Cleveland Clinic Quarterly

Volume 31 APRIL 1964 No. 2

PHYSICIAN'S LIABILITY WHEN USING NEW OR EXPERIMENTAL DRUGS

CARL E. WASMUTH, M.D., LL.B.
Department of Anesthesiology

THE recent publicity given adverse and unanticipated physical reactions of patients who have received new or experimental drugs, and the new statutory regulations, have caused some physicians to question the legal propriety of "clinical trials." While many courts have spoken around this issue, few have faced it directly. This whole field of law is rather complex and may not be condensed into a simple unqualified statement, but a few recent cases do somewhat clarify the issue.

Before determining the extent of the physician's liability for harmful reactions resulting from administration of drugs, one must review the statutory and case law of product liability as it applies to drugs and medicines. In broad terms, liability for harmful reactions produced by a drug can rest on four bases:

(1) The negligence of the druggist or the manufacturer in the compounding or in the labeling of a drug.

(2) The breach of any warranty,* expressed or implied, by the manufacturer

**Warranty—Derivatively, the word imports the same kind of a transaction as a "guaranty," but in legal conception the words are distinguishable. Each of them is an undertaking by one party to another to indemnify or make good the party assured against some possible default or defect in the contemplation of the parties; but a "guaranty" is understood, in its strict legal and commercial sense, as a collateral warranty, and often as a conditional one, against some default or event in the future, whereas "warranty" is generally understood as an absolute undertaking in praesenti as well as in futuro, against the defect, or for the quantity or quality contemplated by the parties in the subject matter of the contract. In the sale of a commodity, an undertaking by the construed as a warranty, though the seller uses the word "guarantee." —Ballentine, J. A.: The College Law Dictionary. Rochester, New York: Lawyers Co-Operative Publishing Company, 1948, p. 528 and 880.*

that the drug or medicine is merchantable and fit for the purpose for which it is intended.

(3) The breach of an implied warranty by the druggist that the drug is wholesome and that the prescription was compounded accurately.

(4) Any fraud or deceit of the manufacturer or of the druggist who sells the drug or medicine which caused the injury.

The Druggist

When the druggist fills a prescription and then sells the compounded medicine to the patient, this constitutes both the exercise of his professional ability and the sale of a product. According to the Uniform Sales Act and Uniform Commercial Code, a prescription is a "sale by description." It will be noted that the physician, the author of the prescription, is not a party to this transaction. By writing the prescription, the physician merely describes the combination of the drugs he advises for the patient and the manner in which they are to be taken. The specific contents are described by the prescription and the compounded medicine must contain these exact agents in their specified quantities. For this, the patient relies wholly upon the integrity of the pharmacist, his ability to compound the prescription, and his knowledge of pharmacology, of toxicity, and of dosage of drugs. While case law does not make the pharmacist an insurer of his product, statutory provisions and cases based on violation of statute tend to approach this end.

The courts have always held the druggist to the "reasonable" standard of care. In fact, the courts have consistently held that the druggist impliedly warrants the prescription compounded by him is "wholesome." Drugs and medicines are classified with food products. The purveyors of food and drugs, in the law warrant that their products are fit for human consumption.

The courts readily appreciate that drugs may be poisonous and harmful. Therefore, they place upon the pharmacist the duty to exercise that degree of care, diligence, and prudence in handling these drugs which is commensurate with the danger involved.[1]

When dangerous and toxic drugs are sold, the pharmacist must be exceedingly cautious. The phrase "ordinary care" must be considered with reference to the special and peculiar hazards and toxicity of the drug.[2]

However, in view of the high degree of care and skill imposed upon the pharmacist, he is not necessarily responsible for an error in judgment which is reconcilable and consistent with the exercise of ordinary skill and care.[3] This is in accordance with fundamental rules of law applied to practitioners in other professions.

A peculiar situation arises, however, when the pharmacist is requested to fill a physician's prescription in which the dose of drug obviously is in error. In this situation the law imposes upon the pharmacist the duty to inquire of the physician whether the physician wished to administer such a large dose of medicine to his

patient. Likewise, if the physician's prescription creates doubt in the mind of the druggist as to what drug is intended, then the druggist must exercise care and clarify the physician's intent.[4] The claim that the physician's handwriting was illegible, or that the prescription was written in Latin is no defense for the pharmacist.[5]

However, when the druggist sells a patent or proprietary medicine in its original package and the purchaser asks for the drug by a specific trademark or proprietary name, the druggist's liability is limited. His responsibilities become those of a retailer who is subject only to the Uniform Sales Act or Uniform Commercial Code. He is not required to analyze the contents of each bottle or package he receives. If he delivers the bottle to the customer who requests it with the proprietary label intact, his liability is limited by the various statutes. In a recent case,[6] the State Pharmaceutical Board of Minnesota sought to enjoin a supermarket from selling prepackaged trade-name drugs and medicines. The court found that there was no greater damage to the public when these drugs were sold at self-service counters in supermarkets than when sold by a clerk in a drugstore. All control over usage and dosage ceased upon completion of the purchase and delivery to the customer.

The sale of medicines and drugs is within the police powers of the individual states. Therefore, many state statutes exist which control sales within the individual state. These are wholly beyond the scope of this report. Some of these statutes require: a written record of sales of poisons; or that the seller inquire of the purchaser whether he is aware of the poisonous character of a substance such as carbolic acid; and further require that the poison will be used for legitimate purposes. Several state statutes require the druggist to question the purchaser about his knowledge concerning the poisonous or deleterious propensities of the drugs. This questioning is an obvious warning to the purchaser that the drug is dangerous. Of most significance, however, is the fact that regulatory statutes have criminal penalties attached, as well as civil liability. It becomes evident that this whole field of statutory law bears little influence on the use of experimental drugs except the duty imposed by the law upon the druggist.

The Drug Manufacturer

Upon the drug manufacturer the law imposes more stringent standards, both by State and Federal statute and by case-law.

It is well-settled law of implied warranties that there can be no recovery against a retail merchant under the following conditions: (1) when the buyer did not rely on the retailer's professional skill and judgment; and (2) when the drug was purchased under a patent or trademark name in its original package. However, under this rule, the patient or purchaser would be without a legal recourse should he be harmed or poisoned by a prepackaged (patent) medicine that he buys over-the-counter. The local pharmacist would not be liable because it is a prepackaged item

compounded by the manufacturer. Yet the manufacturer would not be liable because the patient purchased it from a pharmacy and not from the manufacturer. Ordinarily, to be liable for the sale of a product, the manufacturer must sell directly to the consumer. Once the retailer or wholesaler is interposed, then liability is negated. This situation would be unfair and inequitable. To solve the problem, the courts merely placed upon the manufacturer of the drug an implied warranty: (1) That the product is fit for the purpose intended; (2) That, if taken as prescribed, it will not produce harmful results; (3) That ordinary skill and care have been exercised in the preparation of the medicines; (4) That the medicine is merchantable but not necessarily the best.[7]

The sale of drugs therefore becomes an exception to the general rule requiring privity of contract in the sales of goods.

Based on these premises, interesting legal points arise in the relationship of patient and pharmaceutical manufacturer. Suppose a physician injects into a patient a drug or medicine which is not wholesome or merchantable legally speaking. Can the patient bring an action against the pharmaceutical house? The patient did not purchase the drug from the manufacturer. The physician purchased it from a local pharmacy, a wholesaler, or direct from the pharmaceutical house. The patient was not a party to the purchase. In law, he is said "not to be privy to the sale." Therefore, under many cases, he may not enter suit based on this contract. It is said that lack of privity will bar recovery from a manufacturer.

Currently, this whole field of law is undergoing severe scrutiny by the various courts. "It is a fact of everyday life that product-caused injuries frequently befall one whose contact with the product does not stem from any contractual relationship between himself and the manufacturer or seller of the product. Notwithstanding this absence of contractual relationship the injured party frequently looks to the manufacturer or seller as a source of compensation for his injuries."[8]

It is interesting to note that the Uniform Sales Act does not employ the term "privity." The Uniform Commercial Code, however, touches upon the question of privity in Section 2-318, stating that a seller's warranty whether expressed or implied extends to any natural person "who is in the family household of his buyer or who is a guest in his home" if it is reasonable to expect that such person may "use, consume or be affected by the goods" and who is injured in person by breach of the warranty.

Express Warranty

The prevailing view is that privity is indispensable to a successful warranty action. However, exceptions to this general rule have been made in sales of unwholesome food products. This exception is founded on public policy. An exception is made when the buyer or consumer relies on the manufacturer's statements in advertising or on labels. This exception is based on breach of express warranty, and no privity of contract is necessary. In the now famous Toni Home Permanent Case

in Ohio, the Supreme Court of Ohio stated, "...where a manufacturer of a product makes representations in its advertising as to quality and merit of its products aimed directly at the ultimate consumer, and urges the latter to purchase the product from a retailer, and such ultimate consumer does so in reliance on and pursuant to the inducement of the manufacturer and suffers harm in the use of such product by reason of deleterious ingredients therein, such ultimate consumer may maintain an action for damages immediately against the manufacturer on the basis of express warranty, notwithstanding that there is no direct contractual relationship between them."[9]

In still another case,[10] the court held that in "...articles dangerous to life, if defective, the manufacturer, who alone is in a position to inspect and control their preparation, should be held as a warrantor, whether he purveys his products by his own hand or through a network of independent agencies. This is true since, in either case, the essence of the situation is the same: the placing of goods in the channels of trade, representations directed to the ultimate consumer and damaging reliance by the latter on those representations." In this case, the wife of a restaurant proprietor brought an action for injuries to her hands from using *Tide*. Lack of privity was admitted. Her husband had purchased the *Tide*, but representations of the manufacturer were said to be inducements to buyers and to be regarded as warranties imposed by law directly to the ultimate consumer.

Implied Warranty

Thus, in jurisdictions where privity of contract is required in an action on warranty, exceptions are made (1) when the product is inherently dangerous, (2) when it is a food, and (3) when the manufacturer or advertising warrants the product. In addition, most courts will waive the privity prerequisite when the manufacturer misrepresents the product. This is illustrated in the case[11] where the plaintiff charged the pharmaceutic company with misrepresentation "...by concealing the fatal propensities of its product." The court invoked the rule "...that one who misrepresents for his gain and benefit, at the expense of human life, is answerable in fraud for all the reasonable and foreseeable consequences of his deception."

The court in this case also stated that if the problem of privity of sale bothered anyone, that the court would hold "...that the physician who prescribed the drug was acting on behalf of the (patient) and the fraud committed on the (physician) was, therefore, a fraud upon the (patient)."

In still another case, Parke, Davis & Company manufactured *Camphor Solution Neutral* and advertised it as suitable for hypodermic use. The court said that Parke, Davis & Company " . . . was conducting a highly technical and specialized business. Its products were to be employed in curing the ills of the human body and in preserving human life. The (company) dealt with the public to be treated with its preparations and drugs, not on an equal footing, but with the understanding

that the public would trust the defendant's superior knowledge in the manufacture of (such) products."[12]

The courts in many states now hold the manufacturer of medicines liable in implied warranty to the ultimate consumer or the patient. But it is necessary to show that there was something actually wrong with the product. This would include: (a) Product was negligently compounded. (b) Product was not the product that was ordered. (c) Product was actually poisonous.

There have been several successfully litigated actions against manufacturers of ostensibly harmless but actually harmful drugs and medicine. In 1935, streptococci and staphylococci were, to the court's satisfaction, found to be present as contaminants in a product called *Lactigen*, manufactured by Abbott Laboratories. The accompanying literature did not warn that the agent should not be used if it were coagulated. Within 45 minutes after the injection, a (the) patient's arm, became hot and swollen. Subsequently, streptococci and staphylococci were isolated from the pus in the arm. The court ruled that Abbott Laboratories was negligent in failing to warn the physician that when this substance was coagulated it was unsafe. *Lactigen* was sold for administration only by a physician. Abbott Laboratories was liable for the injuries to the patient based on negligence.[13]

In Wennerhold versus Stanford University School of Medicine,[14] a physician prescribed *Dinitrophenol* for the treatment of obesity. While this agent has been recommended for the treatment of myxedema and obesity by stimulating metabolism, it also had been cited as causing agranulocytosis. In this particular instance, the patient took the medication and lost her vision.

The plaintiff alleged that the manufacturer knew the drug was inherently dangerous to life and liable to cause blindness. The court held the manufacturer liable by false representations made to deceive with the intent to induce the public to purchase the drug. The fact that the patient took the drug on the prescription of a physician did not influence the court. It stated that in an action for fraud, it is not required that the patient's representations be the sole cause of the damage. Even though the patient relied on the advice of her physician, the misrepresentations by the manufacturer were sufficient to induce her to take the *Dinitrophenol*.

Recently, Salk vaccine, a "new" drug, was administered to an infant who then contracted poliomyelitis. The vaccine, which contained live virus, was purchased by the physician from a pharmacy. This vaccine was manufactured according to the requirements of the National Institutes of Health of the United States Public Health Service. Accompanying the ampules was a brochure stating the ". . . virus is inactivated by formaldehyde." Also contained in the brochure was information on dosage and administration. ". . . it is impossible to find a (statement) that the vaccine is fit for its purpose and is merchantable."

The jury found that the Cutter Laboratories was not negligent in the manufacture of the vaccine. However, as mentioned above, the manufacturer impliedly

warrants wholesomeness or purity. "With regard to the law of warranty, however, we feel that we have no alternative but to conclude that Cutter Laboratories . . . (marketed) a vaccine which, when given to plaintiffs caused them to come down with poliomyelitis, thus resulting in a breach of warranty. For this cause alone we find in favor of plaintiffs." This case involved judgments in excess of one-half million dollars.[15]

The Court of Appeals in California considered the case: Can a manufacturer be liable upon implied warranty when the drug was not sold to the patient? In answering this question, the court recognized that drugs and medicine were in a similar category as food. It is the established rule in California that the consumer of a food product may recover from the manufacturer upon implied warranty of wholesomeness.

Cutter strongly argued that public policy would best be served by denying recovery in warranty for "new" drugs. The argument is that development of medicines will be retarded if manufacturers are held to strict liability for their defects. "While this argument might have merit if the warranty involved had to do with the mere failure of a medicine to cure, or, of a vaccine to prevent a disease, it seems to be of little weight where, as here, the warranty is limited to an assurance that the product will not cause the very disease it was designed to prevent."

Contrast this statement on drug warranty with the holding of this same court when it determined the liability of a physician utilizing a new technic in the now famous aortography case. In speaking of the application of the doctrine of res ipsa loquitur (which California courts have been known to apply on several occasions), the court said:[16]

"To apply it (res ipsa loquitur) in all cases where an unexpected result occurs would hamstring the development of medical science. No medical man would dare to use new procedures because if injury resulted, he would be prima facie guilty of negligence. Medical science has developed in leaps and strides in the past few years. Procedures that ten years ago would have been considered impractical and fatal are now being used successfully. . . . Thus, a great responsibility rests upon the courts . . . to be fair to the patient . . . and to be fair to the medical men if there is a result which would occur without negligence . . ."

Physician's Liability

Thus, it may be seen that the manufacturer by case-law is for all intents and purposes an insurer of his manufactured product because of implied warranty. The physician, however, may not be held to such a strict liability when employing new procedures and perhaps, by inference, when administering new drugs.

The law has well established the elements of standards of care required of a physician. In addition, the rules of consent are fairly well delineated. Their applicability to the administration of new or research drugs, has to my knowledge, never

been litigated. It becomes necessary then to review several landmark cases. Recently, the Kansas Supreme Court stated:[17]

"Anglo-American law starts with the premise of thoroughgoing self-determination; each man is considered to be master of his own body and he may, if of sound mind, expressly prohibit the performance of lifesaving surgery or other medical treatment, and while a doctor might well believe that an operation or form of treatment is desirable or necessary, the law does not permit him to substitute his own judgment for that of the patient by any form of artifice or deception."

It is admitted that consent of the patient is required before treatment is instituted. However, it is elementary that consent is implied when the patient consults the physician in his office, or, when the patient is admitted to the hospital for treatment. Whether the patient signs or does not sign a "Consent Form" is a matter of evidence beyond the scope of this paper. Suffice it to say that some courts accept the admission of the patient to the hospital as prima facie evidence of consent to treatment. The question arises immediately: Did the patient consent to ordinary and necessary treatment or did the patient consent to new, experimental, or research treatment?

New or experimental drugs can be administered to animals and their effects observed and monitored. Do these same medicines act similarly in the human? Or, do these medicines have deleterious actions on the human mechanism? This we determine only by administering them to humans.

In *American Jurisprudence*[18] it states that "...although it is the duty of a physician or surgeon to keep up with the advancement made by his profession, it is also his duty to refrain from trying experiments on his patients. It is incumbent upon him to conform to the mode established by his school of practice for the treatment of given conditions, and if he departs therefrom he does so at his peril." However, a physician may adopt new methods as they are approved by the profession.[19]

This qualification gives to the profession the opportunity to make progress after the experimental stage in the development of a new method is passed, but it does not authorize the trying of untested experiments on patients.

The question immediately arises, "What constitutes an experimental stage?" Is it the period of experiments on animals? Does it extend into the subsequent period during which the drugs are administered to human beings? In the legal literature, the answers to these questions are extremely difficult to find. If the treatment used is approved by a "respectable minority of the medical profession," then the physician employing this treatment would be relieved of a charge of malpractice. The physician is obligated only to use reasonable skill, and he fulfills this obligation if he uses methods approved by others of the profession.[20]

To hold otherwise, the court would come close to saying that if a physician did not use the classic method of therapy, his treatment would be tantamount to malpractice. This would be a judicial fiat stating that pneumonia must be treated by "blood letting" or be malpractice.

Let us take the question one step further: Is there liability for selecting one method of treatment to the exclusion of others?

In the Baldor case,[21] the patient suffered from carcinoma of the lips and requested the physician not to operate upon the lesion. The physician then elected to use the Koch method which consisted of the injections of "glyoxylide." The court recognized that there was no sure cure in the treatment of cancer. The record of the case cited numerous references by physicians to the treatment of cancer with chemotherapy, hormones, synthetic chemical compounds, nitrogen mustard, aminopterin, *Krebiozen*. Finally, the court said that the heroic efforts being made by members of the medical profession and other scientists only emphasize that an enemy is so far being fought in the dark and that one man should not be condemned from the fact alone that he chooses a weapon that another may consider a reed. Thus, we find authority for the use of drugs in the treatment of cancer which are accepted only by a minority of physicians. To the court's mind, this was an incurable disease. The court permitted the use of an "experimental" drug. In this case, however, the court, on rehearing, pointed out that the treatment never had any beneficial effects. The physician had the duty of informing the patient that the treatment was not successful and that other methods should be tried. His failure thus to inform the patient, was malpractice.

The mere circumstance that another physician might have adopted a different treatment does not constitute negligence. The test is whether the treatment was a reasonably skillful, careful, and prudent method under the facts and circumstance of the particular case.

We must not draw from the Baldor case[21] more than it contains. An unrecognized form of therapy was utilized for cancer for which the court said, there is no "sure cure." One must make the distinction between an unrecognized and an experimental drug. The court merely held that it does not determine that a certain drug must be used, but that a certain drug *may* be used even though it is not an accepted treatment.

The general rule of law is: "If a physician or surgeon experiments in a mode of treatment or method of operation on a regular patient who is unaware that he is experimenting and such acts are the sole and proximate cause of the damage to such patient, he is liable for such damages as are authorized by law."[22] However, that the treatment used was of comparatively recent origin ought not, ipso facto, to put it in the class of an innovating experiment. Should damage or injury befall the patient as a result of a new treatment, the physician would not be liable for such bad result.[23] In these days of rapid transportation and communication, there is no reason why enlightened medicine with its improved practices and facilities should not be available to all.[24]

Not having found authority for the physician to use experimental drugs, but in fact, having found ample authority that the physician uses such drugs at his legal

peril, how is the medical profession to find and institute new therapeutic agents? The answer is relatively simple—obtain the permission of the patient to use these experimental drugs. Of course, there are alternate methods—for example, do not inform the patient. However, the physician must be cautioned concerning the latter method. Unless he has ample and just medical reason for not informing the patient, the physician is subjecting himself to scrutiny by the courts should a litigation result from the procedure performed without the patient's informed knowledge. The physician occupies a position of trust and confidence in relationship to his patient. Therefore, it is his duty to act with the utmost good faith. A physician is under obligation to speak fairly and truthfully, at the peril of being held liable for damages for fraud and deceit.[25]

In the aortography case,[26] the patient, his wife, and his son were not told that an aortogram was to be performed. Because it was a new technic, they had no knowledge of the dangers of this new and hazardous procedure. The appellate court stated that the physician must make disclosure of all the facts that mutually affect the patient's rights and interest, and make a full disclosure of surgical risks, hazard, and danger. But the physician may exercise discretion with such full disclosure. Was the physician under an obligation to reveal that the treatment was new? If he does reveal these risks, the patient can make an intelligent decision to accept or reject the treatment. As a general rule, the physician is under an obligation to reveal sufficient information so that the consent given is informed. But the physician may withhold information if its disclosure would be harmful to the patient.

In the Salgo decision, the court said:[26]

"A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise, the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. At the same time, the physician must place the welfare of his patient above all else and this very fact places him in a position which he sometimes must choose between two alternatives of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation; no matter how remote. This may well result in alarming an unduly apprehensive (patient) and who may as a result refuse to undergo surgery in which there is in fact minimal risk. It may also result in actually increasing the risks by reason of the apprehension alone. The other is to recognize that each patient represents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent."

Therefore, the patient is entitled to a reasonable disclosure by the physician so that he can intelligently decide whether to take the new, experimental, or hazardous

treatment and assume the risks therein, or, in the alternative, to decline this treatment and take a chance with older types or no therapy at all.

Thus, we see that informed consent is not consent in the strict sense of the term used in medical parlance. Informed consent is a duty of care imposed by the law upon the physician for a full disclosure in that relationship of trust between the physician and his patient. It is the physician's duty to disclose to the patient (except in particular circumstances) that the treatment is new, that the treatment may have side-effects which are as yet undetermined, and that the efficacy of the treatment on human beings is still not known.

The practice of securing authorizations from the patient may be of some value. However, such a form should not be one of consent. The suit resulting from the use of experimental drugs probably will be one of malpractice. Should the physician wish to obtain some protection, he has just to establish a good physician-patient relationship. When there is a complete understanding between the two parties, the probability of litigation becomes ever smaller even without consent. However, in an attempt to guarantee security against suit, some physicians look to written authorizations based on full disclosures:

New Drug Treatment

Date:_____

Doctor_____has offered to prescribe for me (or to administer to me) a new drug_____manufactured by_____. I fully understand that this is a new drug and that it has only limited human trial. I fully understand that there is a risk of untoward reactions occurring as a result of treatment with this medicine.

Signed_____

Witness_____

The physician's liability in administering new or experimental drugs seems to be clear: It is incumbent upon him to exercise reasonable care and skill in the practice of medicine. Tell the patient of the intended use of the new drug and warn the patient of the possible inherent hazards and the dangers not yet determined or determinable. This also fulfills the requirements of the new revisions of the U. S. Federal Food, Drug and Cosmetics Act contained in Public Law 87-871, 87th Congress, S. 1552, October 10, 1962, and as modifying 21 USC 357 (d) 505 providing:

"(2) The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the

drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings.

"Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings."

The situations where the physician need not inform his patient include: (a) where they (the physicians) deem it not feasible to inform the patient, or, (b) where, in their (the physicians') professional judgment, it is contrary to the best interest of the patient to inform him.

In addition to these safeguards the drug should be administered by an expert investigator. This may not include the average practicing physician. Instead, it probably refers to a physician most familiar with the disease treated and who, in all probability, devotes a considerable amount of his time to the treatment of this or associated diseases or to the practice of this specialty area. In addition, such a physician should probably be associated with an institution, hospital, or clinic which devotes a considerable portion of its program to clinical research and which institution has the facilities, personnel, and equipment to observe the patient properly and to make any scientific or analytic determinations to detect abnormal or otherwise unanticipated reaction of the body to the medication.

References

1. Allen v. State SS Co. 132 NY 91, 30 NE 482.
2. Faulkner v. Birch 120 Ill App. 281.
3. Tremblay v. Kimball 107 Maine 53, 77 A 403.
4. Jones v. Walgreen Co. 265 Ill App. 308.
5. Tombari v. Connors 85 Conn 231, 82A 640.
6. State v. Red Owl Stores, Inc. 115 NW_2 643.
7. Wallace v. Clark & Son 21 ALR 368.
8. 75 ALR_2 43.
9. Rogers v. Toni Home Permanent Co. 167 Ohio St. 244 147 NE_2 612. 75 ALR_2 103.
10. 75 ALR_2 87 (Warley v. Procter & Gamble Mfg. Co. 241 Mo App. 1114, 253 SW_2 532).

11. Wechsler v. Hoffmann-La Roche, Inc. (1950) 198 Miss 540, 99 NYS_2 588.
12. Hruska v. Parke, Davis & Co., 1925, C. A. Mo $6F_{2d}$ 536.
13. Abbott v. Lapp decided 1935, 78 Fed. 2nd 170, 79 ALR 2nd, p. 371, 1935, CA7 Ill.
14. Wennerhold v. Stanford University School of Medicine 1942 20 Cal_2 713 128 P_2 572.
15. Gottsdanker v. Cutter Laboratories et al. 6 California Reporter 320, 1960, District Court of Appeals.
16. Salgo v. Leland Standord, Jr. University, Board of Trustees 317 P_2 170.
17. Natanson v. Kline (1960) 186 Kan 393 P_2 1093, clarified and reh den. 187 Kan 186 354 P_2 670.
18. 41 AM Jur 204.
19. Miller v. Toles 183 Mich 252, 150 NW 118.
20. Dohl. v. Wagner 87 Wash 492, 151 P 1079.
21. Baldor v. Rogers (Fla) 81 SO_2 658, 55 ALR_2 453.
22. Am Jur P & P Forms 15-1078. 1.
23. McClarine v. Grenzfelder 147 Mo App. 478, 126 SW 817.
24. Sinz v. Owens (Cal. App.) 196 P_2 52.
25. 41 Am Jur 195.
26. Salgo v. Stanford Univ. 154 Cal App_2 560, 317 P_2 170.