VOL. 20, NO. 7 JULY 1965

Food Drug Cosmetic Law JOURNAL

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; 3 years, $49; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

July, 1965
Volume 20 • Number 7

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

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REPORTS

TO THE READER

Charles A. Adams.—With sorrow we report word from Sir Harry Jephcott, in London, that Mr. Charles A. Adams passed away in April 1965. Mr. Adams, former Director of the Food Standards and Labelling Division, United Kingdom Ministry of Food, was for many years a member of the Editorial Advisory Board of this journal. As recently as August 1964 we carried in our issue of that date a fine article by Mr. Adams on the British Food Advertising Law. We shall miss his counsel and encouragement.

Products Liability—The Ethical Drug Manufacturer's Liability.—Part I of this article by *Paul D. Rheingold,* a member of the District of Columbia and Massachusetts Bars, appeared in the June issue of this journal. In this issue the article is concluded with discussions, starting on page 372, on "Injury Caused by Established Drugs," and "Injury Caused by a Drug in the Experimental Stage."

In discussing cases involving established drugs, Mr. Rheingold states that the majority of the decided ethical drug cases has arisen from harm caused by impure drugs. Impurities encountered have included impure, foreign substances in medicine; wrong ingredients; omissions of intended ingredients; improper preparation; incorrect labeling, etc. Mr. Rheingold states that the legal issues are comparatively simple where impurities are involved, and he illustrates this point with examples of actions in negligence, warranty, and misrepresentation.

When pure drugs are involved the issues become more complicated, and usually involve the drug house's duty to warn; the elements of an adequate warning; the company's duty to know the nature and effects of its product; and the manufacturer's duty to test in order to know when to warn.

Injury caused by drugs still in the experimental stage leads to a very different situation. While there were no decided cases in this area either against manufacturers or doctor-administrators of investigational drugs, Mr. Rheingold discusses possible future litigation.

Scientific Research in the FDA.—In the article beginning on page 427, *William H. Summerson,* Director of the Bureau of Scientific Research, FDA, discusses the drug research program in that agency. He notes that FDA research objectives are associated with some specific aspect of either the safety or integrity of a drug or therapeutic device.

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Food·Drug·Cosmetic Law Journal

Products Liability— The Ethical Drug Manufacturer's Liability

By PAUL D. RHEINGOLD

This Article Is Reprinted from the Rutgers Law Review (Vol. 18, No. 4, Summer 1964) with the Permission of Rutgers—The State University (New Jersey) and of the Author. The First Part of This Article Was Reprinted in the June Issue. Mr. Rheingold Is a Member of the District of Columbia and Massachusetts Bars.

II. Injury Caused by Established Drugs

THE DIVISION OF THE FOLLOWING MATERIAL on the topic of injury arising from the use of established drugs—those already on the market with Food and Drug Administration (FDA) clearance—is primarily that between pure and impure products. In addition, liability for injuries arising from the use of established drugs which are *inefficacious* is considered. Impure drugs are those sold other than as the manufacturer intended, and containing deleterious impurities. Pure drugs, on the other hand, are those sold as the manufacturer intended, but with the harm arising as a side effect because of some inherent quality or, perhaps, because of some constitutional peculiarity on the part of the user. In a general way this division of the drug cases into those based on constructional flaws and those based on design fault is the same division which is commonly made in other areas of products liability law.[131]

[131] See on this distinction 2 Harper & James, *Torts* 1540 (1956) [hereinafter cited as Harper & James]. On design fault see 1 Frumer § 7; Noel, "Manufacturer's Negligence of Design or Directions for Use of a Product," 71 *Yale L.J.* 816 (1962); Rheingold, "Liability for Defective Design," 6 *The Plaintiff's Advocate* 59 (1962).

A. Impure Drugs

A majority of the decided ethical drug cases has arisen from harm caused by impure drugs rather than pure ones. Examples of the types of impurities encountered include the following:

(a) Impure, foreign substances in medicine, such as bacteria, and spoiled medicine;[132]

(b) Wrong ingredients substituted for intended ones, or proper ingredients omitted;[133]

(c) Improperly prepared drugs;[134]

(d) Product labeled improperly or containing incorrect directions, dosages, or the like.[135]

In comparison to the pure drug cases, the legal issues here are relatively simple and to a large extent settled, whether the action be in negligence, warranty, or misrepresentation.

1. *Negligence Action*

The standard of care with which the manufacturer of ethical drugs must comply has sometimes been stated as the ordinary one to which all manufacturers must adhere.[136] On other occasions, it has

[132] *Merck & Co. v. Kidd,* 242 F. 2d 592 (6th Cir.), *cert. denied,* 355 U. S. 814 (1957) (hepatitis in blood plasma; further discussed at footnote 295); *Abbott Labs. v. Lapp,* 78 F. 2d 170 (7th Cir. 1935) (serum contaminated with streptococci and staphylococci bacteria; further discussed at footnote 347); *Russo v. Merck & Co.,* 138 F. Supp. 147 (D. R. I. 1956) impurity in blood plasma; further discussed at footnote 208); *Mochlenbrock v. Parke, Davis & Co.,* 141 Minn. 154, 169 N. W. 541 (1918) (impurity in ether; further discussed at footnote 263); *Krom v. Sharp & Dohme, Inc.,* 7 App. Div. 2d 761, 180 N. Y. S. 2d 99 (1958) (hepatitis in blood plasma; further discussed at footnote 176); *Baudenbach v. Schwerdtfeger,* 224 App. Div. 314, 230 N. Y. Supp. 640 (1928), *appeal dismissed, Baudenbach v. Schlesinger,* 250 N. Y. 555, 166 N. E. 322 (1928) (vaccine ampule contained abscess-producing bacteria); *Larimore v. Brown,* 40 Ohio L. Abs. 385, 57 N. E. 2d 313 (1943) (acne vaccine unsterile due to presence of bacillus subtilis); *Henderson v. National Drug Co.,* 343 Pa. 601, 23 A. 2d 743 (1942) (irritant in liver extract; further discussed at footnote 160); *Sandel v. State,* 115 S. C. 168, 104 S. E. 567 (1920) (typhoid vaccine contaminated in manufacturing process causing protein poisoning).

[133] *Hruska v. Parke, Davis & Co.,* 6 F. 2d 536 (8th Cir. 1925) (base composed of mineral oil rather than animal or vegetable oil); *Randall v. Goodrich-Gamble Co.,* 244 Minn. 401, 70 N. W. 2d 261 (1955) (liniment deviated from master formula; further mentioned at footnote 140); *Thomas v. Winchester,* 6 N. Y. 397 (1852) (belladona in place of extract of dandelion).

[134] *Gottsdanker v. Cutter Labs.,* 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960) (live polio virus in vaccine).

[135] *David v. McKesson & Robbins, Inc.,* 253 App. Div. 728, 300 N. Y. Supp. 635, *aff'd,* 278 N. Y. 622, 16 N. E. 2d 127 (1938) (sodium fluoride in box labeled sodium bicarbonate).

[136] See, for example, *Mochlenbrock v. Parke, Davis & Co.,* 141 Minn. 154, 169 N. W. 541 (1918); *Thomas v. Winchester,* 6 N. Y. 397 (1852).

been said to be a specially high standard based upon the peculiar nature of drugs—life-saving when pure, life-threatening when impure.[137] Litigants harmed by impurities in ethical drugs have generally prevailed on one of two specific applications of the general standard of care, the duty to warn and the duty to inspect and test, responsibilities common to all product cases.

The duty to inspect and test the final product—that is, the duty to avoid negligent construction[138]—may be said to impose upon an ethical drug producer the duty to use quality control methods and other modern procedures to insure the purity of the drugs being produced. Thus, failure to exercise continuing supervision of production as well as final product inspection, if only by sampling, would constitute evidence of negligence.[139] A case in point, although involving a proprietary drug, is *Randall v. Goodrich-Gamble Co.*,[140] where the user of a liniment allegedly suffered a burn from the liniment. The manufacturer defended on the ground that his product was pure because: (a) the chemicals which were combined to make the liniment had been purchased from reputable sources and met United States Pharmacopoeia (USP) or National Formulary Compendium (NFC) requirements;[141] (b) compounding of the chemicals was performed under the supervision of a chemist; and (c) two other employees double-checked all the ingredients as to quality and weight. Plaintiff, on the other hand, produced proof that the individual ingredients had never been examined or tested and that the final product was never compared with the master formula from which defendant purported to work and from which plaintiff alleged it differed substantially. Judgment entered on a jury verdict for the manufacturer was affirmed on appeal when the higher court found that the evidence was in genuine conflict.

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[137] *Henderson v. National Drug Co.*, 343 Pa. 601, 23 A. 2d 743 (1942); *Peters v. Johnson*, 50 W. Va. 644, 41 S. E. 190 (1902) (dictum); see also 1 Hursh § 2:13.

[138] See generally 1 Frumer § 6; 1 Hursh §§ 2:16–26; *accord*, cases involving druggists, gathered in Annot., 79 A. L. R. 2d 301, 320 (1961). On the duty to test in the sense of investigating basic qualities of drugs, rather than examination of assembly line products for individual flaws, see text beginning at footnote 289.

[139] *Accord, Ford Motor Co. v. Zahn*, 265 F. 2d 729 (8th Cir. 1959) (failure to sample finished product to detect defective ashtray in new automobile). On the drug manufacturers' practices in control of assembly line quality, see footnote 102.

[140] 244 Minn. 401, 70 N. W. 2d 261 (1955). The pleadings in this case are set out in 8 Negl. & Comp. Cases Annot. 3d 87 (1957).

[141] On the compendia see footnote 81 in Part I.

While failure to warn is the most commonly alleged deviation from the standard of care in products cases,[142] such a duty has had only minor application in impure drug cases. This situation results from the fact that in impurity cases the failure occurs in *manufacture,* whereas the duty to warn typically arises when the product is technically pure but is capable of being used in a dangerous manner unless cautionary statements are made. Nevertheless, in a number of cases where the impurity was one that was well-known and appeared frequently, the courts have had occasion to discuss the duty to warn. In *Parker v. State,*[143] for example, involving pooled plasma which contained homologous serum hepatitis, the court stated that since the medical profession knew of the possibility of this sort of contamination in blood, there would be no duty to warn. On the other hand, in *Abbott Laboratories v. Lapp,*[144] where Lactigan, a sterilized skim milk product, was occasionally susceptible to contamination by bacteria (due to the fault of no one, apparently), negligence was found in a failure to warn that the drug might become impure and that such defect could be determined from its turning cloudy. Said the court, "Sometimes it is well to have our attention called to things we know best."[145]

Other drug cases involving allegations of negligence have, of course, gone to the jury without citation and proof of any specific act or omission of fault on the basis of inferences drawn from circumstantial evidence or created by the application of *res ipsa loquitur. Res ispa loquitur* is particularly applicable to impure drug cases since its usual requirements are easily met: control by the manufacturer at the time of production, superior knowledge of the manufacturer, and harm which would not normally be associated with taking the drug but for the fault of someone, probably the defendant. Some druggist

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[142] See extended discussion in text beginning at footnote 263.

[143] 201 Misc. 416, 105 N. Y. S. 2d 735 (Ct. Cl. 1951), *aff'd,* 280 App. Div. 157, 112 N. Y. S. 2d 695 (1952). The court also holds that the state, which received the serum from the Red Cross and passed it on to various hospitals, was really only a distributor and not a manufacturer with a result that, as declared, it was under no duty to warn but only to avoid mislabeling. The appellate court added that the defendant "has a right to expect that the profession would use an agency of limited medical usefulness under limited conditions." 280 App. Div. at 160, 112 N. Y. S. 2d at 698. Following *Parker* was *Hidy v. State,* 207 Misc. 207, 137 N. Y. S. 2d 334 (Ct. Cl. 1955), *aff'd without opinion,* 2 App. Div. 2d 644, 151 N. Y. S. 2d 621 (1956), *aff'd without opinion,* 3 N. Y. 2d 756, 163 N. Y. S. 2d 985, 143 N. E. 2d 528 (1957).

[144] 78 F. 2d 170 (7th Cir. 1935).

[145] *Id.* at 176.

cases have involved the successful use of the doctrine,[146] although in several ethical drug manufacturer cases it has been rejected on the facts of the cases.[147] In addition, negligence per se, or at least evidence of the fault, can be made out by violation of the Drug Act, of FDA regulations, or of the various state laws.[148]

In conclusion, if it can be shown that there was an impurity or a potential for impurity in a drug at the time it left the factory, or that its contents or use differed from that on the label or box, a litigant should not have much difficulty in proving a deviation from the standard of care to which the drug manufacturer is held.[149]

2. *Warranty Action*

An action for breach of an express or implied warranty made for an ethical drug represents some of the most interesting problems in product litigation today. These include whether a warranty is broken where the product is commercially salable but causes harm because of inherent side effects,[150] whether there can be a breach if the manufacturer did not know of the defect and used all modern scientific skill at his disposal,[151] whether contributory negligence is a defense,[152] and the extent to which a disclaimer will serve as a shield to an implied warranty action.[153] This section considers the basic elements of warranty actions in any type of ethical drug suit, with emphasis on the case of the impure drug. For purposes of this paper the privity question is considered settled. While some defense of privity may yet be anticipated,[154] the trend of the modern cases and

[146] See, for example, *Tucker v. Graves,* 17 Ala. App. 602, 88 So. 40 (1920). See generally Annot., 79 A. L. R. 2d 301, 329 (1961).

[147] *Webb v. Sandoz Chem. Works,* 85 Ga. App. 405, 69 S. E. 2d 689 (1952); *Mogansen v. Hicks,* 253 Iowa 139, 110 N. W. 2d 563 (1961) (injuries due to an allergic reaction); *Henderson v. National Drug Co.,* 343 Pa. 601, 23 A. 2d 743 (1942); *Tuscany v. United States Standard Prods. Co.,* 243 S. W. 2d 207 (Tex. Civ. App. 1951).

[148] See cases cited at footnote 281. Two sections of the Drug Act which when violated might readily give rise to civil liability are discussed in footnotes 88 and 89 in Part I.

[149] Nothing is said herein of the privity requirement because it is not required in negligence today and even where the halfstep requirement of "imminent" danger lingers on, this condition is easily met with drugs. See generally 1 Frumer § 5; 1 Hursh § 6.

Other matters pertinent to defense of negligence actions involving an impure drug, covered below, are contributory negligence, text beginning with footnote 252; assumption of risk, footnote 230; and intervening acts of the doctor, text beginning at footnote 231.

[150] See text beginning at footnote 210.

[151] See text beginning at footnote 299.

[152] See text beginning at footnote 213.

[153] See text beginning at footnote 182.

[154] See, for example, Freedman, "The 3-Pronged Sword of Damocles: Cutter, Henningsen, and Greenberg," *Defense Research Institute Monograph* (undated).

the view of every impartial commentator is that the privity requirement is an anachronism. If it is not to be dispensed with for all products, the reasoning of food cases should at least be extended to reach all products which come into intimate contact with the body.[155]

The leading impure drug case in the warranty area is *Gottsdanker v. Cutter Laboratories,*[156] the Salk vaccine case which dispensed with privity and sales requirements and found breach of implied warranties of fitness, merchantability, and general wholesomeness.

a. Necessity of a sale

The patient who has been harmed by a drug often may have received the drug other than by a sale. He may, for example, have received a sample from a physician, have been administered the drug in a hospital without a direct charge, or have received the drug during a free public vaccination program. This raises the question of whether the fortuitous mode of receipt of a drug should determine whether a warranty exists. Much law can be cited for the proposition that a technical sale is not required in a tort suit for personal injury arising out of a broken warranty.[157] In the *Cutter* case, the court, assuming *arguendo* that there was no sale of vaccine by the doctor who administered the inoculation to the children, held that where the consumer is the plaintiff, there is no need for him to be a purchaser. The initial sale to the distributor or retailer of pharmaceuticals is sufficient to create the implied warranties breached in that case when the ultimate consumer was harmed. The manufacturer knows and intends that his product will go to a patient by some channel, and from the start looks beyond the immediate sale to the ultimate consumer.

Another question raised is whether the administration of a drug under certain conditions, such as in a hospital or in a public health campaign, should be considered a "service" rather than a sale in the sense that this term has been used in the recent blood transfusion

[155] See Dickerson, *Products Liability and the Food Consumer* (1951); 1 Frumer § 16.03–.04; Prosser, "The Assault upon the Citadel (Strict Liability to the Consumer)," 69 *Yale L. J.* 1099 (1960).

Among the drug cases rejecting privity are *Magee v. Wyeth Labs., Inc.,* 214 Cal. App. 2d 361, 29 Cal. Rptr. 322 (1963); *Gottsdanker v. Cutter Labs.,* 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960). *Contra, Russo v. Merck & Co.,* 138 F. Supp. 147 (D. R. I. 1956); *Dumbrow v. Ettinger,* 44 F. Supp. 763 (E. D. N. Y. (1942); *Krom v. Sharp & Dohme, Inc.,* 7 App. Div. 2d 761, 180 N. Y. S. 2d 99 (1958); *Wecksler v. Hoffman-LaRoche, Inc.,* 198 Misc. 540, 99 N. Y. S. 2d 588 (Sup. Ct. 1950). *Cf. Kaspirowitz v. Schering Corp.,* 70 N. J. Super. 397, 175 A. 2d 658 (App. Div. 1961).

[156] 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).

[157] 1 Frumer § 19.02; Prosser, *Torts* § 83, at 493–96 (2d ed. 1955).

decisions in which courts have refused to find a breach of warranty.[158] These cases have uniformly held that where a hospital administers impure blood it renders only a service and does not make a sale. Thus, the courts have refused to find a breach of warranty.[159] Seemingly, however, these cases can be distinguished from suits against drug manufacturers for impure products on the ground that suit is against the source of the product, the maunfacturer, rather than against a mere conduit for the product, the hospital, which merely applied another's product. In the *Cutter* case, the court expressly rejected the manufacturer's argument, based on the bad blood cases, that the administration of the vaccine had been but a "service."[160] The rationale of the blood transfusion cases, while providing solicitude for charitable, non-profit hospitals, apparently does not similarly apply to manufacturers.[161] While it might also be argued that the hospital or other party administering an impure drug could be considered an agent of the patient, thus eliminating the hospital as an independent factor,[162] the recent case of *Krom v. Sharp & Dohme, Inc.*,[163] has specifically refused to recognize such a relationship.

b. Express warranty action

The personal injury action based upon express warranty has seen extended use in the past few years, grounded on manufacturer repre-

[158] See generally 1 Frumer § 19.02; *accord,* the restaurateur cases which create liability in warranty where food may be more accurately described as served than sold, discussed in 1 Frumer § 24.01; 1 Hursh § 3.32–.33.

[159] *Perlmutter v. Beth David Hosp.*, 308 N. Y. 100, 123 N. E. 2d 792 (1954); *Dibblee v. Dr. W. H. Groves Latter-Day Saints Hosp.*, 12 Utah 2d 241, 364 P. 2d 1085 (1961); *Gile v. Kennewick Public Hosp. Dist.*, 48 Wash. 2d 774, 296 P. 2d 662 (1956).

[160] 182 Cal. App. 2d at 609–12, 6 Cal. Rptr. at 323–26 (1960). Note that also in *Cutter,* at 611–12, 6 Cal. Rptr. at 325–26, the defendant sought to bring the facts of the case within a California statute that made distribution of certain biological substances a service and not a sale expressly to defeat warranty purposes. The legislature had apparently intended a statutory enactment of the *Perlmutter* rule. The court, however, found that the polio vaccine was not within the definition or the intent of the statute.

[161] Critical of the line of transfusion cases are 1 Frumer § 19.02(3), at 502; Farnsworth, "Implied Warranties of Qualities in Non-Sales Cases," 57 *Colum. L. Rev.* 653 (1957); "Comment," 33 *Miss. L. J.* 253 (1962). Frumer states: "But fault is *not* a prerequisite to recovery in warranty. And, any burden on the hospital (which does not outweigh the burden on the injured patient) could be shifted to the manufacturer or the hospital's supplier." 1 Frumer § 19.02(3), at 502. See also *Napoli v. St. Peter's Hosp.*, 213 N. Y. S. 2d 6 (Sup. Ct. 1961) (*Perlmutter* rule does not apply where claim rests on breach of an express warranty, a fine distinction).

[162] See footnote 168.

[163] 7 App. Div. 2d 761, 180 N. Y. S. 2d 99 (1958). This case is criticized in 1 Frumer § 19.02, at 497 n.2.

sentations or affirmations of fact in advertising and other written material.[164] There is a wealth of advertising, labeling, and brochure-issuing emanating from the pharmaceutical trade today. This material characteristically extols in positive and reassuring statements the quality, safety, harmlessness, and non-toxicity of the drug in question.[165] What is peculiar about a drug product is that while the product is intended for the patient-consumer, the pitch is rarely if ever made to him, but rather is directed toward the doctor in order to influence him to prescribe one brand or class of medicine over another.[166]

Assuming, as is fair,[167] that there can be liability for breach of express warranty if false assurances of safety are made directly to the patient, can warranty liability still be created on the basis of misstatements made to the doctor-prescriber? Certainly the motive in this form of advertising—that of creating reliance in order to foster sales and ultimate consumption—is the same. It might be argued along these lines that the doctor is the agent for the patient in receiving these warranty-creating statements, even if it is an agency relationship only in a limited sense.[168] Commentators agree that the representation relied upon need not be made directly to the party who

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[164] See generally 1 Frumer § 16.04[4]; 2 Hursh § 7; Lambert, "Comment," 29 *NACCA L. J.* 33–45 (1963). The primary interest in these recent cases is the demise of privity, not what statements will create an express warranty. As the former problem diminishes, however, the latter can be expected to become more central and crucial.

[165] See text beginning at footnote 112 (20 FOOD DRUG COSMETIC LAW JOURNAL 351).

[166] See text beginning at footnote 106 (20 FOOD DRUG COSMETIC LAW JOURNAL 349).

[167] See *Wennerholm v. Stanford Univ. School of Medicine*, 20 Cal. 2d 713, 128 P. 2d 522 (1942), one of the few cases in which statements were made directly to the patient; further discussed at footnote 195.

[168] It is likely that a court would find an agency for the special purpose of acting for the patient to receive statements from the manufacturer. A number of cases have considered the agency point and have reached contradictory results based upon differing issues. Finding the existence of an agency is *Wechsler v. Hoffman-La Roche, Inc.*, 198 Misc. 540, 99 N. Y. S. 2d 588 (Sup. Ct. 1950) (further discussed in text at footnote 194). Denying the existence of such are *Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154, 169 N. W. 541 (1918) (on issue of malpractice); *Krom v. Sharp & Dohme, Inc.*, 7 App. Div. 2d 761, 180 N. Y. S. 2d 99 (1958); and *Marcus v. Specific Pharmaceuticals, Inc.*, 191 Misc. 285, 77 N. Y. S. 2d 508 (Sup. Ct. 1948).

Alternatively, it could be said that the doctor is the agent of the manufacturer in making express warranties, as was the position taken in *Brown v. Globe Labs., Inc.*, 165 Neb. 138, 84 N. W. 2d 151 (1957). On reliance as a requirement in warranty actions, see footnotes 178, 179. Note that reliance in the typical sales sense could be predicated upon the patient's reliance on a pharmacist if he buys the medicine at a drugstore; but admittedly, this is not reliance on a direct representation by the drug house.

is injured and suing.[169] This has been the holding in a few product cases,[170] although a recent ethical drug case, *Kasperowitz v. Schering Corp.*,[171] appears not to concur.

Whatever form the express warranty action finally takes, it is probable that the courts will continue to require that there be an affirmation of fact tending to induce sales, with reliance on these statements by the doctor presumed or proven.[172] Satisfaction of these requirements ought to be relatively simple in a drug case since, first, drug advertisement statements are generally factual rather than set in a tone which can be characterized as mere "sales talk" or "puffing"; second, the purpose of the statements is invariably to enhance sales; and, third, doctors *do* rely on such statements. Nor does it make a difference that the manufacturer did not know when he made his statement that he was in error or that there was negligence involved in making his statements.[173]

c. Implied warranty—merchantability, fitness and safeness

In *Cutter,* the jury found in special interrogatories that there had been a breach of the traditional implied warranties of merchantability and fitness for particular use since the vaccine contained live polio virus. On appeal, the court affirmed this finding and added that there was also a breach of implied warranty of wholesomeness.[174] In a number of other cases, allegation of breach of implied warranty has

[169] 1 Frumer § 16.04[4], at 440-41; 2 Harper & James § 28.7, 1548; *Restatement (Second), Torts* § 402A, comment *j* (Tent. Draft No. 6, 1962) ("The reliance need not necessarily be that of the consumer who is injured."); Dickerson, "Recent Developments in Food Products Liability," 8 *Prac. Law,* April, 1962, pp. 17, 31.

[170] *Mannsz v. Macwhyte Co.,* 155 F. 2d 445 (3d Cir. 1946); *La Plante v. E. I. Du Pont de Nemours & Co.,* 346 S. W. 2d 231 (Mo. App. 1961).

In the *Cutter* cases the children who received the vaccine could not have relied on any statements of the manufacturer. In *Carmen v. Eli Lilly & Co.,* 109 Ind. App. 76, 32 N. E. 2d 729 (1941), plaintiff alleged that the doctor relied upon the manufacturer's brochure and that the patient relied on the doctor. See also *Marcus v. Specific Pharmaceuticals, Inc.,* 82 N. Y. S. 2d 194 (Sup. Ct. 1948), discussed in footnote 226.

[171] 70 N. J. Super. 397, 175 A. 2d 658 (App. Div. 1961) (discussed further in footnote 257). See also the opinion in the first appeal of *Randall v. Goodrich-Gamble Co.,* 238 Minn. 10, 54 N. W. 2d 769 (1952), wherein neither the husband-purchaser nor the wife-consumer relied on the manufacturer's statements and it was held that no breach of express warranty therefore existed.

[172] See Prosser, *Torts* § 83, at 493-96 (2d ed. 1955); Keeton, "Products Liability—Current Developments," 40 *Texas L. Rev.* 193, 204-05 (1961).

[173] Keeton, see footnote 172. The similarity here of an express warranty suit to one based on fraud or deceit, as considered below, should be noted; it is likely that the law is working toward a merger of these two theories.

[174] 182 Cal. App. 2d at 612, 6 Cal. Rptr. at 326.

been an important part of the suit.[175] While the specific type of warranty created by law will usually not be significant in a suit, it is perhaps worthwhile to give short consideration to the applicability of the two traditional warranties and the newer combination ones.

The *merchantability* concept—that the product is reasonably suited to the ordinary purposes for which it is sold—fairly well covers the type of expectancy and failure which is involved in drug cases, especially where the drug is impure.[176] The warranty of *special fitness* for purpose, although found to be violated in *Cutter,* is somewhat more difficult to apply to the ordinary drug case.[177] As to the specific elements of this type of warranty action, sales law doctrine holds that reliance on the skill and judgment of the seller is required.[178] However, it is by no means clear that any reliance is required for a personal injury warranty action, or, if so, that the doctor's reliance will not suffice.[179]

Use of some general implied warranty would simplify the issues by avoiding the minor technical requirements which have grown out of a Uniform Sales Act approach to warranty. In food cases this general warranty is the well-known, well-accepted one of wholesomeness.[180] The *Cutter* case carried this concept over into the drug area, on the analogy of drugs to food, both being intimate and internal-use products. A more apt term where a breach caused by a drug is involved might be "safety" or "harmlessness," terms which it can be predicted will be encountered in future cases.[181]

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[175] This has been true in cases involving Chloromycetin, Aralen, Altafur, and MER/29.

[176] See 1 Frumer § 19.03. As to breach of implied warranty where the product is technically pure and merchantable, see text beginning at footnote 210.

[177] See 1 Frumer § 19.03. See also generally, Jaeger, "Warranties of Merchantability and Fitness for Use: Recent Developments," 16 *Rutgers L. Rev.* 493 (1962).

[178] See 1 Frumer § 19.03(4), at 518–20; *Magee v. Wyeth Labs., Inc.,* 214 Cal. App. 2d 361, 29 Cal. Rptr. 322 (1963) (further discussed at footnote 243). Reliance is pleaded in virtually every warranty drug action, either on the part of the doctor or the part of the patient.

As to the additional requirement that there be a sale "by description," see 1 Frumer § 19.03.

[179] See footnote 178. On the role of the doctor as agent, see footnote 168. Frequently no reliance is required where a warranty of merchantability is involved.

The argument that the drug cannot be deemed unfit where it has induced an allergic reaction is more applicable where the drug is pure than where it is impure. See Keeton, footnote 172, at 207–210; general discussion beginning in text at footnote 316.

[180] See 1 Hursh § 3:20 (citing cases from 28 jurisdictions).

[181] To this warranty of "safeness" would have to be added a warranty of "efficacy," considered below in section II (C). Once this form of liability is imposed, however, the plaintiff has problems of proving "defective condition" and "unreasonable danger," as is discussed in text beginning at footnote 310.

d. Effect of disclaimers

As liability under implied and express warranty increases, the issue of disclaimer of warranties can be expected to increase. It is well-acknowledged today that a manufacturer can limit warranty liability by the use of express disclaimer clauses.[182] While there is little problem in recognizing a disclaimer when it is written in express and clear terms, that traditional type of disclaimer is not encountered in ethical drug cases.[183] The topical issues in this area deal with the interpretation of the ambiguous language, common in drug literature today, which, after the injury, can be claimed by the manufacturer to have been a disclaimer of warranty liability.[184] Examples of such ambiguous language might include:

(a) reactions to drug have been minimal;

(b) while no toxic reactions have yet been experienced it should be kept in mind that reactions could occur;

(c) as this drug is a steroid, ophthalmic damage, while not reported, is conceivable and hence periodic eye tests should be employed by the treating physician;

(d) drug has been good in treating psoriasis (asserted as a disclaimer that drug is safe for any other condition).

It is not likely, however, that any of these examples would be construed as effective disclaimers. The courts have generally refused to treat such ambiguous language as the basis of a disclaimer in the case of other types of products.[185] Following this lead, the *Cutter* case

[182] 1 Frumer § 16.04[2][e]; 2 Harper & James § 28.25; 1 Hursh § 3:7; *Charles Lomori & Son v. Globe Labs.*, 35 Cal. App. 2d 248, 95 P. 2d 173 (1939) (express warranty action for defective animal medicine effectively disclaimed by statement on label). See generally Comment, "Disclaimers of Warranty in Consumer Sales," 77 *Harv. L. Rev.* 318 (1963).

[183] If such a direct disclaimer were encountered, the type of frontal attack made in *Henningsen v. Bloomfield Motors, Inc.*, 32 N. J. 358, 161 A. 2d 69 (1960), might be expected from a plaintiff. The attack there was a direct public policy argument based upon inequality of bargaining power. While this part of the *Henningsen* approach would lend itself readily to ethical drug litigation, additional justifications of that decision do not, including the offensive type of remedy offered the new car buyer (replacement of parts) which presumably would not be involved in drug sales.

The three manufacturers of Sabin polio vaccine use an express disclaimer in their labeling today. Whether this marks a new trend or is a special situation, only time can tell.

[184] See 1 Frumer § 16:04(2), at 423; 2 Frumer § 33.02, at 245.

[185] See, for example, *Grey v. Hayes-Sammons Chem. Co.*, 310 F. 2d 291 (5th Cir. 1962); *Burr v. Sherwin Williams Co.*, 42 Cal. 2d 682, 268 P. 2d 1041 (1954); *Diamond Alkali Co. v. Godwin*, 100 Ga. App. 799, 112 S. E. 2d 365, *aff'd without opinion*, 215 Ga. 839, 114 S. E. 2d

(Footnote continued on next page.)

explicitly refused to find a disclaimer in statements contained in the manufacturer's directions that the vaccine was "prepared in accordance with the requirements of the National Institutes of Health of the United States Public Health Service" or that "local and other untoward reactions have been minimal using this material."[186] These did not, in the court's opinion, put the user on notice of the presence of live virus, especially since the directions contained the additional statement that the virus was inactivated.[187] As a separate point, the court also refused to find that an express warranty in the directions had prevented the other warranties from being implied as a matter of law since there was no inconsistency between the two.[188] Three points regarding manufacturers' liability bear rephrasing from *Cutter:* (1) assurances of safety can undo any limitations or conditions imposed;[189] (2) there must be a clear conflict between express statements and implications before the former can undo the latter;[190] and, (3) specific intent is required to dispel implied warranties; it is not enough to point after the fact to ambiguous or vague statements.[191] All of these arguments seem sound, and all seem to be based on the common law's aversion to contractual limitations, especially where they are the fruit of inequality of bargaining power.[192]

(Footnote 185 continued.)
40 (1959); *Jarnot v. Ford Motor Co.,* 191 Pa. Super. 422, 156 A. 2d 568 (1959). *But see Taylor v. Jacobson,* 336 Mass. 709, 147 N. E. 2d 770 (1958) (apparently holding that directions for use constitute a disclaimer).

[186] 182 Cal. App. 2d at 610, 6 Cal. Rptr. at 325.

[187] See footnote 186. Cutter Laboratories did, however, make a clear disclaimer as to efficacy, and the court so found.

[188] See footnote 186.

[189] *Accord, McLaughlin v. Mine Safety Appliances Co.,* 11 N. Y. 2d 62, 226 N. Y. S. 2d 407, 181 N. E. 2d 430 (1962) (heating unit said to be "entirely self-contained" and yet it was dangerous without an additional wrapping). For a further discussion on false assurances see text at footnote 272.

[190] As the court points out, express warranties are a device intended to protect the buyer and not to limit the seller's liability. 182 Cal. App. 2d at 610, 6 Cal. Rptr. at 325. See also *Davies v. Motor Radio Co.,* 236 S. W. 2d 409 (Mo. App. 1951).

[191] Note the interesting views of Boshkoff, "Some Thoughts About Physical Harm, Disclaimers and Warranties," 4 *B. C. Indust. & Com. L. Rev.* 285 (1963), who feels that manufacturers of products such as drugs in which at the time of sale there is no knowledge of any harmful aspects may protect themselves by use of a disclaimer which accurately states that anything can happen with the drug because it is a new product, *id.* at 303. It is hard to see how such a "warning" could act as an effective disclaimer to warranty liability. The author notes, however, that if the action were based upon strict liability, such as in the new *Restatement* provision, at footnote 303, a disclaimer would not be effective.

[192] See HEW Release, Sept. 26, 1961; *Modern Medicine,* Oct. 16, 1961, p. 3.

3. *Misrepresentation, Fraudulent and Negligent*

A products liability action resting upon misrepresentation, whether sounding in deceit (that is, fraud) or negligence, is well-founded, although it has not been as commonly used as warranty or negligence theories.[193] Nevertheless, a good number of the reported ethical drug cases have been brought on this theory.

As to the fraud or deceit action, which requires proof of intent to deceive, *Wechsler v. Hoffman-La Roche Co.*[194] is representative. Plaintiff's decedent, who died from reactions to defendant's drug, type unstated, alleged that fraudulent statements were made by the manufacturer to the prescribing doctor. The court held that the elements of fraud were established as a matter of law where it was a foreseeable consequence of the manufacturer's representations, made for its own economic benefit, that injury would occur.[195] The court also determined that the physician who was deceived was the agent for the deceased, making the defendant's fraud one upon the patient.[196] While the intent requirement will prevent many actions where the maker was merely negligent in not detecting or warning of adverse effects, it should not necessarily be a barrier in a significantly large number of cases where the manufacturer conceals or withholds knowledge of possible harm and fails to warn.

There is little law in any type of suit based on negligent misrepresentation, probably because the action is not allowed in many jurisdictions,[197] but there are indications that it will cover and may indeed be especially appropriate in ethical drug actions. Of interest here is the concurring opinion by the late Judge Herbert Goodrich in *Pritchard v. Liggett & Myers Corp.*[198] Although the majority did not use the term "negligent misrepresentation" and did not appear to rely on the concept in this cigarette-cancer case, Judge Goodrich felt that negligent misrepresentation could have been made out for the sale of a

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[193] See generally on these actions 1 Frumer § 17:01, at 443; 1 Hursh § 4.

[194] 198 Misc. 540, 99 N. Y. S. 2d 588 (Sup. Ct. 1950).

[195] See also *Hruska v. Parke, Davis & Co.*, 6 F. 2d 536 (8th Cir. 1925); *Wennerholm v. Stanford Univ. School of Medicine*, 20 Cal. 2d 713, 128 P. 2d 522 (1942) (blindness was alleged as a consequence of taking dinitrophenol manufactured by defendant who had publicized the product widely as being harmless; the user alleged that the manufacturer knew it was not harmless but that he relied on its promises; the court found sufficient evidence to make out intent to deceive); *accord, Hoar v. Rasmusen*, 229 Wis. 509, 282 N. W. 652 (1938) (druggist).

[196] 198 Misc. at 542, 99 N. Y. S. 2d at 590.

[197] See generally 1 Hursh § 4:6 to :7.

[198] 295 F. 2d 292, 301 (3d Cir. 1961) (concurring opinion).

product without knowledge of its harmful propensities but about which statements of safety were made.[199] It was this reckless making of an uninvestigated statement that would be actionable. This wrong was neither breach of warranty nor failure to warn or to test (theories used by the majority in *Pritchard*), but rather a third distinct cause somewhat related to both, as Judge Goodrich explained.

An early products liability drug case, *Willson v. Faxon, Williams & Faxon*,[200] is in point. There a druggist sold a laxative about which he knew little, but he nevertheless held himself out as the manufacturer. In its ignorance the drug company marked on the label that the contents were "purely vegetable," while in fact they were not. Liability was predicated upon a sale of a drug without taking steps to ascertain its true nature.[201] Negligent misrepresentation has also been alleged in certain recent drug cases involving reactions from pure drugs; and it is in this area, considered below, that this theory may be of greatest potential significance. The negligent misrepresentation action provides an important remedy to the drug user whose doctor was influenced to prescribe by recklessly-made statements of safety.

B. Pure Drug—Inherent Side Effects

A number of ethical drug cases have involved harm from drugs which were pure in the sense that they contained no contaminants which the manufacturer did not intend to be present.[202] Four basic issues are raised in this section: (1) the drug house's duty to warn; (2) the elements of an adequate warning; (3) the drug house's duty to know the nature and effects of its product; and (4) the manufacturer's duty to test in order to know when to warn. The section concludes with a consideration of miscellaneous problems arising from incorrect or inadequate instructions and countermeasures.

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[199] Judge Goodrich, citing *Restatement, Torts* § 310 (1934), stated: "And when a person makes to another a statement of fact which he does not know to be true, intending that the other shall act in reliance on the truth of that statement, he is liable for negligent misrepresentation." *Pritchard v. Liggett & Myers Tobacco Co.*, at footnote 198, pages 301-02.

[200] 208 N. Y. 108, 101 N. E. 799 (1913). Although the defendant was a druggist, he was held to the standard of a manufacturer because he held himself out to be one.

[201] *Cf. Valmas Drug Co. v. Smoots*, 269 Fed. 356 (6th Cir. 1920).

[202] See, for example, *Valmas Drug Co. v. Smoots*, 269 Fed. 356 (6th Cir. 1920); *Kramer v. Lakeside Labs.*, 200 F. Supp. 530 (E. D. Pa. 1962); *Stottlemire v. Cawood*, 213 F. Supp. 897 (D. D. C. 1963) (further discussed at footnote 224). See also the other cases cited within this subsection.

1. *Full Warning of Side Effects to Medical Profession*

That group of cases where the manufacturer has discovered an adverse effect of his drug and has fully warned the profession of the danger presents the most common context in which actionable harm may arise. It is at once, however, the most difficult situation in which to find liability. The manufacturer has, after all, satisfied his duty to warn. Nevertheless, there are certain arguments which a litigant could make, especially in a warranty action, which must be considered. The patient's knowledge and consent and the intervening fault of the doctor are also relevant factors to be evaluated.[203]

a. Negligence action

In order to assess negligence in the case of adequate warning, it seems necessary to find that notwithstanding having given adequate warning, a drug manufacturer can still be liable because it was negligent to distribute the product at all due to the unreasonable risk of harm, regardless of warning.[204] While it is true that the design liability cases have sometimes predicated liability upon the creation of such an unreasonable risk without regard to warning,[205] it must be granted that the cases which have considered the effect of warning upon design liability generally hold that warning fully satisfies the producer's duties.[206]

There are however, suggestions in cases and in the views of leading commentators on tort law that if a product is created which is inherently dangerous, and it is therefore probable that no amount of warning will prevent it from being used in a dangerous manner by a substantial group of consumers, the manufacturer should be liable for marketing the ill-designed product.[207] It is unlikely that

[203] As to the possibilities of a deceit or misrepresentation action, see text beginning at footnote 193; on the factor of the allergic plaintiff see text beginning at footnote 316.

[204] It is possible, of course, that a plaintiff may be able to prevail in a pure drug case on negligence by finding some basis for fault other than failure to warn, such as failure to comply with statute or regulations.

[205] See citations in footnote 131.

[206] For example, *Foster v. Ford Motor Co.*, 139 Wash. 341, 246 Pac. 945 (1926); *Comstock v. General Motors Corp.*, 358 Mich. 163, 99 N. W. 2d 627 (1959); *Lovejoy v. Minneapolis-Moline Power Implement Co.*, 248 Minn. 319, 79 N. W. 2d 688 (1956).

[207] See the interesting case of *Goldsmith v. Martin Marietta Corp.*, 211 F. Supp. 91 (D. Md. 1962), involving a switch on an aircraft part which had no safety guard and which created a hazard that the defendant claimed was obvious and that the court found the plaintiff could have seen. The court stated, however, by way of dictum, that the defendant could be found to have created an unreasonable risk even though it was known and obvious, and a danger fully appreciated by the plaintiff.

such a rule would be applied to drug cases since even in the cases of the most notorious reaction-causing drugs, only a very small fraction of the population would be affected. Realistically speaking, however, the FDA would not clear such a drug; or, if the untoward effects were first discovered in use, it would order the product removed from the market. This governmental control plus the manufacturer's fear of bankrupting liability in drug cases keep the situation hypothetical.

In harmony with the view that negligence liability will be difficult to establish in the face of adequate warning is *Carmen v. Eli Lilly & Co.*,[208] which involved a wrongful death action based on fatal paralysis contracted from Lilly's rabies vaccine. Lilly had warned in its literature of the risk of paralysis, albeit remote, citing forty cases of paralysis and two death in 100,000 instances of use. The doctor was aware of the risk and had so informed the patient. On appeal, judgment entered on a verdict for the defendant was affirmed because of the lack of proof of manufacturer's fault.[209] An opposite result on these facts would not comport with common sense.

b. Warranty action

At first glance it would seem no easier to maintain a successful breach of implied warranty suit than a negligence action where a pure, commercially perfect product causes harm of which the manufacturer expressly warned. Indeed, two additional hurdles must first be cleared. Whether there can be a breach of warranty when the product is "commercially salable" is a matter of dispute today, full warning notwithstanding.[210] The recent Third Circuit cigarette-cancer case, *Pritchard*

[208] 109 Ind. App. 76, 32 N. E. 2d 729 (1941).

[209] The court in *Carmen* also stated that the decedent had assumed the risk of injury because he had been fully informed. Other pure ethical drug cases brought on a theory of duty to warn include *Kramer v. Lakeside Labs.*, 200 F. Supp. 530 (E. D. Pa. 1962); *Halloran v. Parke, Davis & Co.*, 245 App. Div. 727, 280 N. Y. S. 2d 58 (1935) (successful action for explosion of a drug based upon failure to warn of danger). See also cases cited at footnote 266. Leading proprietary drug cases are *Valmas Drug Co. v. Smoots*, 269 Fed. 356 (6th Cir. 1920) ("Bon-Opto" eyewash; liability); *Martin v. Bengue, Inc.*, 25 N. J. 359, 136 A. 2d 626 (1957) ("Ben-Gay" ointment; liability). See generally, Annot., 79 A. L. R. 2d 301, 315–21 (1961).

[210] See excellent discussion in 1 Frumer § 19.03[2][a] (Supp. 1962). See also Boshkoff, cited at footnote 191, at page 286. In addition to the *Pritchard* case discussed in the text, see also *Magee v. Wyeth Labs., Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963); *Twombley v. Fuller Brush Co.*, 221 Md. 476, 158 A. 2d 110 (1960); *Zampino v. Colgate-Palmolive Co.*, 10 Misc. 2d 686, 173 N. Y. S. 2d 117 (Sup. Ct. 1958), *rev'd*, 8 App. Div. 2d 304, 187 N. Y. S. 2d 25 (1959), *aff'd*, 8 N. Y. 2d 1069, 207 N. Y. S. 2d 284, 170 N. E. 2d 415 (1959). *Contra, Simmons v. Rhodes & Jamieson, Ltd.*, 46 Cal. 2d 190, 293 P. 2d 36 (1956).

v. Liggett & Myers Tobacco Co.,[211] seems to hold that there can be a breach even though every cigarette had the defect and yet would be deemed merchantable by dealers in the product. In that case the court first suggested that a jury could consider the practices of other manufacturers and the quality of their cigarettes, presumably to see if the defendant's product was inferior, which would make out an obvious case of lack of merchantability. But then, the court added, even if the manufacturer conformed to the practices of the trade, the jury could still find a breach of warranty since practices would not be conclusive as to what was proper. From these comments and those in the concurring opinion,[212] it has been taken that *Pritchard* stands for the proposition that a salable cigarette may still breach implied warranty when it causes personal injury due to inherent side effects. To the cigarette user who expected to have a smoke but not to contract a disease, the product did not live up to a warranty of wholesomeness or safety.

The second hurdle for a plaintiff is to convince the court that warning is no defense in an implied warranty suit. This issue has been seldom raised in product cases. Among the decisions in point, including the recent opinion in *Magee v. Wyeth Laboratories, Inc.*,[213] a few have found in the warning a satisfaction of all duties that might arise from the promise of warranties implied by law.[214] Rationalizations which might be employed are (1) that the warning operates as a type of disclaimer or an express warranty which is in effect a disclaimer,[215] or (2) that there is an automatic assumption of risk when the patient uses the drug with full knowledge, defeating any warranty

[211] 295 F. 2d 292 (3d Cir. 1961).

[212] Judge Goodrich refused to follow the court in finding a breach of an implied warranty since he found no claim made by the plaintiff that the cigarettes were not of commercially satisfactory tobacco. Nevertheless he concurred because he believed that liability could be predicated on negligent misrepresentation and breach of express warranty. 295 F. 2d at 301–02.

[213] *Magee v. Wyeth Labs., Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963). The court emphatically held that adequate warning of dangers given to expected users absolved the manufacturer from liability for breach of warranty. See footnote 224. But the court also appears to justify the same conclusion of lack of breach of warranty upon the ground that there was no duty or warranty in the first place since the plaintiff's decedent was an abnormal person who suffered an allergic reaction. See also footnote 243.

[214] See, for example, *Taylor v. Jacobson*, 336 Mass. 709, 147 N. E. 2d 770 (1958); see also *Hamon v. Digliani*, 148 Conn. 710, 174 A. 2d 294 (1961).

[215] The Taylor case, cited at footnote 214, is a clear example of making a disclaimer out of what was originally intended to be a warning. On the value of disclaimers and their ability to weather judicial attack in products liability cases, see text beginning at footnote 182. Also, note views of Boshkoff, cited at footnote 191.

liability.[216] Nevertheless, it is quite possible for a court to choose not to regard a warning as a disclaimer or as a device upon which to predicate assumption of risk as a matter of law. In the usual drug case, the danger is statistically remote. Liability would be in keeping with the social policy underlying the creation of a warranty—that is, the promise of the supplier to stand behind his goods if they prove to be unfit.[217] If the argument were to be accepted that adequacy of warning is a negligence theory concept having no role in warranty actions, then even though a full warning would negate negligence on the part of the manufacturer, warranty liability would still be open. At such a point it might be more accurate to speak in terms of strict or absolute liability.[218]

Factor: duty to warn patient. Could an argument be made, on behalf of the patient who otherwise cannot prevail, that the manufacturer has a duty to warn the patient directly of side effects? That is, can there be negligent failure to warn when the patient is not informed of the risks he is running in taking the drug? In the usual situation in which an ethical drug is prescribed, the patient does not receive from his doctor any warning of side effects or information on contraindications which the manufacturer has made; often indeed the patient does not even know what drug is being prescribed.[219] Nor is the patient likely to obtain information about the side effects of drugs from sources other than statements from his treating physician.[220]

As a general proposition in products liability law there is a duty to warn the intended or foreseeable consumer of a product about its

[216] In posing this defense it must be shown that the true risk was appreciated and had been brought home to the consumer by the doctor or the manufacturer. See footnote 230.

[217] See 2 Frumer § 33.01[2], at 124–25.

[218] As to policy issues involved in creating any sort of strict liability here, see general discussion in Part IV.

[219] On the medical practice in warning of side effects, see discussion beginning in text at footnote 119. There is, to be sure, a contemporary duty upon the doctor to inform the patient of what treatment he is performing, including what medicine he is administering, and to obtain his informed consent thereto. See Hirsch, "Informed Consent to Treatment," 176 *J. A. M. A.* 436 (1961); Lambert, "Comment on Recent Important Personal Injury (Tort) Cases," 26–27 *NACCA L. J.* 137–142 (1961); 75 *Harv. L. Rev.* 1445 (1962). The problem of lack of information nonetheless exists, however, because this rule is honored in the breach, both out of carelessness and out of considered medical judgment that a patient can make no good use of information on possible adverse effects of drugs.

[220] The common practice is for the druggist to repack the medicine in his own bottle or to cover over the existing label with his own or to rip off that part of the label which contains the warning along perforated lines handily provided by the manufacturer. See footnote 118 (20 FOOD DRUG COSMETIC LAW JOURNAL 352).

dangerous aspects.[221] This duty exists even where there is an intermediary in the chain of distribution who takes some control over the product and who may himself be negligent.[222] An important and sound exception to the requirement that warning be made to the consumer, however, is made in products cases in which the intermediary is not a mere conduit of the product but rather administers it on an individual basis, or recommends it in some way, implying an independent duty to evaluate the risks and transmit relevant warnings to the user.[223] The ethical drug cases, involving as they always do the epitome of such an intermediary, who exercises independent discretion and judgment, would seem to fit more closely within the exception than the rule.

A recent federal case is one of the few ethical drug decisions to consider the duty to warn the public. In *Stottlemire v. Cawood,*[224] involving death from aplastic anemia attributed to Chloromycetin, the representatives of the deceased child, while all but conceding that an adequate warning had been given to the prescribing doctor, alleged that the manufacturer had been negligent in not warning the public of the drug's dangerous characteristics. The court held, however, that "there was no reason why there should be a warning . . . given to

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[221] See 1 Frumer § 8; 2 Harper & James § 22.14, 1255–57; 1 Hursh § 2:28.

[222] See, for example, *Alexander v. Nash-Kelvinator Corp.,* 261 F. 2d 187 (2d Cir. 1958) (dealer failed to inspect automobile); *United States v. Lobb,* 192 F. Supp. 461 (D. Ky. 1961) (manufacturer told dealer of defect in design of brake system but dealer sold car without passing on information to buyer); *Schilling v. Roux Distrib. Co.,* 240 Minn. 71, 59 N. W. 2d 907 (1953) (manufacturer liable for harm from hair dye even though beautician failed to make required patch test); *Gwyn v. Lucky City Motors, Inc.,* 252 N. C. 123, 113 S. E. 2d 302 (1960) (dealer discovered brakes of truck were defective but sold it anyway).

The reasoning in cases of this type often is that it is foreseeable to the maker that the intermediary will fail to discover and correct a defect or to pass on a warning as to its nature.

[223] See, for example, *Holmes v. Ashford,* [1950] 2 All E. R. 76 (C. A.); *Kapp v. E. I. Du Pont de Nemours & Co.,* 57 F. Supp. 32 (D. Mich. 1944); *Willey v. Fryogas Co.,* 363 Mo. 406, 251 S. W. 2d 635 (1952); *Stout v. Madden,* 208 Ore. 294, 300 P. 2d 461 (1956). See 1 Frumer § 11.04; see also 1 Hursh § 2:34.

[224] 213 F. Supp. 897 (D. D. C. 1963). Plaintiff also sued the prescribing doctor but lost since there was no evidence of lack of skill and because the incidence of reaction was so rare (one in 800,000). The view in *Stottlemire* has subsequently been followed in *Magee v. Wyeth Labs., Inc.,* 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963), where the court held that there was no obligation to warn the patient and that reasonable warning to the doctor sufficed. The court relied upon the *Holmes* case, cited at footnote 223, for the proposition that there is only a duty to warn immediate vendees.

the general public."[225] In *Marcus v. Specific Pharmaceuticals, Inc.*,[226] the New York Supreme Court referred to a "duty to apprise the purchasing public of the safe means of use" of the drug, but this was said apparently in regard to a set of facts in which there was no allegation that a prescription drug was involved. In a prior opinion involving an allegation of a prescription drug, however, the court seemed to indicate that there was no duty to warn the public so long as the manufacturer had given adequate warning to the medical profession.[227]

Arguments which can be advanced in support of the view that there is no duty to warn the ultimate consumer are as follows: (1) the doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life.[228] (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.[229] It should also be noted that whether or not the patient received a warning intentionally communicated to him by a manufacturer, if the patient

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[225] A directed verdict was entered for Parke-Davis. The court stated that had the drug been of the over-the-counter type the result would have differed. For the proposition cited in the text the court cited *Parker v. State*, 201 Misc. 416, 105 N. Y. S. 2d 735 (Ct. Cl. 1951), *aff'd*, 280 App. Div. 157, 112 N. Y. S. 2d 695 (1952), discussed at footnote 143. That case holds, however, that where the dangers of a drug are well-known in the medical profession there is no reason to place warnings on labels, whereas for over-the-counter drugs there might be such a duty.

[226] 82 N. Y. S. 2d 194 (Sup. Ct. 1948).

[227] *Marcus v. Specific Pharmaceuticals, Inc.*, 191 Misc. 285, 77 N. Y. S. 2d 508 (Sup. Ct. 1948). The court appeared to regard the doctor who administered the overdosage as the only proper defendant in the case. See also *Weschler v. Hoffman-La Roche, Inc.*, 198 Misc. 540, 99 N. Y. S. 2d 588 (1950) (death action for use of drug).

[228] Representative of the rather technical nature of the warnings given today by drug manufacturers is that for Chloromycetin, set out in text at footnote 99. In addition, there is doubt whether merely giving such warning would satisfy the duty of adequate warning, since it has been said in the products cases that an overly technical warning is none at all. See *Haberly v. Reardon Co.*, 319 S. W. 2d 859 (Mo. 1958) (label stated product contained "calcium oxide;" user not taken to know this meant that there were dangers present to eyesight).

[229] Certainly advertisement could not be counted on. See also footnote 220 on the druggists' practice of relabeling bottles.

in fact knew of the hazards involved and took a calculated risk, his action would more than likely be interpreted as an assumption of risk.[230]

Factor: intervening fault of doctor. Malpractice of the prescribing doctor has the *potential* effect of eliminating the manufacturer's liability if the malpractice is construed to be a legally superseding act.[231] The mere act of prescribing or of exercising some independent control, however, is not generally regarded as superseding.[232] Nor could it be convincingly argued by the manufacturer that the doctor is the patient's agent for acts of malpractice.[233] Furthermore, if the doctor errs because he has relied upon the faulty advice or directions of the drug house, his fault, if any, is foreseeable and again not superseding.[234]

But at the other extreme there are acts of malpractice which would be so unlikely and unreasonable as to be beyond the foreseeability of a drug manufacturer, and which could legally constitute the "proximate" or "sole sufficient" cause of the patient's harm. Examples might be:

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[230] On assumption of risk as a defense in products cases and recognizing the prevailing rule to be that one must appreciate the nature and extent of the risk before his claim is defeated, see 1 Frumer § 14; Prosser, *Torts* § 55 (2d ed. 1955). An example is furnished by the proprietary drug case of *Valmas Drug Co. v. Smoots,* 269 Fed. 356 (6th Cir. 1920), where the user read on the label of the product, Bon-Opto, that it contained zinc sulfate but did not know of the dangerous propensities of the chemical. The court held that there was no assumption of risk as a matter of law and that certain accompanying assurances of safety undid any warning effect which the listing of contents might have.

[231] Generally on malpractice in the use of drugs, see Louisell & Williams, *Trial of Medical Malpractice Cases* § 2.12 (1960) (many cases are gathered in the appendix, 631–32); Stetler & Moritz, *Doctor and Patient and the Law* 86–91 (4th ed. 1962); Lindberg & Newcomer, "Adverse Drug Reactions," 1 *Trauma,* Oct. 1959, p. 3.

[232] A close area of analogy in products cases, the intervening fault of dealers or other intermediaries, is considered in text following footnote 221. In *Gielski v. State,* 3 Misc. 2d 578, 155 N. Y. S. 2d 863 (Ct. Cl. 1956), the court held that the fact that the drug was intended only for prescription would not insulate the manufacturer and distributor from liability to the patient as a matter of law. See also *Parker v. State,* 201 Misc. 416, 105 N. Y. S. 2d 735 (Ct. Cl. 1951), *aff'd,* 280 App. Div. 157. 112 N. Y. S. 2d 695 (1952).

[233] *Mochlenbrock v. Parke, Davis & Co.,* 141 Minn. 154, 169 N. W. 541 (1918), expressly rejected such a contention by the defendant manufacturer. Doctors are not agents or servants of patients for the purposes of imputation of fault, nor is an operation to be regarded as a joint enterprise. *Id.* at 17, 169 N. W. at 544.

[234] See *Abbott Labs. v. Lapp,* 78 F. 2d 170 (7th Cir. 1935), where the doctor erred in applying a contaminated product manufactured by defendant, the condition of which he should have noted. The court held, however, that the manufacturer was nonetheless liable because it had a duty to warn the doctor against the use of the product even when spoiled. *Id.* at 176.

(a) Prescription of a large overdosage of the drug or otherwise not following the manufacturer's directions;[235]

(b) Treating a patient with an obviously adulterated or spoiled drug, especially where its deleterious condition was due to the doctor's acts;[236]

(c) Prescribing a drug without first following the manufacturer's instructions on testing for allergic reactions or taking a history of such reactions;[237]

(d) Use of a drug experimentally for a condition not indicated in the manufacturer's literature;[238] and

(e) Perhaps, prescription of the wrong drug.[239]

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[235] As it is a common practice for a doctor to deviate somewhat from the manufacturer's directions by the application of his own discretion, it would have to be a rather wide deviation to constitute intervening behavior. Among malpractice cases which have involved an overdosage or similar error, see *Trueman v. United States,* 180 F. Supp. 172 (E. D. La. 1960) (dye concentration too high); *Larrimore v. Homeopathic Hosp. Ass'n.,* 181 A. 2d 573 (Del. 1962) (drug overdose); *Julien v. Barker,* 75 Idaho 413, 272 P. 2d 718 (1954) (failure to follow manufacturer's instructions); *Rizzo v. Steiner,* 36 Misc. 2d 701, 233 N. Y. S. 2d 647 (Sup. Ct. 1962); *Boger v. Ader,* 222 N. C. 758, 23 S. E. 2d 852 (1943); *Wood v. Pommerening,* 44 Wash. 2d 867, 271 P. 2d 705 (1954) (bismuth and gold mixture misapplied). In *Ball v. Mallinkrodt Chem. Works,* 381 S. W. 2d 563 (Tenn. App. 1964), the manufacturer of a contrast dye was exculpated when the doctor used 24 cc of the dye in a case where the defendant's literature referred to 15 cc.

[236] See *Henderson v. National Drug Co.,* 343 Pa. 601, 23 A. 2d 743 (1942), discussed in the text. But see Abbott, at footnote 234. An example among the malpractice cases is *Volk v. City of New York,* 284 N. Y. 279, 30 N. E. 2d 596 (1940) (nurse administered decomposed drug which another nurse had negligently failed to remove from drug shelf).

[237] This has been pleaded in the penicillin cases. As examples from the malpractice area see *Horace v. Weyrauch,* 159 Cal. App. 2d 833, 324 P. 2d 666 (1959) (failure to test for sensitivity to iodine dye, Neo-iopax); *Sanzari v. Rosenfeld,* 34 N. J. 128, 167 A. 2d 625 (1961) (death from reaction to epinephrine; failure of dentist to take a history); *Yorston v. Pennell,* 397 Pa. 28, 153 A. 2d 255 (1959) (decedent's sensitivity conveyed to intern who did not relay it to defendant surgeon); *Swartout v. Holt,* 272 S. W. 2d 756 (Tex. Civ. App. 1954).

[238] On the issue of "experimentation" see footnote 347. See also *Young v. Parke, Davis & Co.,* 49 Pa. Super. 29 (1912) (manufacturer of veterinary medicine not liable for injury to plaintiff's horses where doctor made experimental use of drug).

[239] Among malpractice cases, see *Rotan v. Greenbaum,* 273 F. 2d 830 (D. C. Cir. 1959); *Marchese v. Monaco,* 52 N. J. Super. 474, 145 A. 2d 809 (App. Div. 1958), *certification denied,* 28 N. J. 565, 147 A. 2d 609 (1959) (drug too potent for minor disease being treated); *Gifford v. Howell,* 119 S. W. 2d 578 (Tex. Civ. App. 1938) (arsenic and bismuth given for syphillis); *Domina v. Pratt,* 111 Vt. 166, 13 A. 2d 198 (1940) (insulin for condition misdiagnosed as diabetes).

It could be argued that the manufacturer is liable even though the doctor has made a serious error and even

(Footnote continued on next page.)

Henderson v. National Drug Co.,[240] is illustrative even though an impure drug was involved. In that case, a patient had developed an abscess after receiving an injection from the doctor of a liver extract manufactured by defendant. The court affirmed judgment for the defendant on the theory that the evidence was as convincing that the abscess was caused by the failure of the doctor to sterilize the needle as that the drug contained an irritant when made.

There are, however, a wide range of acts on the part of physicians which could well be described as professional error and still not serve to relieve the manufacturer from liability. The following examples illustrate some of the malpractice situations in which it can be argued that there is manufacturer liability:

(a) The doctor fails to obtain the informed consent of the patient to the treatment.[241] This would appear to be irrelevant to manufacturer liability since the error has not affected the original liability which arose out of the harm inevitably done whether consent was obtained or not.

(b) The doctor fails to detect some adverse reaction which is occurring or to check its progress by prescribing counter therapy.[242] Here again it is unlikely that this sort of error would be considered as one superseding that of the manufacturer who, after all, caused the reaction. At most, it would be a case of concurrent tortfeasors, although the court did not accept this reasoning in *Magee v. Wyeth Laboratories, Inc.*[243]

(c) The doctor misapplies or misuses the drug in a manner which is foreseeable to an experienced manufacturer.[244] It

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(Footnote 239 continued.)
though the patient would not have been exposed to the drug but for his acts. If the drug had been *proper* for the patient, the drug manufacturer would be liable, at least as long as the misdiagnosed condition did not make the user particularly susceptible to reaction.

[240] 343 Pa. 601, 23 A. 2d 743 (1942).

[241] On the duty to obtain an informed consent, see footnote 219.

[242] See cases cited at footnote 237 for this situation in the malpractice area.

[243] 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963). Plaintiff's decedent died following use of a prescribed drug. The doctor failed to follow manufacturer's warning to make tests to detect the fatal disease. Plaintiff sued the doctors (who settled) and the manufacturer in warranty. The court held, affirming judgment for the manufacturer, that the intervening negligence of the doctor was not foreseeable as a matter of law, especially as this was a prescription sale.

[244] To a certain degree the manufacturer can foresee some experimentation with new drugs, both on dosage and frequency. See footnote 235. *Love v. Wolf*,—Cal. App. 2d —, 38 Cal. Rptr. 183 (1964), involved an action against

(Footnote continued on next page.)

has been held foreseeable, for example, that a doctor may forget what he read earlier,[245] or that he will not immediately notice a dosage change,[246] or that he will rely upon what he reads even though medical practice has modified what was written,[247] or that he will not heed a warning when in his independent but erroneously exercised judgment he has minimized the risk involved.[248]

(d) The doctor or hospital uses a contaminated drug, which contamination originated in original manufacture and yet might have been detected by the doctor.[249]

In summary, medical malpractice should be regarded as terminating manufacturer liability only where the acts or omissions of the doctor are unusual, gross, and unforeseeable. How far the courts will go in holding that certain acts were foreseeable is unknown, but certain decisions such as *Abbott*[250] and *Weschler*[251] point toward manufacturer liability. There is little to prevent the application of traditional joint tortfeasor concepts in this area.

Factor: contributory fault of patient. If the manufacturer is generally liable for injury caused by its drugs, what acts or omissions of the patient would constitute contributory fault of a type sufficient to defeat his cause of action?[252] An analysis of the following ex-

(Footnote 244 continued.)
a doctor who prescribed Chloromycetin and against the manufacturer, Parke-Davis. The doctor used the drug for a condition which the literature of the manufacturer did not refer to. In holding that plaintiff was due a new trial, the court said, relating to the question of intervening negligence: "[I]f the over-promotion can reasonably be said to have induced the doctor to disregard the warnings previously given, the warning given is thereby withdrawn or cancelled and . . . then the pharmaceutical company's negligence remains as an inducing cause coinciding with the negligence of the doctor to produce the result." *Id. at* —, 38 Cal. Rptr. at page 196.

[245] *Abbott Labs. v. Lapp,* at footnote 234; *cf., Weschler v. Hoffman-La Roche, Inc.,* 198 Misc. 540, 99 N. Y. S. 2d 588 (Sup. Ct. 1950) (duty to warn even if the doctor is an expert).

[246] *Hruska v. Parke, Davis & Co.,* 6 F. 2d 436 (8th Cir. 1925) (manufacturer had changed the base for its camphor solution).

[247] But see footnote 335.

[248] This is the theory behind some of the Chloromycetin actions discussed in footnote 3 in Part I. It is claimed that the manufacturer could have foreseen that a doctor would prescribe the drug for too minor an infection but that it did not warn against this in the clearest possible language.

[249] This apparently was the situation in *Moehlenbrock v. Parke, Davis & Co.,* 141 Minn. 154, 169 N. W. 541 (1918).

[250] *Abbott Labs. v. Lapp,* at footnote 234.

[251] *Weschler v. Hoffman-La Roche, Inc.,* 198 Misc. 540, 99 N. Y. S. 2d 588 (Sup. Ct. 1950).

[252] Generally on contributory negligence in the products liability field, see 1 Frumer § 13; 1 Hursh § 2:121-:123. Regarding contributory fault in druggist cases, see Annot., 79 A. L. R. 2d 301, 329–30 (1961).

amples, showing the various ways in which contributory negligence could be claimed to arise, may help to show the scope of this problem and the law that probably would be applied thereto.

(a) Though the patient has received clear directions from the treating doctor, he fails to follow them, for example, by taking an overdosage. Here there would be a valid defense for the drug house, at least if the act of the patient were a cause-in-fact of his harm.[253] There would probably be no defense, however, where the same harm would have occurred had the patient followed directions correctly or where the directions were in error and the patient in reliance on his doctor followed them.[254]

(b) The patient neglects to report reactions which he is experiencing or fails to tell a doctor about a previous experience with the same drug. If it could be expected that an ordinary, prudent layman would make such a report, his failure to do so could constitute contributory negligence as to the drug manufacture,[255] as well as to the doctor in a malpractice claim.[256] [For footnote 256, see next page.]

[253] Misuse of a product is a standard defense in products cases, 1 Frumer § 15. A well-acknowledged exception exists, however, where the misuse is foreseeable. Momentary forgetfulness can also be anticipated by the manufacturers, as in *Tracy v. Finn Equip. Co.*, 310 F. 2d 436 (6th Cir. 1962), and *Bean v. Ross Mfg. Co.*, 344 S. W. 2d 18, 25 (Mo. 1961). But see *Day v. Barber Colman Co.*, 10 Ill. App. 2d 494, 135 N. E. 2d 231 (1956).

As for the problem of factual cause, it should be noted that mere overdosage may not in itself constitute contributory fault, since even with proper dosage the same harm might nevertheless have occured; this is especially so where the nature of the reaction is an allergic one, unrelated to dosage, frequency or duration of use.

[254] In *accord* with this view, see involving druggists, *Dunlap v. Oak Cliff Pharmacy Co.*, 288 S. W. 236 (Tex. Civ. App. 1926). See also *Gwynn v. Duffield*, 61 Iowa 64, 15 N. W. 594 (1883).

[255] In some cases, for example, the manufacturer has pleaded that the patient failed to give his doctor a complete history and record of all allergic reactions or to advise the doctor of reactions which were presently occurring, or that he failed to revisit the doctor or to stop taking the drug. In many situations the patient would not be under an obligation to report because he did not realize that he was undergoing a reaction separate from that which might be expected to arise from the condition for which he was being treated. Reliance on the knowledge and skill of the doctor is to be expected. See, for example, *Bocck v. Katz Drug Co.*, 155 Kan. 656, 127 P. 2d 506 (1942).

An analogy for consumer fault might lie in products liability law with cases in which one continues to drive a car after he knows the brakes are defective—behavior which has been held to constitute contributory negligence. *Benton v. Sloss*, 38 Cal. App. 2d 399, 240 P. 2d 575 (1952); *Rawls v. Ziegler*, 107 So. 2d 601 (Fla. 1958); *Hembree v. Southard*, 339 P. 2d 771 (Okla. 1959). Also analogous are cases involving users of hair products who have had prior reactions or ignore present indications.

(Footnote continued on next page.)

(c) The patient takes a drug which was not prescribed for him, or otherwise self-administers a drug that is not proper for him. Here courts would tend to find contributory fault on the part of the user, as indeed was the holding in the recent case of *Kasperowitz v. Shering Corp.*[257] The fact that a drug falls into the hands of one for whom it was not prescribed, however, should not constitute a defense of contributory negligence as a matter of law where the mode of access was foreseeable and not illicit.[258]

In summary, it is likely that the general tort rules of products liability cases will continue to be applied in drug *negligence* actions when the defense of contributory negligence is raised. Nevertheless, as was remarked in *Hruska v. Parke, Davis & Co.*,[259] the parties are on grossly different footings and the patient should be treated deferentially by the one with superior knowledge of the propensities of the product he sells. As to the availability of the defense in a *warranty* action, the law is unsettled.[260] A series of recent cases has held that the defense is inapplicable on the grounds that contributory negligence refers to the consumer's behavior and not to the failure of a product to live up to its warranties. The breach occurs, if at all, by virtue of the manufacturer's acts without regard to the subsequent

(Footnote 255 continued.)
See, for example, *Arata v. Tonegato*, 152 Cal. App. 2d 837, 314 P. 2d 130 (1957).

[256] On contributory negligence in malpractice cases, see Louisell & Williams, cited at footnote 231, § 9.03; *Kelly v. Carroll*, 36 Wash. 2d 482, 219 P. 2d 79 (1950).

[257] 70 N. J. Super. 397, 175 A. 2d 658 (App. Div. 1961). Plaintiff purchased a dandruff cure, which was to be sold by prescription only, without a prescription. Upon developing contact dermatitis, plaintiff sued the manufacturer for negligent failure to warn, and for breach of express and implied warranties. The court held that plaintiff was contributorily negligent in buying the drug without a prescription. See Dickerson, "Recent Developments in Food Products Liability," 8 *Prac. Law.* April, 1962, pp. 17, 31. But even in this case it is arguable that the manufacturer should be liable since exactly the same harm resulted as would have if the plaintiff had a prescription, at least in the absence of evidence that a doctor would not have prescribed this shampoo for the plaintiff because of his proneness to contact dermatitis. See footnote 239.

[258] See, for example, involving other products, *Maddox Coffee Co. v. Collins*, 46 Ga. 220, 167 S. E. 306 (Ct. App. 1932) (plaintiff ate coffee with glass in it; while this was not a normal use of coffee, the manufacturer's usual duty to guard against impurities in coffee extended to him); *Harper v. Remington Arms Co.*, 156 Misc. 53, 280 N. Y. Supp. 862 (Sup. Ct. 1935), *aff'd*, 248 App. Div. 713, 290 N. Y. Supp. 130 (1936) (testing-type shells of high power came into possession of hunter with an ordinary gun). See also discussions in footnotes 239, 253.

[259] *Hruska v. Parke, Davis & Co.*, 6 F. 2d 536 (8th Cir. 1925) (further discussed at footnote 195).

[260] See generally 1 Frumer § 16.01[3]; 1 Hursh § 3:9; 15 *U. Fla. L. Rev.* 85 (1962).

acts of the user.[261] A manufacturer, however, cannot be taken to make a promise that his product is safe from all possible types of misuse. Where misuse or abuse of the product, rather than merely contributing fault, causes the harm, there arguably should be no warranty liability.[262]

2. *Inadequate Warning of Known Side Effects*

The drug manufacturer is under the same duty as any chattel supplier to give an adequate warning about dangerous characteristics or unsafe means of using his product.[263] While few drug cases will involve the total absence of warning where the manufacturer does have knowledge of side effects, it can be anticipated that litigation based on *inadequate* warning, the so-called "watered-down" warning, will not be uncommon. Some variations of the allegation of inadequate warning are considered in the following paragraphs.[264]

a. Warning put in some literature but not everywhere

It is not uncommon to see a drug advertisement which has no warning in it except perhaps by the implication raised in a small-type reference to "more detailed material on side effects available on request."[265] It is possible that a doctor may never see the comprehensive, FDA-required warning, and may recall best what has been most prominently brought to his attention—the colored ads with their assurances. If it can be shown that the doctor relied upon the most liberal, watered-down statements available to him, the question raised is whether a manufacturer sued for inadequate warning could defend on the ground that he had complied with FDA requirements as to placing the closely-worded, FDA-approved warning in certain stipulated places, such as in the labeling accompanying the product. The

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[261] *Brown v. Chapman*, 304 F. 2d 149, 153 (9th Cir. 1962), in which it was held that contributory fault of user serves merely to put the warranty to the test: "One may well rely upon a warranty as protection against aggravation of the consequences of one's own carelessness." See also *Wright v. Carter Prods., Inc.*, 244 F. 2d 53 (2d Cir. 1957); *Jarnot v. Ford Motor Co.*, 191 Pa. Super. 422, 156 A. 2d 568 (1959).

[262] This is the view taken by Prosser in "The Assault Upon the Citadel (Strict Liability to the Consumer)," 69 *Yale L. J.* 1099 (1960)—that the real defense is that the plaintiff failed to discover an obvious defect or failed to guard against its known presence. It may be that a better term for the defense in warranty is *assumption of risk.*

[263] 1 Frumer § 8; 2 Frumer § 33.01[3]; 1 Hursh § 2; Annot., 76 A. L. R. 2d 9 (1961).

[264] Detailed discussion of factual cause has been omitted. It is assumed that had the doctor been given an adequate warning he probably would have altered his course or would have told the patient, who would have altered the course.

[265] See discussion beginning at footnote 112.

answer is almost certainly in the negative, since it is incumbent upon the manufacturer to bring the warning home to the doctor.[266] This very failure to include warnings of equal strength in all literature has, in fact, been the basis of liability asserted in several of the recent Chloromycetin cases.[267]

b. Warning given but minimized and accompanied by false assurances of safety

While reversing judgment for plaintiff, the appellate court in *Love v. Wolf*,[268] the famous Chloromycetin case, held that the plaintiff had made out a submissible case of negligent failure to warn, based upon "watering down" and dilution. Plaintiff at trial had claimed and had produced evidence that the prescribed FDA warnings[269] had been changed, if only by a few words, in order to minimize the effect of the warning and thus, to enhance sales.[270] There can be no doubt, based upon precedents in other products liability areas and upon analysis of the special problems involved in drug cases, that the minimization of dangers can amount to inadequate warning.[271] False

[266] The effect of warning given can be evaluated under the terms of the "accompaniment doctrine," footnote 94, which judges the representations of the manufacturer on the basis of all material sent out by the manufacturer and not just the labeling on the box or bottle. Further, it has been routinely held that FDA regulations establish an administrative minimum but do not necessarily establish a proper standard of conduct for civil purposes. See footnote 297. It should also be noted that even if the failure of the doctor to have read the detailed literature could be called an act of malpractice, at most, such fault would only be deemed concurrent with that of the manufacturer in issuing a watered-down statement. See discussion in text at footnotes 244–48.

A number of tort cases involving other classes of products have held that to be effective, a warning must appear in all material which is likely to come to the user's eyes. See, for example, *McLaughlin v. Mine Safety Appliance Co.*, 11 N. Y. 2d 62, 226 N. Y. S. 2d 407, 181 N. E. 2d 430 (1962); *McClanahan v. California Spray-Chem. Corp.*, 194 Va. 842, 75 S. E. 2d 712 (1953). As is ably stated by Hursh, "The view has been taken that when a manufacturer undertakes by printed instructions to advise of the proper method of using his chattel, he assumes the responsibilities of giving accurate and adequate information with respect thereto, and his failure in this respect may constitute negligence." 1 Hursh § 1:29, at 188.

[267] See footnote 3 in Section I.

[268] — Cal. App. 2d —, 38 Cal. Rptr. 183 (1964). The court also rested its new trial order on negligence, based on over-promotion by Parke-Davis; see footnote 244.

[269] See *Kefauver Report* 194; 21 C. F. R. § 146d.301(c) (1962).

[270] Counsel for plaintiff reported that specific instances involved the use of the word *associated* in the phrase that certain diseases had been *associated* with the drug, rather than using the direct word *caused;* Boccardo, in *NACCA 11th Annual Western Regional Transcript* 127, at pages 137–38 (1962).

[271] See 1 Frumer § 8.05; Noel, "Manufacturer's Negligence of Design or Directions for Use of a Product," 71 *Yale L. J.* 816, 843 (1962); *Spruill v. Boyle-*

(Footnote continued on next page.)

assurances have the effect of undoing whatever proper warning might have previously been given;[272] even ambiguity in a warning may negate the effect of the warning.[273]

c. Statements made by detailmen diluting proper warning

Reference has been made to the practice of detailmen making untrue statements about the efficacy and safety of their drugs, either because of the manufacturer's orders or their own drive for sales.[274] Since these men are ordinary agents for the manufacturers, such a dilution, regardless of motive, should be considered as falling within the grounds for inadequacy of warning stated in the preceding paragraph, the accuracy of literature actually accompanying the product notwithstanding.[275]

d. Instructions for use which do not amount to a warning

A manufacturer who has not otherwise given full warnings in the typical form used by the pharmaceutical trade might point to instructions or directions for use of the product as satisfying the duty to warn. Cases involving other products, however, have implied that mere directions do not amount to warnings.[276] And, as a corollary,

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(Footnote 271 continued.)
Midway, Inc., 308 F. 2d 79 (4th Cir. 1962); *Saporito v. Purex Corp.*, 40 Cal. 2d 608, 255 P. 2d 7 (1953); *Tampa Drug Co. v. Wait*, 103 So. 2d 603 (Fla. 1958).

This was the basis for liability in *Marcus v. Specific Pharmaceuticals, Inc.*, 82 N. Y. S. 2d 194 (Sup. Ct. 1948). See also footnotes 226–27.

[272] *Haberly v. Reardon Corp.*, 319 S. W. 2d 859 (Mo. 1958); *La Plant v. E. I. Du Pont de Nemours & Co.*, 346 S. W. 2d 231 (Mo. App. 1961); *Alfieri v. Cabot Corp.*, 17 App. Div. 2d 455, 235 N. Y. S. 2d 753 (1962), *aff'd*, 12 N. Y. 2d 1098, 240 N. Y. S. 2d 163, 190 N. E. 2d 535 (1963); *Crist v. Art Metal Works*, 230 App. Div. 114, 243 N. Y. Supp. 496, *aff'd*, 255 N. Y. 624, 175 N. E. 341 (1930); *Rosenbusch v. Ambrosia Milk Corp.*, 181 App. Div. 97, 168 N. Y. Supp. 505 (1917); *Maize v. Atlantic Ref. Co.*, 352 Pa. 51, 41 A. 2d 850 (1945).

[273] For example, *Schilling v. Roux Distrib. Co.*, 240 Minn. 71, 59 N. W. 2d 907 (1935). See generally 1 Hursh § 2:40, at 187.

[274] See *Kefauver Report* 198. See also "Editorial," 265 *N. Eng. J. Med.* 910 (1961).

[275] An example involving a non-drug product is *Miller v. New Zealand Ins. Co.*, 98 So. 2d 544 (La. App. 1957) (label of cleaner said not to use it in bathtubs but agent displaying it said it was proper for tubs; warning held nullified by contrary representations). See Ruud, "Manufacturers' Liability for Representations Made by Their Sales Engineers to Subpurchasers," 8 *U.C.L.A.L. Rev.* 251, 280 (1961). In the detailman situation envisioned in the text the existence of agency can clearly be made out. There probably would be no parol evidence problem since no written agreement is being altered by contemporaneous oral statements.

The court in *Love v. Wolf*, see footnote 268, specifically found evidence of directions to salesmen to dilute warnings.

[276] *Tampa Drug Co. v. Wait*, 103 So. 2d 603 (Fla. 1958); *Hartmon v. National Heater Co.*, 240 Minn. 264, 60 N. W. 2d 804 (1953); *Schilling v. Roux Distrib. Co.*, 240 Minn. 71, 59 N. W. 2d 907

(Footnote continued on next page.)

when the manufacturer, including the drug supplier, undertakes to give instructions to guide the practice of the physician he can be required to go one step further and disclose the adverse effects, on the grounds that telling half the story amounts to false assurance of safety by omission.[277]

e. Subsequent discoveries of side effects not communicated

The usual practice for a manufacturer who discovers side effects after marketing a drug, after reporting to the FDA, is to send out warnings about the adverse reaction as soon as possible to doctors and dispensaries.[278] It is at least arguable that the failure to adhere to this process of notification constitutes a failure to warn, especially when the causation is fairly definite, the side effect severe, and reasonable means are at hand to send out warnings.[279]

f. Complete absence of warning

Total absence of warning in the face of knowledge, a situation of almost certain liability,[280] is an unusual matter in drug litigation. Where the warning omitted is one prescribed by the Drug Act or regulations issued thereunder, violation of these is evidence of failure to warn and might be regarded as negligence per se.[281] Such complete

(Footnote 276 continued.)
(1935); *Bean v. Ross Mfg. Co.*, 344 S. W. 2d 18 (Mo. 1961). See generally 1 Frumer § 8.05. On use of this same type of language as a disclaimer, see text accompanying footnote 215.

[277] See footnote 272.

[278] See discussion footnote 122 and accompanying text (20 FOOD DRUG COSMETIC LAW JOURNAL 353).

[279] See, for example, involving non-drug cases, *De Vito v. United Air Lines*, 98 F. Supp. 88 (E. D. N. Y. 1951) (medical specialists told manufacturer that carbon monoxide was escaping in plane they were producing but manufacturer did not follow up on advice; liability for a subsequent accident was based upon failure to warn); *Comstock v. General Motors Corp.*, 358 Mich. 163, 99 N. W. 2d 627 (1959) (power brake master cylinder began to fail in use after some automobiles of the new model had been distributed to dealers; manufacturer negligent in not sending a warning letter to purchasers).

[280] Examples among ethical drug cases are *Abbott Labs. v. Lapp*, 78 F. 2d 170 (7th Cir. 1935) (discussed in text at footnote 144); and *Halloran v. Parke, Davis & Co.*, 245 App. Div. 727, 280 N. Y. Supp. 58 (1935). It is of some evidential value that while the manufacturer did not warn about his particular drug, other manufacturers of drugs composed of the same chemicals did warn. This would tend to show both that there was constructive knowledge on the part of the defendant and that he failed to use available reasonable procedures for warning purposes.

[281] *Orthopedic Equip. Co. v. Eustler*, 276 F. 2d 455 (4th Cir. 1960) (violation of misbranding section of Drug Act. negligence per se); *Merck & Co. v. Kidd*, 242 F. 2d 592 (6th Cir.), *cert. denied*, 355 U. S. 814 (1957) (defendant manufactured blood plasma which contained undetectable serum hepatitis; plaintiff sued on the theory of negligence per se for violation of the Federal Drug Act and its state counterpart; the majority held that the plasma was not "filthy" and hence not in violation of the laws). Cases involving

(Footnote continued on next page.)

failure to warn would appear to be good evidence in a suit based on deceit or fraud if there were any accompanying positive representation.[282]

3. *Side Effects Unknown; Manufacturer's Duty to Discover*

The third basic situation, that in which the manufacturer at the time of the patient's injury is unaware of the harmful propensities of his drug, is perhaps the most interesting of the three since it raises a number of issues which may be regarded as unsettled today.

a. The duty to know the nature and effects of a drug

Well-recognized in many products cases is the duty of the manufacturer to make a reasonable effort to know the nature and effects of the product which he puts into commerce.[283] Failure on his part "to know the nature of his beast," as it is sometimes put, can thus expose him to negligence liability. This general requirement has been specifically defined to cover knowledge about the chemical nature of the product sold and its hazardous propensities.[284] The manufacturer, after all, holds himself out to be a highly skilled expert in the product sold[285] and the user can rightly presume this.[286] Where there is a

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(Footnote 281 continued.)
druggists are gathered in Annot., 79 A. L. R. 2d 301, at 326–28 (1961). As to the intent of Congress to make a civil cause of action for violation of the Drug Act, see "Developments in the Law: The Federal Food, Drug, and Cosmetic Act," 67 *Harv. L. Rev.* 632, 722 (1954).

[282] This type of action is considered in text beginning at footnote 193.

[283] 1 Frumer § 8.01, at 144; *id.* § 12.01[1], at 227; 2 Harper & James § 28.4, at 1541; Keeton, "Products Liability—Proof of the Manufacturer's Negligence," 49 *Va. L. Rev.* 675 (1963); Noel, see footnote 271, at page 847. Involving ethical drugs, see *Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154, 169 N. W. 541 (1918) (duty to know uses which medical profession will make of drug); *Gielskie v. State*, 3 Misc. 2d 578, 155 N. Y. S. 2d 863 (Ct. Cl. 1956) (further history stated at footnote 335) (trial court placed a duty upon manufacturer to keep its literature on administration of the drug up to date and revised in accordance with latest medical theories).

[284] *Holland v. St. Paul Mercury Ins. Co.*, 135 So. 2d 145 (La. App. 1961) where child consumed rat poison accidentally, duty to know composition of poison so that defendant-supplier could tell doctor for antidotal purposes); *Braun v. Roux Distrib. Co.*, 312 S. W. 2d 758 (Mo. 1958).

[285] "[A] person who undertakes such manufacturing will be held to the skill of an exert in that business. . . . Thus he must keep reasonably abreast of scientific knowledge and discoveries touching his product and of techniques and devices used by practical men in his trade. He may also be required to make tests to determine the propensities and dangers of his product." 2 Harper & James § 28.4, at 1541. See also *Dalehite v. United States*, 346 U. S. 15, 47, 53 (1953) (dissenting opinion); 1 Frumer § 8.01, at 144–46.

[286] Several Massachusetts cases have created a presumption that the manufacturer knew the nature of the product sold, with the effect that the plaintiff has been able to make out a prima facie case of failure to warn and that the defendant has the burden of rebuttal. See *Farley v.*

(Footnote continued on next page.)

failure to warn and a duty to know, and there have also been assurances or statements by the manufacturer that the product is safe, harmless, or the like, when in fact it is not, a negligent misrepresentation action may also be available.[287] As has been indicated, this type of assurance has not been uncommon in contemporary drug advertising.[288]

b. Duty to make tests and investigations of product

It follows as a corollary to the duty to know the nature and effects of one's product that the manufacturer is under a duty to use reasonable efforts to discover this information.[289] Failure to take reasonable steps prior to marketing a new product to determine whether it will cause harm may constitute negligence. The manufacturer must consult the available scientific and technical literature, and if it is inadequate he must make his own tests and experiments. After marketing, he is obliged to keep abreast of the scientific and medical developments of relevance to his product and to apply new investigational techniques as they are developed.[290] *Pritchard v. Liggett & Myers Tobacco Co.*,[291] a cigarette-cancer case, is a good example of the duty to test. As against the manufacturer's defense that there was no evidence to show that it knew of the carcinogenic effect of its product or that it should have known in the reasonable exercise of

(Footnote 286 continued.)
Tower & Co., 271 Mass. 230, 171 N. E. 639 (1930); *Thornhill v. Carpenter-Morton Co.*, 220 Mass. 593, 108 N. E. 474 (1915). 1 Frumer § 12.01[1], at 228–30.

Note the interesting proprietary drug case of *Pietrus v. Watkins Co.*, 229 Minn. 179, 38 N. W. 2d 799 (1949) (manufacturer held charged with notice of alkali in shampoo).

[287] See text beginning at footnote 197.

[288] See text beginning at footnote 112 (20 FOOD DRUG COSMETIC LAW JOURNAL 351).

[289] Cases announcing this rule, but involving products other than drugs, include *Hopkins v. E. I. Du Pont de Nemours & Co.*, 199 F. 2d 930 (3d Cir. 1952); *Chapman Chem. Co. v. Taylor*, 215 Ark. 630, 222 S. W. 2d 820 (1949); *Saporito v. Purex Corp.*, 40 Cal. 2d 608, 255 P. 2d 7 (1953); *Twombley v. Fuller Brush Co.*, 221 Md. 476, 158 A. 2d 110 (1960); *Ebers v. General Chem. Co.*, 310 Mich. 261, 17 N. W. 2d 176 (1945); *Braun v. Roux Distrib. Co.*, 312 S. W. 2d 758 (Mo. 1958); *O'Donnell v. Asplundh Tree Expert Co.*, 13 N. J. 319, 99 A. 2d 577 (1953).

See generally 1 Frumer § 6:01, at 65–67, § 8:01, at 144–45; 2 Harper & James § 28.4, at page 1541. It should be noted that *testing* is being discussed here in the sense that the design or overall quality of the basic product is being examined and not in the sense of a factory-line inspection of a completed article, which is considered in footnote 138.

[290] See *Braun v. Roux Distrib. Co.*, see footnote 289 (manufacturer deemed to know whatever was in medical literature on possibility of toxic reactions to his hair dye; since he made no tests whatsoever, liable for reaction). Note the parallel here to the duty in malpractice cases upon a physician to stay abreast of modern scientific developments. McCoid, "The Care Required of Medical Practitioners," 12 *Vand. L. Rev.* 549, 575 (1959).

[291] 295 F. 2d 292 (3d Cir. 1961).

care, the Third Circuit held that the issue of knowledge, actual or constructive, should have been left to the jury.

The duty to discover, of course, is only a relative one, and the manufacturer need only show that reasonable steps were taken under the circumstances. Reasonableness here would depend upon the performance of scientifically-acceptable tests and adherence to good standards currently practiced by manufacturers of like products. As far as negligence goes, therefore, a manufacturer who has tried to anticipate the hazards of his products is protected, but the man who has made either no tests or patently inadequate ones is not.[292] It has been stated also that, where a new product potentially dangerous to life is involved, the degree of testing required is greater in quantity and quality than that required for the ordinary product.[293]

Carrying these general propositions over to the ethical drug manufacturer, it is apparent that ethical drugs, more than any other product, are subject to pre-marketing investigation. But even though the degree of testing done for drugs would probably per se satisfy that required for any other class of products, it still remains to determine whether a specific manufacturer whose product has suddenly produced side effects after marketing should have known about the effects before a private patient was harmed. Why the vast clinical trials performed on drugs do not turn up side effects before marketing is an as yet unsettled issue, as has been pointed out.[294] If the accepted reason for failure to detect was that no one knew, or that it was due to "undetectable factors," it would have to be conceded that the mere failure to detect presents no evidence of negligent investigation. Consider, however, the evidentiary value of the following possible explanations for failure to detect adverse reactions before the litigant was harmed:

(a) The sample used was not large enough to detect this unusual side effect;

(b) The wrong sample was used, one omitting, for example, a specific class of persons (for example, pregnant women, arthritics) who reacted to the drug;

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[292] There is, however, in all cases, the factual cause issue. Thus, even had the tests been performed, is it probable that they would have detected the harm which is complained of?

[293] Noel, at footnote 271, at page 853, relying upon *O'Donnel v. Asplundh Tree Expert Co.*, 13 N. J. 319, 99 A. 2d 577 (1953); *Chapman Chem. Co. v. Taylor*, 215 Ark. 630, 222 S. W. 2d 820 (1949). As stated in *Pritchard*, "The precautions necessary to comply with the standard of reasonableness vary with the danger involved." 295 F. 2d at 299.

[294] See text following footnote 119.

(c) The data gathered were improperly or carelessly analyzed for occurrence of reactions;

(d) The data were tailored or rigged, or the supposed tests were not actually performed.

For a litigant to make use of any of these factors he would need proof, first that such a failure did in fact happen, second that it was not good medical or scientific practice to make the omission or other mistake, and lastly that such failure was the cause-in-fact of his harm. This, needless to say, would be rather difficult, unless some sort of procedural device such as the doctrine of *res ipsa loquitur* were applied, or unless fraud or concealment were involved.[295]

Two arguments which might be put forward in defending against liability should be considered. First, the manufacturer might defend on the basis of compliance with the stringent FDA requirements for approval.[296] Certainly such compliance would be substantial evidence of due care; but, as a matter of law, such conduct would generally not constitute due care per se.[297] The second defense—that the manufacturer relied on its doctors who were both carefully chosen and acting as highly skilled independent contractors, and that the manufacturer was not itself skilled in experimentation—ought to be promptly rejected both by simple agency doctrines[298] and by application of the rule above defined that the *maker* himself is taken to be skilled and expert.

c. Strict liability without means of knowing of adverse reactions

In a breach of implied warranty action, the question may be whether the manufacturer should be insulated from liability on the ground that

[295] Expert evidence, especially from a clinical pharmacologist, would be the most persuasive form of proof. For the evidentiary value of manufacturer withdrawal of a drug or modification of its formula to reduce toxicity, see text at footnote 339.

[296] See *Sliny v. Parke, Davis & Co.*, Fed. Dist. Ct., Detroit, Mich., pleadings reported, *Drug News Weekly*, Nov. 14, 1962, p. 8; *Love v. Wolf*, footnote 268.

[297] See generally 1 Frumer § 8.07, at 175. The decision in the *Cutter* cases, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960), indicates that Public Health Service approval of the product did not operate as a defense for the laboratories, even though their counsel argued that compliance with the PHS's "Minimal Requirements" was proof of due care. Cases involving products other than ethical drugs include *Arata v. Tonegato*, 152 Cal. App. 2d 837, 314 P. 2d 130 (1957); *Tampa Drug Co. v. Wait*, 103 So. 2d 603 (Fla. 1958); *Maize v. Atlantic Refining Co.*, 352 Pa. 51, 41 A. 2d 850 (1945). *Contra, Hollingsworth v. Midwest Serum Co.*, 183 Iowa 280, 152 N. W. 620 (1917). See also Kriendler, "Admission and Effect of Government Approval and Certification of Aircraft," 3 *B. C. Ind. & Comm. L. Rev.* 367 (1962).

[298] On evidence of an agency relationship existing between tester and manufacturer, see footnote 168.

he could not have known of the dangerous propensities of his drug by the exercise of reasonable skill and foresight. To create warranty liability here, it would be necessary to hold the manufacturer to strict liability—virtually that of insurer. By definition, he has done all possible, making the product perfect in the commercial sense, and no available scientific knowledge or devices could have discovered the defect in advance.

To date, it has been the cigarette-cancer cases that have raised this question in a clear fashion: Has the manufacturer of cigarettes broken an implied warranty to a smoker who develops cancer where the jury has found as a matter of fact that the manufacturer could not have known of the carcinogenic property of its product by the reasonable application of human skill and foresight? The Florida Supreme Court in *Green v. American Tobacco Co.*,[299] took the liberal view that there could be a breach of warranty under these circumstances, stating:

> [I]mplied warranty liability is not limited by the foreseeability doctrine, the "reasonable application of human skill and foresight" test of tort liability. . . . [A] manufacturer's or seller's actual knowledge or opportunity for knowledge of a defective or unwholesome condition is wholly irrelevant to his liability on the theory of implied warranty. . . . No reasonable distinction can, in our opinion, be made between the physical or practical impossibility of obtaining knowledge of a dangerous condition, and scientific inability resulting from a current lack of human knowledge and skill. . . . To hold that prevailing industry standards supplant the ordinary standard of objective truth and proof, and should be conclusive on the issue of a product's reasonable fitness for human use or consumption, would be to shift to the purchaser the risk of whatever latent defectiveness may ultimately be proven by experience and advancement of human knowledge, a risk which we are convinced was from the inception of the implied warranty doctrine intended to be attached to the mercantile function.[300]

The Fifth Circuit had held otherwise in the same case [301] before it was submitted to the Florida court. The Fifth Circuit subsequently reached

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[299] 154 So. 2d 169 (Fla. 1963).

[300] See footnote 299. The quoted material is taken from throughout the opinion. The Florida court was careful to avoid passing upon the merits of the case, including such issues as whether there was privity, whether the cigarette was unmerchantable as a matter of law, and whether there was assumption of risk. *Green* differs from *Pritchard*, discussed in text at footnote 291, in that *Pritchard* arose on the issue of the manufacturer's duty to know, not whether there could be liability regardless of knowledge.

[301] 304 F. 2d 70 (5th Cir. 1962). The court first held, with judge Cameron dissenting, that there was no breach of warranty, but on rehearing agreed to certify the question to the Florida Supreme Court. After the Florida Supreme Court opinion, the Fifth Circuit remanded the case for a new trial. *Green v. American Tobacco Co.*, 325 F. 2d 673 (5th Cir. 1963). For a thoroughgoing analysis of the earlier *Green* case in the federal court and critical discussion of its reasoning, see Comment, "Cigarettes and Vaccine: Unforeseeable Risks in Manufacturers' Liability Under Implied Warranty," 63 *Colum. L. Rev.* 515 (1963).

a similar result in *Lartigue v. R. J. Reynolds Tobacco Co.*,[302] reasoning that there could be no breach of warranty for inherently unknowable defects in that breach is based upon a manufacturer's superior opportunity to gain knowledge of his product, something he was here unable to do.

Strict liability is also the rule proposed by the *Restatement of Torts*,[303] although the comment to the relevant section would seem to exclude some drug reaction cases.[304] There is much precedent for strict liability, of course, in those food cases in which the harmful foreign substance could not have been provided against,[305] and in the exploding bottle cases.[306] [For footnote 306, see next page.]

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[302] 317 F. 2d 19 (5th Cir. 1963). The court held that there could be no breach of warranty where injury was caused by a product the harmful effects of which no presently existing scientific skill or foresight could discover.

A number of other cases have involved the issue of the liability of the manufacturer who does not know of the defect at the time of manufacture although he was in possession of all of the data which science could supply, but these have involved undetectable *impurities* in the product. See *Kenower v. Hotels Statler Co.*, 124 F. 2d 658 (6th Cir. 1942); *Hunter v. E. I. Du Pont de Nemours & Co.*, 170 F. Supp. 352 (W. D. Mo. 1958); *Pietrus v. Watkins Co.*, 229 Minn. 179, 38 N. W. 2d 799 (1949); see also footnote 344. But see, denying liability, *Merck & Co. v. Kidd*, 242 F. 2d 592 (6th Cir.), *cert. denied*, 355 U. S. 814 (1957); *Livesley v. Continental Motors Corp.*, 331 Mich. 434, 49 N. W. 2d 365 (1951); *Canavan v. City of Mechanicville*, 229 N. Y. 473, 128 N. E. 882 (1920).

[303] Restatement (Second), Torts § 402A (Tent. Draft No. 7, 1962). The Reporter is Dean Prosser whose views on strict liability are reflected in his article on warranty, "The Assault Upon the Citadel (Strict Liability to the Consumer)," 69 *Yale L. J.* 1099 (1960). Comment *d* makes it clear that drugs are included in the section, although the text refers only to food, and that no distinction is to be made between drugs which are ingested and those parenteral ones which come into contact with the skin. The term "warranty" is nowhere used in this section; its omission and the substitution of the concept of strict liability are discussed in comment *m*. The new section has already elicted much comment, mostly critical. The legal counsel for a food manufacturer has attacked the section as not representative of the law as it stands today, Condon, "Product Liability Problems," 57 *Nw. U. L. Rev.* 536 (1962). The court in the *Lartigue* case, footnote 302, cited the section with approval, as did Boshkoff, "Some Thoughts About Physical Harm, Disclaimers and Warranties," 4 B. C. Indust. & Com. L. Rev. 285, 297–300 (1963) (who believes that both the traditional warranty remedy and the new strict liability concept should be maintained as differing theories of recovery).

[304] Comment *k* considers the situation in which a product is valuable and yet it causes a type of harm which is undetectable, citing hypothetically the instance of a vaccine. Here, the comment declares, there should be no strict liability since it cannot be said that the product is *unreasonably* dangerous, a requirement of the section. It is believed that this distinction is erroneous since if applied it would tend to eliminate the great bulk of warranty-non-negligence actions which it is intended to cover.

[305] See Dickerson, "Products Liability and the Food Consumer" §§ 2.20, 3.5 (1951) (relying on the well-known series of trichinae-in-pork cases); 1 Frumer § 25.04[2][d]; Comment, "Cigarettes and Vaccine: Unforeseeable Risks in Manu-

(Footnote continued on next page.)

Strict liability is also applied, of course, in those cases in which liability is based upon engaging in ultra-hazardous activities.[307] Although these cases are not precedent for ethical drug cases, the analogy between the two areas is appealing.[308] The behavior of the drug manufacturer is socially desirable, but it also entails certain inevitable and unusually serious risks. Liability for the harm caused by such risks could be reasonably regarded as the price the supplier pays to engage in this type of business. As stated in the commentary to the new *Restatement* section:

> [P]ublic policy demands that the burden of any accidental injuries caused by products intended to come into intimate contact with the human body, and vital to the life and health of the community, be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained.[309]

These broader issues are discussed in detail in the conclusion of this article.

For those who, when strict liability is discussed, see no end in sight except a complete insurer-type liability, the conditions and limitations which have been placed by the *Restatement* and other commentators should be considered. The new *Restatement* section expressly requires that the food or drug product which has given rise to injury must have been "in a defective condition unreasonably dangerous to the consumer." [310] An additional requirement has been noted by one writer—a reasonable expectations, or normal use test.[311] This view, which along with that of the *Restatement* formed the basis of the *Magee* decision,[312] holds that in some instances a defect which cannot be detected is not an *unreasonable* danger, and cites ethical drugs as an

(Footnote 305 continued.)
facturers' Liability Under Implied Warranty," 63 *Colum. L. Rev.* 515, 526–28 (1963).

[306] See 1 Frumer § 26.

[307] 2 Harper & James § 14, at 785; Prosser, *Torts* § 59, at 329 (2d ed. 1955).

[308] It is submitted that the case of the traveling crop spray, *Chapman Chem. Co. v. Taylor*, 215 Ark. 630, 222 S. W. 2d 820 (1949), is on point. There, ultra-hazardous liability was involved against the manufacturer of a crop spray, which spray due to an inherently unforeseeable quality spread from the applied area to plaintiff's premises. See 43 *Minn. L. Rev.* 531 (1959).

[309] *Restatement (Second), Torts* § 402A, comment *c* (Tent. Draft No. 7, 1962).

[310] *Restatement (Second), Torts* § 402A (Tent. Draft No. 7, 1962). See especially comments *g*, *h*, and *i*, explaining and defining these terms.

[311] Dickerson, *Strict Liability* at page 13; Dickerson, *Recent Developments*. See similar views of Keeton, "Products Liability—Current Developments," 40 *Texas L. Rev.* 193, 207–10 (1961). If a normal use test were strictly applied virtually every side effect would be removed from the ambit of liability, since most side effects are of an allergic nature. This, however, is not the rule, as is discussed in the next section of this paper.

[312] *Magee v. Wyeth Labs., Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963). The court determined that there
(Footnote continued on next page.)

example.[313] Other commentators [314] have sought to draw a line based on the type of product, favoring absolute liability where the product is a "non-essential" or commercial one but not where it is an "essential" one or one related to health.[315] However, this reasoning ignores the fact that there is a profit or commercial motive at base in the manufacturing of every class of product, including ethical drugs.

Factor: the abnormal patient and the idiosyncratic reaction. It is often stated, and widely believed, that the hypersensitivity of the consumer is a good legal defense, whether an action sounds in negligence or warranty.[316] The question of allergy, however, is not as simple as this general proposition suggests. In order to analyze this problem it is necessary to subdivide the subject, depending upon whether the manufacturer knows of the allergenic potential of his product and whether the suit is in negligence or warranty.[317]

(i) *Manufacturer unaware of allergenic effect of the drug*

In negligence actions, the rationale of the cases denying liability seems to rest on the lack of the manufacturer's knowledge—that is,

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(Footnote 312 continued.)
had been no warranty breached in a case of an idiosyncratic reaction to the drug, Sparine. There was no evidence, the court stated, that the drug was not *reasonably* fit for its intended purposes by the normal user. The manufacturer can expect a normal use and user, it explained. The case is further discussed at footnotes 243 and 327.

[313] The author advances as analogous the situation of the first free bite allowed a dog where the owner is unaware of his dog's vicious propensities. Dickerson, *Strict Liability* at page 14. The trouble with taking such a theory seriously is, how does one know when the second bite has been taken? How long may the manufacturer leave the drug on the market after the first tentative association has been made between use of the drug and reaction before he is no longer justifiably ignorant of its propensities? It should also be noted that Dickerson has pointed out that the patient and the doctor can reasonably expect a safe and efficacious pill. Dickerson, *Recent Developments* at pages 31–32. Also favoring non-liability in this situation, see statement by Geoghan, "Symposium—Pharmaceuticals and Products Liability Law," 29 *Tenn. L. Rev.* 231, 250 (1962).

[314] See, for example, 1 Frumer § 16.03 [4].

[315] *Id.* at page 385, relying on the bad blood cases discussed in footnote 159. The new *Restatement* section, comment *k*, discussed at footnote 304, excuses certain manufacturers from the operation of strict liability if they make a "useful and desirable product."

[316] 2 Frumer § 29; 2 Hursh § 8.3; Noel, "The Duty to Warn Allergic Users of Products," 12 *Vand. L. Rev.* 331 (1959); Annot., 26 A. L. R. 2d 963 (1952). The difficulty in analyzing these so-called "allergy" cases arises from (a) uncertainty as to whether the court felt it was deciding an allergy case (cases involving the same product being treated differently); (b) uncertainty as to whether the defendant knew of the allergenic potential of the product.

[317] For the medical aspects of allergy and the hypersensitive person, see section beginning at footnote 14 (20 FOOD DRUG COSMETIC LAW JOURNAL 332).

his inability to warn.[318] This begs the question since it has been shown previously that there is a duty to know, and, indeed, to test in order to know. If he did not know and could not have known, there is no fault. If idiosyncratic reactions are harder to foresee, then on the facts he may well be exculpated; but merely because of this medical difficulty there is no reason to erect a legal barrier against recovery.[319] Inconsistent with this reasoning, however, is the recent ethical drug case of *Morgansen v. Hicks*,[320] wherein plaintiff suffered an allergic reaction when administered an anesthesia. The Iowa Supreme Court, relying on a cosmetics case precedent,[321] briefly dismissed the action against the manufacturer on the basis that there was in Iowa no products liability for allergic reactions. It is not clear whether the Iowa court would have reached the same conclusion, however, had the plaintiff alleged and proved that the manufacturer could have foreseen the defect by the exercise of reasonable care.[322]

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[318] See *Merrill v. Beaute Vues Corp.*, 235 F. 2d 893 (10th Cir. 1956) (cold wave); *Briggs v. National Indus.*, 92 Cal. App. 2d 542, 207 P. 2d 110 (1949) (cold wave); *Moran v. Insurance Co. of North America*, 146 So. 2d 4 (La. App. 1962) (sun tan lotion); *Bennett v. Pilot Prods. Co.*, 120 Utah 474, 235 P. 2d 525 (1951) (cold wave).

[319] Indeed there is an occasional case involving an allergic reaction in which liability for negligent failure to warn has been developed even though the evidence would seem to indicate that the manufacturer did not know of the allergic potential and may not have been able to have discovered it by reasonable effort. An example is *Braun v. Roux Distrib. Co.*, 312 S. W. 2d 758 (Mo. 1958), where the user of defendant's hair dye developed an obscure disease of the arteries due to the paraphenylenediamine in the dye. The court held that the defendant knew or by the exercise of due care should have known of the danger. See also *Wright v. Carter Prods., Inc.*, 244 F. 2d 53 (2d Cir. 1957) (Arrid, a deodorant).

[320] 253 Iowa 139, 110 N. W. 2d 563 (1961). Since both the manufacturer and the doctor who administered the drug appealed from a joint verdict entered for the patient, the court grouped together its consideration of the liability of both parties, with the result that much of the language of the opinion that appears applicable to both defendants probably is only intended for the case of the physician. *Accord, Webb v. Sandoz Chem. Works*, 85 Ga. App. 405, 69 S. E. 2d 689 (1952) (allergic reaction resulted in loss of vision; the court found no specific act of negligence and refused to apply *res ipsa loquitur*); *Willson v. Faxon, Williams & Faxon*, 138 App. Div. 359, 122 N. Y. Supp. 778, *motion to withdraw appeal granted*, 202 N. Y. 542, 95 N. E. 1141 (1910) (drug is not "deleterious" solely because one person in a million of those using it has a reaction to it); *Singer v. Oken*, 193 Misc. 1058, 87 N. Y. S. 2d 686 (N. Y. City Ct. 1949) (druggist not liable for allergic reaction because he was not under a duty to foresee an individual reaction to phenol).

[321] *Bonowski v. Revlon, Inc.*, 251 Iowa 141, 100 N. W. 2d 5 (1959) (sun tan lotion).

[322] Note that when the druggist has supplied the wrong drug originally (or, it might be added, the manufacturer has prepared the wrong drug), it has been held that the fact that the patient's reaction was an unforeseeable allergic one is no defense. See, for example, *Dunlap v. Oak Cliff Pharmacy Co.*, 283 S. W. 236 (Tex. Civ. App. 1926); *Gwynn v. Duffield*, 61 Iowa 64, 15 N. W. 594 (1883).

In warranty, an additional justification for nonliability lies because it is arguable that a warranty means only reasonable fitness or fitness for the usual or normal person.[323] If this is so, then the real question is, what is normal, or, rephrased, how large a group of reactors need there be before they are sizable enough to be considered normal?[324] The issue is again a factual one. More important, if there is warranty liability where the manufacturer has done all he could—the type of strict liability considered in the preceding section—then the issue of foreseeability has been eliminated; whether the plaintiff is one in a million or one in a dozen becomes immaterial.[325] Frumer and Friedman distinguish food cases from drug cases in the following manner:

> Drug products are not natural in the sense that a strawberry is. The potentiality for harm if an ingredient is a sensitizer is usually much greater than in the case of one who develops hives after eating strawberries. If, despite elaborate premarketing testing, a consumer suffers an allergic reaction or adverse side effects, the manufacturer rather than the consumer should bear the risk of injury, at least where the drug was not prescribed by a physician with knowledge of the danger after a balancing of the risks involved.[326]

The recent case of *Magee v. Wyeth Laboratories, Inc.*,[327] however, strongly and clearly lays down the rule that a manufacturer will not be liable for a reaction that is allergic in nature.

(ii) *Manufacturer aware of possibility of drug causing allergic reaction in small group of users*

In negligence suits the weight of the products cases and the commentators agree that there will be liability, regardless of the type of reaction, if there has been failure to warn.[328] These same conclusions would apply to a warranty action.[329] [For footnote 329, see next page.]

[323] See, for example, *Ray v. J. C. Penney Co.*, 274 F. 2d 519 (10th Cir. 1959) (clothes); *Bonowski v. Revlon, Inc.*, footnote 321 (sun tan lotion); *Jacquot v. Wm. Filene's Sons Co.*, 337 Mass. 312, 149 N. E. 2d 635 (1958) (artificial fingernails); *Graham v. Jorden Marsh Co.*, 319 Mass. 690, 67 N. E. 2d 404 (1946) (cold cream).

[324] See, adopting the size-of-class test, *Crotty v. Shartenberg's-New Haven, Inc.*, 147 Conn. 460, 162 A. 2d 513 (1960) (against retailer; hair dye); *Reynolds v. Sun Ray Drug Co.*, 135 N. J. L. 475, 52 A. 2d 666 (1947) (against retailer; lipstick); *Zirpola v. Adam Hat Stores, Inc.*, 122 N. J. L. 21, 4 A. 2d 73 (1939) (against manufacturer; hat); *Esborg v. Bailey Drug Co.*, 61 Wash. 2d 347, 378 P. 2d 298 (1963) (against manufacturer; hair tint).

[325] This has been the result in some cases involving food; see *Dickerson, Products Liability and the Food Consumer* § 4.27 (1951); *Doyle v. Fuerst & Kramer*, 129 La. 838, 56 So. 906 (1911).

[326] 2 Frumer § 29.05, at 123. Thereafter follows, "(It is believed that such liability will not seriously retard the development of new drugs)." *But see* Dickerson, cited at footnote 325, at page 213.

[327] 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963).

[328] *Land O'Lakes Creameries, Inc. v. Hungerholt*, 319 F. 2d 352 (8th Cir. 1963) (fertilizer); *Wright v. Carter*

(Footnote continued on next page.)

(iii) *Manufacturer aware of possibility of drug causing an allergic reaction and gives a warning*

Under the principles discussed above,[330] there would probably be no liability, in either negligence or warranty actions.

In conclusion, it is believed that the physical nature of the plaintiff should be just another factor to be considered in issues of duty to warn, duty to know, and duty to test. Not the least impetus for this approach is the fact that in many cases it is medically undetermined whether a type of reaction is to be regarded as idiosyncratic or not, and in many other cases it is impossible to ascertain the specific nature of the user's reaction.[331] Rather than use the judicial subterfuge of ignoring the issue [332] or calling an allergy a primary irritant,[333]

(Footnote 328 continued.)
Prods., Inc., 244 F. 2d 53 (2d Cir. 1957) (deodorant; the duty to warn is not measured by numbers); *Procter & Gamble Mfg. Co. v. Superior Court*, 124 Cal. App. 2d 157, 268 P. 2d 199 (1954) (detergent); *Gerkin v. Brown & Sehler Co.*, 177 Mich. 45, 143 N. W. 48 (1913) (dye). See generally Dickerson, cited at footnote 325; 2 Frumer § 29.02[2]; 2 Hursh § 8:4; Condon, "Products Law Problems," 57 *Nw. U. L. Rev.* 536, 541 (1963). The manufacturer, after all, is not required to foresee the specific type of harm which in fact is inflicted upon the patient but is only to know of the dangerous propensities of his product in a general way.

[329] See *Crotty v. Shartenberg's-New Haven, Inc.*, 147 Conn. 460, 162 A. 2d 513 (1960) (hair dye); *Bianchi v. Denholm & McKay Co.*, 302 Mass. 469, 19 N. E. 2d 697 (1939) (face powder); *Zirpola v. Adam Hat Stores, Inc.*, 122 N. J. L. 21, 4 A. 2d 73 (1939) (dye in hat).

[330] See text beginning at footnote 203. But even here it is at least arguable that warranty liability can nevertheless exist, even in cases involving allergic reactions. Defense of this position is made in 2 Frumer § 29.05, at 124–25. And, as Harper and James note, where there has been a warning but no device provided for the user to determine if he is one of a class likely to react, there is in fact incomplete warning and the *allergic plaintiff* argument should not be used to shift the risk of harm to the user who is unaware of his allergic potential. 2 Harper & James § 28.8, at 1551, n. 3.

[331] See medical discussion footnote 27. Thus, is an anaphylactoid reaction to penicillin an allergic or toxic reaction? If no antibody-antigen relation can be found, is the reaction an "allergy"? Should the "allergy rule" apply to a toxic reaction to a dose that is proper for 99% of the users but represents an overdose for a very few?

[332] See instances cited in 2 Frumer § 29.01, at pages 103–05. Indeed, some courts conclude that there is no *allergy* issue where there is medically an allergic reaction but where it is not an uncommon one.

[333] See, for example, cases involving the same products as mentioned in preceding footnotes with the same chemical substances but characterized as irritants with a denial that an allergic reaction was involved, *Brennan v. Shepherd Park Pharmacy, Inc.*, 138 A. 2d 494 (D. C. Mun. App. 1958) (hair dye); *Patterson v. George H. Weyer, Inc.*, 189 Kan. 501, 370 P. 2d 116 (1962) (hair dye). Nor is it good medicine to ask about the type of plaintiff rather than the type of ingredient; to declare that the plaintiff should not recover because he is "an allergic type," as the occasional case will state, is to create a pseudo-scientific issue.

the issue should be squarely faced; and, once faced, it should be regarded as a factual question.[334]

4. *Other Factors in Pure Drug Cases*

a. Incomplete or improper directions for use; wrong dosage

In the rare case in which a manufacturer has erred in his directions as to dosage, mode of administration or the like, and this error is the cause of injury to a patient, negligence liability would follow rather clearly.[335] A special problem arises where the directions are correct but the manufacturer has simply not made a pill or capsule of a size fit for a particular patient, usually a child. *Marcus v. Specific Pharmaceuticals, Inc.*,[336] took the view that there was no duty to make a pill of any particular strength or size. This principle of free enterprise would seem correctly applied, short of a case of deception or even negli-

[334] Indeed the "allergy rule" collides with the more fundamental tort principle that "you take your victim the way you find him." See also 2 Harper & James § 28.8, at 1551–52, where the whole allergy matter is given a quick, unsympathetic onceover on the basis of a foreseeability problem. Note also the views of Boshkoff, cited in footnote 303, at pages 301–02, who by proposing the use of a "consumer expectation" test for warranty liability concludes that allergy should not be a defense since the expectations are frustrated.

[335] Generally on improper instructions as a factor in negligence, see 1 Frumer § 8.05. *Accord, Marx v. Schultz*, 207 Mich. 655, 175 N. W. 182 (1919) (druggist applied a label to a prescription drug which called for three teaspoons of the drug rather than the three drops prescribed).

In particular, see *Gielskie v. State*, 9 N. Y. 2d 834, 216 N. Y. S. 2d 85, 175 N. E. 2d 455 (1961), *affirming*, 10 App. Div. 2d 471, 200 N. Y. S. 2d 691 (1960), *settled*, 11 App. Div. 2d 877, 205 N. Y. S. 2d 1003 (1960), *reversing*, 18 Misc. 2d 508, 191 N. Y. S. 2d 436 (Ct. Cl. 1959); *earlier decision, Gielski v. State*, 3 Misc. 2d 578, 155 N. Y. S. 2d 863 (Ct. Cl. 1956). The state provided doctors with tetanus anti-toxin which it had manufactured. In its accompanying literature the state stated that it could be administered several ways including intraspinously. It was plaintiff's contention that the intraspinous route was no longer an accepted method and that in making this statement the manufacturer was being careless. The trial court agreed but the Appellate Division reversed on the basis that evidence was insufficient to show negligent deviation from standard practice. *Gielskie* does raise an interesting issue of whether there is a duty upon a manufacturer at all to describe the proper route for administration of a drug (as compared to volunteering the wrong route). Since the FDA requires this sort of information on some labeling, see footnotes 88 and 97 (20 Food Drug Cosmetic Law Journal 346, 348), and since good manufacturing practice is to recommend or advise possible routes of administration, it would seem that there could well be liability for failure to provide this information, at least when it could be foreseen that the doctor would not be familiar with the proper routes.

[336] 191 Misc. 285, 77 N. Y. S. 2d 508 (Sup. Ct. 1948) (further discussed in footnotes 226, 227). A change of strength without sufficient notice to the profession would be an example of negligence, however, as would any significant but unheralded modification. See also the discussion of *Hruska v. Parke, Davis & Co.*, 6 F. 2d 536 (8th Cir. 1925), footnote 195.

gent misrepresentation about the usefulness of the pill for a certain class of patients.

b. Failure to provide information on contra-indications, on tests to detect reactions, or countermeasures.

Analogous to the duty to be aware of and report on side effects would be a duty to give information on the following three matters, where available:

(a) Contra-indications for use of the drug, that is, pre-existing pathological conditions which will make the use of the drug peculiarly dangerous;[337]

(b) Tests which may be used before administration of a drug to determine whether there will be a reaction, or to detect incipient reactions after use has begun which, if caught in time, can lead to withdrawal before symptoms become permanent;

(c) Countermeasures or antidotes which will prevent a full reaction or a permanent worsening of condition of the patient suffering from a reaction, as was the basis for liability in the recent case of *Charles Pfizer & Co. v. Branch.*[338]

c. Effect of modification or withdrawal of drug or change of directions

In some ethical drug cases the issue will be the evidentiary effect which should be accorded to events which take place after a drug has been marketed. Such events might include modification of the drug's formula or the molecular structure of its active chemical with the purpose of eliminating a side effect; modification of its instructions and warnings; or withdrawal of the drug either voluntarily or pursuant to FDA order. It would appear to be of probative value if, after discovery of a harmful side effect, a manufacturer took one or more of the above actions.[339] On the other hand, none of these acts would prob-

[337] See *Fuhs v. Barber,* 140 Kan. 373, 36 P. 2d 962 (1934) (action against druggist for injuries attributable to use of a drug which druggist recommended and which reacted with a drug she was already using; duty upon druggist to warn that a drug, harmless in itself, may react with other substances).

[338] 365 S. W. 2d 832 (Tex. Civ. App. 1963). *Accord, Johnson & Son, Inc. v. Palmieri,* 260 F. 2d 88 (1st Cir. 1958) (manufacturer of furniture polish liable for inadequate post-accident instructions which advised user to wipe off polish if spilled but did not say to use soap); Federal Hazardous Substances Labeling Act, 74 Stat. 374 (1960), 15 U. S. C. § 1261(g) (Supp. IV, 1963), requiring, *inter alia,* any hazardous substance intended or suitable for household use to carry an instruction, where necessary, for first-aid treatment.

[339] See *Carter Carburetor Corp. v. Riley,* 186 F. 2d 148 (8th Cir. 1951) (CAA's directions for repairs of pumps on airplanes were themselves evidential of the pump's deficiencies).

ably be deemed sufficient to make out a prima facie case. Where official FDA orders or demonstrable behind-the-scene coercion was present, of course, relatively stronger evidence of fault would be present, especially because of the similarity of this situation to that in which a manufacturer has failed to comply with FDA investigation or marketing requirements.[340] Though otherwise relevant, testimony on the several amendatory acts mentioned might be prohibited by application of the *repairs doctrine*.[341] Where modification or withdrawal is compulsory, the rationale of the doctrine would not apply. Also, certain exceptions have all but destroyed the doctrine today; these would justify use of this relevant data for the "limited purposes" of showing knowledge the manufacturer had of the harmful propensities of the drug, or of showing those reasonable steps which the manufacturer could have taken to correct the dangerous situation.[342]

Negligence might also be attributed to the manufacturer in cases in which there had been undue slowness in removing a drug from the market after an FDA order to do so, or after the manufacturer's own voluntary decision; or negligence might be attributed to a failure, after an order or decision to withdraw the product, to recall stock on hand from pharmacies and dispensaries.[343]

C. Inefficacious Drug—Failure to Cure

In a situation in which an ethical drug fails to cure a certain disease which it purports to cure, reliance upon the drug by a doctor and his patient may aggravate the patient's condition and leave him with a permanent disability which he would not have suffered had he been administered another, more effective medicine. Such a lack of efficacy in a drug may be caused either by an inherent lack of

[340] See discussion, at footnote 281.

[341] The argument against the admission into evidence of "repairs" made (after the alleged injury) to an allegedly negligent condition seems to rest on the fear that admissability would discourage the making of repairs, exposing others to injury. See generally 1 Frumer §12.04; McCormick, *Evidence* § 77, at 159, § 252, at 543 (1954); 2 Wigmore, *Evidence* § 283 (3d ed. 1940); Annot., 64 A. L. R. 2d 1296 (1959).

[342] See works cited in footnote 341. In *Young v. Parke, Davis & Co.*, 49 Pa. Super. 29 (1912), a veterinarian used an experimental drug made by defendant upon plaintiff's horse; apparently the manufacturer soon thereafter changed the formula to meet the possibility of future wrong use. The court held that evidence of this change could not be introduced.

[343] In a recent unreported case the basis for liability was failure to recall a drug withdrawn from the market at a proper speed from a hospital dispensary where it was still on hand. It was administered to the plaintiff nearly one year after withdrawal. The settlement, in *Gibson v. Eli Lilly & Co.*, was accepted by the Supreme Court in Buffalo, N. Y. Reported, *Drug News Weekly*, Nov. 28, 1962, p. 15.

ability to cure or by a defective batch from which the active ingredient has been omitted. The question posed in this section is whether there is or should be manufacturer liability in such a situation, or in one in which a vaccine fails to give immunity to a disease, or where an oral contraceptive fails to prevent an unwanted pregnancy?

The problem of drug inefficacy because of a failure of the product to measure up to even the manufacturer's standards may be put to one side as an easy case since this is simply an impure drug. As to the inherent lack of drug efficacy—analogous to design fault—such a suit is virtually without precedent in the ethical drug area.[344] Other types of products liability cases predicated upon safety devices that did not function might be analogized to inefficacious drug cases and thus provide a basis for liability.[345] While it is true that in safety device cases liability has been found because of unsafeness and not inefficacy, still it was the failure to live up to the created expectations of positive performances that underlay liability. Inducing use and creating reliance based upon a false sense of usefulness constitute the culpable conduct of the supplier. Beyond an action for negligence or for negligent misrepresentation, an express warranty action might also be available in the case of an ineffective drug, since such a drug is used only because the manufacturer has claimed it to be proper for a certain condition, and it has not lived up to that express promise.[346]

III. Injury Caused by Drug in Experimental Stage

When a drug is in an experimental stage and has not yet been cleared by the FDA for general marketing, the situation is very different, both medically and legally, from that which has been considered above. While there are no decided cases in this area, either against

[344] An action has been filed against the manufacturer of Norlutin which, it is claimed, failed to prevent a pregnancy. See *Medical Economics*, Jan. 1, 1962, p. 130; 4 *Personal Injury News Letter* 171 (1962). *Accord, Charles Lomori & Son v. Globe Labs.*, 35 Cal. App. 2d 248, 95 P. 2d 173 (1939); *Brown v. Globe Labs., Inc.*, 165 Neb. 138, 84 N. W. 2d 151 (1957).

[345] For example, *Brooks v. Allis-Chalmers Mfg. Co.*, 163 Cal. App. 2d 410, 329 P. 2d 575 (1958) (negligent design of boom safety device); *Beckhusen v. E. P. Lawson Co.*, 9 N. Y. 2d 726, 174 N. E. 2d 327, 214 N. Y. S. 2d 342 (1961), *reversing* 9 App. Div. 2d 536, 196 N. Y. S. 2d 531 (1960) (safety mechanism on paper cutter failed). Many cases involving failure of brakes are collected in 3 Hursh §§ 17:10-:16.

[346] See *Brown v. Globe Labs., Inc.*, cited in footnote 344. The recent amendments to the Drug Act expressly making efficacy a concern of the FDA in New Drug Applications (see footnotes 77-79, 20 FOOD DRUG COSMETIC LAW JOURNAL 345) may sharpen interest in the civil liability aspects as well.

manufacturers or against doctor-administrators of investigational drugs,[347] it would be reasonable to expect litigation in the future. In considering manufacturer liability for injury caused by a drug not marketed, it is necessary to determine what type of person was injured. Four types, corresponding to the stages of testing a new drug, can be distinguished:

(a) Normal subjects, usually paid and under contract, used to determine the most rudimentary data on gross effects and tolerances of a normal person;

(b) Patients, usually in a hospital, on whom the drug is used, not in the hopes of curing them and often without the subject's knowledge.

(c) Patients, usually in a hospital, suffering from the condition sought to be affected, sometimes used without the subject's consent.

(d) Private patients of physicians, treated as they would be if the drug were cleared and on the market, with the consent pattern being the same as that in any ordinary private situation.[348]

What distinguishes a products liability suit in this area is that the manufacturer through its clinical investigators has caused harm while trying out a drug to determine if it is feasible to market, feasibility being measured by effectiveness, safety and profit potential. This distinction cuts two ways. On the part of the protagonists of liability for harm arising from an investigational drug, it may be said that the

[347] There is a body of law in malpractice in which the term *experimentation* is used, opprobriously, to indicate a type of medical fault. In new drug experimentation, however, a doctor is generally investigating a new drug or a new use of an established drug. See generally Stetler & Moritz, *Doctor and Patient and the Law* 326 (1962). In this area of the paper it is better to call the doctor's work *investigation* since he is doing what is proper for studying pre-clearance drugs. Here there would be no automatic malpractice because of *experimentation*, although there is as yet no case law on this point. See footnotes 50-53 (20 FOOD DRUG COSMETIC LAW JOURNAL 340) on the proper precautions such an investigator is to take. In the final stages of testing, when a physician is using a drug at its recommended dosages upon a private patient, the situation is indistinguishable from ordinary use in practice. On the physician's liability in use of drugs before they are marketed see Hatry, "Editorial," 4 *Clin. Pharm. Therap.* 4 (1963) (perceptive article by a lawyer); Ladimer, "Medical Experimentation: Legal Considerations," 1 *Clin. Pharm. Therap.* 674 (1960); Ladimer, "Ethical and Legal Aspects of Medical Research on Human Beings," 3 *J. Pub. L.* 467 (1954); Louisell, "Legal Limits on Human Experimentation," 6 *Arch. Environ. Health* 784 (1963); Markel, "Legal Considerations in Experimental Design in Testing New Drugs on Humans," 18 FOOD DRUG COSMETIC LAW JOURNAL 219 (1963).

[348] See general discussion of these requirements in text beginning at footnote 32 (20 FOOD DRUG COSMETIC LAW JOURNAL 336).

drug manufacturer is risking the life or limb of a person to determine if he has an economically successful product, and for this opportunity the manufacturer should pay his way.[349] The reply might be that the clinical investigation of new drugs is necessary in order to prevent a product from being released into the general stream of commerce which is capable of harming many; that such investigation is required by law and closely controlled by it; and, therefore, if anything, the manufacturer should be no worse off in such a case than if harm arose from an established drug and indeed should be put in a more insulated position, since it is socially desirable to have new drugs developed.

A. Releases and Consents; Medical Dictates

Medical and industrial practices in regard to obtaining releases or informed consents from subjects is also relevant to manufacturer liability. As to industrial practice, it is not uncommon for a drug manufacturer, through the clinical investigator, to pay a person to be a control or normal subject for tests. This payment would tend to exculpate the manufacturer, at least so long as the payment is intended in part to cover the risk of injury. In the usual situation of the unpaid volunteer, however, it would be difficult to make out voluntary consent or assumption of risk. Even if he does know that an experimental procedure is being practiced on him, it is unlikely that the subject realizes the specific risk which he is undertaking. His consent by submission could be properly regarded as consent to the procedure alone.[350]

In most instances, as a result of FDA requirements or general medical practice,[351] a form of consent or release will be obtained from the patient by an administering or prescribing doctor. In this connection it is of interest to note the ethical requirements generally stated to

[349] It is difficult to find analogies in products liability cases since drugs are virtually the only product which go through a recognized trial stage and yet involve the use of a large number of persons as subjects who are not the employees of the manufacturer. Perhaps the very fact that some manufacturers in other industries use employees rather than outsiders for testing adds weight to the argument of the protagonists of liability.

Perhaps error lies in looking to products liability law at all as the source of legal analogy. It could be argued, effectively, that the closest situation is malpractice. The manufacturer in testing out his drug is like the doctor testing out a new substance. The trouble is, there is no more of a body of law here in the malpractice area than in the products area.

[350] On assumption of the risk as a defense, see 1 Frumer § 14; Prosser, *Torts* § 55 (2d ed. 1955).

[351] The relationship between the doctor-investigator and the manufacturer who will eventually market the drug varies. The most common relationship, and the one assumed in this section and in the general discussion on clini-

(Footnote continued on next page.)

apply to physicians using experimental drugs. The following stipulations are those established by the American Medical Association (AMA): [352]

(a) Secure the consent of the patient;

(b) Use drugs supplied only from a reputable source and only if the manufacturer provides written information on animal experiments, previous clinical investigations, recommended dosages, known contra-indications, side effects encountered, and known safety and efficacy of the drug;

(c) Perform tests under adequate medical protection;

(d) Have a reasonably accurate diagnosis of the patient; and

(e) Believe that existing methods of treatment are unsatisfactory.

(Footnote 351 continued.)
cal investigations in the text beginning at footnote 39 (20 FOOD DRUG COSMETIC LAW JOURNAL 338), is that the doctors are selected by and report to the manufacturer, and their agreement with the company can be broken by the latter at any time. It is also possible for researchers to do independent, unsolicited work on a drug, although they usually will at least have to go to the manufacturer for a supply of the drug. Admittedly, even the doctors who are picked by the company and who report to it are independent to a certain extent. They can often select the number of patients, the type of examination to be made, and the dosage and the duration of the study. Nevertheless, the assignments of the doctors and the suggestions in the clinical brochures furnished them by the manufacturer constitute general directions on how to proceed. Indeed, if testing is not uniform it may be impossible to compare the results of one investigation with that of another. The manufacturer knows that it has certain comprehensive data which it must supply in support of its NDA, and these needed pieces do not fall into place by accident.

The issue is whether the elements of selection and direction mentioned above would impute negligence of the investigator during the tests to the manufacturer. Labeling the doctor an "independent contractor" is not a solution because there are aspects of true agency in the relationship and because the law no longer automatically awards immunity from vicarious liability to the employer of an independent contractor. Prosser, *Torts* § 64 (2d ed. 1955); 2 Harper & James § 26.11. More important is an evaluation of the nature of the investigator's acts and omissions, and the benefit derived by the drug house. Different results might follow, for example, if the liability asserted is for the injury of a subject during the trials, the topic of this section, as compared to the situation in which previous careless testing by the investigator is being urged as a ground of negligence where a patient is harmed by the drug after it is marketed. At this point it is interesting to inquire what the theory of action against the manufacturer is. While this paper has been framed in terms of negligence in making and selling, it is also possible to envision liability here in terms of "malpractice"—the doctor's malpractice is that of the manufacturer under principles of respondeat superior. As to the two aspects of investigational negligence discussed above, subject injury and careless testing, manufacturer negligence would be applicable to both, but malpractice would probably be applicable only to the former.

[352] Reply to Query, *A. M. A. News*, July 10, 1961, p. 4; AMA, *Opinions and Reports of the Judicial Council* 14 (1960); AMA, *Medicolegal Forms* 37 (1961). In
(Footnote continued on next page.)

Specifically as to the consent requirement, attention has already been given to the battle which developed when the FDA and members of Congress advocated placing in the proposed new drug regulations a requirement that a clinical investigator obtain an *informed* consent from every patient or subject before an investigational drug could be administered.[353] Massive criticism from organized medicine and individual practitioners of high stature, as well as from the drug industry, led to modification of the requirement, leaving a loophole not requiring consent if it would not be scientifically feasible or good for the patient.[354] A seeming conflict exists between the AMA legislative attitude that consent should not always be required and its ethical pronunciamento that it is an obligation of the doctor to always obtain an informed consent.[355] A partial explanation may lie in applying the AMA rules to the final stage of drug testing, where there is a private patient-physician relationship, and not to the highly impersonal true investigational stages. Such a line is not only hard to draw but it is also hard to justify.

If the manufacturer is mentioned in the release, and especially if it runs to the manufacturer, the release would probably protect him from suit for harm caused by the drug. Even if the form did not mention the manufacturer, the same concept of agency which makes the manufacturer liable for the experimenter's malpractice could be applied to make the manufacturer the principal whose agent, the doctor, receives this release or consent. This would be so, however, only if it were an informed consent and a knowing and unambiguous release. The patient would have to know more than that he was being treated with a new drug not yet on the market. He would have to know the risks associated with the specific drug, including such details as were known or should have been known to the manufacturer.

B. Negligence Actions

On what basis could a *negligence* action be brought where harm arises from a drug which is in its pre-clearance stages? It would seem

(Footnote 352 continued.)
the last reference, note especially Form 29, "Authority for Treatment with Drugs Under Clinical Investigation," a form of perhaps questionable validity since it does not on its face purport to inform the patient what the actual risks are but only generally that the procedure is experimental. See text beginning at footnote 347.

[353] See footnote 44 (20 FOOD DRUG COSMETIC LAW JOURNAL 339).

[354] See footnote 55 (20 FOOD DRUG COSMETIC LAW JOURNAL 341).

[355] This is pointed out by Lear, "Human Guinea Pigs and the Law," *Saturday Review*, Oct. 6, 1962, p. 55. It is possible that the whole consent requirement in medical practice is inserted more to insulate the doctor from suit than to inform the patient. The medical profession tends to feel that no layman can really be told what a drug is and what it is being used for.

that an action here would be no different than a negligence action in the case of an established drug. It would be difficult to require *more* care here than in established drug cases, since the manufacturer proceeds under greater handicaps and with less knowledge. Some of the specific acts or omissions which might be found to constitute negligent deviation from the general standard of care in this area could include the following:

(a) Failure to inform the doctor of known side effects or contraindications which have turned up in previous animal or human subject tests;

(b) Failure to know about existence of side effects or contraindications because of inadequate previous testing, errors in studies, choice of poor investigators, or the like;

(c) Failure to comply with FDA regulations relating to the proper method of conducting investigations or making reports thereon, violated provisions of which are proximately related to the subsequent injury;

(d) Use of more than a necessary number of subjects and patients, thereby exposing the injured plaintiff to an unnecessary risk;

(e) Allowing the drug to be sold by a pharmacist or used by a doctor in ordinary prescription treatment by distributing samples too widely and without an intent to benefit specifically from the results of the use of the drug in the particular case in which there was harm; and

(f) Developing intentionally a useless or practically useless drug by either combining two known drugs for no benefit except sales or developing an inefficacious drug.

Since it appears that injury or even death of trial subjects can probably never be eliminated, and since the burden of their injuries can not fairly be put upon the subjects themselves because they are volunteers, or because of the social need for doing experiments, or on the theory that injury to the lesser is a beneficial protection of the greater, solutions involving compensation plans [356] or indemnification of drug manufacturers by the government[357] have also been proposed. [For footnote 357 see next page.]

[356] See, for example, Comment, "Legal Implication of Psychological Research with Human Subjects," 1960 *Duke L. J.* 265. Special legislation was proposed for the victims of the Cutter vaccine accident, H. R. 8082, 8th Cong., 1st Sess. (1957), but it was not passed. See discussion in Note, "Strict Liability for Drug Manufacturers: Public Policy Misconceived," 13 *Stan. L. Rev.* 645, 651 (1963).

Individual doctors have successfully sought indemnity agreements with the

(Footnote continued on next page.)

IV. The Imposition of Strict Liability upon the Drug Manufacturer

Relatively little problem has been encountered in this paper regarding the use of a negligence theory of action against the ethical drug manufacturer. When it comes to strict liability, however, there is much dispute—whether accomplished through warranty theory, a strict tort theory, or the theory that non-fault liability follows from engaging in a hazardous business. Both as to drugs and products generally there has been much partisan writing and some impartial commentary on strict liability.[358] Any such evaluation of the maximum liability which should be fixed upon the drug houses, as a matter of social policy, involves two subordinate questions; namely, the effect of strict liability upon the manufacturer and the protection it affords the consumer.[359]

The imposition of strict liability has sometimes been justified on the basis that it will produce greater care on the part of the manufacturer.[360] Of all the types of products, however, ethical drugs would

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(Footnote 356 continued.)
manufacturers of drugs with which they are experimenting. This is reported to be a common but unadvertised practice. Lasagna, *The Doctors' Dilemma* 144 (1962).

[357] According to HEW General Counsel, Alanson Wilcox, the subject of indemnification has been proposed from time to time, but if the government were to participate, legislation would be required and it might well be limited to only those situations in which the government had some control over the drug, such as ordering its withdrawal. *Medical Tribune,* Nov. 16, 1962, p. 8. See also Editorial, 137 *Science* 989 (Oct. 14, 1960). A possible parallel in legislation exists in the Atomic Energy Act, 71 Stat. 576 (1957), 42 U. S. C. § 2210 (Supp. IV, 1963), provisions for indemnification of private users for reactor explosions and similar disasters. See Ely, "Nuclear Liability, Limitations and Indemnification," 30 *Ins. Counsel J.* 217 (1963).

[358] See Ehrenzweig, *Negligence Without Fault* (1957); Dickerson, *Strict Liability;* Dickerson, *Recent Developments;* James, "General Products—Should Manufacturers Be Liable Without Negligence?," 24 *Tenn. L. Rev.* 923 (1957); Keeton, R., "Conditional Fault in the Law of Torts," 72 *Harv. L. Rev.* 401 (1959); Prosser, "The Assault Upon the Citadel (Strict Liability to the Consumer)," 69 *Yale L. J.* 1099 (1960); Note, "The Cutter Polio Vaccine Incident: A Case Study of Manufacturers' Liability Without Fault in Tort and Warranty," 65 *Yale L. J.* 262 (1955); Note, "Strict Liability for Drug Manufacturers: Public Policy Misconceived," 13 *Stan. L. Rev.* 645 (1961); Comment, "Cigarettes and Vaccines: Unforeseeable Risks in Manufacturers' Liability Under Implied Warranty," 63 *Colum. L. Rev.* 515 (1963). These three student notes, incidentally, form a most interesting contrast in student attitudes toward manufacturer liability and liberality of tort law.

[359] This subject is badly in need of a socio-economic study to determine factually what the impact of strict liability would be upon the drug industry. Extralegal studies of the drug industry of this type, but on different aspects, have been cited in footnotes 39 and 106 (20 FOOD DRUG COSMETIC LAW JOURNAL 338, 349).

[360] James, cited at footnote 358; Note, 65 *Yale L. J.* 265, 272 (1955).

seem to least fit this reasoning.[361] Numerous factors presently hold the drug houses to a very high standard of care, including (1) the existence of rigid scientific and medical standards which are in large part closely followed; (2) internal production controls and a tradition of absolute purity in manufacture; (3) stiff competition in the industry and commensurate concern for reputation; (4) exceedingly strict governmental requirements and supervision; and (5) the imposition of negligence law requirements. Also, some side effects appear simply to be undetectable, no matter how intense the effort, until they are first encountered in clinical practice. It is not accurate, however, to declare that negligence law today sets as high a standard as possible, or that strict liability by its nature can add nothing to responsibility, being by definition liability without fault.[362] It is conceivable that a manufacturer, informed by its counsel of the possibility of the imposition of strict liability, will proceed with even greater care and use more tests for the early detection of impurities or side effects.

Even if strict liability can not be justified by increasing the care given by the manufacturer and thus ultimately decreasing the number of reactions to drugs, it may nonetheless have a desirable effect by inducing the manufacturer to spread the risk of injury, either by obtaining insurance or otherwise providing for the contingency of harm.[363] It is true, of course, that a manufacturer can not accurately insure against harm from a new drug, because he does not know what type of harm

[361] See "Strict Liability of Manufacturers for Injuries Caused by Defects in Products—An Opposing View," 24 *Tenn. L. Rev.* 938, 945 (1957); Prosser, footnote 358, at page 1119; 13 *Stan. L. Rev.* 645, 646-47 (1961); 63 *Colum. L. Rev.* 515, 538 (1963). There seems to be little basis for making a distinction, on the basis of preventability, as the Columbia Note does, between new and established drugs. The deterrence of liability factor is not more significant in new drugs than in established ones, especially since new side effects are often discovered in thoroughly "established" drugs.

[362] This is the view taken in 13 *Stan. L. Rev.* 645, 646-47 (1961).

[363] On products liability insurance generally see 2 Frumer § 50; Arnold, "Products Liability Insurance," 1957 *Wis. L. Rev.* 429. Generally on the topics of risk spreading, loss allocation and the like see Calabresi, "Some Thoughts on Risk Distribution and the Law of Torts," 70 *Yale L. J.* 499 (1961); Morris, "Enterprise Liability and the Actuarial Process—The Insignificance of Foresight," 70 *Yale L. J.* 554 (1961). See also Sellinger, "Beneficiaries of Sales Warranties in New York: Some Questions and Comments on New Legal Doctrine," 4 *B. C. Ind. & Com. L. Rev.* 309 (1963), and works cited at footnote 358. If the resource allocation justification of Professor Calabresi were adopted for strict liability in the ethical drug trade, the problem of lack of foresight for the spreading of risks on unforeseen drug reactions would be avoided as the liability incurred would just be part of doing business.

and in what degree it may be anticipated.[364] However, the almost universal practice is for insurance to be obtained for all drugs manufactured, or at least for a large number of one type, which significantly diminishes lack of actuarial foresight.[365] Insurance coverage today is believed to be adequate for most drug reaction situations,[366] except perhaps for the occasional "disaster," such as involved Cutter Laboratories. The area of investigational drugs probably presents a loophole in adequate insurance coverage, but the incidence of liability is quite small. There is already a form of compensation in existence through the industry's policy of voluntary care for injured subjects, and its reimbursement of doctors who are successfully sued.[367] Strict liability may also lead to the request by manufacturers that the government cover their losses, especially those of a catastrophic nature.[368]

Critics of strict liability predict that its imposition will harm the industry and thereby ultimately hurt the consumer.[369] These predicted effects include the following: (a) driving some firms into bankruptcy and squeezing others out of business due to loss of profits; (b) stifling progress and inhibiting the development of new drugs by decreasing incentive; (c) raising the cost of drugs; and (d) delaying the marketing of needed drugs while further testing and experimentation is carried on. None of these arguments is valid, it is believed, when the nature of the drug industry is realistically considered.[370]

As to bankruptcy, it is hard to imagine any drug company today whose financial situation is so marginal that it is unable to purchase insurance and itself be a self-insurer beyond the limits of the coverage. Cutter Laboratories, often given as an example of the bankrupting effects of strict liability,[371] is in fact very much in business today.[372]

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[364] See 13 *Stan. L. Rev.* 645, 648(1961).

[365] Letter from Dr. Irving Ladimer to Paul D. Rheingold, April 8, 1963.

[366] See results of a survey of manufacturers, 13 *Stan. L. Rev.* 645, 648-49 (1961).

[367] See footnote 356.

[368] For a detailed discussion of governmental compensation, see Rosenthal, Korn & Lubman, *Catastrophic Accidents In Government Programs* (1963).

[369] See Plant, cited at footnote 361; Sellinger, footnote 363, at page 329; 13 *Stan. L. Rev.* 645, 649-51 (1961).

[370] There is a paucity of literature on the economics of the drug industry. See Lessing, "Laws Alone Cannot Make Drugs Safe," *Fortune,* March 1963, p. 123; Hampton, "Ethical Drugs —A Close Look at the Embattled Ethical Drug Industry," 91 *Chem. Week* 134 (1962); Bauer & Field, "Ironic Contrast: United States and U. S. S. R. Drug Industries," *Harv. Bus. Rev.* 89 (Sept.-Oct. 1962).

[371] See, for example, 13 *Stan. L. Rev.* 645, 648 (1961).

[372] See "How Cutter Came Back," *Business Week,* Feb. 24, 1962, p. 139. Cutter's estimated loss is therein set at $4 million, an amount which includes losses on the product itself in part occasioned by the recalling of the unused vaccine.

If a particular drug company chose to absorb the costs of civil suits rather than pass them on to the consumer, and if that company were one operating on a marginal profit, it might indeed be forced out of business, but it would be hard to show that the public would thereby be the loser. If, on the other hand, the cost of obtaining insurance is passed on to the consumer, the price of drugs will concededly rise; however, it is not likely that it will rise significantly because of the large volume of sales of a particular drug which will absorb the extra cost.[373]

Those who attack strict liability seem to feel that they have dealt it its most stunning blow by their reference to the effect upon the research on new drugs.[374] A close examination of this assertion proves it to be without substance, however, since a company is impelled to search for and develop new drugs for its very existence. To stay in business it must develop new products. No company will go out of business because of increased tort liability.[375] Indeed, if civil liability were capable of such disastrous effects, such effects would already have been caused by the imposition of negligence liability.[376] Or, if that would not have done it, and if this negligence liability were survived, the stringent governmental requirements would have administered the financially crippling blow. As for the final supposed "danger" of strict liability, the delay in marketing new drugs, it seems difficult to say that a rule which requires more testing, which testing will directly tend to eliminate injurious qualities, is undesirable. Clearest of all is the proposition that the ultimate loss should not be borne by the individual who suffers a devastating reaction to a drug.[377] There exist adequate

[373] The drug industry is not a particularly good example of "elastic demand." A slight increase in cost will not lead either to a significant decrease in demand nor to the use of substitutes. For example, there is only one manufacturer of Chloromycetin, Thalidomide, Aralen, and most of the drugs discussed in this paper, due to the patent laws.

[374] See articles cited at footnote 369.

[375] See Prosser, footnote 358, at page 1122. See also Boshkoff, "Some Thoughts About Physical Harm, Disclaimers and Warranties," 4 *B. C. Indust. & Com. L. Rev.* 285, 302-03 (1963). The reason which the last author advances for the ability of any enterprise to stay in business even after an increase in its extent of liability is that it has the ability to warn of the dangers and thus shift off the risk to the consumer. This, however, is unrealistic; it would be hard to imagine a court that would say that a warning which ran "Caution: any number of unknown side effects may come to be associated with use of this product" would preclude a plaintiff from suit. See footnote 191.

[376] See Prosser, footnote 358, at page 1122; 65 *Yale L. J.* 262, 264 (1955).

[377] There is, however, some dissent. One student author, for instance, has declared that "it seems to be fortuitous whether a manufacturer is better able to shift losses than is an individual plaintiff." 13 *Stan. L. Rev.* 645, 648 (1961).

means of shifting this liability, whether it is to the public in its role as the drug buyer or in its role as the stockholder. This is the price paid for engaging in a risky business.[378] As stated by Professor James, "When unexpected dangers develop from the use of a valuable new product, the industry producing it . . . would have to compensate the innocent victims of those dangers."[379]

V. Summary

It is concluded that as to *established* drugs, where the drug can be shown to be impure, there will be little difficulty in an injured user's maintaining either a negligence or a warranty action. A misrepresentation action, based upon either intent or negligence, can also be easily maintained where the drug is impure. As for side effects inherent in pure drugs, the breach of the duty to warn adequately will often constitute sufficient ground for negligence liability. If there has been full warning to the doctor (and it is only he who needs to be warned), there will be no negligence, and probably no breach of warranty. The manufacturer may be found negligent even where he did not know of the effects of his drug if it can be shown that he deviated from his standard of care in not knowing, and specifically, in not making tests adequate to discover the untoward effects. Even in the situation in which the manufacturer could not have known by any exercise of scientific care of the adverse effects until they first occurred, it is arguable that a breach of warranty exists. This is especially so if a concept of strict liability is applied. The role of allergy as a defense is minor, if applicable at all; but contributory negligence, assumption of risk, and intervening negligence of the doctor are available defenses. Liability for harm arising from an experimental drug is relatively easier to establish than that for an established drug since the manufacturer is engaging in a risky business. Finally, strict liability, where its prerequisites are met, is not an undue burden upon the manufacturer, who can take reasonable steps to shift his losses. [The End]

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[378] See discussion relating extra-hazardous activities to drug liability beginning at text accompanying footnote 307.

[379] James, "Products Liability," 34 *Texas L. Rev.* 192, 215 (1955). See also Keeton, R., *Legal Cause in the Law of Torts* 103-17 (1963).

The Role of Scientific Research in the Food and Drug Administration

By WILLIAM H. SUMMERSON

The Following Article Was Presented at the Annual Research and Scientific Development Conference of The Proprietary Association Held in New York City on December 10, 1964. Dr. Summerson Is Director, Bureau of Scientific Research, Food and Drug Administration.

AS THE TITLE OF MY TALK INDICATES, I propose to discuss briefly with you today the role of scientific research in the Food and Drug Administration (FDA). I shall relate my remarks as specifically as possible to drug research, since I am sure that this will be of more interest to you than if I were to present our total research program.

The first question that may well come to your mind might be why the FDA supports any scientific research programs at all. The basic mission of FDA is to protect the consumer by insuring the safety and integrity of our foods, drugs, therapeutic devices and cosmetics. At first glance, there would appear to be little requirement for scientific research in such a mission. However, when one looks into the mechanisms which must be used to establish and maintain the safety and integrity of consumer goods, the requirement for scientific research becomes somewhat more evident. In general, standards of safety and integrity are quantitative standards; they must be established and defined on the basis of scientific experimentation and analytical methodology. Deviations from these standards, if they occur, must also be definable in terms of scientific fact.

Specifically, the establishment by FDA of effective rules regarding the safety of foods, drugs and colors must be based on a review by skilled scientists of the experimental data submitted by industry

in support of applications for the distribution of new products. Furthermore, this technical review must keep in step with the constantly expanding technological base of the food and drug industries. For example, over the five-year period from 1957 to 1962, the drug industry expanded its research expenditures from $104 million annually to approximately $275 million annually, and this expansion is still continuing. Scientific technology is also expanding at a rapid rate, particularly with respect to instrumentation and automation, as we all know. If our scientists are to serve the best interests of industry and of the consumer, they must be a part of this steady stream of scientific progress, and contribute to it by their own research efforts. Our scientific research should assist in answering questions of the moment, where the data are inadequate or inconsistent. It should also provide a sound basis for understanding future technical problems as they arise. Only by maintaining an active research competence can we expect our scientists to be able to cope with the rapid progress being made today in science and in industry. These then are some of the reasons for the maintenance of an active scientific research program by the FDA.

FDA's Research Structure

Let us now take a brief look at the research structure within the Food and Drug Administration. Research programs of one kind or another are actively in progress in the Bureau of Medicine, the Bureau of Regulatory Compliance, the Bureau of Scientific Standards and Evaluation, and the Bureau of Scientific Research. Of these various bureau programs, I propose to discuss only that of the Bureau of Scientific Research, since this is the bureau of which I am the director, and about whose program I know the most. Furthermore, the Bureau of Scientific Research has by far the largest and most active research program within FDA, and it likewise has a responsibility for long-range research as well as for research which is generated by scientific problems of the moment.

The Bureau of Scientific Research is a relatively new organization. The bureau was organized approximately one year ago to provide the FDA with an organization which could devote the major portion of its time and talents to the scientific research problems which are associated with the mission requirements of FDA, and which would at the same time be relatively free from the technical and administrative pressures which are inevitably associated with the

responsibilities of a regulatory agency. It is believed that such a research organization should be able to make much more rapid progress toward the solution of FDA's research problems than was possible under the previous organization. It is not possible at the present time to give a true measure of the validity of this concept since, as I have indicated, this approach is a relatively new one. Only the future will provide evidence regarding its adequacy or inadequacy to meet the needs which generate it.

Let us take a more specific look at the resources available to the new organization. The Bureau of Scientific Research presently contains about 450 people of whom approximately 60% have a professional degree in one field or another. Of our professional staff, approximately two-thirds are chemists. The remaining professional specialists include microbiologists, pharmacologists, biologists, veterinarians, medical officers, mathematicians, food technologists, and physicists. The largest group other than chemists consist of microbiologists, to the extent of approximately 14% of the total professional staff, followed by pharmacologists and medical officers who comprise 9% of the total staff. The other specialists are present in relatively small numbers.

Looking more closely at the chemists among our professional personnel, we find that approximately 48% are analytical chemists, followed by 26% biochemists, and 21% general chemists. We also have a few organic and physical chemists.

It is clear from this professional talent profile that our major research programs employ the disciplines of chemistry, microbiology, and pharmacology, supported by a number of other disciplines to a minor extent. Within the field of chemistry, our major interest is clearly analytical chemistry, but there is also a significant emphasis on biochemistry and nutrition.

This group of professional personnel is supported by a budget which currently amounts to approximately $5.5 million a year. Almost all of this budget is devoted to in-house research. I feel that this is a major imbalance at the present time and I am doing what I can to expand the support of our research program by research grants and contracts placed outside of our organization. If we can increase our extramural research program significantly, I feel that the resulting total program will provide us with a much better opportunity for obtaining new research ideas and concepts than we now have.

With regard to facilities, our laboratories at the present time are located in Washington and we have a special animal pharmacology laboratory at Beltsville, Maryland. Our laboratories at the moment are crowded and relatively inadequate with respect to modern requirements. However, just being completed is an up-to-date modern laboratory building in Washington, which will house most of our research activities. We expect to occupy these new and very modern laboratory quarters some time next spring.

While I have indicated that our current laboratory facilities leave much to be desired, I must hasten to add that, in my opinion, our laboratory equipment is excellent. We have every variety of modern equipment which can be useful to our research program and we have some advanced research equipment which is found to only a limited extent elsewhere. This points up one of our main program objectives, which is to keep abreast of modern technological developments in laboratory research regardless of their sophistication, so that we may exploit fully the possible application of such new techniques to the routine technical requirements of the entire FDA organization.

I should now like to give you a few specific examples of the types of research currently in progress with respect to drugs. In the field of analytical chemistry for example, we are applying modern techniques of UV, IR, and NMR spectrometry to the differentiation of drug isomers, the detection of cosmetic components, and the precise identification of very small quantities of known drugs. We have recently published a comprehensive library of the infrared spectra of a variety of known drugs, and I have here an example of this publication. In the field of nuclear magnetic resonance or NMR spectra, we are pioneering the application of this powerful tool to the identification of a wide variety of pharmaceutical substances. As a first step in the process, we are preparing an NMR library comparable to the IR library I just mentioned. We constantly seek to provide improved chemical procedures for the precise analysis and identification of National Formulary items, and we also have a program on improving the U.S.P. methods for the chemical analysis of various drugs. An additional example of our research is a program for obtaining optical crystallographic data on all National Formulary XII crystalline substances so that these materials can be precisely identified under the crystallographic microscope.

Another one of our research programs which will be of interest to you is the so-called "pillistics" program. Here we are concerned

with the identification of drug tablets or pills with regard to their site of manufacture. We have assembled a large collection of drug tablets from many manufacturing sources and have catalogued these tablets in terms of their physical characteristics, such as size, shape, color, proprietary markings and marks associated with the use of specific dies or presses to produce the tablets. With this information available, we feel that we can identify almost any drug tablet submitted to us with respect to the place of manufacture, at least within the United States. This information is primarily of value to us in helping to establish the identity or spuriousness of drug tablets collected by our field inspectors from either labelled or unlabelled sources. We use the comparison microscope for this purpose, quite analogous to the procedure used by police laboratories in determining whether or not two different bullets have been fired from the same gun. It is because of this analogy that we have labelled this our "pillistics" program.

Turning now to certain biological aspects of our drug research program, an important research area relates to *drug bioassay*. Not infrequently, a characteristic biological effect of a drug may be the best measure available of the potency of a drug preparation. We seek improvement with respect to specificity or simplicity in the bioassay of drugs. For example, we are currently evaluating methods for determining the biological activity of thyroid preparations. We are also exploring the possible use of drug-induced ventricular fibrillation as a basis for evaluating the efficacy of antiarrythmic drugs proposed for clinical use. We are also developing tissue culture techniques as a basis for a better understanding of the action of drugs at the cellular level.

Another aspect of our biological research program relates to the precise measurement of skin irritancy and eye irritancy. We are measuring the skin irritancy of certain cosmetic components, and the eye irritancy of plastic contact lenses. Our goal here is not so much the measurements themselves but rather the development of experimental techniques which will be of direct applicability to man. We also have some basic studies underway with regard to the mechanisms of skin and eye penetration, and of skin sensitization.

As I indicated earlier, I have limited my examples of research in progress largely to drugs and related areas. Just for the record, I should like to add here that we also have research programs on various scientific aspects of the safety and integrity of foods as well

as drugs; research programs which parallel in many ways those I have just described for drugs, and which likewise serve to support FDA in the discharge of its assigned mission.

I should like to add one final word with regard to our research philosophy. All of the research programs that I have described to you today are, in my opinion, in the area of *applied research.* You will have noted that the research objectives are invariably associated with some specific aspect of either the safety or the integrity of a drug or a therapeutic device. I feel that this is the way it should be. Scientific research on foods, drugs and cosmetics has an important role in the accomplishment of the FDA mission. Our goal is the establishment and maintenance of a scientific research capability which will support FDA objectives not only for the present but also for the future. **[The End]**

DRUG ABUSE CONTROL AMENDMENTS BECOME LAW

On July 15, 1965, the President signed the "Drug Abuse Control Amendments of 1965." The amendments are designated "An Act to protect the public health and safety by amending the Federal Food, Drug and Cosmetic Act to establish special controls for depressant and stimulant drugs and counterfeit drugs, and for other purposes." They become effective the first day of the seventh month after enactment, that is, on February 1, 1966.

The amendments provide stronger controls over manufacture, distribution, delivery and possession of counterfeit drugs and of depressant and stimulant drugs, including barbiturates ("sleeping pills"), amphetamines ("pep pills") and other psychotoxic drugs having a potential for abuse because of their depressant, stimulant or hallucinogenic effects.

The law eliminates the necessity for the FDA to prove interstate traffic in counterfeit drugs or in depressant and stimulant drugs. The controls apply regardless of the interstate or intrastate origin of the drug traffic.

Under the law wholesalers who handle depressant or stimulant drugs must register with the FDA, and manufacturers will be required to supplement their existing registration if they make these drugs. All persons who deal in these drugs will be required to prepare a complete and accurate inventory of their stocks on hand as of the effective date, February 1, 1966. After that, required production, shipment, and sales records will enable FDA to make any necessary checks. Pharmacists and doctors who dispense the drugs must also keep invoices and prescriptions for the covered drugs for a period of three years.

FDA inspectors assigned to the illegal drug traffic area of enforcement will have the authority to seize the illegal drugs and to arrest persons who are engaged in illegal operations. Special penalties are provided for those who illegally sell or give the drugs to anyone under 21 years of age. Otherwise, penalties for violations of the Federal Food, Drug and Cosmetic Act apply.

FOOD DRUG COSMETIC LAW JOURNAL

PUBLISHED BY

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

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