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Food Drug Cosmetic Law JOURNAL

Pesticide Laws and Legal Implications of Pesticide Use (Part II)

. . . . . DOUGLASS F. ROHRMAN

Question and Answer Panel of the FDLI—FDA Eleventh Annual Educational Conference

A COMMERCE CLEARING HOUSE PUBLICATION
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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

Pesticide Laws and Legal Implications of Pesticide Use — Part II. — Part I of this article by *Douglass F. Rohrman* appeared in the March issue of the JOURNAL. Part II, which begins on page 172, examines pesticide use liability. Mr. Rohrman, a member of the Illinois Bar, is an associate of Spray, Price, Hough and Cushman, Chicago, on leave of absence, 1967—1968. He is currently Legal Co-ordinator, Pesticides Program, National Communicable Disease Center, Bureau of Disease Prevention and Environmental Control, Public Health Service.

Question and Answer Panel of the FDLI—FDA Eleventh Annual Educational Conference. — The Question and Answer Panel held during the Eleventh Annual Educational Conference of the FDLI-FDA is featured on page 185 of this issue. The moderator was *Fred J. Delmore*, Director of the Bureau of Education and Voluntary Compliance of the FDA.

Members of the panel were: *Theodore E. Byers*, Director, Division of Regulatory Compliance, FDA; *M. L. Yakowitz* of Smith, Kline and French Laboratories in Philadelphia; *R. Keith Cannan*, Special Assistant to the President of the National Academy of Sciences-National Research Council; *Vincent A. Kleinfeld*, partner in the Washington, D. C. law firm of Kleinfeld and Kaplan; *Julius Hauser*, Assistant for Regulations, Office of the Associate Commissioner for Compliance; *R. W. Ballard*, Executive Medical Director of McNeil Laboratories, Inc.; *Kenneth M. Endicott*, Director of the National Cancer Institute.

Sampling and Testing of Drugs.— Beginning on page 200, *Theodore E. Byers*, Director of the Division of Case Guidance, Bureau of Regulatory Compliance of the FDA, discusses the difficulty of obtaining and testing adequately representative samples of drugs on the market. This article was a speech delivered at the FDLI-FDA Eleventh Annual Educational Conference.

A View from the Top—The Pharmaceutical Manufacturer's Multi-Responsibilities.—The article by *Dr. Austin Smith*, which begins on page 203, was originally presented at a meeting of The Practising Law Institute on November 17, 1967 in New York City. The author outlines the responsibilities of drug manufacturers, and stresses the urgent need for restoration of the industry's good public image.

Legal Aspects of Modified and Vegetable Fat Dairy Products.—This was the topic of an address presented by *Charles M. Fistere* at the New Products Symposium of the North Central Milk and Ice Cream Association at Minneapolis on January 18, 1968. Mr. Fistere, General Counsel for the Milk Industry Foundation, discusses federal law, state law, the law of the North Central states, and recent court cases which are applicable to modified dairy products. The article begins on page 209.

Voluntary Compliance Encouraged by Bureau Changes.—In the article beginning on page 227, *Fred J. Delmore* discusses the recent reorganizations in the FDA internal structure which illustrate the Agency's commitment to industry-assured compliance programs. Despite these changes, however, quality assurance may not be rapidly achieved, for many firms will have to modernize their quality control systems. Mr. Delmore is Director, Bureau of Voluntary Compliance. The article is reprinted from *FDA Papers*, February, 1968.

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Pesticide Laws and Legal Implications of Pesticide Use—Part II

By DOUGLASS F. ROHRMAN

Mr. Rohrman, a Member of the Illinois Bar, Is an Associate of Spray, Price, Hough and Cushman, Chicago, on Leave of Absence, 1967—1968. He Is Currently Legal Co-ordinator, Pesticides Program, National Communicable Disease Center, Bureau of Disease Prevention and Environmental Control, Public Health Service, Department of Health, Education and Welfare. The First Part of the Following Article Appeared in the March Issue of the *Food Drug Cosmetic Law Journal*.

Pesticide Use Liability

IN RECENT YEARS there has been a very rapid advance in the discovery, synthesis and manufacture of pesticides. One of the more famous and spectacular of these is 2,4-Dichlorophenoxyacetic acid or 2,4-D. This compound was first synthesized in 1941 and was first used as a weed killer in 1944.[60] 2,4-D is a selective herbicide which, generally speaking, will kill broad-leaved plants but not most grasses when applied in proper quantities. It is extremely valuable in killing weeds in grains, including wheat, rice, and corn, and in grass used as hay or pasture. However, of great importance to a

[60] See Hayes, *Clinical Handbook on Economic Poisons*, 1966, pp. 106-109 for further information on the chlorophenoxy herbicides such as 2,4-D and 2,4,5-T. See also 7 C. F. R. 362.115 for special 2,4-D; 2,4,5-T and MCPA labeling regulations. See *Burns v. Vaughan*, 216 Ark. 128, 224 S. W. 2d 365 (1949) for a case involving the remarkable drifting power of 2,4-D mentioned in text, below. See also *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 10, 2091-2182, 1964 for discussion of drift.

legal analysis is the fact that it has the tendency to drift very easily and, in some cases, has been known to drift as far as twenty miles when applied in windy weather by aircraft. Also, considerable drift has been known to occur when 2,4-D is applied by ground equipment. Damage to broad-leaved crops such as cotton, tomatoes, and other vegetables has resulted from drift. 2,4-D in dust and certain other formulations is particularly likely to drift, and application in this form by aircraft has not been approved by the Department of Agriculture. Therefore, the use of this compound has presented a basic pesticide dilemma: when properly applied, it has considerable agricultural benefits; however, when allowed to drift, it may cause significant plant or crop injury. Application of such a substance sets up a definite legal duty on the part of the custom applicator or the user to apply 2,4-D and similar compounds with reasonable care. Many pesticides have characteristics analogous to 2,4-D, and are potentially dangerous if used, applied, stored and disposed of in a negligent manner. The consequences of negligent use or willful misuse of such materials is obvious.

DDT and other chlorinated hydrocarbon pesticides also have another characteristic which may be important from a legal standpoint. Some of these pesticides owe their effectiveness in part to their long persistence after application. Coupled with moderately high toxicity, this persistence of some of the chlorinated hydrocarbons may pose a serious problem of causation and, in turn, legal duty when a poisoning takes place some time after actual application.[61] Persistence, or bioconcentration, can also have a significant effect on lower organisms of high-sensitivity, thus threatening the ecological balance and essential links in the food chain.

The agricultural dangers are, however, not the only problems that have and will occur again in connection with the careless use of pesticides. While not as clearly documented as the possible injuries to vegetation, the potential dangers of pesticide poisoning to man, when a substance is not given proper precautionary attention or is used improperly, are of great concern to many.[62] A sizeable

[61] See "What We Mean by Persistence of a Pesticide," *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 6, 1167-1168, 1963; "Persistent Pesticides," 22 *Ag. Chem.* 30-23, 1967; and Lichtenstein, "Persistence and Degradation of Pesticides in the Environment," *Scientific Aspects of Pest Control* 221, 1966.

[62] See Lehman, *Summaries of Pesticide Toxicity*, 1965 for an indication of the possible dangers to man of many pesticides used today. See also Hayes, "Toxicological Problems Associated with Use of Pesticides," 5 *Ind. Tropical Health* 118, 1964 and Hayes, *Clinical Handbook on Economic Poisons*, 1966.

number of pesticide poisonings are known to have occurred either through direct application and contact, improper storage and disposal of containers, or acute occupational and environmental exposure.[63] It may be that some number of pesticide injuries and deaths are not recognized, not reported or incorrectly diagnosed.[64] One study in southern Florida has shown that pesticides "are definitely the most significant causative agents in accidental death by poisoning of children."[65] Also, as an illustration, in 1961 there were 119 deaths in the United States due to pesticides, with most of them

[63] For example, see Hayes and Pirkle, "Mortality from Pesticides in 1961," 43 *Arch. Environ. Health*, 1966, in which 119 pesticide deaths in 1961 were analyzed. Hayes and Pirkle attributed 58% of these deaths to compounds in use before the discovery of DDT, 34% to newer compounds, and in 8% to no specific compound. Fifty-one percent of the cases were children under ten. This figure emphasizes the need for control over the storage and disposal of pesticides which may come into the hands of children unable to comprehend the danger of the substances. Geographically the Hayes study pointed out that the Southwestern and mountain regions of the United States showed a higher ratio of pesticide deaths. The relatively small number of pesticide poisonings in California is noteworthy in view of the extensive use of pesticides in that state. A sound explanation for this is the comprehensive and well-administered set of laws in that state. In spite of this, however, a recent study reported 830 pesticide accidents leading to personal injuries in California in 1965. Hillis, "The Pesticide Regulatory Program in California," Speech before the International Conference on Educational Aspects of Pesticide-Chemical Usage, July 10, 1967. See also Davies and others, "Disturbances of Metabolism in Organophosphate Poisoning," *Industrial Medicine and Surgery* 58-62, 1967. This study analyzed the deaths in Dade County, Florida, from pesticide poisoning in the years 1959 to 1965. In that period, 72 people died of pesticide poisoning. Twenty-eight of the deaths were deemed accidental, 19 involved children and 42 of the total were attributed to organophosphate pesticides (most notably). Another report by Reich, *The Characteristics of Pesticide Poisoning in South Texas*, U. S. P. H. S., Unpublished, 1967, catalogued 129 non-fatal pesticide poisonings in Cameron County, Texas from 1961 through 1966. Dermal exposure was found responsible for 98% of the cases. This report, unlike others, studied poisonings of 126 adult males, one adult female and only two children. By occupation, 74 were workers for spray pilots, 38 were farm laborers, eight were spray pilots, four were formulators or workers in formulating establishments, one was a farmer, two were children and two were unknown. Only six of these cases had been previously poisoned. Ethyl and/or methyl parathion were found responsible for 96% of the reported poisonings. In addition, see also these excellent articles: Wolfe and Durham, "Exposure of Workers to Pesticides," 14 *Arch. Environ. Health* 622, 1967 and Hayes, "Monitoring Food and People for Pesticide Content," *Scientific Aspects of Pest Control* 314, 1966.

[64] This one factor minimizes the dramatic effect of pesticide death analyses. For further reference, see Davis, "Clinical Epidemiological and Forensic Aspects of Pesticide Poisonings," Speech before the Inter-American Conference on Toxicology and Occupational Medicine, Aug. 1966.

[65] See footnote 64 at 3. Davis states also that many more pesticide poisonings were very probably not discovered or diagnosed as such.

ascribed to identifiable materials.[66] Since some potentially harmful pesticides also have been found to be absorbed readily into the fat of cattle which feed upon vegetation sprayed with these compounds, the appearance of pesticides residues in milk may create another field in pesticide liability.[67] In actuality, however, the acute instances of pesticide poisoning, while patently important to a legal analysis, are not of greater concern than the less obvious and more subtle potential effects of low level long-term exposure of pesticide chemicals on man.[68]

The growth of custom spraying and dusting, the rapidity of new discoveries, the possibility of injury to man's health, plants and animals, including wildlife, and the possibility of both dangerous and fraudulent practices makes public regulation increasingly necessary.[69] Cognizant of these issues, the Department of Agriculture from time to time limits the use of specific pesticides on certain crops through certain means of application, thereby alleviating obvious hazards to the food supply and man's health.[70] Also, state and local regulations, as well as federal laws, as mentioned above, have been designed to meet the need for public regulation in some of the areas of concern.

The foregoing leads to several difficult problems in connection with the application of pesticides. The question of liability for injury to persons, crops, and animals resulting from drift of the materials

[66] See footnote 63.

[67] Clifford, "Pesticide Residues in Fluid Market Milk," 72 *Pub. Health Reports* 729, 1957. See allied articles of interest: Dale and others, "Storage and Excretion of DDT in Starved Rats," 4 *Toxicology and Applied Pharmacology* 80-106, 1962; Hayes and others, "Storage of DDT and DDE in People With Different Degrees of Exposure to DDT," 18 *Arch. Ind. Health* 398-406, 1957; and Hayes, "Monitoring Food and People for Pesticide Contact," *Scientific Aspects of Pest Control* 314-342, 1966.

[68] Kraybill, "Federal Health Activities in the Field of Pesticides," *Proc. Short Course on Pesticides* 287-307, 1964.

[69] Around 350 million pounds of insecticides alone were used in the United States in 1962. They are distributed annually over 90 million acres or more (1 acre out of 20 within the 48 contiguous states). Herbicides were used on just about the same number of acres with some overlap. Thus, the land area treated with pesticides is approximately one acre in twelve. About 45 million pounds are used each year in addition in urban areas and around homes, much of this by municipal spraying operations and individual home owners. See *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 1, 41, 1963. See also footnote 100 for Federal Agricultural Aircraft (FAA) aerial spraying statistics.

[70] For a list of pesticide uses for which registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) has been denied see *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 3, 744-748, 1963.

is the most dramatic and one of the most important.[71] Damage can be quite substantial and often there are significant evidentiary problems. First, there is the question of who, in fact, had the responsibility of not allowing pesticides to drift. This problem is amplified seriously when more than one person is engaged in spraying in the locality or, obviously, when the spraying takes place so far away that the sprayer is unknown. Still another problem in this area is that of causation. Is the negligence of the applicator the legal cause for the injury? Or, is there some intervening cause such as a totally unexpected gust of wind or a freak inversion layer? Tort law, of course, requires that there be some link in the chain of causation which will logically join the breach of duty of the applicator to the injury sustained by the plaintiff.

The liability problems could be decreased by some measure if there were proper standards and regulations set up to minimize the human error factor. As the House Committee on Agriculture stressed in House Report No. 313 in 1947, in support of FIFRA: "a great measure of protection can be accorded directly through the prevention of injury, rather than having to resort solely to the imposition of sanctions for damage after injury has been done."[72] There is no way that an applicator of pesticides can anticipate unforeseeable intervening or superseding causes, acts of God and the like. Injuries sustained due to those conditions are, under our present legal reasoning, written off as the price some few must pay for living in an organized society which is constantly attempting to improve its condition.[73] However, experience has shown that statutes and ordinances, when properly and vigorously enforced, reduce or even eliminate a great number of the injuries that might have occurred absent any clearly defined legal guidelines.[74] Where injuries still

[71] See *Chapman Chemical Co. v. Taylor*, 215 Ark. 630, 222 S. W. 2d 820 (1949) and *Lenk v. Spezia*, 95 Cal. App. 2d 296, 213 P. 2d 47 (1949). See, also footnote 60.

[72] 1947 U. S. C., *Cong. Serv.*, 1200-1206.

[73] Of great importance to the pesticide cases involving spraying operations is the principle that the defendant is to be held knowledgeable of weather conditions in a particular area. Prosser, *Law of Torts* (3d ed.), p. 312.

[74] When injuries occur due to the use of a pesticide in violation of a law or ordinance, the negligence of the defendant may become irrebuttable and negligence per se liability may result. For instance, failure to label as required by law has resulted in negligence per se liability in at least two cases. *Gonzalez v. Virginia-Carolina Chemical Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5448, 239 F. Supp. 567 (1965) and *Perry Creek Cranberry Corp. v. Hopkins* Agricultural Chemical Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5489, 29 Wisc. 2d 429, 139 N. W. 2d 96 (1966). See also Prosser, *Law of Torts* (3d ed.), p. 141 ff.

occur in spite of statutory safeguards, common law principles are sufficient to deal with most situations which arise.

Still another field of pesticide liability has arisen. Manufacturers and sellers may be liable for injuries which result from basically three means: defective products, failure to warn adequately of possible harmful effects to humans, animals or plant life that may occur even when directions are followed, and fraudulent or misleading claims.[75] Defective products can cause serious injury to those applying a pesticide and to the neighboring area which, absent any negligence, should be normally free of harm. While state and federal laws generally demand accurate and comprehensive statements on the labels and prospectuses concerning harmful effects and contraindication.[76] in the case of a resulting injury, a manufacturer may still be liable under a common law duty to warn of possible hazards. And he most certainly may be guilty of a statutory violation for mislabeling.[77] Fraudulent or misleading claims can also cause damage in a variety of ways. If the substance is more potent than indicated, harmful residues may occur, and, in some cases, damage from over-application may result. If, on the other hand, a pesticide has a weak dosage, it may cause injury by nature of its ineffectiveness.

Specifics of Pesticide Use Liability

Liability of a manufacturer or seller of pesticides for injury to a person or property allegedly caused by such compounds is, and will probably remain for some time, in a state of flux.[78] Generally, however, the principles of law deducible from various jurisdictions may be stated briefly. A duty of care binds manufacturers and sellers

[75] Products liability is currently one of the most actively expanding fields of law. For a comprehensive annotation see 81 ALR 2d 138 ff. (liability of manufacturer or seller for injury caused by animal feed or medicines, crop sprays, fertilizers, insecticides, rodenticides, and similar products). As to a manufacturer's duty to warn generally, see 76 ALR 2d 9. See also *Jamieson v. Woodward & Lothrop*, 247 F. 2d 23; cert. denied, 355 U. S. 855 (1957) (trees killed by spray) and *Reasor-Hill Corp. v. Kennedy*, 244 Ark. 248, 272 S. W. 2d 685 (1954) (insecticide manufacturer). Claims of fraud are the least used theory upon which plaintiffs have based their cases. See, however, *Kramer v. Carbolineum Wood Preserving Co.*, 105 Wash. 401, 177 P. 771 (1919) (action against seller of insecticide).

[76] See footnote 19, Part I of this article, 23 FOOD DRUG COSMETIC LAW JOURNAL 148 (March, 1968).

[77] See footnote 74; see also, for example, 7 U. S. C. 135g (mislabeling on the federal level).

[78] See 81 ALR 2d 138.

of pesticides.[79] This duty includes a duty to warn of product-connected dangers,[80] a duty on the part of the manufacturer to subject the compound to reasonable tests,[81] and a duty on the part of the seller to subject the product to reasonable inspection.[82] The first and second duties are incorporated in part in FIFRA, the various state registration laws, commercial law and the law of torts. The third is a common law duty imposed as a matter of law and practicality.

While a manufacturer can be held liable for an injury caused by a breach of these duties either by statutory violation or by common law negligence principles, the area of greatest activity is the possible liability under a breach of warranty theory.[83] There is a considerable authority to the effect that manufacturers and sellers of pesticides are bound by the implied warranty of fitness for a particular purpose and the implied warranty of merchantability. Both of these warranties are covered in differing form under the Uniform Sales Act or the Uniform Commercial Code, either of which is the law in all 50 states.[84] Moreover, such a manufacturer or seller may bind himself by express warranties, the breach of which will give rise to liability for resulting injuries.[85]

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[79] Manufacturer's duty: *E. I. DuPont de Nemours & Co. v. Baridon*, 73 F. 2d 26 (8 Cir. '34) (fungicide); *Rose v. Buffalo Air Service*, 170 Neb. 806, 104 NW 2d 431 (1960) (insecticide). Seller's duty: *Crouse v. Wilbur-Ellis Co.*, 77 Ariz. 359, 272 P. 2d 352 (1954) (insecticide).

[80] Manufacturer's duty to warn: *Jamieson v. Woodward*, case cited at footnote 75; Seller's duty to warn: *Crouse v. Wilbur-Ellis Co.*, case cited at footnote 79.

[81] Manufacturer's duty to test: *Chapman Chemical Co. v. Taylor*, case cited at footnote 71.

[82] A manufacturer's or seller's duty of inspection means that he will be held liable only when he sells products which contain imperfections discoverable by the exercise of the general duty of reasonable care imposed upon him. 81 ALR 2d 149.

[83] 81 ALR 2d 155-162. For cases involving implied warranties, see *Burr v. Sherwin Williams Co.*, 42 Cal. 2d 682, 286 P. 2d 1041 (1954); *Diamond Alkali Co. v. Godwin*, 100 Ga. App. 799, 112 S. E. 2d 365 (1959); *Gibson v. California Spray-Chemical Corp.*, 29 Wash. 2d 611, 188 P. 2d 316 (1948); *Van Antwerp-Aldridge Drug Co. v. Schwarz*, 363 Ala. 207, 82 So. 2d 209 (1955); and *Vormak v. Farmers' Co-op. Ass'n*, 11 N. J. Super. 416, 78 A. 2d 421 (1951).

[84] The implied warranty of fitness for a particular purpose is found in U. C. C. § 2-315 [U. S. A. § 15 (1), (5)]. The implied warranty of merchantability is found in U. C. C. § 2-314 [U. S. A. § 15(a)].

[85] Express warranties are governed by U. C. C. § 2-313 (U. S. A. §§ 12, 14, 16). See also *Van Antwerp-Aldridge Drug Co. v. Schwarz*, case cited at footnote 83; *Sawan, Inc. v. American Cyanamid Co.*, 211 Ga. 764, 88 S. E. 2d 152 (1955) (insecticide injured seed corn); *Simpson v. American Oil Co.*, 217 N. C. 542, 8 S. E. 2d 813 (1940) (insecticide injury); *Start v. Shell Oil Co.*, 202 Ore. 114, 273 P. 2d 225 (1954) (insecticide damaged lily crop); and *Ingraham v. Associated Oil Co.*, 166 Wash. 305, 6 P. 2d 645 (1932). Express warranties which are breached generally lead to absolute liability on the part of the defendant. Prosser, *Law of Torts* (3d ed.), p. 651.

The warranty theories, while on the surface simple and easily applied, are fraught with many problems. Traditionally, warranty liability could only be used by a prospective plaintiff who could prove first that he was injured, secondly, that the injury resulted from the manufacturer's negligence, and finally, that he was in privity of contract, that is, that there was a direct contractual relation with the manufacturer involving the sale of the product.[86] The last problem of proof, privity of contract, has been an important stumbling block to the plaintiff who was injured due to the manufacturer's negligence, yet is unable to prove it. Undoubtedly the most significant legal factor in such litigation is the view that privity of contract is a prerequisite to recovery in a negligence action growing out of a product-caused injury. It is obvious in most jurisdictions that, absent an adequate showing of privity or an adequate allegation of the inherent danger of pesticides, the plaintiff may not recover when he or his property has been injured by a pesticide seller's or manufacturer's negligence. The area of privity, however, is in a state of great change. Some few jurisdictions have altered this requirement or wholly obliterated it. However, many have retained this doctrine.[87] It is generally agreed that in the future the privity of contract prerequisite may be wholly eliminated from product liability cases, especially when dangerous compounds such as pesticides are involved. However, until then, it may continue to be an important factor in a case of pesticide injury and subsequent litigation against a manufacturer or seller.[88] It is well to note, however, that in a suit of this sort, no formal prerequisites to recovery may be required if, as a matter of law, the pesticide involved can be considered an inherently dangerous product.[89]

[86] See generally 75 ALR 2d 39 and more specifically 81 ALR 2d 161.

[87] See CCH PRODUCTS LIABILITY REPORTS ¶ 1210. Of particular significance is *Henningsen v. Bloomfield Motors, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 4509, 32 N. J. 358, 161 A. 2d 69 (1960), one of the first decisions rejecting outright the requirement of privity. Other states besides New Jersey which have rejected the rule requiring a showing of privity by court decisions are Arkansas, California, Connecticut, Illinois, Iowa, Kentucky, Michigan, Mississippi, Missouri, New York, Ohio, Oklahoma, Oregon, Pennsylvania and Tennessee. Arkansas and Virginia have statutes denying the lack of privity prerequisite as a defense available to a manufacturer or dealer of a defective product. Other states are borderline or still require privity.

[88] See footnote 86.

[89] Generally, those who market an inherently dangerous product are held to strict liability. That is, no allegation of negligence must be made prerequisite to the plaintiff's recovery. Strict liability will never be found unless the defendant is aware of the danger and has voluntarily allowed the product to be marketed. Mere negligent failure to discover or prevent is not enough,

(Continued on next page.)

Another somewhat less significant theory in the case of a person injured by a deficient pesticide is that of fraud and deceit.[90] Here again, if a plaintiff alleges fraud or deceit in the sale of a pesticide in an effort to recover for some injury he has suffered, he may be forced to prove that he was in privity of contract with the manufacturer or seller. As in warranty theory, however, the doctrine of privity in relation to fraud is also changing, although the inherent danger of the compound has nothing to do with the decline of the privity doctrine in these cases.[91]

An interesting area in which the actual use of pesticides has created a significant amount of litigation concerns aerial spraying.[92] Most of the cases in this field of law have involved damage to crops or vegetation; however, there are some few which involve injury to

(Footnote 89 continued.)
although it may, of course, be an independent basis of liability once the defendant willfully markets the product which is inherently dangerous, thus becoming an insurer against the consequences of his conduct. See generally, Prosser, *Law of Torts* (3d ed.), p. 519 ff. See also CCH PRODUCTS LIABILITY REPORTS ¶ 4070.

[90] Fraud, while not often alleged in pesticide cases, usually comes about by way of express warranties made by the manufacturer or seller to the buyer. The elements of fraud (or its old common law counterpart, deceit) are first, a misrepresentation; second, knowledge or belief on the part of the defendant that the representation is false; third, intention by the defendant to induce the plaintiff to rely upon the misrepresentation; fourth, justifiable reliance on the part of the plaintiff; and fifth, damage to the plaintiff, resulting from such reliance. See Prosser, *Law of Torts* (3d ed.), p. 695 ff. for an excellent and detailed discussion. See also *Kolberg v. Sherwin Williams Co.*, 93 Cal. App. 609, 269 P. 975 (1928) (action against manufacturer of product designed to destroy citrus tree scale).

[91] See 75 ALR 2d 39 for complete discussion. Inherent danger will not enter into a case of fraud since fraud is based upon a misrepresentation of the product's *nature* rather than the dangerous consequences of the product's *use*. Both theories, of course, might be alleged simultaneously under the same set of circumstances.

[92] For an excellent, although older, discussion see 12 ALR 2d 436 (liability for injury consequent upon spraying or dusting of crop). See also *Hammond Ranch Corp. v. Dadson*, 199 Ark. 846, 136 S. W. 2d 484 (1940) (spray pilot killed cattle with arsenic spray); *S. A. Gerrard Co. v. Fricker*, 42 Ariz. 503, 27 P. 2d 678 (1933) (bees killed by aerial spraying); *Miles v. A. Arena & Co.*, 23 Cal. App. 2d 680, 73 P. 2d 1260 (1937) (dusting was done while wind blowing toward plaintiff's bees); *Uherhill v. Motes*, 158 Kan. 173, 146 P. 2d 374 (1944) (grasshopper poison spread in such a manner that cattle on adjacent farm could reach it); *Burns v. Vaughan*, 216 Ark. 128, 224 S. W. 2d 365 (1949) (dealt with drift of 2,4-D in wind); *Lenk v. Spezia*, 95 Cal. App. 2d 346, 213 P. 2d 47 (1949) (drift of arsenic killed bees); *Brown v. Sioux City*, 242 Iowa 1196, 49 N. W. 2d 853 (1951) (loss of bees and honey due to pesticide spraying); *Romero v. Chris Crusta Flying Service*, 140 So. 2d 734 (1962) (2,4-D damage by way of drift); *Trahan v. Bearb*, 138 So. 2d 420 (1962) (damage to cotton field from weed spray used on neighboring rice field); *Young v. Darter*, 363 P. 2d 829 (1961) (drift of pesticide); *Pitchfork Land & Cattle Co. v. King*, 162 Tex.

(Continued on next page.)

animals, including wildlife.[93] In the case of aerial spraying, it has been recognized that due care must be exercised by the applicator to see that weather conditions are correct, the time of day is right and the actual application is accomplished in such a way that the person or property of another or wildlife is not harmed.[94] To insure safety, some state laws require due notice of impending spray operations.[95]

Normally, the owner of the premises being sprayed is liable for any damage done to persons, other persons' property, or wildlife caused by such activities.[96] It must be noted here that when a property owner hires a custom applicator to spray his fields, the latter becomes the agent of the former, and, therefore, the principal or master is liable for all the torts of the agent or servant, especially when ultrahazardous or inherently dangerous, and thus, nondele-

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(Footnote 92 continued.)
331, 346 S. W. 2d 598 (1961) (spray contractor held liable); *Rose v. Buffalo Air Service*, 170 Neb. 806, 104 N. W. 2d 431 (1960) (bee and crop destroyed by insecticide); *Wise v. Hayes*, 58 Wash. 2d 106, 361 P. 2d 171 (1961) (manufacturer held liable — improper labeling); *Cross v. Harris*, 230 Ore. 398, 370 P. 2d 703 (1962) (sprayer ruins crops with herbicide). See also Harper & James, *Torts*, Vol. 2, § 14.6. As a matter of further interest, when the U. S. Government conducted spraying operations in wildlife preserves, crop damage sustained by adjoining landowners was held non-compensable under the *"Dalehite* rule," 346 U. S. 44. *Harris v. U. S.*, 205 F. 2d 765 (10 Cir. 1953); *Bowden v. U. S.*, 200 F. 2d 176 (4 Cir. 1952). See also, Quinby, "Tetraethyl Pyrophosphate Poisoning Following Airplane Dusting," 191 J. A. M. A. 1 (1965), which concerned mild topical pulmonary poisoning of humans and fatal poisoning of some cattle.

[93] See *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 10, 2206 ff., 1964 for discussion of injury to bees. See also Tarzwell, "Hazards of Pesticides to Fishes and the Aquatic Environment," Exhibit 105, *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 9, 1811-1819, 1964; "Effects of Pesticides on Fish and Wildlife: A Review of Investigation During 1960," *U. S. Fish and Wildlife Service Circular* 143, 1962, *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, appendix IV to pt. 1, 985-987, 1963 and Dykstra, "Pesticides in Relation to Wildlife," Speech Before Conference on Pesticides and Public Health (U. S. P. H. S. May 1967). There are numerous criminal cases involving poisoning with pesticides, including several suicides. A report from Finland shows that deaths from suicide due to parathion rose from one in 1952 to 94 in 1957. Toivonen, and others, *Lancet*, ii, 1959, 175.

[94] See 3 Am. Jur. 2d 347. See also Exhibit 246, *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 11, 2463-2466, 1964, and Weaver, "Arsenic Poisoning in Cattle Following Pasture Contamination by Drift of Spray," 74 The Veterinary Record 249, 1962.

[95] *Jeanes v. Holtz*, 94 Cal. App. 2d 826, 211 P. 2d 925 (1959), and *Brown v. Sioux City*, case cited at footnote 92.

[96] See footnote 92 for appropriate cases. For FAA Operations see *FAA Regulations*, 14 C. F. R. 137 and following.

gable, activity is involved.[97] Therefore, the landowner may be liable in damages if he should hire an applicator who negligently sprays pesticides or allows drift to occur from his operations. In such a case, the applicator also may be jointly liable with the property owner who hired him, and this joint responsibility can be of importance to a prospective plaintiff since the landowner may be judgment proof while the applicator may have or may be required under local laws to possess sufficient financial responsibility.[98] If, however, such activity can be considered ultrahazardous or inherently dangerous, then the landowner is liable even if the sprayer is an independent contractor, since the duty of care in spraying highly poisonous substances cannot be delegated or passed on from the owner to the sprayer.[99]

As stated above, when an aerial sprayer is applying pesticides which are dangerous to human health, he may be considered in most jurisdictions to be engaging in so-called ultrahazardous activities.[100] Such activity carries with it the burden of using the highest degree of care and can impose absolute liability upon him for any injury to a person which is caused by the use of that sort of pesti-

[97] "The agriculturalist or farmer may not delegate the work of dusting or spraying a crop with poisonous insecticides to an independent contractor [or agent] and thus [completely] avoid liability." 3 Am. Jur. 2d § 47, p. 814. See *Walton v. Sherwin Williams Co.*, 191 F. 2d 227 (8 Cir. 1951); *McKennon v. Jones*, 219 Ark. 671, 244 S. W. 2d 138 (1951); *Pendergrass v. Lovelace*, 57 N. M. 661, 262 P. 2d 231 (1953); *Burke v. Thomas*, (Okla.) 313 P. 2d 1082 (1957); *Alexander v. Seaboard Airline RR. Co.*, 221 S. C. 477 71 S. E. 2d 299 (1952).

[98] See 12 ALR 2d 444. See also cases cited at footnote 92 and *Parks v. Atwood Crop Dusters, Inc.*, 118 Cal. App. 368, P. 2d 653 (1953); *Sanders v. Beckwith*, 79 Ariz. 67, 283 P. 2d 235 (1955) (operator and landowner liable); *Aerial Sprayers, Inc., v. Yerger Hill and Son*, 306 S. W. 2d 433 (1957) (operator and landowner liable); *Southwestern Bell Tel. v. Smith*, 220 Ark. 223, 247 S. W. 2d 16 (1952) (operator and employer liable); *Kentucky Aerospray, Inc. v. Mays*, 251 S. W. 2d 460 (1952) and *Miller v. Maples*, 278 S. W. 2d 385 (1954). Manufacturers may be joined as third party defendants under the Uniform Contribution Among Tort Feasors Act which is the law of many states.

[99] See Harper & James, *Torts* Vol. 2, § 14.16, and footnote 97. See also *McKennon v. Jones*, 219 Ark. 671, 244 S. W. 2d 138 (1951); *Southwestern Bell Tel. Co. v. Smith*, 220 Ark. 223, 247 S. W. 2d 16 (1952); *Alexander v. Seaboard Airline RR Co.*, 221 S. C. 477, 71 S. E. 2d 299 (1952).

[100] See footnote 89. See also Yuill, "Research on Aerial Spraying," *The Yearbook of Agriculture* 252-258, 1952. To demonstrate the amount of aerial application taking place in the United States, consider the official FAA aerial application flight hours logged in 1962; a. monoplane: 476,966 hours; b. biplane: 444,377 hours; c. helicopter: 22,973. This gives a total in 1962 of 944,316 hours flown. Note also *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 10, 2171-2172, 1963. See also footnote 56.

cide.[101] In such a case, the injured party may readily recover damages without a showing of negligence when he himself is free of any contributory negligence or did not assume the risk of pesticide exposure.[102] The same legal consequences apparently would follow in connection with crops or vegetation when an injurious herbicide is applied resulting in an injury or loss to the plant life on adjoining or nearby property.[103] These sorts of injuries can be prevented, of course, by intelligent use and application of pesticides, with an awareness of the possible injurious effects of those materials on the surrounding environment.[104]

Another area involving pesticide liability deals directly with the question of an exterminator or pest control operator's responsibility for personal injury or death.[105] While most of the cases hold that liability in the fumigation or pest control business depends upon a showing of negligence, several have held and still others have suggested that by reason of the inherent danger of the operations, the applicator is absolutely liable without proof of negligence.[106] In some instances, such as the plaintiff's contributory negligence, his assumption of risk or even his trespassing upon fumigated property, pest control operators, otherwise negligent, were not found liable. However, both the owner of the property and the exterminator may be liable for a failure to warn a tenant or other person who has a

[101] It is well to note the opinion of at least two legal scholars: "as the sprays have become better known, their obvious utility militates against imposing strict liability while their high potential for harm argues for it. It is not clear what the ultimate doctrine will be but it is likely that most plaintiffs will recover on one theory or another . . . ." Harper & James, *Torts*, Vol. 2, § 14.16. See also Prosser, *Law of Torts* (3d ed.), p. 519 ff. For absolute liability in case involving toxaphene injury to fish see *Kentucky Aerospray, Inc. v. Mays*, case cited at footnote 98.

[102] See Prosser, *Law of Torts* (3d ed.), p. 426 ff. and 450 ff. In some states contributory negligence may not be a defense to ultrahazardous activity, while in most states assumption of risk is available as a defense regardless of the nature of the activity.

[103] See *Gotreaux v. Gary*, 232 La 373, 94 So. 2d 293 (1957), and *Trahan v. Bearb*, case cited at footnote 92.

[104] See Wolfe and Durham, "Safety in the Use of Pesticides," *2 Proc. E. Wash. Fert. & Pest. Conf.* 14-21, 1966.

[105] See *Luthringer v. Moore*, 31 Cal. 2d 489, 190 P. 2d 1 (1948); *Ellis v. Orkin Exterminating Co.*, 24 Tenn. App. 279, 143 S. W. 2d 108 (1940) and *Holland v. St. Paul Mercury Ins. Co.*, (La. App.) 135 So. 2d 145 (1961). See also Chisholm, "The Nature and Uses of Fumigants," *The Yearbook of Agriculture* 331-339, 1952. Although not directly dealing with pest control operators, general household insecticide spray can interpretations are found in 7 C. F. R. 362, Int. 15, Rev. 1; Int. 22, Rev. 1; and Int. 23.

[106] *Luthringer v. Moore*, cited at footnote 105; see also 53 ALR 393; 72 C. J. S. 168.

right to be on the property of the use of pesticides.[107] Exterminators are also required in some jurisdictions by statute or common law to know the nature and effect of the pesticides they use. A showing of the lack of such knowledge coupled with a resultant injury may be sufficient to constitute negligence and justify ultimate recovery for the plaintiff.

Conclusion

One can conclude that pesticide laws and common law principles applicable to the use of pesticides do a reasonably adequate job of protecting persons and property from injury. However, we should not be satisfied with the laws as they stand. Much improvement is necessary in the administration of present controls. The development of further regulation by way of statutes and rules is also necessary in some instances before adequate, useful and practical means are made available to minimize pesticide accidents. Statutory control should not only regulate and restrict, but should also serve as educational tools to delineate the proper activities of users, sellers and applicators. Statutes which merely prohibit do serve a useful purpose. However, in the case of a law limiting the activities of individuals, while the reasons for the limits may be obvious to law makers, this is not always the case with the affected or regulated parties. Statutory language, while not necessarily explanatory per se, should be detailed enough to point out the proper means of compliance.

It will no doubt take years of hard work on a number of fronts to obtain relatively uniform and comprehensive pesticide labeling and use and application legislation. However, liberal access to the courts and favorable decisions for plaintiffs indicate a fertile area for extension of present common law remedies. Therefore, if any legal action, or even more, the initial injuries to persons and property by the sale or use of pesticides, can be avoided by increased statutory control, more support for this legislation must be generated. Not that we need or wish to over-legislate. It is only that we must confront the pesticide legal problem intelligently and vigorously.

[The End]

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[107] 72 C. J. S. 168.

Question and Answer Panel of the FDLI—FDA Eleventh Annual Educational

The Following Material Is from the Question and Answer Panel Which Was a Highlight of the Drug Panel Workshop ct the Eleventh Annual Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration on November 27, 1967.

Mr. Byers

Q. Is there any reason why the Food and Drug Administration (FDA) analysts can't determine quantitatively the active as well as the inactive ingredients on Rx drugs, especially since they have access to the formulae?

A. There is no reason why the analysts cannot get this information. For instance, the inspector could revisit the plant when we have an analytical problem. Recently, a return visit to a plant by our inspector revealed that the firm was using an inert ingredient that was interfering with the sample analysis.

The firm changed the formula to remove the interfering product. Actually, the firm's laboratory or its control laboratory is often in a better position than the FDA to resolve analytical problems. For example, the firm already knows exactly what the inert ingredients are. Also, because of ready access to house samples, the firm is able to make up a so-called product blank. This task would be extremely difficult for the FDA laboratory because we would have to gather the ingredients from all of the suppliers, and then they may not be from the same lot.

Mr. Yakowitz

The manufacturer of a drug product would do well to stay with one particular supplier of each of his raw materials, a supplier that

can be depended upon to always furnish raw material of the same quality, time after time.

Mr. Byers

We have found a number of firms that are adequately testing their active ingredient raw materials, but are not adequately checking the so-called inert ingredients—or do not even have adequate specifications for them.

Drug Efficacy Review

R. Keith Cannan, M. D.

Q. Do you know whether the Academy Research Council efficacy report to the FDA will be routinely made available to the manufacturer of the drug in question?

A. The reports of the Academy are made to the FDA. It is the responsibility of the FDA to release information as it sees fit to the public and to interested parties. There are conversations in progress between the Academy staff and the staff of the FDA which have made it evident that it is the desire of the FDA to release as much information as it can, as rapidly as possible. It is our understanding that our reports will be released verbatim and not in abbreviated form.

Q. May it be expected that the opinions and evaluations of the Academy Research Council's Drug Efficacy Review will or possibly will be the basis of Dr. Goddard's Drug Compendium?

A. I would think that the reports of the Academy will provide an important source of material for any compendium that may be devised.

Q. Can you tell us what your study indicates as to equivalent of brand name drugs of the same generic ingredient and generic drug to the brand name counterpart?

A. The study has been based upon the assumption of the therapeutic equivalence of generic drugs. Should a question on the therapeutic equivalence of any class of drugs arise in the future, it may then be necessary to re-evaluate the pertinent reports rendered by the Academy.

Q. Recent public statements by Dr. Alfred Gilman, who occupies a rather strategic position in the Drug Efficacy Study, suggests that he may be biased in favor of established brand name drugs. What precautions were taken to make sure that participants in the study were free of potential conflicts of interest, specifically, were they asked

to disassociate themselves from considering products which they had previously investigated for a manufacturer, or from considering products competitive to those which they had investigated for a manufacturer?

A. There are two parts to this question. One is relative to the testimony of Dr. Gilman at Senator Nelson's hearings, and the second is in respect to the possibility of conflict of interest affecting the judgment of panels. With respect to Dr. Gilman's statements, he was testifying as an individual scientist. He did not identify himself with the study, nor did he consult the policy committee of the study prior to his testimony.

Secondly, within the matter of conflict of interest, when conversations were first initiated with Commissioner Goddard, we pointed out the obvious fact that if you wanted competence of judgment you had to have men of experience, and men of experience in this field meant men who were likely to have associations of one sort or another with industry. It was agreed that the responsibility for surveillance of possible conflict of interest in the panel members should be left entirely for the Academy to determine. Our rules have been very simple. We said that if you have a suspicion of conflict with respect to any particular drug or drug house, or any particular relationship to the problem, you will disassociate yourself from judgment on these issues. We believe that panel members have honored this obligation.

Advertising—The Brief Summary

Mr. Kleinfeld

Q. Representatives of the FDA persist in making the unilateral claim that advertisements today are more informative and effective communications than they were before the FDA got into the advertising act. Industry is well aware that regulations have increased costs in many ways, and that readership of the required labeling information is extremely low. Please bury the FDA myth.

A. Well, that's not easy. I personally think that most advertisements are more informative than they were. I think the trouble is this: if the government construes full disclosure and brief summary as to virtually require the use of a package insert, this will defeat the very purpose that Congress had in mind and presumably the FDA had in mind, to wit, getting doctors to read full disclosure and brief summary. If we make full disclosure and brief summary virtually a package insert, I think the medical profession just won't read them.

Mr. Hauser

It is not the intent of the regulations to require full disclosure in prescription drug advertising. Full disclosure as defined in the proposed and the existing regulations, requires adequate information for use of the drug under all conditions for which it is offered in any labeling or advertising. This idea has not been included in the proposed advertising regulations. The advertisement, for example, may be limited to a selected indication for use. The full disclosure concept in labeling requires adequate information for professional use including not only indications, but effects, dosages, routes, frequency, and duration of administration. None of the information concerning dosage, routes, frequency, or duration of administration is required in advertising either in the current regulations or in the proposed regulations. There is a substantial difference between full disclosure and the requirements of the proposed regulations. They do require in the proposal that all of the adverse information which must be disclosed in a package circular must also appear in the advertising.

Mr. Kleinfeld

I knew there was a difference between full disclosure and brief summary in advertising. What I meant to point out was that very often there are subjective interpretations of what brief summary is. Brief summary should mean, "brief", and a "summary." But when a particular official or doctor construes "brief summary" so that it is virtually equated not only with full disclosure but with the package insert as well, then the very purpose of Congress is perverted, and again I say the doctors in that case won't pay any attention to the brief summary. If we had a bonafide brief summary, there would be no problem. My point is that too often, it has been equated with something much more extensive.

Mr. Hauser

The concept in the Act concerning a true statement of information in brief summary is used in connection with the effectiveness of the drug quite as much as in relation to information concerning side effects and contraindications. The proposed regulations would not require more than the information in brief summary relating to side effects, contraindications, and effectiveness. However, we find it is a common practice in the industry to run advertisements six to ten pages in length to promote the sale of a drug. This is not a brief summary. We are not relying on this provision of the law to prohibit

extensive advertisements, ads of ten or a dozen pages. This is permitted. But when an advertisement, optionally on the part of the advertiser, runs that length, then our concept is that the meaning of a true statement of information with respect to side effects, contraindications and effectiveness, requires that the adverse information about the drug not be so subordinated, presented in the utmost telegraphic style, as to subordinate the adverse information, when you have information presented at great length and with great clarity in full sentences in regard to the advantages of the drug. This is where the concept of fair balance comes in. The option of using more than the information in brief summary relating to side effects, contraindications and effectiveness still lies with the manufacturer or the advertiser.

Key Points in Drug Advertising Regulations

Q. Would you repeat the five or six key points which you are striving to attain in the proposed drug advertising regulations and explain why these points could not constitute the regulations, instead of the 34 points that have been proposed?

A. First, let me say that the five or six points are not all; we have a number of additional ones which I haven't included because my talk was limited. To answer this question more specifically, point no. 5 reads, "A list of frequently encountered offensive advertising practices will be retained to make the rules quite clear even to those most persistent in professing their inability to understand the regulations." Now, point 5 includes the other 34. As a matter of fact we may reduce that number. We will rework them with the help of the fine advice we received in the written comments from industry. And we will cooperate with industrial representatives to clarify the language of certain points. If there are any points that we cannot clarify adequately, we will drop them. So, there may be less than 34 points.

Q. No manufacturer can object to giving full information on significant side effects, etc. The requirement to feature a rare side effect at a level of visibility equal to a claim for efficacy established in a large number of patients and many studies is, however, ridiculous. When will FDA publish a regulation requiring adequate data for inclusion of a side effect in labeling in order to avoid providing false and misleading information through inclusion of inadequately supported side effects, precautions, warnings, etc.?

A. There are two points here. The current and the proposed regulations would not require the featuring of either a rare side effect or a frequently occurring one with the same conspicuousness or the same size print as is required for the promotional claims in the advertisement. This question was the subject of correspondence between the Commissioner and representatives of industry who were involved in the hearing of 1963. The exchange of correspondence made it clear that this was not a requirement of the regulations proposed in 1963. Such requirements are not contemplated in the proposed revised regulations either. The same size print would not be required whether the side effect is rare or frequent. We do recognize that it is the main function of advertising to promote the sale of an article and to attract attention so someone looks at what the ad says in the first place. But the information concerning side effects, even what may be rare, must be disclosed in the ad.

The second question is when will we publish a regulation requiring adequate data for inclusion of a side effect rather than false and misleading information concerning them. This, I think, suggests that the writer has expressed an idea we have seen in some written comments from an association representing advertising agencies. The idea here is that we should be very scientific and not require disclosure in an advertisement or labeling of any adverse experience about a drug until there is substantial evidence that the drug does, in fact, cause this experience. I submit that whoever has this idea ought to discuss the situation with responsible medical people. It is time for all parts of the pharmaceutical industry, even those who are engaged in preparing advertisements, to recognize that we're dealing with drugs that may make the difference between life and death. We do not require substantial evidence of the causal relationship between the use of a drug and an adverse effect before mention is made of the possibility that this drug may cause the adverse effect. This information should be supplied to the physician who may use it, at a possible risk, even though it has not been definitely determined that the drug is causally related to what might be a very serious adverse effect. At least this is the position of FDA and we will maintain it.

Q. Do antibiotic drug advertisements always need to have preclearance by FDA or other government agencies?

A. No, FDA may not require preclearance of advertisements for antibiotic drugs or any other prescription drug except in extraordinary circumstances. That's written into the law.

Q. What changes would occur in the type of permissible advertising if sutures had to be considered "drugs" instead of devices?

A. Our position is that sutures are drugs, so they are subject to the advertising provision of the law. If they were devices instead of drugs, then they would not be subject to the advertising provision. I'm assuming here that a suture is a prescription drug.

Dr. Ballard

Q. My observation has been that the journalistic zealot is, more often than not, fed his material by the industrial representative who is looking for competitive advantage, DMSO, for example.

A. I'm glad whoever wrote this picked DMSO. Because this is a direct result of public relations on the part of the University of Oregon and not on the part of industry. This was a therapeutic, or what they thought was a therapeutic breakthrough in Oregon, and their public relations office played this thing up so big and for so long that finally industry had to get on the band wagon and start investigating DMSO. But this did not come out through industry originally. What I was driving at when I mentioned the journalistic zealot and the overly-ambitious politician, who take isolated facts and play them up out of proportion to reality, was such things as a recent article in the *Ladies Home Journal* about the oral contraceptives. This was an article that played up only the side effects and adverse reactions. If I read this as a layman, not knowing about oral contraceptives, I would have been frightened to death. Now, I think this is irresponsible journalism. But we are treading on ground here that gets on to freedom of speech. I think it is poor journalism to play up the bad effects and make the drug look worse than the benefits. I just can't buy this sort of journalism. On the part of politicians, I look at isolated instances. Well, off the top of my head I can go back to the original Kefauver Hearings where the drug industry was accused of 4,000% and 5,000% mark-ups. This is like saying steel costs $40 a ton, why does a 2-ton automobile cost $5,000. A second answer to that is another question: how much does Picasso pay for his paint?

Q. Is there any readily available compendium listing the rate for side effects and mortality risks for available old and new drugs? The need is for rapid availability of information which goes beyond the estimates given in "PDR."

A. Simply, the answer is no. There is no compendium. The rates given in PDR usually reflect those that the company picked up in its clinical trials and, somewhat, the rate that has occurred since it has been on the market. But all adverse effects that occur with drugs are not reported to the company concerned, so therefore they do not have the true incidence. I suppose that eventually the adverse reaction program of the FDA may eventually throw some light on this. I hope that when they do compile statistics in this area, the FDA will use only the side effects that are actually proven as side effects and not those alleged to the drug.

Human Experimentation

Q. Do you have any criticism on present FDA policy regarding human experimentations and are there many abuses of responsible or ethical experimentation on the part of the medical profession?

A. My complaints against the FDA are usually not in the area of human experimentation. So I can say no to that. As far as abuses of responsible or ethical experimentation on the part of the medical profession are concerned, I personally am unaware of very much of this in the area of drugs. But I am somewhat alarmed in the area of surgical experimentation, because here, I think, some of the investigators are taking license that they shouldn't take on human beings. But, in the area of drugs, and I think we can thank the New Drug Regulations for this, the monitoring of drug studies is much more close now than it used to be before these regulations and, as such, abuses just are not occurring. At least I'm not aware of them. Maybe someone from FDA can make a statement about it.

Mr. Hauser

I'm sure I don't have any statistics on this. I do have the impression that general practices have been much improved as a result of the Investigational Drug Regulations.

Anticancer Therapy

Dr. Endicott

Q. Do you have any comments on the combination of irradiation and anticancer drugs? Is this a promising therapy?

A. Yes, I have a comment. There are some indications that it is possible to do one of two things. Either to increase the radiation sensitivity of a tumor by a drug which is selectively absorbed by the tumor, or conversely, to reduce the radiaton sensitivity of normal tissue. This is more theoretical than real, however. We do not have adequate animal test models to explore this satisfactorily. What little we know has fallen out more as a result of accidental observations in man than anything else. I think many people would agree that actinomycin D and x-ray offer some advantages over either one alone in the treatment of certain childhood tumors. This is an area of the future though. We don't have much knowledge about it now.

Q. In view of your statements that both benefits and risks of cancer drugs are lower than is commonly thought, how can one justify the continuing high expenditure of public funds for the shotgun approach of the National Chemotherapy Screening Program of the National Cancer Institute?

A. In the first place, in the present scheme of government expenditures for health research, the funds spent in screening anti-cancer drugs is not high. It's small. In view of the consensus of the scientists in the cancer field that we've gone about as far as we're going to go with radiation and with surgery, any further improvements in the management of cancer is going to be in the drug field. I think its shamefully low. With regard to the reason for expenditure of public funds, there is a good reason. Cancer is really a collection of relatively rare diseases, so the market for anti-cancer drugs, unless we get a panacea drug, will probably be quite small. Most of the cancer drugs now on the market are not profit items. The industry is disinclined to invest the kind of money, in this sort of drug development, that it takes to get the job done. Based on my experience, if we don't use public funds for this purpose, the job won't get done. Now with regard to the shotgun part, I think that drug development in the cancer field, like drug development in any field, has some scientific basis but to a considerable extent has been, is now, and always will be, substantially an empirical trial and error method. Whether this justifies the funds or not is a matter of opinion, but up to now I've had good luck with the Congress.

Dr. Cannan

Q. What precautions are used to be sure that in the drug efficacy study all the panels are exercising uniform standards in judging the drugs?

A. This question can be interpreted in several ways. I think we are alert to aberrant behavior in individual panels, a therapeutic nihilist point of view in one and a libertarian view in another group. This is being effectively monitored by a professional staff of 15. Moreover, this is also a function of the policy advisory committee. An interesting corollary of the question is the matter of comparative efficacy. FDA has not invited us to comment on the relative efficacy of different drugs for the same indication. Yet a panel can not review the claims for a series of drugs without making comparisons. A judgment is made against the background of related judgments. Answering the question in another way, one might say that there cannot be uniform standards over the whole front of therapeutics. You do not judge a topical application for a skin disorder, or a nasal spray, by the same standards as you would an anti-neoplastic agent.

Inert Raw Materials

Mr. Yakowitz

Q. Do you really expect the drug formulator to examine the manufacture of inert ingredients by a supplier, if the firm is reasonably well known, and the product meets the user's specifications (which essentially is identity, checks etc.)?

A. That question arose because of the statement that I made in my prepared talk:

> In developing the dosage form the prudent manufacturer attempts to restrict the other components such as excipients and diluents, to those substances for which he already has reliable suppliers. To the extent that it is feasible to do so, the drug manufacturer purchases such components from the primary manufacturer. In many cases, he will send his own inspector to the plant where the material is made in order to check on the manufacturing procedure and controls.

I'd certainly agree that there is room for judgment here. If the material that we're talking about is sugar from a well known refinery that's turning out hundreds of tons per day, I would think it's reasonable for the drug manufacturer to rely only on the tests made on the product as received and the drug formulator would not have to

send somebody down to the sugar refinery to make sure they do their work properly. On the other hand, if it is a complex organic material supplied by only one or two firms and not made in large quantity, the drug formulator using that material may wish to send his inspector to the firm that makes it, to see how they make it, to be sure they can make uniform batches and to ascertain what tests they are applying to this material to insure its purity and uniformity.

Mr. Byers

A manufacturer should routinely check his raw material specifications, to make certain that they are adequate to assure him that he will not get some impurity that will affect the product's stability. An example of this might be liquid products which would be adversely affected by trace amounts of iron or other metal.

Q. You mention an incident concerning the migration of nitrate ester? Does the FDA intend to make public the methodology used in this case or other similar instances?

A. I believe that Dr. Banes's group does plan to make information available on such incidents.

This migration problem brings up an important point. Many times we take stability for granted, especially on a product that has been on the market for awhile, and one that already has, what we believe are adequate stability studies.

This can be an illusion, especially when we consider changes in packaging material or techniques. For instance, when a package is changed from glass to plastic, the product is in a new environment. Therefore, to comply with the Good Manufacturing Practice (GMP) Regulations a new stability study should be made.

The incident of the migration of the nitrate ester is an example of this problem. The product, as packaged in an unopened glass container was relatively stable. However, here was a case where the active ingredient was selectively removed from the tablet by being solubilized in a contact cement between a plastic and a foil in the packaging material.

A good analytical chemist who thinks for himself should come up with the answer. If the active ingredient was in the tablet when packaged and not there when analyzed, and tests showed it didn't

migrate to the plastic or the aluminum foil, then it must be in the cement. Analysis of the cement confirmed the presence of the ester.

This case also illustrates another salient point, that even with all of the sophisticated equipment available to the chemist, the most important instrument is still his brain.

Q. Do you find that most Investigational New Drugs and New Drug Applications (NDA) have adequate standards in their analytical sections?

A. I don't have the information available to answer the first parts of the question. However, the guidelines for the adequacy of such sections are no different than the guidelines in the current GMP regulations. They are no different than good sound analytical procedures which characterize or determine the nature of the product and its strength and purity.

"Feature" and "Running Text"

Mr. Kleinfeld

Q. What is the meaning of "feature" in the new generic name regulations? I realize that these regulations have not been discussed today, but they are closely tied to advertising. Also, what is "running text"?

A. Well, as far as I'm concerned there is only one virtue to these new generic name regulations. Complex and ambiguous as they are, they are far better than the requirement that had been imposed that the generic name appear each and every time a brand name was used. That position didn't make sense and I don't know why it was taken except perhaps to please a few congressmen. I doubt that the terms "feature" and "running text" can be enforced in court. They're typically vague and ambiguous terms that are used, as I see it, for the purpose of being so ambiguous that officials can say in a particular case that we have "running text" which isn't complied with or we have a name that is "featured" and isn't complied with.

I think these terms are so vague and ambiguous that I doubt that any court would enforce them.

Mr. Hauser

I don't particularly agree with you as to how ridiculous the regulation was. On the matter of "feature" and "running text", "fea-

ture" is headlined. It is given special prominence as compared to the rest of the copy. "Running text" is what you have in a column of discussion, which is a very common thing. The "feature," if any, is up at the top. And there may be some portions which are headlined in larger type. Those might be considered "feature." In package inserts for prescription drugs, which are one of the most important areas affected by this proposed regulation, it is not at all uncommon to have headlined material and copy that is larger than the sentences that convey the details of the message. Perhaps it will present all the problems you suggest. Apparently, this is the best industry could come up with

"Grandfather" Drugs

Q. If, as stated this morning, it is the intent of FDA to inform physicians of the availability and merit of new therapeutic agents by means of full disclosure or brief summary in all advertisements, why is it necessary to propose regulations to include this same information with "grandfather" products that the physician should be completely familiar with through long use? What will be the rationale for determining new information for "grandfather" drugs?

A. It is true that FDA wants to have physicians informed of the availability and merit of new drugs, but that does not exclude our desire to have physicians truthfully informed about old drugs. It is a matter of law that advertisements for prescription drugs shall include a true statement of information in brief summary relating to side effects, contraindications and effectiveness with no distinction made between new drugs and old or "grandfather" drugs.

On the second part of the question about the rationale for determining new information for "grandfather" drugs. I think the answer to that is clear. It is new experience that shows either new adverse experience, new side effects, new contraindications, or of course there can be times when a new experience will suggest new uses for "grandfather" drugs. Before the drug can be marketed with labeling offering it for new uses, if it is not generally recognized as safe and effective for those new uses, it would be considered a new drug which would therefore require prior approval.

Q. I have been told that one of the drug companies had been advised that unpublished clinical studies may not be cited, summarized

or referenced in advertising. (1) Is this the position of FDA? (2) If so, what is the basis in law or regulation for such a prohibition?

A. As a matter of fact, I think that frequently a substantial part of advertisements are based on unpublished clinical studies. Some of these appear in NDA's and have been the principal basis of approval of a new drug, even though the studies have not been published at the time that the approval has been made.

There's no basis in law for prohibiting reference to unpublished studies, but I think we should say in all fairness that many physicians become angry and offended by references to unpublished studies, since they cannot check out the basis for the claims made in an advertisement. Industry certainly would do better to cite published references that can be read by the physician, if they're interested in getting a favorable reaction from their customer.

Q. A physician has reported an adverse side reaction from use of a certain drug in a recognized American medical journal but has not communicated in any way with the manufacturer of the drug. The manufacturer knows of no other similar incident. Is the manufacturer required under the current regulations to make a formal report to the FDA of this journal article on the new adverse reaction reporting form?

A. The answer to that is no. We are in the process of publishing an amendment to the regulations that will make this clear, among other revisions in the current regulations having to do with reports of adverse experiences. Adverse experiences reported in medical literature and on which the manufacturer has no additional information will not have to be reported in the new adverse reaction reporting form.

Q. Will you discuss the areas where "FDA-industry" accord is likely to be achieved by redrafting, so industry will no longer "misunderstand" the meaning of the proposals?

A. It's rather easy to misunderstand the meaning of this question. If I can translate it, presumably the question is where do we feel that FDA and industry can reach agreement on the proposed advertising regulations. In general, I think it may be fair to say that FDA will not retreat from the intent of the significant concepts embodied in the published proposals as to the advertising regulations. There is full willingness to discuss the language, to clarify the intent so

that there are no misunderstandings. Obviously there have been some. Where we cannot agree or cannot develop language that is clear in its meaning, we may drop some provision, for example, out of the list of 34 practices that have been defined as offenses. I don't know whether FDA's position to adhere to the basic concepts in these proposed regulations will be accepted by the industry. It is possible that we will get into a hearing and litigation, but we will do the best we can. We are working together to minimize, if not eliminate, areas of disagreement.

Q. What criteria are used to determine whether or not a so-called "device" is subject to FDA regulations?

A. The term "device" is not further defined in our regulations (you can correct me, Counselor Kleinfeld if I'm in error) than in the text of the Act itself. If an article is intended for diagnosis, cure, mitigation, prevention, or treatment of a disease, and is in the nature of what is commonly considered to be a device rather than a drug, that is, apparatus, contrivance, etc., then it would be considered a device and subject to the provisions of the Food, Drug and Cosmetic Act, and subject to FDA regulations.

Mr. Kleinfeld

Q. First, I want to say this is one of the most unusual phenomena—that we rely entirely on the statutory definition of a device without any regulations. It's hard to understand. I think you suggest in your paper that the contraindications, etc., material in the ad be made more readily readable. How do you feel this would be greeted by FDA or the advertiser?

A. I think with enthusiasm. Certainly the advertiser with his skill and expertise, could very well make the contraindications, etc., more readily readable. As far as the FDA is concerned, if its position on what should be in the brief summary is pursued, I'm sure the agency would not object to making the contraindications and side effects paragraph more readily readable and perhaps more interesting, so that the doctor may be more likely to read it than otherwise.

[The End]

Sampling and Testing of Drugs

By THEODORE E. BYERS

The Following Article Was Delivered at the FDLI-FDA Eleventh Annual Educational Conference in Washington, D. C. on November 27, 1967. Mr. Byers Is the Director of the Division of Case Guidance, Bureau of Regulatory Compliance of the Food and Drug Administration.

THE SAMPLING AND TESTING of drugs is a challenging problem. It is an old axiom in analytical chemistry that the analysis of a product is no better than the validity and adequacy of the sample. Obtaining a sample which is truly representative of a production lot and the analyses of which will give assurance that the product has the identity and strength which it purports to have is a complex matter and often depends upon the nature of the particular product as well as its manufacturing history. For this reason the regulations promulgated under the Food, Drug, and Cosmetic Act, with a few exceptions, give little in the way of specific sampling instructions. For instance, the Good Manufacturing Practice Regulations (§ 133.11 Laboratory Control) speak of testing adequately representative samples. The antibiotic regulations mention (§ 146.2(a)) a sampling ratio. In this case samples of unit dosage form shall be collected by taking single tablets at such intervals throughout the entire time of the product batch that the quantities tableted during the intervals are approximately equal. In no case shall more than 5,000 tablets have been tableted during each interval of sampling. The nature of the production of a given batch determines the method of sampling to obtain an "adequately representative sample." For batches of tablets this adequately representative sample often consists of a composite of the "check weight" samples taken by the pressman during a given compression run. This would superficially appear to be adequate. However, this procedure may contain a hidden hazard which could result in the "masking" of uniformity in the batch. Therefore, the manufacturer should determine the adequacy of his sampling by various means in the pilot batch and initial batch status of a given product, including tests for uniformity of tablets, as set forth in several monographs in

the official compendia. This problem of uniformity has a very direct bearing on sampling.

In the case of the collection of regulatory samples by the Food and Drug Administration (FDA), we have often relied in the past upon the collection of a single sample of a given lot of a product. If the product were in fact uniform this would offer no problem in ascertaining that the product did in fact meet its labeled strength and purity. Should a product fail to meet its labeled strength or purity we still had a basis for legal action under section 501. With the additional analytical capability provided by the recently established National Center for Drug Analyses in St. Louis we shall eventually be able to collect and analyze, on a statistical basis, the overall drug supply. Thus we can give greater assurance, especially in the case of non-uniform batches, that the consumer is adequately protected from adulterated drugs.

Good Manufacturing Practice Regulations 133.11 has the following instructions with regard to the actual testing of drugs: "Laboratory controls shall include adequate specifications and test procedures to assure that component drug preparations in the course of processing, and finished product conform to appropriate standards of identity, strength, quality and purity." The regulations also mention that laboratory controls shall include "adequate provision to check the reliability, accuracy and precision of any laboratory test procedures used."

Giant Strides

From my personal experiences in drug analyses, beginning in 1950, I have noted giant strides in analytical techniques and capability, especially in the field of instrumentation. Only 20 years ago in the FDA field laboratories about the only analytical instrument worthy of note (and it was still new) was the U. V. spectrophotometer. Today in our district laboratories recording spectrophotometers, including those in the infrared range, are commonplace as are gas chromatographs. In addition, some laboratories are equipped with the nuclear magnetic resonance spectrophotometer and the mass spectrograph. With these advances it is important that "adequate provision to check the reliability, accuracy and precision of any laboratory test procedure be used."

While the basic requirements and principles are the same with regard to adequate testing and testing methods for drugs, the criteria for judging the suitability of a procedure for regulatory drug analyses may be quite different from those used by a manufacturer in choosing

a control method. A manufacturer seeking a procedure to control a formulation is free to select any rapid, convenient method which affords a reliable analysis since he knows the composition of all the constituents in his preparation and the conditions to which they are subjected during manufacturing. He can ascertain, for any procedure, the interference due to the "inert" ingredients. By applying the selected analytical procedure to a "sample blank" containing all the ingredients except the one being determined, he may compensate for any error or interference and thus achieve an acceptable determination. Generally speaking, lacking this information about the "ingredient" which does not appear on the label, the regulatory agency must devise an assay method which will give the desired accuracy and precision. Of course, in the case of drugs which appear in the official compendia we must first turn to the methods set forth in them for analytical procedures and, in fact, drugs appearing in them must be capable of being analyzed by the methods set forth in those compendia.

With these great advances in the field of analytical chemistry, we would expect it to be a very rare occurrence to encounter a product on the market which did not meet its labeled specifications. Unfortunately, this is not the case. The reasons for this are obvious and are as follows: (1) Failure to devise and apply adequate methods of analysis to each batch produced; (2) Failure on the part of the manufacturer to assure uniformity of his production; (3) Failure to adequately sample his production to assure that the analysis is truly representative of the quality of the product; (4) Failure to meet current good manufacturing practices with regard to assuring stability of a product; (5) Lack of adequate provisions to check reliability, accuracy and procedures of any laboratory test procedures used, including the reliability of outside or consulting laboratory services.

It is incumbent upon all manufacturers and distributors of drugs to assure themselves, and thus assure the consuming public, that their products are of the highest quality and are of the strength and purity which they are represented to possess. To assure that the public will receive the highest quality drugs, we in the FDA are continually striving to improve our ability in the area of drug analyses and our capability to analyze more and more samples of products in the marketplace. It is, therefore, obvious that we have common goals, and we hope that we will be using common methods. The manufacturer of a drug product can make no better investment to protect his future reputation and financial standing, than to assure the quality control of his product. **[The End]**

A View from the Top— The Pharmaceutical Manufacturer's Multi-Responsibilities

By AUSTIN SMITH, M.D.

The Following Article Was Presented at a Meeting of the Practising Law Institute Held at the Penn Garden Hotel in New York City on November 17, 1967. Dr. Smith Is the Chairman of the Board of Parke, Davis & Company, Detroit, Michigan.

WHILE I AM GLAD to attempt to outline at least some of the multiple responsibilities involved in the management of a pharmaceutical manufacturing firm, I somehow feel that it might be more appropriate to designate them as a view from the bottom rather than from the top, since the pharmaceutical industry, in recent years, has reached a new low position on the totem pole of public approval and acceptance, not to mention the continual harassment to which it has been subjected by government agencies and congressional committees.

It is, however, neither my purpose nor my intention to appear here as a disciple of gloom or as one who feels that there is no solution to the problems which beset the industry. To the contrary, I sincerely believe that we possess the ability to solve these problems and perhaps we may even benefit, in the long run, from the harsh and often unjustified criticisms which have been leveled against us in congressional committees, in books, pamphlets, news media, and television.

In briefly touching upon some of the multiple responsibilities of a drug manufacturer, I must preface my comments by recognition that

many of the day-to-day responsibilities we accept are those common to all well-run business organizations. It is possible, however, because of the present public and legislative attitude toward our business, that we have acquired responsibilities which are peculiar to this industry and which are much more difficult to perform. Indeed, these problems might well also be listed as responsibilities since they must be resolved and the solutions will become added responsibilities. In general, however, our responsibilities include the following:

1. A research effort that is unceasing and constantly alert to opportunities for development of new and better medicines and health care products. This research must also continually study possible new applications and improvements in existing products. We must be alert to the health needs of our changing society and utilize our very best resources for the development and introduction of new products designed to meet such needs. It has been said that the products of the pharmaceutical industry face the highest rate of obsolescence of any commodity, and this is probably true. This dictates a definite challenge and a most important added responsibility to enhance, if possible, the life of existing products and to keep well abreast of all developments in our field and even in those which might normally be considered somewhat remote.

2. An adequate productive capacity to meet the growing worldwide demands for better health and freedom from disease. With respect to all products, whether old or new, we must continue to develop and maintain the highest possible production and product standards, and the rigid maintenance of total quality control procedures is a must.

3. Complete and accurate information regarding the use of our products must be conveyed to those who are to use them, whether it be the physician, the dentist, the pharmacist, or the ultimate consumer —and such information must be conveyed in clear, concise, and understandable language.

4. A well-organized and aggressive selling force fully equipped with the specialized knowledge essential to the proper promotion of ethical products must be maintained, and they must have a proper realization of their role of keeping the medical profession fully and accurately informed on available medication, its advantages and disadvantages, and its proper application.

5. A financial policy which will provide an adequate return to our shareholders, provide for the continuance and expansion of the

business, and especially provide the enormous research investment required if medicine is to progress in anything approaching the spectacular fashion which has characterized the past 25 to 50 years.

6. The ability to compete and the determination to justify its existence by continuous contributions to the physical betterment of mankind. This involves the most effective use of the abilities of all personnel and the proper utilization of highly specialized technical people.

7. Truthful, non-misleading advertising which should be conducted not merely because it is required by law but primarily because such concepts are in the public interest and are the only ones which deserve public acceptance.

8. We must keep abreast of pending legislation affecting our industry to the extent that if we support such legislation we must let it be known. If, on the other hand, there are any reasons why we are in disagreement with the purpose of the proposed legislation or the means by which the purposes are to be accomplished, we must communicate our views to our legislators. We must not object to proposed legislation simply because it may result in added inconvenience or expense to us. But unnecessary expense merits our immediate opposition. After all, such an extra burden is one which the public should not have to bear. If there is an overriding public interest to be served and which the legislation is designed to accomplish, we should lend our support. We must oppose legislation prompted by those who would seek only to hinder private enterprise while purporting to be acting in the public interest. Whenever feasible, we should work toward encouraging our legislators to be as specific as possible in setting forth directions and standards and thereby minimize the possibility of well-intended administrative agencies misinterpreting the meaning of the legislation or expanding its authority. Our recent experiences in the "generic-name-every-time" and the more recent prescription drug advertising regulations are prime examples of the difficulties that can arise because of imprecise legislation.

As responsible manufacturers, we should pledge our full cooperation to governmental agencies, but at the same time we should retain our right to object to unreasonable, ill-conceived or unduly restrictive legislation, and we should strongly resist unauthorized exercise of legislative authority by government agencies. We must become more aggressive in legislative matters not only at the federal level but, just as importantly, at the state and local levels.

Increased Need for Responsible Counsel

For us as manufacturers to fulfill these dedicated responsibilities, we must be constantly aware of the law and regulations that affect our industry and our own individual companies. And, so we look to you in the field of law for the necessary guidance, along a sometimes rocky path, so that we can reach our goals within the guideline set forth.

This meeting is replete with topics which identify some of the multiple problem areas which must concern the executives of drug and cosmetic companies, and the fact that these subjects appear on your program demonstrates that legal advice and guidance are becoming more than ever important in management's decisions in this industry. The scope of necessary counseling has become so wide that meetings of this type are not only advisable but essential.

A decade ago, a meeting of this type, with its technical agenda, would have been neither possible nor necessary, since the problems we now have simply did not exist, or at least they were not so obvious. It is not my purpose to discuss either the legislative, the social, or political history which have led to our present situation, but I submit that we have seen, in recent years, the development in some quarters of a public and political attitude which might well be called "consumerism"—a basic and threatening dissatisfaction of the consumer with American business in general and specifically with those areas of industry which personally and directly affect him. Among these certainly is the element of medical care. It might be well for all of us to continually reflect that illness is always dreaded and that financial outlay for medication is always resented. It might be said that the drug manufacturer is producing a product which nobody wants to buy or products which do not appeal to the buyer in the same way as do his purchases of clothing or automobiles or any of the other numerous commodities in which he can take pride and satisfaction. We are, therefore, in a most vulnerable position when our industry is attacked with accusations of high prices and especially when allegations are made that our products do not measure up to the public expectation that all drugs are miracle drugs.

For too many years this industry ignored too frequently its opportunities to enhance its public prestige and understanding and failed to take the steps, which would then have been so much easier, to justify its price structure and to convince the public of the overall excellence of its technical performance and of its public responsibility.

Since we failed to do these things, we are now faced with the necessity of "coming from behind" and attempting to convince an antagonistic audience of our competence and our right to exist without harassment and excessive legislative control.

Since, however, the situation is as it is, we cannot ignore it with the hope that it is temporary or that the spotlight of criticism will be shifted to some other industry or some other subject. We face, in my opinion, a future of more attempts at legislative control, since it is obvious that restrictive proposals affecting this industry are politically attractive and meet a ready public response. As Professor Joseph D. Cooper of Howard University recently said: "This issue is not whether regulation is needed. Rather, it is what the form of regulation is to be. Implicit in this is the related question of how much regulation can be imposed before it becomes insufferably self-defeating."

In his comments, which were entitled "Decision-Making in the Regulation of Drugs," Professor Cooper, in discussing the present conduct of the Food and Drug Administration, said:

> Its mission must undergo change consistent with profound alterations which have been taking place in the character of new drug research and development. Above all, it is most imperative that future decisions governing the availability and use of medicines be reached through scientific dialogues in an environment free of the temptations of political opportunism.

It seems to me that government agencies concerned with the drug and cosmetic industries must further develop a posture of dispassionate responsibility toward the rights of both the public and the industry. In such an atmosphere, necessary dialogue on improvement in industrial practices or governmental regulation can, and will, proceed with good will on both sides and with far greater ultimate benefit to the public we both serve.

"Generic Versus Trade Name"

People have become confused over this "generic versus trade name" issue and have been led to assume that anything sold under a generic name will be less expensive than the same product sold under a brand name. This is a false assumption because several studies over the past few years have shown that there is considerable variation in price; and that, sometimes, brand name products are available at lower prices than generic counterparts.

Unfortunately, at the same time, there has been generated, in a very misleading way, acceptance of the concept that there is equivalency between all finished dosage forms with the same basic drug

ingredient. This too is a false assumption. I might add, also, that the drug manufacturer does not quarrel with the physician's right to choose between a generic name and a brand name. He only quarrels —as does a vast majority of the medical profession—with attempts to force prescribing doctors to use *only* generic names. Not only would such restrictions be against the best interests of the patient but also would represent flagrant discrimination against an industry, a profession, yes, even the sick public, such as has never been seen before in this country.

Quality and Effectiveness

There is no quarrel on the part of responsible pharmaceutical manufacturers with the absolute necessity of rigid and total quality control of their products. Chemical identity, uniformity of production batches, accurate and continuous surveillance of laboratory criteria and adherence to all established official compendia is not only required but completely desirable. However, these procedures do not and cannot predict the eventual physiological and pharmacological effect of many drug formulations when they are administered to an actual patient, and they were never intended to do so. This is the serious discrepancy which is inescapable if total dependency is placed on chemical laboratory tests alone. In the final analysis, there is no other way to establish the effectiveness of a drug in humans than to thoroughly test it in humans.

In conclusion, may I say that while I regard myself as an optimistic type of individual, I see a long, difficult road ahead during which the pharmaceutical manufacturer will continue to be the target of the politician, government agencies, consumer groups, and crusading writers. We have been living in an atmosphere of anxiety, uncertainty, and hostility for some years, and we can anticipate that it will continue for more years to come. Despite untiring efforts to develop and supply the very best drug products for the health of the world's peoples, we must at every turn engage in controversies with those who would have the public regard this industry as run by dishonest and irresponsible persons, seeking to deal unfairly with their customers. A reversal of this onslaught of uncomplimentary, inflammatory indictments is no simple undertaking, but is one which must be accomplished if we are to survive as one of this great nation's leading and reputable industries. And the advice, counsel and guidance of the legal profession is vital if we are to avoid mistakes of omission or commission. This is our mutual responsibility. **[The End]**

Legal Aspects of Modified and Vegetable Fat Dairy Products

By CHARLES M. FISTERE

The Following Article Was Presented at the New Products Symposium of the North Central Milk and Ice Cream Association at Minneapolis on January 18, 1968. Mr. Fistere Is General Counsel for the Milk Industry Foundation.

The Federal Law

WHEN WE SPEAK OF THE FEDERAL LAW applicable to modified dairy products, we are speaking essentially of the Federal Filled Milk Act (21 U. S. C., Secs. 61-64). This statute, enacted by Congress in 1923, casts a long shadow over the entire field of dairy product regulation.

The Filled Milk Act, in Section 1, defines the term "filled milk" to mean any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated.

Section 2 of the Act declares that filled milk, as so defined, is an adulterated article of food and is injurious to the public health, and its sale constitutes a fraud upon the public. It is declared to be unlawful for any person to manufacture any filled milk within any territory or possession, or within the District of Columbia, or to deliver any filled milk for shipment in interstate or foreign commerce.

The constitutionality of the Act has been sustained by the Supreme Court of the United States in two cases. These two im-

portant cases are *United States v. Carolene Products Company* (1938), 304 U. S. 144, and *Carolene Products Company v. United States* (1944), 323 U. S. 18. The same product was involved in both cases, except for the fact that in the second case the product had been fortified with vitamins and minerals so that it had virtually the same nutritive values as evaporated milk. The product was essentially a compound of skimmed evaporated milk and coconut oil.

The court held that it was within the province of Congress to decide whether these products should be permitted to be sold in interstate commerce and that the prohibition of such sales was not violative of due process of law. Congress has plenary authority, the court declared, to exclude from interstate commerce articles whose use it may reasonably conceive to be injurious to the public health, morals, or welfare in the states for which these articles are destined.

The court found the danger of fraud to be magnified where the product in question is indistinguishable from a valuable food of almost universal use, thus facilitating fraudulent distribution and rendering the protection of the consumer more difficult. Whether the public would be adequately protected by the prohibition of false labels and misbranding, and whether it was necessary to prohibit the substitute product altogether when the two products are not distinguishable is a matter of legislative judgment.

In the same year in which the Supreme Court decided the second *Carolene* case, it also upheld as valid under the United States Constitution a state law regulating filled milk. This was in the case of *Sage Stores v. State of Kansas* (1944), 323 U. S. 32.

In discussing the federal law, the fact that there is a federal statute specifically dealing with filled milk may tend to make us unmindful of federal laws of more general application. Here I have most particularly in mind Section 403 of the Federal Food, Drug and Cosmetic Act, and especially the provisions of Subsections (c) and (g) thereof.

Subsection 403 (c) prescribes that a food shall be deemed to be misbranded if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

Subsection 403 (g) declares that a food shall be deemed to be misbranded if it purports to be, or is represented as, a food for which a definition and standard of identity has been prescribed by regulations as provided by Section 401 of the Act, unless (1) it conforms to such

definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients present in such food.

In this broader context, it is important to note another case decided by the United States Supreme Court, which, while not involving a dairy product, is probably the leading federal case in the area of imitation products in general. This is the case of the *62 Cases of Jam v. United States* (1951), 340 U. S. 593.

In this case, the Supreme Court upheld as lawful for interstate commerce a product which did not comply with the federal standard of identity for jam in that it contained only 25% fruit instead of the required 45%. The manufacturer's contention was that the product was labeled in complete compliance with Subsection 403 (c) of the Federal Food, Drug and Cosmetic Act in that, although an imitation of another food, its label bore, in type of uniform size and prominence, the word "imitation," and, immediately thereafter, the name of the food imitated.

In upholding this contention, the court said that the words "imitation jam" connote exactly what the product is, a different preserve not meeting defined specifications. In making this determination, the court used the now-famous language: "Congress did not give an esoteric meaning to the word 'imitation' "but rather . . . left the meaning of the word to the understanding of ordinary English speech."

We briefly note one more federal case in the general area of imitation products. This is the interesting District Court case of *United States v. 651 Cases of Chil-Zert,* 114 F. Supp. 430 (DC N. Y., 1953). Here the government proceeded against a shipment of the product "Chocolate Chil-Zert" upon the ground that it was in fact an imitation chocolate flavored ice cream and was not labeled "Imitation Ice Cream" under the provisions of Section 403 (c).

The court found that Chil-Zert was similar to chocolate ice cream in taste, color, texture, and method of manufacture. It differed from ice cream only in the respect that it contained soy fat and soy protein in place of milk products. However, it was clearly labeled "Not an Ice Cream." The court declared that the question of whether a food is an imitation, within the meaning of Section 403 (c), is determined by the effect of a composite of all elements of similarity, but added that resemblance is not enough and that there must be inferiority in the sense that the product is cheapened by the substitution of

ingredients. Finding these requirements present, the court held that the use of the words "Not an Ice Cream" did not exempt the product from the requirement that it bear the declaration "Imitation."

Returning briefly to the Federal Filled Milk Act, it is the belief of knowledgeable persons that it is a quite viable law and that the Federal Food and Drug Administration (FDA) will proceed to institute criminal proceedings if these products are shipped in interstate commerce.

Section 403 (c) of the Federal Food, Drug and Cosmetic Act likewise is a quite viable law, and there can be no doubt of its efficacy in the general area of imitation products and of the readiness of the FDA to proceed against imitation products shipped in interstate commerce without the requisite "Imitation" label.

This indicates that the existing problems, and future development of the law, are a matter for the states. Historically, the industry has left to the states the decision as to whether they wanted to legalize, and in some instances standardize, products made of fats other than milk fat, particularly in the ice cream industry, or to seek legislation to prohibit their processing and sale.

The State Law

To summarize the law of the 50 states concerning even a simple question of law is not without difficulty. To summarize the law of all the states concerning a difficult and sometimes unclear matter of law is apt to be a really formidable undertaking.

We are especially fortunate, therefore, to have available the report of a state survey on the "Legal Status of Imitation and Filled Milk Products." The survey was conducted by the Milk Industry Foundation in October 1967.

The survey took the form of a questionnaire addressed to the appropriate officials of all the states. The questionnaire sought to elicit information concerning the legal status of five products. But since each product was inquired about with reference to both imitation and filled formulations, there were actually ten products. These were as follows:

Imitation Milk
Imitation Whipping Cream
Imitation Half and Half

Imitation Coffee Cream
Imitation Sour Cream
Filled Milk
Filled Whipping Cream
Filled Half and Half
Filled Coffee Cream
Filled Sour Cream

For purposes of the survey, the following definitions were used:

Imitation milk—"A combination of non-dairy ingredients (that is, vegetable fat and soya solids) made in semblance of milk."

Filled milk—"A combination of skim milk or milk solids and non-dairy fat made in semblance of milk."

Comparable definitions were used for the other products included in the survey.

With reference to each of the ten products, the following questions were asked:

Is the sale of the product legal in your state?

If the answer is "yes," is the product required to be labeled:

(a) "An Imitation Milk" (for example)?

(b) "A non-dairy product"?

(c) A fanciful name or brand name?

(d) Other?

Is the product "Legal to Process in Milk Plant?"

The results of the survey are most interesting. The results were, first, as to *Imitation Products:* Of the 40 states responding, 35 states (80%) permit the processing and sale of all imitation products listed in the survey. Two additional states permit a limited number of imitation products to be sold (Montana and Wisconsin).

In regard to the labeling of imitation products, 15 states require an "imitation" label; the use of a "fanciful name" only is permitted in nine states; and the remaining 16 states provide a combination of "imitation," "fanciful," and "non-dairy."

Second, as to *Filled Products:* Of the 42 states responding, only ten (25%) permit the processing and sale of the filled milk products surveyed. Two more states allow a limited number of filled milk products to be made (North Carolina and Ohio).

Third, as to the *labeling* of filled milk products: seven states require an "imitation" label, and three states permit a "fanciful name."

Fourth, as to *both imitation products and filled milk products,* of all responding states permitting these products, only four replied that it is not "Legal to Process in Milk Plant."

Responses from some of the state regulatory officials indicate that the filled milk laws of some of the states are under study. Some of the responding officials indicate that they have grave doubts that their laws would stand up in court.

The Law of the North Central States

It is understood that the North Central Association embraces five states, Minnesota, North Dakota, South Dakota, Iowa and Wisconsin. It is of special interest, therefore, to observe what the enforcement officials of these states have said about the status of the law in their states.

We turn first to filled milk products, and we find that *none* of the five filled milk products covered by the survey is permitted to be sold in *any* of the five states. There is only one small exception: With reference to the product "filled whipping cream," the Wisconsin officials report that "canned whipped filled cream can be sold in Wisconsin if properly labeled." We may properly say, therefore, that in these five states, at the present time, filled products not only may not be sold interstate but also may not be sold intrastate.

As to the five imitation products, there is no unanimity, and we must accordingly take them state by state.

North Dakota, while responding as to filled products, provided no data as to the imitation products.

Minnesota advised that imitation milk, imitation whipping cream and imitation sour cream *may* be sold. The latter two may be sold under a "fanciful" name.

Wisconsin made the same response as Minnesota except for the fact that the two imitation products that may be sold may apparently be sold under both "non-dairy" and "fanciful" labels.

South Dakota permits the sale of all five imitation products and requires a "non-dairy" label.

Iowa permits the sale of all five imitation products but requires an "imitation" label and permits a "fanciful" label.

Special mention may be made of the situation in Minnesota in that the responding state official advises that even these products, filled and imitation, which may not be *sold* in Minnesota, may nonetheless be *manufactured* in Minnesota for sale elsewhere. Whether this would be true of any given state would depend upon the scope of the acts prohibited under its filled milk act and statutes pertaining to imitation dairy products.

Recent Cases in the Courts

Preliminarily I wish to emphasize that the cases we shall now consider are recent cases. The validity of numerous legislative enactments in the field of filled and imitation products has, in the past, been upheld, and in other cases stricken down, by state courts under the provisions of state constitutions. Most of these cases go back a number of years, and time and space do not permit reviewing them here. And so we turn directly to cases that may properly be called "recent" cases in the light of historical perspective.

Midget Products, Inc. v. Jacobson, Director of Agriculture of the State of California, 295 P. 2d. 542. (Cal. Ct. App. 1956).

This case involved a product known as "Mel-O-Dee Whip Topping" and also as "Mel-O-Dee Zert Topping." The plaintiff manufacturer sued to enjoin interference with sale of the product in California.

Pointing out that the product contains no milk or product of milk, the court says that it is a "blend of water, hydrogenated vegetable fats and nut fats, sucrose, vegetable protein, corn syrup, salt monoglycerides, diglycerides, stabilizer, artificial flavor, and artificial color." The product was intended primarily for sale to commercial customers such as bakeries and confectioners, but it was intended that in the future it should be sold to the retail trade in liquid form and also in a pressurized container.

Defendant contended that the product was an imitation milk product within the meaning of the Agricultural Code and must hence be labeled as such. Also, plaintiff must be licensed and persons handling the product must display signs stating "Imitation milk is used and served here."

The Court of Appeals affirmed the judgment of the trial court granting plaintiff declaratory relief and an injunction.

The court ruled that the product was "not an imitation milk product but is a food compound singular and distinctive to itself." This is true even "although it may reasonably be said to have the appearance of a milk product."

The court said that,

> Section 651 of the Agricultural Code, insofar as it purports to classify as an imitation milk any substance other than milk or milk products, intended for human food and having the appearance of milk, is whimsical, arbitrary, and unconstitutional, and would, if valid, legally define as an imitation milk product such substances as coconut milk, marshmallow cream, and soybean powder dissolved in water, not one of which is an imitation milk product.

The court also says that to attempt to apply the statutory provisions in question to plaintiff's product would constitute "an unreasonable interference with plaintiff's property and business."

Aeration Processes, Inc. v. Jacobsen, Director of Agriculture of the State of California, 184 Cal. App. 2d. 836 (Cal. Ct. App. 1960).

Unlike the earlier California case of *Midget Products, Inc. v. Jacobsen*, this case involved a product which contains a dairy ingredient. The product is called "Instantwhip Topping," and its ingredients are stated by the court to be "soybean fat, cottonseed and coconut oils (20%) nonfat milk solids (7⅓%), stabilizers, water, sugar, vanilla. The percentage of water is not specified but it appears that the combined nonfat milk solids and water constitute 70 percent of the manufactured product."

The court said that the product is sold to hotels, bakers, confectioners, and like commercial establishments, mainly in pressurized containers, but some sales are made in liquid form to customers who have their own pressurizing containers and separately purchase the nitrous oxide gas for aeration.

In principal issue were Section 651 of the Agricultural Code, which defines an imitation milk product as "any substance, mixture, or compound other than milk or milk products, intended for human food, made in imitation of, or having the appearance or semblance of, milk or any product thereof;" Section 654, which requires such products to be labeled "imitation;" and Section 638, which, with exceptions not here pertinent, proscribes the manufacture or sale of any milk product to which any fat or oil other than milk fat has been added either under the name of such product or any fictitious or trade name.

The court's analysis of the case follows:

> Essentially the question that is determinative of the major issues involved herein is whether or not there is evidence to support the [trial] court's finding that plaintiff's product is a separate and distinct food product and not a milk product at all. The question may be restated: Does the substitution of nonfat milk solids to the extent used by plaintiff change the essential character of the product and make it a milk product, thus taking it out of the category of the toppings ruled upon in the Midget Products case?

The court said:

> Imitation is a question of fact not tested by appearance alone but by many factors, such as taste, smell, texture, consistency, melting points, and use. The test is not the presence or absence of any one element of similarity but the composite effect of all of them.

The court affirmed the granting of an injunction against enforcement of the Code provisions referred to, but in view of the findings of non-imitation and inapplicability, concluded that it is unnecessary to pass upon constitutional questions.

Coffee-Rich, Inc. v. Donald N. McDowell, Individually, and as Director, Wisconsin Department of Agriculture, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,047, 130 N. W. 2d. 203, (Wis. Cir. Ct. 1963)

This was an action by the plaintiff, Coffee-Rich Inc. to enjoin the defendant, Director of the State Department of Agriculture, from interfering with the sale of its product "Coffee-Rich" in Wisconsin. The injunction was granted.

"Coffee-Rich" was described by the court as being "a pasteurized, homogenized blend of water, vegetable fats, corn syrup solids, sodium caseinate, sodium citrate, carrageenan, sorbitan monostearate, polysorbate 60, and beta carotene." The court said further:

> Coffee-Rich is a fluid developed through chemical research to act as a substitute for the dairy product commonly known as Half & Half. The label on the carton reads 'a vegetable product' which 'contains no milk or milk fat' and is 'ideal for use in coffee, on cereals, fruits and desserts . . . . with soups . . . . and sauces.' It is admittedly a wholesome, healthful food containing no deleterious substances.

Section 97.25 of the Wisconsin Food, Drug and Cosmetic Act provides that a food is adulterated if it is an imitation of another article or if it is colored or flavored in imitation of the genuine color or flavor of another substance. Section 97.39 prohibits the sale of any food that purports to be or is represented as a dairy product but which contains any fat other than milk fat.

The court says that these were merely false advertising statutes intended to prevent merchandising in such a manner as to deceive the public. The court then proceeds to rule that,

> The conclusion of the Attorney General that a sale of Coffee-Rich in a frozen state in a store is not a violation of any statute constitutionally construed is well taken, because such sale is not of an 'imitation product' but rather the sale of a substitute, but nevertheless a distinct and different product. Mere resemblance in color, taste, or texture does not make a product an imitation within the meaning of the statute when it is clearly labeled and identified by its frozen state as being a different product.

Upon appeal to the Wisconsin Supreme Court, one justice did not participate and the other members of the court being equally divided as to whether the judgment should be affirmed or reversed, the court held that judgment should be affirmed.

Coffee-Rich, Inc. v. State Board of Health of Virginia, CCH FOOD DRUG COSMETIC LAW REPORTS, ¶ 40,082, (Va. Cir. Ct. 1962).

This was an action by the plaintiff, Coffee-Rich, Inc., for a declaration that Sections 35.42.2 through 35.42.8 of the Code of Virginia are not applicable to its product "Coffee-Rich" and that this statute is unconstitutional under both the Virginia and the United States Constitutions, and for an injunction restraining the defendant Board of Health from enforcing the statute as against the plaintiff and its product. Finding that the statute is inapplicable, the court granted the injunction but found it unnecessary to consider the question of constitutionality.

The controversy centered mainly around the cited statute, which is referred to as the "Imitation Cream Statute." In general, this statute defines "Imitation Cream" as

> Any substance, mixture, or compound which contains vegetable and animal fats, or oils, or other substances, mixtures, or compounds made in imitation of cream, half & half, or milk and is used or mixed with coffee or other beverages, cereals, soups, sauces, or other foods prepared for man.

The statute requires that the container in which any such product is sold be labeled "Imitation Cream" and prohibits the serving of any such product at a public eating place unless a notice that "Imitation Cream" is served is prominently displayed and printed on the menu.

After reviewing the points of similarity and of difference between Coffee-Rich, on the one hand, and cream, half and half, and milk on the other, the court turned to a consideration of the language "made in imitation of." The court concluded that the legislature intended it

to denote a product which is inferior in its ability to perform the functions usually performed by the dairy products and which has the same or almost the same, physical characteristics perceivable to the consuming public, such as color, texture, taste, smell, and the like.

The court ruled that upon the evidence before it, Coffee-Rich is not an imitation milk product. "It is rather a manufactured food product which, though resembling in some degree the dairy products in question, has distinctive characteristics of its own . . . ."

An appeal by the State Board of Health was rejected by the Virginia Supreme Court, the court stating:

. . . the court being of the opinion that the said decree is plainly right, doth reject said petition and refuse said appeal and supersedeas, the effect of which is to affirm the decree of the said circuit court.

Coffee-Rich, Inc. v. The Kansas State Board of Health, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,094, 388 P. 2d. 582, (Kan. Sup. Ct. 1964).

Here, the Kansas Supreme Court affirmed a judgment of a District Court enjoining the defendant Board of Health from interfering with the sale of Coffee-Rich.

The Board had taken the position that Coffee-Rich is an imitation of cream, half and half, or milk, and that the sale of the product without the label "imitation" was violative of the Kansas General Statutes, 1961 Supp., Ch. 65, Art. 6; 65-657 and following. This statute provides that,

A food shall be deemed to be misbranded: (c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word, imitation, and, immediately thereafter, the name of the food imitated.

The court reviewed the authorities at length and engaged in an exhaustive comparison of Coffee-Rich with cream. The court said,

Courts, common usage, and dictionary definitions are agreed that 'imitation' connotes an inferior quality or watered down version of the imitated item.

The court summarized its deliberations and its conclusions as follows:

We reach the inescapable conclusion that Coffee-Rich is not an imitation of cream or half and half and that it is a new and distinct food product having characteristics unique unto itself. Coffee-Rich is no more an imitation of cow's cream, half and half, or any other dairy product than nylon is an imitation of silk, saccharine an imitation of sugar, or Crisco an imitation of lard. These products, and Coffee-Rich, are separate, distinct, individual products developed as a result of modern scientific and technical advances and inventions. They are products sui generis.

State of Washington v. Coffee-Rich, Inc., et al, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,109, (Super. Ct. Wash. 1963).

The State sought to enjoin Coffee-Rich, Inc. from manufacturing and distributing its product, which the State alleged, violated the uniform Washington Food, Drug and Cosmetic Act and the Washington Filled Dairy Products Act. The injunction was denied.

The court found as a fact that while Coffee-Rich resembled cream and half and half, it "is not an imitation of cow's cream, half and half, milk, skim milk or any other dairy product." It is a "distinct and original product," having "its own distinct physical properties."

The court also found as a fact that the presence of sodium caseinate as an ingredient in Coffee-Rich did not cause the product to be a filled dairy product. Sodium caseinate is a chemical substance derived from milk casein substances in skim milk by a complex series of chemical and mechanical operations, but "in Coffee-Rich, sodium caseinate is not used as a food, but is used solely as a functional ingredient intended to stabilize the emulsion of fat in water, and particularly to enable Coffee-Rich to maintain its emulsion condition upon freezing and thawing." Coffee-Rich is therefore not a filled dairy product within the meaning of the Washington Filled Dairy Products Act.

Coffee-Rich, Inc., et al. v. Michigan Department of Agriculture and the Director thereof, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,197, 135 N. W. 2d 594 (Mich. Ct. App. 1965).

This was an action for an injunction and a declaration of unconstitutionality brought by Coffee-Rich, Inc. and the owner of a Detroit restaurant against the Michigan Department of Agriculture and the Director thereof.

At issue were the contentions of the defendants that the product Coffee-Rich is made in imitation of cream within the meaning of Public Act 235 of the Michigan Public Acts of 1961 and must hence be labeled "Imitation Cream;" that conspicuous notice must be given that imitation cream is served in a public eating house; that each serving of Coffee-Rich in a public eating place must be served in its original factory packaged container labeled in accordance with Public Act 235. Defendants urged that the legislative purpose was to prevent fraud and deception through passing off of "imitation cream" as cream, half and half, or milk, which items are dairy products with standards defined by law.

The record of the trial proceedings indicates that the trial court made findings as follows:

That Coffee-Rich is not made in imitation of cream, half and half, or milk; that the product is not an imitation but a separate product, having distinctive characteristics, purposes, and advantages; that the present labeling does not mislead the public, whereas to require the labeling of "imitation" would be, on the facts, false and untrue and would tend to mislead the public, including the ultimate consumer.

In a brief opinion, the Court of Appeals said there was adequate basis for these findings and affirmed the granting of an injunction. This ruling made it unnecessary to consider the constitutional question.

Coffee-Rich, Inc. v. James F. Short, Director of Agriculture, Oregon State Department of Agriculture, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,214, (Ore. Cir. Ct. 1965).

This was another suit for injunctive and declaratory relief.

At issue was an Oregon statute somewhat different from any involved in the other cases under discussion. The statute provides that,

'Imitation milk product' means . . . any product not milk which . . . product is made to have or has the appearance, taste, texture, or general composition similar to that of a fluid milk product . . . which is used or offered for use as a fluid milk product.

The sale and service of such a product involved the usual requirements and consequences.

The court first compared Coffee-Rich with cream and milk, and in this connection said, "The difficulty, of course, is to determine what degree of similarity the legislature had in mind." The court replied,

It is the court's opinion that in this regard the legislature intended to include products which have a resemblance to milk even though they are not completely the same in appearance, taste, and texture. To this extent, Coffee-Rich is similar to milk and cream.

The court appeared to regard this portion of the definition as inconclusive. However, the court then continued:

The second part of the definition of 'imitation milk . . . requires that to be so defined, a product must be used or offered for use 'as a fluid milk product.' This language is more precise. From the proof made, it is found that Coffee-Rich was not intended as and actually is not an imitation of milk or cream. It is not used or offered for use as a milk product. It is offered and used as an original fluid vegetable food product . . . . It is offered as a distinct and different product that may be used instead of milk.

The court concluded that the statute does not apply to Coffee-Rich and enjoined the defendant Director from attempting to enforce the statute against it.

Aeration Processes, Inc. et al. v. Commissioner of Public Health of the State of Massachusetts et al., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,079, 194 N. E. 2d 838, (Mass. Sup. Jud. Ct. 1963).

This case involved "Instantblend." The formulation of this product, which is substantially similar to that of Coffee-Rich, is described by the court as being "a pasteurized blend of water, hydrogenated vegetable oils, dextrose, sucrose, enzyme modified casein, mono-and di-glycerides, protein stabilizers, salt, and artificial color and flavor."

A Massachusetts statute declares food misbranded if "in imitation or resemblance of any other food" unless, in certain cases, labeled as an imitation. But it does not permit the imitation, even with labeling, "of any food for which a standard has been established by law, other than as specifically provided herein." Massachusetts has established standards for cream and ungraded cream.

In this situation, the court stated that if Instantblend is an "imitation" of cream, it is misbranded, however labeled, and is subject to an embargo.

Saying that "the meaning of 'imitation' is not limited to a substance inferior to the product which it resembles" and that "intent to pass off, impose, or defraud is not required as a test of an imitation," the court proceeded to find that Instantblend is indeed an imitation of cream. The court was largely influenced in this finding by the fact that the sales involved consisted of only service of the product at public eating places and at employer-maintained vending machines in factories.

Pointing out that the Fourteenth Amendment to the Federal Constitution does not bar State action prohibiting the sale of an admittedly nutritious product as a measure with the police power aimed at avoiding consumer confusion, the court added.

> The facts do not require us to consider whether the statute would be unconstitutional in application if relied upon to bar distribution in retail stores, or elsewhere, in such a way that consumers would be informed as to the nature of the product sold or served and there would be no reasonable possibility of their mistaking it for cream.

Coffee-Rich, Inc. v. Commissioner of Public Health of the State of Massachusetts et al., CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,166, 204 N. E. 2d. 281, (Mass Sup. Jud. Ct. 1965).

Here the Massachusetts court had before it for consideration, not Instantblend but Coffee-Rich, and applying the same reasoning under the same statutes, found Coffee-Rich too, to be "in imitation or semblance" of cream.

However, the sales involved this time were retail sales at retail stores, the court saying, "Coffee-Rich is sold as a frozen food product in Massachusetts, and is displayed in and and purveyed only from the 'Frozen Food' sections of . . . various retail outlets." Furthermore, the court found that consumers were not confused as to the identity of the product under the conditions of sale. Upon these facts, the court held the application of the Massachusetts statute to such sales to be unconstitutional and permanently enjoined the Commissioner of Public Health from interfering therewith.

The court pointed out that in the *Aeration* case, while ruling that the statute was not unconstitutional as applied to service of the imitation product in public eating places and at employer-maintained vending machines in factories, it had taken the position that the facts of that case did not require it to consider whether the statute would be unconstitutional in application if relied upon to bar distribution in retail stores, provided that consumers were adequately informed as to the nature of the product.

The court recognized that the total prohibition by a state of the sale of a wholesome product is a method permissible under the Fourteenth Amendment to the Federal Constitution to avoid consumer confusion with other food products. However, the court did not decide the issue upon a federal ground but under provisions of the Massachusetts Constitution. "What is permissible under the Federal Constitution in matters of State economic regulation is not necessarily permissible under State law. The constitution of a State may guard more jealously against the exercise of the State's police power."

The court said that whether the complete prohibition of the sale of Coffee-Rich in Massachusetts was a valid exercise of the police power depended upon whether such prohibition "bears a real and substantial relation to the public health, safety, morals, or some other phase of the general welfare." The court decided that it did not.

United States v. 856 Cases of "Demi," CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 60,138, 254 F. Supp. 59 (DC NY, 1966).

This was a libel action involving the seizure of 856 cases of a product called "Demi" and labeled "Imitation Margarine." The court held that the claimant was entitled to summary judgment upon motion.

The position of the government upon trial of the motion was as follows:

> Demi violates the Federal Food, Drug, and Cosmetic Act because Congress has declared that *all* products made in semblance of butter are to be called 'margarine;' that there shall be but one imitation of butter and it shall be called margarine; and that imitations of butter which must be called margarine must, in all cases, comply with the standard of identity for margarine. Since this product does not so comply, it violates the law.

The court referred to the foregoing as a "dogmatic assertion" and said ". . . there is nothing evident to me in the legislative history or the several statutes involved to such effect." The court said that the case came squarely within the provisions of Section 403 (c) of the Federal Food, Drug and Cosmetic Act and that Congress has not declared that any product other than margarine can be marketed in semblance of butter.

Reesman, Kenneth et al v. State of Washington and Donald Moos, Director of Agriculture for the State of Washington, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,271, (Wash. Sup. Ct. 1967).

Involved here is the product marketed in California, Oregon, and Idaho under the trade name of "Farmer's Daughter." It is described by the court as follows:

> The product contains powdered dry milk as a base in combination with coconut oil and other chemicals, chiefly sodium caseinate, vegetable oil, corn syrup, dextrose, mono- di glyceride [*sic*] carrageenan, imitation butter flavoring and vegetable protein. There are added 2,000 U. S. P. units of Vitamin A and 400 U. S. P. units of Vitamin D per half gallon. It is the color of milk and to some tastes and smells like milk and is therefore in semblance of milk.

The plaintiff dairy operator sought a ruling that the Washington filled dairy products statute was unconstitutional as applied to "Farmer's Daughter" and asked an injunction.

The court had no great difficulty finding that the product is indeed a filled dairy product as defined in, and prohibited by, the statute. It found that the product is not compounded "in imitation" of milk but concluded from evidence that the product "looks like milk and to some people tastes and smells like milk;" and that it *is* compounded "in semblance" of milk.

The court concerned itself principally with the question of constitutionality. Upon this issue, it held that while sales of such a wholesome and nutritious product as this may be strictly regulated because of their semblance to milk, they may not be prohibited, since this is not a valid exercise of the police power. The requested injunction was therefore granted.

The memorandum opinion of the trial court, upon which this analysis is based, does not appear to state just how the product is labeled. However, it is understood that it is labeled "Farmer's Daughter —Imitation Milk—Hi Protein Drink."

The case is reported to be on appeal to a higher state court.

Shamrock Dairy v. Odle, Arizona State Dairy Commissioner, (Ariz. Super. Ct. 1967).

In this case the trial court entered a judgment, the relevant portions of which are as follows:

> The court further orders, adjudges, and decrees that Hi Protein Drink and Chocolate Flavored Beverages are not milk products and that White Satin Dressing is a milk product, and that Hi Protein Drink and Chocolate Flavored Beverage are therefore not subject to the jurisdiction or regulatory powers of the defendant, Ezra Odle as State Dairy Commissioner; that any designation or determination, either formal or informal, made by the defendant that the said products Hi Protein Drink and Chocolate Flavored Beverage, or either of them, are milk products was in excess of the lawful authority and outside the scope of the jurisdiction of the defendant, and is therefore invalid and of no force and effect.

The court wrote no opinion, but from a Memorandum of Points and Authorities that has been made available, it appears that the case involved the contention of the State Dairy Commissioner that the provisions of the 1953 U. S. Public Health Service Milk Ordinance and Code govern the production, transportation, handling, and sale of milk and milk products within the State of Arizona, and involved the fact that he had validly ruled these products to be milk products within the meaning of Section K of said Ordinance and Code.

The court did not assign a particular reason for holding that Hi Protein Drink and Chocolate Flavored Beverage are not milk products. Plaintiff (Shamrock Dairy) urged that the products are outside the class on two counts. First, it contended that whether taken as a percentage of the total ingredients or as a percentage of only the milk solids and water, the milk solids of neither constitutes 8¼% of the total, a prerequisite for considering a product to be a milk product. The second reason assigned by plaintiff relates to the process

of making these products. It contended that the element of combining a substance (vegetable fat) to a milk product (reconstituted skim milk) is missing. There never is at any stage of the process a reconstituted skim milk. Which, or whether both, of these arguments appealed to the court is not revealed in the judgment.

Conclusion

Several conclusions might be drawn concerning the legal aspects of filled and imitation products. However, one conclusion is self-evident, and it holds much significance. This conclusion is that the trend is running strongly in the direction of liberalization of the state law. **[The End]**

CLOSER REGULATION OF USE OF ANTIBIOTICS IN FOOD-PRODUCING ANIMALS

The Food and Drug Administration has announced that it is regulating more closely the use of antibiotics in food-producing animals. The FDA has also proposed changes in regulations which would end the use of all injectable streptomycin products and some penicillin preparations in these animals. Many of the antibiotic products currently used to prevent or to treat disease may be affected.

The FDA will take a number of steps to prevent the occurrence of unsafe residues of antibiotics in foods. One of these is that all exemptions from food additive regulations granted before 1958 will be revoked. Safe uses of antibiotic preparations will then be covered by new food additive regulations. Another measure will be the withdrawal of approval of new-drug applications where there is inadequate residue information. Also, all antibiotic products intended for food-producing animals will be considered to be new drugs or certifiable antibiotics, and evidence of their safety will be required.

Many antibiotic preparations used in animals cause residues in foods, and thereby pose a potential health hazard to man, the FDA has pointed out. The Food Additive Amendments of 1958 established withdrawal periods to keep residues at a low level. Available data show that the residues from some antibiotics persist long after the drugs are used. Since these residues are unapproved, the foods are adulterated within the meaning of the Food, Drug and Cosmetic Act.

There are several reasons that antibiotic residues constitute a potential hazard. One is that those who are sensitive to antibiotics may suffer a reaction to the residues in food. And there is the danger that sensitivity to antibiotics could develop from continued exposure. Also, the constant exposure of bacteria to antibiotics tend to enable bacteria to build up and transfer resistance to these drugs.

Voluntary Compliance Encouraged by Bureau Changes

By FRED J. DELMORE

Mr. Delmore, Director of the Bureau of Voluntary Compliance, Joined FDA in 1965 After Retiring from Military Service.

THE REEVALUATION of the Food and Drug Administration's (FDA) mission under the leadership of Commissioner James L. Goddard brought an examination of ways to assure maximum compliance with the Food, Drug and Cosmetic Act. It became apparent that compliance assurance is a responsibility shared by the regulated industries, state food and drug control authorities, and FDA.

Accordingly, FDA's traditional reliance on enforcement of the Food, Drug and Cosmetic Act through its own inspection and laboratory staffs is being reinforced to add other ways to reach a full industry-state-FDA partnership.

FDA contracted with Booz, Allen, & Hamilton, management consultants, to study ways to improve Agency District Office operations. One resulting recommendation: that District Offices apply new compliance approaches.

As an example, the summary report suggested: "An industry workshop may be a more effective way to solve a poor manufacturing practice within an industry than increasing the number of establishment inspections among the firms in that industry."

This philosophy was tested during fiscal 1967 by FDA Districts under the guidance of the Bureau of Education and Voluntary Compliance (BEVC). Nearly a hundred District workshops aired specific compliance problems of major health significance concerning drugs (good manufacturing practices, drug abuse control), and foods (microbiological contamination, chemical residues, sanitation). Response was excellent: 8,147 individuals representing 2,955 firms attended.

BEVC also conducted a dozen seminars and conferences on specific compliance problems and registered 2,593 industry participants.

A basic question is posed in any consideration of additional approaches to voluntary compliance: How much reliance can FDA place in industry-assured compliance, as contrasted to traditional law enforcement through punitive measures against violators?

Effective industry-assured compliance requires that most food, drug, and cosmetic firms understand and appreciate the consumer's concern with quality and make efforts to satisfy the keystone of their operations.

But quality, even in foods, is no longer easily recognized by the most informed and sophisticated of consumers. In drugs, especially, quality results only from the combined efforts of the researcher, the physician, the FDA, the pharmaceutical manufacturer's production and quality control teams, the pharmacist, and others. Clearly, quality —for foods or drugs—extends beyond the product itself. Congress has recognized this by enacting and periodically amending the Federal Food, Drug and Cosmetic Act.

The agreed-upon attributes of a definition of quality for foods are specific for each product. Food additives make these quality attributes increasingly various. Additives can be used only if cleared beforehand by FDA, which frequently limits the amount that can be present. For assured compliance a quality assurance program for a food manufacturer is a necessity.

A quality assurance program must be companywide, not shunted to the quality control department. Inauguration and support must come from top management and involve all departments. A number of food, drug, and cosmetic firms, recognizing this, have made quality assurance directors responsible to top management.

How do such emerging concepts of quality and quality assurance adapt to the traditional way of enforcing the pure food and drug laws?

For many years those administering these laws relied on legal sanctions. It was adequate at a time when most adulteration involved filth contamination of foods traceable to insanitary plant conditions. Most food producers got the message, instituted sanitation control programs, and raised sanitation standards in U.S. food plants. It worked because the manufacturer could control the cause of adulteration. It continues to work in many cases.

New Adulteration Problems

But in the early sixties, new adulteration problems arose, their origins not always directly traceable to the manufacturer's negligence, their control requiring both new and complex equipment and scientific expertise. As the use of chlorinated pesticides spread in the late fifties, for example, chemical residues appeared in milk from many areas. Manufacturers using milk in their products encountered a new and staggering problem—control of these residues.

Responsibility was not theirs alone. Milk control authorities of states and cities, and the FDA in interstate milk shipments, were legally responsible for purity of the milk. The FDA also was responsible for preventing feeds adulterated with pesticide residues, if in interstate commerce, from being fed to dairy cattle.

With the problem came a spread of its complexity. The question was, not who to blame or to punish, but how to get at the extent and sources of the contamination. Basic data were needed on pesticide residues in all types of food raw materials. In 1962 it was found that even liver oils from ocean fish contained such residues.

FDA began by developing analytical methods to detect pesticide residues and making them available to industry and state officials. Some trade associations realized that testing for residues in raw materials was beyond the capabilities of some individual firms and initiated a central laboratory testing program. More important, they began a program to control spraying by contract growers. FDA and the Department of Agriculture mounted broad, coordinated educational programs for growers of raw agricultural commodities.

Another area where traditional enforcement was tested and found wanting was in *Salmonella* contamination in foods and drugs. As early as 1962, Dr. Glenn Slocum, former Director of FDA's Division of Microbiology, sounded a warning about the hazards of *Salmonella*.

At about the same time the Public Health Service's Communicable Disease Center organized a Salmonella Surveillance unit and in 1964, under Dr. Goddard's leadership, staged a National Conference on Salmonellosis. A number of food industries and producers of animal feed and ingredients participated. It was obvious that control required a coordinated government-industry effort. It was equally evident that traditional law enforcement was not the sole answer.

This was recognized to some extent by FDA, particularly after the Citizens Advisory Committee's Second Report in 1963. A separate

Bureau of Education and Voluntary Compliance was formed in 1964 to educate consumers about the protections of the Food, Drug and Cosmetic Act, and to provide the regulated industries with facts and techniques needed for voluntary compliance with regulations and standards. BEVC emphasized information to industry and the importance of two-way communication. The information program sought answers to questions raised by industry. But resources were limited for problem areas. The idea exchange, moreover, required no commitment by industry to implement the oft-repeated phrase, self-regulation.

Programs for industry-assured compliance are not entirely new. Several trade associations have initiated quality improvement programs. Others have adopted ethics codes aimed at assuring compliance. These, although of some value, have limitations and usually concern a current specific industry problem. Quality assurance, of course, cannot be limited to one aspect of production or marketing.

The other serious shortcoming is that primary responsibility for compliance must rest with the individual firm and cannot be delegated to an association. Every firm needs its own policing. Industry-assured compliance must be based on commitments by individual companies to share with FDA the formidable task of assuring quality.

Such limitations of trade association compliance programs should not obscure their roles in promoting voluntary compliance. Besides acting as spokesmen for members they can serve as leaders, setting the industry's tone, spurring members to achieve their goals and possibly providing inspection services to members. Several trade associations had a major part in drawing up good manufacturing practice (GMP) guidelines, which have helped FDA in promulgating GMP regulations. One important trade association role has been communication between FDA and industry. A number of trade associations, particularly during fiscal year 1967, cosponsored seminars and workshops with FDA for profitable exchanges of ideas.

Recognition of the basics for adequate assured compliance led to development of a program for self-certification for quality assurance in 1967. The first such program was established recently by voluntary agreement between the General Foods Corporation and FDA for an in-plant pilot test.

This pilot plan currently is limited to two products produced in the firm's plant at Dover, Delaware. Briefly, the company and the Agency are sharing records on the quality of the two products, in-

cluding the firm's evaluation and performance records and qualitative formulas. FDA agrees to submit to General Foods a copy of the inspection reports on the two products, along with any complaints FDA receives about them.

Self-certification can add a firm's approved quality assurance program to FDA's own arsenal of consumer protection. Taken together, they enhance the consumer's assurance that quality is protected as much as food technology will permit.

The genesis of the Dover experiment is based on mutual respect by industry and FDA for each other's sense of responsibility. It's not entirely coincidental that the company so ready to take part should be General Foods, whose present chairman and chief executive, C. W. Cook, stated in an address on "Looking Ahead" at the 1962 national conference of FDA and the Food Law Institute: "As we compete aggressively with the ultimate objective of influencing the decision of the individual consumer, we respect the government's function of establishing rules of fair play, and in turn we seek respect for our own sense of responsibility."

The time is at hand. The challenge is clear. Reliance depends on the extent of the commitment by industry and by FDA.

Reorganization

FDA has committed itself by reorganizing BEVC into a new Bureau of Voluntary Compliance (BVC). The new Bureau was approved by the Department of Health, Education, and Welfare on January 11, 1968. Its charter: to promote industry-assured compliance so the regulated industries can take their place in the state-industry-FDA partnership.

The reorganization abolishes the Bureau's Division of Consumer Relations and restores its functions to the Office of the Assistant Commissioner for Education and Information for improved coordination of consumer education with closely related information work. In place of the Division of Industry Education are established the Divisions of Drug and Device Industry Relations and Food Industry Relations.

The Bureau will devote its efforts "solely to working with industry in promoting voluntary compliance with FDA regulations," with responsibility for developing voluntary compliance programs, admin-

istering FDA's program for self-certification and providing technical assistance on quality control.

This will require many approaches—workshops, self-inspection, self-certification for quality assurance, technical assistance by FDA on quality assurance—all recognizing that the many industry groups preclude any single formula. But the philosophy of maximum reliance on industry-assured compliance can apply to all, must apply to all, for the quality assurance demanded by today's consumers for foods drugs, and cosmetics.

The road to quality assurance may not be easy or rapid. Many firms will have to modernize their quality control systems. An adequate control system must cover raw materials, production and engineering, sanitation, laboratory testing and stability of finished products. FDA will make its scientific expertise and inspectional experience available to individual firms. BVC will act as the catalyst, bringing industry and FDA together through workshops and seminars on mutual problems. The Bureau will provide its own experts on quality assurance and will be assisted by all other FDA units. BVC also will coordinate the voluntary compliance efforts by FDA districts and headquarters scientists so that word of the progress of the joint FDA-industry effort can be spread and other firms encouraged to adopt industry quality assurance programs.

The Bureau welcomes new ideas on how to promote industry-assured compliance and will carry forward the best of these for consumer protection promptly and efficiently. **[The End]**

NATIONAL DRUG CODE DIRECTORY ISSUED

A prototype edition of the National Drug Code Directory, which was prepared by the Food and Drug Administration for the Department of Health, Education and Welfare, has been issued by the government. Four thousand prescription and over-the-counter drugs are described by trade name, labeler, strength, product form, and package size. Each product has been assigned a product identification number, but, if they choose, manufacturers and repackagers will be allowed to pick their own numbers. A revised edition of the Directory will be published this summer.

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