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Food Drug Cosmetic Law JOURNAL

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

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REPORTS

TO THE READER

Sword or Shield.—In his article, "Statutory Liability: The Federal Hazardous Substances Labeling Act," on page 412, *Ralph Levine,* a recent Food Law Institute Fellow and at the present time a member of the Legal Department of Carter Products, Inc., New York, has attempted to establish that the Act can be a powerful sword in the hands of an injured consumer. He carefully notes that the Act can also be an effective shield for the manufacturer who adheres to its requirements.

The Act now provides the following benefits to a manufacturer of household products:

(1) It sets up specific guidelines for determining which products are considered inherently dangerous and which therefore require a warning statement; and

(2) It specifies in great detail, the content, position, and prominence of the warning statements which must appear.

"If the Act is complied with, the only question that would remain to be decided in a civil suit for damages would be whether or not the warning given was adequate," the author states.

British Food Advertising Law.—In an article on page 441, the author, *C. A. Adams,* the former director of the Food Standards and Labeling Division of the United Kingdom Ministry of Food, presents a picture of modern food legislation in Britain. The author states that it was not until the passing of the 1938 Food and Drugs Act that advertisements were even mentioned. The author continues with a rapid survey of the relationship of the basic measures, and considers how things have gone since the Food and Drugs Act of 1938 first brought misleading labels and advertisements into the net.

"If there are trends in food advertising today which are open to criticism as being unethical and contrary to the consumer's interest, there is now power to deal with them by regulation," the author emphasizes. However, he goes on to state, "I believe it is high time that some of the trends in modern food advertising were critically and officially reviewed."

The Physician and FDA.—". . . good and potent drugs continue to appear for your use. But as the potency of these drugs increases, so generally does their complexity and their potentiality for harm. Consequently, it is your duty to fully inform yourself of the composition, mode of action, efficacy, and potential toxicity of these agents before you embark on their use. This information is readily available to you in all package inserts, in direct mailing pieces, and in brief summary form even in prescription drug advertising. You owe a duty to your patient to use this information." *Joseph F. Sadusk, Jr., M. D.,* FDA's medical director, expressed this opinion in an article appearing at page 451.

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Food·Drug·Cosmetic Law Journal

Statutory Liability: The Federal Hazardous Substances Labeling Act – Sword or Shield?

by RALPH LEVINE

The Following Paper Was Written by Ralph Levine, a Recent Food Law Institute Fellow. Mr. Levine Is in the Legal Department of Carter Products, Inc., New York.

THE IMPOSITION OF LIABILITY based on the violation of a statute is not something new or foreign to the courts. The rules that are applicable have become settled and are discernible.

Where the violation of a statute is relied upon, the prospective plaintiff will be able to utilize the statute either to maintain a cause of action theretofore unrecognized by the law or to assist with the burden of proof in an existing cause of action.[1] In the latter case, the proceeding is not a statutory one, but rather a common law action in negligence. The nature of the proceeding was expressed in *Midwest Game Company v. M. E. A. Milling Company*,[2] a civil action for damages based upon violation of the Federal Food, Drug and Cosmetic Act:

> We therefore assume that the plaintiffs pleaded the violation of the act in an effort to aid their claims of negligence on the part of defendant under the general rule that a violation of a statutory duty . . . designed for the protection of the person claiming to have been injured by reason of the violation is negligence . . . and an injured party may institute an action at common law for negligence, and set up and prove a violation of a statute . . . as constituting a negligent act on the part of the defendant.[3]

[1] See, *Restatement, Torts*, Sec. 286, comment (a) at pp. 519-20 (1934).

[2] 320 S. W. 2d 547 (Mo. 1959).

[3] Case cited at footnote 2, at p. 552.

It is basic to the concept of fault liability grounded on negligence that there can be no liability where the actor conformed to the standard of conduct of a reasonable man under like circumstances.[4] This standard of conduct may be established by a legislative enactment, judicial decision, or may be applied to the facts of the case by the jury.[5] Where it is established by a legislative enactment, it may be interpreted as fixing a standard for all members of the community. Any deviation from this standard would be negligence. As was said in *Osborn v. McMasters:*

> Negligence is the breach of legal duty. It is immaterial whether the duty is one imposed by the rule of common law requiring the exercise of ordinary care not to injure another, or is imposed by a statute designed for the protection of others . . . . The only difference is that in the one case the measure of legal duty is to be determined upon common law principles, while in the other the statute fixes it, so that the violation of the statute constitutes conclusive evidence of negligence . . . . All that the statute does is to establish a fixed standard by which the fact of negligence may be determined.[6]

Some statutes specifically provide for the creation of civil liability. However, the bulk of the statutes which have been found to create a statutory duty are penal in nature. This fact will not prevent it from imposing civil liability even though there is no express provision for it.[7]

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[4] *Charbonneau v. MacRury,* 84 N. H. 501, 153 A. 457 (1931); *Osborne v. Montgomery,* 203 Wis. 223, 234 N. W. 372 (1931); See, James, "The Qualities of the Reasonable Man in Negligence Cases," 16 *Missouri Law Review* (1951); Seavey, "Negligence—Subjective or Objective," 41 *Harvard Law Review* 1, 27 (1927); *Restatement, Torts,* Sec. 283 (1934).

[5] See, Lowndes, "Civil Liability Created by Criminal Legislation," 16 *Minnesota Law Review* 361 (1932); Morris, "The Relation of Criminal Statutes to Tort Liability," 46 *Harvard Law Review,* 453 (1933); Notes, 32 *Columbia Law Review* 712 (1932); 13 *Cornell Law Quarterly* 634 (1928); 19 *Minnesota Law Review* 666 (1935); *Restatement, Torts,* Sec. 285 (1934).

[6] 40 Minn. 103, 105, 41 N. W. 543, 544 (1889). See, Thayer, "Public Wrong and Private Action," 27 *Harvard Law Review* 317, 322 (1914).

[7] *Parker v. Barnard,* 135 Mass. 116 (1883); *Kavanagh v. New York, O. & W. R. Co.,* 196 App. Div. 384, 187 N. Y. S. 859 (1921), aff'd 233 N. Y. 597, 135 N. E. 933 (1922). This result has been explained by postulating that a reasonable man would obey the criminal law, and if he does not, he is not acting as a reasonable man and therefore must be negligent; *Thayer,* cited at footnote 6. Prosser, in 32 *Minnesota Law Review* 105, 108 (1948), sets forth what he feels to be a more sensible theory:

"No doubt the most tenable explanation is that the court finds in the statute an expression of a policy for the protection of a particular class of people against the forbidden conduct, and that in furtherance of that policy it is proceeding by a species of judicial legislation, well grounded in precedent, to afford an additional remedy of its own. If there has to be a theory, this one at least preserves some leeway for discrimination, and avoids the strait jacket of any reasoning which would

(Continued on following page.)

In many cases, the evident policy of the legislation is to protect only a limited class of individuals, and the plaintiff must bring himself within that class in order to maintain an action based on the statute.[8] The same limitation is further expressed in the requirement that the harm suffered must be of the kind which the statute was generally intended to prevent.[9] Where the statute is interpreted as having been intended to protect the class of persons in which the plaintiff is included against the risk of the type of harm which has in fact occurred, the weight of authority holds that an unexcused violation is negligence per se and that the court must so direct the jury.[10] The question of negligence is no longer an issue in the proceedings. The defendant's liability is based upon the failure to comply with an absolute rule of law embodied in the statute, rather than a social standard created by the jury for that particular case.[11]

A considerable minority has held that violation of a statute is only evidence of negligence which the jury may accept or reject as it sees fit.[12] When translated into procedure, this rule simply means that the jury is to have the function of deciding the fault issue. Here, instead of the legislature creating and setting the standard, the jury sets one of its own.[13]

(Footnote 7 continued.)
result in a rigid rule allowing a tort action for all damages resulting from any criminal act." Contra, *Richmond v. Warren Institution for Savings,* 4 NEGLIGENCE CASES 904, 307 Mass. 483, 30 N. E. 2d 407 (1940); Lowndes, cited at footnote 5.

[8] *Meshbesher v. Channellene Oil & Mfg. Co.,* PRODUCT LIABILITY CASES 824, 107 Minn. 104, 119 N. W. 428 (1909); *Boronkay v. Robinson & Carpenter,* 247 N. Y. 365, 160 N. E. 400 (1928); *Kelly v. Henry Muhs Co.,* 71 N. J. Law 358, 59 A. 23 (1904).

[9] *Lang v. New York Central R. R. Co.,* 255 U. S. 455 (1921); *St. Louis, S. F. R. Co. v. Conarty,* 238 U. S. 243 (1914); Lowndes, cited at footnote 5.

[10] *Larkins v. Kohlmeyer,* 229 Ind. 391, 98 N. E. 2d 896 (1951); *Martin v. Herzog,* 228 N. Y. 164, 126 N. E. 814 (1920); *Schell v. Du Bois,* 94 Ohio St. 93, 113 N. E. 664 (1916). See, Notes, 32 *Columbia Law Review* 712 (1932); 29 *Kentucky Law Journal* 489 (1941); *Restatement, Torts,* Sec. 286 (1934).

[11] See note, "The Effect of Pure Food Statutes on Civil Liability," 26 *Virginia Law Review* 100 (1939). The author of this note states that there is a fundamental distinction between negligence in the sense of lack of due care and negligence as a matter of law arising from the violation of a statutory duty. In the former case, the measure of the legal duty is determined by the jury; in the latter it is predetermined by the legislature. Since the legislature is paramount, he feels it would be incorrect to refer to a violation of a statutory duty as only prima facie evidence of negligence or as mere evidence of negligence.

[12] *Guinan v. Famous Players-Lasky Corp.,* 267 Mass. 501, 167 N. E. 235 (1929); *Jones v. Co-Operative Ass'n,* 109 Me. 448, 84 N. E. 985 (1912).

[13] See Morris, cited at footnote 5.

A few jurisdictions have held that the violation of a statute creates a presumption of negligence.[14] This presumption can be rebutted where the defendant can show adequate reasons for noncompliance. In the absence of such showing a binding instruction must be given.

Proximate Cause

Regardless of whether the violation of a statute is considered as negligence per se, evidence of negligence, or a presumption of negligence, the plaintiff, to be entitled to recover, must show a casual connection between the injury received and the violation of the statutory prohibition or mandate. In other words, he must show that the violation of the statute was the proximate cause of the injury.[15]

Foreseeability and Due Care

Common law negligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk. It involves a foreseeable risk, a threatened danger of injury, and conduct unreasonable in proportion to the danger. If the defendant could not reasonably foresee any injury as the result of his act, or if his conduct was reasonable in the light of what he could anticipate, there is no negligence, and therefore no liability.[16] However, where the negligent act, complained of is based on the violation of a statute, the person guilty of it is liable for the consequences, whether he could have foreseen them or not.[17] This is predicated upon the principle that when an act is forbidden by express provision of law, the standard of the legislature becomes absolute. For the very same reason, liability will be imposed irrespective of the amount of care the defendant might have exercised.[18]

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[14] *Satterlee v. Orange Glenn School Dist.*, 29 Cal. 2d 581, 177 P. 2d 279 (1947); *Nadeau v. Perkins*, 135 Me. 215, 193 A. 877 (1937); *Landy v. Hubert*, 101 Vt. 111, 141 A. 593 (1928).

[15] *Cary v. Los Angeles Ry. Co.*, 157 Cal. 599, 108 P. 682 (1910); *Milbury v. Turner Centre System*, 247 Mass. 358, 174 N. E. 471 (1931); *Klinkenstein v. Third Ave. R. Co.*, 246 N. Y. 327, 158 N. E. 886 (1927).

[16] *Mendelson v. Davis*, 281 F. 18 (CA-8 1922); *Nunam v. Bennett*, 184 Ky. 591, 212 S. W. 570 (1919); *Stephens v. Mutual Lumber Co.*, 103 Wash. 1, 173 P. 1031 (1918); Carpenter, "Workable Rules for Determining Proximate Cause," 20 *California Law Review* 229, 396 (1932); Foster, Grant, and Green, "The Risk Theory and Proximate Cause," 32 *Nebraska Law Review* 72 (1952); *Restatement, Torts*, Sec. 435 (1934).

[17] *Lynghaug v. Payte*, 247 Minn. 186, 76 N. W. 2d 660 (1956); *Butts v. Ward*, 227 Wis. 387, 279 N. W. 6 (1938); 56 A. L. R. 2d 1090 (1957).

[18] *White v. Rose*, 241 F. 2d 94 (CA-10 1957); *Donaldson v. Great Atlantic & Pacific Tea Co.*, 1 NEGLIGENCE CASES 96, PRODUCT LIABILITY CASES 942, 188 Ga. 870, 199 S. E. 213 (1938).

Compliance with a Statutory Duty—Only Evidence of Due Care

Whereas violation of a statute may be negligence, it should be noted that compliance with it will not in all cases be considered due care. The statutory standard may be only a minimum and does not necessarily preclude a finding that the actor was negligent in failing to take additional precautions.[19]

Defenses: Contributory Negligence and Assumption of Risk

To the common law liability for negligence, contributory negligence of the plaintiff is ordinarily a good defense.[20] The same is true for the defense of assumption of risk.[21] The question has frequently arisen as to whether the same rules apply where the duty of care arises not under the common law rules of negligence, but under statutes prescribing or prohibiting a course of conduct.

The great majority of courts have taken the view that unless expressly precluded by statute, contributory negligence of the plaintiff is a good defense to an action based on the violation of a statute.[22] The theory underlying the view of the majority is that the court will not abrogate a common law defense unless it is negated expressly by the statute.

A number of courts argue that the common law effect of contributory negligence is confined to actions for negligence under the common law. Therefore, unless contributory negligence is adopted expressly by the statute, they will not apply it to actions for violation of statutory duty.[23]

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[19] *Grand Trunk R. Co. v. Ives,* 144 U. S. 408 (1892); *Phillips v. Roux Laboratories, Inc.,* 286 App. Div. 549, 145 N. Y. S. 2d 449 (1955); *Curtis v. Perry,* 171 Wash. 542, 18 P. 2d 840 (1933).

[20] *Ware v. Saufley,* 194 Ky. 53, 237 S. W. 1060 (1922); *Chesapeake & O. R. Co. v. Wills,* 111 Va. 32, 68 S. E. 395 (1910); *Gilman v. Central Vermont R. Co.,* 93 Vt. 340, 107 A. 122 (1919); James, "Contributory Negligence," 62 *Yale Law Journal* 691 (1953); *Restatement, Torts,* Sec. 463 (1934).

[21] *Brisson v. Minneapolis Baseball & Athletic Ass'n,* 185 Minn. 507, 240 N. W. 903 (1932); *Murphy v. Steeplechase Amusement Co.,* 250 N. Y. 479, 166 N. E. 173 (1929); *Cleary v. Eckart,* 191 Wis. 114, 210 N. W. 267 (1926).

[22] *Narramore v. Cleveland, C. C. & St. L. R. Co.,* 96 F. 298 (CA-6, 1899); *Brown v. Siegle, Cooper & Co.,* 191 Ill. 226, 60 N. E. 815 (1901); *Keenan v. Edison Electric & Co.,* 159 Mass. 379, 34 N. E. 366 (1893); *Bentson v. Brown,* 186 Wis. 629, 203 N. W. 380 (1925); 10 A. L. R. 2d 853 (1950); 171 A. L. R. 894 (1947).

[23] *Byrne v. Kansas City Ft. S. & M. R. Co.,* 61 F. 605 (CA-6, 1894); *Bartzfield v. Sutton,* 180 Kan. 46, 299 P. 2d 584 (1956); *Hairston v. United States Leather Co.,* 143 N. C. 512, 55 S. E. 847 (1906); 10 A. L. R. 2d 853 (1950).

Where the question of assumption of risk has arisen, the majority of courts have held that this defense can also be asserted by the defendant to defeat recovery.[24]

When Contributory Negligence Is Not a Defense—Exceptional Statutes

There are certain statutes which seek to protect a limited class of persons from their inability to protect themselves. It has been held that the evident purpose of these statutes would be defeated if the defendant were permitted to set up the contributory negligence of the plaintiff, and that the legislature must have intended that no such defense should be available.[25]

Sometimes, as in the Federal Employers' Liability Act, the statute contains express language leaving no doubt.[26] However, the statute itself is usually silent, and the court will then find the intent from its character and obvious purpose, from the background of the social problem, and from the particular hazard at which it is directed. Typical cases are those of the child labor acts. These are found to be intended to place all responsibility for injuries to a child upon the employer, thus making him liable even though he has acted in good faith and has employed the infant in ignorance of his age.[27]

A close analogy is suggested by these statutes to the pure food acts of various states. These are intended for the protection of

[24] *White v. Cochrane,* 189 Minn. 300, 249 N. W. 328 (1933); *LeDux v. Alert Transfer & Storage Co.,* 145 Wash. 115, 259 P. 24 (1927); *Knipfer v. Shaw,* 210 Wis. 617, 246 N. W. 328 (1933).

[25] *Marinao v. Lehmaire,* 173 N. Y. 530, 66 N. E. 572 (1903); *Lenahan v. Pittston Coal Mining Co.,* 218 Pa. 311, 67 A. 642 (1907); *Pinoza v. Northern Chair Co.,* 152 Wis. 473, 140 N. W. 84 (1913).

[26] 35 Stat. 65 (1908), 45 U. S. C. Secs. 51-60 (1940). (The Act provides that contributory negligence is not a complete defense but goes only to reduce the damages.) The Federal Safety Appliance Act does not deprive a carrier of the right to interpose the defense of contributory negligence. However, by a provision of that act the defense of assumption of risk is expressly included. *Schlemmer v. Buffalo R. & P. R. Co.,* 220 U. S. 590 (1911). The same is true for the Federal Employers' Liability Act. In some states, the defense of contributory negligence in certain types of actions is expressly abolished by statute. For example, *Williams v. Atlantic Coast Line R. Co.,* 168 N. C. 360, 84 S. E. 408 (1915) (in actions by servants against masters for personal injuries).

[27] *Lenahan v. Pittston Coal Mining Co.,* cited at footnote 25; *Pinoza v. Northern Chair Co.,* cited at footnote 25. Similar statutes are those prohibiting the sale of firearms and other dangerous articles to minors. *Pizzo v. Wieman,* 149 Wis. 235, 134 N. W. 899 (1912). To the same effect are statutes requiring precautions for the protection of intoxicated persons. *Hauth v. Sambo,* 100 Neb. 160, 158 N. W. (1916); *Davies v. McKnight,* 146 Pa. 610, 23 A. 320 (1892). See *Restatement, Torts,* Sec. 483 (1934).

purchasers who, in many instances, are likewise little able to protect themselves. But ordinary public safety statutes, like the pure food acts, are found to lack the special considerations and background of policy contained in such legislation as the child labor acts. Thus, it has consistently been held that contributory negligence is a defense to a charge of negligence based upon their violation.[28]

The Federal Hazardous Substances Labeling Act

The Federal Hazardous Substances Labeling Act [29] became law on July 12, 1960, with an effective date of February 1, 1961. The purpose of the Act was to fill the legislative gap in regulation of labeling hazardous household products. Economic poisons are regulated under, and labeled in accordance with, the provisions of the Federal Insecticide, Fungicide and Rodenticide Act of 1947.[30] Foods, drugs and cosmetics are subject to the provisions of the Federal Food, Drug and Cosmetic Act of 1938.[31] Except for the 12 chemicals listed in the Federal Caustic Poison Act,[32] substances which were neither economic poisons nor foods, drugs, or cosmetics were not regulated at the federal level with respect to precautionary labeling.

The new Act is intended to cover the great variety of cleaners, polishes, waxes, detergents and specialty chemical products brought about by research during and following World War II. Many of these products, although toxic, are not offensive in appearance or odor, and physicians have become alarmed at the increasing number of injuries, sometimes fatal, which result from their accidental ingestion. In the past, some products have been labeled to caution against misuse; but others have not, or have not afforded the essential data on composition and antidotes which a physician may need. Without such information, ensuing delays in treatment have often proved fatal. In a single year, there were more than 200,000 poisonings in the United States, resulting in approximately 5,000 deaths and the

[28] *Kelly v. John R. Daily Co.*, 56 Mont. 63, 181 P. 326 (1919); *Friedman v. Beck*, 250 App. Div. 87, 293 N. Y. S. 649 (1937); *Kurth v. Krumme*, 11 NEGLIGENCE CASES 69, 143 Ohio St. 638, 56 N. E. 2d 227 (1944); *Tate v. Mauldin*, 157 S. C. 392, 154 S. E. 431 (1930).

[29] FOOD DRUG COSMETIC LAW REPORTS ¶ 1000, 74 Stat. 372 (1960), 15 U. S. C. 1261-1273 (Supp. 1961). Citations to this act will hereinafter be cited as FHSLA, Sec. —.

[30] FOOD DRUG COSMETIC LAW REPORTS ¶ 840; 61 Stat. 163 (1947), 7 U. S. C. 135 (1958).

[31] FOOD DRUG COSMETIC LAW REPORTS ¶ 25, 52 Stat. 1040 (1938), 21 U. S. C. 301-392 (1958).

[32] FOOD DRUG COSMETIC LAW REPORTS ¶ 950, 44 Stat. 1406 (1927), 15 U. S. C. 401-411 (1958).

loss of over 89,000 man-years.[33] The gravity of the situation led to the creation of over one hundred and thirty-two Poison Control Centers throughout the country, and to the creation of a National Clearing House for Poison Control Centers in Washington, D. C.[34]

The agitation and need for a more comprehensive law culminated in the passage of the Hazardous Substances Labeling Act. It is designed to warn users and parents of the inherent dangers which exist in things commonly seen and used around the home, to prescribe adequate precautionary measures, to inform physicians and others of the composition of a hazardous product, and to provide adequate first-aid measures where necessary.

Definition of a Hazardous Substance

To come within the statutory definition of a hazardous substance, a product must meet three tests. First, it must be in a container "intended or suitable for house-hold use." [35] Secondly, it must be a substance or a mixture of substances that is toxic,[36] an irritant,[37] a

[33] Vital Statistics of the United States (1958), in press, United States Department of Health, Education and Welfare, National Office of Vital Statistics.

[34] A Poison Control Center is a place to which a physician can phone when called upon to treat a poisoning victim and obtain any available information concerning the composition of the ingested article and any available antidote information.

[35] FHSLA Sec. 2(p)(1), FOOD DRUG COSMETIC LAW REPORTS ¶ 9081. By regulation the term "container" has been given a liberal interpretation to include any carton, bottle, can, bag, tube, or other container which under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around the household, 21 CFR 191.1(c), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301. Also included are containers for such articles as polishes or cleaners designed primarily for professional use, but available in retail stores (such as hobby shops) for non-professional use. Such items as antifreeze and radiator cleaners, although principally for car use, are also included because they may be stored in or around dwelling places. However, industrial supplies that might be taken into a home by a service man would be excluded. The term "household" itself has been broadly defined to encompass a house, apartment or other place where people dwell, or in or around any related building or shed, including but not limited to a garage, carport, barn or storage shed.

[36] A *toxic* substance is defined as any substance which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface. FHSLA Sec. 2(g), FOOD DRUG COSMETIC LAW REPORTS ¶ 9063. The regulations particularize "toxic" substance in terms of specific test procedures. 21 CFR Sec. 191.1(f), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301. Substances which are "highly toxic" are defined in the Act itself in terms of specific test procedures. FHSLA Sec. 2(h)(1), FOOD DRUG COSMETIC LAW REPORTS ¶ 9065. See 21 CFR Sec. 191.1(e), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

[37] An *irritant* is defined as any substance not corrosive but which on immediate, prolonged or repeated contact with normal living tissue will induce a

(Continued on following page.)

strong sensitizer,[38] corrosive,[39] flammable,[40] or one that will generate pressure through decomposition, heat, or other means.[41] Thirdly, it must be a product that "may cause substantial personal injury or substantial illness[42] during or as a proximate result of any customary

(Footnote 37 continued.)
local inflammatory reaction. FHSLA Sec. 2(j), FOOD DRUG COSMETIC LAW REPORTS ¶ 9069. By regulation the term is interpreted to include primary irritant to the skin as well as substances irritant to the eye or to mucous membranes. 21 CFR Sec. 191.1(g), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

[38] A *strong sensitizer* is defined as any substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance, and which is designated as such by the Secretary. FHSLA Sec. 2(k), FOOD DRUG COSMETIC LAW REPORTS ¶ 9071. The regulation denotes a "strong allergenic sensitizer" as any substance that produces an allergenic sensitization in a substantial number of persons who come into contact with it. The regulation then explains that an allergic reaction ordinarily does not develop on first contact because of the necessity of a prior exposure to the substance in question. The sensitized tissue then exhibits a greatly increased capacity to react to subsequent exposures and such subsequent exposure may produce severe reactions with little correlation to the amounts of excitant involved. A "photodynamic sensitizer" is specified as any substance that causes an alteration in the skin or mucous membranes so that when these areas are subsequently exposed to ordinary sunlight or equivalent radiant energy, an inflammatory reaction will develop. 21 CFR Sec. 191.1(i), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301. In Section 191.6 (FOOD DRUG COSMETIC LAW REPORTS ¶ 9306) of the regulations, the Secretary, having considered the severity of reactions, and the frequency of occurrence, concluded that the substances listed in that regulation are substances that have a significant potential for causing hypersensitivity and therefore meet the definition of a strong sensitizer.

[39] A *corrosive* substance is defined as any substance which in contact with living tissue will cause destruction by chemical action. FHSLA Sec. 2(i), FOOD DRUG COSMETIC LAW REPORTS ¶ 9067. The regulations require visible destruction or irreversible alterations in the tissue at the site of contact. 21 CFR Sec. 191.1(h), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

[40] The terms *flammable* and *extremely flammable* are defined in the Act itself in terms of specific test procedures. FHSLA Sec. 2(1), FOOD DRUG COSMETIC LAW REPORTS ¶ 9073. See 21 CFR Sec. 191.1(j)-(1), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

[41] FHSLA Sec. 2(f)1(A)(vi), FOOD DRUG COSMETIC LAW REPORTS ¶ 9061. See 21 CFR Sec. 191.1(m), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

[42] FHSLA Sec. 2(f)1(A), FOOD DRUG COSMETIC LAW REPORTS ¶ 9061. "Substantial personal injury or illness" is defined in the regulations as any illness or injury of a significant nature. It does not have to be severe or serious. What is excluded by the word "substantial" is a wholly insignificant or negligible injury or illness. 21 CFR Sec. 191.1(p), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301. It is evident that the regulation does not aid in defining the scope of the term any more than the statute does. The accompanying house report is of some help:

"The term 'substantial,' in the expression 'substantial personal injury or substantial illness,' should be read in the light of the purposes of the bill. On the one hand, it is not intended to impose the impracticable and self-defeating requirement of cautionary labeling against wholly insignificant or negligible illness or injury, such as the very temporary indisposition that a child

or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." [43]

The Act expressly excludes from its coverage economic poisons subject to the Federal Insecticide, Fungicide and Rodenticide Act; foods, drugs and cosmetics subject to the Federal Food, Drug and Cosmetic Act; and substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house.[44]

Prohibited Acts

The Act prohibits the introduction or delivery for introduction into interstate commerce of any misbranded package of a hazardous substance.[45] The term "misbranded package of a hazardous substance"

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might suffer from eating a piece of the standard type of toilet soap. The committee recognizes that virtually every substance used in or about the household is capable of causing some degree of illness or injury if accidentally or intentionally misused. If labeling were required to caution against the risk of even the most trifling indisposition there would hardly be any substance going into the household which would not have to bear cautionary labeling. So that consumers would tend more and more to disregard label warnings, thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness. On the other hand, the term 'substantial' is not intended to limit the requirement of cautionary labeling to situations in which the injury or illness to be guarded against would be severe or serious." H. R. Rept. No. 1861, 86th Cong., 2d Sess. to accompany S. 1283 (1961).

[43] "Reasonably foreseeable handling or use" is further defined in the regulations to include the reasonably foreseeable *accidental* handling or use, not only by the purchaser or intended user of the product, but by all others in a household, especially children. 21 CFR Sec. 191.1(r), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

The Act also provides that the Secretary may designate any substance a hazardous one if, by regulation, he finds that it meets the three tests set out in the text. FHSLA Sec. 2(f)1(B), FOOD DRUG COSMETIC LAW REPORTS ¶ 9061. The Secretary can also designate any radioactive substance to be a hazardous one, if with respect to such substance as used in a particular class of article or as packaged, he determines that the substance is sufficiently hazardous to require labeling in accordance with this Act, FHSLA Sec. 2(f)1(C), FOOD DRUG COSMETIC LAW REPORTS ¶ 9061.

[44] FHSLA Sec. 2(f)2, FOOD DRUG COSMETIC LAW REPORTS ¶ 9061. The regulations limit the exemption as it applies to substances intended to be used as fuels. These are exempt from the requirements of the Act only while in containers installed or intended to be installed as part of the heating, cooking or refrigeration system of a house. Thus, under these regulations, a portable container used for delivery or temporary additional storage would not be exempt even though it contains a fuel. 21 CFR Sec. 191.61(b), FOOD DRUG COSMETIC LAW REPORTS ¶ 9361.

[45] FHSLA Sec. 4(a), FOOD DRUG COSMETIC LAW REPORTS ¶ 9101. The Act also prohibits among other things:

(a) The doing of any act to the label of a hazardous substance or the doing of any other act with respect to a hazardous substance if such act is done while the substance is in interstate com-

(Continued on following page.)

is defined to mean a hazardous substance in a container intended *or* suitable for household use which fails to bear a label [46] which states conspicuously:

(1) The name and place of business of the manufacturer, packer, distributor, or seller.

(2) The common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard. However, the Secretary, by regulation, can permit or require the use of a recognized generic name.

(3) The signal word "Danger" on substances which are extremely flammable, corrosive, or highly toxic.

(4) The signal word "Warning" or "Caution" on all other hazardous substances.

(5) An affirmative statement of the principal hazard or hazards, in wording descriptive of the hazard.

(6) Precautionary measures describing the action to be followed or avoided.

(7) Instructions, when necessary or appropriate, for first-aid treatment.

(8) The word "poison" for any hazardous substance which is defined as being "highly toxic."

(9) Instructions for handling and storage of packages which require special care in handling or storage.

(10) The statement "Keep out of the reach of children," or its practical equivalent.[47]

(Footnote 45 continued.)
merce or while the substance is held for sale (whether or not the first sale) after shipment in interstate commerce, and results in the hazardous substance being in a misbranded package. FHSLA Sec. 4(b), FOOD DRUG COSMETIC LAW REPORTS ¶ 9103.

(b) The introduction into interstate commerce or the receipt in interstate commerce and subsequent delivery of a hazardous substance in a reused food, drug or cosmetic container, or in a container which, though not a reused container, is identifiable as a food, drug or cosmetic container by its labeling or other identification. The mere reuse of a food, drug or cosmetic container as a container for a hazardous substance shall be deemed to be misbranding within the meaning of the Act. FHSLA Sec. 4(f), FOOD COSMETIC LAW REPORTS ¶ 9111. It thus appears that proper cautionary labeling in this case will not avail the seller.

[46] The term *label* is defined in the Act as any display of written, printed or graphic matter upon the immediate container of any substance. It is further provided that any word, statement or other information required to appear on the label must also appear on the outside container or wrapper, if any, (unless it is easily legible through the outside container or wrapper) and that it must also be given with all accompanying literature containing directions for use, written or otherwise. FHSLA Sec. 2(n), FOOD DRUG COSMETIC LAW REPORTS ¶ 9077. The regulations define "accompanying literature" as any placard, pamphlet, booklet, book, sign or other written, printed or graphic matter which provides directions for use and is used in connection with the display, sale, demonstration or merchandising of a hazardous substance. 21 CFR Sec. 191.1(o), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301. It is interesting to note that the "directions for use" referred to above can be a printed word, picture, design, or any combination of such methods. 21 CFR Sec. 191.105, FOOD DRUG COSMETIC LAW REPORTS ¶ 9405.

[47] FHSLA Sec. 2(p)(1), FOOD DRUG COSMETIC LAW REPORTS ¶ 9081.

The required statement must be located prominently on the label. It must also be in the English language and in conspicuous type which is in contrast by typography, layout, or color with other printed matter on the label.[48]

If the Secretary finds that the above labeling requirements are not adequate for the public's protection, he may by regulation establish additional requirements.[49] The Act also provides that the Secretary may promulgate regulations exempting substances from the requirements of the Act where the size of the package or the minor hazard presented makes full compliance impracticable.[50]

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[48] FHSLA Sec. 2(p)(2), FOOD DRUG COSMETIC LAW REPORTS ¶ 9081. In addition, the regulations provide that bearing on the effectiveness of a warning might be the effect of the package contents if spilled on the label. In other words, the label should be as far as practicable of such construction as to withstand reasonably foreseeable spillage through foreseeable use. 21 CFR Sec. 191.1(d), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

A controversial regulation is the one that requires the signal word, the statement of the principal hazard or hazards, and the instructions to read carefully any cautionary information that may be placed elsewhere on the label, to appear together on the *main panel* of the label. 21 CFR Sec. 191.101(a), FOOD DRUG COSMETIC LAW REPORTS ¶ 9401. The regulation also provides that these statements must be in capital letters of a certain specified point type. 21 CFR Sec. 191.101(c), FOOD DRUG COSMETIC LAW REPORTS ¶ 9401.

If the product is "highly toxic," as defined in the regulations, the labeling must also contain, in conjunction with the word poison, the skull and crossbones symbol. 21 CFR Sec. 191.101(b), FOOD DRUG COSMETIC LAW REPORTS ¶ 9401. See 21 CFR Sec. 191.101(d), FOOD DRUG COSMETIC LAW REPORTS ¶ 9401.

[49] FHSLA Sec. 3(b), FOOD DRUG COSMETIC LAW REPORTS ¶ 9093. On the basis of human experience as reported in the scientific literature and to the Poison Control Centers and the National Clearinghouse for Poison Control Centers, the Secretary concluded that the substances listed in Section 191.7 of the regulations (FOOD DRUG COSMETIC LAW REPORTS ¶ 9307) are hazardous because of their involvement in accidental ingestion. He further found that these substances present special hazards and that the labeling required by Section 2(p)(1) of the Act (FOOD DRUG COSMETIC LAW REPORTS ¶ 9081) is not adequate. He, therefore, prescribed specific labeling requirements for these products. For example, on carbon tetrachloride products, the label must include the signal word "danger" and the additional word "poison," and the "skull and crossbones" symbol. Also, the statement of the hazard must include "May be fatal if inhaled or swallowed" and "avoid contact with flame or hot surface." 21 CFR Sec. 191.7(a), FOOD DRUG COSMETIC LAW REPORTS ¶ 9307.

[50] FHSLA Sec. 3(c), FOOD DRUG COSMETIC LAW REPORTS ¶ 9095. Pursuant to this authority regulations have issued which exempt from the requirements of the Act the following items: (1) Common matches, including book matches, wooden matches and safety matches. (2) Paper items such as newspaper, wrapping papers, toilet and cleansing tissues, and paper writing supplies. (3) Thread, string, twine, rope, cord and similar materials. 21 CFR Sec. 191.63 (1)-(4), FOOD DRUG COSMETIC LAW REPORTS ¶ 9363.

These items have been exempted from the labeling requirements of Section 2(p)(1) of the Act (FOOD DRUG COSMETIC LAW REPORTS ¶ 9081) insofar as

(Continued on following page.)

Repeal of the Federal Caustic Poison Act

The Federal Caustic Poison Act (with one exception) is repealed as of the effective date of the Hazardous Substances Labeling Act, that is, February 1, 1961.[51] Those corrosive substances which were covered by that statute and in the concentrations listed in that Act are subject to the provisions of the Federal Hazardous Substances Labeling Act and will have to bear on their label the word "poison" instead of a signal word.[52] However, the Caustic Poison Act will remain in effect in respect to any dangerous caustic or corrosive substance that is subject to the Federal Food, Drug and Cosmetic Act.[53]

Civil Actions Which Utilized Similar Federal and State Statutes

The Federal Hazardous Substances Labeling Act was patterned, to a large extent, after the Federal Food, Drug and Cosmetic Act. The majority of states which have adopted food law statutes have also, to a large degree, patterned them after the federal act. Therefore, it is not unreasonable to conclude that court opinions interpreting these statutes and similar federal and state statutes are characteristic of the way in which these courts will interpret the Hazardous Substances Labeling Act.[54]

It must be noted at the outset that federal statutes, particularly the Food, Drug and Cosmetic Act, have rarely been pleaded by plaintiffs. In contrast to this the state statutes, especially in recent years, have been pleaded with increasing frequency.[55]

(Footnote 50 continued.)
they apply to the products considered hazardous because of being "flammable," "highly flammable," or "extremely flammable" as defined in Section 191.1(k) of the regulations (FOOD DRUG COSMETIC LAW REPORTS ¶ 9301). The fact that these items had to be excepted from the requirements of the Act indicates that the Administration considered them within the provisions of the Act. The nature of these items reveals the broad interpretation the Administration will give to the Act. For a more restricted view of the nature of the items to which the Act was intended to apply, see Scriba, "The Federal Hazardous Substances Labeling Act," 16 FOOD DRUG COSMETIC LAW JOURNAL 615 (1961).

[51] FHSLA Sec. 18, FOOD DRUG COSMETIC LAW REPORTS ¶ 9179.

[52] 21 CFR Sec. 191.109, FOOD DRUG COSMETIC LAW REPORTS ¶ 9409.

[53] FHSLA Sec. 18, FOOD DRUG COSMETIC LAW REPORTS ¶ 9179.

[54] "(M)any of the provisions of this new law are not really new at all. They were drawn directly from the Federal Food, Drug and Cosmetic Act, with which we have lived rather closely over more than twenty years. Judicial guidance to the meaning of the law is readily available in a great many reported decisions." Goodrich, "Legal Problems Arising Under the Federal Hazardous Substances Labeling Act," 16 FOOD DRUG COSMETIC LAW JOURNAL 715 (1961).

[55] For example, *Dupee v. Great Atlantic & Pacific Tea Co.*, 8 NEGLIGENCE CASES 1067, 69 Ga. App. 144, 24 S. E. 2d 858

In *Orthopedic Equipment Company v. Eutsler*,[56] an action for civil liability was based on violation of the Federal Food, Drug and Cosmetic Act. Plaintiff brought suit in a federal district court to recover for personal injuries ensuing from the use of an allegedly misbranded surgical nail. He claimed that the nail was a device within the meaning of the Act and that it was misbranded. Judgment for the plaintiff was affirmed by the Fourth Circuit Court of Appeals. The court declared itself bound by local law and cited an earlier Virginia state court opinion which held that the violation of a motor vehicle statute was negligence per se. The court then held:

> Since Virginia law seems to regard violation of motor vehicle statutes as negligence per se . . . we think that a violation of the Federal Food, Drug, and Cosmetic Act is negligence per se in Virginia. . . .[57]

(1943); *Alphin v. La Salle Diners*, PRODUCT LIABILITY CASES 359, 197 Misc. 415, 98 N. Y. S. 2d 511 (1950); *Tedder v. Coca-Cola Bottling Co.*, 2 NEGLIGENCE CASES (2d) 744, PRODUCT LIABILITY CASES 745, 224 S. C. 46, 77 S. E. 2d 293 (1953).

[56] 10 NEGLIGENCE CASES (2d) 1036, 276 F. 2d 455 (CA-4, 1960). See, 79 A. L. R. 2d 390 (1961).

[57] 276 F. 2d at 461. There were two cases, decided by Virginia courts, that would give support to the holding in the *Eutsler* case. The first was the case of *Chesapeake & Ohio R. R. Co. v. American Exchange Bank*, 94 Va. 495, 23 S. E. (1896). Plaintiff had shipped its horses over the defendant's railroad and defendant had failed to properly feed and water the animals, leading to their injury. Aside from other claims, the plaintiff also relied on a federal statute that made it a crime to fail to feed and water animals after 28 consecutive hours of traveling. Over the objection of the defendant who claimed that the statute could not be applied to this case and that no damages could be recovered for its violation, the court affirmed a judgment for the plaintiff. In answer to the defendant's contention that the statute was essentially penal in nature and therefore could not be pleaded as the basis for a cause of action in a civil suit, the court said that,

"The violation of a statute of the United States may be made the basis of an action of negligence in a state court. These principles apply not only where the statute or ordinance discloses that persons violating it shall be liable for any damages sustained of its breach, but also where it contains no such provisions, and simply imposes a penalty, by way of fine or otherwise, for disobedience." 94 Va. at 497, 23 S. E. 937.

The second case was *McClanahan v. California Spray Chemical Corp.*, 2 NEGLIGENCE CASES (2d) 34, 94 Va. 842, 75 S. E. 2d 712 (1953). This was an action by the plaintiff to recover for damage to his apple orchard, which allegedly resulted from the application of a spray manufactured by the defendant. The gist of the case was the alleged failure by the defendant to give adequate directions for use and warnings of the hazards inherent in its product. Plaintiff based this claim on the Federal Insecticide, Fungicide and Rodenticide Act as well as the Virginia insecticide statute. In reversing the lower court and reinstating a jury verdict for the plaintiff, the Virginia Court of Appeals held that the federal act and the Virginia act imposed on a manufacturer a duty to warn users of the hazards involved in the use of its product and that the failure to so warn constituted negligence as a matter of law.

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The Federal Food and Drugs Act of 1906[58] and the Federal Flammable Fabrics Act have also been pleaded in civil actions.[59]

Virtually all states now have comprehensive laws regulating the manufacture and sale of food, drugs and cosmetics.[60] The majority of courts which have passed on these statutes have held their violation to be negligence per se.[61] The others have held the violation to be at least some evidence of negligence.[62] Many states have also enacted statutes and regulations dealing with particular types of products.[63] Here also, the courts which have passed on these statutes have held their violation to be negligence per se or evidence of negligence.[64]

The Manufacturer's Common Law Duty to Warn

In order to determine the effect of the Federal Hazardous Substances Labeling Act in a civil action, it will be necessary to review the common law duty of the manufacturer to warn of hazards in his product.[65] Afterwards, a comparison of the duty imposed by the Act with that which the courts have already imposed under common law principles will reveal wherein the Act may have a different effect.

Under the common law, a manufacturer is liable for injury which has resulted from an inherently dangerous product which he has

[58] *Armour v. Wanamaker,* 202 F. 423 (CA-3 1909) (holding that the failure to disclose the presence of alcohol in a hair preparation was a violation of the Act and was negligence per se).

[59] *Ingalls v. Messner,* 11 NEGLIGENCE CASES (2d) 1116, 11 Wis. 2d 371. 105 N. W. 2d 748 (1960) (holding that compliance with the Act was some evidence of due care).

[60] See, Compilation of Laws Affecting Proprietary Drug and Allied Industries, Vol. 1 and 2 (1960) The Proprietary Association, Washington, D. C.; CCH FOOD DRUG COSMETIC LAW REPORTS All States Volume.

[61] For example, *Donaldson v. Great Atlantic & Pacific Tea Co.,* cited at footnote 18; *Meshbesher v. Channellene Oil & Mfg. Co.,* cited at footnote 8; *Kelley v. John R. Daily Co.,* 56 Mont. 63, 181 P. 326 (1919); *Pine Grove Poultry Farm, Inc. v. Newtown By-Products Mfg. Co.,* 248 N. Y. 293, 162 N. E. 87 (1928).

[62] For example, *Wright v. Carter Products, Inc.,* 244 F. 2d 53 (CA-2, 1957); *Welter v. Bowman Dairy Co.,* 8 NEGLIGENCE CASES 1173, 318 Ill. App. 305, 47 N. E. 2d 739 (1943); *Gering v. Berkson, 223* Mass. 257, 111 N. E. 785 (1916).

[63] See, Appendix, Vol. 2, Compilation of Laws Affecting Proprietary Drug and Allied Industries (1960), The Proprietary Association, Washington, D. C.

[64] For example, *Ives v. Welden,* 114 Iowa 476, 87 N. W. 408 (1901); (statute regulating the labeling of gasoline); *Farrell v. G. O. Miller Co.,* 147 Minn. 52, 179 N. W. 566 (1920) (statute regulating the labeling of kerosene); *Peterson v. Standard Oil Co.,* 55 Ore. 511, 106 P. 337 (1910) (statute regulating the labeling of oil).

[65] The Act would also be applicable to the wholesaler and retailer and in many instances the plaintiff could sue one or both of them. What is said as to the manufacturer will in most respects be applicable to the others as well.

marketed without the necessary cautionary statements.[66] The danger is said to be "inherent" when it derives from the nature of the article itself, as opposed to dangers resulting from a defectively made article that is ordinarily harmless.[67] Thus, the duty to warn may arise even in those instances where the product is perfectly made.

The rule that a manufacturer must warn of inherent danger is clearly stated in *Noone v. Perlberg.*[68] The plaintiff was burned when her skirt, which had been treated with nitrocellulose sizing, ignited after being brushed by a cigarette. The New York court imposed liability on the manufacturer and held:

> . . . when a manufacturer sells an inherently dangerous article for use in its existing state, the danger not being known to the purchaser and not patent, and notice is not given of danger or it cannot be discovered by reasonable inspection, the manufacturer is legally liable for personal injuries received by one who uses the manufactured article in the ordinary and expected manner.[69]

Foreseeability of the Danger

The manufacturer is not an insurer of the safety of his product.[70] Before the plaintiff can establish a prima facie case based on the negligent failure to warn of an inherent danger, he must offer evidence to the effect that the manufacturer either knew, or through the exercise of reasonable care should have known, of the existence of the danger.[71] The duty to warn thus unquestionably rests upon the issue of foreseeability.

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[66] *Beadles v. Servel, Inc.,* 19 NEGLIGENCE CASES 875, 344 Ill. App. 133, 100 N. E. 2d 405 (1951) (duty to warn that refrigerator gives off carbon monoxide); *Steele v. Rapp,* 8 NEGLIGENCE CASES (2d) 707, 183 Kan. 371, 327 P. 2d 1053 (1958) (duty to warn of inflammable nature of fingernail polish remover); Frumer & Friedman, *Products Liability,* Sec. 8.01-.06 (1960); 50 A. L. R. 1454 (1927); 86 A. L. R. 947 (1933); Dillard & Hart, "Product Liability: Directions for Use and the Duty to Warn," 41 *Virginia Law Review* 145 (1955); Comment, 37 *Boston University Law Review* 519 (1957); *Restatement, Torts,* Sec. 388 (1934).

[67] *Farley v. Edward E. Tower Co.,* 271 Mass. 230, 171 N. E. 639 (1930).

[68] 10 NEGLIGENCE CASES 1122, 268 App. Div. 149, 49 N. Y. S. 2d 460 (1st Dept. 1944).

[69] 268 App. at 152, 49 N. Y. S. 2d at 462.

[70] *E. I. DuPont DeNemours & Co. v. Baridon,* 73 F. 2d 26 (CA-8, 1934); *Arkansas Baking Co. v. Aaron,* 8 NEGLIGENCE CASES 451, 204 Ark. 990, 166 S. W. 2d 14 (1942); *Rose v. Buffalo Air Service,* 11 NEGLIGENCE CASES (2d) 789, 170 Neb. 806, 104 N. W. 2d 431 (1960).

[71] *Rankin v. Harlan Retreading Co.,* 11 NEGLIGENCE CASES 366, 298 Ky. 461, 183 S. W. 2d 40 (1944); *Victory Sparkler & Specialty Co. v. Price,* 146 Miss. 192, 111 So. 437 (1927); *Levin v. Muser,* 110 Neb. 515, 194 N. W. 672 (1923); *Campo v. Scofield,* 18 NEGLIGENCE CASES 1047, 301 N. Y. 468, 95 N. E. 2d 802 (1950).

To assist the plaintiff with his burden of proof on this question, the courts have held that a manufacturer is held to the skill of an expert in his particular business. He is bound to an expert's knowledge of the arts, materials, and processes that are involved in the manufacture of the product and he must keep abreast of scientific knowledge and discoveries related to his field.[72] He also must conduct reasonable tests and inspections to discover latent hazards.[73] Even if tests and inspections are made, the manufacturer's duty is not discharged if they are inadequate.[74] The question ordinarily put to the jury is whether the defendant in the exercise of reasonable care should have known of the danger and forewarned the plaintiff.[75]

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[72] *Peaslee-Gaulbert v. McMath,* 148 Ky. 265, 146 S. W. 770 (1912); *Farley v. Edward E. Tower & Co.,* cited at footnote 67; *Statler v. George A. Ray Mfg. Co.,* 195 N. Y. 478, 88 N. E. 1063 (1909); 2 Harper & James, *Torts,* Sec. 28.4 at p. 1541 (1956); 86 A. L. R. 941 (1933).

[73] *Hopkins v. E. I. DuPont DeNemours & Co.,* 1 NEGLIGENCE CASES (2d) 487, 199 F. 2d 930 (CA-3 1952); *Herman v. Markharm Air Rifle Co.,* 258 F. 475 (DC Mich. 1919); *Reasor Hill Corp. v. Kennedy,* 224 Ark. 248, 272 S. W. 2d 685 (1954); *Warner v. Santa Catalina Island Co.,* 4 NEGLIGENCE CASES (2d) 814, 44 Cal. 2d 310, 282 P. 2d 12 (1955).

In *Crotty v. Shartenbergs-New Haven Inc.,* 11 NEGLIGENCE CASES (2d) 624, 147 Conn. 460, 162 A. 2d 513 (1960), the court held that if despite elaborate premarket testing, a consumer suffers an allergic reaction or adverse side effects, the manufacturer rather than the consumer should bear the risk of injury.

[74] *Maecherlin v. Sealy Mattress Co.,* 6 NEGLIGENCE CASES (2d) 559, 145 Cal. App. 2d 275, 302 P. 2d 331 (1956); *Ebers v. General Chemical Co.,* 310 Mich. 261, 17 N. W. 2d 176 (1945); *Foley v. Pittsburgh-Des Moines Co.,* 17 NEGLIGENCE CASES 329, 363 Pa. 1, 68 A. 2d 517 (1949). As stated by the late Justice Jackson, dissenting in *Dalehite v. United States,* 1 NEGLIGENCE CASES (2d) 1080, 346 U. S. 15 at 51-52 (1953),

"This is a day of synthetic living, when to an ever-increasing extent our population is dependent upon mass producers for its food and drink, its cures and complexions, its apparel and gadgets. These no longer are natural or simple products but complex ones whose compositions and qualities are often secret. Such a dependent society must exact greater care than in more simple days and must require from manufacturers or producers increased integrity and caution as the only protection of its safety and well-being. Purchasers cannot try out drugs to determine whether they kill or cure. . . . Where experiment or research is necessary to determine the presence or the degree of danger, the product must not be tried out on the public, nor must the public be expected to possess the facilities or the technical knowledge to learn for itself of inherent but latent dangers. The claim that a hazard was not foreseen is not available to one who did not use foresight appropriate to his enterprise."

[75] *Hopkins v. E. I. DuPont DeNemours & Co.,* cited at footnote 73. In cases involving new products it is clear that a duty to warn will depend on the extent to which knowledge of the danger should reasonably be attributed to the manufacturer. If the product is launched prior to adequate testing, to attribute knowledge would seem reasonable. Dillard & Hart, cited at footnote 66. In Massachusetts the courts have held that the plaintiff is entitled to the benefit of a presumption that the manufacturer had knowledge of a possibly dangerous substance in its product. Thus it was held in *Sylvania Electric Products, Inc. v. Barker,* 228

Adequacy of the Warning Given

Even if there is some word of caution or some mention of misuse in the directions, the question still remains whether this constitutes an adequate warning in the light of the foreseeable use by the user of the product. In *Maize v. Atlantic Refining Company,* the court held that a warning can be inadequate if it is not sufficiently prominent.[76] In *Tampa Drug Company v. Wait,* the court held that a warning can be inadequate if it is not sufficiently intense.[77] It has been held that the labels used by nationally known manufacturers and labels promulgated by the labeling committee of the Manufacturing Chemists Association were properly admitted into evidence merely as a guide to a determination of the adequacy of the warning furnished by the defendant.[78]

Whether or not a given warning is adequate depends upon the language used and the impression that it is calculated to make upon the mind of an average user of the product.[79]

F. 2d 842, 848-49 (CA-1, 1955), cert. denied 350 U. S. 988 (1956) that:

"In Massachusetts the rule seems to be that every manufacturer is presumed to know the nature and qualities of his product. . . . Thus, once a plaintiff establishes in a Massachusetts court that a manufacturer-defendant's product is dangerous in its ordinary use and that no warning of its danger was given, a presumption of the defendant's knowledge of the danger arises, and this presumption with, of course, proof of causation and injury completes the plaintiff's prima facie case." Accord, *Peaslee-Gaulbert Co. v. McMath,* cited at footnote 72; *Thornhill v. Carpenter-Morton Co.,* 220 Mass. 593, 108 N. E. 474 (1915).

[76] 12 NEGLIGENCE CASES 78, 352 Pa. 51, 41 A. 2d 850 (1945). The plaintiff's decedent died from the inhalation of carbon tetrachloride fumes while using defendant's rug cleaner product. The container bore on all four sides the words "safety clean" in ½ inch to ¾ inch letters and on the two narrow sides appeared the word "Caution" in ¼ inch letters and the warning, "Do not inhale fumes, use only in well ventilated place" in ⅛ inch letters.

[77] *Tampa Drug Company v. Wait,* 8 NEGLIGENCE CASES (2d) 262, 103 So. 2d 603 (Fla. 1958). Defendant's product contained carbon tetrachloride. The court held that whether the warning "Volatile solvent, vapor harmful, use with adequate ventilation, avoid prolonged or repeated breathing of vapor" was sufficient to caution against the dangers involved, was a question for the jury. See *Tingey v. E. F. Houghton & Co.,* 14 NEGLIGENCE CASES 914, 30 Cal. 2d 97, 179 P. 2d 807 (1947) (warning must be appropriate); *Marigny v. Dejoie,* 172 So. 808 (La. 1937); *Lovejoy v. Minneapolis-Moline Power Implement Co.,* 9 AUTOMOBILE CASES (2d) 1030, 248 Minn. 319, 79 N. W. 2d 688 (1956) (warning must be accurate).

[78] *Tampa Drug Company v. Wait,* cited at footnote 77. See, *Maize v. Atlantic Refining Co.,* 12 NEGLIGENCE CASES 78, 352 Pa. 51, 41 A. 2d 850 (1945).

[79] *Walton v. Sherwin-Williams Co.,* 19 NEGLIGENCE CASES 994, 191 F. 2d 277 (CA-8 1952).

No Duty to Warn of Obvious Danger

If the danger is obvious, the courts have held that there is no duty to warn. Thus in *Jamieson v. Woodward & Lothrop*,[80] the court denied liability where plaintiff was injured when an elastic exerciser she was using slipped off her foot and hit her in the eye. The court said:

> It seems clear under all or any of the cases or text authorities that where a manufactured article is a simple thing of universally known characteristics . . . the only danger being not latent but obvious to any possible user . . . (and) injury occurs through a mishap in normal use, the article reacting in its normal and foreseeable manner, the manufacturer is not liable for negligence. . . . There was no duty on the manufacturer to warn of that simple fact.[81]

No Duty to Warn of Dangers Incident to an Unintended Use of the Product

It has also been held that there is no liability where the product was not used for the purpose for which it was intended, even though there was no warning given of the inherently dangerous characteristics. Thus, in *Lawson v. Benjamin Ansehl Company*,[82] a distributor of fingernail polish remover which was harmless when used as intended, but which contained portions of a highly flammable element and was not marked to show the presence of it, was found not liable for the death of a five-year old who splashed the contents of the bottle on his clothing, touched a lighted match thereto, and set himself afire. The court recognized that a warning would have notified persons who could read to keep the bottle away from children, but held that liability follows only when the product which is inherently dangerous and improperly labeled is used *in the way it was intended to be used* and causes injury. Here it was not so used.[83]

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[80] 6 NEGLIGENCE CASES (2d) 1172, 247 F. 2d 23 (CA D of C 1957).

[81] 247 F. 2d at p. 28. Accord, *District of Columbia v. Moulton*, 182 U. S. 576 (1901); *Sawyer v. Pine Oil Co.*, 13 NEGLIGENCE CASES 660, 155 F. 2d 855 (CA-5, 1946); *Campo v. Scofield*, cited at footnote 71; *Blissenbach v. Yanko*, PRODUCT LIABILITY CASES 634, 90 Ohio App. 557, 107 N. E. 2d 409 (1951). It is also well established that there is no duty to warn where the person who claims to be entitled to warning has actual knowledge of the danger; *Procter & Gamble Mfg. Co. v. Superior Court*, 124 Cal. App. 2d 157, 268 P. 2d 199 (1954); or where the danger may reasonably be expected to be within the knowledge of the user, *Gibson v. Torbert*, 115 Iowa 163, 88 N. W. 443 (1901). Thus it has been held that there is no duty to warn of the caustic properties of ready mixed concrete containing lime. *Simmons v. Rhodes & Jamieson, Ltd.*, 5 NEGLIGENCE CASES (2d) 785, 46 Cal. 2d 190, 293 P. 2d 26 (1956); *Dalton v. Pioneer Sand & Gravel Co.*, 37 Wash. 2d 946, 227 P. 2d 173 (1951).

[82] 10 NEGLIGENCE CASES 902, 180 S. W. 2d 751 (Mo. 1944).

[83] Accord, *Marker v. Universal Oil Products Co.*, 250 F. 2d 603 (CA-10 1957); *Boyd v. Frenchee Chemical Corp.*, 5 NEGLIGENCE CASES 268, 37 F. Supp.

The liability of a manufacturer for failure to adequately warn of dangers incident to the use of his product does not depend upon whether the injury is to the person using the product, or the person or object to which the product is to be applied.[84]

The Requirement of Privity

A few jurisdictions still pay lip service to the requirement of privity of contract in tort, but the vast majority of courts are no longer so bound by the notion that recovery is refused the ultimate purchaser. So long as the court can reasonably conclude that the product is inherently dangerous, the precedents are clear that the ultimate consumer can sue the manufacturer directly.[85]

The Allergic Consumer

Since the courts emphasize the "dangerous character" of the substance, the majority of them have held that if the manufactured article is incapable of injuring the ordinary, normal person, the manufacturer owes no duty to warn the abnormally susceptible user.[86]

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306 (DC N. Y. 1941); *Pedroli v. Russell,* 7 NEGLIGENCE CASES (2d) 1236, 157 Cal. App. 2d 281, 320 P. 2d 873 (1958). See 50 A. L. R. 1454 (1927). Contra, *Wolcho v. Arthur J. Rosenbluth Co.,* 81 Conn. 358, 71 A. 566 (1908); *Petzold v. Roux Labs.,* 1 NEGLIGENCE CASES 846, 256 App. Div. 1096, 11 N. Y. S. 565 (1939). These courts have held that directions for use which merely tell how to use the product and which do not say anything about the danger of foreseeable misuse do not necessarily satisfy the duty to warn. Therefore, under the reasoning of these cases, misuse or failure to follow directions may be foreseeable.

[84] *McClanahan v. California Spray-Chemical Corp.,* cited at footnote 57.

[85] *Ebers v. General Chemical Co.,* cited at footnote 74; *MacPherson v. Buick Motor Co.,* PRODUCT LIABILITY CASES 827, 217 N. Y. 382, 111 N. E. 1050 (1916); Bohlen, "Liability of Manufacturers to Persons Other Than Their Immediate Vendees," 45 *Law Quarterly Review* 343 (1929); *Restatement, Torts,* Sec. 395 (1934).

[86] "The record is devoid of any evidence indicating that the product in question had ever caused . . . irritation prior to its use in the instant case. . . . We conclude that the evidence would not support a judgment in favor of plaintiff against the defendant (manufacturer) on the grounds stated (failure to warn). . . . It was not shown that the solution used on the plaintiff was in fact dangerous or an irritant to the skin of any person any more than many cosmetics, face powders, cold creams and nail polish universally used by women. There is nothing in the testimony indicating that many persons were susceptible to the product and might suffer damage through its use. In fact, from the record, plaintiff's complaint is the only instance in which injury from it was claimed." *Briggs v. National Industries, Inc.,* 17 NEGLIGENCE CASES 206, PRODUCT LIABILITY CASES 260, 92 Cal. App. 2d 542 at 545-46, 207 P. 2d 110, 112 (1949). Accord, *Gould v. Slater Woolen Co.,* 147 Mass. 315, 17 N. E. 531 (1888); *Bennett v. Pilot Products Co., Inc.,* 19 NEGLIGENCE CASES 949, PRODUCT LIABILITY CASES 510, 120 Utah 474, 235 P. 2d 525 (1951); 26 A. L. R. 958 (1923).

An increasing number of courts have started to follow the decision of *Gerkin v. Brown & Sehler Company*,[87] holding the manufacturer liable for failure to warn where he had knowledge that the substance may be harmful to some persons, even though the number may be small.[88] In the *Gerkin* case the court held:

> When the fact is once established and demonstrated by experience that a certain commodity apparently harmless contains concealed dangers, and when distributed to the public through the channels of trade and used for the purposes for which it was made and sold is sure to cause suffering to, and injure the health of, some innocent purchaser, even though the percentage of those injured be not large, a duty arises to and responsibility rests upon the manufacturer and dealer with knowledge to the extent, at least, of warning the ignorant consumer or user of the existence of the hidden danger.[89]

Pleading a Violation of the Federal Hazardous Substances Labeling Act

The Federal Hazardous Substances Labeling Act is designed to affect a very specific area of the manufacturer-user relation. It defines the duty of the manufacturer to warn of the hazard inherent in his product.

The Act is essentially penal in nature. There is no provision for a civil remedy.[90] Therefore, the Act does not establish a new and separate cause of action and it can be used, if at all, solely to aid the plaintiff with his burden of proof.[91] Basically, there are two types of

[87] 177 Mich. 45, 143 N. W. 48 (1913).

[88] *Wright v. Carter Products, Inc.*, cited at footnote 62; *Taylor v. Newcomb Baking Co.*, 317 Mass. 609, 59 N. E. 2d 293 (1945); *Cahill v. Inecto, Inc.*, 208 App. Div. 191, 203 N. Y. S. 1 (1924). In *Carter v. Yardley & Co.*, 13 NEGLIGENCE CASES 179, PRODUCT LIABILITY CASES 1078, 319 Mass. 92, 64 N. E. 2d 693 (1946), the court expressly abandoned the old rule of manufacturer's liability requiring either a contractual relationship or an inherently dangerous product and held that a manufacturer of perfume had a duty to warn though the number of persons susceptible was small. For a very comprehensive article on this entire area see, Noel, "The Duty to Warn Allergic Users of Products," 12 *Vanderbilt Law Review* 331 (1959). Also see, Frumer & Friedman, *Products Liability*, Secs. 28-32 (1961); 1 Hursh, *American Law of Products Liability*, Sec. 2.28-2.58 (1961); Note, 10 *Alabama Law Review* 476 (1958).

[89] *Gerkin v. Brown & Sehler Company*, cited at footnote 87.

[90] The Act provides for criminal prosecutions, Sec. 5: seizures, Sec. 6; and injunction proceedings, Sec. 8. The first seizure pursuant to the provisions of the Act occurred in March, 1962 and involved a soldering compound implicated in the death of a six-year-old, Jamaica, Long Island, child. The product contained 88 per cent zinc chloride but failed to bear any warning statements. Pharmacological tests showed the product is highly irritating and corrosive.

[91] See footnote 1 and accompanying text. It should be noted that even in jurisdictions still adhering to the requirement of privity, the plaintiff can maintain a cause of action based on the violation of the Act whether privity exists or not.

actions in which a violation of the Act can be pleaded. The first is one in which the plaintiff having used the product in a reasonably foreseeable manner is injured. The second would be where the plaintiff was injured due to a reasonably foreseeable accidental use of the product. In both cases, the claim of negligence would be that there was either no warning or that the warning given was inadequate. The liability of the defendant will thus depend upon whether or not he had a duty to warn this plaintiff and whether or not he had breached this duty.

Before the plaintiff can establish a prima facie case based on the negligent failure to warn, he must offer evidence to the effect that the product is inherently dangerous; that he used it according to any instructions and warnings; that the product was the proximate cause of the injury; that the injury was a foreseeable one; and that the manufacturer was negligent in marketing this product.

Inherent Danger of the Product

The plaintiff's burden of proving that the product was inherently dangerous may be greatly lessened by the Act. He would only have to prove that the product was a hazardous substance within the meaning of the Act. In many instances, the ingredients of the product will be specifically enumerated in the statute or in the regulations.[92] At other times, the specific test procedures and definitions which are provided will facilitate the plaintiff's burden of proof.[93] In this respect, it should emphasize that whether a product is a hazardous substance is basically a question of whether or not it will cause "substantial personal injury." [94] The term "substantial" has already been defined to mean any harm except inconsequential damage.[95]

Foreseeability

In any case involving an alleged breach of the duty to warn, the crucial issue will be the question of knowledge on the part of the manufacturer. According to common law principles, if there is no knowledge of danger, actual or imputed, there is no duty to warn and therefore there can be no liability.[96] Where the plaintiff's cause of

[92] For example, 21 CFR Sec. 191.6, FOOD DRUG COSMETIC LAW REPORTS ¶ 9306; 21 CFR Sec. 191.7, FOOD DRUG COSMETIC LAW REPORTS ¶ 9307.

[93] For example, FHSLA Sec. 2, FOOD DRUG COSMETIC LAW REPORTS ¶ 9061-9081; 21 CFR Sec. 191.1; FOOD DRUG COSMETIC LAW REPORTS ¶ 9301; 21 CFR Sec. 191.10-16, FOOD DRUG COSMETIC LAW REPORTS ¶ 9310-9316.

[94] See footnote 42.

[95] See footnote 42.

[96] See footnote 71.

action is based on the violation of a statutory duty, it has been held that the manufacturer's knowledge of the danger is not an element of the case. Thus in *White v. Rose*,[97] the plaintiff sued in a federal district court for damage to his cattle caused by defendant's feed product. He based his claim upon the violation of a Colorado statute regulating the quality of animal feed. The trial court, in holding for the defendant, found that he did not know, and in the exercise of reasonable care could not have known, that the feed manufactured by him, if used as recommended and directed, would cause injury. The court of appeals reversed, stating that:

> The statutory violation becomes actionable and no element of ordinary negligence is essential. . . . The statute places a duty upon the manufacturer not to place upon the market an adulterated product. . . . An action may be maintained . . . though the manufacturer did not know, or in the exercise of ordinary care could not have known the deleterious characteristics of the commodity sold. These are requirements of common-law negligence, and do not apply to statutory liability.[98]

The manufacturer is thus forced to assume the risk that any item put out on the market by him will not violate an applicable statute.[99]

Proximate Cause

Whether the plaintiff is suing for breach of the statutory duty or for negligence under ordinary common law principles, his burden of proving causation will be the same.[100]

Contributory Negligence and Due Care

In a majority of courts this is also true as to the defense of contributory negligence.[101] However, in those courts which refuse to

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[97] *White v. Rose*, cited at footnote 18.

[98] 241 F. 2d at pp. 97, 98.

[99] Although the Act does not require a showing that the harmful nature of the product was foreseeable, it does state that before a product will be deemed to be a hazardous substance it must be shown that it may cause substantial personal injury "during or as a proximate result of any customary or reasonably foreseeable handling or use." FHSLA Sec. 2(f) 1(a), FOOD DRUG COSMETIC LAW REPORTS ¶ 9061. See footnote 43. It is enlightening to note the statement in the House Report which accompanied the Act: "Judicial decisions relating to the duty of manufacturers, distributors, or sellers to warn of the hazards of products may also be resorted to for further light on the meaning of the 'if' clause of the definition of 'hazardous substance' in section 2(f)1(A) of the bill, it being the committee's view that, in the event of conflict among such decisions, those decisions will be more in consonance with the legislative intent which is more liberal in recognizing the foreseeability of accidental handling or misuse of a hazardous household substance in the absence of adequate warning." H. R. Rept. No. 1861, 86th Cong., 2d Sess. (1960).

[100] See footnote 15.

[101] See footnote 22.

extend this defense to actions for violations of statutory duty, the plaintiff is in a very favorable position. In effect, these courts are imposing strict liability on the defendant manufacturer.[102] Once the plaintiff establishes that a statute was violated and that the violation was the direct cause of the injury, no amount of evidence of due care exercised by the defendant or lack of due care of the plaintiff will defeat liability.

Adequacy of the Warning

Where the manufacturer of an inherently dangerous article failed to give a warning of any kind, it would not be difficult for the plaintiff to prove his negligence. Once the plaintiff has established that the product was inherently dangerous, that it was the proximate cause of the injury, and that the injury was a foreseeable one, the case would fall within the general rule that a manufacturer is liable for failing to warn of any inherent danger in his product.[103] However, where the defendant has given a warning, the plaintiff is faced with the difficulty of establishing to the satisfaction of the court and the jury that such warning was inadequate. In many instances, this burden has proven too great for the plaintiff. In *Shaw v. Calgon,*[104] the plaintiff sought to recover for injuries to her hand sustained as a consequence of using defendant's detergent. The product was intended for use in automatic dishwashers, but due to an error, the plaintiff used it for washing venetian blinds. She immediately felt a burning sensation and realizing her error, she looked for, but could not find any antidote printed on the package. The package contained the statement that the detergent was not to be used for tasks involving "contact with the hands with the wash water." The court, affirming a judgment in defendant's favor, rejected plaintiff's contention that the defendant could be charged with liability for failing to state on the box the *nature of the contents* of the product and *an antidote* therefor. The court held that the defendant could not reasonably have

[102] See footnote 23.

[103] See footnote 66.

[104] 4 NEGLIGENCE CASES (2d) 978, 35 N. J. Super. 319, 114 A. 2d 278 (1955). See, *McClaren v. G. S. Robins & Co.,* 7 NEGLIGENCE CASES 894, 349 Mo. 653, 162 S. W. 2d 856 (1942). This latter case held that the statement "volatile solvent, use with adequate ventilation, avoid prolonged breathing" was an adequate warning and denied recovery for the death of plaintiff's decedent. Under the Act this warning would not be sufficient. The case involved a product containing carbon tetrachloride. The regulations require on any product containing carbon tetrachloride the signal word "danger," the word "poison" and the "skull and crossbones" symbol. In addition, the statement of the hazard must include, "May be fatal if inhaled or swallowed." 21 CFR Sec. 191.7 (b)(1).

been required to do more than give specific instructions for the use of its product and a warning against contact with the hands. There was said to be no authority for the proposition advanced by the plaintiff that a manufacturer of detergents is required (in addition to giving proper directions as to use and a warning of possible injury) to state on the container both the chemical nature of the contents and the antidote or neutralizing agent to be used in case of injury.[105]

In an action based on the violation of the Act, plaintiff would be greatly aided with his burden of proof in a similar situation. The Act, together with the regulations, specifically sets out the exact nature of the statements which must appear on items which come within its ambit. Therefore, the question of the adequacy of any particular warning statements would no longer be a question for the trier of facts but would be resolved as a question of law. If the warning failed to conform to the requirements of the Act, the defendant would be liable.

The Act Imposes New Duties

There are a number of instances where the Act will impose on the manufacturer a duty to warn, where the courts have previously held that no such duty existed.

Several courts have held that where the danger is obvious, the manufacturer has no duty to warn the user.[106] Under the Act no such broad exemption exists. Although Section 3(c) permits the Secretary to promulgate regulations exempting certain substances from the requirements of the Act, he can do so only when the size of the package or the hazard involved makes such warning unnecessary. Thus, the key to such an exemption is not whether the danger is obvious, but whether the danger is minor.

There are also cases which preclude the plaintiff from recovering where the product was not used for the purpose for which it was intended.[107] This has been the result though no warning was given. The Act specifically provides that a hazardous substance is one that may cause injury "as a proximate result of any reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." [108] It will be recalled that the regulation dealing with this section provides that "reasonably foreseeable" includes *accidental handling or*

[105] 35 N. J. Super. at 332, 114A. 2d 285.

[106] See footnote 81 and accompanying text.

[107] See footnotes 82 and 83 and accompanying text.

[108] FHSLA Sec. 2(f)1(A), FOOD DRUG COSMETIC LAW REPORTS ¶ 9061.

use.[109] Therefore, the fact that the product was not used as intended may no longer be a defense. Provided the accidental use was reasonably foreseeable, the failure to warn would be a breach of the defendant's duty.

The specific labeling requirements, especially the duty to give first-aid instructions, including any possible antidote, go far beyond the obligations presently resting upon the manufacturer.[110]

The regulations require that the signal word, the statement of the principal hazard or hazards, and the instructions to read carefully other cautionary statements, must appear on the main panel of the label.[111] This was not required in the past.

One far-reaching regulation promulgated under the Act has been interpreted to include within its coverage the local garageman or hardware store proprietor.[112] These individuals are accustomed to selling kerosene, turpentine and gasoline in bottles which they fill from a bulk container. They now have to label such bottles in the same manner as the bulk container was or should have been labeled.

The Allergic Consumer

For the allergic consumer-plaintiff, the Act provides some limited advantage. A substance is a "strong sensitizer" only when so designated by the Secretary.[113] To date, the Secretary has specified only five chemicals.[114] As to these, the Act may afford relief to the allergic consumer. The majority of courts have held that the manufacturer had no duty to warn where the product was incapable of injuring the

[109] 21 CFR Sec. 191.1(r), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301.

[110] See footnote 104.

[111] 21 CFR Sec. 191.101(a), FOOD DRUG COSMETIC LAW REPORTS ¶ 9401.

[112] 21 CFR Sec. 191.1(c), FOOD DRUG COSMETIC LAW REPORTS ¶ 9301. Although the regulation does not specifically mention this type of situation, such is the construction given to it by the FDA. In a speech given by Commissioner Larrick before the Medical Advisory Committee Session held in Chicago, Illinois, on November 13, 1961, he said, "An education program will be required to get the various firms and dealers who repack hazardous substances to do it properly. For example, hazardous substances such as kerosene and gasoline poured into small containers must be appropriately labeled. In the past, little or no labeling has been applied to them. There have been many instances, as you know, of serious injuries and deaths in the home from mishandling such products. The new law requires that informative labeling be carried through not only on the merchandise as it crosses a state line in household size packages, but also on the merchandise that is repacked into small containers after it crosses a state line. Service station operators and others will need to be advised how they can meet the requirements of the law." 17 FOOD DRUG COSMETIC LAW JOURNAL 164, February 1962.

[113] See footnote 38.

[114] CFR Sec. 191.6, FOOD DRUG COSMETIC LAW REPORTS ¶ 9306.

ordinary, normal person.[115] In accordance with the mandate of the Act, such failure may now result in liability with respect to those chemicals enumerated therein. It should be noted, however, that this advantage will most likely be limited to products whose labeling fails to comply with the Act and the Regulations.

The Federal Hazardous Substances Labeling Act—A Sword

There is sufficient precedent for a plaintiff in a civil action to plead a federal statute that is essentially penal in nature. Whether the violation will be considered negligence per se, evidence of negligence, or a presumption of negligence will depend upon the jurisdiction in which the action is brought.

It is apparent that being able to plead a violation of the Federal Hazardous Substances Labeling Act comes as a practical boon to a plaintiff injured by a product whose label does not comply with the Act. He is relieved of the need to show either that the product was inherently dangerous or that the manufacturer had or should have had knowledge of this fact. Furthermore, the difficult jury issue dealing with the adequacy of the warning actually given is simplified since the statutory standards are supplied.

The statutory remedy has the further advantage that once its violation is proven, liability follows as a matter of law regardless of the defendant's proof of adherence to a standard of reasonable care. In those jurisdictions which hold that the defense of contributory negligence cannot be pleaded in an action based upon violation of a statute, we have the imposition of strict liability on the defendant. Suing on the statute also unshackles the bonds of privity in those states still adhering to it.

The plaintiff may thus establish his claim merely by showing that the commodity was embraced in the statutory regulation, that the label failed to meet the standards set forth in the statute, and that this failure caused or contributed to the injury. In many instances, the plaintiff can plead the violation of a duty which prior to the enactment of the Act did not exist.

It is further suggested that the Federal Hazardous Substances Labeling Act will have its greatest impact on civil litigation in yet another manner. Within a relatively short period of time after the Federal Food, Drug and Cosmetic Act was passed, states began to copy the federal act and passed their own pure food laws. Almost

[115] See footnote 86.

every state now has such a statute.[116] The result of this trend has been that plaintiffs have both a federal statute and a state statute which they could plead, yet they have with much greater frequency pleaded only a violation of their own state acts. Though the reasons prompting such action are not significant for this paper, the results are. Plaintiffs have been successful in recovering for violations of such state statutes and the plaintiffs' bar is becoming increasingly aware of this.

Prior to the passage of the federal Act, a number of states had passed hazardous substances acts.[117] It is probable that additional states will now legislate on the subject, and, no doubt, will be influenced by the federal statutory pattern.[118] In such event, we may anticipate a greater incidence of civil cases based on violations of such state statutes.

The Federal Hazardous Substances Labeling Act—A Shield

Up until this point, I have been attempting to establish that the Federal Hazardous Substances Labeling Act can be a powerful sword in the hands of an injured consumer. However, it should be carefully noted that the Act can also be an effective shield for the manufacturer who adheres to its requirements.

As I mentioned in an earlier part of this paper, the Federal Hazardous Substances Labeling Act is designed to affect a very specific area of the manufacturer-user relation. It defines the duty of the manufacturer to warn of the hazard inherent in his product. In the past, many manufacturers were held to be liable as a result of their failure to include a warning statement on the label of their product.[119] In other cases, although a warning was given, it was held

[116] See Appendix, Table 1, Vol. 2, Compilation of Laws Affecting Proprietary Drug and Allied Industries (1960), The Proprietary Association, Washington, D. C.

[117] Colorado, Connecticut, Illinois, Indiana, Kansas, Ohio, Texas and Vermont.

[118] A recent check reveals that the following states have now adopted Hazardous Substances Labeling Acts: California, Kentucky, Massachusetts, Minnesota, North Dakota, Oklahoma, Wisconsin (limited to combustible substances only).

[119] See footnote 66. Accord, *Butler v. L. Sonneborn Sons, Inc.*, 13 NEGLIGENCE CASES (2d) 743, 296 F. 2d 623 (CA-2 1961) (manufacturer of liquid concrete floor hardening compound held liable for failing to warn users to keep the product away from fire); *Kieffer v. Blue Seal Chemical Co.*, 20 NEGLIGENCE CASES 614, 196 F. 2d 614 (CA-3 1952) (manufacturer of drain cleaner held liable for failing to warn of explosive nature of product); *Howard Stores Corp. v. Pope*, 6 NEGLIGENCE CASES (2d) 410, 1 N. Y. 2d 806, 135 N. E. 2d 599 (1956) (distributors of floor finish held liable for failing to warn of the inflammability of the product).

by the court to be inadequate.[120] The Act now provides the following benefits to a manufacturer of household products:

(1) It sets up specific guidelines for determining which products are considered inherently dangerous and which therefore require a warning statement; and

(2) It specifies in great detail, the content, position, and prominence of the warning statements which must appear.

If the Act is complied with, the only question that would remain to be decided in a civil suit for damages would be whether or not the warning given was adequate. It is recognized that compliance with a statute will not, in all cases, be considered due care.[121] In many cases the statutory standard has been held to establish only a minimum and did not preclude a finding that the defendant was negligent in failing to take additional precautions.[122] However, the standards established by the statute are so comprehensive and detailed that it is not unreasonable to conclude that a court would have to find that the warning statements required in the Act, if complied with, are completely adequate. It is difficult to imagine in what respects the warnings required by the Act could be held to be inadequate or lacking.

During the past two decades, regulation of the activities and products of manufacturers by the various government agencies has been steadily increasing. As a result of this, manufacturers have become acutely aware of the need to keep apprised of newly enacted statutes and regulations and the need to comply with them. It is to be expected, therefore, that the majority of manufacturers of "hazardous substances" will be aware of the requirements of the Act and will be in a position to comply with its requirements and obtain the defensive benefits afforded by it. **[The End]**

[120] See footnotes 74, 76-79 and text accompanying footnotes 76-79. Accord, *Twombley v. Fuller Brush Co.*, 10 NEGLIGENCE CASES (2d) 864, 221 Md. 476, 158 A. 2d 110 (1960) (manufacturer of cleaning fluid held negligent in failing to adequately warn purchaser of danger in inhaling fumes from the product); *Haberly v. Reardon Co.*, 8 NEGLIGENCE CASES (2d) 34, 319 S. W. 2d 859 (Mo. 1958) (manufacturer of cement paint held liable because of failure to give adequate warning concerning corrosive properties of product).

[121] See footnote 19.

[122] See footnote 19.

Food Advertising Law

By C. A. ADAMS, C.B.E., B.Sc., F.R.I.C.

This Is a Current Revision of an Address on British Food Advertising Law Which Previously Appeared in the February 1, 1958 *Chemistry and Industry*. The Address Was Delivered at a Joint Meeting of the Manchester Section and the Food Group of the Society of Chemical Industry at the University of Manchester on November 1, 1957. Mr. Adams, a Member of This Magazine's Editorial Advisory Board, Is the Former Director, Food Standards and Labeling Division, United Kingdom Ministry of Food.

IT IS ESSENTIAL to make a rapid survey of such law as has operated during the present century so that we may better understand the potential value of the new legislation which was enacted as recently as 1953 and 1955. This in turn involves some consideration of the standards of practice which ought to apply to advertising, and to advertising of foods in particular, i. e., the ethics of food advertising.

Modern food legislation in this country started less than 100 years ago with the Food Adulteration Act of 1860. (Incidentally it is hoped to arrange for the celebration of the centenary of this measure in three years time.[1]) The 1860 Act was a watertight measure, and only covered the adulteration of foods, but a few years later it was amended to include drugs.

Looking back over the years, it is still difficult to realize that it was not until the passing of the 1938 Food and Drugs Act that advertisements were even mentioned in this legislation. That Act made it an offence to issue a label or advertisement which either falsely described a food or drug, or which was otherwise calculated to mislead as to its nature, substance or quality. This landmark is well known, but it would be wrong to conclude that from 1860 to 1938 all food packers were a race apart in the honest presentation of their goods. Human nature being what it is, it seems more likely that the public had been fairly long suffering! Be that as it may, the suggested corollary would still not be accurate, even from the legal angle, for the actual application of false or misleading trade descriptions to goods in

[1] The centenary celebrations came to fruition; see 15 FOOD DRUG COSMETIC LAW JOURNAL 697 (November 1960).

general had been dealt with in the Merchandise Marks Acts from 1887 onwards. The last Merchandise Marks Act, that of 1953, aimed at putting teeth into this legislation by considerably widening the scope of its application. Indeed, such properties as quantity, quality, country of origin, method of manufacture, composition, and even the use of illustrations can now all be challenged on the grounds that they may be part and parcel of a false trade description applied to goods.

There are, however, three main faults with the Merchandise Marks Acts, namely:

(1) Although the coverage is good, it is limited to written descriptions, and should be extended to oral descriptions.

(2) No duty of enforcement is placed on anyone. The Board of Trade has power to take proceedings (see Bell's *Sale of Food and Drugs*, 13th ed., at p. 599), but in practice this comes to trivial action on complaint. The vast majority of prosecutions is undertaken by local authorities who have no power of enquiry or inspection or sampling (and only undertake it in peril of being surcharged by the District Auditor) but who have power to prosecute where the interests of the ratepayers are affected (Local Government Act, 1933). A duty of enforcement should be placed upon them.

(3) Responsible Ministers should be given power to make Regulations as to the composition, labelling and safety of goods.

In all these three respects the Merchandise Marks Acts should be brought into line with the Food and Drugs Act.

Two Major Acts

Today, therefore, there are two major Acts covering some of the same ground:

(1) The Merchandise Marks Act, administered by the Board of Trade but under which any person can institute proceedings, and which deals with the actual application of false trade descriptions to any goods.

(2) The Food and Drugs Act, administered by the Ministries of Agriculture, Fisheries and Food and of Health, and enforced by some 375 local food and drugs authorities, in relation to the use of false or misleading labels and advertisements for foods and drugs only.

The inter-relationship of these enactments invites further comment. Consider first the legal definition of "advertisement." This

will be found in Section 135(1) of the Food and Drugs Act, but not in the Merchandise Marks Act, and is as follows:

> Advertisement includes any notice, circular, label, wrapper, invoice or other document, and any public announcement made orally or by any means of producing or transmitting light or sound.

No parallel definition is necessary in the Merchandise Marks Act, for here the offence is the actual attachment of a false description to the goods sold and not the publication of some statement about them. Even so, by an amendment of 1938,[2] goods delivered as the result of a request made by reference to a trade mark or description appearing in an advertisement now come within the protection of the Merchandise Marks Act. At first sight it would appear that a straight oral description would still not come within the provisions of the Merchandise Marks Acts, but if the connexion between the statement and the actual sale were close enough, there seems little doubt that proceedings could be taken.

Heavier Penalties

Those who are particularly interested in the enforcement of the Food and Drugs Act might also care to notice, since action might in appropriate cases be taken under either measure, that the penalties for offences under the Merchandise Marks Act are heavier than under the Food and Drugs Act. Further, whereas special sampling procedures have to be observed in food and drugs cases, with a time limit applying to the institution of proceedings, no such conditions apply to actions under the Merchandise Marks Act. There are, of course, limitations to proceedings under the Merchandise Marks Act. So far as proceedings on indictment are concerned, section 15 (Bell, cited at footnote 2, at p. 566) operates, but it seems probable that in the case of summary proceedings, the six-month limit of section 104 of the Magistrates Courts Act, 1952, would apply. These differences might well influence a local authority instituting proceedings, though normally one would expect the authority to take action under the Food and Drugs Act, under which their normal duties arise.

Since the Merchandise Marks Act antedated the 1938 Food and Drugs Act by some 50 years, it is not surprising to find that the greater volume of case law has arisen from the application of false trade descriptions to foods. Some of these actions might have been

[2] This was sub-section 2A to section 5 of the Merchandise Marks Acts, 1887, which was inserted by the Patents, etc., (International Convention) Act of 1938, section 10. See Bell's *Sale of Food and Drugs*, 13th ed., at p. 563.

taken today under the Food and Drugs Act. One or two cases under the Merchandise Marks Act are quoted to illustrate this point.

Lemy v. Watson (1915) established that brisling, treated and packed like sardines, were falsely described as sardines.

In *Holmes v. Pipers* (1914), the Court made the man-in-the-street's knowledge their guide in condemning the description "British Tarragona Wine" applied to a five-to-one mixture of British wine with Tarragona, and held that the apparent contradiction in terms in the description would not be apparent to those without special knowledge. "These Acts are designed to protect persons who have not all this knowledge" was the dictum of one of the judges.

Again, though there was a trade practice to describe mixtures of Scotch and Irish whiskey as "Scots Whiskey," the practice was not known to the public, and in *Henderson and Turnbull v. Adair* (1939), this was held to be a false trade description. Lastly, in the recent case of *Kat v. Diment* (1951), the description "non-brewed vinegar" applied to a synthetic acetic acid product was condemned. The Court held that vinegar was a product of the acetous fermentation of alcohol, and it therefore followed that this synthetic product did not come within the genus vinegar. The species qualification "non-brewed" could not clear the falseness of the basic description, even though it had been used for many years and may not have misled the purchaser. It would seem to follow that the time-honoured description "non-alcoholic wine" could be challenged under this ruling; at any rate, it has been dropped from the Ministry of Agriculture, Fisheries & Foods Orders dealing with soft drinks. Indeed, it might be an interesting exercise to consider whether other "popular" descriptions applied to certain foods might not also be challenged on the strength of the ruling in *Kat v. Diment.*

Incidentally, the "Scots Whiskey" case and the "non-brewed vinegar" case are typical instances of the value of the Merchandise Marks Act in resolving the claims of rival trade interests. Both could have been taken under the Food and Drugs Act had one of the parties been able to persuade a local food and drugs authority to spend its ratepayers' money on the proceedings. But local authorities are not quite so green as to fall for this view of their duties—nor was the Ministry of Food, which was also an enforcing authority by this time.

Misleading Labels

So much for a rapid survey of the relationship of these basic measures. Let us now consider how things have gone since the

Food and Drugs Act of 1938 first brought misleading labels and advertisements into the net, remembering at the same time that power was given to the Minister to make "food regulations" regulating the labelling, but not the advertising of food.

The second World War had started before the Act came into force. Ministers had something else to think about, and it is not surprising, therefore, that there were no immediate developments. By 1943, however, action could no longer be delayed, for food substitutes had flooded the market and malpractices born of food shortages had to be tackled. The Defence (Sale of Food) Regulations of that year made the wartime Ministry of Food responsible for the administration of the new powers in Section 8 of the 1938 Act. But the Defence Regulations went a little farther than this. They laid down specifically that a label or advertisement which misleads as to the nutritional or dietary value of a food misleads as to its nature, substance or quality—a most valuable clarification of the legal position. Again, by an additional power not formerly enunciated, the Minister was empowered to restrict by Order claims on labels or in advertisements as to the presence of vitamins and minerals in food. In due course the new power was exercised in the Labelling of Food Order, and it has been of enormous help in preventing an uncontrolled "vitamins-in-food" campaign. Until the 1955 Food and Drugs Act came into force, this was the only specific control of food advertising in our food and drugs legislation.

Long-awaited Remedy

Looking back to 1943, one is inclined to wonder whether, under the exigencies of war, powers to regulate food advertisements generally, on a par with those applying to food labels, might not have been obtained. I think the truth is that no one thought of this. However, the absence of power to regulate food advertisements has proved a serious handicap to the better protection of the consumer, and the remedy has taken 12 years to appear. To my mind, one of the most important new provisions in the 1955 Act was the inclusion of this very power. Strangely enough, it has gone almost unnoticed, and has occasioned remarkably little comment. No Food Advertising Order, corresponding with the now well-established Food Labelling Order, has yet been made, nor has there been even the suggestion that one is on the stocks.

Let me emphasize, therefore, that if there are trends in food advertising today which are open to criticism as being unethical and contrary to the consumer's interest, there is now power to deal with them by regulation. From the consumer's angle, it must be obvious that advertising is of greater importance than labelling. When one thinks of the power of advertising, with some six million of the adult population viewing the I. T. A. programme every day, the futility of controlling certain claims on food labels and leaving the advertising of the same products practically free from control should be obvious. Somehow or other, we seem to have put the cart before the horse. This is shown by the evidence given by the Food Manufacturers' Federation before the Willis Committee in 1934, when they stated that unless food advertisements were subjected to the same regulations as labels, the law would be stultified.

What then are the labelling controls already in force which logically should also apply to advertisements, even if our reforming zeal carried us no farther than this?

The case of vitamin and mineral claims has already been mentioned. The Advertising Association has continued to do much good supporting work.

Another quite important control is that, under the Labelling Order, tonic claims on labels must not be based on the presence of alcohol, carbohydrates, protein derivatives or caffeine in the food. Further, in the case of beverages, tonic, restorative or medicinal claims (for example, "beneficial to invalids") may not be made unless the tonic ingredient is named on the label and the quantity present is disclosed. Clearly, these are only half-measures unless advertisements have to conform to the same measure of control.[3]

Special labelling requirements apply to particular foods, to ensure, for example, that canned garden peas can be distinguished from processed peas by examining the label rather than waiting for the evidence obtained on opening the tin. Similarly, the use of the terms "French" coffee and "Viennese" coffee are regulated to avoid confusion with ordinary coffee. Surely advertisements for all these products should be subject to at least the same, if not, indeed, more stringent control.

[3] It should be pointed out that since this paper was written, a limited use of the power to make regulations as to the advertising of foods has been exercised by the Ministry in Article 7 AC of the Labelling of Food Order, 1953 (Bell, cited at footnote 2, at p. 455) and in more recent Orders relating to Emulsifiers and Stabilizers, Preservatives, Bread & Flour, etc.

Even were this done, most advertisements would escape such regulatory control because, since the claims made in the advertisement do not appear on the labels, no labelling regulation has been called for. This leaves us with little to go upon but the desirability of examining advertisements to determine whether any alternative action is necessary. I have no doubt that in the consumer's interest this is the case. Indeed, some of the simpler and more obvious cases have been dealt with administratively by the Ministry, even without amending the labelling regulations. An example is the discouragement given to the use of such words as "Doctor" or "Nurse" as a prefix to the names of foods, and its general acceptance by the trade.

I believe it is high time that some of the trends in modern food advertising were critically and officially reviewed. Good food advertising can legitimately discuss nutritional value, coupled with excellence of production, but surely special health claims and pseudo-medical claims should be banned, except in the case of foods put up for special dietary purposes, for example, diabetic foods. No single food holds the keys to good health, but from some advertisements one might almost begin to believe that this was the case. Today the Press carries advertising themes which on occasion descend to a type of "fear advertising." I have in mind an advertisement some months ago which implied that there was a connexion between thrombosis and the intake of cholesterol; its moral was: "Eat more fish and less meat." This kind of statement should have no place in good advertising. Hardly less objectionable are those food advertisements which urge you to avoid partial or disturbed sleep, or to obtain (on the doctor's advice!) the right sort of sleep, and so on. From this we proceed to advertising appeals on the importance of counteracting, from the cradle to the grave, certain adverse factors in the diet if you want to enjoy full health. If only the medical profession could prescribe accordingly for the welfare of the community, what long lives we could all look forward to!

In all these cases the food advertised is a worthy product—it is the exaggerated style and trend of the advertising to which objection is taken. Surely manufacturers need not go to these lengths to sell their goods? Unfortunately when one trader starts it, competitors feel they have to follow. In this connexion it is interesting to notice that India has gone a step ahead of us, for in her Prevention of Food Adulteration Rules of 1955 a ban is placed on the use of words implying recommendation by the medical profession on food labels. How

welcome should be similar action by this country, in relation to both labels and advertisements.

Again, one is invited to eat ourself slim, and so on. This may indeed be possible, but slimming practices, without medical advice, are not free from danger. Generally speaking, it is open to question whether it is in the consumer's interest for the advertising of foods to follow these paths. At the opposite end of the scale there are the energy claims and the recommended use in convalescence of carbohydrate foods and especially of dextrose (under the less accurate description glucose). The medical evidence in favour of consuming a relatively expensive sugar like dextrose in preference to sucrose is somewhat thin, at any rate so far as the vast majority of the population is concerned. Further, such claims become less worthwhile when applied to fruit drinks, since those made from cane sugar are completely inverted within a day or so of manufacture. The really disturbing part of this fashion for boosting glucose by one advertiser is that again it pushes rival traders to try to cash in by similar methods. Such advertising seems basically unethical and of no service to the average consumer. In the long run it seems more than likely that it will do the reputable food manufacturer little good. If our legislators will not intervene, perhaps the Advertising Association can be persuaded to do something about it.

Wordy Advertisements

A word of warning is warranted on the verbose character of some advertisements, though of itself this need not call for criticism. The advertising agent and his client are presumably the best judges of their value, but still their very wordiness may not be free from danger. Whereas no single statement could be pinned down as misleading, yet on occasion the over-all impression leaves the critic uneasy. I remember a judgment in the American courts arising out of the advertising of a multiple vitamin and mineral capsule, when the judge held that the advertisements were fairly "intended to induce the general public belief that the ordinary food diet of the U. S. is deficient in minerals and vitamins and that it is necessary to supplement the diet in practically all cases by a composition of vitamins and minerals." He accepted the evidence of "several competent and experienced physicians" that this was not the case. Thereupon he stated that "in determining the question of falsity, the advertisements must be considered in their entirety and as they would be read or understood by those to whom they appeal."

The same point was made in another judgment in these words: ". . . the law is not made for experts but to protect the public—that vast multitude which includes the ignorant, the unthinking, and the credulous, who, in making purchases, do not stop to analyse, but too often are governed by appearance and general impressions." And yet again—another dictum—". . . words and sentences (in advertisements) may be literally true and yet be framed in such a setting as to mislead or deceive."

This last statement is surely in agreement with Section 6(5) of our own Food and Drugs Act, which states that "the fact that a label or advertisement . . . contained an accurate statement of the composition of the food or drug shall not preclude the court from finding that the offence (that is, that the label or advertisement was misleading) was committed."

It seems legitimate to quote these American judgments, for the offence of issuing a misleading label or advertisement is the same in both countries. Further, it should not be without interest to notice how closely the dictum, quoted earlier in *Holmes v. Pipers,* is followed. I have some confidence for suggesting, therefore, that our own High Court would adopt the same views, and this point might well be taken by the Advertising Association in their own efforts to improve the ethical standard of food advertising.

I have already referred to the power of TV advertising. The I. T. A. has issued a booklet on the principles of TV advertising which is most useful and informative. It is clear therein that the advertising of medicines is controlled most carefully, but that of foods is not. Canada has tackled this subject in the most forthright manner, for under the regulations of the Canadian Broadcasting Corporation every script for the broadcasting of food and drug continuities must have the prior approval of the Department of National Health and Welfare.

The better protection of the consumer can hardly be obtained without recourse to the new powers that have been given in the 1955 Act, but the Government certainly seems slow to use them. It is high time a start was made.[4] Failing that, one can only hope that the Advertising Association will continue their valuable advisory work with the trade. Perhaps the announcement by the late Sir Frederick Hooper, on behalf of the Association, about the formation of a Con-

[4] The Ministry's Food Standards is at present reviewing the labelling and advertising of food, and it may be anticipated that some further application of the power to regulate advertisements may be recommended.

sumers' Council is another pointer. The Council, we are told, is designed to bring about closer contact between consumer and advertiser and its aims should have our fullest support.

I hope my paper has not given the impression that all food advertising is bad, or even that most of it is open to criticism. That would not be my opinion, and, moreover, it would be far from the truth. But bad habits seem to be creeping in, and bad habits seem to grow quicker than good ones. The law at last gives power to deal with these matters, and I hope for the benefit of all concerned that you will be persuaded to use what influence you have to press for the implementation of these powers. **[The End]**

MULTI-MILLION DOLLAR VITAMIN AND FOOD SUPPLEMENT BUSINESS HALTED

A federal court has ordered a halt to a multi-million dollar, nationwide business by six interlocking firms selling vitamins and other food supplements with false health claims in the labeling, the Food and Drug Administration, Department of Health, Education and Welfare announced. Judge Arthur S. Lane of the District Court at Trenton, New Jersey, issued a temporary restraining order against the six firms. Judge Lane will set a hearing on a preliminary injunction for later this month.

The complaint for injunction charged that the defendants receive bulk drums of food supplements in capsule form from various firms and repack the capsules into retail size containers. Large quantities of promotional literature are used to induce purchasers to buy the preparations. Judge Lane's order prohibits these products from interstate distribution under false and misleading claims. The injunction complaint charged that the products are misbranded as follows:

(1) The labeling falsely suggests that the nutritional needs for men and women differ.

(2) By listing certain ingredients the labels falsely imply and suggest that the nutritional value of various capsules is enhanced by their presence.

(3) Labeling statements falsely imply that large amounts of common foods must be consumed to furnish quantities of nutrients equal to those present in one of the food supplement capsules.

(4) The products are falsely represented to be effective for the treatment or prevention of some 38 disease conditions.

(5) The product's labeling falsely suggests that nearly everyone in this country is suffering from or is in danger of suffering from a dietary deficiency of vitamins, minerals and proteins which is likely to result in specific deficiency diseases.

(6) The products are further misbranded because they are often represented to contain a "lipotropic factor" (a substance involved in the liver's metabolism of fat) and their labeling fails to bear adequate directions for use as such.

The Physician and the FDA

By JOSEPH F. SADUSK, JR., M.D.

This Paper Was Presented Before a Joint Meeting of the Sections on Autoimmune Diseases, Experimental Medicine and Therapeutics, Internal Medicine, Pathology and Physiology, and Preventive Medicine, at the American Medical Association Convention in San Francisco on June 23, 1964. Dr. Sadusk Is Medical Director of the Food and Drug Administration.

WHILE SOME STATES had taken elementary steps toward drug regulation at the turn of the century, the problems of unwarranted promotion of drugs were basically uncontrolled until the passage of the first Pure Food and Drug Law in 1906. This law, judged by today's standards, was totally inadequate, but for the first time it provided a limited control of interstate traffic in drugs. Judged by the standards of 1906, it was a landmark law of first importance.

Over the following years, some improvements were slowly made in the 1906 statute. For instance, a provision instituted in 1912 made it possible for the government to take action on false therapeutic claims for drugs, but *only* if it could be established that such claims were made fraudulently.

Then came the Elixir of Sulfanilamide disaster in 1937—leading to the death of over 100 people before the product could be removed from the market—and this had to be done on a legal technicality. The Congress took action, adding a New Drug Section to the Pure Food and Drug Law in 1938. This provided that a manufacturer not only had to test a new drug for safety, but also that he had to report the results to the government before the drug could be marketed.

Another major step occurred in 1962 with the passage of the Kefauver-Harris Drug Amendments which provided the following safeguards to the public:

(1) The producer of a drug had to prove that his drug was effective, as well as safe, for its intended uses;

(2) Adequate controls were provided for the distribution and use of investigational drugs;

(3) Prescription drug advertising was carefully controlled;

(4) Improved procedures and strengthened requirements for approving and withdrawing approval of new drug applications were promulgated;

(5) Principles were established for the production of drugs under good manufacturing practices; and

(6) Provisions were made for record keeping and reporting of experience with approved drugs by the manufacturer, permitting the government to continuously and regularly follow a drug when it appeared on the market; thus that if safety or effectiveness could no longer be assumed, the drug could be removed from the market or its labeling could be appropriately revised.

I cannot overemphasize the importance of these amendments. For the first time, the Food and Drug Administration was given adequate authority to refuse to approve or to withdraw approval of a new drug on the grounds that the claims for effectiveness were not adequately supported by the evidence available.

These amendments were at first greeted with dismay by investigators and the drug industry. The investigator feared that his freedom in research was going to be stifled by some provisions of the Act, particularly that portion dealing with the need for obtaining consent from the patient before embarking upon the use of an experimental drug. But the need for such consent was not new since the Judicial Council of the American Medical Association some years ago outlined three requirements to be satisfied before a physician could experiment with new drugs or procedures in the human. These were:

(1) The voluntary consent of the person on whom the experiment is to be performed must be obtained;

(2) The danger of each experiment must be previously investigated by animal experimentation; and

(3) The experiment must be performed under proper medical protection and management.

The investigator's fears about the patient-consent provision of the federal law are unnecessary, since under that law an investigator may dispense with such consent when this is not feasible, or where in the investigator's professional judgment, it would be contrary to the best interests of the patient under investigation.

The pharmaceutical industry believed that the clearing procedure by FDA would be so formidable that new drugs would not find their way to the physician. This fear has also been found to be unjustified since new compounds do regularly continue to reach the doctor. In brief, while the clearance of drugs has become more demanding, the public has benefited by our rigorous process of carefully screening a drug for both safety and effectiveness.

Let us go more thoroughly into this concept of balancing usefulness of a drug against its dangers, since the physician is faced every day with the problem of deciding *for his patient* whether the potential benefits from use of a medication justify the risk in administering it. This is a basic problem since no drug, even aspirin, is without danger. The only difference is that some drugs are more toxic than others. Some produce adverse reactions relatively frequently, others rarely. The more toxic a drug is, the more care a physician must take in its use. He must not use potent drugs, which are capable of producing death and disability, for trivial complaints.

In this respect, what is the relationship between the doctor and the FDA? The relationship is a close one, and indeed, the relationship will grow closer as time goes along. The Congress, in the public interest, has charged the FDA with the responsibility of seeing that the profession is provided with effective and safe drugs for their patients and with adequate information for the safe and effective use of these drugs. Consequently, the physician and the FDA have a mutual interest—and this carries with it a mutual responsibility—in the careful and judicious administration of medications.

Now, to a certain extent this is done by the FDA under its responsibilities to provide assurance, insofar as is humanly possible, that under the conditions of use proposed in its labeling, a new drug may reasonably and responsibly be judged to offer the benefits claimed for it and that the benefits outweigh the potential hazards. But we must also depend upon the physician to apply these principles of balancing efficacy against toxicity at the individual patient level. The doctor must decide, in light of a drug's potential toxicity, that its use is warranted for his patient.

Such a drug, efficacious but also capable of significantly serious toxic reactions, was introduced to the physician in February of 1961. This drug was tranylcypromine, perhaps better known to you as

Parnate—a name which I shall use during the remaining presentation. Due to the appearance of what seemed to be an excessive number of adverse reactions, the drug was removed from the market by the manufacturer in February 1964, upon the recommendation of FDA.

Since then, the FDA has continued to collect and evaluate the adverse reaction information on an estimated 1.5 million patients treated with Parnate in the United States up to February 1964. In addition to side effects, such as hypertension, vertigo, tachycardia, cardiac arrhythmia, nausea and vomiting, chest pain and dilatation of pupils, more serious reactions such as headache, neckache, and hypertension, with or without a stroke, were found. These more serious reactions seemed to bear a relationship, in some instances, to other medications administered simultaneously, such as other mono amino oxidase inhibitors, sympathomimetics (including amphetamines) and vasoconstrictors. Even cheese, presumably due to its tyramine content, seemed to be associated in some cases with these reactions, especially the appearance of hypertension.

The most serious reaction observed was that of the hypertensive crisis and which, in some cases, was connected with a cerebral vascular accident. Approximately 500 cases of induced hypertension were found. In addition, 38 cerebral vascular accidents were collected, among which 21 deaths were recorded. These cases have been carefully analyzed by our Bureau of Medicine staff. The usual difficulty of determining whether the relationship of the stroke to Parnate was causal or temporal was compounded by the fact that other significantly important drugs were being received by the patient at the time he took Parnate. But be that as it may, our medical review would indicate that there was a highly probable causal relationship in only 7 of the 38 cerebral vascular accidents. Of these 38 strokes, 25 were on concomitant medication, and 10 were of age 60 or above. Of the 21 deaths from stroke, six were of age 60 or above.

In final summary of the toxic potentiality of Parnate, we concluded that it was a drug capable of severe side reactions, some even leading to death, but that these serious reactions were seemingly low in incidence. Nevertheless, it remains clear that the use of Parnate calls for continuing care on the part of the physician, not only from the aspect of selecting patients carefully, but also from the point of careful observation and follow-up of the patient.

We then evaluated the efficacy of the drug, taking into account the definition of "substantial evidence" which, as defined in the Federal

Food, Drug and Cosmetic Act means "evidence consisting of adequate and well-controlled investigations . . . by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." While we found only a small number of controlled studies, these did indicate effectiveness of Parnate in the treatment of depression. Our conclusions were supported not only by experts from the National Institute of Mental Health of the United States Public Health Service and St. Elizabeth's Hospital, but also by investigators, and academic and practicing psychiatrists. In addition, many individual physicians have indicated to us that Parnate is a useful drug and indeed, that some patients appear to be Parnate "specific."

Thus we concluded that the hazards of Parnate were justified by its usefulness in the treatment of severe depression, since this was an illness in which suicide was possible and in which electroconvulsive therapy could not always be used for one or more reasons. Furthermore, it seemed to us that these hazards could be minimized and substantially avoided by careful use of the drug. Consequently, we have accepted a drastic revision of the labeling of Parnate from the drug's manufacturer which will allow this drug to re-enter the market for use only in severe cases of mental depression.

To meet its obligation under the law, the FDA accepted revised labeling which imposes drastic restrictions on the use of Parnate. Some of these restrictions are: (1) Parnate is to be used only in cases of *severe* depression; (2) Parnate is to be used only on patients who are either hospitalized or in patients who are under close observation and in whom electroconvulsive therapy is not indicated and other medication has been found to be ineffective; (3) Parnate is not to be used in patients over 60 years of age or in whom there is evidence of history of hypertension or other cardiovascular disease; (4) The maximum dosage of Parnate used is to be significantly reduced, employing a recommended top level of 30 mgm. per day, as compared to a top level of 60 mgm. per day which was indorsed in the previous labeling of September 1963; and (5) Parnate is not to be used in combination with many other potent drugs, all of which will be carefully outlined in the new labeling. Particular warning will also be given to the need for the patient to abstain from cheese while on Parnate.

The drug's manufacturer has estimated a maximum of six weeks before the drug reappears on the market and, prior to the reintroduction of the drug, the manufacturer will mail a copy of the package

circular in booklet form to all physicians. I urge all of you to read this circular with great care before embarking upon the use of Parnate, since it is a potent drug and I have been able to cover only a small number of the important points today. Your care in the use of Parnate will merit our trust in you—the practicing physician—in permitting the return of this drug to the market.

Just one final word on the package circular. This is a concise, but very informative set of recommendations to the physician on the use of a drug. Indications and limitations of use, warnings and precautions, side effects, and administration and dosage are carefully outlined. The manufacturer includes one of these package circulars with every bottle of a drug. It is to your interest and to your patient's interest that you obtain these circulars and read them carefully, since the manufacturer and the FDA put much time and effort into their preparation.

The claims for effectiveness, side effects, contraindications, and cautions are required to appear in brief summary form in every advertisement for a prescription drug. Such advertisement must present in fair balance what the drug may reasonably be expected to do, the limitations on its use, and what hazards surrounding its use should be borne in mind.

To a limited extent the circulars which I mentioned above are reproduced in the *Physicians' Desk Reference,* published by Medical Economics. Physicians receive an annual copy of this book from Medical Economics.

Finally, you should also read the American Medical Association publication, *New and Nonofficial Drugs.* This is published annually by the AMA and contains a wealth of information on the use of certain drugs.

In closing, may I briefly reiterate the fact that good and potent drugs continue to appear for your use. But as the potency of these drugs increases, so generally does their complexity and their potentiality for harm. Consequently, it is your duty to fully inform yourself of the composition, mode of action, efficacy, and potential toxicity of these agents before you embark upon their use. This information is readily available to you in all package inserts, in direct mailing pieces, and in brief summary form even in prescription drug advertising. You owe a duty to your patient to use this information.

[The End]

Use This Check List to Add to Your Permanent Food and Drug Law Library

Wherever things happen of importance to Food and Drug Men, you'll find CCH there with handy desk helps on food, drug and cosmetic law. Each of these books was written by an outstanding authority in the field and published by Commerce Clearing House, Inc., for The Food Law Institute. They serve as a chronicle of the development of food law, including the associated drug and cosmetic laws; provide an adequate library for everyone concerned.

Some BOOKS IN THE FOOD LAW INSTITUTE SERIES:*

- ✓ General State Food and Drug Laws—Annotated, by David H. Vernon and Franklin M. Depew. Table of contents; 816 pages. Price: $17.50 a copy.
- ✓ Constitutional Questions in Food and Drug Laws, by Thomas W. Christopher. Topical index; 128 pages, 6" x 9", heavy paper covers. Price: $3.50 a copy.
- ✓ Federal Food, Drug, and Cosmetic Act—Judicial and Administrative Record. All these publications include indexes and case tables.
  - 1958-1960, (Kleinfeld & Kaplan), 528 pages. Price: $17.50 a copy.
  - 1953-1957, (Kleinfeld & Dunn), 1,444 pages. Price: $25.00 a copy.
  - 1951-1952, (Kleinfeld & Dunn), 588 pages. Price: $12.00 a copy.
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