacturer's failure to warn) and breach of warranty. The Supreme Court of Oregon affirmed, and set forth in its opinion the full text of *Restatement (Second) Torts* Section 402A, and Official Comment "k" thereto. The Court concluded:

(Footnote 52 continued.)

against the unknowable risk because the alleged harmful effects of cigarettes could not have been avoided by any developed skill or foresight. In *Lartigue v. R. J. Reynolds Tobacco Co.*, 317 F. 2d 19 [C. A. 5, 1963] the court opined that liability existed "only for a defective condition not contemplated by the consumer, the harmful consequences of which, based on the state of human knowledge, are foreseeable." See also *Laporte v. U. S. Radium Corp.*, footnote 46, wherein the manufacturer of radium paint was held not liable for radium poisoning contracted by the plaintiff, because science and medicine in 1917-1920 was not aware of the danger and had not devised means to protect against it for several years after plaintiff's cause of action arose.

[53] — Ariz. —, 402 P. 2d 584 (1965).

[54] Comment "k" of the *Restatement (Second) Torts.*

[55] Contrast the prescription drug with the defectively-made surgical instrument which scars the patient. Recovery against hospital was affirmed in *South Highlands Infirmary v. Camp*, 180 So. 2d 904 (Ala. 1965).

[56] See footnote 48.

[57] In *Greenman v. Yuba Power Products Inc.*, 59 Cal. 2d 57, 27 Cal. Rptr. 697, 377 P. 2d 897 (1963) the highest California court adopted the standard of Strict Liability in Tort, but required the plaintiff to prove that the product had "a defect that causes injury to a human being." Here the lathe was allegedly not built with a proper fastening device. Such a defect, it is submitted, would be synonymous with or characterize the product "in a defective condition" under Section 402 A of the *Restatement (Second) Torts.*

> The far reaching consequences that may ensue if we were to take so bold a step as to impose the absolute liability suggested by plaintiff are beyond the ability of a court to know or comprehend. It is, indeed, easy for compassion to dictate an absolute liability against the makers of a product that can cause blindness. But once the liability is imposed, it could not be judicially limited only to cases involving disastrous consequences.

In the *Cudmore* case,[58] dealing with the prescription drug MER-29 which plaintiff claimed caused cataracts in his eyes, the Texas Court of Civil Appeals refused to charge the manufacturer "with the burden of absolute liability—the liability of an insurer." Chief Justice Roger J. Traynor of the California Supreme Court has succinctly stated the principle: "It should be clear that the manufacturer is not an insurer for all injuries caused by his product."[59]

An allergic reaction of a susceptible patient to a prescription or ethical drug does not make that drug product "defective."[60] *Comment "h"* to Section 402A of the *Restatement of Torts Second* explicitly states that "a product is not in a defective condition when it is safe for *normal* . . . consumption." Illustrations under *Comment "j"* recommend that the seller warn if the product contains an ingredient to which a substantial or appreciable number of the population is allergic, and if the ingredient is one whose danger is not known or if known is one which the user would reasonably expect to find in the product. The Connecticut Supreme Court of Errors at its October Term 1965 in *Corneliuson v. Arthur Drug Stores, Inc.*[61] squarely placed the burden of proof upon the user not only to demonstrate that the particular product "as compounded, had a tendency to affect injuriously an appreciable number of people," but also that the product was, in fact, defective:

> The basic test (of defectiveness) must be applied to the particular product as compounded, which necessarily includes any incorporated substance or ingredient in the strength and quantity used in the particular product, not in the strength and quantity which such substances or ingredients may be used in some other products.

Indeed, there can be nothing wrong with the product that produces an allergic response in a patient predisposed to it by virtue of his idiosyncrasy or peculiar constitution.[62] The defect is not in the

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[58] See footnote 47.

[59] 32 *Tennessee Law Review* 363, 366 (Spring 1965).

[60] See *Kaspirowitz v. Schering Corp.*, 70 N. J. Super. 397, 175 A. 2d 658 (1961).

[61] The highest Connecticut court herein set aside the verdict and judgment for the plaintiff, and then ordered a new trial.

[62] See Freedman *On Allergy and Products Liability* (1961).

product but in the patient whose personal susceptibility to that product at that time and place initiated the allergic response.[63]

Foreseeability is properly an element in the law of Strict Liability. Where the pure and unadulterated prescription drug allegedly caused a reaction, and the state of medical knowledge was such that at the time of the injury the manufacturer in the exercise of ordinary care could not have anticipated such a reaction, the manufacturer cannot be liable to the patient.[64] The California court in *Magee v. Wyeth Labs. Inc.*[65] summarized:

> In the ordinary case the maker may also assume a normal user, and is not liable where the injury is due to some allergy or other personal idiosyncrasy of the consumer found only in an insignificant percentage of the population . . . . The manufacturer's duty is "to reasonably guard against probabilities, not possibilities . . . ."

The rationale behind imposition of Strict Liability in Tort is the unjustifiable belief that it will produce greater care on the part of the ethical drug manufacturer. The extremely high standard of care maintained by the industry has resulted from rigid governmental supervision, fierce competition within the industry, and from the strict scientific and medical standards necessarily self-imposed by the manufacturers. To burden the ethical or prescription drug manufacturer with "products compensation"[66] would produce no appreciable

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[63] After wearing defendant's dyed rubber boots for less than three days, the plaintiff miner alleged that his feet became irritated and infected. Suit was brought upon negligence in manufacture and upon warranty (the demurrer to which was sustained), and the jury found for the plaintiff. The Montana Supreme Court in *Jangula v. U. S. Rubber Co.* on September 30, 1965, reversed and remanded upon failure of plaintiff to prove that the product was "defective." Medical evidence suggested that the condition could have been due to a fungus infection. Plaintiff's own dermatologist could not pinpoint the cause of the condition; nor could he prove the allergic dermatitis "without additional patch tests of the various ingredients used in the manufacture of the boots." According to the Court, this dermatologist opined that "there is nothing based on a reasonable medical certainty, to which you can point your finger as a specific chemical ingredient which caused this man's condition."

[64] See *Cudmore* case, footnote 47. Also, Warren Freedman, "A Hatband and a Tube of Lipstick: The New Jersey Minority Rule on Allergic Responses," 21 Food Drug Cosmetic Law Journal 293 (May 1966); and Warren Freedman, "Allergy and Products Liability Today," 24 *Ohio State Law Journal* 479 (1963).

[65] See footnote 30.

[66] Professors Robert Keeton and Jeffrey O'Connell in their book, *Basic Protection for the Traffic Victim* (1965) have outlined a basic protection plan permitting recovery by motorists for their own personal injuries *without proof of fault.* Such a scheme, *if applied to products liability* would require every person to carry his own insurance policy which would pay all of his own out-of-pocket costs up to $10,000—in event of injury sustained by use of a

(Footnote continued on next page.)

increase in efficacy, nor reduce the number of product complaints. On the contrary, it may well serve as an impediment to the continued development and marketing of beneficial, life-saving prescription or ethical drugs. By casting the prescription drug manufacturer in the role of an insurer, there is the risk that these manufacturers will assume the posture of an insurance carrier guided more by self-compensating theories of "risk of loss" rather than by continued, dedicated service to the public interest. The "risk-spreading" argument simply means that the patient is to be the "insurer" as the cost of injury will be borne ultimately by the patient in the form of higher prices for that product and for other beneficial, life-saving drugs of the same manufacturer. The "risk-spreading" mechanism also overlooks the vulnerable position of the small manufacturer who can be priced out of the market by strict liability.

Conclusion

The prescription or ethical drug is indeed *sui generis*, having few, if any, of the characteristics of the consumer product. Special rules on warranty, failure to warn, and strict liability in tort are called for, which rules must take into consideration the special characteristics of the prescription or drug product. A properly prepared and marked product with a proper warning to physicians should satisfy the legal obligation of the prescription or ethical drug manufacturer. **[The End]**

(Footnote 66 continued.)
product. These costs would include hospital and medical bills, if any, as well as 90% of lost wages, if any, and these sums would be paid out as they actually occurred rather than in a lump sum after settlement. Regardless of whether the product was at fault, the injured person would receive immediate insurance benefits from his own policy rather than from the product manufacturer's policy. Under this scheme the insurance carriers should accumulate necessary funds to provide immediate benefits because all persons would be required by law to carry insurance and hence contribute premiums, and because all damage suits involving less than $10,000 would be eliminated. All claims based upon pain or suffering unless they exceed $5,000 are outlawed. Also, see Warren Freedman, "Products Compensation: Who's Pushing Whom?" in November 1964 *The Business Lawyer* 167-171.

The Scientists' Forum

Food Additives

By BERNARD L. OSER

Dr. Oser, This Magazine's Scientific Editor, Prepared This Article from Excerpts Found in Recent Issues of the Magazine *Chemical and Engineering News.*

Introduction

CHEMICAL AND ENGINEERING NEWS, a weekly publication of the American Chemical Society, recently published a feature article on Food Additives under the authorship of Howard J. Sanders, an associate editor. The article appears in two parts in the issues of October 10 and 17, respectively. It is the most comprehensive survey of developments in this field since the enactment of the Food Additives Amendment of 1958 and is the result of considerable research and many interviews.

Part 1 treats the subject from a rather broad perspective and deals with the need for and use of food additives, the growth of sales of these substances, the impact of the Food Additives Amendment on the producers and users of food additives, public concern over the safety of these compounds, and industry's efforts to educate the public on the value of additives.

Part 2 is concerned with the various categories of food additives and certain specific ones, largely from a technological standpoint.

Except for the concluding paragraphs, the following excerpts are from Part 1 and are published here with the kind permission of the editors of *Chemical and Engineering News.* Reprints of the entire two-part feature article are available from the Reprint Department, American Chemical Society Publication, 1155 16th Street, N. W., Washington, D. C. 20036 at the price of 75 cents each.

Excerpts

Increased Demand for Food Additives

In recent years, the demand for food additives has been steadily climbing. According to estimates by Arthur D. Little, Inc., the use of additives in foods made in the U. S. has risen from 419 million pounds in 1955 to 661 million pounds in 1965—a gain of 58% in 10 years. Looking to the future, ADL estimates that the use of food additives will climb to 852 million pounds in 1970 and to 1.03 billion pounds in 1975.

On a dollar basis, the value at the manufacturers' level of additives used in foods made in the U. S. has increased from $172 million in 1955 to $285 million in 1965—a gain of 66%. By 1970, these sales are expected to reach about $400 million and by 1975 are likely to exceed $500 million.

Fifteen or 20 years ago, . . ., many chemical companies supplying the food industry were content merely to fill orders, with no overwhelming enthusiasm, for chemicals that the food companies happened to need and had been using for years—acids, alkalies, gums, bleaching agents, colors, and so on. Often these were chemicals used in much larger quantities by other industries. The food industry, therefore, was "just another incidental customer."

Now, more and more chemical companies are eagerly going out of their way to develop chemicals specifically designed to meet the specialized needs of the food industry. More and more chemical firms are working closely with food companies to help solve the intricate scientific and technical problems involved in developing new foods.

Reasons for Courting the Food Industry

Chemical companies have many compelling reasons for assiduously courting the food industry:

- The food industry is the largest industry in the U. S.
- Sales of the food industry are growing. Retail food sales have climbed from about $40 billion in 1950 to an anticipated $80 billion in 1966. This has come about partly because of the nation's expanding population and rising standard of living.
- The food industry is continually introducing new products—products that generally place a high demand on food additives.
- Sales of convenience foods, which use especially large amounts of additives, have been sharply increasing.
- In the past few years, a sharp increase has occurred in the sales of low-calorie foods.

• The public is becoming increasingly interested in more sophisticated foods, more flavorful foods, more exotic foods.

• Foods are being shipped greater distances and are being stored for greater lengths of time.

• The food industry is becoming more technically knowledgeable. More food companies are willing to experiment with radically new food formulations. More are willing to try out not only new uses for traditional food additives but also compounds that are totally new.

• Industry experts agree that the years ahead will see rapidly expanding use of food substitutes—simulated meats, simulated orange juice, simulated coffee, and many others.

Pointing to the huge benefits made possible by convenience foods, Dr. Emil M. Mrak, chancellor of the University of California, Davis, says, "Convenience foods have literally disenslaved the housewife. They have permitted her to serve with ease a diversity of nutritious foods of consistent high quality. . . . These great advances have been brought about through the work of chemists, their development of new processes, and the safe use of chemicals."

Food Additive Defined

Recognizing the broad scope of the term "food additive," the Food Protection Committee of the National Academy of Sciences-National Research Council several years ago came up with an all-encompassing definition. "A food additive," the committee said, "is a substance or a mixture of substances, other than a basic foodstuff, which is present in food as a result of any aspect of production, processing, storage, or packaging." Clearly, this definition, which will serve as our definition of "food additive" in this report, includes both intentional and nonintentional additives.

In this report, however, the emphasis will be primarily on intentional food additives.

The Food Additives Amendment of 1958

By far the most significant development in the food additives field in the past decade was the enactment on Sept. 6, 1958, of the Food Additives Amendment to the Federal Food, Drug and Cosmetic Act of 1938. This amendment, which took effect on March 6, 1960, completely altered the Government's method of regulating the use of additives in foods.

The law provided, for the first time, that no additive could be used in foods unless the Food and Drug Administration, after a care-

ful review of the test data, agreed that the compound was safe at the intended levels of use. An exception was made for all additives that, because of years of widespread use in foods, were "generally recognized as safe" (GRAS) by experts in the field.

In the case of most GRAS substances, the Food and Drug Administration has not established tolerance levels. In other words, it has not specified the maximum allowable concentration of the additive in each type of food. FDA merely requires that the additive be of appropriate food grade, that the user follow good manufacturing practice, and that he use the least amount needed to accomplish the intended result.

The Food Additives Amendment not only requires that an intentional additive be safe in its intended use but implies that it must also perform its intended function. The manufacturer must submit to FDA the data indicating the minimum amount of an antioxidant, for example, actually needed to retard oxidation, so that the tolerance, if any, may be set no higher than necessary. Under the law, FDA is not required to pass judgment on whether the function served by the additive is, in fact, desirable. This judgment is left to the market place.

As of June 30, 1966, about 2430 food additives (not including GRAS substances) were subject to FDA regulations under the Food Additives Amendment. This figure compares to about 2400 additives subject to regulations as of June 30, 1965, and 1540 additives as of June 30, 1964. The sizable increase of about 860 between fiscal 1964 and 1965 was caused mainly by the large number of synthetic and natural flavors that were finally granted official clearance.

Much of the early apprehension and criticism of the Food Additives Amendment has long since vanished. The most frequently heard comment today about FDA's handling of the law is that it has been "entirely reasonable." Many companies praise FDA for its "able handling of a difficult set of regulations."

Although plenty of paper work is involved in getting FDA approval of new compounds and although long, frustrating delays sometimes occur, applications for new additives normally do not get "hopelessly bogged down." FDA does not have any deliberate inclination to ban the use of new additives because this is the "easier and safer" alternative. The compositions of secret formulations do not have to be revealed. Because the cost of food additives generally represents only a tiny fraction of the total cost of food products, the increase

in food cost brought about by greater testing of these additives has been almost negligible.

The Food Additives Amendment kicked the fuzzy, unscientific, and largely unworkable poison per se doctrine out the window. By setting up a system of additive tolerances, the amendment gave formal recognition to the fact that a potentially hazardous substance can be used safely if the level of intake is low enough. This level, of course, depends both on the concentration of the substance in a food and the amount of the food consumed.

The concept that, under specified conditions, potentially hazardous substances can be used safely was also fully recognized in the Color Additive Amendments of 1960. These amendments established a system of tolerances not only for synthetic colors (as in the previous law) but for natural colors as well.

A system of tolerances was likewise established under the 1954 Miller Pesticide Amendment, which covers pesticide residues on fresh fruit, vegetables, and other raw agricultural crops.

A major virtue of the 1954, 1958, and 1960 amendments was that they provided necessary operating guidelines. For the first time, producers and users of food additives had formal procedures for determining in advance what was acceptable to the Government and what was not.

Effects of the Amendment

The Food Additives Amendment has had far-reaching effects on chemical companies serving the food industry, as well as on the food industry itself. Compared to the situation before the amendment, the law has:

- Lengthened the time required to develop new food additives.
- Increased the cost of developing new additives.
- Reduced the number of available food additives.
- Tended in many cases to change the types of compounds that companies are investigating as possible new food additives.
- Tended virtually to eliminate some companies as developers of new food additives.
- Forced some companies to abandon their research on various additives—not because the compounds were ineffective or were known to be unsafe but because the cost involved in obtaining FDA approval would have been prohibitive.

Lengthy Testing

Although the amendment has unquestionably increased the time necessary to develop a new food additive, it is difficult, if not impossible, to make reliable estimates of exactly how much.

Now, FDA usually requires that a new additive undergo at least a two-year feeding test in two species of animals (one a rodent and one a nonrodent). Actually, the amount of testing demanded by FDA is highly variable and depends on the additive and its proposed use. In the case of some compounds, FDA has asked for feeding studies of as long as seven years or in as many as four different species of animals. The trend in recent years has been for FDA to require longer testing in more species of animals before it is convinced of the safety of a new additive. And in some cases, it also requires testing in humans.

The problem of long test periods in determining the safety of food additives may not be insurmountable, however. Scientists are working on methods to reduce markedly the time it takes to determine the safety of food chemicals with laboratory animals. Hopefully, in the future, it may be possible to find out in six months what may now take two years or more. Also, the results might be obtained with fewer animals and at lower cost.

Some companies are now submitting to FDA the data from such intensified studies in their petitions for approval of new food additives. However, these data are still not being accepted by FDA in place of information from conventional long-term animal tests. The reason, FDA explains, is that the reliability and predictive value of such intensified, short-term studies have not yet been adequately determined.

Cost of Research

For the same reasons that the amendment-caused increase in research time required to develop a new food additive is so difficult to measure, it is also difficult or impossible to determine accurately the increase in research cost. Needless to say, the cost has gone up.

Today, a two-year feeding study in rats and dogs (including metabolism, reproduction, and other studies) may cost $100,000 or more. When cancer studies in two or more species of animals are also required, the total cost may exceed $300,000.

Actually, the cost of safety testing is only one part of the total cost of developing a new additive. There is, of course, the cost of working out methods for synthesizing the compound in the laboratory and in the plant. There are the costs of proving the commercial use-

fulness of the additive and of developing precise methods for analyzing for the additive and its degradation products in foods. The cost of developing suitable analytical methods—methods that are often nowhere to be found in the scientific literature—may actually be as great as that of determining the safety of the compound. In addition, there is the cost of legal work involved in getting FDA approval, the cost of additional testing often required by FDA, and other expenses, sometimes wholly unanticipated, that never existed prior to the amendment.

Reduced Number of Additives

Because of the Food Additives Amendment, the number of available intentional food additives has decreased by about 15% since 1960. In general, the additives no longer on the market are those that previously found only limited use or were inferior to available compounds. Thus, the effort to get them approved would scarcely have been justified. The manufacturers simply let these compounds fall by the wayside.

The amendment has had a particular effect in reducing the number of additives that may enter foods inadvertently. This is especially true of chemicals used in packaging materials—chemicals that, before the amendment, had in many cases undergone relatively little testing and were largely unregulated by the Government. Although the Food Additives Amendment was designed primarily to control intentional additives, it has probably had an even greater impact on the nonintentional compounds.

Suddenly, companies selling paper, plastics, or other packaging materials to the food industry had to be sure that the waxes, resins, colors, sizing agents, slimicides, defoamers, and other chemicals they used would be safe if any of these materials migrated into foods.

New Emphasis in Research

In many chemical companies, the Food Additives Amendment has tended to shift the emphasis in food additive research. A marked trend has developed to investigate compounds that are already present naturally in foods or are chemically related to such compounds.

Understandably, FDA is much more stringent in its safety-testing requirements in the case of synthetic compounds that are totally new.

This trend toward research on naturally occurring materials is particularly evident in the flavoring field. It is hopelessly uneconomic for a flavoring manufacturer to spend hundreds of thousands of dollars to get FDA approval of a unique synthetic flavoring material if

he is only going to sell 100 pounds of it a year—which is not at all uncommon in this field where a little goes a long way. Companies, therefore, have developed renewed interest in flavor components present naturally in foods.

Another major impact of the Food Additives Amendment is that it has tended to discourage research on additives that are not significantly better than compounds already on the market. There is not much point in spending vast sums of money in safety testing an additive if it is just a me-too item that, at best, may capture only a small percentage of the total market. The cold, harsh reality of the situation is forcing many chemical companies to examine much more thoroughly than ever the sales potential of new additives before they take the plunge in a costly safety-testing program.

Because of the increased cost of getting new additives on the market, the small company with limited financial resources is largely ruled out today as a developer of new food chemicals. The cost is just too massive a financial burden. Some small companies are hoping to solve this problem, however, by pooling their resources and developing new compounds jointly.

An inevitable question: Has the Food Additives Amendment tended, in general, to discourage research on new food additives? The inescapable answer: Yes, it has—to an extent. Certainly, the amendment has not dangerously stifled research. Today, experimentation on new food additives is moving ahead at a reasonably rapid pace. Admittedly, this research is more selective—with the result that when a new compound does come on the market it is more likely to be a significant advance.

Cancer Clause

Ever since the Food Additives Amendment came into existence in 1958, a swirling controversy has centered on its so-called cancer clause.

This clause, often called the Delaney clause, is probably the most hotly controversial section of the entire Food Additives Amendment. Supporters of this provision argue that, since we know so little about cancer and how it is produced by chemicals, we cannot take the risk of adding any amount of a known carcinogen to the food supply.

Supporters of the cancer clause also emphasize that, although some people claim that certain specified low levels of carcinogens are harmless, this has never been proved.

Opponents of the cancer clause are convinced that threshold levels of carcinogenic activity do exist and that safe levels can be determined.

Many scientists are sharply critical of the idea that a chemical can be banned if it produces cancer when given in any amount. Even table salt and glucose, they assert, can induce cancer in animals if injected in huge doses. The law, they believe, should be changed to read that a compound cannot be approved "if found to induce cancer when ingested by man or animal *in amounts and under conditions reasonably related to its intended use.*" The present cancer provision, many scientists bitterly complain, prohibits "the proper exercise of scientific judgment."

Meanwhile, the debate rages on. While some people at FDA may grumble privately about the "scientific irrationality" of the cancer clause, they can do nothing about it. Their hands are tied by the law.

The likelihood that the law will be changed in the foreseeable future to allow the setting of tolerances for carcinogens in foods is virtually nonexistent. As of now, no Congressman in his right mind is likely to endorse the removal or modification of the cancer clause and thus face the accusations of wildly indignant voters that "he came out in favor of cancer." However, some observers say that, in time, as more becomes known about the causes of cancer, this controversial provision will be eliminated—just as the poison per se doctrine was abandoned in 1958.

Zero Tolerances

Also intensely controversial has been the concept of zero tolerance. In the past, the Government has said that, in the case of some compounds, no amount may be present in foods.

Under the provisions of the 1954 Pesticide Amendment, certain pesticides can only be used on certain crops if they leave absolutely no residue.

As scientists patiently attempt to explain, no analytical method can prove that zero amount of a material is present. All that a method can show is that, in certain cases, nothing is detectable. And even though nothing is detectable, some very low concentration of the material may, of course, still be present.

The problem of zero tolerances has become especially acute as scientists develop more sensitive methods of analysis. With the ad-

vent of gas chromatography, thin-layer chromatography, atomic absorption spectrophotometry, and other refined techniques, scientists can now measure materials in extremely low concentrations.

Hence, what yesterday might have been a nondetectable, perfectly acceptable level may today be readily measurable and a clear-cut violation of the law.

Surveying the problem, a special *ad hoc* committee of the National Academy of Sciences-National Research Council in 1965 concluded that zero tolerances (established by the Food and Drug Administration) and no-residue registrations (established by the Department of Agriculture) were "scientifically and administratively untenable and should be abandoned." The Government now, in part, agrees.

In April, the Government announced that, in place of zero tolerances, the Food and Drug Administration, wherever possible, will set finite, negligible-residue tolerances for pesticides—chemical by chemical, use by use. In addition, all no-residue registrations will be cancelled on Dec. 31, 1967, unless extensions are granted because studies are still in progress to determine safe tolerances.

What this means is that the Department of Agriculture will no longer accept applications for the registering of pesticides on the old no-residue basis. Moreover, all pesticides used on food crops will be subject to finite tolerances authorized by FDA. At last, the control of pesticides on foods will be placed on a sounder scientific footing.

Worried About Additives

How many people in the U. S. actually believe that chemicals in foods are a severe threat to their health is difficult to determine. No large-scale polls have ever been taken. One government official, as a rough guess, estimates that the group seriously worried about food additives and militantly opposed to their use constitutes no more than 5% of the total adult population. "It includes," he says, "not only the victims of absurd rumors and hearsay but also members of the inevitable lunatic fringe."

Many observers in the food additives field and the food industry hasten to point out that the number of people gravely concerned about "poisons in our foods" is on the decline. Confidence in the food supply is growing, they say, because of increasing public recognition that the Government, through FDA and the Department of Agriculture, is making a concerted effort to guard the safety of American foods.

The public, by and large, not only has confidence in the Government's supervision of the food supply but in the vigorous supervision exercised by food companies themselves.

Some companies have been deeply concerned—if not inordinately sensitive—about the public's possibly negative reaction to various chemical names on food labels. For years, some food manufacturers hesitated to use fumaric acid in their products on the grounds that the name would conjure up images of fuming sulfuric acid and other hideously corrosive materials.

Informing the People

Part of the credit for the growing public awareness of the value of food additives goes to a variety of companies, government agencies, and private organizations. In recent years, these groups have been making special efforts to inform the public about the importance of additives. Monsanto, Pfizer, Dow, Du Pont, Union Carbide, and other chemical firms have used their company magazines and other publications to tell the factual story of food additives.

Food Chemicals Codex

Although as yet few members of the general public are even remotely aware of its existence, the Food Chemicals Codex should also help to increase public confidence in food additives. The Codex, which first began appearing in loose-leaf installments in December 1963, is a compilation of quality standards for approved food additives. It sets standards of purity for food chemicals and specifies methods for identifying and determining the purity of these compounds. It also gives information on the physical properties of these compounds, methods of packaging and storing them, and other details.

The status of the Food Chemicals Codex received a major boost on July 1, when Dr. James L. Goddard, Commissioner of the Food and Drug Administration, wrote the director of the Codex, "I am pleased to endorse the specifications in this Food Chemicals Codex prescribing minimum requirements of purity for an appropriate grade of food chemicals for intentional and purposeful use in food for man. The FDA will regard the specifications in the Food Chemicals Codex as defining an 'appropriate food grade' within the meaning . . . of the food additive regulations . . ."

The published standards are sure to increase the purity of many commercial food-grade chemicals.

Technical Level in the Food Industry

A source of keen frustration to food additive producers is what they regard as the relatively low level of scientific skill in many food companies—particularly the smaller ones.

However, the food industry's spending on R&D is far below that of the chemical industry. Compared to the $135 million spent on R&D by the food and kindred products industry in 1964, the chemical and allied products industry spent $1.28 billion. These figures represent only 0.4% of net sales in the food and kindred products industry in 1964, compared to 4.2% of net sales in the chemical and allied products industry.

Because of the relatively low R&D expenditures in the food field, chemical firms serving the food industry are obliged to do a major share of the research and development on food additives.

Chemical firms complain that, all too often, food companies will not even give a cursory look at a new additive unless it has already received FDA clearance. On the other hand, a chemical company does not really know for sure whether its product has an adequate market and is worth spending vast sums of money on to get FDA approval unless food companies express sufficient interest in it. Trapped in this dilemma, chemical producers are forced to do a great deal of use testing and market research on their own.

(Part 2 of this survey is devoted to a review of various classes of food additives and of certain individual agents (including radiation) from the standpoint of their functional properties and uses. The article concludes with a section entitled "New Additives Wanted," from which the following is excerpted.—*Ed.*)

New Additives Wanted

Despite the vast array of food additives already available, these compounds do not satisfy all the requirements of the food industry. Asked to pinpoint some of the major unmet needs for food additives, chemical companies and food companies gave these examples:

- Nonnutritive sweeteners that have properties more nearly like those of sugar. Especially needed are compounds with no objectionable aftertaste.

- Additives that enhance the flavor of fruits, cereals, and other high-carbohydrate foods to the extent that monosodium glutamate improves the flavor of high-protein foods.

• More potent antioxidants, including those that are soluble in both water and oil.

• Better additives to improve the rewetting properties, texture, and flavor of freeze-dried foods.

• A single preservative that completely destroys molds, yeasts, and microorganisms and is still safe for use in foods.

• A wider range of synthetic food colors, particularly red, orange, and yellow dyes.

• Better antistaling compounds for bread. About 10 to 15% of the bread now made is returned to bakers because of staling.

• Flavoring agents to make commercial breads taste more like homemade bread. Flavorings to make instant coffee taste more like freshly brewed coffee. Flavorings to give low-fat foods the appealing taste normally imparted by fats. Flavorings that duplicate the taste of high-quality beef (what one industry man wryly describes as "rich, mouth-watering beef chloride").

• Additives to give longer shelf life to draft beer.

• Additives to accelerate the aging of wines, such as Burgundy and claret, and to prevent the deterioration of wines, such as Rhine wine and Moselle, in closed bottles.

Says Dr. George F. Stewart, director of the Food Protection and Toxicology Center at the University of California, Davis, "Chemistry has helped us to develop food products in many ways superior to those available naturally. In the years ahead, the use of chemicals in food processing will continue to be one of our most powerful and useful tools in giving consumers the foods they want and need."

[The End]

THE FAIR PACKAGING AND LABELING ACT SIGNED BY PRESIDENT JOHNSON

President Johnson signed the Fair Packaging and Labeling Act into law on November 3, 1966. The Act provides requirements with respect to the packaging and labeling of foods, drugs, devices and cosmetics. Section 4 of the Act contains information that must be stated on the labels of consumer products after July 1, 1967. Section 5 provides discretionary provisions which authorize the administering agencies to proceed on a product-by-product basis, upon a determination that there is a need, to regulate standards for describing packages as "small," "medium," and "large," price reduction promotions, disclosure of ingredients of nonfoods, and nonfunctional slack-fill in packaging. The new law also provides for the development of voluntary package size standards by industry.

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