VOL. 25, NO. 5 MAY 1970

Food Drug Cosmetic Law JOURNAL

New Foods and the Imitation Provisions of the Food, Drug, and Cosmetic Act

. . . . . WILLIAM F. CODY

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

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.

May, 1970
Volume 25 • Number 5

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

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . May, 1970

VOLUME 25 NUMBER 5

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Twenty-Fifth Annual Meeting of the Food, Drug and Cosmetic Law Section of the New York State Bar Association.—The following article is the final paper presented at this meeting, which was held on January 27, 1970, at the New York Hilton Hotel.

"New Foods and the Imitation Provisions of the Food, Drug, and Cosmetic Act" is by *William F. Cody*, who is associated with CPC International. Mr. Cody discusses the food industry's efforts to ameliorate the dietary problems of obesity and coronary heart disease in the context of the Food, Drug, and Cosmetic Act, and the regulatory philosophy and activity of the Food and Drug Administration. His hypothesis is that the food industry has made significant efforts in these two areas, but that FDA policies have delayed, and indeed harassed, these efforts. Mr. Cody's article begins on page 220.

1969 Meeting of the Food, Drug and Cosmetic Division of the Corporate, Banking and Business Law Section of the A. B. A.—The following three papers were presented at this meeting of the American Bar Association, which was held in Dallas, Texas, on August 13, 1969.

In "The Trial of an Injunction Suit," *George M. Burditt* discusses some of the experiences encountered in the trial of a suit for an injunction under Section 302 of the Federal Food, Drug, and Cosmetic Act. Mr. Burditt reveals the remedies sought by FDA in an injunction suit, pretrial procedures and problems, and suggests activities for the defendant and the defense attorney to follow from the point at which suit is initiated, through compliance with the findings and conclusions of the court. Mr. Burditt is a Partner in the law firm of Burditt and Calkins, and a member of the Illinois Bar. His paper begins on page 238.

In "Plaintiff's Fault as a Defense to Strict Liability," *William J. Condon* examines the effect of an injured consumer's conduct upon the application of strict liability to a defectively manufactured product. His review of several varieties of product liability cases leads him to believe that clear conclusions can be reached in some instances, but that many questions of strict liability are left unanswered. The author does conclude, however, that while strict liability is liability without negligence, it is not liability without fault, and the fault of the plaintiff, however it may be described, which contributes to the result, will be a bar to recovery. Mr. Condon, whose article begins on page 246, is an attorney with Condon and McMurray.

In an article entitled "Fault in Marketing—As an Element of a Manufacturer's Strict Liability," *William P. Woods* inquires into the legal responsibility, under the strict liability theory, of the manufacturer who has designed his product properly and has produced it as intended, to one who is harmed by reason of his use of that product. The author's aim is to learn the precedents relating to strict liability as formulated by judicial pronouncements. Mr. Woods, whose article begins on page 254, is a member of the New York State Bar Association.

Vol. 25, No. 5 May, 1970

Food·Drug·Cosmetic Law
Journal

New Foods and the Imitation Provisions of the Food, Drug, and Cosmetic Act

By WILLIAM F. CODY

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UNTIL FAIRLY RECENT YEARS, general discussions of the American diet have usually led to the flowery conclusion that Americans are the best nourished people in the world. The government regulatory attitude, to the same effect, is exemplified by the Food and Drug Administration's (FDA's) roseate pronouncement that "vitamins and minerals are supplied in abundant amounts by commonly available foods"[1]—implying strongly that all are, and will continue to be, well nourished by the fare that Grandmother used to lay on. Our efforts to develop low-cost, innovative food products have, by and large, been pointed at markets outside the U. S.—the fish flour project being an example. In brief, the conventional wisdom has been that the traditional meat, potatoes and vegetable diet is entirely satisfactory for our population from both qualitative and quantitative aspects.

[1] 21 CFR 80.1(f) (Dietary Supplements and Vitamin and Mineral Fortified Foods), 31 FR 15730 ff., December 14, 1966 (effectiveness stayed pending hearing).

Quite recently, however, it has been pointed out that the United States does have shortcomings in its diet. Overweight has been referred to as one of the leading health problems; usually, its origins are dietary. Coronary heart disease is another substantial national health problem, with significant dietary implications. Most recently, the White House Commission on Food and Nutrition has focused national attention on the fact that many of our people are hungry and even malnourished in the medical sense.[2]

Hypothesis

Taking obesity and coronary heart disease as examples, I would like to discuss the food industry's efforts to ameliorate these dietary problems in the context of the Food, Drug, and Cosmetic Act[3] and the regulatory philosophy and activity of the Food and Drug Administration. My hypothesis is that the food industry has made significant efforts in these two areas, but that FDA policies have delayed, and indeed harassed these efforts. I believe that these two examples typify the statutory and regulatory problems which we have encountered, and will encounter in approaching the new problems of an American diet for the last third of the twentieth century.[4]

Certainly, overweight can be largely eliminated through dietary adjustments—for example, reduction of total calorie intake. Most medical authorities also agree that dietary adjustments—reduction of the intake of saturated fats, the type of fat which favors an increase in the serum cholesterol level—will improve one's chances of avoiding, or surviving, a heart attack. Presented this way, these two problems appear to be simple to solve: quantitative adjustment of the diet in the case of overweight, and qualitative adjustment in the case of coronary disease. However, the solutions are not really that simple. It is extremely difficult for the average man to change his dietary patterns to an extent which will accomplish significant results in either of these two areas. The preferred approach—perhaps the only

[2] White House Conference on Food, Nutrition and Health. Final Report dated December 24, 1969 (see, for example, Reports of Panels III-1, III-2, V-3 and VI-A3).

[3] 21 USC 301 and following.

[4] Although the two examples relate to specific dietary problems associated with illness, I believe that the considerations are the same in respect of "synthetic" versions of basic foodstuffs which may solve the actual hunger problems that are being disclosed by such studies as the White House Conference on Food and Nutrition. For example, for such "new foods" to achieve widespread use, they will probably have to simulate traditional foodstuffs, and will certainly require informative labeling, rather than such pejorative, non-informative nomenclature as the "imitation" hallmark.

workable approach—is to provide palatable modifications of the high-calorie, high-saturated-fat foods; these special foods should look, smell and taste like the traditional food—but should be reformulated so as to reduce or eliminate the objectionable characteristics. Smoking presents somewhat of an analogy in a comparable public health problem. The simple solution is to stop smoking; however, the only really effective approach (at least with the present generation of smokers) may be to develop a safe cigarette. If one may enhance his long-term health prospects without disruption of established patterns of behavior, he is more likely to do so.

Accordingly, the food industry has introduced a number of food products which are modified, technologically and nutritionally, to correct dietary problems without significant changes in established dietary patterns. I have selected, for discussion, two of these products —one directed to the obesity problem, and the other to the coronary heart disease problem. The first example is one of the traditionally high calorie foods, margarine, for which we now have a number of highly palatable lower-calorie versions which are produced by using about forty percent of vegetable oil rather than the traditional eighty percent. A second example is one of the perennial problem foods in the cholesterol-heart disease area—the egg. It is possible to produce a dehydrated egg which has been processed or adjusted to remove or minimize saturated fat and cholesterol, without reducing any important nutritive value, or organoleptic characteristics, of the egg. There are numerous other innovative food products which could be mentioned in connection with these, and other, dietary problems; however, the two examples I have referred to are, I think, fairly typical in relation to legal problems.

I will not go any further into the medical need[5] for such products or their availability as a matter of food technology. Accepting these two premises, one may proceed to the regulatory problems encountered with such food products.

The "Imitation" Provisions

The basic regulatory problem these products have encountered is the "imitation" provisions of the Act—Section 403(c) and Section 403(g). These sections provide, respectively, that a food which is

[5] See, for example, "Improvement of Nutritive Quality of Foods" (Joint Statement of AMA Council on Foods and Nutrition and the Food and Nutrition Board of NAS-NRC) *Journal of the American Medical Association,* Sept. 16, 1968, pp. 160 and following.

an "imitation" of another food product is misbranded unless prominently designated "imitation" on its label, and that a food which purports to be, or is represented as, a food which has been standardized, is misbranded if it does not comply with the standard.[6]

I will not attempt a general dissertation on imitation food products under the Act; there have been many papers published on the subject.[7] I do wish to make one historical observation that is germane to the points I propose to make with respect to the two special purpose foods to which I have referred. The practices which justified the 1906 Act provision regarding imitations, and which called for the 1938 Act's amendment of those provisions, were primarily in the area referred to as "economic adulteration"—the manufacture of a cheaper, inferior version of a traditional food product for no other reason than to reduce costs, and the judicial pronouncements regarding 403(c) and 403(g) are in accord.[8] Not all of such practices were as baldly nefarious as watered milk; for example, the low-fruit jam-type products which gave rise to the landmark *Imitation Jam* decision were, according to the record in that case, often sold to the consumer at prices reflecting the ingredient cost savings.[9] However, the principal consideration underlying the evolution of this legislation has been the belief, shared by Congress, the administrative agencies and the courts, that such products, with valuable ingredients reduced or omitted for the sole purpose of reducing costs, have an inherent capacity to deceive or mislead. This was the reasoning of the Supreme Court in

[6] These two products are also affected by the provisions of the Act, and the regulations, relating to foods for special dietary use. (21 USC 343(j); 21 CFR § 125). However, those matters are currently the subject of a public hearing which is beyond the scope of any brief discussion (or perhaps any intelligible discussion whatsoever). Therefore, the scope of this paper is limited to the "imitation" problem, which has presented, in itself, a substantial legal impediment to sensible nutrition.

[7] See, for example, Markel, "The Law on Imitation Foods," 5 FOOD DRUG COSMETIC LAW QUARTERLY 145 (April, 1950); Williams, "The *Jam* Decision, An Analysis," 6 FOOD DRUG COSMETIC LAW QUARTERLY 327 (May, 1951); Austern, "Ordinary English But Not Ordinary Jam," 6 FOOD DRUG COSMETIC LAW JOURNAL 909 (December, 1951).

[8] See, for example, *U. S. v. Ten Cases . . . Bred Spred*, 49 F. 2d 87 (8th Cir. 1931); *Land O'Lakes Creameries Inc. v. McNutt*, 133 F. 2d 653 (8th Cir., 1943); *U. S. v. 651 Cases . . . Chocolate Chil-Zert*, 114 F. Supp. 430 (N. D. NY, 1953); H. R. 2139, 75th Cong. 3rd Session, 1938; (See Dunn, Federal Food, Drug and Cosmetic Act, pp. 815 and following); *U. S. v. 30 Cases . . . Leader Brand Strawberry Fruit Spread*, 93 F. Supp. 764 (S. D. Iowa, 1950); *Armour & Company v. Freeman*, 304 F. 2d 404 (D. C. Cir., 1962), cert. denied, 370 U. S. 920 (1962). Congress, in enacting the 1938 Act, clearly had in mind the kind of case Thoreau referred to in his observation that circumstantial evidence is the discovery of a trout in the milk.

[9] *62 Cases . . . Jam v. U. S.*, 340 U. S. 593 (1951).

the *Carolene* case, which upheld the Filled Milk Act and which has been cited by the Supreme Court subsequently as the basis for upholding the FDA's administrative authority to declare what can and cannot be sold under a given product nomenclature.[10]

Therefore, I think that we can safely say that the imitation provision of the Act owes its existence to the problem of cheapened, inferior food products, which were, or might be expected to be, accepted by the consumer as the genuine article.[11] This is entirely consistent with the broad, basic purposes of the misbranding provisions of the federal food and drug legislation, as stated by the Supreme Court in the *Lexington Mill* decision:

> . . . to make it possible that the consumer should know that an article purchased was what it purported to be; that it might be bought for what it really was and not upon misrepresentations as to character and quality. *U. S. v. Lexington Mill & Elevator Co.*, 232 U. S. 399, 409 (1914).

Nomenclature

Against this backdrop, I would like to consider the legal status of the two products I have described—low calorie margarine and the low-cholesterol egg. There are standards of identity for margarine and dehydrated eggs. Because of the adjustment of the ingredients, neither of the two special products complies with the relevant standard, and FDA has taken the position that both are therefore "imitations" of the standardized products, and must be labeled "imitation margarine" and "imitation dried eggs" respectively.[12]

One more premise should be stated at this point—that the "imitation" nomenclature inhibits the marketing and consumer acceptance

[10] *Carolene Products Co. v. U. S.*, 323 U. S. 18 (1944); *FSA v. Quaker Oats Co.*, 318 U. S. 218 (1943). Although the *Chil-Zert* decision (see footnote 8 above) holds that it is not necessary for the government to prove that the accused product was "passed off" as the traditional product, this decision would appear to go no further than to recognize the legislative presumption of the inherent capacity of *cheapened* products to deceive, and Congress' designation of the exclusive means of curing this deceptive capacity —for example, the "imitation" designation.

[11] Most of the imitation decisions refer to "inferiority"—for example, *Jam* and *Chil-Zert* decisions referred to at footnotes 8 and 9, and *Ham* decision referred to below at footnote 21.

[12] See *U. S. v. 856 Cases . . . Demi*, 254 F. Supp. 57 (N. D. NY. 1966), and *U. S. v. 84 Cases . . . Miracle-Egg Brand Instant Egg White Mix with Golden Egg Yolk Substitute*, Admiralty #87, Northern District Indiana (1963). In conferences with the writer, FDA officials indicated that they might promulgate a standard of identity for low-calorie margarine, but only under the name "imitation margarine."

of these products. There are a number low-fat margarines on the market under the imitation nomenclature; they seem to sell fairly well, but one is inclined to agree with the marketing men's position that this "imitation" nomenclature confuses the consumer, conjures up an image of something highly synthetic or cheapened, and generally discourages broader consumption of these useful products.[13] The Report of the Panel on New Foods of the recent White House Conference on Food, Nutrition and Health corroborates this point.[14]

The point I wish to explore is whether such products should, and can, be sold without the impediment of the "imitation" nomenclature. Are these products properly classified as imitations under the Food, Drug, and Cosmetic Act? If the answer is yes, can any administrative action short of requesting new legislation from Congress ameliorate the nomenclature situation under the present statutory provisions?

On the first point, I do not believe that FDA correctly interprets the Act in declaring that these products are "imitations" within the contemplation of Section 403(c). They are not really imitations in the semantic sense,[15] since their particular, non-standard compositions have independent significance other than reduced cost. Indeed, they may well cost more to manufacture, and may sell at retail prices above those of the traditional version of the product. Therefore, they are not just *another way* to provide the *same* characteristics of the traditional product at a lesser cost; they are different, in critically important aspects from the traditional product, and they are marketed by *emphasizing* these differences, not by *concealing* them. In other words, to those consumers who seek the precise characteristics that these products reflect, they are superior, in important nutritional aspects, to the traditional product.[16] This distinction—superiority, by reason

[13] An example of the extremes to which rigid regulatory attitudes carry food product nomenclature is a popular soft drink which bears the name "Imitation citrus-flavored dietary artificially sweetened carbonated beverage." The product sells widely, but probably because the name is so long that it travels the entire circumference of the bottle, and thus does not really give its full affront to the consumer from any one vantage point. This probably encourages the consumer to refer to this product, to the chagrin of trademark counsel, by its registered trademark "Fresca." Generic use of tradesmarks is obviously encouraged by "jaw-breaker," or non-informative, nomenclature such as "imitation."

[14] See Recommendation 3, Panel III-2, at Conference Report referred to above at footnote 2.

[15] Webster's *New International Dictionary* (Second Edition) defines imitation as: "That which is produced as a copy, an artificial likeness, a counterfeit, simulating something superior." The *Oxford Dictionary of the English Language* defines imitation as ". . . something made to look like something it is not."

[16] See footnote 5.

of the characteristics in respect of which the product departs from the norm or standard resulting in a separate, distinct identity—has been recognized by a substantial number of state courts in the decisions holding that the vegetable-based coffee whiteners are not "imitation cream,"[17] and need not bear the "imitation" stigma as long as they are truthfully labeled. The Food, Drug, and Cosmetic Act does not define the word "imitation," nor have the federal courts defined it in any yardstick fashion. Perhaps the best discussion of the imitation concept in the federal decisions can be found in the *Chil-Zert* case.[18] There, the District Court said that while elements of imitation may be isolated—resemblance in organoleptic characteristics, manufacturing, packaging, sale and use, inferiority by reason of substitution of cheapening ingredients, capacity to deceive—no single element is dispositive by its presence or absence. The court concluded that the test is the "effect of a composite of all such elements" —or a sort of "gestalt" theory of misbranding. This may be a sound proposition as far as consumer psychology is concerned, but it affords an unfortunate criterion for a statute with criminal penalties. It will be noted, however, that the federal court decisions usually emphasize inferiority, as well as the fact that the product is offered for the same *use* as the product imitated, as important indicia of "imitation" status.[19] The two products I have referred to are not inferior, and they have *special uses* for which they are uniquely qualified by virtue of those characteristics wherein they differ from the traditional formulations. To my knowledge, the status, under § 403(c), of a demonstrably superior, non-conforming product, with unique uses or applications for which the consumer selects the product, has not yet been litigated under the Food, Drug, and Cosmetic Act, nor does the FDA appear to have accepted this argument.[20]

Another argument which I believe would be persuasive is that the "imitation" label is deceptive when applied to a product which

[17] For example, *Coffee Rich Inc. v. Kansas State Board of Health,* 194 Kan. 431, 388 P. 2, 582, (1964).

[18] See footnote 8 above.

[19] For example, *Imitation Jam* and *Chil-Zert* decisions, above, footnotes 8 and 9.

[20] It is, however, significant that FDA has not attacked the vegetable coffee whiteners under the Federal Act. Also, there are a number of sweetener products on the market, which incorporate a non-nutritive sweetener into a non-saccharine carrier to form a product which resembles sucrose, and is volumetrically interchangeable with sucrose for table use. To date, I know of no FDA enforcement action charging that such products are "imitation sugar." On the other hand, FDA has brought an action against a textured soy protein product on the ground that it is "imitation bacon," and perhaps the issue will be determined in that case. *U. S. v. . . . Bacos . . . ,* Civ. #1966-77, (W. D. NY 1966).

has been improved or reformulated for specific nutritional reasons. For example, one might be led to believe that "imitation margarine" has *as much* fat as ordinary margarine, but of different or inferior variety or origin, or on the other hand, one might believe that all "imitation margarines" are low in calories, which is not necessarily the case. In the *Imitation Ham* decision, the concurring opinion points out that to apply the "imitation" label to a genuine ham which contains excess moisture resulting from an entirely honest, legitimate curing process, is fraudulent and deceptive to the consumer, in that he is thereby unable to distinguish such a desirable, useful product from one which is truly cheapened and counterfeit, but is also labeled "imitation."[21]

FDA's Position

FDA has historically taken an extremely rigid attitude in the "imitation" area. Until the Supreme Court rejected the strained FDA construction of the Act, in the *Jam* case, FDA asserted that there could be *no* imitation of any food product for which a standard of identity had been promulgated, regardless of what the product label stated. In the recent *Demi* case, FDA advanced the argument that no margarine-type product (which did not comply with the margarine standard) could be marketed under *any* nomenclature (including "imitation"), notwithstanding the *Jam* decision. Again, this argument was rejected; the District Court for the Western District of New York

[21] *Armour & Company v. Freeman*, 304 F. 2d 404, 411 (D. C. Cir., 1961). See also Brief for Appellee, United States of America, in *62 Cases . . . Jam v. U. S.* above, footnote 9, where FDA argued that the term "imitation jam" is inherently confusing in that such a product might contain as much as forty-four parts of fruit or virtually no fruit at all. In the *Coffee Rich* case referred to above at footnote 17, the Trial Court made the finding of fact that the "imitation cream" nomenclature would be deceptive to consumers. The contention that "imitation" nomenclature may well be deceptive in some circumstances is not the private preserve of food manufacturers. A proposal for a standard of identity for low-fat cottage cheese was recently submitted to FDA by the Milk Industry Foundation and the Ohio and New York State Departments of Agriculture. The National Association of State Departments of Agriculture, aware of FDA's affection for the "imitation" nomenclature, has urged that the product be standardized as "low-fat cottage cheese," on the ground that the "imitation" nomenclature would be misleading to consumers. *Food Chemical News*, Oct. 13, 1969, p. 23. See also *Nolan v. Morgan*, 69 F. 2d 471 (7th Cir., 1934), where the Court of Appeals (dealing with the McNary Mapes Amendment, prior to the enactment of § 403(c)), ruled that FDA could not adopt a standard of quality for canned immature peas, whereby canned mature peas became substandard. The Court found that the two products had distinct identities, and stated that: ". . . to say that canned ripe peas are an inferior grade of canned immature peas is, in our judgment, at once illogical, unreasonable and unfair."

professed that it really did not understand the FDA argument.[22] These two decisions are somewhat off the main track of my discussion; however, I think they are useful illustrations of FDA's peculiar rigidity in the imitation area. These decisions also illustrate that there are indeed two aspects to the problem: first, what the Food, Drug, and Cosmetic Act clearly provides; and second, the FDA attitudes and philosophies which color FDA's interpretation and enforcement of the Act. FDA's philosophy has been to approach new food products with a "knee-jerk" reaction in respect of consumer deception, far transcending the actual capacity of these products to deceive, and with an almost casual lack of concern with the nutritional advances these products may represent. Granted, one of FDA's basic missions is to preclude deception of consumers; however, FDA also has the responsibility at least to permit, if not encourage, nutritional progress. The latter function cannot be discharged in the context of FDA's presumption that no altered or improved food formulation can be any different from watered milk.[23]

Because of its historical rigidity regarding wholesome, nutritious food products which do not comply with the standard or traditional formulations, considerable persuasion may be required to convince FDA that the stigmatic word "imitation" should be dispensed with in certain circumstances. I think it entirely likely that FDA would commence an enforcement action against low-fat margarine or low-saturated-fat egg products unless they were labeled "imitation." If such a case were brought, I think it altogether possible that the manufacturer would prevail on the "superiority" (and thus separate identity) argument, buttressed by a clear showing that the nomenclature and label statements were such as to preclude deception.[24] On balance, however, I doubt that any manufacturer would risk such

[22] See footnote 12 above.

[23] The Supreme Court of Kansas stated in its *Coffee Rich* decision that "Kansas is not committed to the proposition that nothing new and distinct is possible." See footnote 17 above. FDA apparently *is* committed to that proposition.

[24] However, I think that such a case would be distinguishable from, and possibly slightly weaker than, the state decisions on vegetable coffee whiteners. The latter products contain no genuine cream, and thus represent a wholly novel compositional approach to the coffee whitening function. The two products I am discussing are, on the other hand, altered versions of the traditional products, containing largely the same ingredients, though with some reductions or substitutions. This distinction has only metaphysical significance, in my opinion, but FDA has practised metaphysics in the past, and the courts certainly give some deference to FDA's "expertise."

litigation, in view of the expense of launching a new product, the uncertain prospects for success in the litigation and the inevitable bad publicity of an FDA seizure.

The Solution—Administrative Interpretation

What, then, can be done administratively to alleviate this problem? The ideal solution, of course, would be an administrative interpretation, or policy statement, by FDA that products such as those I am discussing, when labeled honestly, prominently and informatively, do not purport to be, and are not represented as, the standard or traditional articles. I think that this is wholly possible as a legal proposition; it would be no more than an interpretation of the meaning of the Act, but as a practical matter it would dispose of the issue, since no enforcement actions would thereafter be instituted by FDA. Such an interpretation would not require that the plain language of the Act be disregarded, since the dictionary definition of "imitation" excludes patently superior products, and the Supreme Court has declared in the *Imitation Jam* decision that the word "imitation" is to be accorded its ordinary meaning.[25] It *would* require FDA to acknowledge that Congress was aware of, and concerned with, economic deception (for example, "Bred Spred") in enacting 403(c) in 1938, but that the "new foods" discussed here were not then in existence, and that there is no reason for a Procrustean application of § 403(c) in circumstances the Congress did not foresee. Professor Llewellyn's admonition to judges is equally applicable to FDA, which to a great extent serves as the definitive interpreter of this statute:

> Here the quest is not properly for the sense originally intended by the statute, for the sense sought originally to be *put into it*, but rather for the sense which *can be quarried out of it* in the light of the new situation. Llewellyn, *The Common Law Tradition—Deciding Appeals*, 374 (1960).

In brief, FDA can, and should, acknowledge that where the product is not inherently cheapened or deceptive, and no counterfeit is being passed off, the *Chil-Zert* misbranding gestalt does not occur, and there

[25] "Imitation" connotes counterfeit (see footnote 15). If a product has its own identity—its own raison d'etre by reason of characteristics which the consumer desires and is thoroughly informed of—it is not a "counterfeit," and the "ordinary meaning" of the word "imitation" would not include it. The *Land O'Lakes* decision states that mere resemblance does not make an imitation product and that § 403(c) is directed at "spurious" products being passed off as genuine.

is a greater interest in telling the purchaser what such a product *is* rather than telling him what it is *not*.[26]

There are significant precedents in food product nomenclature—for example, decaffeinated coffee has never been referred to as "imitation coffee." "Decaffeinated coffee" is the most useful, informative nomenclature to the insomniac consumer of this product, who would certainly be amused by the suggestion that the product has been economically adulterated by the omission of a valuable constituent, caffeine. By the same token, no one has seriously suggested that skim milk should be called "imitation milk;" although originally only a by-product of butter manufacture, this product is now purchased precisely *because* of its low fat content, not in spite of it, or without knowledge of it. In the *Imitation Ham* decision, the Court of Appeals for the District of Columbia deemed the U. S. Department of Agriculture's (USDA's) requirement that a ham containing added moisture used in curing be labeled "imitation ham" to be arbitrary and capricious, in an appeal involving Armour's motion for a preliminary injunction.[27] The Court stated that USDA could easily have solved the problem by requiring that the label state informatively that the ham contained added moisture, and that requiring the "imitation" nomenclature actually required Armour to violate the Meat Inspection Act's prohibition of false and deceptive label statements.[28] The concurring opinion of Judge Prettyman points out that if ham with added moisture is called "imitation ham," the consumer will have no means of distinguishing that nutritious, acceptable product from a truly ersatz, cheapened product, which would also be sold as "imitation ham." At the very least, the *Ham* decision suggests that the "imitation" nomenclature is not appropriate for every deviation from unmodified purity.[29]

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[26] I do not suggest that *any* deviation from a standard of identity should be condoned as long as it is clearly disclosed on the label. Compare *Libby, McNeill & Libby v. U. S.*, 148 F. 2d 71 (2d Cir., 1945). My argument is limited to foods modified in a manner for which there is genuine consumer demand, to the extent that the modification yields a separate, distinct "identity." My argument would, perhaps suggest that the *Buitoni* decision is questionable; however, it is not at all clear from that decision that the difference betwen Buitoni's 20% protein and the 13% maximum prescribed by the standard would support an argument of separate identity. *U. S. v. 20 Cases, etc., "Buitoni 20% Protein Spaghetti"* (CA-3 1955; aff'g D. C. Del.) 228 F. 2d 912.

[27] See footnote 21 above.

[28] See footnote 21, at 406.

[29] See footnote 21, concurring opinion at 413.

There are also regulatory precedents in non-food consumer products. For example, the Federal Trade Commission (FTC) has recently issued an advisory opinion that ground leather applied to a fabric base may be called "shredded (or pulverized) leather laminated to fabric," as alternatives to "imitation or simulated leather."[30] This FTC opinion attaches at least *as much* importance to telling what the product *is* as to telling what it is *not*. Moreover, in administering the Textile Fiber Products Identification Act, (in the context of new man-made fibers, which are substantially analogous to "new foods"), FTC baptizes new fibers as they come on the market, without resort to the "imitation" concept.[31]

Hopefully, FDA will also come to an awareness that its duties include the encouragement of progress as well as the inhibition of fraud, and FDA may then be capable of a sensible policy statement regarding nutritionally improved food products. At very least, FDA should be prepared to rule that a specific nutritionally-improved food product, in the context of specific label and advertising representations, is not an "imitation."[32]

An Alternative Approach

An alternative approach is the promulgation of standards of identity for these special-purpose foods. There are a number of precedents in this area in FDA's own actions, involving standards of identity for products which, in the absence of standards, might be argued to be imitations. Examples are margarine (which the butter industry insisted was imitation butter),[33] Neufchatel cheese (which might have been characterized as imitation cream cheese),[34] and salad dressing (susceptible to characterization as imitation mayonnaise).[35] These products had established identities, to some extent, when the respective food standards were promulgated in the early 1940's. The low-calorie margarine product I have mentioned clearly

[30] *FTC Advisory Opinion Digest* No. 391, November 18, 1969.

[31] Textile Fiber Products Identification Act, Sec. 7(c), 15 USC (70-70k).

[32] FDA may have made such a ruling (though it has not been publicized) in connection with certain low-calorie table sweeteners in a granulated form resembling refined sugar—which are sold under label nomenclature such as "sugar substitute."

[33] *Land O'Lakes Creameries Inc. v. McNutt*, see footnote 8 above.

[34] *Columbia Cheese Co. v. McNutt*, 137 F. 2d 576 (2d Cir., 1943); cert. denied 321 U. S. 777 (1944).

[35] 21 CFR 25.3. See also 21 CFR 14.12 (chocolate product, with vegetable oil in lieu of cacao fat, for functional reasons).

has an established identity; it has been marketed for several years. The low-saturated-fat egg product may not have an identity which has been generally established in the minds of consumers at large, since it has not been marketed widely. However, the lack of a generally accepted identity in the minds of consumers would seem no reason in the Act, in logic, or in public policy why a newly modified or wholly new product may not have a standard of identity established for it.[36] FDA has demonstrated its authority under Section 401 to confer separate identity upon relatively new variations of traditional products by enacting standards of identity under Section 401 for artificially sweetened preserves and other fruit products, and by proposing standards for artificially sweetened soft drinks, diluted fruit juice drinks, liquid margarine, etc. Similar authority regarding new substitutes for traditional foodstuffs has been reflected in the proposed standards for textured soy protein meat analogs and for non-dairy milk-type products. Clearly, the day has long since passed when standards were to be established in terms of the housewife's conception of the food, based upon her preparation of it in the home kitchen. Although Congress considered home recipes a basis for standardization when Section 401 was added to the 1938 Act,[37] home recipes certainly can no longer be considered the exclusive basis, or even a significant basis, for food standards; very few fabricated or formulated foods are made by the housewife today, nor would the housewife have the facilities or the need to use the processes and ingredients needed in large-scale production of such foods for widespread distribution in convenient form at reasonable prices.

Thus, the two products I have referred to could be, in my opinion, standardized under Section 401 of the Act, and would thereby have independent identity bestowed upon them. This would seem to offer a sensible solution to manufacturers, and it would further accommodate the consumer by assuring that low-calorie margarines are indeed low in such ingredients, by establishing specifications for

[36] In case of analogs of traditional foods, the consumer *does* have specific expectations, at least in respect of nutritional quality. It is also most likely that the consumer has expectations regarding most new food products—for example, low calorie margarine—by reason of their label nomenclature and advertising. Compare Forte, "Definitions and Standards of Identity for Foods," 14 *UCLA Law Review* 796, 807 (n. 57) 1967.

[37] See, for example, House Report on S. 5 (H. R. Rep. No. 2139, 75th Congress, 3rd Sess., 1938) at Dunn, *Federal Food, Drug, and Cosmetic Act* (1938), p. 819.

such products, assurances not provided by the "imitation" nomenclature. The latter could be accomplished by means of standards of identity or standards of quality. It would certainly appear that this would be a rational and reasonable application of the Food, Drug, and Cosmetic Act's standard-making authority under Section 401.[38] This seems to have been done in respect of artificially sweetened lemonade, fruit products, etc., which have been standardized under informative nomenclature other than the word "imitation."[39] However, FDA's rigid approach is still applied in some instances. For example, FDA has proposed to standardize vegetable milk-type products, but under the label nomenclature "imitation milk,"[40] and an inquiry to FDA regarding a standard for low-calorie margarine has elicited the reply that this could probably be done, but only under the label nomenclature "imitation margarine." This certainly does not enlist the aid of the manufacturer, because he gets off just where he got on as far as undesirable product nomenclature is concerned.

Moreover, it seems to be entirely inconsistent with the imitation concept—that is, the term "imitation" seems to be have been intended by Congress to signify that the product is substandard, and does not comply with applicable specifications. It also raises the logical quibble of what, then, to call an imitation of this "imitation margarine," since the *Jam* case teaches us that imitations of standardized products are not to be foreclosed. FDA may take the position that since these products have been sold under "imitation" nomenclature, that term has become part of the "common or usual name" of such products, and that Section 401 requires standardization under the "common or usual name" of the product.[41] However, Section 401 ac-

[38] In fact, FDA suggested in its brief in the *Imitation Jam* case that this was a preferable alternative, in the case of low-fruit jams, to "imitation" nomenclature, since the latter gave the consumer no information or assurance as to the manner or extent in which the article deviated from the traditional jam. See Brief for Appellee, United States of America, in *62 Cases . . . Jam v. U. S.*, footnote 9 above.

[39] 21 CFR 27.

[40] 21 CFR 18.550, proposed at 33 F. R. 7456 (May 13, 1968), and republished at 34 F. R. 15657 (Oct. 9, 1969).

[41] An FDA spokesman recently stated that FDA is obliged by the *Chil-Zert* decision to standardize vegetable-milk-type products as "imitation milk" if in fact those products are imitations within the meaning of § 403(c) as interpreted by *Chil-Zert*. (*Food Chemical News*, September 8, 1969, at p. 9.) This is hardly convincing; *Chil-Zert* did not refer in any manner to FDA's power to ordain separate identity under Section 401 of the Act; the decision dealt only with the effect of Section 403(c) on a non-standardized product allegedly imitating another non-standardized product. If FDA wishes to promote progress and informative labeling, that agency can easily find that vegetable milk substitutes have a separate identity, re-

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tually provides that the common or usual name be applied only ". . . so far as practicable . . . ," and it hardly seems "practicable" to standardize a product under a name which gives the consumer no idea of what the product really is, and probably suggests to the consumer that the product does not comply with any applicable standards.[42]

FDA's Authority to Standardize

Moreover, there is adequate precedent in FDA's own past practises, affirmed by the Court of Appeals, for developing new nomenclature in standard-making proceedings. In the *Columbia Cheese* case, FDA selected the name Neufchatel cheese for a cream cheese-type product which was lower in fat than the conventional cream cheese.[43] Certain manufacturers objected to this nomenclature, on the ground that the name had never been used on the product in question, had been used at one time for *another* cheese product, and could only confuse the consumer; these manufacturers would have preferred the nomenclature "Cream Cheese, Grade B." The Court upheld FDA, on the ground that FDA's determination of nomenclature was supported by the evidence that the name Neufchatel had previously been associated with some soft, low-fat cheeses and apparently would thus be informative. This suggests that FDA may select any reasonably descriptive name in standardizing a food, where there is no well established, non-confusing nomenclature.

Another example of FDA's own expression of rather flexible nomenclature powers in the food standards area appears in the diluted fruit juice drink standards.[44] These standards (currently stayed)

(Footnote 41—continued.)
quiring descriptive nomenclature other than "imitation," and I cannot imagine that a court would overturn that finding.

[42] This nomenclature provision in § 401 was apparently included to safeguard against the application of technical names—such as "bovine lacteal fluid" for milk—where there is in existence a common designation which is more informative, or less deceptive, to the consumer. Austern, "The Formulation of Mandatory Food Standards," 2 FOOD DRUG COSMETIC LAW QUARTERLY 532, 545 (1947). Where no common or usual name exists, or if the common or usual name is the non-informative "imitation," then it is not "practicable" to attach the common or usual name, and it seems entirely within the statutory mandate to adopt informative nomenclature. It has been noted (Austern, p. 547) that the record in the *Quaker Oats* case reflected an FDA finding that although the product involved had not yet acquired a "common or usual name," the designation "enriched farina" was the appropriate nomenclature.

[43] *Columbia Cheese Co. v. McNutt,* footnote 34 above.

[44] 21 CFR 27.120 through 27.128; effectiveness stayed at 33 F. R. 10713 (July 27, 1968).

apply a range of names to fruit drinks, each name including the percentage of undiluted juice present—for example, "orange juice drink, contains not less than 50% orange juice." There is no indication that these names have regularly been applied to the respective products; certainly the statement of the percentage of juice present is a wholly novel nomenclature device. On the other hand, FDA clearly indicates that it has the authority to assign names in a manner which will provide information as to the composition of these products. The products are named by reference to what they *are*, rather than what they are *not*. To call them all "imitation orange juice" would be absurd.

I therefore have no doubt that FDA has the legal authority to standardize the two special-purpose foods discussed herein, under rational, informative nomenclature other than the pejorative term "imitation." The imitation provision of the Act obviously is with us still, and still has utility where actual economic adulteration or "passing off" justify its application. However, FDA does not advance the consumer interest, the food industry interest or FDA's own interests as an effective regulatory voice, by applying a statutory provision of the 1930's, enacted to guard against cheapened products, to products which were neither technologically available nor dietetically desired, and thus not even within the contemplation of Congress, in 1938 when the Act was adopted. If FDA cannot bring itself into the second half of the twentieth century, by reasonable and imaginative utilization of existing laws to accommodate and advance the needs of public health and the accomplishments of modern food technology, then new legislation would seem to be the only alternative.[45]

The two products I have dealt with are not isolated cases. The vegetable milk analogs and vegetable protein meat analogs, which I have also mentioned, are both useful in weight and cholesterol control, because the type and quantity of fat present may be carefully controlled by the manufacturer; furthermore, they may provide more economical, or at least more convenient, nutrition. There are also numerous other low-calorie foods; for almost every widely-used food product in which fat or sweeteners contribute substantial calories, there is available a reduced-calorie counterpart with highly satis-

[45] To a certain extent, the vegetable milk problem cannot be solved without amendment of the Filled Milk Act (21 USC § 61-§ 64).

factory organoleptic characteristics. All can be said to have separate identity, and should be labeled informatively. FDA apparently proposes no constructive initiative in this area, to permit (and even to encourage) broad distribution of such products by allowing informative, sensible label nomenclature. It is unfortunate that FDA, far from leading this effort to improve the American diet, comports itself as an *impediment* to industry initiatives in this area.

In the course of the recent White House Conference on Food, Nutrition and Health, the "New Foods" Panel of that Conference recommended that FDA revise its administrative approach to the "imitation" question. After stating that innovation is necessary for product and process improvements which will solve the nation's food and nutrition problems, the panel observed that the primary barriers to innovation are a small number of regulatory policies, which, because they restrict innovation, are no longer in the best interest of consumers. Specifically, the panel recommended ". . . a policy of truthful disclosure wherein names for foods accurately describe what the foods are."[46] The panel classified "new foods" in three categories: (1) traditional foods nutritionally improved; (2) foods which simulate traditional foods; and (3) wholly new classes and types of foods. Examples of each class would be, respectively: (1) lysine-fortified bread; (2) soy protein meat analogs; (3) fish flour or petro-proteins. The panel concluded that where the new food is superior to the old, the term "imitation" may actually be misleading, and FDA should permit and encourage the development of informative generic names for such products to show what the product is rather than what it is not.[47] Perhaps this semi-official endorsement

[46] Report of Panel III-2: White House Conference on Food and Nutrition; Final Report dated December 24, 1969.

[47] "Presently, new foods are often required by Government regulatory agencies to be called 'imitation' products. The 'imitation' label has been regarded as equally applicable when the new product is inferior to the old as it is when the new product is superior to the old. Thus, the use of such oversimplified and inaccurate words are potentially misleading to consumers, and fail to inform the public about the actual characteristics and properties of the new product. More accurate and useful labeling is needed.

"Under existing law, Government agencies could adopt an administrative policy no longer requiring or permitting over-simplified and inaccurate words. Instead, they could require an informative and descriptive generic name for every food. The existing legal prohibitions against false or misleading labeling and advertising could be utilized to prevent the use of any terminology that could mislead consumers about

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of the arguments reviewed above will persuade FDA to reconsider its philosophy regarding the nomenclature of new or improved food products.

Fair and Rational Interpretation

The problem has been generated by FDA's premise that the statutory language (for example, "imitation" and ". . . purports to be or . . . represented as . . .") has a demonstrable, unambiguous and necessary meaning, and that FDA is the prisoner of this precise meaning in its interpretation and enforcement of the Food, Drug, and Cosmetic Act. I submit that the statutory language does not compel such a premise, since the language is vague and there is no legislative history precisely circumscribing its meaning. Since this premise is not required by the statute, and since it inhibits nutritional progress and informative labeling, it is indefensible to allow it to shape administrative policy in such an important area. The sensible regulatory approach would be for FDA to acknowledge that these statutory terms are imprecise, and to declare that they will be construed by that agency in the light of today's circumstances, in a manner which fairly and rationally balances the interests in improved nutrition, convenience and economy on the one hand, and economic protection of the consumer, on the other hand. **[The End]**

(Footnote 47—continued.)
the identity or characteristics of the new product. Existing law could also be used to establish, by regulation, a uniform generic name that would accurately reflect reasonable expectations of consumers.

"Such a policy would better serve the public interest. It would provide more accurate and useful information for consumers about the identity of foods than is presently the situation. It would also encourage the development and marketing of variations of traditional foods and of completely new foods, that can provide consumers a greater variety of acceptable, higher quality, and more nutritious food products at lower prices." Report of Panel III-2, White House Conference on Food and Nutrition; Final Report dated December 24, 1969.

The Trial of an Injunction Suit

By GEORGE M. BURDITT

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ONE YEAR AGO TODAY, five lawyers and numerous experts on both sides of the table were engaged in the trial of a suit for an injunction under Section 302[1] of the Federal Food, Drug, and Cosmetic Act. Paragraph (a) of this section gives federal district courts jurisdiction to restrain violations of Section 301[2] except paragraph (h), relating to false guaranties, paragraph (i), relating to forging and counterfeiting, and paragraph (j), relating to the revealing of trade secrets. All other violations may be restrained.

The Food and Drug Administration (FDA) has customarily dealt with routine alleged violations of the Act by seizure actions under Section 304.[3] These are actions in rem which begin in admiralty and quickly metamorphose into actions at law,[4] with, of course, the right to a trial by jury. Situations which FDA views more seriously are dealt with by criminal information[5] or by indictment[6] under Section 303.[7] But if FDA feels that it simply does not have

[1] "The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of Section 17 (relating to notice to opposite party) of the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes,' approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (h), (i), and (j)." 21 U. S. C. 332(a).

[2] 21 U. S. C. 331.

[3] 21 U. S. C. 334.

[4] *443 Cans of Frozen Egg Product v. U. S.*, 226 U. S. 172, 33 S. Ct. 50, 57 L. Ed. 174 (1912).

[5] *U. S. v. Greenbaum,* 138 F. 2d 437 (C. A. 3, 1943).

[6] *Van Liew v. U. S.,* 321 F. 2d 664 (C. A. 5, 1963).

[7] 21 U. S. C. 333.

the attention of the firm or individual,[8] or if FDA believes that a particular situation simply cannot be corrected,[9] or if FDA wants to prevent further shipments of a particular product,[10] a suit for an injunction is the obvious remedy.

Because of the severity of the remedy, and the scope of the prayer in the complaint for injunction, the likelihood, indeed the necessity, of a full trial on the merits is greater than in seizure actions, most of which are disposed of by default, summary judgment, or consent decree; or than it is in criminal cases, most of which are disposed of by nolo or guilty pleas. The remedy sought by FDA in an injunction suit is generally a prohibition against further shipments from a particular plant,[11] a prohibition against shipments of a particular product,[12] a prohibition against further shipments to particular customers,[13] or in extreme cases, a prohibition against doing business.[14] Few orders can be more conclusive than this one.

Another type of injunction suit, which is going to be more common in the near future, is a suit for an injunction against FDA,[15] particularly in the drug field. While many of my comments and observations may be applicable to this reverse situation, I would like to restrict this paper to suits in which the FDA is the plaintiff, and a food, drug or cosmetic manufacturer or distributor is the defendant.

Pretrial Procedures

First, consider some of the pretrial problems. The first problem for the defense is likely to be how to prevent the entry of a tem-

[8] *U. S. v. 184 Barrels ... Eggs,* 53 F. Supp. 652 (E. D. Wisc., 1943).

[9] *U. S. v. Swift & Co.,* 53 F. Supp. 1018 (M. D. Ga., 1943).

[10] *U. S. v. Wilson Williams, Inc.,* 277 F. 2d 535 (C. A. 2, 1960); *U. S. v. Ellis Research Laboratories,* 300 F. 2d 550 (C. A. 7, 1962).

[11] *Hygrade Food Products Corp. v. U. S.,* 160 F. 2d 816 (C. A. 8, 1947).

[12] See footnote 10 above.

[13] *U. S. v. Vitasafe Corporation,* 345 F. 2d 864 (C. A. 3, 1965); *U. S. v. Lanpar Co.,* 293 F. Supp. 147 (N. D. Texas, 1968).

[14] I trust this will not be your client.

[15] *Ewing v. Mytinger & Casselberry, Inc.,* 339 U. S. 594, 70 S. Ct. 870, 94 L. Ed. 1088 (1950); *Hoxsey v. Folsom,* 155 F. 2d 376 (D. C., 1957); *Durovic v. Palmer,* CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 40,099, Christopher, see footnote 16, page 647, (N. D. Ill., 1964), and 342 F. 2d 634 (C. A. 7, 1965); *Ivy v. Celebrezze,* CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 40,179 (N. D. Ill., 1964).

porary restraining order or a preliminary injunction.[16] The argument is likely to center around such issues as whether there is "a strong probability that the respondent's allegedly illegal acts will continue in the future,"[17] whether "there exists some cognizable danger of recurrent violations,"[18] whether there may be danger to health,[19] whether there may be "irreparable injury,"[20] and whether the defendant could make restitution if a permanent injunction is entered, but a preliminary injunction denied.[21] Absent an obvious danger to health, one very logical decision for the court to make is to deny the temporary restraining order or preliminary injunction, but to set an early date for a full trial on the merits.

Once the temporary restraining order hurdle is crossed, the defendant may wish to file motions in the usual form to dismiss the complaint outright, to strike certain portions of the complaint, or at least to require the government to be more specific. Because of the seriousness of injunction suits, however, it is extremely important for the defendant not to take any action which the court might consider to be dilatory. For the same reason, an answer should be filed as promptly as possible, so the lawyer for the defendant is going to be reasonably busy.

An injunction suit is, of course, in equity, and the defendant is, therefore, not entitled to a jury trial. This may tend to make injunction suits more attractive to FDA, but to the best of my knowledge, there has not been any abuse of administrative discretion by bringing injunction suits solely for this reason. Further, the defendant may ask for an advisory jury. But since the findings of the advisory jury are not binding on the court, and since there may be an implication that the defendant who asks for an advisory jury does not have full confidence in the judge, and since the judge is likely to pay closer attention to the details of the case if there

[16] *U. S. v. Cowley Pharmaceuticals, Inc.*, Kleinfeld & Dunn, *Federal Food, Drug & Cosmetic Act, 1938-1949* (1949) at page 473, Christopher, *Cases and Materials on Food and Drug Law* (1966) at page 630, (D. Mass., 1948); *U. S. v. Lazere*, 56 F. Supp. 730 (N. D. Iowa, 1944).

[17] *U. S. v. Cowley Pharmaceuticals, Inc.*, footnote 16 above.

[18] *U. S. v. Cargill, Inc.*, CCH Food Drug Cosmetic Law Reporter, ¶ 40,150; Chistopher, see footnote 16 at page 634.

[19] *U. S. v. Lazere*, footnote 16 above.

[20] *U. S. v. Chattanooga Bakery, Inc.*, Kleinfeld & Dunn, *Federal Food, Drug & Cosmetic Act, 1949-1950* (1950) at page 241, Christopher, see footnote 16 at page 632 (E. D. Tenn., 1949).

[21] *U. S. v. Wilson Williams, Inc.*, footnote 10 above.

is no jury, the defense counsel is probably better advised not to ask for an advisory jury.

Meanwhile, the defendant should also be busy. Injunction cases frequently involve charges of violations of the insanitary plant provision of the food section of the Act,[22] or the current Good Manufacturing Practice (GMP) provision of the drug section of the Act.[23] The court has a great deal of discretion in the remedy to be imposed, and it behooves the defendant to make certain that the GMP conditions of which FDA is complaining are carefully reviewed, and if necessary, are corrected promptly and thoroughly. If the defendant does not acknowledge that the GMPs have been violated, or at least that there is a question as to whether they have been violated, the defendant may prefer to continue business as usual. However, in most cases which FDA deems sufficiently serious to warrant an injunction suit, defense counsel will probably decide that the risk of continuing to do business as usual is more serious than the risk involved in acknowledging that defects exist and correcting them forthwith.

Pretrial Problems

One of the pretrial problems which defense counsel may face in injunction suits alleging GMP violations is the financial problem.[24] Correcting a situation serious enough to result in an injunction suit can be very expensive, since it may require plant modifications, purchase of new production and laboratory equipment, employment of more qualified personnel, improvements in record-keeping procedures, and other major steps to bring the plant into compliance with the GMPs. Even if the defendant has limitless funds and is willing to accept all of his attorney's suggestions, and I am sure we all have clients like that, the problem of space within the existing plant to accomplish all of the desired changes may be almost insurmountable. So build a new plant—in the next thirty days before we go to trial! Or even worse, the main source of the problem may be, at least to some degree, beyond the control of the defendant;

[22] 21 U. S. C. 342(a)(3) and (4); *U. S. v. Swift & Co.*, footnote 9 above; *Hygrade Food Products Corporation v. U. S.*, footnote 11 above; *U. S. v. Lazere*, footnote 16 above; *U. S. v. Cargill, Inc.*, footnote 18 above; *U. S. v. Chattanooga Bakery, Inc.*, footnote 20 above.

[23] 21 U. S. C. 351(a)(2)(B); 21 C. F. R. Part 133; *U. S. v. Lanpar Co.*, footnote 13 above.

[24] *U. S. v. Cargill, Inc.*, footnote 18 above; *U. S. v. Chattanooga Bakery, Inc.*, footnote 20 above.

for example, a contaminated raw material supply.[25] Correction of the alleged GMP deficiencies may justify denial of the permanent injunction,[26] and under any circumstances it may help to ameliorate the extent of the injunction and permit the defendant to continue in business without interruption, even if the injunction is entered. The court may feel, however, that the defendant really ought to comply with the GMPs, and a permanent injunction may help just a little.[27]

The injunction suit may also involve sales and promotion situations to which FDA takes exception under the labeling sections of the Act.[28] In these situations, FDA is generally trying to drive the defendant out of a particular line of business.[29] Unlike the GMP situation, when you get into the sales area, defense counsel may not be able to make as many constructive pretrial suggestions to help in the litigation and in the post-litigation activities of the defendant. For example, if FDA is seeking to prevent the sale of a particular drug, regardless of how it is labeled, there is very little defense counsel can do except to advise his client either to prepare for expensive and extensive battle, or to surrender unconditionally. A recommendation of unconditional surrender may require a great deal of courage and at least some expertise, and in some circumstances it is undoubtedly the soundest advice an attorney can give his client. Doing battle in these situations does, of course, require very substantial expertise, both on the part of the lawyer and on the part of the witnesses, and thorough pretrial preparation is as always absolutely essential.

Final Steps

One of the final pretrial steps is the preparation of a trial memorandum. The government will probably prepare an extensive trial memo, and the defendant should do likewise. The memo should set forth the facts, the issues, the relevant statutory and regulatory

[25] *U. S. v. Swift & Co.*, footnote 9 above; *Hygrade Food Products Corporation v. U. S.*, footnote 11 above.

[26] *U. S. v. Cargill, Inc.*, footnote 18 above.

[27] *U. S. v. Lanpar Co.*, footnote 13 above.

[28] 21 U. S. C. 343 and 352; *U. S. v. Wilson Williams, Inc.*, footnote 10 above; *U. S. v. Vitasafe Corporation*, footnote 13 above; *U. S. v. Lanpar Co.*, footnote 13 above; *U. S. v. Ellis Research Laboratories*, footnote 10 above.

[29] *U. S. v. Nutrition Service, Inc., Drosnes-Lazenby Cancer Clinic, et al.*, 227 F. Supp. 375 (W. D. Pa., 1964).

provisions, and the defendant's arguments on each point. The pre-trial memo should, of course, be filed as soon as possible in order to give the court adequate opportunity to become familiar with the facts, the law and the positions of the parties.

Counsel for the defendant, in my opinion, should virtually always consider the possibility of negotiations leading to settlement of the case without trial. This may be extremely difficult in an injunction case, since FDA would not have brought suit in the first place if it had not decided that the alleged violations were so serious that the most extreme remedy provided for in the Act should be invoked. Having taken this position, it is unlikely that FDA can settle for anything less than an injunction. But there are injunctions and there are injunctions, and in some situations, for example a GMP case, the defendant might be willing to accept an agreed-upon injunction and avoid an expensive trial and the risk of a more comprehensive injunction after trial. In the interest of effectuating the purposes of the Act, and conserving on the serious shortage of manpower in the General Counsel's office, it seems to me that FDA should also be willing to negotiate a settlement. As a matter of fact, as a lawyer I find it extremely difficult to understand FDA's reluctance to negotiate on much more of its litigation. For example, the unwritten policy not to discuss relabeling and other matters in seizure actions until after the defendant signs a consent decree seems to me to be contrary to the public interest as well as to the interests of the court, of FDA and of the defendant.

The Trial

Now let's discuss the trial itself. The government's case will be handled by an Assistant U. S. Attorney and an attorney from the office of the General Counsel of FDA. Opening argument may be presented by either of these attorneys, although normally the FDA attorney is necessarily a little more familiar with the case because of his longer exposure to the matter and, therefore, may be the logical attorney to handle the opening argument. Defense counsel also will be afforded an opportunity to present an opening argument. The Assistant U. S. Attorney normally handles most of the direct and cross-examination of witnesses, although the two attorneys may divide up the witnesses by subject matter, for example, the FDA attorney taking all GMP witnesses and the witnesses establishing

the identity of samples, interstate commerce, etc., and the Assistant U. S. Attorney taking all other witnesses.

For the convenience of the court, if the case is a very comprehensive one, it may be desirable to take the case issue by issue and hear all witnesses on both sides on a given issue before moving on to the next issue. For example, the court may want to hear all GMP witnesses first, and reserve witnesses on other issues until the GMP issue is fully heard. The trial procedure is, of course, quite flexible since this is an equity case and there is no jury. Normally, however, the government will present its case in full, at the conclusion of which the defendant may file a motion to dismiss, and if the motion is denied the defendant proceeds to present its case.

The type of witnesses will, of course, depend on the issues in the case. In a GMP case, FDA will probably present its inspectors who inspected the defendant's plant, the chemists who analyzed the products, and an FDA official who is an expert on GMPs. The defendant should present witnesses who can establish, if it is the fact, that defendant's practices complied with the GMPs, and also to show what changes, if any, were made to assure compliance. Testimony on this latter point may not prevent the entry of an injunction, but it does show that the defendant understands that old familiar equitable doctrine of clean hands and a pure heart. And, of course, the firms in the food and drug industries should always be considering new and improved means of protecting the public health and providing the best services and products to the public by continually updating their GMP procedures. Incidentally, that word "current" in Section 501(a)(2)(B)[30] requires this continual updating.

Defendant's witnesses should normally include the responsible officers of the firm, and any defendants who are named in the complaint. In a GMP case, the director of quality control, the director of production, the director of the assay lab, and the supervisors of departments such as raw materials and the several production departments—formulating, tableting, coating, labels, packaging and shipping in a pill plant—are all likely witnesses. It may also be advisable to call outside experts as witnesses on any one of several GMP issues such as assay results, plant sanitation, and competitors' practices. In a non-GMP case, the witnesses must, of course, be

[30] 21 U. S. C. 352(a)(2)(B).

qualified to discuss the particular issue; for example, a pharmacologist to discuss safety, a physician to discuss efficacy, and an English professor to discuss semantics. A consumer survey may also be relevant, although FDA may be expected to take the position that only its surveys are relevant, material and admissible.[31] My guess is that we are going to see a good many FDA cases in the near future in which the clash of witnesses is between FDA's physicians and professors with eminent qualifications and little or no practical experience, and industry's equally well-qualified experts whose curricula vitae may not be equal to that of the FDA experts, but whose practical experience is far superior. The NAS-NRC review probably makes this medical collision course unalterable.

At the conclusion of the testimony in the injunction case, both sides present closing arguments, which, for the government, again may be split between the Assistant U. S. Attorney and the FDA attorney. Defendant's closing argument should, of course, summarize its case and emphasize the weaknesses of the government's case. Both sides also will normally present proposed findings of fact and conclusions of law to the court. The court then makes its findings and conclusions, and will deny or enter the injunction. When the government seeks a long series of injunctions, the court may, of course, deny some and enter others.[32]

Compliance

If an injunction is entered, counsel for the defendant should make certain that the defendant understands the terms of the injunction. In case of violations of an injunction which also constitute violations of the Act, defendant is entitled to a jury trial under Section 302(b) of the Act.[33] But one trial in this area is enough for anybody, so the public interest, defendant's purse strings, and defense counsel's ulcers all demand strict and absolute adherence to the terms of the injunction. **[The End]**

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[31] *U. S. v. 4 Cases... Slim Mint,* No. 59 C 712 (N. D. Ill., 1960), and 300 F. 2d 144 (C. A. 7, 1962).

[32] *U. S. v. Lanpar Co.,* footnote 13 above.

[33] 21 U. S. C. 332(b).

Plaintiff's Fault as a Defense to Strict Liability

By WILLIAM J. CONDON

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WHAT IS THE EFFECT of an injured consumer's conduct upon the application of strict liability to a defectively manufactured product? Does plaintiff's contributory negligence bar his recovery in a strict liability situation? If so, is this contributory negligence the traditional concept applied over the years to ordinary negligence actions?

An appropriate starting point in seeking answers to these questions is to be found in the comment to Section 402A of the Restatement of Torts (second). Comment (n) to that section reads as follows:

> Since the liability with which this Section deals is not based upon negligence of the seller, but is strict liability, the rule applied to strict liability cases (see Section 524) applies. The contributory negligence of the plaintiff is not a defense when such negligence consists merely in a failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense under this Section as in other cases of strict liability. If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.

The language quoted is deceptively simple. However, as is the case with so many other rules of law, the application of this language to specific factual situations is not always quite so easy.

Divergent Conclusions

Indeed, courts which cite the quoted language with approval reach widely divergent conclusions as to its meaning. For example, the Supreme Court of Texas, in *Shamrock Fuel and Oil Sales Co., Inc. v. Tunks,* CCH PRODUCT LIABILITY REPORTS, 5796 (1967) said:

Under modern conditions of advertising and marketing, there exists a strong consumer reliance upon the integrity of the manufacturer and vendor of a product. The representation of safety in use is not restricted to those consumers of the reasonably prudent variety. It would be incongruous to hold that one could not recover upon the representation that a product was safe because he had failed to meet the test of the reasonably prudent man in discovering that the representation was not true.

Contrast that with the language of the Illinois Supreme Court in *Williams v. Brown Manufacturing Company, Inc.,* CCH PRODUCT LIABILITY REPORTS, 6193, wherein the Court said:

It is universally agreed that a necessary element of plaintiff's case is a showing that the defective condition renders the product unreasonably dangerous. In our opinion this necessarily implies that a plaintiff exercising due care for his own safety would not have discovered the defect. This conclusion is supported by Restatement comment which adopts the reasonable-man standard in the following language: 'The article sold must be dangerous to the extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.' (Restatement (Second) of Torts, 402A, comment(i).) Under this analysis, if a reasonable man would have discovered the defect, there is no defective condition unreasonably dangerous to the consumer and no cause of action exists.

The Illinois Court in the *Williams* case differentiated between contributory negligence, which it called the objective standard, and assumption of risk, which it called a subjective standard. The holding of the Court was clear that conduct of the plaintiff, which failed to measure up to the objective standard of the reasonably prudent man, and contributed to his injury, would be a bar to his recovery. It is equally clear that the Texas Court in *Shamrock* took a different view.

Contributory Negligence and Assumption of Risk

Three New Jersey cases may be useful to add to the confusion. In *Cintrone v. Hertz Truck Leasing,* 45 N. J. 434 (1965), the Court had held that the issue of contributory negligence was properly submitted to the jury where the facts showed that the plaintiff driver of the leased truck had known for several days that the brakes thereof were defective, and yet continued to drive the truck. You may recall that he also tried to drive a thirteen-foot truck through an eleven-foot underpass, but this was not the issue before the jury. Later that same year, in *Maiorino v. Weco Products Co.,* 45 N. J. 570 (1965), the Court again sustained the submission of the contributory negligence issue to the jury. Evidence indicated the plaintiff had cut his hand trying to open a glass toothbrush-container in an unusual and careless manner.

In March of this year, the issue was once again before the New Jersey Court in the case of *Ettin v. Ava Truck Leasing Inc.,* CCH

PRODUCT LIABILITY REPORTS, 6133. Plaintiff urged that *Cintrone* was concerned only with assumption of risk, and *Maiorino* only with misuse of property, and thus sought to have the Court confine any bar to plaintiff's recovery to those two situations. The Court declined, but did not make it clear that it would not do so in a proper case. The plaintiff's plea sought to avoid "the asymmetrical importation of contributory negligence terminology into an action not grounded on negligence." "But," said the Court, "that would involve the reintroduction of confusing terms and classifications which we have elsewhere sought to obviate (citing case) and although we consider it hardly necessary, the term 'contributory fault' could, if so desired, readily be substituted for the term 'contributory negligence'."

The so-called "assumption of risk" cases present no serious conceptual difficulties. Thus, we have no problem with the workman who inserts his hand into a glass-breaking machine while it is breaking glass. The Court held that even though the machine could have, and maybe should have, been designed with a guard by that opening, the action of plaintiff in putting his hand in the machine at that time constituted contributory negligence as a matter of law. As the Court said, "We hardly believe it is any more necessary to tell an experienced factory worker that he should not put his hand into a machine that is at that moment breaking glass than it would be necessary to tell a zookeeper to keep his head out of a hippopotamus' mouth." *Bartkewich v. Billinger,* CCH PRODUCT LIABILITY REPORTS, 6075 (Pa.) (1968).

So, too, we have little difficulty in agreeing with the Court that plaintiff was guilty of contributory negligence as a matter of law when, after cleaning his corn-picker with the power take-off running, he chose to remount the tractor from the front of the picker by placing his foot on the wet fender over the snapping rollers. When his foot slipped, the rollers amputated his leg (*Blunk v. Allis-Chalmers Manufacturing Company,* CCH PRODUCT LIABILITY REPORTS, 6076 (Ind.) (1968)).

In both of these cases, it was clear that the plaintiffs voluntarily exposed themselves to known and obvious dangers.

Misuse of Product and Foreseeable Use

Although it nowhere appears in the quotation from the comment to Section 402A with which we began, a third element of contributory negligence which crops up with increasing frequency in the cases is plaintiff's misuse of the product. Although it could be argued

that misuse by the plaintiff may negative a defect in the product, or may properly be directed to the issue of proximate cause, it is generally held by the Courts to be encompassed in a charge to the jury on contributory negligence. Inherent in the concept of misuse of the product is the necessity of defining the intended use. It should be obvious that intended use will encompass more than just the specific, narrow purpose for which the product is designed, if the manufacturer has reason to know that the product may be, and, in fact is, used for other purposes. It has been suggested that intended use may be no more than an adaptation of the idea of reasonable foreseeability. Here, again, the cases are not entirely harmonious with respect to the limits of such reasonable foreseeability.

The case of *Helene Curtis Industries, Inc. v. Pruitt*, CCH PRODUCT LIABILITY REPORTS, 5851 (USCA-5, 1967) contains a lengthy and lucid discussion of this problem. Plaintiff suffered loss of hair and burns to her scalp and ears as a result of the application of a bleach to her hair by a friend who was not a beautician. The bleaching process involved the mixture of two products of different manufacturers, both of which were marketed for professional use only, and at least one of which carried explicit instructions that it was to be mixed only with certain specified products which did not include the other used on the plaintiff. The Court of Appeals reversed a verdict for the plaintiff for the reason that the application of these products by an amateur was not within the marketing scheme of the defendants, and that their mixture was not an intended use of these products. Accordingly, plaintiff's injury was not within the ambit of reasonable foreseeability.

A comparable case is *Procter & Gamble Manufacturing Company v. Langley*, CCH PRODUCT LIABILITY REPORTS, 5960 (Tex. Civil Appeals, 1967). This was an action for injuries suffered by the plaintiff to her hair through the application of a permanent wave lotion. The jury found that the application of the product was the proximate cause of the loss of plaintiff's hair. The jury also found that plaintiff failed to follow directions with respect to a test curl, after her hair felt sticky and gummy she failed to use liquid neutralizer at once as directed, and that she waved more hair after feeling strands which were sticky and gummy, but that such acts on the plaintiff's part were not negligence. The Appellate Court reversed the judgment entered on the verdict of the jury and found for the defendant, holding that plaintiff's conduct amounted to an obvious misuse of the product.

It will be noted that in each of the two preceding cases, the Court found misuse or lack of intended use as a matter of law. In most cases these issues will be questions of fact.

For example, in *McDevitt v. Standard Oil Company of Texas,* CCH PRODUCT LIABILITY REPORTS, 5932 (USCA-5, 1968), plaintiff had insisted upon using oversized tires on his stationwagon in the face of warnings by the dealer that they were not appropriate. In addition, plaintiff disregarded the instructions in his owner's manual with respect to proper inflation pressures. He rode his car at high speeds and over rough terrain. When two tires came off while plaintiff's wife was driving at a high speed, resulting in serious injury to plaintiff's wife and several children, the Court held that the Trial Court properly submitted the issue of contributory negligence to the jury based upon plaintiff's misuse of the tires.

The final aspect of the question, to wit, the ambit of foreseeable use, was considered in *Olsen v. Royal Metals Corporation,* CCH PRODUCT LIABILITY REPORTS, 5896 (USCA-5, 1968). This case involved a hospital bed manufactured by the defendant which was sold as part of a hospital suite and not intended for the purpose of moving patients around the hospital. Plaintiff was a nurse whose Achilles tendon was severed when it was struck by a sharp bar on the leading edge of the bed while she was guiding the bed from one part of a hospital to another in the course of moving a patient. It was clear that there is a substantial difference in the construction of beds intended for moving patients and those which are intended to be stationary. However, there was also evidence that the hospital involved in this case, as well as other hospitals, frequently used beds of this type for moving patients and that this fact was known to the defendant. Under the circumstances, the Court held that whether or not the use of the bed in this case for moving a patient was a reasonably foreseeable use, and thus one for which the defendant would have responsibility, was a question of fact for the jury. It is prudent to assume that defendant will be liable for injuries caused by a defect in his product, not only during an intended use thereof, but also during a reasonably foreseeable misuse.

Combination of Concepts

The product area which promises to be the most prolific source of litigation, and which is guaranteed to produce the most complex combination of the concepts of intended use, misuse, reasonable foreseeability, and contributory negligence in general, is that of the

manufacture and design of automobiles. What is the responsibility of an automobile manufacturer when his product fails to withstand the impact of a head-on collision? One would expect this to be a very simple question to answer. It is not. Assuming, arguendo, that the manufacturer may have some responsibility, is that affected by the fact that plaintiff was driving while drunk? Does it make any difference whether the collision was caused by a defect in the car, or whether the injury resulted from the so-called "second collision" of the occupant with the interior of the vehicle? In the face of all that has been written and said about vehicle safety in recent years, it is not too rash to suggest that, in the immediate future, many garden-variety automobile negligence cases will be transformed into product liability actions.

The cases vary widely in their conclusions. In *Evans v. General Motors Corp.*, 359 F. 2d 822 (CA-7) cert. denied 385 U. S. 836, plaintiff's decedent was killed in a collision while driving a stationwagon manufactured by defendant. The complaint alleged that defendant, in not providing frame siderails, created an unreasonable risk to the occupants of the automobile in the event of an impact against the side of the vehicle. In upholding the dismissal of the complaint the Court of Appeals said: "The intended purpose of an automobile does not include its participation in collisions with other objects, despite the manufacturer's ability to foresee the possibility that such collisions may occur."

Conversely, the 8th Circuit in *Larsen v. General Motors Corp.*, 391 F. 2d 495, said: "While automobiles are not made for the purpose of colliding with each other, a frequent and inevitable contingency of normal automobile use will result in collisions and injury-producing impacts. No rational basis exists for limiting recovery to situations where the defect in design or manufacture was the causative factor of the accident, as the accident and the resulting injury usually caused by the so-called 'second collision' of the passenger with the interior part of the automobile, all are foreseeable."

It is important to note that the Evans Court was concerned with a charge that defendant had failed to make its car safer, whereas the Court in *Larsen* was dealing with an allegation that the manner in which the steering mechanism was manufactured greatly enhanced the danger to plaintiff in the event of a collision. In *Snipes v. General Motors Corp.*, CCH PRODUCT LIABILITY REPORTS, 6037 (Ohio Common Pleas, 1968), the Court of Common Pleas of Ohio dismissed a complaint charging that the defendant failed to design and manu-

facture the front portion of its automobile so as to withstand the impact of a head-on collision. The thrust of the opinion seems to be that a head-on collision was not an intended, even though it might be a foreseeable use of the vehicle.

In March of this year the Supreme Court of Georgia, in *General Motors Corp. v. Friend*, CCH PRODUCT LIABILITY REPORTS, 6131, was faced with the issue of the adequacy of a complaint which alleged that the truck manufactured by the defendant was defective in that the seats were inadequately attached to the vehicle. Plaintiff and his wife were riding in the truck when plaintiff drove off the road and hit a culvert. The sudden stop of the vehicle caused the shifting of 300 pounds of photographic equipment and other materials in the back of the truck against the seats which broke loose, causing injuries to both plaintiffs. The Georgia Court said:

> Driving the truck off the highway proper and hitting a culvert on the shoulder of the road, thus causing the shifting of the cargo, cannot be held to be a use intended by the manufacturer of the truck.

Where the evidence is sufficient to sustain a finding that the accident occurred as a result of a defect in the vehicle, plaintiff's contributory negligence is a question of fact for the jury. In *General Motors Corp. v. Walden*, CCH PRODUCT LIABILITY REPORTS, 6099 (USCA-10, 1969), there was evidence to sustain a finding that plaintiff's one-car accident was caused by a defect in the car. The Court held that the issue of contributory negligence, consisting of failure to use the seat belt and of driving while intoxicated (with a blood sample of .19% alcohol) was properly submitted to the jury. It follows, since this issue is one of fact, that the jury's determination that plaintiff's drunkenness and failure to use the seat belt did not contribute to his death, would not be disturbed on appeal.

There remains one further case to be considered in this area. This is *Adams v. Ford Motor Company*, CCH PRODUCT LIABILITY REPORTS, 6111 (Ill. App., 1969). Plaintiff had a new pickup truck, manufactured by defendant, for approximately three weeks. As he was rounding a curve, the truck ran onto the rippled area separating two lanes of traffic, veered to the right and went down an embankment. When the truck came to rest, the cab was separated from the chassis and plaintiff was injured. There was evidence from which the jury could have found that one of six bolts securing the cab to the chassis was missing and that this was the cause of the separation. There was also evidence from which the jury might have found that plaintiff was driving while intoxicated, driving at an excessive speed,

and failed to keep his vehicle under proper control. The Trial Court refused to permit defendant to amend his answer so as to allege contributory negligence, on the ground that, in a strict liability action, plaintiff's misconduct would not be a bar unless it was the sole cause of his injury. The Appellate Court of Illinois reversed on this issue, holding that plaintiff's contributory negligence will be a bar if it is a contributing cause, not necessarily the sole cause. In reaching this conclusion, the Court examined the Illinois law and found that contributory negligence, as it pertains to a case of strict liability, consists of voluntarily and unreasonably proceeding to encounter a known danger. It is not entirely clear what known danger the Court had in mind in this particular case. Surely, there was no evidence that plaintiff was aware of the missing bolt. This being so, the Court must have been considering the danger that exists generally in driving while intoxicated, or driving at an excessive speed. In spite of the Court's language, it would appear that this is an application of the traditional concept of contributory negligence.

Conclusions and Questions

A review of all of these cases leads to some reasonably clear conclusions and leaves the reader with some unanswered questions. It is apparent, for example, that one who proceeds to expose himself voluntarily and unreasonably to a known danger will be denied recovery. It is equally obvious that a consumer is not under an obligation to search for defects in products, and his recovery will not be denied by the mere fact that he has failed to guard against their existence.

With respect to the misuse of a product, we can conclude that recovery will not necessarily be barred where the misuse is reasonably foreseeable by the manufacturer. Whether the particular use is within the ambit of reasonable foreseeability will generally be a question of fact rather than law.

Finally, to what extent plaintiff will be barred from recovery by general acts of negligence, such as driving while intoxicated or conducting himself in such a fashion that the defect in the product, even though it exists, would not have produced his injury, is an area which is yet to be explored.

In any event, it appears clear that while strict liability is liability without negligence, it is not liability without fault, and the fault of the plaintiff, however it may be described, which contributes to the result, will be a bar to recovery. **[The End]**

Fault in Marketing— As an Element of a Manufacturer's Strict Liability

By WILLIAM P. WOODS

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OF THE MORE THAN FIVE HUNDRED SECTIONS of the Restatement of Torts, Second, there is little doubt that in recent years Section 402 A, which has no counterpart in the original Restatement, has been the best known and most widely cited. The Section itself has an interesting history, being more a statement of what its promulgators predicted would be "the law of the immediate future,"[1] rather than of what the law was at the time of publication.[2] One must concede, however, that the authors of Section 402 A correctly diagnosed the developing legal climate in the field of product liability;[3]

[1] Dean Keeton, writing in 1964 about Tentative Draft No. 10 of S402A of the Restatement of Torts (Second), which ultimately was adopted by the American Law Institute, stated "the American Law Institute made an educated guess or prediction as to what most courts would do when presented with the problem (of strict liability)," Keeton, Products Liability, "The Nature and Extent of Strict Liability," 16 *U. of Ill. L. F.* 963, 700 (1964).

[2] RESTATEMENT, (SECOND), TORTS S402A (Tentative Draft No. 10, 1964), 2. In 1962, when Tentative Draft No. 7 was distributed, the principle enunciated by S402A was limited to food and other products intended for intimate bodily use.

[3] Dean Prosser's ability as a prognosticator improved between 1960 and 1964. In the former year he wrote: "Thus far there has been very little indication that the time is ripe for what possibly may be the law of fifty years ahead. As in the case of the related agitation for automobile drivers, there are too many vested interests in the way and sudden change is likely to be regarded as too radical and disruptive, and progress in the direction of a broad general rule (of strict liability) cannot be expected to be rapid." Prosser, "The Assault Upon the Citadel," 69 *Yale L. J.* 1099, 1120-1 (1960).

for now, only five years after the adoption and promulgation of that section by the American Law Institute, a substantial and growing majority of American jurisdictions have espoused "strict liability," either as a tort, or by broadening the concept of implied warranty. However, although the phrase "liability without fault" is not infrequently found in judicial language, it does appear that the courts are far from imposing an insurer's liability on the nation's manufacturers.

Let us assume, for present purposes, that a manufacturer who markets a defective or faultily designed product will be held "strictly liable" to one who suffers injury by reason of the defect or fault. The aim of this paper is to inquire into the legal responsibility, under the strict liability theory of the manufacturer who has designed his product properly and has produced it as intended, to one who is harmed by reason of his use of that product, and to try to learn the "rules of the game" as formulated by judicial pronouncements.

Let us begin our inquiry by quoting that staunch advocate of "strict liability," Dean Prosser. Discussing the approach taken by various tribunals, he writes:

> There are still courts which have continued to talk the language of 'warranty'; but the forty-year reign of the word is ending, and it is passing quietly down the drain. . . . It would be easy, however, to overestimate the significance of the change, *which is more of theory than of substance.* It is only the rules of contract which have been jettisoned where there is no contract. The substance of the sellers' undertaking remains unaffected; and, as Chief Justice Traynor himself has agreed, the precedents of the 'warranty' cases will still determine what he must deliver. (Emphasis supplied.)[4]

The warranty cases, if I read them correctly, do not require a seller to deliver goods which are perfect, but only reasonably wholesome or fit for the purpose for which they are sold.[5]

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[4] Prosser, "The Fall of the Citadel," 50 *Minn. L. Rev.* 791, 804-805 (1966). Dean Wade argues that "(i)n strict liability, except for the element of scienter, the test is the same as that for negligence." Wade, "Strict Tort Liability of Manufacturers," 19 *S. W. L. J.* 5, 15 (1965).

[5] *E. G. Ryan v. Progressive Grocery Stores,* 255 N. Y. 388, 175 N. E. 105 (1931); *Taylor v. Jacobsen,* 336 Mass. 709, 147 N. E. 2nd 770 (1958); *Henningsen v. Bloomfield Motors, Inc.,* 32 N. J. 385 161 A. 2d 69 (1960). See also Williston on Sales, S. 243 (Rev. Ed. 1948). But, compare Rheingold, "What Are the Consumers' 'Reasonable Expectations'", 22 Bus. Law. 589 (1967) in which the author argues that the consumers' "reasonable expectations" are the criteria for evaluating the manufacturer's responsibility.

How, then, have manufacturers whose products were prepared and delivered in the condition intended, fared when damages have been sought by those injured as the result of the use of those products? A great deal depends on how the product has been marketed —did the manufacturer expressly warrant that his goods possessed a quality not actually present, were reasonable efforts taken to communicate adequate directions for use to the consumer, and did appropriate warnings accompany the product?

Polio Vaccine Case

One of the manufacturers of Sabin polio vaccine has fallen afoul of strict liability, applied as Montana law by the U. S. Court of Appeals for the Ninth Circuit in *Davis v. Wyeth Laboratories, Inc.*[6] Plaintiff complained that he had contracted poliomyelities as a result of consuming defendant's vaccine, but after receiving a charge that the manufacturer's duty was to supply vaccine "reasonably fit and reasonably safe for consumption by the public as a whole," the jury brought in a defendant's verdict. The Court of Appeals, while refusing to effect "such a far-reaching change in the law of products liability"[7] as would be involved in imposing what it called absolute enterprise liability, reversed the District Court's judgment on the grounds that defendant had failed to warn plaintiff of the risk to which the latter exposed himself when he took the vaccine.[8] Recognizing that, in the case of prescription drugs, the manufacturer discharges his obligation to warn if he directs the warning to the medical profession,[9] the Court refused to apply that rule to polio vaccine, dispensed "to all comers at mass clinics without an individualized balancing by a physician of the risks involved."[10]

The Court of Appeals relies on Section 402 A of the Restatement of Torts, Second, but reads the sentence beginning: "One who sells

[6] CCH PRODUCTS LIABILITY REPORTER ¶ 5908, 399 F. 2d 121 (CA-9 Idaho 1968).

[7] See footnote 6, above; 399 F. 2d at 126.

[8] Defendant had thoroughly warned the medical society which sponsored the polio immunization program and had revised its package insert to quote extensively the U. S. Surgeon General's report on the polio vaccine.

[9] *McGee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963); *Love v. Wolf*, 236 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); *Sterling Drug, Inc. v. Cornish* 370 F. 2d 82 (8th Cir., 1966).

[10] See footnote 6; 399 F. 2d at 131.

any product in a defective condition unreasonably dangerous to the user or consumer or his property is liable . . ." as if the word defective were not present. Comment (k) to Section 402 A, noting that some products "are quite incapable of being made safe for their intended and ordinary use," states that "(s)uch a product properly prepared, and accompanied by proper directions and warning, is not defective nor is it *unreasonably* dangerous" (emphasis in original).[11] The thrust of the language is clear, although the choice of words leaves something to be desired. An innately hazardous product, properly prepared and labeled, is neither defective nor unreasonably dangerous; without proper instructions and warnings, it is both.

The teaching of the *Davis* opinion is plain to see. The manufacturer of any drug which, although restricted by law to distribution under a physician's prescription, may be administered in a situation where the traditional individual patient-physician relationship is absent (consider, for example, drugs distributed at publicly-sponsored birth control clinics) acts at his peril if he fails to see that the consumers of the drug are informed of the possible adverse effects of taking the drug. While the consequences of this rule of law can be disastrous for public health programs involving mass administration of an immunizing prophylactic or therapeutic drug, where voluntary public cooperation is essential,[12] it is not necessarily equivalent to liability without fault. In *Davis,* the manufacturer, as the Court of Appeals viewed the record before it, could have been found to be at fault in failing to warn the consumers of the vaccine of the potential dangers of ingesting it, and the jury should have been given an opportunity to reach a decision on that issue. However, a basic flaw in the conclusion reached in *Davis* lies in the failure of the court to distinguish between the nature of the warning given to the medical profession, and that which might be given to laymen. The former must be detailed and technical; the latter would have

[11] See also RESTATEMENT OF TORTS (SECOND), S402A, comment (j), which states that a warning may be required to prevent a product from being unnecessarily dangerous if the hazard in the use of a product is not generally known and the seller does or should have knowledge of that danger.

[12] See *The New York Times,* May 22, 1968, p. 49 for a news story entitled "Children Frolic and Get 'Candy' Polio Vaccine."

to be comprehensible by the medically unlearned. The burden placed on a manufacturer of a product like a vaccine, not only to devise accurate and understandable warnings, but to police those over whom it has no real control in the latter's distribution procedures, may, in practice, prove to result in absolute liability. Such a result, I believe, would not only be bad law but, in several senses, bad medicine.

Insufficient Warning to Doctors

While the *Davis* case dealt with a drug manufacturer which had given a thorough warning to the medical profession, the Court of Appeals for the Eighth Circuit, in *Sterling Drug, Inc. v. Yarrow*[13] laid low a drug manufacturer who, according to the Court, was insufficiently assiduous in issuing to physicians a warning relating to possible adverse consequences of the use of one of its prescription drugs. The Appellate Court rejected the assertion that the District Court, in which the case had been tried without a jury, had imposed the duty upon defendant to warn the medical profession of the possible side-effects of its product "by the most effective method." However, the Court did find fault in the failure of the defendant to make use of its staff of detailmen, who regularly make calls on the practicing physicians who prescribe defendant's products, to bring to the attention of those physicians the newly discovered adverse side-effects of the drug which had been administered to plaintiff. The Court concluded:

> . . . that where a drug is manufactured without negligence, but is unreasonably dangerous if a reasonable warning of a side effect is not given, . . . the manufacturer may be held liable for the injury resulting from the failure to give a warning *reasonable under the circumstances.* (Emphasis supplied.)[14]

With the change of a few words, this language would be applicable to the universe of manufactured products. I submit that, in *Yarrow*, fault was found in the conduct of the defendant manufacturer, and it was this fault in marketing that provided the basis for the adverse opinion of the Court of Appeals. And the lesson of *Yarrow* is not hard to find—a manufacturer who discovers that one of his

[13] CCH PRODUCTS LIABILITY REPORTER ¶6125, 408 F. 2d 978 (CA-8 SD 1969).

[14] See footnote 13, above; 408 F. 2d at 993.

products, although properly designed and made, may cause harm to one who uses or consumes it, is most imprudent if he fails to inform the users or consumers of the danger by the same major means of communications that he uses to inform them of the beneficent qualities of his merchandise.

Warnings to Technicians

As I noted in discussing both the *Davis* and *Yarrow* cases, the manufacturer of a prescription drug is obliged to warn the medical profession of the dangers involved in the use of the drug. Counsel for manufacturers of equipment used under the direction of technicians or engineers probably have developed a greater interest in the prescription drug cases upon encountering the opinion of the U. S. Court of Appeals for the Ninth Circuit in *Jacobsen v. Colorado Fuel and Iron Corp.*[15] The Court, in affirming a judgment in favor of the manufacturer of steel reinforcing wire in an action brought to recover for the death of an employee of a manufacturer of prestressed reinforced concrete, specifically approved, as "obviously correct" a conclusion of law of the District Court with respect "to chattels, the use of which is to be directed by technicians and engineers." The manufacturer of such products, like drug manufacturers, need warn only the technically trained class which will direct the use of the products, and:

> there is no duty to warn those who simply follow the directions of the engineers and technicians, or to put it differently, there is no duty of the supplier of a chattel to foresee that the engineers or technicians will fail to follow warnings given or to employ knowledge possessed.[16]

The Court's language evinces an understanding that meaningful directions for use and warnings can be given only to those possessing the background necessary to understanding the intricate technology involved in the construction and operation of the products under consideration. One wonders, and not entirely in jest, whether manufacturers of such products should place in their literature, and perhaps even on the goods themselves, a statement reading "Caution: Not to be used except by or under the supervision of a licensed engineer."[17]

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[15] CCH PRODUCTS LIABILITY REPORTER ¶ 6171, 409 F. 2d 1263 (CA-9 Mont. 1969).

[16] See footnote 15, above; 409 F. 2d at 1273.

[17] See 21 CFR S1.106 (c)(2)(i), exempting certain veterinary drugs from labeling requirements if they bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

Warnings to Ultimate Users

A Court of Appeal of the State of California, the chief justice of whose Supreme Court has contributed so greatly to the development of the law of products liability,[18] came to grips with the duty to warn owed by a manufacturer of a tire to an employee of a retailer whose business included the sale of defendant's tires to the public. In *Casetta v. United States Rubber Co.*,[19] a tire repairman appealed a judgment entered against him notwithstanding a verdict in his favor. The sole issue submitted to the jury was that of the responsibility of the defendant tire manufacturer and distributor in strict liability by reason of the allegedly defective state of the tire that exploded as plaintiff was endeavoring to mount it on a rim. The Court of Appeal ruled that there was insufficient evidence in the record to support a finding that the involved tire had been defective, but reversed the trial court's judgment on the ground that the jury should have been given the opportunity to decide whether the defendants had discharged their responsibility to give appropriate directions for mounting their tires and had adequately warned the ultimate users of the tire, in which class it placed plaintiff, of the dangers of failure to follow those instructions. The manufacturer defendant, knowing that improper handling of his product during the mounting procedure could cause a serious accident, had distributed posters containing directions for proper use of the tires and warnings of the consequences of misuse. He had also placed a sticker on each tire stating mounting safety precautions. But the Court of Appeal saw two unresolved issues of fact:

1. Should defendants have known that its instructions were not being followed, and if so, should its warning have been strengthened by specific reference to safety rims?

2. To what extent were the instructions "communicated to the retailer by the manufacturer and the distributor in this instance, and to the plaintiff himself?"

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[18] Traynor, "The Ways and Meanings of Defective Products and Strict Liability," 32 *Tenn. L. Rev.* 363 (1965); *Vandermark v. Ford Motor Co.*, 61 Cal. 2d 256, 391 P. 2d 168 (1963); *Greenman v. Yuba Power Products, Inc.*, 39 Cal. 2d 57, 377 P. 2d 897 (1963); *Escola v. Coca Cola Bottling Co.*, (concurring opinion), 24 Cal. 2d 453, 150 P. 2d 436 (1944).

[19] CCH PRODUCTS LIABILITY REPORTER ¶ 5980, 260 Cal. App. 2d 792, 67 Cal. Rptr. 645 (1968).

Regarding the first issue, while one cannot quarrel with the proposition that a manufacturer is charged with knowledge of how his products are used generally and cannot ignore a widespread abuse, no fault can be attributed to the manufacturer if, in the absence of that situation, harm is inflicted on one who does misuse his products.

But the second issue, as framed by the Court of Appeal, seems to refer to actual communication of the instructions and warnings to plaintiff. I suggest that the manufacturer's duty does not go that far. The manufacturer is responsible for utilizing means reasonably calculated to bring instructions and warnings to the users and consumers of his goods.[20] If a user or consumer actually does not see the warning or directions despite those efforts of the manufacturer, that failure is not, as I see it, the fault of the manufacturer and, consequently, the latter should not, under such circumstances, be held responsible for any injury incurred by the uninstructed or unwarned user or consumer. But the lesson of *Casetta* comes through loud and clear. A manufacturer with a problem product, having prepared adequate instructions and warnings and having devised reasonably effective means of distributing the warnings (in the case of consumables, the label obviously is the means of communication best calculated to reach the consumer) should make continued effort to find out how the product is actually being used. He may find out, as suggested by the California Court, that his warning should be strengthened, or his instructions clarified. Or, he may have to make some alteration in his product or formula to prevent uses or manner of employment of his product against which he has warned, but which, nevertheless, continue to be prevalent.

Contents and Communication

In light of the references in this paper to "warnings reasonable under the circumstances"[21] and "means reasonably calculated to bring instructions and warnings to users and consumers"[22] of goods, it is not inappropriate to explore the knotty and related subjects of the

[20] RESTATEMENT OF TORTS (SECOND) S.388, comment (1).

[21] See footnote 14 above.

[22] See footnote 20 above.

content of the instructions and warnings and the means used to communicate them. The concept of reasonableness is, of course, elastic, and not at all subject to precise delimitation. However, there are some vague guides. If goods are to be used only by or under the direction of skilled professionals, for example, prescription drugs or highly technical equipment, as in *Jacobsen,* the instructions and warnings are to be directed to those professionals and should be technically detailed and comprehensive. In the case of goods intended for use or consumption by the public, the instructions and warnings which must be publicized in such a manner as to reach the consumer, usually on the label, must be clear and accurate, sufficiently prominent,[23] and intelligible to the consumer,[24] with an intensity appropriately related to the foreseeable risk involved in the product's use.[25]

Between the manufacturers whose products are used only by or under the direction of professionals and those who produce goods for public consumption are the producers of goods for use in industry. The actual users of such products are the employees of the manufacturer's customers, and the manufacturers are faced with the difficulty of deciding the means of warning those exposed to the hazards of use. The Court of Appeals for the First Circuit in *Hubbard-Hall Chemical Co. v. Silverman*,[26] an action based on negligence, approved a plaintiff's verdict in favor of the representatives of two hired hands who had died as a result of exposure to defendant's parathion spray. The decedents apparently had ignored the instructions given to them to use masks and coats which their employer, who had purchased defendant's product, had available. They were of limited education and one could not read English. Consequently, said the appellate court, despite the governmentally-approved warning appearing on the label of defendant's product stating that it was dangerous and that persons using it should cover themselves, the jury was within its province in finding that defendant should have foreseen that the

[23] *Maize v. Atlantic Refining Co.*, 352 Pa. 51, 41 A. 2d 850 (1945).

[24] *Haberly v. Reardon Co.*, 319 S. W. 859 (Mo. Sup. Ct., 1958).

[25] *Spruill v. Boyle-Midway, Inc.*, 308 F. 2d 79 (4th Cir., 1962).

[26] 340 F. 2d 402 (1st Cir., 1965).

spray would be used by uneducated people like the decedents and that a pictorial warning, such as a skull and bones, would be needed to give an "adequate instruction or warning."

The holding of *Hubbard-Hall* is a hard one, since defendant clearly had communicated the hazards of use of its products to its customer who, at trial, testified that he specifically told his employees, including the decedents, to wear masks and coats. Perhaps the proper evaluation of *Hubbard-Hall* was very recently made by the Kansas Supreme Court which affirmed a judgment in favor of the manufacturer of a resin product sold to an airplane manufacturer.[27] One of the latter's employees asserted that he had been injured by exposure to the product which was admitted to be "potentially dangerous if inhaled over a long period of time." The Kansas Court noted that *Hubbard-Hall's* product could and did produce sudden death and, therefore, its manufacturer could not content itself with utilizing a third party to warn of the dangers of use. The court quoted, with approvation, the following from the Restatement of Torts (Second):

> Since the care which must be taken always increases with the danger involved, it may be reasonable to require those who supply others chattels which, if ignorantly used, involve grave risk of physical harm to those who use them and those in the vicinity of their use, to take precautions to bring the information home to the users of such chattels which it would be unreasonable to demand were the chattels of a less dangerous character.[28]

Judicial Activism

I think we all recognize that the change which has been effected in our concepts of product liability in the last decade is the result of a judicial activism comparable to that displayed by judges in the areas of civil rights[29] and of legislative representation.[30] The

[27] *Younger v. Dow Corning Co.*, CCH PRODUCTS LIABILITY REPORTER ¶ 6135, 202 Kan. 674, 451 P. 2d 177 (1969).

[28] RESTATEMENT OF TORTS (SECOND) S388, comment on Sub-Section (c) (1965).

[29] For example, *Brown v. Board of Education*, 347 U. S. 483 (1954); *Hunter v. Ericson*, 393 U. S. 385 (1969); *Shapiro v. Thompson*, 394 U. S. 681 (1969).

[30] For example, *Baker v. Carr*, 369 U. S. 186 (1962); *Reynolds v. Sims*, 377 U. S. 533 (1964); *Lucas v. Forty-Fourth General Assembly of Colorado*, 377 and S. 713 (1964).

law does not and, indeed, cannot live in a vacuum and it is unavoidably shaped by mutations in technology, social conditions and public mores. Lord Abinger, in 1842, wrote that "the most absurd and outrageous consequences, to which I can see no limit, would ensue"[31] if the obligation of the owner of a mail coach, hired out to the Postmaster General, to keep his equipment safe for use were held to protect any one other than the Postmaster General with whom he had contracted; Chief Justice Traynor, in 1963, stated:

> The purpose of such (strict) liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers which put such products on the market, rather than by the injured persons who are powerless to protect themselves.[32]

The two learned judges are but products of their times, and the chasm which separates their approach to a manufacturer's liability for defective products simply mirrors the vast difference between early Victorian England and mid-twentieth century America. However, even in this age of mass production and media advertising, we have not reached the stage of absolute liability. A manufacturer who properly designs his products to accomplish their objectives, and who manufactures those products so that they are not defective, has fulfilled his obligation to the users and consumers of those products if, in marketing them, to use a phrase which probably would be viewed with horror by Lord Abinger, "he tells it like it is."

[The End]

[31] *Winterbottom v. Wright*, 152 *Eng. Rep.* 402, 405 (1842).

[32] *Greenman v. Yuba Power Products, Inc.*, 59 Cal. 2d 57, 63, 377 P. 2d 897, 901 (1963).

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LAW JOURNAL

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