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Norman Rubinoff

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NOTE

Drug Liability—Survey, Study, and Prognosis

INTRODUCTION

In the last decade, few areas of the law have expanded as rapidly as that of drug liability. Perhaps *Gottsdanker v Cutter Laboratories*¹ precipitated more interest and litigation in this area than any other single factor. That decision was timely for many reasons. Improvements in communication, commercialization of medicine, public interest in medical problems, perfection of testing techniques, and new cures for widely feared illnesses have all led to an informed and demanding public. The public's expectations as to the quality of new drugs has been elevated, as well as the legal concepts to meet those expectations. This Note will deal with these changing expectations as reflected in the law of drug liability. Consideration will be given primarily to a "horizontal" presentation of the drug liability problem; a "vertical" approach or analysis of the many legal issues involved will be treated only secondarily.

This survey of drug liability will include a discussion of such drugs as thalidomide, Parnate, Mer/29, and the Sabin Oral Vaccine. More specifically, this discussion will examine what impact these new and "experimental" wonder drugs have had and will have on drug laws, both civil and criminal; how the concepts of warranty and negligence have changed; the technical problems facing the parties, *i.e.*, lawyers, drug manufacturers, legislators, doctors and pharmacists; and what effect competition has had in increasing costs and public demand.

CAUSATION

Proving the causal connection between use of a defendant's drug and a plaintiff's injury is one of the most difficult problems facing parties in new drug litigation. Obviously, causation is easier to establish when there is a large number of injuries available to examine and compare. The new drugs, however, present unique problems in that only *some* users experience unusual and unintended side effects. Consequently, expert medical researchers must make comparisons and devise and adapt tests to determine whether these injuries are a result of using a particular drug. These studies are directed toward improving drugs and defining the risks involved in their use. As a result, a drug is either improved, dropped, or its use is knowledgeably controlled.

1. 182 Cal. App. 2d 602, 6 Cal. Rep. 320 (1960)

For those injured by a drug, there may be recovery against the drug manufacturer, doctors, handlers, and promoters. In determining this liability, the attorney's problems with causation parallel those of the medical researcher. Understanding the body chemistry involved with anti-depressants, vaccines, or contraceptive pills requires more technical know-how than that required for "simpler" injuries such as sprains, broken bones, and bullet wounds. Thus, an attorney's medical acumen with respect to drug litigation must approach, and in some instances even surpass, that of the medical researchers.

The history of drug liability is replete with litigation involving the negligence of druggists² and manufacturers.³ There is a rather well defined range of defects in drugs which has given rise to legally redressable injury. Technically, drugs are susceptible to substitution of ingredients,⁴ impurities,⁵ poisons,⁶ harmful quantities,⁷ or improper labelling.⁸ But the new drugs present somewhat different types of defects. Very often the ultimate problem is in knowing too little about the drug before it is released. This stems from the inadequacy of testing procedures or, simply, the impossibility of devising procedures elaborate enough to detect minute risks. In some instances drug companies de-emphasize or overlook possible risks. In addition, some drugs are of such a nature that they cannot be made as safe as originally desired. However, the benefits may still outweigh the risks so as to justify the drug's release. The new drugs may not be impure in the sense that they contain poison, but in many instances, the injuries resulting from their use may be as serious as though they did. New and experimental drugs generally work in strange and often unknown ways in producing injury as well as cure. It is necessary at this point to examine separately a representative group of these drugs.

Salk Vaccine

The type of injuries caused by the Salk vaccine are now history; yet, some discussion is required here with respect to the problem of causation. The Salk vaccine is a preparation of "killed" (inactivated) polio viruses which, when introduced into the body, stimulate development of specific

2. Annot., 79 A.L.R.2d 301 (1961); 18 OHIO JUR. 2d *Drugs & Druggists* §§ 25-31, at 472 (1958).

3. 2 FRUMER & FRIEDMAN, *PRODUCTS LIABILITY* § 33.01 (1961).

4. *McGahey v. Albritton*, 214 Ala. 279, 107 So. 751 (1926); see also *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925).

5. *Abbott Lab. v. Lapp*, 78 F.2d 170 (7th Cir. 1935).

6. *David v. McKesson & Robbins Co.*, 253 App. Div. 728, 300 N.Y. Supp. 635 (1937), *aff'd*, 278 N.Y. 622, 16 N.E.2d 127 (1938).

7. *Blood Balm Co. v. Cooper*, 83 Ga. 457, 10 S.E. 118 (1889).

8. *Thomas v. Winchester*, 6 N.Y. 397 (1852).

antibodies which ward off future attacks by live polio viruses.⁹ The *Cutter*¹⁰ case, for example, involved the development of paralysis in children immunized with this killed vaccine. Other cases revealed paralysis localized around the sites of the injection which, of course, simplified the proof of causation. In such cases, it was discovered that some live polio virus particles were, by clumping together,¹¹ escaping the treatment with *formalin* which was designed to kill them. The Cutter Company had followed all government manufacturing procedures¹² and argued, therefore, that this would obviate the charge that reasonable care was not observed. However, negligence did not become a factor in granting of recovery, since the suit was also based on a breach of warranty.¹³ Although it is not necessary in a warranty action to show how the vaccine became contaminated, it is important in this discussion to note the real reason for this injury in that it foreshadows a new aspect of drug causation analysis — inadequate manufacturing and testing procedures.

Thalidomide

The story behind the distribution and use of thalidomide in the United States typifies the abuses which lead to thousands of injuries and hundreds of law suits. At first it was not known what effect thalidomide had on the human body. Because of its chemical structure it was tested as a barbiturate, but was found to have absolutely no such effect on animals. When tried as an anti-convulsant for epileptics, it was found to have some sedative qualities and was thereafter marketed as a sleeping pill and tranquilizer. In Germany, it was manufactured "by the ton" and sold without prescription.¹⁴ While in use, it produced few of the common side effects normally associated with the use of tranquilizers, such as drowsiness or habit forming dependency. Although thalidomide was widely used in Europe, it was used only on an experimental basis in the United States as a result of wise caution exercised by one member of the Food and Drug Administration (FDA). In this country, the drug was given only to "selected" researchers for "limited" use.¹⁵

Tracing the Cause of Injury.—Slowly, the appearance of thousands of deformed babies began to stun the public. The problem was a hidden

9. WILSON, MARGIN OF SAFETY 75-76 (1963)

10. *Gottsdanker v. Cutter Labs.*, 182 Cal. App. 2d 602, 6 Cal. Rep. 320 (1960).

11. *Id.* at 610, 6 Cal. Rep. at 325.

12. Spencer, *Where Are We Now on Polio?*, Saturday Evening Post, Sept. 10, 1955, p. 19.

13. Negligence is not a factor in breach of warranty. *Pabon v. Hackensack Auto Sales Inc.*, 63 N.J. Super. 476, 164 A.2d 773 (1960). In the *Cutter* case neither Dr. Salk nor the Government were considered liable for the wrong manufacturing directions.

14. Taussig, *A Study of the German Outbreak of Phocomelia*, 180 A.M.A.J. 1106-14 (1962).

15. *Hearings on Interagency Coordination in Drug Research and Regulation Before the Senate Subcommittee on Reorganizations of the Committee on Government Operations*, 87th Cong., 2d Sess., pt. 1, at 264-65 (1962).

danger in the use of this drug by pregnant women which led to the birth of babies with various deformities, the most common of which was *phocomelia*.¹⁶

A Senate subcommittee has investigated the thalidomide story and reported as follows: drug salesmen were directed to department chiefs and senior members of medical and surgical staffs; their main purpose was to establish local studies the results of which would "spread the word" among other staff members; detailed reporting was not required because the FDA was sure to approve it very shortly; "basic clinical research had been conducted" and the toxic safety well established.¹⁷

Since the FDA required qualified investigators in experimental field trials, the salesmen were told to be sure to obtain the doctors' signature on the "statement of proposed investigation." Today, this requirement of qualified investigators is spelled out in the controversial section 505 (i) of the 1962 amendments to the Federal Food, Drug and Cosmetics Act.¹⁸

Within one week after the sales meeting described in the hearings, the salesmen had helped to institute 162 studies, covering 6,648 patients. Within a month there were 762 studies covering 29,413 patients.¹⁹

16. *Ibid.* "Seal limbs" is the common term for phocomelia.

17. *Hearings on Interagency Coordination in Drug Research and Regulation Before the Senate Subcommittee on Reorganization and International Organizations of the Committee on Government Operations*, 87th Cong., 2d Sess., pt. 1, at 262 (1962).

18. Federal Food, Drug and Cosmetic Act § 505 (i), 76 Stat. 781 (1963), 21 U.S.C. § 355 (i) (Supp. V, 1964).

This section has generated much discussion since its enactment in 1962. It exempts investigational drugs from certain other formal requirements. There are two points of interest. One concerns the requirement that "experts qualified by scientific training and experience" be chosen to investigate new drugs. There are no other provisions defining the requisite qualifications of experts. The only requirement appears to be a statement signed by the expert as to the limitations on the use of the drug. The second problem arises out of the following section which appears to be self-neutralizing in effect:

[T]he sponsor of the investigation [must also require the investigators to notify the patients that they are being given drugs in an investigational program, obtain their consent,] *except [in cases where the investigator] deems it not feasible or contrary to the best interests of [the patient to be so informed.]* (Emphasis added.)

This section is the subject of much concern because of the wide publicity given the injuries from thalidomide, an experimental drug. One such problem arises as to whether a patient should be told of the seriousness of his illness; but does this discretion extend to the use of new, experimental drugs? When a drug is very new and its effects on man can not be properly assessed without human trials, researchers frequently obtain permission from guardians of insane persons, or consent from long-term prisoners, to use them as guinea pigs. Apparently, these human beings are given more consideration than the consuming public who are given other new or experimental products without knowing any of the risks, suspected or potential, in the drugs. Although the drug companies do not intend to use the consuming public as guinea pigs, this is often the result with drugs containing a harmful quality which can not be discovered until after prolonged use. Neither the patients' inability to prescribe for themselves, nor the doctors' freedom and responsibility to do what is in the patient's best interest extends so far to make any man an experimental animal without his knowing it.

The American Medical Association is now in the process of promulgating a new series of principles governing clinical investigation. These rules may serve as a standard which may be helpful to the legal profession.

19. Senate Hearings, *supra* note 17, at 272.

Where is the objectivity and fair representation required to uncover the inherent dangers in a drug? This type of approach to development, testing, manufacture and distribution results in an escalation of the number of drug injuries.

The main question to be answered in suits of this type is that of causal connection. As indicated previously, the effective cause is traceable to a commercial rather than a scientific approach to marketing. Simple tests on pregnant animals would have exposed the risk. Arrival at an ultimate effective cause was initiated by a search for some common factor among all these injuries. The mothers it was learned had all at one time used thalidomide.²⁰ Specific case studies and general comparisons of the sales of the drug with appearances of phocomelia indicated the danger period was limited to the first few weeks of pregnancy. During the early stage of embryonic growth, the limb buds appear. The limbs apparently are not affected by thalidomide if their development is beyond the six-week stage; taking the drug before this time very often resulted in phocomelia.²¹ The resulting injuries have led to several suits against the manufacturer²² and there has been some report of settlements.²³

The thalidomide suits present several novel legal problems. It has been noted that the only danger from this drug is in the first few weeks after conception. What then is the law on recovery for prenatal injuries? Under what circumstances can a child recover for injuries inflicted before birth?

Recovery for Prenatal Injury.—Until recently, the weight of authority favored the common law view that, absent a statute to the contrary, an

20. At this point, the suspected drug should have been removed from the market; however, this was not done until the drug was more than just under suspicion. But within a few weeks after it was suspected, thalidomide was withdrawn. Taussig, *supra* note 14, at 1109. The drug was removed from the market in November 26, 1961.

The singular effectiveness of thalidomide as a sedative or tranquilizer was well established before its hazards were discovered; it was virtually impossible to commit suicide with it even by swallowing huge quantities of the drug. There is great need for a drug with these qualities. Nevertheless, numerous questions must be resolved before the drug can be released for controlled use. For example, there may still be an undiscovered risk, such as an effect on male users. Lutwak-Mann, *Observations on Progeny of Thalidomide-Treated Male Rabbits*, 1 BRITISH MEDICAL J. 1090 (1964).

Hopefully, the possibility of a residual effect of thalidomide upon future pregnancies will be studied. However, safer but equally effective substitute drugs may be found in the interim. Again, the Food and Drug Administration may have to balance the benefits and the risks of this drug.

21. Taussig, *supra* note 14; but see Apgar, *Drugs and Pregnancy*, 190 A.M.A.J. 840-41 (1964), where it is indicated that only 20% of the mothers taking thalidomide during the danger period had abnormal babies.

22. *Thalidomide Maker is Sued by Parents of Deformed Twins*, N.Y. Times, Oct. 19, 1962, p. 33, col. 1.

23. 6 Personal Injury Newsletter 189 (Feb. 10, 1964). An additional side effect injury occurring in adults is termed peripheral neuropathy. One Virginia case involving this injury has been settled.

infant has no right of action for injuries sustained by him *en ventre sa mere*; however, the modern trend seems to be in the other direction. Those courts adhering to the common law rule give several reasons in support of this approach to prenatal injuries. First, it is said that there can be no recovery because the child is a part of the mother and has no separate legal existence which can be injured.²⁴ Second, it is stated by some authorities that if recovery for prenatal injuries were allowed, there is no reason why an infant could not sue its own mother for injuries caused by the mother's negligence before giving birth.²⁵ A third reason is based on the practical difficulty of finding reliable proof to establish causation.²⁶ On the other hand, the modern view argues: (1) that the embryo is a part of the mother only in the sense that it lives within her and obtains its nourishment there — it is a separate biological unit;²⁷ (2) that natural justice demands recognition of the legal right of the child to begin life unimpaired by physical or mental injuries resulting from a prenatal injury;²⁸ and (3) that the law recognizes the existence of an unborn child in other areas and ought to apply the same principles in tort law. For example, in the area of pretermisison, the right of inheritance of after-born children is protected. The policy supporting the law in this area is so strong that even if a decedent leaves a will, a pretermitted child cannot be excluded from a share unless there is a clear intention to do so in the will.²⁹ The "non-existent" child is also recognized in criminal law where certain types of abortion are made a crime.³⁰

Fortunately, in tort law most courts are moving toward a view which is responsive to the scientific fact that an unborn child has some form of existence. The modern view is that a right of action does exist,³¹ though it has been limited to cases in which the child can be said to be viable, *i.e.*, able to exist outside the body of the mother.³² A fetus may become viable roughly between the twenty-fifth and twenty-eighth week of intra-uterine life.³³ Some courts have said that "quickness" in the womb can

24. *Stanford v. St. Louis-San Francisco Ry.*, 214 Ala. 611, 108 So. 566 (1926).

25. *Allaire v. St. Luke's Hospital*, 184 Ill. 359, 56 N.E. 638 (1900), *overruled*, *Amann v. Faidy*, 415 Ill. 422, 114 N.E.2d 412 (1953).

26. *Bliss v. Passanesi*, 326 Mass. 461, 463, 95 N.E.2d 206, 207 (1950).

27. *Kelly v. Gregory*, 282 App. Div. 542, 125 N.Y.S.2d 696 (1953).

28. *Bliss v. Passanesi*, 326 Mass. 461, 95 N.E.2d 206 (1950).

29. *E.g.*, OHIO REV. CODE § 2107.34 (Supp. 1964); see *Twitchell v. Alexander & Liggett*, 115 Ohio App. 51, 184 N.E.2d 421 (1961).

30. See *Verkennes v. Corniea*, 229 Minn. 365, 38 N.W.2d 838 (1949).

31. *Damasiewicz v. Gorsuch*, 197 Md. 417, 79 A.2d 550 (1951); *Smith v. Brennan*, 31 N.J. 353, 157 A.2d 497 (1960); *Woods v. Lancet*, 136 N.Y.S.2d 492 (Sup. Ct. 1954).

32. *Wendt v. Lillo*, 182 F. Supp. 56 (N.D. Iowa 1960); *Hall v. Murphy*, 236 S.C. 257, 113 S.E.2d 790 (1960).

33. See generally, MONTAGU, *PRENATAL INFLUENCES* 328 (1962)

Drugs administered to the pregnant mother at any time during the pregnancy are

be the point in time when there is legal existence.³⁴ A few courts have even held that recovery will be permitted for prenatal injury tortiously inflicted at *any time* after conception, provided the child was born alive.³⁵ However, no court has gone further than conception and considered injury to the sperm or ova. Where the child is born dead, there is a split of authority on whether an action will be allowed, but some courts have allowed a personal representative to recover on behalf of the next of kin.³⁶

In those jurisdictions which have not yet carried recovery back to conception, the thalidomide cases may make new law. The causal relationship is clear, even though the exact mechanism which off-balances the fetal growth is not yet understood. The line of recovery in prenatal injuries must necessarily be extended with thalidomide, since the only danger so far demonstrated is in the first few weeks of pregnancy. If the other legal and causal factors are met, it is hard to imagine a court refusing to extend this "line" back to or near conception in order to cover thalidomide injuries.

Mer/29

Mer/29, or triparanol, is a drug which was developed to control cholesterol in the blood by inhibiting its biosynthesis.³⁷ Among the unintended side effects are cataracts, alopecia (hair loss), and ichthyosis (dry harsh skin with adherent scales). Instructions accompanying the drug warned against the possibility of liver damage and side effects of nausea, vomiting, temporary vaginal bleeding, dermatitis, and thinning of the hair.³⁸ Warnings against use during pregnancy were also included. In many cases, these warnings were not adequately conveyed to the user.³⁹ However, not all of the pending suits are based on injuries specifically covered by the warnings.

Negligence need not be a troublesome factor in the *Mer/29* cases for two reasons. First, the manufacturers violated FDA rules regarding

likely to be harmful to the fetus. Drugs that produce no apparent effect upon the pregnant mother may produce very appreciable effects upon the fetus. The two are interdependent but quite different physiological systems. The failure to recognize this simple fact can be catastrophic.

See *Amann v. Faidy*, 415 Ill. 422, 114 N.E.2d 412 (1953).

34. Quickness refers to a heart beat or fetal movements which appear in three to four months. *Porter v. Lassiter*, 91 Ga. App. 712, 87 S.E.2d 100 (1955).

35. *Dailey v. Meier*, 33 Ill. App. 2d 218, 178 N.E.2d 691 (1961) (one month pregnant); *Smith v. Brennan*, 31 N.J. 353, 157 A.2d 497 (1960) (injury seventy-five days before birth).

36. *Amann v. Faidy*, 415 Ill. 422, 114 N.E.2d 412 (1953).

37. *Flexman, MER/29 (Triparanol) and Cataract*, Med. Trial. Tech. Q. 11 (Dec. 1963).

38. *Id.* at 16.

39. The warnings and instructions are sent with the drug to the administering physician as well as the pharmacist. Exercising his professional judgment, the doctor will tell the patient as much or as little of these warnings as he deems important.

disclosure of adverse test results and were subject to criminal sanction.⁴⁰ Second, some adverse effects appeared while the drug was being tested, but in spite of this the drug was released for public consumption in utter disregard of the public good.⁴¹

Parnate

Parnate, or tranlycypromine sulphate, is used to relieve symptoms of mental depressive reactions.⁴² This drug illustrates a unique problem in that it must be used for a long enough period to permit the accumulation of a sufficiently large number of cases before uncommon but serious side effects become apparent. Shortly after Parnate was approved in 1961, a few users suffered sudden and severe rises in blood pressure. Medical literature reports the following injuries:

A severe reaction to tranlycypromine (Parnate) sulfate has been characterized by intense headache, nausea, vomiting, photophobia, sweating, pallor and mild hypertension. Most of the patients have made a spontaneous recovery, but death, usually associated with intercranial hemorrhage, has occurred.⁴³

Mechanism of Injury.—Some persons, injured while using Parnate, were found to have consumed cheese prior to suffering hemorrhages, while others were using different drugs at the same time they took Parnate, e.g., amphetamines, reserpine, and certain diuretics. Parnate functions through its effect on the monoamine oxidase (MAO) enzyme system, one of the enzyme systems which serve to dissolve certain drugs and

40. Loory, *Hid Drug Danger, Firm Gets Top Fine*, N.Y. Herald Tribune, June 5, 1964, p. 1, 14 col. 1; *Drug Maker Fined \$80,000 in Failure to Tell of Danger*, N.Y. Times, June 5, 1964, p. 11, col. 1. The civil action based upon violations of a criminal statute will be discussed later. See generally Annot., 79 A.L.R.2d 301 (1961).

41. Flexman, *op. cit. supra* note 37. The wilful or wanton character of defendant's conduct will often negate the effect of any contributory negligence as well as provide a basis for punitive damage claims.

It is estimated that there were 400,000 to 500,000 users of the drug distributed throughout 45 states. Although it was marketed around the world, there is no information available as to foreign law suits. The drug company reported 3,000 injuries; the cases pending involve about 600 injured users. *Hearings on Interagency Coordination in Drug Research and Regulation before the Subcommittee on Reorganization and International Organizations of the Committee on Government Operations*, 88th Cong., 1st Sess., pt. 4, at 1955-78 (1963).

42. Leonard, Gifford, Williams, *Tranlycypromine Sulfate Therapy*, 187 A.M.A.J. 957-58 (1964).

43. *Id.* at 958. Letters were sent to doctors on October 9, 1963, warning of the danger to persons with confirmed cerebral vascular or cardio-vascular defect or disease. A recent fact sheet distributed by the FDA reported that since April of 1961, there were 430 cases of arterial hypertension with cerebral reactions. U.S. Dept. of Health, Education, and Welfare, Food and Drug Administration, Washington, D.C., *Parnate Fact Sheet*, March 16, 1964. Among these were 50 cases of "cerebral vascular accidents" and 15 or 16 fatalities among users of Parnate. The drug was withdrawn after protest and a hearing requested under § 505(e) of the Federal Food, Drug and Cosmetic Act. 76 Stat. 781 (1963), 21 U.S.C. § 355(e) (Supp. V, 1964).

foreign compounds. One of the foreign compounds is *tyramine*, a substance found in cheese. Unless controlled by the MAO enzyme system, tyramine tends to greatly increase blood pressure unless its usually rapid inactivation by monoamine oxidases is interfered with by inhibitors such as Parnate. It is believed that when the action of the enzymes was blocked by Parnate, the ingestion of certain blood pressure increasing substances resulted in injury.⁴⁴

In examining the causation in the Parnate injuries, one realizes the extensive investigational program required to uncover risks.⁴⁵ The Food and Drug Administration has made Parnate available again, providing that adequate warnings are given for its use.⁴⁶ Several suits have been filed alleging inadequate testing of the drug.⁴⁷

Sabin Poliomyelitis Vaccine

All of the foregoing drugs present unique legal and medical problems, but the Sabin Oral Vaccine is exceptional in this respect. The problem here was the report of a very few cases of paralysis shortly after the vaccine was administered. Was there any causal connection? Until recently, polio was a particular problem only in civilized societies. In less hygienic living conditions, most children at one time or another contracted some mild form of polio that spread rapidly and immunized others early in life.⁴⁸ With improved sanitation and cleaner living, less and less children developed this natural immunity. Albert Sabin succeeded in isolating live polio virus particles that were "non-paralytic." Apparently, this strain of virus particles was similar to the mild type which immunize most people at an early age. The Sabin vaccine was therefore developed to replace and improve upon natural immunity

For convenience, the three poliomyelitis types have been classified as I, II, and III. A basic problem with all three polio viruses is their inability to grow in most standard culture mediums. In addition to the human body, which is the best medium for growth of polio viruses, monkey kid-

44. Goldberg, *Monoamine Oxidase Inhibitors*, 190 A.M.A.J. 456, 460 (1964)

45. Very often, long term experimentation on human beings is required before the exact causes of injury can be determined. However, the law should afford protection to those injured in the process. At the very least, trained and conscientious investigators should be used to discover and help reduce the number of such injuries. Since the number of injuries from any given new drug can be statistically predicted, the drug companies can easily be required to spread the cost of compensating these injuries in advance, by requiring those who benefit from the drugs to pay more.

46. *Parnate Will Re-enter Market Under Revised Labeling*, 19 FOOD DRUG COSM. L.J. 325 (1964).

47. Fulbright, *\$1 Million Sought Here In Drug Suit*, N.Y. Herald Tribune, March 26, 1964, p. 7, col. 1.

48. WILSON, *op. cit. supra* note 9, at 40: "In other words, modern hygiene, by protecting children from the mild attacks of infancy, which hardly ever affected nerves, had left them unprotected by immunity in adult life."

ney tissue was also found suitable.⁴⁹ Using this medium, scientists worked toward "cleaning up" the virus so that it could be presented in vaccine form. There were several unsuccessful attempts by other scientists before Sabin's vaccine was finally approved.⁵⁰ The attenuated or non-paralytic virus particles were obtained by growing the virus in monkey kidney tissue. The virus was "passed through" these cultures and the safest strains selected. Scientists searched for strains which produced no noticeable sickness, adequate immunological response, and no paralysis.

Developing an immunity to polio with the Sabin vaccine contemplated a growth of the virus particles in the intestinal tract. By directly injecting the virus into the brains and spinal cords of monkeys, scientists were able to study the activity of the virus under more stringent conditions than that required for man.⁵¹ It was hoped that the virus would never get to man's nervous system.

With this type of immunological process, it is possible for one who did not take the Sabin vaccine to be infected by another who did take it. The virus, multiplying in the intestines for weeks or months, passes out of the system in the feces thereby creating the possibility of infection in others.⁵² In other words, the live vaccine actually gives the user an active, persistent, and contagious case of polio.

There was much concern over the danger of infection of one who did not take the Sabin vaccine by one who did. This contact case may in turn spread the disease through a series of other persons. In this fashion, the process of obtaining a safe virus may be reversed, thus selecting out wilder strains in a human culture medium. The question then arises as to whether these contact cases may result in paralysis from a reverted wild form of virus.⁵³ There is still some question on this point. Essen-

49. Ramos-Alvarez & Sabin, *Intestinal Viral Flora of Healthy Children Demonstrable by Monkey Kidney Tissue Cultures*, 46 AM. J. PUB. HEALTH 295 (1956).

50. WILSON, *op. cit. supra* note 9, at 224-34. Much debate was stimulated over which of the available vaccines should be used — Salk or Sabin. The Sabin vaccine was more convenient, but serious questions were raised concerning its reliability. Sabin's vaccine was said to give longer and more complete protection although many felt more secure with a dead vaccine (Salk) that was not growing and could not change. WORLD HEALTH ORGANIZATION, PAN AMERICAN HEALTH ORGANIZATION, LIVE POLIOVIRUS VACCINES: SECOND INTERNATIONAL CONFERENCE ON LIVE POLIOVIRUS VACCINES (Pan Am. Health Org. Science Publ. No. 50 1960) [hereinafter WHO]. The live vaccine could be swallowed on candy, while Salk's dead vaccine had to be injected with a syringe.

51. Sabin, *Behavior of Chimpanzee — Avirulent Poliomyelitis Viruses in Experimentally Infected Human Volunteers*, 68 TRANSACTIONS OF THE ASS'N OF AM. PHYSICIANS 64-72 (1955).

52. Gelfand, LeBlanc, Potash, Clemmer, Fox, *The Spread of Living Attenuated Strains of Polioviruses in Two Communities in Southern Louisiana*, 50 AM. J. PUB. HEALTH 767 (1960); Gelfand, Potash, LeBlanc, Fox, *Intrafamilial and Interfamilial Spread of Living Vaccine Strains of Polioviruses*, 170 A.M.A.J. 2039 (1959).

53. Sabin, *Characteristics and Potentialities of Experimentally Produced and Naturally Occurring Variants of Poliomyelitis Virus*, 61 ANNALS OF N.Y. ACADEMY OF SCIENCES 924 (1955); Melnick, *Problems Associated With Use of Live Poliovirus Vaccine*, 50 AM. J. PUB. HEALTH 1013 (1960).

tially, reversion presents a problem of stability. There is concern that the virus will not remain homogenous in that it will become wild as it passes from one individual to another. Other questions raised were: (1) how many persons can the original attenuated virus pass through before it reverts to "neurovirulence", (2) were all "bad" polio virus particles removed or was there just a mixture which was predominantly attenuated; (3) can some of the non-paralytic particles become "bad" as they grow and multiply in the person who took the vaccine (mutation), (4) are there any undiscovered viruses in the vaccine which can cause different illnesses;⁵⁴ (5) how long does Sabin immunity last; (6) are there enough people unprotected by either Salk or natural immunity to make the risk of a mass program worthwhile; (7) how serious is the interference of other intestinal viruses with the growth of Sabin's virus; and (8) do all people have the same resistances, *i.e.*, will the attenuated virus grow just in the intestinal tract of all people or, in some, spread to the blood (viremia) and nervous system (paralysis)?

Mass Immunization.—These and other questions stimulated skepticism as to whether the whole program was not being hurriedly conducted.⁵⁵ Serious questions of whether the risks involved would be minimized enough to make a mass program advisable were raised. As mentioned, a major concern was the possibility of reversion; however, in time, most of these questions were answered and the drug was approved.⁵⁶ It was felt that the chance of reversion through a series of contact cases could be averted. This would be accomplished by urging as many people as possible to take the vaccine. "It seems that the surest way to initiate the use of live virus vaccine in this country would be on a mass basis so that the entire population in a community receives the vaccine virus simultaneously, thus lessening the number of susceptibles who might become infected with reverted virus."⁵⁷

The American people had to be convinced of the wisdom, safety, and public responsibility involved. It was a "Wipe Out Polio Forever" cam-

54. WORLD HEALTH ORGANIZATION, REQUIREMENTS FOR BIOLOGICAL SUBSTANCES 6 (WHO Tech. Rep. Ser. No. 237, 1962)

55. WHO, *op. cit. supra* note 50.

56. Terry, U.S. Dept. of Health, Education and Welfare, *The Association of Cases of Poliomyelitis With The Use of Type III Oral Poliomyelitis Vaccine*, p. 2 (Sept. 20, 1962) Type I was licensed for distribution on Aug. 17, 1961; Type II on Oct. 10, 1961; and Type III on March 27, 1962. Prior to these dates, experimental lots of the respective vaccines were employed in a number of small scale and some large scale community programs.

57. Melnick, *Population Genetics Applied to Live Poliovirus Vaccine*, 52 AM. J. OF PUB. HEALTH 472, 482 (1962).

In Russia, the problem was relatively easy in that people had little choice in the matter and were more easily directed to take the vaccine. Sabin, *Poliomyelitis Incidence in the Soviet Union in 1960*, 176 A.M.A.J. 231 (1961) The results of large scale Russian experiments were carefully studied before the FDA approved the vaccine for use in the United States. WHO, *op. cit. supra* note 50.

paign. The program was to be a triumph for science and epidemiology, erasing the poor image which followed the *Cutter* injuries. In order to encourage mass participation the vaccine was generally made available without charge. This situation presents the seed of the legal problems. In these mass participation programs, there was, in effect, a blanket warranty of merchantability in order to persuade everyone to take the vaccine; yet the vaccine was usually offered without charge. Hence no sale, usually associated with warranties, was involved. Two problems arise which will be considered in detail. (1) whether there are sufficient causal links present to justify a law suit; and (2) whether warranty may be alleged without a sale.

With respect to causation, the polio vaccine cases are not as easily resolved as the thalidomide and Parnate cases. No interfering product such as cheese was found as was the case with Parnate, nor was the paralysis associated with any special physical condition of the drug user as was the case with thalidomide, *i.e.*, pregnancy. A common explanation for the paralysis was that the patient was nurturing the wild community virus at the time he received the attenuated vaccine virus.⁵⁸ One major difficulty with this explanation and the entire causation problem in the polio vaccine cases is the fact that relatively few people were really paralyzed. Medical literature suggests many reasons for the few cases of paralysis,⁵⁹ but studies have been unable to explain away all the cases. The unexplained cases are lumped together under the term "compatible." In this context, the term "compatible" imports consistency with a vaccine cause. Tests and standards have been developed for determining the degree of compatibility,⁶⁰ but the causal ties are neither as clear nor as conclusive as with other drug injuries.⁶¹ However, in the most recent medical literature, there appears to be a shift in attitude.⁶² The Public Health

58. Sabin, *Is There an Exceedingly Small Risk Associated With Oral Poliovirus Vaccine?*, 183 A.M.A.J. 268 (1963).

59. *Ibid*; Wehrle, Leedom, Portnoy, Pierce, Cowper, *Safety of Sabin Oral Poliomyelitis Vaccine Strain*, 186 A.M.A.J. 821 (1963).

60. The Poliomyelitis Surveillance Committee has prescribed a number of standards based on knowledge of the incubation period and vaccine characteristics, such as antibody response, marker tests, the type of virus isolated, and the type of paralysis. Final classifications used were probable, improbable, uncertain, and excluded.

61. Gelfand, *Oral Vaccine: Associated Paralytic Poliomyelitis*, 1962, 184 A.M.A.J. 948, 949 (1963), reads as follows:

Because OPV [Oral Poliomyelitis Vaccine] produces active infection which stimulates the natural process, we expect to find the virologic and serologic evidence indicative of current infection in recent vaccinees. When this evidence is accompanied by paralytic illness, we have only limited means of assaying the relationship of the two events in the individual. An aggregate of cases which are individually inconclusive may, however, have epidemiologic characteristics and consistent laboratory findings which would either suggest or tend to rule out vaccine as the etiologic agent.

62. A series of articles appeared on Oct. 5, 1964: Henderson, Witte, Morris, and Langmuir, *Paralytic Disease Associated With Oral Polio Vaccines*, 190 A.M.A.J. 41 (1964); Special

Service has recognized that some of the compatible cases were probably *caused* by the vaccine. The problem is in stopping the growth and spread of the virus into the blood and nervous system. A suggestion which has appeared several times is that the Sabin vaccine should be used in connection with the Salk vaccine, *i.e.*, immunize the gastro-intestinal tract (Sabin) after the dead vaccine (Salk) has been used to raise the antibody titer level of the blood.

In a same series of articles on Sabin Poliomyelitis Vaccine published in the *Journal of the American Medical Association*, the number of so-called compatible cases is now said to total fifty-seven, although reports of suspected vaccine injuries are far more numerous.⁶³ There is even a report of some household "contact" cases. The Advisory Committee recommended changes in emphasis in this report, stressing immunization of infants and pre-school age children.⁶⁴

Since type II Oral Poliomyelitis Vaccine is believed to give some protection to the "slight" but now recognized risk in types I and III, the committee recommends that type II be given first. In the same series of articles, Dr. Sabin replies to this new position.⁶⁵

PRACTICAL LIMITATIONS

Since the use of drugs often involves a matter of life and death, there is great public interest surrounding even experimental drugs. However, advancement requires use. The benefits of new drugs are studied in relation to other drugs available, as for example Sabin with Salk, and then balanced against the risks. In contrast to the benefits and risks are policy considerations, *i.e.*, the demand for new drugs, freedom to compete in a large and growing market, and the desire to give maximum value, protection, and safety to drug consumers. However, it is extremely difficult to balance the potential good against an unknown level of risk, even in

Report of Advisory Committee of the Public Health Service, *Oral Poliomyelitis Vaccines*, 190 A.M.A.J. 49 (1964); Sabin, *Commentary on Report of Oral Poliomyelitis Vaccines*, 190 A.M.A.J. 52 (1964)

63. The most reliable statistics appear to be those of the Public Health Service, Poliomyelitis Surveillance Committee, but they cover only the most serious injuries. Many other people complained of sickness probably associated with the mild disease which the vaccine was supposed to create.

There are over a dozen Sabin cases now pending. At the time of this printing, one Sabin suit has been won with a verdict for the plaintiff for \$120,000.00. *Polio Victim Gets \$120,000.00*, Oklahoma City Times, Nov. 19, 1964, p. 6, col. 1. In two Oregon suits, one ended with a decision for the defendant, the other in a mistrial. *The Oregonian*, Feb. 27, 1965, p. 13, col. 1.

64. Special Report, *supra* note 62, at 50.

65. Sabin, *supra* note 62. Dr. Sabin admits that most adults do not need to take the oral vaccine because they are already naturally immune, but he emphasizes that there is no easy way of identifying those who are not immune. Consequently, he points to the "demonstrated superiority" and "lack of positive evidence of contraindications" as reasons in favor of mass use of his vaccine. *Id.* at 54.

light of public necessity. Choosing informed decision makers is vital. Certainly, some controls and assurances of uniformity are required at that level. The essential question is how to protect the consumer without restricting medical progress. Informed consent on the part of the eventual user has been one answer,⁶⁶ improved testing another,⁶⁷ and insurance⁶⁸ still another.

Discussing thalidomide in a recent periodical, one author recognized part of the problem:

This [drug] forcefully calls attention to possible serious effects of new drugs on the fetus as a result of use during pregnancy. It poses the problem of what constitutes adequate clinical studies to detect this potentiality.⁶⁹

More control over the manufacture, testing, and use of drugs is suggested by the types of injuries and trade practices discussed earlier, yet one author writes that "the public policy historically applicable to medicine in this country has been to preserve substantial freedom in medical practice."⁷⁰ But the size and complexity of today's society requires some control over, or cooperation among, drug companies so as to insure uniform standards of safety and effectiveness.

In a recent article discussing the practical problem of industry competition, it is said that public demand and industry competition urge rapid marketing of new drugs.⁷¹ Furthermore, the productivity of the drug industry creates a situation wherein it becomes more difficult to thoroughly investigate all drugs. Trained and objective investigators are often scarce for the more mundane drugs, although "wonder" drugs are much more likely to stimulate interest and cooperation. This scarcity of qualified investigators results in erroneous decisions with respect to marketing, and the accumulation of inadequate data to support advertising claims for new drugs.⁷² When the decision is made to market a drug, "there can be no wishy-washy approach to its promotion."⁷³ Therefore, most drug advertisements are more persuasive than educational. On the other hand, drug houses are reluctant to spend time and money in routine toxicity testing, unless the drug shows promise, *i.e.*, until the first human tests are encouraging. Thus, human tests may be pushed ahead of animal

66. *Maericlein v. Smith*, 129 Colo. 72, 266 P.2d 1095 (1954)

67. Lasagna, *Problems of Drug Development*, 145 SCIENCE 362 (1964).

68. 2 FRUMER & FRIEDMAN, PRODUCTS LIABILITY § 50, at 1101 (1960).

69. *Smith*, *New Drug Applications*, 17 FOOD DRUG COSM. L.J. 497, 501 (1962)

70. Ringuette, *Authority, Drugs and the Practice of Medicine*, 16 FOOD DRUG COSM. L.J. 393, 408 (1961).

71. Lasagna, *supra* note 67; see also MacDonald and MacKay, *Adverse Drug Reactions*, 190 A.M.A.J. 1071 (1964); Modell, *Safety in New Drugs*, 190 A.M.A.J. 141 (1964)

72. Lasagna, *supra* note 67, at 363.

73. *Id.* at 364.

testing. In this regard, it is said that animal testing should be required by law before extensive field trials are allowed.⁷⁴ At the present time, the Food and Drug laws provide some protection in that the Secretary may require preclinical animal testing.⁷⁵

Plaintiff's Attorneys Groups

For the lawyer, all of the foregoing discussion of drugs and drug problems means many more valuable hours spent in medical research. The complexity of the subject matter represents important practical problems which necessarily call for the aid of a consulting expert. Finding specialists who are conversant with a particular drug is difficult in itself. In addition, a jury of laymen must be made to understand vast technical problems and decide issues upon which even the most learned disagree.

In meeting these difficult problems, plaintiff's attorneys have recently been banding together. The first "group" to be organized was the Mer/29 group in 1963. Thirty-five lawyers met in Chicago envisioning a cooperative effort in the preparation of their cases both legally and medically. Presently, there are 230 lawyers and law firms in this group, representing five hundred to six hundred cases.⁷⁶

The work done by the groups is general in scope, *i.e.*, each lawyer handles his own pleadings, settlement, and trial. However, assistance is

74. Letter from the Pharmaceutical Manufacturers Association to the writer, Aug. 1, 1962.

75. Federal Food, Drug and Cosmetic Act § 505 (i), 76 Stat. 781 (1963), 21 U.S.C. 355 (i) (Supp. V, 1964).

Although most reputable companies conduct some animal tests, they continue to object strenuously to all new impositions whether legislative or judicial. The claim is made that manufacturers, with the specter of liability present, may tend to diminish both the quality of testing and development of new drugs. Gibson, *The Effect of the Investigational Drug Regulations on Drug Research and Development*, 19 FOOD DRUG COSM. L.J. 153 (1964); Comment, *Strict Liability for Drug Manufacturers: Public Policy Misconceived*, 13 STAN. L. REV. 645, 649 (1961). In reality, this "hue and cry" about increasing costs and adverse effects is a mere shibboleth. One has only to examine the annual financial reports of the drug companies to discover how small liability looms in the profit growth picture of the industry. *Hearings Before the Subcommittee on Reorganization & International Organizations of the Committee on Government Operations*, 88th Cong., 1st Sess., pt. 4, at 1955-78 (1963). The 1962 amendments are themselves an attempt to correct unfair trade practices uncovered by the Kefauver Committee. The effort is towards quality, safety and understanding. Special Announcement, *New Book on Drugs — 1965*, 190 A.M.A.J. 206 (1964).

Although NND [New and Nonofficial Drugs] proved useful to many as a reference book, the rapid introduction of a large number of new drugs has made it inadequate to meet the needs of practicing physicians.

The NND is being replaced with a new book entitled *New Drugs*. The contents are oriented to fit the needs of the practitioner and the information is said to be objectively presented. See generally, Coggeshall, *Drug Safety and Drug Control*, 3 J. NEW DRUGS 147 (1963); Meyers, *The Food & Drug Administration's Role in the Testing of New Drugs*, 3 J. NEW DRUGS 338 (1963).

76. *Hearings Before the Subcommittee on Reorganization & International Organizations of the Committee on Government Operations*, 88th Cong., 1st Sess., pt. 4, at 1955-78 (1963)

available through the group at the trial stage if requested. The activities of the group involve the taking of depositions, discovery of documents, medical and legal research, and news reporting on trials. Most important is the handling of medical experts. They are consulted by representatives of the group and the results are made available to all. Harassment of experts by hundreds of attorneys is avoided and as a result the few experts available on individual drugs are more inclined to cooperate by supplying information or witnesses.

The Mer/29 group provided the pattern for three other groups involved with Enovid, Sabin, and Aralen. The Enovid group is one of the newest; only a few cases have been filed. No group is yet organized for Parnate.⁷⁷

The advantages of group efforts are obvious. First, the pooling of information is an attempt to gain an even advantage with the defendant who, as a rule, has access to all the facts of all cases. Second, there are economic savings in that the work is done just once for all cases. Third, it is felt that by grouping efforts the legal issues in these cases can be raised more clearly. As a result, there is likely to be an increase in the number of appellate opinions concerning drug products.

Although the group approach has been highly successful, it is important to note that there are significant limitations to such efforts. Only products which cause wide-spread and contemporaneous harm are adaptable to the nation-wide "group" approach. Since the main advantage of this system is in helping the attorneys to prepare, it would be somewhat limited to situations where all are preparing at approximately the same time. In addition, since much of the progress of, and advantage from, these groups comes from negotiation rather than litigation, cooperation of the manufacturer and its insurer is vital.

The group system represents a movement toward more equal justice. The public can anticipate the appearance of more such groups as lawyers seek to better their preparation, reduce costs, and properly represent the injured client. With some understanding of the drugs, the injuries complained of, the problem of causation, and the other pressures upon drug researchers, manufacturers, and attorneys, the changing legal picture can now be drawn.

MISREPRESENTATION

Although negligent conduct can sometimes be shown, the major reliance in new drug cases is on the legal aspects of misrepresentation; but this is a nebulous term. It appears in connection with many actions

77. No figures are yet available for the number of Parnate cases arising before the new labels were ordered.

such as deceit, fraud, warranty, and so on.⁷⁸ Because the courts do not agree on the exact nature of these actions, any attempt to distinguish between them is necessarily oversimplified and partly inaccurate.

Notwithstanding this confusion, it is necessary for purposes of proper analysis to examine the traditional approaches to this subject. There is no better starting point than Dean Prosser's analysis. He states that misrepresentation runs all through the law and has been merged indistinguishably with all kinds of misconduct.⁷⁹ Attempts to treat misrepresentation as a distinct cause of action in tort has caused confusion with the common law action of deceit. Misrepresentation is broader than deceit, deceit being only one part of a familiar scheme in tort law. In other words, misrepresentation may include (1) an intent to deceive (deceit), (2) negligence (negligent misrepresentation), and (3) statements made under circumstances which give rise to a policy of strict liability, as for example through warranty.⁸⁰

Although deceit is available and has been used in drug cases,⁸¹ it has limitations. There are two elements in this action which are difficult to prove: (1) *scienter*, or a knowledge or belief on the part of the defendant that the representation is false; and (2) *intention* to induce the plaintiff to do or refrain from doing some act in reliance upon the misrepresentation. In many drug liability cases, the representation is innocently made and therefore the case cannot rest upon deceit. Consequently, concern here is with warranty and negligent misrepresentation. The latter form of misrepresentation is rarely used, but because of its appearance in the new drug cases it deserves some explanation. A case brought under a theory of negligent misrepresentation requires no proof of an *intentional* misstatement. Instead, the plaintiff need only show that the representation from which the product-caused injury is alleged to have flowed was one that an ordinarily careful man would not have made under the circumstances.⁸² The representation may be negligent because of the manner of expression,⁸³ or because of the type of business involved.⁸⁴ That is, if the person who makes the representation does so in the course of a business or profession of supplying services which require special com-

78. Bohlen, *Misrepresentation as Deceit, Negligence, or Warranty*, 42 HARV. L. REV. 733 (1929); Carpenter, *Responsibility for Intentional, Negligent and Innocent Misrepresentation*, 24 ILL. L. REV. 749 (1930); Smith, *Liability for Honest Misrepresentation*, 24 HARV. L. REV. 415 (1911).

79. PROSSER, TORTS § 100, at 697-98 (3d ed. 1964).

80. *Id.* at 698.

81. *Wennerholm v. Stanford Univ. School of Medicine*, 20 Cal. 2d 713, 128 P.2d 522 (1942).

82. *Cunningham v. C. R. Pease House Furnishing Co.*, 74 N.H. 435, 69 Atl. 120 (1908)

83. See *Nash v. Minnesota Title Ins. & Trust Co.*, 163 Mass. 574, 40 N.E. 1039 (1895)

84. See *Toth v. Vazquez*, 3 N.J. Super. 379, 65 A.2d 778 (1949); *Ultramares Corp. v. Touche*, 255 N.Y. 170, 174 N.E. 441 (1931).

petence, he should have the competence thus professed.⁸⁵ The basis of this liability is the reliance of the consumer upon the qualifications of one who has a particular profession, talent, skill, or knowledge.

There is a series of product cases where negligent misrepresentation was the basis for liability,⁸⁶ but there is still authority supporting application of this doctrine only in cases where there has been an invasion of interests of a financial or commercial character, *i.e.*, in the course of business dealings.⁸⁷ There are also specific drug product cases which have failed under this theory. One involved an anti-rabies vaccine.⁸⁸ The pamphlet accompanying the vaccine warned of a .04 percent risk of paralysis and decedent was shown the pamphlet by the treating physician. The court presumed that he had acquainted himself with the pamphlet and had thus assumed the risk.⁸⁹ But the availability of contributory negligence and assumption of the risk may make negligent misrepresentation uninviting, particularly in light of the fact that these defenses are not well defined in this action. The standards for these defenses are complicated in that negligence is based on words rather than acts.

In addition to the obstacle of negligence defenses, there is the difficulty of establishing a standard of care for the person making the representations. Courts may very well find a lower standard for negligent representations, because elaborate testing ought to minimize the risk upon which the standard may depend. But this argument is used to reduce the standard for regular negligence actions in this field. The real source of difficulty is the necessity of proving *words* instead of *acts*.

Proof that defendant knew or should have known of certain dangers or adverse affects is an additional stumbling block. In the case of thalidomide, this element of proof hinges on whether there is knowledge that certain drugs can pass the placental barrier and produce various abnormalities or even abortions. Negligence would then arise in failing to test the drug on pregnant animals, pretending that the drug was safe, and assuring physician and patient that the drug could be used during pregnancy. In short, this involves inducing reliance on information which the supplier did not know to be true. Perhaps the success of more cases on the negligent misrepresentation action will stimulate a new concern for knowing the truth before there is wide distribution of a drug.

85. SALMOND, TORTS § 501 (11th ed. 1953).

86. Segal v. Carroll Furniture Co., 51 Ga. App. 164, 179 S.E. 775 (1935) (bed collapsed); Andreottala v. Gaeta, 260 Mass. 105, 156 N.E. 731 (1927) (prescription filled incorrectly); Holly v. H. L. Green Co., 3 Misc. 2d 941, 155 N.Y.S.2d 197 (1956) (used soda fountain exploded); Williamson v. Faxon, 208 N.Y. 108, 101 N.E. 799 (1913) (laxative); Rulane Gas Co. v. Montgomery Ward Co., 231 N.C. 270, 56 S.E.2d 689 (1949) (hot water heater explosion).

87. United States v. Neustadt, 366 U.S. 696, 711 n.26 (1961)

88. Carmen v. Eli Lilly Co., 109 Ind. App. 76, 32 N.E.2d 729 (1941).

89. *Id.* at 84, 32 N.E.2d at 731.

STRICT LIABILITY

The discussion concerning strict liability is not concerned with whether it should be applied to drug cases, but rather what forms it should take when applied. Strict liability is, of course, liability without fault. It can be imposed through warranty, by statute, or in tort.

Warranty

It has been noted that courts have blended deceit, negligent misrepresentation, and warranty⁹⁰ Actions in deceit have been allowed "for an honest but carelessly or unavoidably inaccurate statement."⁹¹ This takes deceit into the field of negligence. With respect to warranty, there has been a steady movement into the tort area; privity is being dropped and negligence defenses have been added.⁹² More litigation in negligent misrepresentation may reverse these terms, thus confining deceit to intentional and conscious misrepresentation and reaffirming privity and contract theories in warranty. At this time it can be said that warranty is a specie of strict liability in that wrongful intent or negligence on the part of the defendant need not be shown. The more difficult problems of proof will be examined in greater detail.

Sale.—Plaintiffs seeking to recover for injuries will, if warranty is the basis for their action, experience some difficulty in overcoming the lack of a sale. Some courts have denied any implication of warranty by insisting on a technical sale.⁹³ When the drugs are administered by a physician in a course of treatment, the proof of a sale may be more difficult. This was the difficulty encountered when "no sale" was argued in the *Cutter and Perlmutter v. Beth David Hospital*⁹⁴ cases.

There are three ways in which the sale problem may arise: (1) administration of the drug by a physician; (2) administration of the drug during experimental drug testing; and (3) public distribution of vaccines. The *Cutter* case answered the argument with respect to doctor administered drugs. The court said: "Clearly, it is the patient and not the doctor who is the ultimate consumer of the vaccine. [The] implied warranties run to the benefit of persons intended to be the consumers."⁹⁵

90. Bohlen, *supra* note 78.

91. Bohlen, *supra* note 78, at 733.

92. See *Webster v. Blue Ship Tea Room, Inc.*, 198 N.E.2d 309 (Mass. 1964), noted in 16 W. RES. L. REV. 454 (1965) (food case; fishbone in fish chowder). In the *Blue Ship* case the court seems to be recognizing the defense of assumption of the risk in a warranty action. See generally Boshkoff, *Some Thoughts About Physical Harm, Disclaimers, and Warranties*, 4 BOSTON INDUST. & COM. L. REV. 285 (1963), where it is pointed out that the consumer generally demands perfection in drugs, but only average quality in cigarettes. If the exceptions are deemed unreasonable, then as a matter of law there is contributory negligence.

93. *Perlmutter v. Beth David Hosp.*, 308 N.Y. 100, 123 N.E.2d 792 (1954)

94. *Ibid.*

95. *Gottsdanker v. Cutter Labs.*, 182 Cal. App. 2d 602, 609, 6 Cal. Rep. 320, 324 (1960)

In *Perlmutter*, during the course of hospital treatment, the plaintiff received a blood transfusion which resulted in hepatitis. It was held that the use of a blood serum was a service and not a sale. If there is no sale then there is no liability in implied warranty.⁹⁶ A statute has been enacted in another state to provide this exception for injuries resulting from blood and serum use.⁹⁷ Therefore, problems in proving a sale may be encountered with the new drugs if they were given by a physician as part of a continuing service as in a hospital.

The "experimental drug" aspect of the warranty cases is very new. It appears as though the thalidomide cases have been the first to raise problems in this area. However, the legal problems here, at least with respect to "sale," should be no different than doctor administered and approved drugs.

With respect to publicly distributed drugs, the Sabin vaccine presents the most interesting problem. The Sabin program in most areas of the country involved free distribution of live virus on sugar cubes or in little cups of water. It was advertised as free to all, yet at the distribution centers a "donation" box was placed somewhere along the line. Often a sign was posted suggesting "25 cent donations" or "donations of any amount." For all practical purposes, everyone gave something.⁹⁸ The question then arises as to whether there is a sale if one pays for a "free sample."

The Uniform Commercial Code may have some effect on the technical sale requirement. The UCC theory of liability does not rest on any equitable notions of distributing the loss as appears to be the case with some forms of strict liability. Rather, the code establishes several special requirements as a basis upon which recovery may be had in warranty. Imposing a requirement of a sale as a *sine qua non* of recovery seems unduly restrictive; however, section 2-313 may do just that. The section speaks of "seller," "buyer," and "bargain." The definitions section of the UCC, 2-106, purports to cover the entire sales article when it defines a sale as the passing of title from *seller* to *buyer* for a *price*. Section 2-204 emphasizes the contractual basis of a sale. These sections may be held to apply to the terms of 2-313 regardless of the official comment which reads:

[T]he warranty sections are not designed in any way to disturb those lines of case law growth which have recognized that warranties

96. *Perlmutter v. Beth David Hosp.*, 308 N.Y. 100, 103, 123 N.E.2d 792, 795 (1954), reads in part as follows: "[I]f the transaction were to be deemed a sale, liability would attach irrespective of negligence or other fault. The act of healing frequently calls for a balancing of risks and dangers."

97. CAL. HEALTH & SAFETY CODE § 1623 (Deering 1961).

98. Berland, *Doctor Sabin's 30 Year War With Polio*, *Today's Health*, Sept., 1962, p. 54 (Cleveland, Ohio averaged 24.8 cents per donation).

need not be confined either to sales contracts or to the direct parties to such a contract.⁹⁹

It has been noted that the rules governing sales warranties are extended by analogy to contracts for bailment and for labor and materials.¹⁰⁰ By the same analogy, protection can certainly be extended to food and drug products which are closer to "sale" than are bailments.

Privity.—The application of the privity requirement has in the past depended partly upon the nature of the product involved. Today, for example, food cases are turning more on traditional strict tort liability than negligence or warranty; however, courts often say no privity need be proved, and an award is made on the basis of warranty.¹⁰¹

In the past, many fictions have been utilized to dispense with privity. The warranty has been held to run with the goods¹⁰² or inure to the ultimate consumer's benefit.¹⁰³ Courts have used the third party beneficiary theory¹⁰⁴ and have also held that the retailer's warranty from the manufacturer is assigned or extends to the ultimate consumer.¹⁰⁵ The tort character of the warranty has either been stressed¹⁰⁶ or privity has been plainly rejected.¹⁰⁷ Therefore, the trend of modern case law is away from the privity requirement.¹⁰⁸

99. UNIFORM COMMERCIAL CODE § 2-313, comment 2 [hereinafter cited as UCC]. Citations are to the 1962 official text published by the American Institute and the National Conference of Commissioners on Uniform State Laws.

100. Farnsworth, *Implied Warranties of Quality in Non-sales Cases*, 57 COLUM. L. REV. 653 (1957).

101. An analogy to food products may bring these drug cases under the wing of protection from the privity requirement which food cases enjoy. *Crystal Coca-Cola Bottling Co. v. Cathey*, 83 ARIZ. 163, 317 P.2d 1094 (1957) (fly in coke); *Ward Baking Co. v. Trizzino*, 27 OHIO APP. 475, 161 N.E. 557 (1928) (needle in cake); *Swift & Co. v. Wells*, 201 VA. 213, 110 S.E.2d 203 (1959) (infected pork). Similarly, one could validly argue that drugs whether injected, swallowed, inhaled, or rubbed on, are consumed. However, it is important to realize that the basic similarity between food and drugs is not in the method of application or consumption, or in its intimate connection with the body, but in the very essence of the product itself. In this respect, the courts must look at who has control over the product (opportunity to discover defects), the normal expectations of people regarding the product, and the nature and importance of the product in relation to health, sustenance and normal needs of the human body. Drugs are as important as food in these respects.

2 FRUMER & FRIEDMAN, PRODUCTS LIABILITY § 33.02(2); *but see id.* § 16.03(4)(a), at 386 (1961)

102. *Coca-Cola Bottling Works v. Lyons*, 145 MISS. 876, 111 SO. 305 (1927)

103. *Klein v. Duchess Sandwich Co.*, 14 CAL. 2d 272, 93 P.2d 799 (1939)

104. *Ward Baking Co. v. Trizzino*, 27 OHIO APP. 475, 161 N.E. 557 (1928)

105. *Madouros v. Kansas City Coca-Cola Bottling Co.*, 230 MO. APP. 275, 90 S.W.2d 445 (1936)

106. *Mazetti v. Armour & Co.*, 75 WASH. 622, 135 PAC. 633 (1913)

107. UCC § 2-318; *see also Crystal Coca-Cola Bottling Co. v. Cathey*, 83 ARIZ. 163, 317 P.2d 1094 (1957) (food case)

108. In *Henningson v. Bloomfield Motors, Inc.*, 32 N.J. 358, 161 A.2d 69 (1960), there was an injury caused by a defective automobile. Liability to third persons was established through implied warranty as it was through negligence in *MacPherson v. Buick Motor Car*

The drug cases are part of this trend. The *Cutter* case, for example, dispensed with privity, holding that *the policy favoring drug companies and freedom for them* is not warranted where the drug actively caused the disease it was designed to prevent.¹⁰⁹ The privity requirement should not, however, rest solely on a "policy" of protecting the manufacturer. The *Cutter* case, after establishing this policy as the basis for the retention of privity, abrogated it by simply demonstrating the serious nature of the injury. When a drug's reaction is exactly opposite from that intended, no policy favoring manufacturers ought to save them from liability by application of an outworn technicality such as privity.

One might distinguish cases involving drugs which only failed to cure, or vaccines which failed to protect, from cases which caused "side-effects." Side-effect injuries are not the type contemplated in *Cutter* where the court dispensed with privity. Therefore, unless the injuries caused by Parnate and thalidomide were anxiety and depression, or unless Mer/29 created cholesterol which led to a heart attack, great reliance on *Cutter* alone may be unwise. The Sabin vaccine, of course, falls in line with the "opposite-from that intended" argument used in *Cutter*, but plaintiffs in other drug cases will have to show that the side effect injury itself was so serious as to overcome the policy favoring drug firms. Certainly, in the event that privity is retained in these new drug cases, it should be extended to the intended users.

UNIFORM COMMERCIAL CODE

Although the UCC was not designed "to disturb those lines of case law growth"¹¹⁰ which are liberalizing recovery in warranty, there are some noteworthy modifications. Section 2-313 deals with an express warranty between seller and buyer. Express warranty rests on the "dickered" aspects of individual bargaining, whereas implied warranty rests on the surrounding facts and circumstances of the sale.¹¹¹ In some jurisdictions, the wording of this section may have a liberalizing effect. The words "any affirmation" are meant to eliminate requirements of intent or reliance.¹¹²

Merchantability

Section 2-314 deals with the implied warranty of merchantability. Instead of a requirement that the buyer rely on the seller's skill or judg-

Co., 217 N.Y. 382, 111 N.E. 1050 (1916). That is, the implied warranty extends to users and others injured by the product.

109. *Gottsdanker v. Cutter Labs.*, 182 Cal. App. 2d 602, 6 Cal. Rep. 320 (1960).

110. UCC § 2-313, comment 2.

111. UCC § 2-313, comment 1.

112. UCC § 2-313, comment 3.

ment, this section demands that the seller be a merchant dealing in the goods sold. In section 2-314, the implied warranty arises in a contract of sale, course of dealing, or usage of the trade. This section includes the serving of food or drink. Six requirements¹¹³ of merchantability are outlined in this section. Drugs, for example, which are not compatible with the purpose for which intended are unmerchantable under this section.

Fitness

Section 2-315 deals with the implied warranty of fitness for a *particular purpose*. There are two requirements: (1) the seller must have reason to know the particular purpose for which the goods are required;¹¹⁴ and (2) the buyer must prove he relied on the seller's skill and judgment in the matter.¹¹⁵ The comments following this section make it clear that the implication of warranty is a factual as opposed to a legal question. The buyer must actually rely on the seller, but need not affirmatively indicate his reliance to the seller so long as the circumstances are such that the seller should know of it.¹¹⁶

Class of Plaintiffs

Little difficulty is anticipated with sections 2-313, 314, 315, or 316, simply because they effect little change in existing law. On the other hand, section 2-318 is of particular interest in the new drug cases for

113. UCC § 2-313.

Goods to be merchantable must be at least such as

a) pass without objection in the trade under the contract description; and b) in the case of fungible goods, are of fair average quality within the description; c) are fit for the ordinary purpose for which such goods are used; and d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among units involved; and e) are adequately contained, packaged, and labeled as the agreement may require; and f) conform to the promises or affirmations of fact made on the container or label if any.

114. UCC § 2-315.

115. *Ibid.*

116. Sections 2-314 and 2-315 define two different kinds of implied warranty. The key to 2-315 is contained in the words "particular purpose," and this is said to envisage a specific use by the buyer which is peculiar to the nature of his business. UCC § 2-315, Comment 2. Conceivably, a product could be either unmerchantable or not fit for the particular purpose intended, or both.

It is worth noting that there may be liability under § 2-315 for allergic reactions if the seller, at the time of the sale, had reason to know of the buyer's peculiar sensitivity and the buyer relied on the seller's skill to furnish a suitable product. *Wright v. Carter Prods., Inc.*, 244 F.2d 53 (2d Cir. 1957).

This section also modified the rule which prevented recovery if the buyer requested a patent or trade name. Comment 5 following this section in the 1962 revision of the UCC states that "the mere fact that the article purchased has a particular patent or trade name is not sufficient to indicate non-reliance by the seller as adequate for the buyer's purpose."

some jurisdictions. It states:

A seller's warranty whether express or implied extends to any natural person who is in the family or 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. A seller may not exclude or limit the operation of this section.¹¹⁷

While the last sentence does not prevent disclaimers, it does prevent a seller from limiting the warranty to the immediate buyer. For some jurisdictions, this section may have extended the scope of coverage; for others, it may have given a rebirth to the concept of privity by *describing the class* of plaintiffs and defendants.¹¹⁸ The comments, however, quickly halt such speculation by saying that the section "is not intended to *enlarge* or *restrict* the developing case law on whether the seller's warranties extend to other persons . . ."¹¹⁹

Notice of Breach

Section 2-607 deals with notice of breach. The buyer is required to notify the seller within a reasonable time after injury that the transaction may involve a breach.¹²⁰ This does not mean the notice must contain a clear statement of all objections, a threat of litigation, or a claim for damages. Simple notice is required in reasonable time, but more time is accorded retail consumers than merchant buyers.¹²¹ If the seller's breach is made in bad faith the time requirement is given a very liberal construction.¹²²

STRICT TORT LIABILITY

Several rationales have been set forth to justify strict tort liability.¹²³ Among the most common are: (1) One who undertakes to supply products which may endanger person or property has a special responsibility imposed upon him to protect those who are forced to rely on his products. (2) The manufacturer is in the best position to discover defects and

117. UCC § 2-318.

118. Freedman, *Products Liability Under UCC in New York and Other States*, 19 FOOD, DRUG COSM. L.J. 178, 182 (1964).

119. UCC § 2-318, comment 3. (Emphasis added.)

120. UCC § 2-607, comment 4, par. 2.

121. UCC § 2-607, comment 4, par. 1.

122. UCC § 2-312, comment 2. The notice requirements, as other sections of the Code, will have to be analyzed on a case-by-case approach which is beyond the scope of this article. However, it is important to realize the potential variations the UCC may effect in the warranty law of those states which have adopted the Code.

123. Dickerson, *The Basis of Strict Products Liability*, 16 FOOD DRUG COSM. L.J. 585, 589 (1961); Green, *Should the Manufacturer of General Products be Liable Without Negligence*, 24 TENN. L. REV. 928 (1957); Pound, *Law in the Service State: Freedom versus Equality*, 36 A.B.A.J. 977, 981 (1950).

should therefore be motivated to improve his product and use all possible care. (3) Strict liability generally places the loss on the one best able to handle and distribute it.¹²⁴

Although strict liability has been criticized as an expression of radical jurisprudence, of dubious morality, as well as a novel social theory and bad economics,¹²⁵ it is here to stay. In the area of drugs, strict liability simply means that the manufacturer will be liable without fault for an injury caused by his product. One need only prove that the drug caused the injury. A proposed addition to the *Restatement of Torts*¹²⁶ adds the requirement that the product be "defective" or "unreasonably dangerous." This new section¹²⁷ originally applied only to strict liability for food injuries; however, the American Law Institute's recent Tentative Draft No. 10 for the *Restatement of Torts, Second*, section 402A recognized the rapid changes in this area and proposed strict liability for *any product* which is sold in a dangerous or defective condition. The suggested limitations on the application of this rule have some relevance in the drug cases. In comment K to section 402A it is noted that certain products such as drugs and vaccines are often unavoidably unsafe. However, it is clearly stipulated that the drug product be properly *prepared and marketed* and proper *warning* be given where the situation calls for it, otherwise the rule of strict liability will apply. Even with this stipulation, the new *Restatement* section appears to be perpetuating a distinction based on the manufacturer's ability to know of the presence of a dangerous defect. If the reasons given in support of strict liability are to retain any validity, no exception for drugs should be made.¹²⁸

124. RESTATEMENT (SECOND), TORTS § 402A, comment c (Tent. Draft No. 10, 1964)

125. Coleman, *The Deep Pocket Rule and the Jumping Warranty: Strict Products Liability of Manufacturers*, 18 FOOD DRUG COSM. L.J. 654 (1963)

126. RESTATEMENT (SECOND), TORTS, § 402A (Tent. Draft No. 7, 1963).

127. *Ibid.* The section reads as follows:

SPECIAL LIABILITY OF SELLER OF PRODUCT TO USER OR CONSUMER

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property, is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Caveat—The Institute expresses no opinion as to whether the rules stated in this Section may apply

- (1) to harm to persons other than users or consumers;
- (2) to the seller of a product expected to be processed or otherwise changed before it reaches the user or consumer; or
- (3) to the seller of a component part of a product to be assembled.

128. Certainly, no person should go uncompensated for an injury caused by a drug which medical science is advanced enough to invent and market, but too careless to evaluate and investigate properly. The problem is not in knowing too little about a drug, but in taking too little time to apply what is known.

Further examination of the strict liability theory reveals that the rule announced in section 402A pertains only to a manufacturer, dealer, or seller of a product. In addition, the burden is on the injured plaintiff to show that the product was defective when it left the seller. This includes "packaging, necessary sterilization and other precautions" necessary to insure the safety of the product through its normal anticipated use. No distinction should be made between a product which is inherently dangerous and one which is impure or contaminated. The term "defective" should encompass both types of products.

In addition to the defective quality of the product, it must be "unreasonably dangerous" to the user or consumer. Essentially, this means the product must cause an injury not contemplated by the normal expectations of an average person. If an overdose of a normally safe drug produces injury, there is no proof that it is unreasonably dangerous. But if the drug is used as prescribed and produces injury which is not a part of the community's common knowledge as to its characteristics, then the injury does qualify under section 402A¹²⁹ as defective.

In allergy cases, it should be the seller's duty to warn the purchaser if the product contains a substance to which a relatively large number of people may be allergic. It is nearly impossible for the consumer to know just what drugs may be harmful to him. Using a standard of "reasonable human skill and foresight," the drug manufacturer must discover and warn of inherent dangers.¹³⁰

Strict liability is no longer a "novel social theory" and "bad economics"; it is a movement in law which is directly responsive to social needs. The drug industry purports to protect the public; in pursuance of that aim, the law should contribute toward complete protection of the consumer.

GOVERNMENT TORT LIABILITY

Recent discussions have suggested the possibility of government liability for drug injuries brought under the Federal Tort Claims Act (FTCA). C. Joseph Stetler, general counsel for the Pharmaceutical Manufacturers Association, recently addressed the Federal Bar Association on this very problem.¹³¹ He theorized that a combination of increased government control and scientific advancements are creating a legal duty on the part of the government to exercise care in testing and approving new drugs. The drug law amendments of 1962 increase the government's power and authority, as well as the responsibility and potential liability of the government.

129. RESTATEMENT (SECOND), TORTS § 402A, comment 1 (Tent. Draft No. 10, 1964).

130. RESTATEMENT (SECOND), TORTS § 402A, comment j (Tent. Draft No. 10, 1964). This same result is reached now in many states by case law.

131. Stetler, *Government Tort Liability Under the Drug Amendments of 1962*, 3 J. NEW DRUGS 266 (1963).

Outside of the FTCA there is little authority for government liability based upon certification, license, approval, or "guarantee" of a product.¹³² Under the Federal Tort Claims Act, however, there is some precedent which may illumine the area of drug liability. The act subjects the government to liability for negligent acts of its employees who are acting in the scope of their employment. The types of injuries covered include loss, personal injury, or death. Mr. Stetler points out that government action under the new drug laws comes within the scope of the act as interpreted. Indeed, because of its benevolent purpose the act has been liberally construed; but the exceptions within the act are correspondingly subject to strict construction.¹³³

The Food, Drug and Cosmetics Act may also provide some remedy in drug cases. Duty, the basic element in any negligence action, exists in the act and is said to exist for the ultimate consumer.¹³⁴ However, the nature of this duty did prevent recovery in one tort claims case based on the Food, Drug and Cosmetics Act.¹³⁵ *Anglo-American & Overseas Corp. v United States* involved an action by a wholesaler-purchaser of tomato paste against the federal government. The government elected to test a sample of the imported food product and subsequently cleared its shipment. Later, it was discovered that the shipment was impure and the entire lot was destroyed. The wholesaler based his claim on the defendant's failure to reject the paste as an impure imported product. Negligence in the original examination and issuance of a certificate clearing the product was alleged. The court said that the duty under the Food and Drug Act is primarily for the ultimate consumer¹³⁶ not for an intermediate dealer. This would seem to open a door for drug consumers who depend on the government to test not just a sample, but, as is the case with some drugs, every batch, lot, or shipment. However, as quickly as this "door" is opened, it is slammed shut. The *Overseas Corp.* case also added weight to a defense which has been developing since the early

132. It has been determined that the approval of a structural design by the Civil Aeronautics Authority is nothing more than a determination of conformity with minimum standards of the Civil Air Regulations. *Prashker v. Beech Aircraft Corp.*, 258 F.2d 602 (3d Cir.), *cert. denied*, 358 U.S. 910 (1958). The court directed a verdict for defendant without considering the argument that certification was conclusive as to the safety and fitness of the plaintiff's design. This case was directed against the manufacturer, not the government, so there is no law clarifying the effect of government approval of aircraft or, similarly, of drugs.

133. *Jones v. United States*, 126 F. Supp. 10 (D.D.C. 1954), *aff'd*, 228 F.2d 52 (D.C. Cir. 1955).

134. *United States v. Sullivan*, 332 U.S. 689 (1948); *United States v. Dotterweich*, 320 U.S. 277 (1943).

135. *Anglo-American & Overseas Corp. v. United States*, 144 F. Supp. 635 (S.D.N.Y. 1956), *aff'd*, 242 F.2d 236 (2d Cir. 1957).

136. *Id.* at 636.

fifties.¹³⁷ To understand this defense, the FTCA must be examined to discover its own specific exceptions. One such exception holds the entire act inapplicable in cases where the claim arises out of misrepresentation or deceit.¹³⁸ The *Overseas Corp.* case held that the exception encompasses misrepresentations which are negligent as well as those which are wilful.¹³⁹ Other cases have held further that even where there is a negligent act, the FTCA will not apply if the act became operative through misrepresentations. Thus, where a negligent act is coupled with a resultant false misrepresentation on which plaintiff relies to his economic detriment, the real cause of injury is said to be the misrepresentation.¹⁴⁰

In capsule form, it can be said that the trend of recent cases is that there is no liability for misrepresentation, even if negligently made, so long as the resulting damage is of an economic or business character. Were the government to be sued for negligently approving a drug which caused physical harm, the courts could find liability simply by refusing to extend the Section 2680(h) misrepresentation defense against an ultimate consumer with this type of injury. This could be based on the government's extensive duty to refrain from approving a drug which is unsafe, impure, or ineffective. It seems, though, that these physical harm cases could meet difficulty in maintaining the theory that negligence becomes operative through misrepresentation. In other words, there are two approaches. (1) Plaintiff says that he was injured because of defendant's representations as to the safety of the drug. This contemplates the possibility of the court's disallowing the misrepresentation defense on the basis of the policy stated above. (2) Plaintiff says he is the ultimate consumer who has suffered bodily injury from defendant's negligent acts, though no misrepresentations may have been made directly to him. In this case, there may be recovery without any conflict with 2680(h)¹⁴¹

137. *National Mfg. Co. v. United States*, 210 F.2d 263 (8th Cir.), cert. denied, 347 U.S. 967 (1954).

138. 28 U.S.C. § 2680(h) (1958).

139. *Anglo-American & Overseas Corp. v. United States*, 144 F. Supp. 635, 637 (S.D.N.Y. 1956), aff'd, 242 F.2d 236 (2d Cir. 1957).

140. The line of cases espousing the defense seems to have been solidified by the United States Supreme Court decision in *United States v. Neustadt*, 366 U.S. 696, 702 (1961), where it was said that the misrepresentation exclusion bars claims arising out of negligence as well as intentional misrepresentation. But this Tort Claims Act case was based on the National Housing Act where the Federal Housing Administration insured the partial repayment of certain loans. The alleged negligence was in furnishing a statement reporting an inaccurate FHA inspection and appraisal. The plaintiff purchaser of a home relied on the representation that there were no defects. The plaintiff's damages were a *loss in value* due to cracking in the ceiling of the house — an economic loss. Indeed, all of the cases which deny recovery under this section of the FTCA deal with misrepresentations which resulted in a pecuniary loss. This is the basis for distinguishing this defense from our present drug fact situations — personal as opposed to pecuniary loss.

141. *Brown v. United States*, 193 F. Supp. 692 (N.D. Fla. 1961)

Extensive research has uncovered no drug cases which have named the United States as a defendant; but in light of the increased responsibilities being assumed by the Food and Drug Administration such a possibility cannot be foreclosed.

CIVIL LIABILITY

In addition to civil liability of the government itself, it is important to consider civil liability based on violation of government statute. Civil liability based on violation of statute is not new; it is a form of strict liability. Many state pure food acts do in fact make the manufacturer or seller of defective goods liable to the injured consumer.¹⁴² If the federal act contained similar provisions, there would be little need for acrobatics with warranty concepts, and the field of strict liability would be under legislative action where many feel it belongs.¹⁴³

When dealing with a statute which imposes only criminal sanctions, violation of it can be evidence of negligence,¹⁴⁴ presumptively negligent conduct,¹⁴⁵ or negligence per se.¹⁴⁶ It is hornbook law that compliance with a criminal statute is not necessarily evidence of due care, since statutes usually describe only minimum standards. Thus, negligence can still be shown by proving a failure to exercise some additional care.¹⁴⁷

A notable case in the food and drug law area is *Orthopedic Equipment Co. v Eutsler*. There, a surgical nail was misbranded according to FDA standards. As a result, plaintiff's leg was injured when the wrong size hole was drilled to contain the nail. The court said:

[Although] the Federal Food, Drug and Cosmetic Act does not expressly provide a civil remedy for injured consumers, [it] does impose an absolute duty on manufacturers not to misbrand their products, and the breach of this duty may give rise to civil liability.

[We] think that a violation of the Federal Food, Drug and Cosmetic Act is negligence per se in Virginia, and that the District Judge correctly based his charge on that premise.¹⁴⁹

142. *Meshbesh v. Channellene Oil & Mfg. Co.*, 107 Minn. 104, 119 N.W. 428 (1909); *Great Atl. & Pac. Tea Co. v. Hughes*, 131 Ohio St. 501, 3 N.E.2d 415 (1936).

143. PROSSER, *TORTS* § 84 (2d ed. 1955); Patterson, *The Apportionment of Business Risks Through Legal Devices*, 24 COLUM. L. REV. 335, 358 (1924); Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1134 (1960).

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

145. *Satterlee v. Orange Glenn Sch. Dist.*, 29 Cal. 2d 581, 177 P.2d 279 (1947), *rev'd on other grounds*, 50 Cal. 2d 617, 327 P.2d 897 (1958).

146. *Martin v. Herzog*, 228 N.Y. 164, 126 N.E. 814 (1920).

147. PROSSER, *TORTS* § 35, at 205 (3d ed. 1964).

148. 276 F.2d 455 (4th Cir. 1960).

149. *Id.* at 460-61.

An expansion of this concept can be expected as one of the first new results of the pending drug litigation. The Mer/29 cases are in the best position to take advantage of the *Orthopedic* case rule, because these cases involve criminal sanctions imposed for violation of the act.¹⁵⁰ Other cases which do not have a similar advantage must first prove that the drug manufacturer did violate the act in order to base any civil liability on a breach of the statutory duty. This will be difficult, for much of the information concerning production, testing, safety, and efficacy is kept confidential.

SPECIFIC DEFENSES

Allergy

The allergy problem is an additional aspect of the earlier discussion of causation. If the defendant-manufacturer knows or has reason to know of certain allergic risks inherent in a particular drug, there ought to be a duty to warn the consumer.¹⁵¹ Absent such warning, there is negligence. How specific the warning must be is still an open question.

With respect to allergic risks, there is no analogy to food cases as exists in the area of warranty-privity. When food is sold in its natural state and consumption results in an allergic reaction, there is no liability.¹⁵² One might argue that since drugs are like food for purposes of privity, they are, likewise, like food with respect to recovery for allergic injuries. However, drugs are not in a natural state like strawberries; they are artificial products. It is the processing or manufacture of the drug which appears to distinguish it legally from unprocessed natural food products. Hence, liability for an allergic drug injury is not summarily excluded. On the other hand, one could attack the "natural-processed" distinction by saying that all products, even food, undergo some processing. The seller has a responsibility to inspect and maintain the quality of his product; he is in a better position to discover risk and thus has an obligation not to sell poisoned strawberries or defective drugs.

It has been noted that the mechanism involved in allergy is similar to immunization.¹⁵³ When a foreign substance is introduced into the body, antibodies are formed to ward off future attacks from the disease. Allergy is produced in somewhat the same manner. Antigens (foreign substances) initiate a sensitivity reaction which results in an "allergic" disease. Therefore, the plaintiff whose resistance would make him

150. Loory, *Hid Drug Danger, Firm Gets Top Fine*, N.Y. Herald Tribune, June 5, 1964, pp. 1, 14, col. 1.

151. 1 FRUMER & FRIEDMAN, PRODUCTS LIABILITY § 2504, at 667 (1960).

152. *Bennett v. Pilot Prods. Co.*, 120 Utah 474, 235 P.2d 525 (1951).

153. Horowitz, *Allergy of the Plaintiff as a Defense in Actions Based Upon Breach of Implied Warranty of Quality*, 24 SO. CAL. L. REV. 221, 224 (1950).

susceptible to an infectious disease carried in a product is not in any different legal posture than an individual whose resistance would make him sensitive to an antigen in a product.¹⁵⁴ The legal consequences of the above comparison are obvious. Although some limitations are offered, *z.e.*, where the vendee had sufficient foreknowledge of the presence of antigens, this reasoning would eliminate the defense of allergy. Also, although it might be easier to prove that plaintiff's drug injury is due to other causes, the defense of unusual susceptibility seems to be available.¹⁵⁵ But with foreknowledge of a susceptibility, the defendant may still be liable.¹⁵⁶

Disclaimer

Section 2-316 of the UCC provides that wherever a disclaimer is reasonable, it will be construed to be consistent with the warranties. To negate an implied warranty of merchantability, the negating words must mention merchantability. If the disclaimer is in writing, it must be conspicuous to the consumer. All implied warranties may be excluded either by the expressions "as is," "with all faults," or when the buyer has first fully examined the goods. A particular course of dealing may indicate the exclusion of all implied warranties.

Plaintiff may be saved, however, by section 2-302(1) of the UCC which permits a court to enforce all portions of a contract except the disclaimer, if it is not unconscionable. The court can pass directly on this matter using a general test of circumstances and trade custom. But since no cases have been decided under section 2-302, it is difficult to assess its true value in the drug area. The section aims at preventing oppression and unfair surprise. The test elaborated in the comments is one which requires sound proof that the disclaimer is unconscionable in light of all surrounding circumstances.

FOOD AND DRUG LAWS

On May 28, 1964, the Food and Drug Administration approved new rules which may prove to solve the drug liability problem at its core. Although drugs which are clearly toxic seldom reach the market, other drugs in which the risk of harm is statistically small are too often distributed too soon. Many times, extensive use of the drug is required before defects are discovered. The methods of distributing and reporting on new

154. *Id.* at 236.

155. *Willson v. Faxon*, Williams & Faxon, 138 App. Div. 359, 122 N.Y. Supp. 778 (1910), *motion to amend decision denied*, 143 App. Div. 961, 128 N.Y. Supp. 1151 (1911); *Singer v. Oken*, 193 Misc. 1058, 87 N.Y.S.2d 686 (N.Y. City Ct. 1949); *cf. Machlitt v. Myers*, 23 Ohio App. 160, 155 N.E. 248 (1926)

156. *Gerhin v. Brown & Sehler Co.*, 177 Mich. 45, 143 N.W. 48 (1913).

drugs lies close to the heart of this problem. One of the physician's primary sources of information about a drug is from the drug companies through their distributors and salesmen — "detail men." The drug companies likewise depend upon the doctors to report on the success of a drug. The flow of information between the company and the investigators is not, however, equal in both directions. The doctors are much more quickly informed of the merits of a drug than are the manufacturers informed of its defects. Doctors' distaste for paper work and detailed reports also hinders reporting. The duty, therefore, must be placed logically at its source — the drug companies. There must be a de-emphasis of "sale" and a concentration on "safety" and efficacy. The Food and Drug Administration is moving in this direction.¹⁵⁷ The new rules help to preserve objectivity and accuracy in drug advertisements by providing for stricter reporting to the FDA of any

information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations or tests, whether or not determined to be attributable to the drug¹⁵⁸

On any new drug application or drug supplement for human use, the FDA requires a review of all promotional material currently in use, including labeling and advertising. If clinical experience indicates the need for change in claims for effectiveness or in side effects, warnings, or contraindications,¹⁵⁹ then new advertising which is consistent with results is to be submitted. The new rules are revolutionary. Not only is the safety of the drug under careful scrutiny, but also its effectiveness. These changes will not only lead to a more informed group of decision makers and a great deal more paper work for drug companies and their research staff, but hopefully to an informed and protected public.

CONCLUSION

The changing legal picture appears to envisage an expanding liability, *i.e.*, more protection for the masses of people who are consuming tons of drugs. The major hurdles are found in proof of causation and adjustments of legal concepts to the many practical problems of science and

157. Stetler, *Government Tort Liability Under the Drug Amendments of 1962*, 3 J. NEW DRUGS 266, 268 (1963) "The availability of these data may affect drug malpractice cases in the sense of expecting physicians to be more fully informed on the hazards and benefits of drugs."

158. Food and Drug Rules, 29 Fed. Reg. 7020 (1964), amending 21 C.F.R. § 130.13(b) (2) (i) (rev. ed. 1964).

159. 21 C.F.R. § 130.35(b) (6) (rev. ed. 1964) But foremost in potential adverse effects from the new regulations is the possibility of "documentary congestion." The tendency of the FDA to require submission of nearly every piece of information about a drug may delay or foreclose the availability of a valuable new medication. Austern, *Drug Regulation and the Public Health*, 39 N.Y.U. L. REV. 771, 782 (1964).

the drug industry. Outworn technicalities such as privity are being discarded in an effort to harmonize freedom in the drug industry with responsibility to the drug user.

The wide publicity given to both drug cures and drug injuries has created a demanding public. When consumers are no longer in a position to bargain and fully understand what they are getting, the drug industry must take the responsibility for compensating the injured consumer. The difficulty is in tempering the profit motive with social consciousness. The solutions to these problems are heading toward perfection of the drug program and protection of the consuming public. It is hoped that the law may complement the field of medicine in obtaining these ends.

NORMAN RUBINOFF