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Volume 14
Issue 3 *Medicolegal Symposium*

Article

1965

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Recommended Citation

Edward T. Haggins, *Due Care by Physicians in Use of New Drugs*, 14 *Clev.-Marshall L. Rev.* 506 (1965)

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Due Care by Physicians in Use of New Drugs

*Edward T. Haggins**

HOW CAREFUL must a physician be in using new drugs on his patients? There are enough cases to give us some idea of the proper standard of care.

A young switchboard operator sustained a cut on the middle finger of her left hand while cleaning her glasses. She was sent to a nearby hospital for emergency treatment by her supervisor. Upon arriving at the hospital emergency ward, she was given a penicillin shot followed by a skin sensitivity test in the upper right arm to determine her susceptibility to "horse serum," which is the most common base used in tetanus antitoxin. Approximately five minutes later she received 1,500 units of antitoxin by hypodermic injection in her upper right arm. By the time she reached her car, the sensitivity test was showing a positive reaction. Fifteen days later, a roaring began in her ears. Five months later she suffered 50 to 55 percent permanent loss of hearing in both ears.¹

In Hackensack, New Jersey, a dentist administered the drug "epinephrine" to a female patient before making an extraction. This drug is used to constrict blood vessels. The patient, who was suffering from hypertension, died of a stroke after leaving the dentist's office.²

In a recent California case, a patient was injected intravenously with a dose of "Bicillin" (a pharmaceutical trade name for a preparation of penicillin). About three hours later he experienced some itching and discomfort. Several days later his condition worsened, with swelling about the face. He was hospitalized in a serious condition. After going through a critical stage, he recovered; however, in doing so, he suffered the loss of sight in one eye and serious impairment of vision in the other eye.³

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¹ *Neely v. St. Francis Hospital and School of Nursing Inc.*, 188 Kan. 546, 363 P. 2d 438 (1961).

² *Sanzari v. Rosenfield*, 34 N. J. 128, 167 A. 2d 625 (1961). Defendant failed to take a medical history from plaintiff before administering drug.

³ *Johnston v. Brother*, 190 Cal. App. 2d 464, 12 Cal. Rptr. 23 (1961).

Do these cases suggest that one who suffers harm from the administration of a new and dangerous drug has a cause of action against the physician or hospital?

Further, does the advent of so many new drugs on the market mean that new medico-legal standards of skill and care must be used by the physician or hospital?⁴

Before discussing these questions, we must look at three problems: (1) What role does the physician play in the new drug picture? (2) What are some of the new drugs and their side effects, and (3) What steps must a new drug go through before it is placed on the market for public consumption?

A physician is not liable if he prescribes a proper remedy or treatment for a patient and it does not produce good results.⁵ The fact that the unfortunate results might have been prevented will not render a physician liable unless he failed to use proper skill and care.⁶

In the past it would appear that as long as a physician thought a drug was proper, he would be safe in prescribing it. Today's physician cannot safely rely on this rule of law in prescribing drugs, and the reason is that it has been determined that there are dangerous side effects in many of the new drugs.⁷

⁴ Oleck, *New Medico-Legal Standards of Skill and Care*, 11 *Clev-Mar. L. Rev.* 443 (1962): "The lower the body of medical knowledge, generally the lower is the legally required standard of a doctor's skill and care. Conversely, the higher the legal duty arises." For an example of the qualification of a physician-expert on use of medication see, 1 *Encyc. of Negligence* § 218 (1962).

⁵ *Morton v. U. S.*, 233 F. Supp. 1011 (No. Car. 1964); *Ball v. Mallinkrodt Chemical Works*, 381 S. W. 2d 563 (Tenn. 1964). Where a contrast agent selected was one used throughout the country a physician could not be held liable when he used his best judgment in selecting the contrast agent: *Hill v. Boughton*, 146 Fla. 505, 1 So. 2d 610 (1941), in which the court stated, "If treatment recommended and applied by physician was proper treatment for malady from which patient suffered, the physician would not be liable for using such treatment though it did not produce good results."

⁶ *Johnston v. Brother*, *supra* n. 3. However if the physician fails to exercise the care and skill required of him, it is no defense to a charge of negligence that "he did the best he could." *Schueler v. Strelinger*, 204 A. 2d 577 (N. J. 1964).

⁷ Hunt, *Side Effects: A New Worry For Doctors*, *Look Magazine* (Dec. 31, 1963) p. 24. The article stated: "Not only are modern drugs a two-edged sword; the same is true of nearly all modern diagnostic and therapeutic procedures. This is no reason to avoid them, but it is reason for both doctors and patients to weigh each use and make sure it is necessary and important." For many illustrations of new drugs, cases, and effects see, Oleck (ed.), *Negligence & Compensation Service* (bi-weekly, since 1955, Central Book Co., Brooklyn, N. Y.) under the heading of "Drugs."

As one writer observes:⁸

Ninety percent of the prescription drugs now in use did not exist 20 years ago. Virtually all antibiotics, steroids, anti-histamines and tranquilizers have been developed and put on the market since the average 45-year old doctor left medical school. This flood of chemical creations threatens to nullify the doctor's skills by outdating his training and adding new data at a rate he cannot absorb while practicing his profession. . .

The doctor's conscience and medical oath demand that he do his best for his patients, rather than turn his back on the host of new drugs. Yet to keep up with the output of published reports on them is out of the question. (In 1962 the National Library of Medicine estimated that about 200,000 articles on drugs are published each year.) In simple despair, most doctors look for shortcuts; they learn about new drugs first from the "detail men," the advance runners of the drug companies, or from drug company advertising and direct mail brochures.⁸

No drug is absolutely safe for everyone. The problem is, that if all the drugs bearing a risk were banned, there would be hardly any drugs left. A medicine strong enough to influence a disease is sure to have some effect on the body.

What are "detail men"? They are traveling salesmen employed by the drug companies to make appointments with doctors, and to sell the company's line of products.

It is estimated that as of 1960 there were 150,000 doctors in the United States, and that the drug companies spent \$750 million on promotion of their products to these physicians, which averages about \$5,000 for every doctor in the country. It is further estimated that the drug firms employ about 15,000 "detail men" to push their products.⁹

To further complicate matters, the doctor is usually under pressure from his patients for the latest cure. If he won't prescribe it, they will go to another doctor who will.

Doctors are taught in medical school to write prescriptions by the Latin name. However, thanks to the "detail men," it is estimated that 89 percent of doctors now prescribe drugs by brand name rather than by the Latin name. One reason

⁸ Hunt, *supra*, n. 7; and see, "Drugs, How Safe is Safe Enough," *Life* (July 3, 1964) p. 37; "Drugs Worth Risk Taking," *Science News Letter* (March 21, 1964) p. 180.

⁹ Smith, *The Health Hucksters* (Cornwall Press, Cornwall, N. Y., 1960) p. 88.

for this could be that the companies have placed on the market so many new drugs that most physicians do not feel competent in making their own decisions about what to prescribe.¹⁰

In a recent case the Secretary of Health, Education and Welfare, was made a defendant by 37 drug companies in an action asking for a judgment declaring invalid new regulations promulgated by him. The regulation would have required that the generic name be placed in conjunction with every appearance of the trade name of the drug on labels and advertising. Verdict was for plaintiffs.¹¹

Dr. Louis Lasagna of Johns Hopkins University states: ¹²

Investigators sometimes offered drugs on which extensive safety tests have been run in animals, but sometimes, perhaps by the same manufacturer, we are offered drugs on which little animal work has been done. It is reprehensible for man to be the first experimental animal on which tests are run simply because by passing the tests in animals saves time and money.

Dr. Charles D. May of New York University, a member of the American Medical Association's Council on Drugs, testifying before the Kefauver Committee on regulation of the drug industry, testified:

Hectic promotion of unwarranted products subjects patients to illogical and excessive use of drugs. Individual doctors cannot evaluate each drug's usefulness. If they could, they would not have gone on prescribing leeches for so many years.¹³

We therefore find that the physician plays one of the most important roles in the prescribing of a new drug. This is so because he is the vehicle that is used to transport the drug from the manufacturer to the consumer.

New Drugs and Their Side Effects

It is estimated that there have been 2½ million allergic reactions since the advent of the drug "penicillin."¹⁴ One of the

¹⁰ *Ibid*, p. 89.

¹¹ *Abbott Laboratories v. Celebrezze*, 228 F. Supp. 855 (Del. 1964). The original act required the established name to be prominently displayed on drug labeling, but not every time the trade name was used.

¹² "Doctors, Drugs, and Dollars," *Time* (August 4, 1961), p. 53; "Testing," *Newsweek* (Mar. 9, 1964) p. 52.

¹³ *Ibid*.

¹⁴ *Current Medicine For Attorneys*, 19 (Feb. 1963).

most serious complications following the administration of penicillin is the "immediate reaction." Within a few seconds to an hour after administration of this drug the patient may experience any of the following symptoms: generalized urticaria, asthma and rhinitis, gastrointestinal or uterine cramps, unconsciousness, collapse, and anaphylactic death.¹⁵ Based on the projection of statistics, it is reasonable to assume that from 100 to 300 such fatal immediate type reactions occur annually in the United States.¹⁶

It is not hard to balance these reliable figures against the small discomforts of a cold, or against the known dangers of a serious infection, to come to a rational decision whether to use the drug. But all the data on the side effects of a new drug are not nearly as reliable as this. After initial testing and release by the Food and Drug Administration, side effect reports of the drug appear slowly in the professional journals.¹⁷

It is estimated that many of the approximately 1,230 doctors who dispensed thalidomide to their patients without warning them that they were to be human guinea pigs in the testing of a new drug, have been raising their malpractice insurance reportedly from \$300,000 to \$1,000,000.¹⁸ Thalidomide is a drug taken by women in early pregnancy to relieve nausea, and by others as a tranquilizer.

What medical testimony and government investigations had failed to achieve through numerous reports, and hundreds of hours, the thalidomide tragedy accomplished with sudden swiftness. The pill-taking public found that doctors and pharmaceutical companies are not infallible, and that the new pills flooding the market at the rate of one every three days are not all miracle drugs.¹⁹

Thalidomide in the United States was distributed as "Kevadon" by the William S. Merrell & Company. A few years ago, a

¹⁵ Feinberg, "Allergy From Therapeutic Products," 178 J. A. M. A. 815 (Nov. 25, 1961).

¹⁶ For a case history of such a reaction see "Letters to the Editor," "Anaphylactoid Reaction To Demethylchlortetracycline Hydrochloride," 454 J. A. M. A. 181 (Aug. 4, 1962).

¹⁷ Hunt, *op. cit. supra* n. 7.

¹⁸ "Doctors in More Trouble," Parade Magazine (Oct. 7, 1962) p. 8.

¹⁹ "Tragedy From A Pill Bottle, Some Sad Lessons Learned," Newsweek (Aug. 13, 1962) p. 52.

2.5 million dollar damage suit was filed in the United States District Court against the William S. Merrell Company and Richardson-Merrell, the parent company of William S. Merrell Company. This suit was initiated by the parents of a child born without arms as a result of the drug thalidomide. The suit alleged that the drug was administered to the mother of the child in a clinic during the second month of pregnancy. The petition alleged that the two firms were negligent in their failure to properly determine whether the product was dangerous when used by pregnant human females.²⁰

Sometimes, after the most exhaustive tests, unexpected and harmful side effects of a new drug are discovered only after the drug has been put on the market.²¹ However, one new drug, "Triparanol," sold by William S. Merrell Company under the trade name of "Mer-29," clearly indicated in advance some of its harmful effects. In applying for approval of this drug, Merrell withheld information in its files that "Triparanol" had caused cataracts in animals. In March 1964, the Merrell Company went on trial with three of its executives, and its parent company, Richardson-Merrell, Inc., on twelve counts of supplying the Food and Drug Administration with false, fictitious and fraudulent data. The company and its executives pleaded *nolo contendere* on eight counts.²²

In a recent civil action arising from use of the same drug, Mer-29, the William S. Merrell Company was named defendant in a suit filed in the United States District Court in Illinois. The complaint charges the Merrell Company with knowingly and negligently causing the plaintiffs to suffer eye cataracts, and numerous other nerve, muscle and tissue damage by marketing Mer-29.²³ The drug, withdrawn from the market in April 1962, was intended to reduce high blood cholesterol counts.²⁴

Another popular new drug is a pill that is being taken by females as an oral contraceptive to prevent pregnancy. It is principally known by the trade name of "Enovid." It has been stated, however, that these popular drugs are still in the experi-

²⁰ Current Medicine For Attorneys, p. 19 (Feb. 1963).

²¹ "Triparanol Side Effects," Time (April 3, 1964) p. 79.

²² *Ibid.*

²³ Herbert R. Bennett v. Richardson-Merrell, Inc., 231 F. Supp. 150 (D. C. Ill. 1964).

²⁴ *Ibid.*

mental stage and that not enough scientific data has been gathered to know if they are really safe or not.²⁵

A report by the American College of Surgeons indicated that these drugs may work on the body in a manner that extends the fertile period until the time of menopause, resulting in pregnant grandmothers. It is believed that the young women who are consulting doctors for oral contraceptives do not expect to become pregnant grandmothers. The doctor therefore, under the doctrine of informed consent, has a duty to inform all of his young female patients to whom he prescribes this drug, that it is possible that her child-bearing years may be extended, and when the woman is fifty, and has supposedly ended her period of conception, she may possibly become pregnant.²⁶ This then would be a new medico-legal standard of care on the part of a physician, from which a malpractice action might spring if it is neglected. Another possible side effect that may stem from the use of this drug is unexpected bleeding. The drug also alters physiological processes.²⁷

Another antibiotic that gives a reaction similar to penicillin is "Neomycin."²⁸

The use of serums and vaccines may cause allergic reactions called "serum sickness," which produces symptoms similar to the ones seen in penicillin reactions. The doctor has a duty to pre-test any patients who are to receive any horse serum extracts. Not all horse dander sensitive patients are allergic to the serums, but when they are, they are usually more allergic than those who acquired their sensitivity by a prior serum inoculation. Tetanus toxoid should be used in allergic individuals and is considered a must for persons who are horse serum sensitive.²⁹ Tetanus antitoxin may produce a very serious serum sickness.³⁰

²⁵ DeCosta, "Those Deceptive Contraceptives," 181 J. A. M. A. 122 (July 14, 1962).

²⁶ Ringrose, "Pregnant Grandmas? Blame Oral Contraceptives," 182 A. M. A. J. 28 (Oct. 27, 1962).

²⁷ DeCosta, *op. cit. supra*, n. 25.

²⁸ Marchese v. Monaco, 52 N. J. 474, 145 A. 2d 809 (1958). The plaintiff was treated with "mycifradin" which is the trade name for "neomycin," and as a result of negligent treatment became deaf. Plaintiff was awarded damages in the amount of \$56,000.

²⁹ Feinberg, *op. cit. supra* n. 15.

³⁰ Gorlin v. Master, 180 N. Y. S. 2d 84 (1958). A scratch test was given to plaintiff prior to injection of tetanus antitoxin. Such injection resulted in

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Iodine preparations used in X-Ray diagnosis can produce severe reactions.³¹

On September 17, 1964, the United States Food and Drug Administration released a publication which stated that:

Dr. Joseph F. Sadush, Jr., Medical Director of F. D. A., said that since 1959, 40 reports of blood dyscrasias associated with dipyrone ingestion, with 13 fatalities, have been collected by the American Medical Association.^{31a}

The drugs aminophrine and dipyrone are pain killing drugs, and are considered responsible for at least 26 deaths occurring largely in Europe.³²

The new drugs that are responsible for causing diseases are far too many to list here. The few mentioned will give an idea of how dangerous some of the new drugs may be. It is obvious that from the dangerous propensities of these drugs, the physician has a high standard of care in prescribing them for his patient.

Steps Before Releasing New Drugs

What is a "new drug"? Under the 1962 amendments to the Federal Food, Drug and Cosmetic Act, it is defined as a drug not recognized by experts as safe and effective. A further classification of this definition would be:

If labeling of the drug represents it for prevention or treatment of a condition for which qualified experts do not recognize it as effective, then the drug is a "new drug."³³

Dr. Frances O. Kelsey, Chief of the Investigational Drug Branch of the Division of New Drugs, F. D. A., in a seminar conducted at La Jolla, California, on April 5 and 10, 1963 stated that a new drug is not necessarily an entirely new entity, but may be an old drug prepared for a new use, a combination of

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the plaintiff contracting serum poisoning. However the court commented: "Indeed failure to administer it, regardless of the possibility of allergic reaction, might be medically unsound and reprehensive."

³¹ *Horace v. Weyrauch*, 159 Cal. App. 2d 833, 324 P. 2d 666, 64 A. L. R. 2d 1276 (1958).

^{31a} U. S. Department of Health, Education, and Welfare, Food and Drug Administration, Release No. HEW C53 (Aug. 17, 1964).

³² "Debate Drug Use," *The Cleveland Press*, Home Edition (Sept. 7, 1964) p. F-7.

³³ U. S. Department of Health, Education and Welfare; Food and Drug Administration, Publication Number 5, 1963, p. 1.

two or more old drugs, or it may be a new drug because it contains a new component such as an excipient, carrier, coating or menstruum.

Dr. Kelsey is the F. D. A. doctor who prevented thalidomide from becoming the tragedy in America that it was in Europe, by refusing to approve the new drug application submitted by the manufacturer. In fact, it was the drug "thalidomide" that caused Congress to pass the 1962 amendment to the Federal Food, Drug and Cosmetic Act.³⁴

To get a safety clearance, the manufacturer must submit a new drug application to the F. D. A. In the application, any information about the drug that would affect its safety, such as results of tests on human beings, results of tests on animals, the ingredients, and the amounts of each in the formula, description of manufacturing procedures, all labels and accompanying literature; and qualifications of personnel must be stated.³⁵

The results of human and animal testing, and the other information in the application, are then studied carefully by F. D. A. doctors and chemists, who are specialists in drug testing. These experts must be satisfied that the drug can be used safely, and that the proposed label contains all important information and warnings about possible side effects, and any other information necessary for safe use.³⁶

If the drug can be safely used only by a physician or under his care, it will be released for sale by prescription only.³⁷

Most new drugs are released for prescription sale only, at first, because this provides an extra safety factor while more experience with the drug is being obtained. However, if it is demonstrated that the new drug can be used safely without

³⁴ "Towards Safer Drugs," *Consumer Reports* (Oct. 1962), p. 509: "That thalidomide was not cleared for sales here was more luck than anything else. If it had been developed here instead of in Germany, it probably would have been cleared. Pre-marketing safety tests considered adequate before the thalidomide incident probably would not have revealed the drug's dangers."

³⁵ U. S. Department of Health, Education, and Welfare; Food and Drug Administration, *op. cit. supra* n. 33, p. 2. Smith, "New Drug Application," 17 *Food Drug & Cosmetics L. J.* 497 (1962).

³⁶ *Ibid.*, pp. 2, 4. Sec. 102(b) 76 Stat. 781 (1962). The manufacturer must show by substantial evidence that the drug has the effect claimed or suggested on its labeling. This section of the statute also lists the grounds for refusal of a new drug application.

³⁷ *Ibid.*, p. 2.

medical supervision, it may be released for sale without prescription. The labeling of the package for consumer use must then contain adequate instructions and warning for the ultimate user.³⁸

Experimental drugs are exempted from the aforementioned requirement of the Act when shipped to qualified investigators for research.³⁹ There are many other requirements that must be met by the manufacturer before the drug is released by F. D. A., but the steps mentioned are the basic ones.^{39a}

Although no case in point can be cited, it is believed that most courts would still hold the physician liable for negligently administering a new drug, even though it was approved by the F. D. A. prior to dispensing by the doctor.

Standards of Care

A question of the duty owed always arises in cases of medical malpractice.⁴⁰

A physician in treating a patient impliedly represents that he possesses, and the law gives him the duty of possessing, that reasonable degree of skill and learning that is ordinarily possessed by physicians in the community in which he practices who are engaged in the same line of practice.⁴¹

An analysis of this rule reveals a further duty, that the physician must stay abreast of the times, and must follow the approved methods in general use.⁴² Courts have held that it is the

³⁸ *Ibid.*

³⁹ *Ibid.*, p. 6.

^{39a} "Drugs Makers v. Review," *Science News Letter* (Aug. 8, 1964) p. 94. "Drugs, Safety, and Effectiveness," *Time* (Mar. 13, 1964) p. 82.

⁴⁰ *Parkell v. Fitzporter*, 301 Mo. 217, 256 S. W. 239 (1923); *Edwards v. Lamb*, 69 N. H. 599, 45 A. 480 (1899); *Prosser, Law of Torts* 231 (3rd ed. 1964).

⁴¹ *Richardson v. Doe*, 176 Ohio St. 370, 199 N. E. 2d 878 (1964); *Wells v. McGehee*, 39 So. 2d 196 (La. App. 1949); *Wolfsmith v. Marsh*, 51 Cal. 2d 832, 337 P. 2d 70 (1959). In *DeLaughter v. Womack*, 164 So. 2d 762 (Miss. 1964), the defendant physician contended that the proximate cause of plaintiff's injury was an allergic reaction to an injection of penicillin for which he had pre-tested. Plaintiff contended that the injection was negligently administered. See also, *Norton v. Argonaut Ins. Co.*, 144 So. 2d 249 (La. App. 1962); *Snyder v. Pantaleo*, 143 Conn. 290, 122 A. 2d 21 (1956); *Ardoline v. Keegan*, 140 Conn. 552, 102 A. 2d 352 (1954).

⁴² *Bowers v. Santee*, 99 Ohio St. 361, 367, 124 N. E. 238 (1919). *Oleck, op. cit. supra* n. 4, at p. 447, states: "Establishment of new services and infor-

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duty of a physician to avail himself of more advanced and favorable modes of treatment facilities and training than might be present in the community in which he practices, because easier means of communication and transportation now exist.⁴³

However, a pure accident, or a mistaken diagnosis which happens in spite of all reasonable precautions, usually are not enough to show lack of care and skill.⁴⁴

In "harmful drug" actions, as in other malpractice suits, this lack of care and skill must rest upon the testimony of an expert witness who is qualified to express an opinion as to the standard of care usually exercised by physicians in the same community where the treatment complained of was administered.⁴⁵

In a recent case the plaintiff sued his physician for negligently causing an allergic reaction by placing the drug "neo-synephrine" in his eyes without testing to determine if he was allergic to it.⁴⁶ In holding for the defendant, the court stated that a patient has no cause of action against his physician either in treatment or diagnosis, unless he proves by an expert witness of the same school of medicine as the defendant that the injury complained of was negligently administered, and that it was the proximate cause of the plaintiff's injuries.

In a case decided in 1964 by a California court the plaintiff recovered substantial damages against a physician who adminis-

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mation sources for physicians are likely to affect the physician's standard of skill and care. For example, a new telephone and/or mail information service makes available to physicians complete data on any drug, on a routine or emergency basis. This service, centered in Washington, D. C., cost \$15/year, and had a file of 15,000 separate drug descriptions by late 1961. Availability of this service may make less easily excusable a physician's lack of data on available drugs."

⁴³ Tvedt v. Haugen, 70 N. D. 338, 294 N. W. 183 (1940); Cook v. Lichtblau, 144 So. 2d 312 (Fla. App. 1962).

⁴⁴ Meador v. Arnold, 264 Ky. 378, 94 S. W. 2d 626 (1936); Gorlin v. Master, *supra* n. 30; Wilson v. St. Francis Hospital and School of Nursing, Inc., 190 Kan. 150, 373 P. 2d 180 (1962). Plaintiff suffered an anaphylactic reaction as the result of an injection of tetanus antitoxin, and where there was a positive reaction to a sensitivity test administered prior to the injection. The court observed that where there was a possibility of tetanus infection, it would be negligence on the part of the physician not to give a tetanus antitoxin injection even in the face of a positive reaction.

⁴⁵ Ardoline v. Keegan, *supra* n. 41; Stryker, Courts and Doctors 84 (MacMillan Co., New York, 1932); Johnston v. Brother, *supra* n. 3; Sinz v. Owens, 33 Cal. 749, 205 P. 2d 3 (1949). For an excellent discussion on expert witnesses see: Trial Tactics in Handling The Medical Expert Witness, 29 Tenn. L. Rev. 208 (1962).

⁴⁶ Scott v. Leigh, 355 S. W. 2d 798 (Tex. Civ. App., 1962).

tered the antibiotic "chloromycetin" which is the trade name for chloramphenicol, a wide spectrum antibiotic.⁴⁷ The plaintiff was treated on two occasions by the physician, who both times recommended the drug "chloromycetin." Altogether 96 capsules of 250 milligrams each were dispensed to the plaintiff. The physician took no culture or blood test during the period of treatment. Nine months later, the plaintiff was diagnosed as having aplastic anemia. Aplastic anemia is a rare and very often fatal disease (approximately 1,000 fatal cases occur annually in the U. S.). The expert witness for the plaintiff testified that the drug was a valuable antibiotic if used properly, but stated that its use was dangerous, attended by serious risk, and that it should only be prescribed for a very limited number of diseases.

It is only in a case where there is manifest such obvious gross lack of care or skill as to afford, of itself, an almost conclusive inference of want of care, that the testimony of an expert witness is not necessary.⁴⁸ This type of situation is often referred to as one of "res ipsa loquitur."

In *Morgensen v. Hicks*,⁴⁹ the plaintiff sued his physician, the pharmaceutical company that produced the anesthesia, the hospital where the services were rendered, and the druggist who sold the drug, as a result of an allergic reaction suffered from the administration of the drug "pyribenzamine." The court refused to apply the doctrine of res ipsa loquitur, and gave two reasons: (1) That the instrumentalities causing the injury were not in the full control of the doctor, and (2) the allergic reaction of the plaintiff was beyond the doctor's control. In rejecting the doctrine, the court said:

The doctor's contacts are with the frailties, idiosyncrasies, physical and mental weaknesses and allergies of human nature. They may affect the condition, and yet are beyond his control.

⁴⁷ *Love v. Wolf*, 38 Cal. Rptr. 183 (Cal. App. 1964).

⁴⁸ *Grantham v. Goetz*, 401 Pa. 349, 164 A. 2d 225 (1960). The plaintiff was given an intravenous injection of a drug known as "Levophed." This drug is a blood vessel constrictor utilized to increase the blood pressure in case of shock. The drug caused a blister to form, and skin tissue was burned. In ruling for the defendant the court commented: "No presumption or inference of negligence arises merely because the medical care or surgical operation terminated in an unfortunate result which might have occurred even though proper care and skill had been exercised." See also, *Prosser, op. cit. supra* n. 40, at 231, 232. *Toy v. Rickert*, 53 N. J. 27, 146 A. 2d 510 (1958) involved injury from penicillin; the court, after much discussion, rejected the contentions for applying the doctrine of res ipsa loquitur.

⁴⁹ 253 Iowa 139, 110 N. W. 2d 563 (1961).

In *Sanzari v. Rosenfield*,⁵⁰ the court decided that the doctrine of "res ipsa" should at least allow a jury to infer negligence so as to avoid a dismissal at the end of the plaintiff's case. The court in this case invoked the "common knowledge doctrine," which permits the jury to apply the standard of care that should have been used.

The physician or hospital has the duty to give a skin sensitivity test before administering drugs such as penicillin, tetanus antitoxin, and other antibiotics in order to determine the patient's allergic reactions.⁵¹ Failure to do so may render the physician liable for lack of due care.⁵²

There is usually a prescribed waiting time between giving the sensitivity test and administering the drug.⁵³ Failure to wait the prescribed time may render one liable for damages.⁵⁴

Recently, the legal doctrine of "informed consent" has arisen in the United States. In the few cases tried under this doctrine, the courts have held that a physician must explain to the patient the risks involved in the treatment.⁵⁵

A physician who treats a patient and furnishes pills to be taken internally which he represents as harmless and safe, whereas such pills contain "dinitrophenol," a harmful, dangerous, and unofficial drug, by such representation warrants their

⁵⁰ *Supra* n. 2.

⁵¹ *Snyder v. Pantaleo*, *supra* n. 41; defendant physician after learning that plaintiff had no "known" allergies, gave her a skin test, which showed a one plus reaction. Disregarding the test, he administered 20 cc. of drug "diodrast," which caused plaintiff to suffer convulsions. The court held for plaintiff.

⁵² *Yorston v. Pennell*, 397 Pa. 28, 153 A. 2d 255 (1959). Patient was given skin test for tetanus antitoxin, but not penicillin. The court noted that: "Medical testimony shows that of all the antibiotics penicillin is the one most likely to cause allergic reactions, and this has been known since 1943. Such reactions may occur immediately, that is, within a minute or two or as much as four weeks later, and can have serious consequences involving the brain, nerves, gastrointestinal tract, skin and the blood."

⁵³ *Neely v. St. Francis Hospital and School of Nursing, Inc.*, *supra* n. 1. The expert witness for the plaintiff testified, "Throughout the country the universal practice was to wait not less than 10 minutes and if the shot was in the upper arm one should wait at least 30 minutes." Witness testified that not more than 5 minutes elapsed between the test and the injection.

⁵⁴ *Ibid.*

⁵⁵ *Woods v. Brumlop*, 71 N. M. 221, 377 P. 2d 520 (1962). *Hirsch*, "Informed Consent to Treatment," 176 J. A. M. A. 436 (1961). *Natanson v. Kline*, 186 Kan. 393, 350 P. 2d 1093 (1960); *DiFlippo v. Preston*, 53 Del. 539, 173 A. 2d 333 (1961).

safety, and is liable for breach of warranty, regardless of any negligence in administering them. This warranty also may extend to the drug manufacturer.⁵⁶

A physician in California was suspended from practicing medicine for 180 days for violation of a statute making it unprofessional conduct to prescribe dangerous drugs without either prior examination or medical indication thereof. The physician prescribed the drug "Seconal," a dangerous drug, without examining the patient.⁵⁷

Conclusion

We must conclude from these facts that physicians are not justified in prescribing potentially dangerous drugs for trivial ills, that physicians and hospitals have the duty to test or at least inquire about any allergies that the patient may possess, and that the medical profession and public alike must learn that all new drugs are not magical cures for all the ailments that beset us.

⁵⁶ *Morningstar v. Jones*, 31 Ohio L. Abs. 440 (1940). A case brought under the Ohio Uniform Commercial Code (adopted July 1, 1963) may bring a different result. *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960): Defendant found guilty for breach of implied warranty of merchantability in that a drug which was intended for introduction into the body of a human being contained a live poliomyelitis germ. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 Rutgers L. R. 947 (1964) is an excellent article that discusses the standards of care a drug manufacturer must use in giving adequate warnings to the public in the sale of new drugs.

⁵⁷ *Sunseri v. Board of Medical Examiners*, 36 Cal. Rptr. 553 (Cal. App., 1964).