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Liability in Mass Immunization Programs

*Nina S. Appel**

In January and February of 1976, army personnel at Fort Dix, New Jersey, became ill with flu-like symptoms. When studies showed a viral infection similar to the one responsible for the 1918-1919 Swine Flu pandemic, President Ford (and others) urged the appropriation of emergency funds for a nationwide influenza immunization program.¹ Congress hurriedly appropriated \$135,064,000,² but problems developed almost immediately. One of the four manufacturers³ of the vaccine produced the wrong strain, and distribution was delayed. All four manufacturers raised liability insurance concerns and were unwilling to provide any vaccine without adequate insurance coverage.⁴ Concern arose that the mass-immunization program would not begin before the influenza season.

I. MASS IMMUNIZATION UNDER THE SWINE FLU ACT

A. *The Congressional Response*

President Ford's active involvement as well as the publicity associated with the mysterious outbreak of Legionnaires' Disease in Philadelphia in July 1976, may have provided the needed stimulus for congressional action. The Swine Flu Act⁵ provided

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1. Several excellent articles deal with the Swine Flu Program of 1976, including Baynes, *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 ST. LOUIS U.L.J. 44 (1977); Franklin & Mais, *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CALIF. L. REV. 754 (1977); Note, *Apportioning Liability in Mass Inoculations: A Comparison of Two Views and a Look at the Future*, 6 N.Y.U. REV. L. & SOC. CHANGE 239 (1977); Note, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235 (1976).

2. Act of April 15, 1976, Pub. L. No. 94-266, 90 Stat. 363 (1976).

3. The four manufacturers were Merrill-National Laboratories; Merck Sharpe & Dohrne; Parke, Davis & Co.; and Wyeth Laboratories. See *Swine Flu Claims Pile Up in Washington*, BUSINESS WEEK, January 24, 1977, at 23-24.

4. See N.Y. Times, July 31, 1976, at 9, col. 6; 122 CONG. REC. 26,634 (1976).

5. National Swine Flu Immunization Program of 1976, 42 U.S.C. § 247b(j)-(l) (1976).

the necessary assurance to the drug manufacturers by making lawsuits against the government the exclusive remedy for all actions connected with the Swine Flu program. The Act was passed precipitously,⁶ but not without concern that it could create an undesirable precedent.⁷ The United States accepted liability "for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it under [the Federal Tort Claims Act]."⁸

Although the government cannot be held strictly liable under the Federal Tort Claims Act,⁹ the flu statute contained an exception: the liability of the United States could "be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty."¹⁰ "Program participant" was to mean the manufacturer or distributor of the vaccine, and the public or private agencies, organizations, and medical personnel who provided swine flu inoculations without charge and in compliance with the informed consent form and procedures.¹¹ The government also agreed not to invoke the "discretionary" act exemption of the Federal Tort Claims Act.¹² Furthermore, if the swine flu action was brought within two years of the date of inoculation and was dismissed for failure to file an administrative claim, a plaintiff was given the longer of thirty days after dismissal or two years from the date the claim arose to file an administrative claim.¹³ The remedy against the United States was exclusive,¹⁴

6. Indeed, one commentator has pointed out that the bill as stated in the *Congressional Record* is not the bill as stated in the *United States Code Congressional and Administrative News*. Congress may not have known what was actually being enacted. See Note, *Apportioning Liability in Mass Inoculations: A Comparison of Two Views and a Look at the Future*, 6 N.Y.U. REV. L. & SOC. CHANGE 239, 259 n.128.

7. See 122 CONG. REC. 26,627 (1976).

8. 42 U.S.C. § 247b(k)(2)(A) (1976).

9. *Laird v. Nelms*, 406 U.S. 797 (1972).

10. 42 U.S.C. § 247b(k)(2)(A)(i) (1976).

11. *Id.* § 247b(k)(2)(B).

12. *Id.* § 247b(k)(2)(A)(ii).

13. *Id.* § 247b(k)(2)(A)(iii). See, e.g., *Low v. United States*, 463 F. Supp. 948 (E.D. Va. 1978) (administrative remedies must be exhausted in accordance with 28 U.S.C. § 2675 (1976)).

14. 42 U.S.C. § 247b(k)(3) (1976).

and the case was to be tried without a jury as under the Federal Tort Claims Act.¹⁵ Notwithstanding any provision of state law, the United States was entitled to indemnity against any program participant whose failure to carry out a contract with the government or whose negligence caused the injury.¹⁶

A key concern addressed in the Act was the development of "a written informed consent form" with accompanying procedures, to assure that the risks and benefits from the swine flu vaccine were fully explained to each individual to whom the vaccine was to be administered.¹⁷ The Secretary of Health, Education, and Welfare (HEW), in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, was directed to draft and implement this form.¹⁸ Notably, the consent form that was developed did not specifically warn of the possibility of contracting Guillain-Barre disease, a neurological disorder.¹⁹ After describing the influenza and the vaccine, the form included a paragraph entitled "Special Precautions," which stated: "as with any vaccine or drug, the possibility of a severe or potentially fatal reaction exists. However, the flu vaccine has rarely been associated with severe or fatal reactions." The vaccinee, or his guardian, signed in two places to affirm that he had read the statement about swine flu and the special precaution. A second form indicating that legal remedies were available against the United States Government was also distributed.²⁰

The Act required the Attorney General to defend all claims arising out of the swine flu program against federal government employees or program participants and their insurers.²¹ Upon certification of the Attorney General, the United States was to be substituted as party defendant and the action removed to the appropriate federal district court.²² However, a program partici-

15. *Id.* § 247b(k)(5)(A); 28 U.S.C. § 2402 (1976).

16. 42 U.S.C. § 247b(k)(7) (1976).

17. *Id.* § 247b(j)(1)(F).

18. *Id.*

19. Guillain-Barre is a neurological syndrome marked by burning or tingling limbs, general muscular weakness, and sometimes paralysis or even death. See *STEDMEN'S MEDICAL DICTIONARY* 1383 (23d ed. 1976).

20. This form, entitled "Important Information from the U.S. Public Health Service about Swine Flu and Victoria Flu Vaccines," referred the vaccinee to the U.S. Public Health Services Claims Office in Rockville, Md., for further information.

21. 42 U.S.C. § 247b(k)(4) (1976).

22. *Id.* § 247b(k)(5)(A)-(B).

pant could lose its protected status if it failed to cooperate with the government in processing or defending a claim. If this occurred, the court was required to substitute that party as defendant in place of the United States, and upon motion, remand any such suit to the court in which it was instituted.²³ Of course, status as a program participant required that the public or private agency or health personnel provide the inoculation without charge and in compliance with the informed consent procedures.²⁴

B. *The Guillain-Barre Litigation*

Public concern about the safety of the vaccine and skepticism of the need for the program plagued the mass immunization efforts. After reports of suspected association between the swine flu vaccine and Guillain-Barre syndrome, the program was halted in December 1976. Under the provisions of the Federal Tort Claims Act, as incorporated in the Swine Flu Act, a claim had to be filed within two years after accrual.²⁵ For nearly all claimants the accrual date would be the date of inoculation or shortly thereafter; hence, the filing deadline for most claimants would have been within a short period after December 1976.²⁶

As of December 1979 a total of 912 suits had been filed against the United States for \$1,150,000,000 in damages.²⁷ Of these suits, 814 have been consolidated for pretrial procedure in the District of Columbia.²⁸ Four hundred and ninety-four of the claimants allege Guillain-Barre syndrome, 121 allege other neurological disorders, and 252 claim nonneurological disorders. Forty-five deaths are alleged to have occurred as a result of Guillain-Barre. As of December 1, 1979, 3,813 administrative claims had been filed for a total of \$3,417,000,000 in damages. Of these claims, 118 have been paid (settlements totalled \$3.7 million), 1,580 have been denied, and 102 have been closed (withdrawn or abandoned by the claimant).²⁹

23. *Id.* § 247b(k)(6).

24. *Id.* § 247b(k)(2)(B).

25. 28 U.S.C. § 2401(b) (1976).

26. The program was resumed in February 1977 on a limited basis following an outbreak of A-Victoria flu in Florida.

27. Statistics obtained in a telephone conversation with Ms. Janice McLeod, paralegal specialist, Department of Justice, Civil Division, Torts Branch (December 4, 1979).

28. *Id.* See *In re Swine Flu Immunization Prod. Liab. Litigation*, 446 F. Supp. 244 (J.P.M.D.L. 1978).

29. Information supplied by Ms. McLeod, *supra* note 27. The statistics are not pub-

On June 16, 1978, HEW Secretary Califano announced that claimants for federal compensation would "not need to prove negligence by Federal workers or others in the Swine Flu program as required by Federal law and the law in many states."³⁰ Most claimants could therefore recover by showing that they developed Guillain-Barre as a result of the vaccination and that they consequently suffered the alleged damages. The Secretary adopted the policy for two related reasons. The first was that the consent form had neither warned individuals that there was a "one in one hundred thousand" risk that a person would contract Guillain-Barre, nor that "one in every two million" would die from the condition.³¹ The second was that the federal government, in an unprecedented effort, had actively urged Americans to be vaccinated.³² The Secretary emphasized, however, that this policy did not apply to any non-Guillain-Barre cases arising under the swine flu program, or to claims arising under any other government sponsored or supported immunization program.³³

C. *Scope of Government and Manufacturer Liability*

To date, constitutional attacks on the Swine Flu Act have been made in four reported cases.³⁴ The statute has been attacked as being violative of due process, equal protection of the laws, the seventh amendment right to trial by jury, and the tenth amendment reservation of power to the states. Nevertheless, the constitutionality of the Act has been upheld in all the cases.

Before enactment of the federal liability legislation, some states, led by California, had adopted legislation exempting participants (licensed health professionals or facilities) from liabil-

lished but are available upon request.

30. U.S. Dep't of Health, Education, and Welfare, HEW News 2 (June 20, 1978).

31. The Secretary observed that the lack of warning was probably defensible as a matter of law, since there was no evidence linking flu vaccinations to Guillain-Barre when the form was developed. *Id.* at 3.

32. *Id.* at 4.

33. *Id.* at 2.

34. See *Ducharme v. Merrill-Nat'l Laboratories, Inc.*, 574 F.2d 1307 (5th Cir.), cert. denied, 439 U.S. 1002 (1978); *Jones v. Wyeth Laboratories, Inc.*, 457 F. Supp. 35 (W.D. Ark.), aff'd, 583 F.2d 1070 (8th Cir. 1978); *Wolfe v. Merrill-Nat'l Laboratories, Inc.*, 433 F. Supp. 231 (M.D. Tenn. 1977); *Sparks v. Wyeth Laboratories, Inc.*, 431 F. Supp. 411 (W.D. Okla. 1977).

ity unless their behavior involved "willful misconduct."³⁵ In a recent swine flu case, the California statute was upheld despite claims that it involved special legislation, fostered economic discrimination, and violated the supremacy clause.³⁶ When the federal legislation assumed its present form, the federal government was to be liable only if a private person "would be liable to the claimant in accordance with the law of the place where the act or omission occurred."³⁷ Therefore, in states like California, those injured by negligence during the administration of the program may receive no compensation.

Claims brought directly against the vaccine's manufacturers have been similarly unavailing. An argument made in such efforts to sue the manufacturers directly is that the signing of an informed consent form is a *sine qua non* of the Act's operation. This, however, is troublesome in view of the fact that an estimated 13% of those vaccinated may never have signed any form.³⁸ In a recent case,³⁹ the plaintiff, a doctor who had inoculated herself without signing the form, argued that because she had not signed the form her case fell outside the scope of the Act. The court refused to hold that drug manufacturers were required to comply with the informed consent procedures before they could be considered program participants. In dictum, however, the court stated that it was "arguable" that program participant status might not be conferred on an inoculating agency or other health personnel absent such compliance.⁴⁰

35. See CAL. GOV'T CODE § 856.6 (West Supp. 1979); MASS. GEN. LAWS ANN. ch. 112, § 12C (West 1971); N.Y. PUB. HEALTH LAW § 329 (McKinney 1971); 42 PA. CONS. STAT. ANN. § 8334 (Purdon 1978); R.I. GEN. LAWS § 23-8-2 (Supp. 1979); S.C. CODE § 44-29-210 (Supp. 1979).

36. *Heitz v. County of Sacramento*, 87 Cal. App. 3d 754, 151 Cal. Rptr. 429 (1978).

37. 28 U.S.C. § 1346(b) (1976).

38. Note, *Apportioning Liability in Mass Inoculations: A Comparison of Two Views and a Look at the Future*, 6 N.Y.U. REV. L. & SOC. CHANGE 239, 253 n.85 (citing N.Y. Post, Dec. 18, 1976, at 3, col. 2 (final ed.)).

39. *Wolfe v. Merrill Nat'l Laboratories, Inc.*, 433 F. Supp. 231 (M.D. Tenn. 1977).

40. Similar questions of program participant status could be raised if the vaccine had been sold, or if the program participant otherwise refused to cooperate with the government. Suppose, for example, that a negligent, insolvent doctor were to injure a vaccinee in a jurisdiction that did not exonerate program participants for negligence. If the doctor cooperated with the government, the Act's provisions would substitute the government as a defendant and presumably the plaintiff could recover. The government would then bear the risk of the doctor's insolvency in an indemnity claim. Could the same doctor, merely by refusing to cooperate with the government, force the plaintiff to sue him personally in a state court? This was surely not the intention of the Act, and equitable considerations might dissuade the government from so acting were the situation to arise.

The full range of injuries to be compensated under the provisions of the Act remains undetermined. The language used by Congress is very broad, referring as it does to "personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant."⁴¹ The Act further provides that "liability" may be based on any theory "that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty."⁴² Injuries resulting from negligently broken or unsterilized injectors, or from negligently administered inoculations, would certainly be covered in those jurisdictions where negligence is actionable, but other situations are less certain. For example, a pending case⁴³ alleges that the plaintiff fainted while leaving the building in which she had received a swine flu vaccination. Her fall resulted in several chipped teeth. If she merely tripped over a step, or had fallen on her way into the building, her injury could arguably fit within the broad language of the Act. Another injury arguably within the scope of the Act is negligently inflicted emotional distress. Many jurisdictions recognize the tort, especially where the requisite "impact" has been alleged. The inoculation itself would surely be sufficient impact.

II. LIABILITY OF DRUG MANUFACTURERS

During the Senate debate on the proposed swine flu legislation, many were made uneasy by the fact that the insurance companies viewed the risks of the program as being too great to insure against.⁴⁴ A brief review of recent cases involving the liability of drug manufacturers in regard to ethical drugs suggests that the concern was not unfounded.

A. *Drug Liability and the Duty to Warn*

A claimant in any product liability action usually has a

41. 42 U.S.C. § 247b(k)(2)(A) (1976).

42. *Id.* § 247b(k)(2)(A)(i).

43. *Childress v. United States*, No. 1-77-313 (E.D. Tenn., transferred to the U.S. District Court for the District of Columbia, *In re Swine Flu Immunization Prod. Liab. Litigation*, 453 F. Supp. 648 (J.P.M.D.L. 1978)).

44. 122 CONG. REC. 26,628 (1976) (Senator Taft referred to "only . . . two settlements of law suits arising out of neglect in the production of vaccine in the past 7 years . . . and only . . . 16 cases since 1920.").

choice of several legal theories. Depending on the law of the jurisdiction and on the facts of the case, a plaintiff may proceed on theories of negligence, breach of warranty (implied or express), strict liability in tort, or misrepresentation. Obviously, practical considerations regarding evidentiary matters, the relevant statute of limitations, available defenses, and the availability of punitive damages, may well make one theory preferable to another. But often, the pleadings are couched in the alternative. The claimant with a drug related injury is no different from other plaintiffs in that he must allege one of the above legal theories in order to be heard and must establish the elements of his case in order to prevail. To date, the concept of no-fault recovery for drug-induced injuries urged by several legal scholars, particularly in mass immunization cases,⁴⁵ has been resisted in this country. The courts have also been unwilling to hold manufacturers "absolutely liable," rejecting the theory that the production of drugs is an ultrahazardous activity.⁴⁶

The ethical-drug manufacturer has a duty to test and develop the drug properly,⁴⁷ to comply with all government regulations,⁴⁸ to keep abreast of developments in regard to the drug,⁴⁹ and to warn of side effects—a troublesome responsibility in recent years.

In the case of prescription drugs, a warning to the doctor is ordinarily held to satisfy the manufacturer's duty.⁵⁰ For a breach

45. See generally Baynes, *supra* note 1; Franklin & Mais, *supra* note 1, at 773; McKean, *Products Liability: Trends and Implications*, 38 U. CHI. L. REV. 3 (1970); O'Connell, *Expanding No-Fault Beyond Auto Insurance: Some Proposals*, 59 VA. L. REV. 749 (1973).

46. See *Gaston v. Hunter*, 121 Ariz. 33, 47-48, 588 P.2d 326, 341-42 (1978) (refusing to impose absolute liability on the manufacturer of an investigational drug); *McCreery v. Eli Lilly & Co.*, 87 Cal. App. 3d 77, 86, 150 Cal. Rptr. 730, 736 (1978).

47. See, e.g., *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3d Cir. 1973); *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967).

48. Government regulations are beyond the scope of this paper. See generally *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974); *Rheingold, The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CALIF. L. REV. 116 (1968).

49. See, e.g., *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969); *O'Hare v. Merck & Co.*, 381 F.2d 286 (8th Cir. 1967); *Mahr v. G. D. Searle & Co.*, 72 Ill. App. 3d 540, 390 N.E.2d 1214 (1979); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967).

50. See, e.g., *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Love v. Wolf*, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (1967); *Magee v. Wyeth Laboratories*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. Ct. 418, 307 A.2d 440

of that duty, the manufacturer is directly liable to the patient.⁵¹ It has been said that the manufacturer's compliance with this duty enables the prescribing physician, the "learned intermediary between the purchaser and the manufacturer,"⁵² to balance the risk of possible harm against the benefits to be gained by the patient's use of the drug.⁵³ The rationale is that if the doctor is properly warned "there is an excellent chance that injury to the patient can be avoided. This is particularly true if the injury takes place slowly . . ."⁵⁴ The duty to warn the medical profession is not measured in all cases by quantitative standards. In some circumstances, the manufacturer may have a duty to warn those few persons it knows will be injured by the drug's side effects.⁵⁵ Furthermore, the warning has to be brought home to the doctor⁵⁶ undiluted by overpromotion of the drug.⁵⁷

A further controversial and unresolved question is whether a drug manufacturer may be held liable for failure to warn of unforeseeable risks, or whether its liability for failure to warn is limited to those risks which it knows or has reason to know are inherent in the use of its drug.⁵⁸ In a recent case, *Hamilton v. Hardy*,⁵⁹ the two theories were distinguished by the Colorado Court of Appeals. Finding error in the trial court's refusal to instruct the jury on strict liability for the defendant doctor's failure to warn concerning the dangers of Ovulen, the court remarked that "the evidence which proves a failure to warn is the

(1973).

51. See, e.g., *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974).

52. *Sterling Drug, Inc. v. Cornish*, 370 F.2d at 85.

53. See, e.g., *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. at 387, 528 P.2d at 529.

54. *Sterling Drug, Inc. v. Cornish*, 370 F.2d at 85.

55. See, e.g., *Basko v. Sterling Drug, Inc.*, 416 F.2d at 430; *Sterling Drug, Inc. v. Cornish*, 370 F.2d at 85.

56. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 *RUTGERS L. REV.* 947, 993 (1964); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1979); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969).

57. See, e.g., *Salmon v. Parke-Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975); *Stevens v. Parke-Davis & Co.*, 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973); *Love v. Wolf*, 249 Cal. App. 2d 882, 58 Cal. Rptr. 42 (1967); *Incollingo v. Ewing*, 444 Pa. 263, 291, 282 A.2d 206, 220 (1971).

58. See, e.g., *Basko v. Sterling Drug, Inc.*, 416 F.2d at 426; *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Mahr v. G. D. Searle & Co.*, 72 Ill. App. 3d at 560, 390 N.E.2d at 1220; *Woodill v. Parke-Davis & Co.*, 58 Ill. App. 3d 349, 353, 374 N.E.2d 683, 686 (1978); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. at 386, 528 P.2d at 530.

59. 37 Colo. App. 375, 549 P.2d 1099 (1976).

same under both theories,"⁶⁰ but refused to find the theories identical.

Under strict liability, the test is whether the failure of Searle to adequately warn of the potentially dangerous propensities of its product rendered that product unreasonably dangerous. It is of no import whether the drug manufacturer's warning comported with the warning a reasonably prudent drug manufacturer would have given. "[S]trict tort liability shifts the focus from the conduct of the manufacturer to the nature of the product."⁶¹

The court proposed the following test to determine whether the evidence submitted warranted a finding for the plaintiff:

"A way to determine the dangerousness of the article, as distinguished from the seller's culpability, is to assume the seller knew of the product's propensity to injure as it did, and then to ask whether, with such knowledge, he would have been [acting unreasonably] in selling it without a warning."⁶²

The opposing view was articulated clearly by the Michigan Supreme Court in the recent case of *Smith v. E. R. Squibb & Sons, Inc.*⁶³ The plaintiff's deceased wife suffered a rare anaphylactic reaction when the defendant's product, Renografin-60, was injected into her blood stream. Breach of implied warranty and negligence were pleaded, but the trial court refused to instruct the jury regarding the warranty theory. The supreme court affirmed, commenting:

[W]hen the factual issue is not whether the product itself is defective, but is whether the manufacturer has provided adequate warnings, the existence of a product defect and a breach of duty is determined by the same standard—reasonable care under the circumstances. . . .

. . . Consequently, when liability turns on the adequacy of a warning, the issue is one of reasonable care, regardless of whether the theory pled is negligence, implied warranty or strict liability in tort.⁶⁴

60. *Id.* at 383, 549 P.2d at 1106.

61. *Id.* at 383-84, 549 P.2d at 1107 (quoting 2 L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY § 16A[4][e] (1975)). See also Wade, *Strict Tort Liability of Manufacturers*, 19 S.W.L.J. 5 (1965).

62. 37 Colo. App. at 385-86, 549 P.2d at 1108 (brackets in original) (quoting Phillips v. Kimwood Machine Co., 269 Or. 485, 525 P.2d 1033 (1974)).

63. 405 Mich. 79, 273 N.W.2d 476 (1979).

64. *Id.* at 89-90, 273 N.W.2d at 480.

It has been held that the manufacturer's duty to warn the medical profession extends beyond the prescribing physician.⁶⁵ In a case involving oral contraceptives, the Oregon Supreme Court stated:

It is especially important that the treating doctor receive the manufacturer's warning where it is impossible to predict in advance whether a particular patient is apt to suffer adverse effects from a drug, since the treating doctor may be more likely to observe the actual symptoms of the drug's untoward consequences. . . .

. . . The warning should be sufficient to apprise the general practitioner as well as the "unusually sophisticated medical man" of the dangerous propensities of the drug.⁶⁶

B. *The Polio Cases and the Duty to Warn*

Several recent cases involving polio vaccines have further delineated the drug manufacturer's duty to warn, and in so doing have greatly alarmed the drug industry. The original polio vaccine was the Salk vaccine (dead virus). Later the Sabin oral vaccine was developed, as types I, II, and III. The Sabin vaccine was licensed by the Division of Biologic Standards (DBS), which was then a part of HEW. In 1960 an advisory committee was established by the Surgeon General to review polio prevention. After a showing of some association between the type III Sabin polio vaccine and the development of polio in adults, the advisory committee recommended in 1962 that the vaccine's use be limited to children in nonepidemic situations. The committee further recommended that the type III vaccine only be used for adults with the full recognition of its minuscule risk (estimated to be about 7.6 per million for persons over twenty years of age). The manufacturers sold their vaccines to mass immunization clinics that were often established with the assistance of drug salesmen. In most instances, no warnings were given, and doctors did not individually evaluate a person's need for the drug.

In *Davis v. Wyeth Laboratories, Inc.*,⁶⁷ the plaintiff contracted polio thirty days after receiving a type III Sabin vaccine

65. See *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 141 (3d Cir. 1973); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 387-88, 528 P.2d 522, 528 (1974).

66. *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. at 387-88, 528 P.2d at 529; see *Mahr v. G. D. Searle & Co.*, 72 Ill. App. 3d 540, 561-62, 390 N.E.2d 1214, 1229-30 (1979).

67. 399 F.2d 121 (9th Cir. 1968). See also *Stahlheber v. American Cyanamid Co.*, 451 S.W.2d 48 (Mo. 1970) (on causation and failure to warn in oral polio vaccine injury).

in a Montana clinic. A pharmacist had been delegated the task of administering the vaccine in the absence of a doctor. The court considered the manufacturer's alleged failure to warn the plaintiff of the risk as sufficient to expose it to strict liability in tort. Since the vaccine presented a known risk that could not be narrowly defined, it could be properly marketed only by "full disclosure of the existence and extent of the risk involved."⁶⁸ The court observed that the risk of the plaintiff contracting polio from the wild virus was about the same as the risk of contracting polio from the vaccine. Even though Wyeth had technically warned the medical society, it failed in its responsibility since it knew that the drug was not dispensed as a "prescription drug" and that the warnings were not reaching the consumer. The court suggested means of communication the manufacturer could have undertaken, such as advertisements, posters, oral warnings, or releases to be read and signed by recipients of the vaccine.

In *Reyes v. Wyeth Laboratories*,⁶⁹ an eight month-old child given trivalent vaccine at a health clinic in a rural Texas community developed polio. The mother had been given no warnings by the registered nurse who administered the vaccine. Although the defendant contended that there was an epidemic of wild polio in the county at the time the child became ill, and that samples of the virus taken from the child upon admission to the hospital were "probably wild,"⁷⁰ the jury found that the vaccine caused the child's polio. The court established two tests whereby a manufacturer would be liable: (1) whether the product was so unsafe that its marketing alone was "unreasonably dangerous per se," or (2) whether the product was marketed without sufficient safeguards and was therefore "unreasonably dangerous as marketed."⁷¹ Because of the legitimate public interest in preventing polio, marketing the vaccine was held to be justified. However, under the circumstances of the vaccine's administration, where no individualized medical judgment intervened between the manufacturer and the ultimate consumer, the manufacturer was "required to warn the ultimate consumer, or to see that he [was] warned."⁷² The court postulated a rebuttable pre-

68. 399 F.2d at 129.

69. 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974).

70. *Id.* at 1271.

71. *Id.* at 1273.

72. *Id.* at 1276.

sumption "that the consumer would have read any warning provided by the manufacturer, and acted so as to minimize the risks."⁷³

The fifteen year old patient in *Cunningham v. Charles Pfizer & Co.*⁷⁴ was given the type I Sabin vaccine in a Tulsa, Oklahoma clinic and subsequently developed polio. The defendant claimed there was no evidence that the plaintiff would have refused to take the vaccine had the warnings been given to him or to his parents. The court held that the plaintiff was not required to present any direct evidence on this point and was entitled to a rebuttable presumption. In view of the fact that there was considerable risk of contracting polio from natural sources at the time the vaccine was given (twelve cases of polio occurred in Tulsa during October and November 1962, two months before the plaintiff's inoculation), the court concluded that the issue of whether the plaintiff as a reasonably prudent person would have refused to take the vaccine had adequate warning been given was for the jury.

In *Givens v. Lederle*,⁷⁵ the plaintiff's young daughter was given an oral vaccine by her pediatrician. The mother, who had never received a polio vaccination of any kind, developed polio within nine days of her daughter's ingestion of the third dose of vaccine. On the insert packaged with the vaccine, the defendant Lederle had stated that:

Paralytic disease . . . has been reported . . . , in some instances, in persons who were in close contact with subjects who had been given live oral polio virus vaccine. Fortunately, such occurrences are rare, and it could not be definitely established that any such case was due to the vaccine strain and was not coincidental with infection due to naturally occurring poliomyelitis, or other entroviruses.⁷⁶

Mrs. Givens had received no warnings from her pediatrician. At the first trial, the judge had kept the jury from hearing evidence on the issue of whether oral vaccine can cause polio. After the *Reyes* decision, the court reversed itself and granted the plaintiff's motion for a new trial. In turn relying upon *Reyes*, the reviewing court upheld the lower court's action, and stated that in

73. *Id.* at 1281.

74. 532 P.2d 1377 (Okla. 1974).

75. 556 F.2d 1341 (5th Cir. 1977).

76. *Id.* at 1343.

Reyes it was not a significant factual distinction that the vaccine had actually been ingested by the plaintiff, because the defendant's "warning" admitted that some persons in close contact with vaccinees had developed paralytic diseases. The only issue was whether polio could be transmitted to someone in close contact. Testimony showed that a mother changing her baby's diapers would be particularly susceptible to contracting the disease. In addition, because administration of the vaccine by a private pediatrician rather than personnel in a county health clinic, was not "nearly so great" a difference as the defendant had argued it to be, the manufacturer's duty to warn the patient extended to this situation. The doctor testified that the vaccine had been administered in a manner more similar to procedures followed at a small health clinic than to normal procedures used in prescribing drugs. If this was true, then the defendant was responsible for taking definite steps to warn the consumer directly. Even if the drug were considered a prescription drug, the court found that the enclosed warning did not adequately state the risk. The doctor testified that the manner of stating the one in three million risk was a "very nebulous way of putting it."⁷⁷

Thus, the drug manufacturers' duty to warn has been extended beyond the prescribing physician to the entire medical community. How this warning is to be communicated to doctors specializing in different areas of medicine is not clear. Furthermore, in the absence of a learned intermediary, the warning must be given to the patient himself, and sometimes even to a third party. In *Givens* a close relative was allegedly harmed, but the court did not limit its holding to close relatives. Therefore, the scope of the duty owed third persons remains unclear. It is also unclear how a proper warning is to be drafted when a manufacturer possesses incomplete information, but has some suspicion, based on a statistically small sample of reported cases, that its drug may cause adverse side effects.

The fact that the drug package insert has been approved by the FDA does not relieve the drug manufacturer of its obligation to communicate an adequate warning to the users of the drug.⁷⁸ An Oregon case⁷⁹ indicating that a drug complying with FDA regulations was reasonably safe as a matter of law has been ex-

77. *Id.* at 1345.

78. *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978).

79. *Lewis v. Baker*, 243 Or. 317, 413 P.2d 400 (1966).

pressly overruled.⁸⁰ The warnings required by such agencies may be only minimal,⁸¹ and therefore do not provide an adequate standard by which to measure a manufacturer's duty.

C. *The DES Cases and the Problem of Proving Causation*

There are other uncertainties peculiar to drug litigation. Because of the lengthy time interval between ingestion of a drug and manifestation of the injury, and the even longer period between the injury and the identification of the drug as its probable cause, a plaintiff may have difficulty in identifying the drug's manufacturer. Nowhere is this problem evidenced more clearly than in the current DES litigation.⁸²

In 1941 the FDA approved DES after twelve drug companies filed new drug applications. In support of their request the companies submitted a joint clinical file. The purpose for which the drug was approved in 1941 did not include its subsequent and popular use for the prevention of miscarriages. In 1947 new applications for that use were submitted by the twelve companies and others, and from 1947 to 1971 the drug was manufactured by hundreds of drug companies and prescribed for millions of women. In 1971 statistical evidence indicated a significant association between DES and the development of cancer in the users' daughters,⁸³ who had been exposed *in utero*. The FDA banned the drug in 1971 as unsafe and ineffective in preventing miscarriages.⁸⁴ Although there were several hundred manufacturers of DES and related drugs, it was estimated that Eli Lilly and five or six other manufacturers accounted for 90%

80. See *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 398, 528 P.2d 522, 534 (1974).

81. See, e.g., *Salmon v. Parke-Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975); *Stevens v. Parke-Davis & Co.*, 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973). See also 21 U.S.C. § 355 (e)(1) (1976) (approval of new drug application may be withdrawn if clinical or other experience, tests or other scientific data show the drug to be unsafe); 21 C.F.R. § 310.300 (1979) (requires a manufacturer holding an approved new drug application to maintain records so that the FDA can determine whether there are grounds for suspension or withdrawal); 21 U.S.C. § 352(a) (1976) (a drug or device is misbranded if its labeling is false or misleading in any way).

82. DES is the acronym for diethylstilbestrol, a manmade estrogen. For a full discussion of the problems faced by plaintiffs in DES actions, see Note, *DES and a Proposed Theory of Enterprise Liability*, 46 *FORDHAM L. REV.* 963 (1978).

83. In addition, a possible decrease in fertility has been noted in users' sons.

84. The 1962 Amendment to the Food, Drug and Cosmetic Act required proof of effectiveness as well as safety. 21 U.S.C. § 355 (1976).

of the market.⁸⁵ Nevertheless, it was extremely unlikely that any plaintiff would be able to trace back the particular DES taken by her mother to any one individual manufacturer.

Prior tort cases provided some guidelines for the DES plaintiffs. *Hall v. E. I. Du Pont De Nemours & Co.*⁸⁶ consolidated two cases arising out of eighteen separate accidents in which children were injured by dynamite blasting caps. The explosions destroyed the evidence of manufacture in most cases. The plaintiffs joined the six major domestic manufacturers of blasting caps and their trade association, alleging that the defendants knew that the caps were dangerous and that they had agreed not to put warnings on them.⁸⁷ The court held that the defendants were not entitled to a dismissal of the plaintiffs' claims since the plaintiffs were claiming joint control of risk by explicit agreement—*i.e.*, concert of action.⁸⁸ The court went on to add that the plaintiffs could either "submit evidence of defendants' parallel behavior sufficient to support an inference of tacit agreement,"⁸⁹ or allege that, acting independently, the defendants had adhered to an industry-wide standard with regard to the safety of blasting caps.⁹⁰ The court discussed enterprise liability and emphasized its special applicability to industries composed of a "small number of units."⁹¹ The burden of proving causation was shifted to the defendant,⁹² despite the possibility that the caps might have come from other unnamed sources.

Another approach for DES plaintiffs is the "alternative liability theory." In *Summers v. Tice*,⁹³ the plaintiff's two companions fired their guns simultaneously and carelessly in his direction. Only one bullet actually hit the plaintiff, but it was impossible to prove which defendant had caused the injury. The court justified its concept of joint and several liability on the grounds that when all the defendants are potential wrongdoers, fairness requires a finding of joint liability unless the defendants can individually exonerate themselves.

85. B. SEAMAN, *WOMEN AND THE CRISIS IN SEX HORMONES* 33 (1977).

86. 345 F. Supp. 353 (E.D.N.Y. 1972).

87. *Id.* at 359.

88. *Id.* at 373-74.

89. *Id.* at 374.

90. *Id.*

91. *Id.* at 378.

92. *Id.* at 378-80.

93. 33 Cal. 2d 80, 199 P.2d 1 (1948). *See also* *Ybarra v. Spangard*, 25 Cal. 2d 486, 154 P.2d 687 (1944).

In the related case of *Anderson v. Somberg*,⁹⁴ the plaintiff was injured when part of a surgical instrument broke off in his spinal canal during an operation. He sued the doctor and hospital for negligence, the distributor for breach of warranty, and the instrument's manufacturer in strict liability. The court held that because it was apparent that at least one of the defendants was liable for the plaintiff's injury, all were jointly liable unless proven otherwise. No other theory of liability could reasonably be applied. "Since defendants had engaged in conduct which activated legal obligations by each of them to plaintiff, . . . the failure of any defendant to prove his nonculpability would trigger liability; and further, . . . at least one would be liable."⁹⁵

Plaintiffs have recently used analogous arguments—with varying degrees of success—in attempting to trace liability back to the DES manufacturers. In *McCreery v. Eli Lilly & Co.*,⁹⁶ the court refused to accept the "sketchy and limited factual circumstances presented in [the plaintiff's] argument of concerted activity," and held that the plaintiff must, "before benefiting from the shift of the evidentiary burden, identify the manufacturer."⁹⁷ Since knowledge of the manufacturer was more accessible to the plaintiff (whose mother had known of and possessed the prescription, and had chosen the doctor and druggist), the court affirmed the summary judgment for the defendant. A contrary result was reached in *Sindell v. Abbott Laboratories*,⁹⁸ where the plaintiffs alleged concerted action and theories of alternative liability. And in the much publicized New York case of *Bichler v. Eli Lilly & Co.*,⁹⁹ a jury awarded \$500,000 to a twenty-five year old woman who developed vaginal and cervical cancer as a result of her mother's ingestion of DES. There the plaintiff alleged joint enterprise liability. This approach, if successful on appeal, is sure to have a major impact on the more than 400 DES suits still pending.

D. Application of Statutes of Limitation

Since a plaintiff in a drug liability action may plead a variety of legal theories—e.g., negligence, warranty, strict liability in

94. 67 N.J. 291, 338 A.2d 1, cert. denied, 423 U.S. 929 (1975).

95. 67 N.J. at 298, 338 A.2d at 4.

96. 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978).

97. *Id.* at 84-85, 150 Cal. Rptr. at 735.

98. 85 Cal. App. 3d 1, 149 Cal. Rptr. 138 (1978).

99. N.Y. Times, July 17, 1979, § 3, at 11, col. 6 (N.Y. Sup. Ct. July 16, 1979).

tort—it is necessary at the outset to determine which statute of limitations period applies to each cause of action pleaded. Typically, the tort or personal injury limitation is two or three years and accrues at the time of injury. The warranty limitation under the Uniform Commercial Code is four years¹⁰⁰ and accrues from the date the sales contract is breached. It is, of course, entirely possible that the limitation period for one cause of action will have expired while that of another remains viable.¹⁰¹

A second and far more complicated question is when the cause of action accrues. The Uniform Commercial Code provides that the “action accrues when the breach occurs, regardless of the aggrieved party’s lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made”¹⁰² Nonetheless, there are at least four points at which a tort cause of action may accrue: (1) when the defendant breaches his duty, (2) when the plaintiff suffers harm, (3) when the plaintiff is or should be aware of his injury, or (4) when the plaintiff is or should be aware of the causal relationship between his harm and the defendant’s misconduct. In most tort actions these events occur simultaneously and the time of accrual is clear. But this is seldom the case in drug induced injuries. It is impossible to generalize the law regarding statutory interpretation insofar as it affects drug litigation,¹⁰³ except to point out that it is in a state of flux.

Some jurisdictions, led by New York, have adopted the strict position that the cause of action accrues when there is a wrongful invasion of personal or property rights,¹⁰⁴ regardless of whether the plaintiff realizes he has been injured. Most lower courts in New York have persisted in this “first breath” rule,¹⁰⁵ despite a more liberal approach to malpractice claims that in-

100. U.C.C. § 2-725.

101. See *Berry v. G. D. Searle & Co.*, 57 Ill. 2d 548, 309 N.E.2d 550 (1974), in which the court held that the two-year period for strict liability in tort had elapsed while the four-year statutory period for implied warranty had not.

102. U.C.C. § 2-725(2).

103. See Birnbaum, “*First Breath’s*” *Last Gasp: The Discovery Rule in Products Liability Cases*, 13 FORUM 279 (1977); Note, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 970 n.23; Annot., 4 A.L.R.3d 821 (1965).

104. See *Schwartz v. Heyden Newport Chemical Corp.*, 12 N.Y.2d 212, 188 N.E.2d 142, 237 N.Y.S.2d 714, *amended*, 12 N.Y.2d 1073, 190 N.E.2d 253, 239 N.Y.S.2d 896, *cert. denied*, 374 U.S. 808 (1963).

105. So-called because the *Schwartz* plaintiff’s injury for inhalation of dust accrued with his “first breath.” See, e.g., *Reis v. Pfizer, Inc.*, 61 App. Div. 2d 777, 402 N.Y.S. 2d 401 (1978), *aff’d*, 48 N.Y.2d 664, 397 N.E.2d 390, 421 N.Y.S.2d 879 (1979).

volve the leaving of a foreign object in a patient's body—for which the statute does not begin to run until the patient could reasonably have discovered the injury¹⁰⁶—and despite the more liberal tolling of the statute by the continued treatment by the physician.¹⁰⁷ Recently, exceptions to these rules have been made in products liability cases brought for occupational disease in strict tort liability.¹⁰⁸ It has also been held that the continuous treatment of an attending physician may be imputed to the manufacturer of a medical device, thus tolling the statutory period applicable to claims against the manufacturer.¹⁰⁹

Other jurisdictions have adopted the liberal discovery of injury rule. Yet even with these jurisdictions generalizations are dangerous. Clearly, the plaintiff may learn of his injury many years before he is able to identify its cause. Some courts have held that the statute begins to run at the time the plaintiff knew or should have known of his injury. Knowledge of injury is only apparent if the injury is a “traumatic” one.¹¹⁰ However, if the plaintiff has not been made aware that his rights were violated, the modern trend and majority position in products liability actions is that the plaintiff's action accrues when he discovers, or in the exercise of reasonable diligence should discover, that his injury may have been caused by the defendant's conduct,¹¹¹ rather than when he simply discovers that he has been injured. On the issue of fairness to the drug companies, the New Hampshire Supreme Court has observed:

With respect to their expectations of repose, drug companies are unique among most potential tortfeasors. The harmful propensities of drugs are often not fully known at the time the drugs are marketed. These companies know or at least should expect that some time may pass before the harmful effects of

106. See, e.g., *Flanagan v. Mount Eden Gen. Hosp.*, 24 N.Y.2d 427, 248 N.E.2d 871, 301 N.Y.S.2d 23 (1969).

107. See N.Y. CIV. PRAC. LAW § 214-a (McKinney Supp. 1979-1980).

108. See, e.g., *McKee v. Johns Manville Corp.*, 94 Misc. 2d 327, 404 N.Y.S.2d 814 (Sup. Ct. 1978).

109. See *Holdridge v. Heyer-Schulte Corp.*, 440 F. Supp. 1088 (N.D.N.Y. 1977).

110. *Berry v. G. D. Searle & Co.*, 56 Ill. 2d 548, 309 N.E.2d 550 (1974). *But see Roper v. Merkle*, 59 Ill. App. 3d 706, 375 N.E.2d 934 (1978). In this case *Berry* was restricted to traumatic injuries. In addition, the statute of limitations for medical malpractice cases was held to begin to run when the plaintiff knows that he has a physical injury and that it may be the result of someone's negligence.

111. See *G. D. Searle & Co. v. Superior Court*, 49 Cal. App. 3d 22, 122 Cal. Rptr. 218 (1975); *Raymond v. Eli Lilly & Co.*, 117 N.H. 164, 371 A.2d 170 (1977); *Gilbert v. Jones*, 523 S.W.2d 211 (Tenn. Ct. App. 1974).

their products manifest themselves in drug users and that there may be another lapse of time before the injured person is able to discover the causal connection between his injury and the drug he consumed. . . . Given these unique circumstances and the fact that the scope of a drug manufacturer's liability is substantial and seems to expand continually through the growth of substantive tort and warranty doctrines, . . . we do not think the drug company can reasonably expect to be immune to suit before its customer has a fair opportunity to discover the company's tortious conduct.¹¹²

E. The Recent DES Case of Mink v. University of Chicago

A recent case, *Mink v. University of Chicago*,¹¹³ posed many of the issues discussed in this article. There the plaintiffs brought a diversity action on behalf of themselves and some 1,000 women who were given DES as part of an experimental study allegedly conducted by the named defendant and Eli Lilly & Co. They claimed that they and their children had suffered reproductive tract abnormalities and had incurred an increased risk of cancer. In their complaint they sought recovery on three causes of action. They first alleged battery, since the medical experiment was conducted without their knowledge or consent. The court distinguished this case from those in which the patients at least knew that they were being given some form of a drug.¹¹⁴ In those cases negligent failure to disclose risks had to be pleaded and proved, and injury had to be alleged. The gist of the battery claim was nonconsent—the tort being complete without hostile intent, and without personal injury. The issue of whether implied consent had been given was left to the jury. The second count was in strict liability and was dismissed because the named plaintiffs had alleged no injury to themselves. In their amended complaint they sought damages for alleged injury to other class members, but this was held to be an insufficient allegation of injury to the named plaintiffs.¹¹⁵ The third claim was that no effort had been made to notify the plaintiffs of their participation in the experiment until 1975 or 1976, even

112. *Raymond v. Eli Lilly & Co.*, 117 N.H. at 173-74, 371 A.2d at 176 (citations omitted).

113. 460 F. Supp. 713 (N.D. Ill. 1978).

114. *Id.* at 717.

115. 460 F. Supp. at 722-23 (citing *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26 (1976)).

though the relationship between DES and cancer was known to the medical community as early as 1971. The court recognized a continuing duty to warn on the part of both the university and the drug manufacturer,¹¹⁶ but dismissed this count for failure to state a cause of action. In their amended complaint, plaintiffs sought to compel the defendants to notify all the women given DES as part of the experiment. Since the plaintiffs' proposed class had never been certified, and since the named plaintiffs already were aware of the DES menace, the plaintiffs could not show that there was an ongoing controversy at the time the complaint was filed. The named plaintiffs knew of the dangers and thus had no need for further notice.¹¹⁷

The concerns of the manufacturers and their insurers therefore appear more understandable in the context of recent developments in drug litigation. Despite the articulated concerns of Congress, it seems inevitable that future mass inoculation programs will involve an attempt to have the government underwrite the costs of liability. For this reason it is important to refer to the Federal Torts Claims Act, and particularly to the "discretionary act" exception,¹¹⁸ which has so often been invoked by the government in avoiding liability.

III. MASS IMMUNIZATION AND THE FEDERAL TORT CLAIMS ACT

Two cases are particularly relevant in considering governmental liability for drug approval and distribution. In *Griffin v. United States*,¹¹⁹ the plaintiff allegedly contracted polio as a result of ingesting the type III Sabin vaccine. She brought an action against the government claiming that the vaccine had been negligently tested by the Division of Biologic Standards (DBS) and had been approved for release in violation of agency standards. Since the application and not the content of the agency rules was attacked, the court held that the discretionary function exception did not apply. The court commented:

"The "discretion" protected by the section is not that of the judge—a power to decide within the limits of positive rules of law subject to judicial review. It is the discretion of the executive or the administrator to act according to one's judgment of

116. *Id.* at 720.

117. *Id.* at 723.

118. 28 U.S.C. § 2680(a) (1976).

119. 500 F.2d 1059 (3d Cir. 1974).

the best course, a concept of substantial historical ancestry in American law. . . . Where there is room for *policy* judgment and decision, there is discretion."¹²⁰

While DBS had the right to weigh five criteria of neurovirulence, its judgment was that of a professional, not a policy maker. It was purely a scientific determination since DBS's responsibility was limited to merely executing the policy judgments of the Surgeon General. Furthermore, in approving this lot of vaccine, DBS had exceeded its authority by disregarding the mandatory regulatory command and had diluted the results of the tests performed by considering "biological variation." "The violation of a nondiscretionary command takes what otherwise might be characterized as a 'discretionary function' outside the scope of the statutory exception."¹²¹

However, in *Gray v. United States*¹²² the plaintiff was unsuccessful in her suit. She alleged that she had been injured when her mother ingested DES and sued both Eli Lilly and the federal government, relying on *Griffin* as precedent. Summary judgment was granted both defendants. The court commented that "[t]he FDA was given a general statutory mandate to assure the public that a marketed drug [was] safe for use."¹²³ There were no particular scientific tests or measuring sticks existing whereby the FDA had to qualify a new drug, but rather it was given the liberty to consider all factors it deemed relevant in the determination of a drug's safety. "Congress [had] chosen the FDA to be the decision maker, . . . and its judgments . . . must be beyond private scrutiny and litigation."¹²⁴

IV. CONCLUSION

Thus, a clear message emerges: in any future mass inoculation program, agency action must be "nondiscretionary" if the federal government is to be held liable. To the extent possible, specific "measuring sticks" or tests should be specified. In view of the strict liability claim frequently made in drug litigation, it is likely that the government will be forced to concede liability

120. *Id.* at 1064 (emphasis in original) (quoting *Dalehite v. United States*, 346 U.S. 15, 34-36 (1953)).

121. *Id.* at 1068-69.

122. 445 F. Supp. 337 (S.D. Tex. 1978).

123. *Id.* at 340.

124. *Id.*

on that ground despite the present limitation on liability.¹²⁵ It is clear that the government must develop clear guidelines for protecting participants in the mass immunization programs it deems necessary. In the absence of such protection, we may expect continued resistance from drug manufacturers, health care providers, and their insurers to any participation in such programs.

125. See *Laird v. Nelms*, 406 U.S. 797 (1972).