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Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes

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Vaccine manufacturers and their insurers were uneasy about participating in the swine flu immunization program due to cases that had expanded traditional tort doctrine to impose liability on polio vaccine manufacturers. This Article discusses the tensions between tort law and public health policy, noting the courts' apparent eagerness to compensate plaintiffs injured by their participation in mass immunization programs. Since that participation confers a benefit on the public through contributing to the prevention of communicable diseases, the authors conclude that a non-tort system of compensating victims of mass immunization programs should be considered.

This Article considers the tensions between the traditions of tort law and the goals of mass immunization programs. The Article first focuses on *Reyes v. Wyeth Laboratories,*[1] in which a vaccine producer was held liable for injuries suffered by a polio victim whose illness was allegedly caused by the vaccine itself. Thus far, the courts have compensated victims of polio immunization programs by stretching traditional tort doctrines to impose liability on manufacturers. As a result, pharmaceutical manufacturers and their insurers asserted reluctance to participate in the proposed swine flu immunization program. After discussing the governmental response to this reluctance, the Article concludes that the public interest in encouraging citizens to participate

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1. 498 F.2d 1264 (5th Cir.), *cert. denied,* 419 U.S. 1096 (1974).

in mass immunization programs justifies a non-tort compensation system for those injured by the vaccine or its administration. This might be accomplished by a program that builds upon some of the basic elements of the national swine flu immunization program.

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THE POLIO VACCINE EXPERIENCE: THE *Reyes* DECISION

The major reason for the manufacturers' and insurers' concern about supplying flu vaccine was *Reyes v. Wyeth Laboratories,*[2] decided in 1974.[3] The plaintiffs'[4] infant child contracted polio in 1970, two

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2. *Id.*

3. *See* Curran, *Public Warnings of the Risk in Oral Polio Vaccine,* 65 AM. J. OF PUB. HEALTH 501 (1975).

Although *Reyes* was the most widely criticized of the polio vaccine cases, the courts have decided virtually every polio vaccine case for the plaintiff on one or another theory. Some courts have imposed liability using warranty law. Grinnell v. Charles Pfizer & Co., 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1st Dist. 1969) (manufacturer held liable for breach of an express warranty that "There are no known contraindications to oral polio virus vaccines," when live virus in Sabin vaccine produced the disease); Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1st Dist. 1960) (manufacturer held liable for breach of an implied warranty of merchantability when live virus in Salk vaccine produced the disease, despite a jury finding that the manufacturer had followed government instructions and was not negligent in the manufacture of the vaccine). One court imposed liability on a negligence theory. Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), 353 F. Supp. 324 (E.D. Pa. 1973), *aff'd in part, rev'd in part and remanded,* 500 F.2d 1059 (3d Cir. 1974) (United States government held liable for negligently releasing a batch of live-virus vaccine after test results showed that the batch did not meet the safety standards imposed by administrative regulation). Others have imposed liability for the failure to give an adequate warning. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968) (liability imposed upon manufacturer under Montana law for failure to warn ultimate user of dangers inherent in live-virus vaccine even though such a warning was given to the medical society that purchased the vaccine); Stahlheber v. American Cyanamid Co., 451 S.W.2d 48 (Mo. 1970) (liability imposed upon manufacturer for lack of adequate warning of dangers inherent in live virus vaccine); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377 (Okla. 1974) (verdict against manufacturer for failure to warn of dangers inherent in live virus vaccine reversed and remanded to determine whether a reasonable person in plaintiff's position would have refused the vaccine if an adequate warning of the risks had been given); Givens v. Lederle, No. 73-59-CIVTK (S.D. Fla. 1975), *appeal docketed* Dec. 22, 1975 (the jury found that the plaintiff contracted polio by handling her infant's diapers after the child had been given live-virus vaccine and imposed liability upon the manufacturer for failing to warn the child's physician of the risk of contracting polio from contact with the recipient of the vaccine), *cited in* Comment, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn,* 29 VAND. L. REV. 235, 249-50 (1976) [hereinafter cited as *Mass Immunization Cases*].

Most of these cases were brought by plaintiffs who contracted polio shortly after receiving the vaccine in a mass immunization program, and this Article will primarily address the problems associated with mass immunization. *See also id.*

4. Epifanio Reyes, the father of the infant polio victim, sued individually and as next friend of his daughter, Anita Reyes. It was Mrs. Reyes who took Anita to

weeks after receiving Sabin oral polio vaccine in a mass immunization program sponsored by the Texas Department of Health. Although the vaccine carried a warning of its dangers, that warning was not conveyed to individual recipients of the vaccine. The plaintiffs alleged that live polio virus in the vaccine caused the child's polio, and that the manufacturer's failure to warn them rendered it liable for marketing a defective product.[5] The jury agreed and awarded the plaintiffs $200,000 in damages. The Fifth Circuit upheld the judgment against a variety of challenges. The court followed the Restatement theory of strict products liability.[6] Under this theory, an "unavoidably unsafe product" such as the Sabin vaccine—that is, a product that cannot be made safe no matter how carefully it is manufactured—is defective if it is *unreasonably* dangerous. A two-step analysis is required to determine whether the product was "unreasonably dangerous."[7] The court concluded that the product was not "unreasonably dangerous per se" because the benefits from its use outweighed its potential for harm.[8] Nevertheless, the vaccine was "unreasonably dangerous as marketed" because an "unavoidably unsafe" product is defective unless it is properly prepared and marketed with an adequate warning.[9]

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the clinic to be immunized. In this article Mr. and Mrs. Reyes are referred to as "the plaintiffs" for the sake of simplicity.

5. There was no indication in the opinion that the vaccine had been improperly prepared. By way of contrast, see Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), 353 F. Supp. 324 (E.D. Pa. 1973), *aff'd in part, rev'd in part and remanded*, 500 F.2d 1039 (3d Cir. 1974); Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1st Dist. 1960).

The court held that contracting polio from Sabin vaccine could not be characterized as an allergic reaction because "the risk appears to be distributed evenly among that substantial segment of the population that is not naturally immune to polio." 498 F.2d at 1279. This analysis avoided conflict with a line of Texas cases that held that where the danger posed by a product involved only allergic users, the manufacturer need not warn of the risk unless the product would harm a substantial number of persons. C.A. Hoover & Son v. O.M. Franklin Serum Co., 44 S.W.2d 596, 598 (Tex. 1969); Alberto-Culver Co. v. Morgan, 444 S.W.2d 770, 776-77 (Tex. Civ. App. 1969); Cudmore v. Richardson-Merrill, Inc., 398 SW.2d 640, 644 (Tex. Civ. App. 1965), *cert. denied*, 385 U.S. 1003 (1967). RESTATEMENT (SECOND) OF TORTS § 402A, Comment j (1965) also would not require a warning for allergic users of a product unless a "substantial number" would be harmed and the danger to these users was reasonably foreseeable. For a more detailed discussion of the problems of warnings and the allergic user, *see* Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1 (1973); Comment, *Strict Liability and Allergic Drug Reactions*, 47 MISS. L.J. 526 (1976).

6. *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965), which is quoted at length in the *Reyes* opinion.

7. 498 F.2d at 1273.

8. *Id.* at 1274.

9. *Id.* at 1274-78. In reaching this conclusion the court cited the RESTATEMENT (SECOND) OF TORTS § 402A, Comment k (1965):

> *K. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the

Wyeth Laboratories, the manufacturer, contended that its duty to warn was discharged by the warning distributed to the public health officials because the vaccine was a prescription drug and those who prepare such drugs are not required to warn ultimate consumers.[10] The court held the prescription drug rule inapplicable since the "vaccine was not administered as a prescription drug at the Mission Clinic." The prescription drug rule only applies where there has been an individualized medical judgment regarding the risks of the treatment, and no such judgment was provided at the Mission Clinic.[11] When the manufacturer has reason to know that the drug will be distributed in such a manner, a warning that reaches only the physician is insufficient. The manufacturer must provide individual recipients with sufficient information to enable them to balance the risks and benefits of the product.[12]

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field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . .

10. While manufacturers of over-the-counter goods are usually under a duty to provide ultimate users with adequate warnings, the unique circumstances involved in marketing prescription drugs makes this duty inapplicable to prescription drug manufacturers. In these cases a warning to the prescribing physician is sufficient because the physician can provide an individualized balancing of the risks involved in light of the patient's needs and susceptibilities. *See* Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968); Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966); Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (3d Dist. 1964), *second appeal,* 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (3d Dist. 1967).

11. 498 F.2d at 1276-77.

12. The cost and the nature of required warnings pose a problem. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 131 (9th Cir. 1968) stated:

> [I]t is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warnings itself or by obligating the purchaser to give warning. . . . This duty does not impose an unreasonable burden on the manufacturer. . . . [M]eans of communication such as advertisements, posters, releases to be read and signed by recipients of the vaccine, or oral warnings were clearly available and could easily have been undertaken or prescribed by appellee.

In an effort to avoid liability or to obtain indemnity, pharmaceutical manufacturers have apparently begun inserting in their letters to public health departments an obligation that the departments not administer any drug unless the recipient signs a prescribed consent form. Although no reported cases have emerged involving this clause, it is likely that if a manufacturer supplies products it has reason to know are going to be used in a mass immunization program without individual consent despite the agreement with the state health department, the manufacturer could still be held liable for failure to warn. It is possible, however, that the department's failure to perform its obligation might be a basis for a claim for indemnity on the part of the manufacturer who is held liable.

After concluding that the product was defective because of the manufacturer's failure to warn, the court turned to two causation issues involved in every failure to warn case: (1) whether defendant's product caused the injury, and (2) whether a sufficient warning would have caused the plaintiff to act differently.[13] Despite conflicting testimony at the trial, the court upheld the jury's finding that live virus in the vaccine had caused the plaintiff's polio.[14]

On the second issue, the court said:

> Where a consumer, whose injury the manufacturer should have reasonably foreseen, is injured by a product sold without a required warning, a rebuttable presumption will arise that the consumer would have read any warning provided by the manufacturer and acted so as to minimize the risks. In the absence of evidence rebutting the presumption, a jury finding that the defendant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable.[15]

The court held that there was no evidence rebutting the presumption and upheld the judgment against Wyeth. In so doing the court did not discuss the expert testimony estimating the child's risk of contracting polio from the wild virus in the community at one in 3,000 and the risk of contracting this type of polio from the vaccine itself at one in 5.88 million.[16] Even allowing some margin for error in the statistics, and even assuming that an adequate warning would also warn of any other risks associated with the vaccine, the great disparity between these two figures suggests that a reasonable person in plaintiffs' position would have taken the vaccine even if provided with this information. On the assumption that the plaintiffs' only choices were to have their child take Sabin vaccine or remain without immunity from the virus, this evidence

13. 498 F.2d at 1279-82.

14. The finding that the vaccine was the cause of the polio was highly controversial. In the spring of 1970, there was a major outbreak of polio cases in Southern Texas. Of the 33 cases reported in the United States in 1970, 22 occurred in the Hidalgo County areas in which Anita Reyes lived and was inoculated. The virus that infected the child was Type I virus, the same type that was wild in the area at the time. At the trial, the only witness who testified that the child's polio was caused by the vaccine was a local doctor who treated her after hospitalization. The defense, on the other hand, produced a number of expert witnesses who disputed the causation of the child's disease. One of these witnesses characterized the virus contracted by Anita Reyes as probably wild. It was undisputed that the child's risk of contracting polio from the vaccine itself was approximately 1 in 5.88 million. On the other hand, one witness, a professor at Johns Hopkins University, estimated the child's risk of contracting polio from a wild virus as 1 in 3,000, using available figures on the prevalence of the disease in the community. Nevertheless, the jury found that the vaccine, not the virus, caused the illness. *See* Reyes v. Wyeth Laboratories, 498 F.2d at 1284; Curran, *Public Warnings of the Risk in Oral Polio Vaccine, supra* note 3.

15. 498 F.2d at 1281.

16. See note 14 *supra*.

would appear to rebut the presumption that an adequate warning would have prevented the injury.[17] The court, however, apparently thought that another alternative was to immunize the child with the killed-virus Salk vaccine, a vaccine that does not carry with it the risk of causing polio.[18] In discussing the evidence concerning the presumption, the court noted, without any elaboration, that "at least by the time of trial" some pediatricians in Hidalgo County "had begun administering killed-virus vaccine to infants in order to build up their level of antibodies before feeding them the live-virus drug."[19] The court saw this as "[b]uttressing the presumption that Mrs. Reyes might have taken preventive steps" to avoid the risk of the Sabin vaccine if she had been warned.[20]

This is the only reference in the causation part of the opinion to the possibility of using killed-virus vaccine. At the end of the opinion, however, the court returned to the subject in addressing amici briefs filed by the American Academy of Pediatrics [AAP] and the Conference of State and Territorial Epidemiologists [CSTE].[21] These groups insisted that requiring individual warnings to participants in mass immunization programs would undermine these programs by discouraging large-scale participation. They argued that any effort to warn participants would lead to confusion, fright, and a decision not to be vaccinated. The court rejected the assertion that a warning advising the patient

17. On similar facts, the Oklahoma Supreme Court reversed a judgment for the plaintiff because of erroneous instructions and remanded for a determinatiou of the question whether "a reasonably prudent person in plaintiff's position would have refused to take the vaccine if adequate warning had been given." The court followed *Reyes* in stating that the plaintiff was entitled to a rebuttable presumption, but found that the evidence of a polio outbreak at the time plaintiff took the vaccine was sufficient to raise a question for the jury and remanded the case. Cunningham v. Charles Pfizer & Co., Inc., 532 P.2d 1377, 1382 (Okla. 1974).

The objective test of causation presumes a dispassionate individual who calmly weighs the risks in determining whether to accept or refuse treatment and makes that determination eutirely on the basis of probable safety. Experience might indicate, however, that patients tend to fear the immediate risks of unknown treatment and medication more than the future risk of disease, even when the dangers of the disease are substantially greater than those of the drug. Are the courts suggesting that the question of individual response to warning is an impossible standard to administer, or that it should not be the test even if such facts could be determined? *See, e.g.*, Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

18. Salk vaccine is completely safe if properly manufactured because the virus is clinically "killed" and made incapable of causing the disease. *See* Reyes v. Wyeth Laboratories, 498 F.2d at 1296.

19. 498 F.2d at 1282. This passage refers to a practice that may be utilized when there is no imminent risk of polio in the community. When an outbreak is underway, the need for rapid immunization dictates the use of Sabin vaccine. This presents another problem with the court's analysis which is discussed in the text accompanying note 31 *infra*.

20. 498 F.2d at 1282.

21. *Id.* at 1293-95.

of the risk of contracting polio from the vaccine would necessarily be terrifying or confusing.[22]

The amici briefs also argued that a warning was unnecessary because epidemiologists had decided that considerations of public health dictated universal vaccination and because a Texas statute required that schoolchildren receive polio vaccine. The court disagreed:

> This argument assumes, of course, that the only options available are to ingest the oral vaccine at the clinic or to eschew immunity. Obviously, however, one can choose to be innoculated with killed-virus Salk vaccine, either to provide complete immunity or as a precautionary prelude to ingesting oral vaccine.[23]

The court relied heavily in this part of the opinion on *Davis v. Wyeth Laboratories, Inc.*[24] That case involved a 39 year-old Montanan who contracted polio after participating in a mass immunization program employing Sabin vaccine. In *Davis* the court had observed that the plaintiff's odds of getting polio from wild virus and his odds of getting polio from the Sabin vaccine were about the same—one in a million.[25] The court concluded, therefore, that had the plaintiff received a warning of the relative risks he might well have decided not to take the vaccine.

In *Reyes* the court used *Davis* to support the point that a warning might have spurred the plaintiffs to use Salk instead of Sabin vaccine. The court stated that reasonable alternatives to taking the Sabin vaccine were available. It concluded that a "true choice judgment" was therefore involved, as in *Davis*, and that the choice was not so clear-cut that

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22. *Id.* at 1293.

23. *Id.*

24. 399 F.2d 121 (9th Cir. 1968).

25. There are three separate types of Sabin vaccine. Each is designed to immunize the recipient against contracting polio from a corresponding type of polio virus. Although some risk is inherent in each type of vaccine, the degree of risk varies with the age of the patient and the type of vaccine received. The risk associated with Type III vaccine, which Davis received, "is almost exclusively limited to adult populations." Davis v. Wyeth Laboratories, Inc., 399 F.2d at 122-23. The risk associated with Type I vaccine, which Anita Reyes received, is much lower and is not limited to members of her age group. This is why the risks involved in the two cases differ. *See Mass Immunization Cases, supra* note 3, at 239-40.

The most recent figures show that between 1969 and 1976, 44 cases of paralytic polio associated with Sabin vaccine were reported. During that period 114.5 million people in the United States were vaccinated. Ten of the 44 reported polio victims were recipients of the vaccine, making the odds about 1 in 11.5 million that one would get polio from taking the live-virus vaccine. The other 34 cases occurred in parents and others who came in contact with vaccine recipients. The 44 cases together yield a rate of about four cases of polio for each 10 million inoculations. Boffey, *Polio: Salk Challenges Safety of Sabin's Live-Virus Vaccine*, 196 SCIENCE 35 (1977) [hereinafter cited as Boffey].

offering an opportunity to choose would be meaningless.[26] In its analysis, the court failed to consider three important points.

First, the court did not discuss the availability of Salk vaccine at the time plaintiffs' child was vaccinated. In fact, manufacturers discontinued making Salk vaccine and concentrated on the Sabin vaccine after the government selected Sabin vaccine for its mass immunization programs in the early 1960's. Indeed, from 1968 to 1975 no Salk vaccine was manufactured in this country, although small amounts were imported.[27] Although the court referred to immunizations in Hidalgo County using Salk vaccine in the early 1970's,[28] it is likely that these units were imported and not generally available. Thus, those who would have chosen Salk vaccine after being warned of the danger of Sabin vaccine would have had a difficult time obtaining the alternative.

Second, the court did not discuss the significance of the fact that the plaintiffs' child was vaccinated during an outbreak of polio in her area.[29] When quick protection is essential, Sabin vaccine has been preferred despite the risk from the live virus.[30] Therefore, even if Salk vaccine had been available it is unlikely that a well-informed person seeking protection would have chosen it. The failure to address this question raises serious problems with the court's determination of causation, for the objective standard of causation would indicate that a person receiving a complete warning, including a description of the Salk alternative, would have chosen Sabin in order to minimize the risk.[31]

Finally, even if the Salk alternative had been available and had been preferable, a warning of the risks of the Sabin vaccine would not necessarily have caused the plaintiffs to choose the Salk alternative. The warning would have disclosed only a minute chance of contracting polio from taking Sabin, and perhaps an adequate warning would not have to mention the Salk vaccine. Though the court does not discuss this, it appears to have concluded implicitly either that alternatives must be

26. 498 F.2d at 1294.

27. Boffey, *supra* note 25.

28. 498 F.2d at 1282.

29. The use of the word "outbreak" may be confusing, since only 33 people in the United States contracted polio in 1970. See note 14 *supra*. Yet the concentration of 22 of these cases in the Hidalgo County area would apparently warrant use of the Sabin vaccine. See note 30 *infra*.

30. Live-virus vaccine has been preferred over killed-virus vaccine during major outbreaks of the disease because live-virus vaccine produces a harmless infection in the alimentary tract that interferes with wild virus infection even before the development of antibodies. This quick protection is not provided by the Salk vaccine. Even Dr. Salk, who has been sharply critical of the use of oral polio vaccine in the United States, concedes that the live-virus vaccine "is distinctly advantageous during an outbreak." D. Salk & J. Salk, The Control of Influenza and Poliomyelitis by the Use of Killed Virus Vaccines, at 18 (1976) (unpublished article).

31. On the objective standard of causation, see notes 17 & 20, *supra*.

disclosed in the warning or that the user will minimize the risk by inquiring into alternatives once a warning has disclosed the risk of Sabin vaccine. The former type of warning would be much more likely to achieve its purpose than the latter. The question is whether a warning that did not mention the Salk alternative would have been adequate.

Generally, even in so-called strict liability cases the adequacy of a warning is judged by negligence standards, in that the manufacturer need only warn of risks that are known or should be known.[32] The manufacturer must warn of those risks that a consumer would want to know about before using the product, and the warning should contain information as to the magnitude of those risks.[33] But need the warning include a description of safer alternative products? The "informed consent" cases already require that warnings include a description of alternatives to the recommended treatment.[34] In these cases a physician is required to disclose to the patient "the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the plaintiff remains untreated."[35]

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32. The duty to warn attaches only when the manufacturer has reason to foresee a risk from the use of the product. Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969); Christofferson v. Kaiser Foundation Hosps., 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1st Dist. 1971). Although the danger involved in Sabin vaccine was not known prior to the implementation of the mass immunization program, it was soon discovered. In *Stahlheber, Davis, Reyes,* and *Cunningham* where a duty to warn was found critical, the courts held that sufficient information was known by the manufacturer at the time of distribution of the critical batch of vaccine to require a warning.

Dean Keeton has argued that the fact that the "manufacturer was unaware of the existence of the defect does not alter the fact that [the product] was defective"—and would justify liability without regard to warnings. Keeton, *Products Liability—Liability Without Fault and the Requirement of a Defect,* 41 TEXAS L. REV. 855, 861 (1963). A few jurisdictions appear to have followed Keeton's theory that the manufacturer may be held liable even though one cannot say that he should have known of the defect. *See, e.g.,* Green v. American Tobacco Co., 154 So. 2d 169 (Fla. 1963) (question certified to Florida Supreme Court by the Fifth Circuit in Green v. American Tobacco Co., 304 F.2d 70 (5th Cir. 1962), *rev'd and remanded,* 325 F.2d 673 (5th Cir. 1963), *cert. denied,* 377 U.S. 943 (1964)). Other jurisdictions do not impose liability upon a manufacturer for injuries arising out of a "scientifically unknowable" risk. Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969) (applying Connecticut law); Christofferson v. Kaiser Foundation Hosps., 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1st Dist. 1972).

The adequacy of the warning once the duty to warn attaches is also tested by the standards of reasonableness. See cases cited in note 33 *infra.*

33. *See* Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076 (5th Cir. 1973), *cert. denied,* 419 U.S. 869 (1974); Tampa Drug Co. v. Wait, 103 So. 2d 603 (Fla. 1958); Stahlheber v. American Cyanamid Co., 451 S.W.2d 48 (Mo. 1970).

34. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied,* 409 U.S. 1064 (1972); Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

35. Canterbury v. Spence, 464 F.2d at 787-88. In *Cobbs v. Grant* the court imposed "a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each." 8 Cal. 3d at 243, 502 P.2d at 10, 104 Cal. Rptr. at 514.

One group of authors has suggested that the rationale of "informed consent" cases should be utilized to impose liability upon the manufacturer of a dangerous product where a warning, if given, would not reduce the inherent risk of the product.[36] Using *Davis* as an example, they conclude that since a warning would make the vaccine no less dangerous but would merely provide the consumer with information to make an informed choice on whether to accept the vaccine, the issue is not one of making the product safer but of giving a prospective user an indication of the irreducible risk that inheres in the product.[37] Such an analysis might lead to a requirement that warnings on unavoidably unsafe products, such as vaccines, must include a description of alternatives to the product and of the risks and benefits of the alternatives.[38] The informed consent cases have held that although a physician has made an individualized judgment that a certain treatment is desirable, advising the patient of alternatives is still required.[39] There is more reason to place such an obligation on a manufacturer of flu or polio vaccine that knows that the recipients will not get such individualized attention.

A recent regulation of the Food and Drug Administration setting minimum requirements for warnings accompanying oral contraceptives is a step in this direction. Included among the requirements are:

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36. Donaher, Piehler, Twerski & Weinstein, *The Use and Abuse of Warnings in Products Liability—Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495, 517-21 (1976).

37. *Id.* The utility of the "informed consent" analysis for the failure to warn of inherent dangers in a product seems to be limited to drugs that are "unavoidably unsafe."

For a discussion of warnings of irreducible risks, see Calabresi & Hirschoff, *Toward a Test for Strict Liability*, 81 YALE L.J. 1055, 1062-63 (1972).

38. Such treatment might also lead to another change. It has been argued that "focusing on the issue of choice rather than on the unreasonably dangerous nature of the product" will eliminate the difficult problem of causation, and that if the authorization of treatment was not given by an informed consent, the case should be properly treated as a battery with the only issue being whether the touching was unauthorized. Donaher, Piehler, Twerski & Weinstein, *supra* note 36 at 520 n.59. In *Cobbs v. Grant*, the California Supreme Court disagreed:

> The battery theory should be reserved for those circumstances when a doctor performs an operation to which the plaintiff has not consented. . . . [Where, however] the doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information . . . the action should be pleaded in negligence.

8 Cal. 3d at 240-41, 502 P.2d at 8, 104 Cal. Rptr. at 512. Both the *Cobbs* and *Canterbury* courts found it necessary to address the causation problem, and both articulated fundamentally the same objective standard required by *Reyes*—that is, what would a prudent person in plaintiff's position have decided if adequately informed of all significant perils? Thus it seems unlikely that an "informed consent" analysis will avoid the causation problem.

39. See note 35 *supra*.

(v) A statement of the effectiveness of oral contraceptives, including the differences in effectiveness among different types and the relationship between effectiveness and estrogen dosage.

(vi) A summary of the effectiveness of other methods of contraception. . . .

(xi) A comparison of the risk of death from various contraception methods (oral contraceptive, IUD, condom or diaphragm, condom or diaphragm with abortion in the event of pregnancy, no contracetpion but abortion in the event of pregnancy, and no contraception or abortion).[40]

Requiring a description of alternatives is particularly appropriate for participants in a mass immunization program. These are healthy individuals incurring a risk for the benefit not only of themselves but of others,[41] and they are arguably even more entitled to be made fully aware of the potential consequences of their decisions than are patients who undergo treatment solely for their own benefit.[42]

Reyes and the other polio vaccine cases[43] indicate that the courts have been most solicitous of the plaintiffs and have actively sought bases for recovery.[44] The courts have rejected suggestions that public health considerations should draw the courts toward nonliability. To better understand these conflicting pressures, one must examine the public health aspects of the polio situation.

II

TORT LAW AND PUBLIC HEALTH POLICY

In one aspect of their work, public health officials seek to reduce public risk by controlling the outbreak and spread of communicable

40. 41 Fed. Reg. 53,630 (1976) (to be codified in 21 C.F.R. § 310.501(a)).

There is obviously a problem of overload of information lurking here. These regulations may require so much information that a reasonable customer cannot assimilate it or understand the charts and the other ways in which the data are presented. The common law analogy would not be the "greatest disclosure possible" but rather a reasonable amount of information, including alternatives to the extent that these would be significant in a reasonable person's decision.

41. A person who receives the vaccine is unlikely to be a transmitter of the disease to others. The process by which immunization of some persons protects the community as a whole by decreasing the spread of viral infection is known as the "herd effect." See D. Salk & J. Salk,the Control of Influenza and Poliomyelitis by the Use of Killed Virus Vaccines, at 6 (1976) (unpublished article).

42. In *Davis* the court seemed impressed that "[a]ppellant testified that he had no knowledge of the risk, relied on the posters and was convinced by the campaign's advertising that it was his civic duty to participate." 399 F.2d at 125.

Because of the protection aspect of mass immunizations, they do not present nearly as clear a case of "altruism" as do volunteer blood donors. See Franklin, *Hepatitis, Blood Transfusions, and Public Action*, 21 CATH. U. L. REV. 683 (1972).

43. See note 3 *supra*.

44. Compare the results in the polio cases, *supra* note 3, with the rationale expressed in the Restatement, § 402A, Comment j, *supra* note 5.

disease. An individual is likely to seek to optimize personal risk. Often, but not always, the two objectives will coincide and mandate an identical course of action. When these interests diverge, tort law has focused primarily on the individual's concerns. This tension is illustrated by the history of polio immunization.

Polio is a contagious disease caused by an enterovirus that grows in the intestinal tract after being introduced into the body orally.[45] The disease attacks certain cells in the spinal column, causing muscular paralysis. The first vaccine that effectively protected against the disease, developed by Dr. Jonas Salk in the early 1950's, was made with polio virus grown in a tissue culture and clinically "killed" so as to be incapable of causing the disease. Since no chemical alteration occurs in killing the virus it acts as an antigen when injected into the body by inducing the body to produce antibodies sufficient to destroy a virulent strain of polio that might enter the bloodstream.

In the late 1950's Dr. Albert Sabin developed a vaccine that used living, but attenuated, polio virus. An attenuated virus is rendered incapable of producing the disease (to the extent of the attenuation) but retains sufficient strength to cause the production of antibodies to destroy virulent polio virus.

In the early 1960's, public health officials decided to use Sabin vaccine in their mass immunization programs:

> Authorities concluded that the live-virus vaccine would be more acceptable to the public (because it is given orally on a sugar cube rather than by injection); would produce longer-lasting immunity; and would even immunize many people who had not bothered to get vaccinated but who came into contact with those who had and caught a generally harmless infection from them. They also felt that the live-virus vaccine would do a better job of eradicating the wild polio virus from the environment because the live-virus vaccine suppresses the wild virus from the intestinal tract, thereby interfering with the spread of polio through fecal matter and sewage, whereas the killed-virus vaccine does not.[46]

At the time, some warned that because it used live-virus the Sabin vaccine would cause polio in some who took it.[47] This danger had not

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45. *See generally* the discussion of polio in Appendix B to the *Reyes* opinion, 498 F.2d at 1295-98. *See also* Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), 353 F. Supp. 324 (E.D. Pa. 1973), *aff'd in part, rev'd in part and remanded,* 500 F.2d 1059 (3d Cir. 1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 122-25 (9th Cir. 1968).

For a discussion of polio from an exclusively medical perspective, see the medical sources cited in *Mass Immunization Cases, supra* note 3.

46. Boffey, *supra* note 25, at 35.

47. *Id.*

yet been established, but soon after the national program of immunization began, confirmed cases of vaccine-associated polio began to be reported.[48]

Even though Sabin vaccine might be less "safe" than Salk vaccine, several other factors enter into any decision on what vaccine to use in a national mass immunization program. Public health officials are seeking a vaccine that will create the desired immunity in the fewest number of easy and quick administrations, preferably at low cost. Since safety is only one of the many factors to be considered in mass immunization programs,[49] the decision to use Sabin might still have been made even with knowledge of the dangers involved. Whether the public health decision was wrong at the time or is wrong now is another question—and one that still rages in medical circles and in Congress.[50]

The tension between the goals of mass immunization programs and tort law is heightened by the polio experience. From the perspective of public health officials, tort decisions compensating victims of these programs are likely to achieve one or both of two unfortunate consequences. They are likely to (1) impose additional costs on vaccine manufacturers, doctors and nurses, or governments operating immunization programs and thereby cause them to refuse to participate or to charge more for their participation; or (2) lead these groups to seek to avoid additional costs by informing prospective recipients fully of the dangers involved. This is likely to lower the number of persons who are willing to be immunized, thus reducing the public benefit from the program.

Surely the courts deciding the tort cases are aware of these concerns. Why have they given them such short shrift? It is hard to believe that the courts are not aware that their decisions are likely to increase the costs of immunization programs or reduce public participation in them. Are the tort rules so clearly applicable to these cases that to avoid liability courts would have to distort basic tort doctrine? The short answer is "No." In most of the polio cases, the courts had to struggle to find a basis for imposing liability, for the cases do not fit well into traditional categories.[51] One must search for unarticulated explanations, because the obvious one—that the courts were simply applying general tort principles—will not stand.

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48. Davis v. Wyeth Laboratories, Inc., 399 F.2d at 122-25, 129.

49. Even safety is not unidimensional. Some safety risks connected with the Salk injection process are absent from the administration of Sabin vaccine. On the public health level, the "herd effect" indicates that the safety of a society's members is not to be calculated solely in terms of the safety of each individual. In addition, of course, the presence of an "outbreak" may change the safety analysis. See note 30 *supra*.

50. Boffey, *supra* note 25. See note 55 *infra*.

51. See note 3 *supra*.

One possible explanation is that the courts are trying to force public health decisionmakers to consider all the costs incurred as a result of their decisions. There is always the danger that those making decisions will emphasize the costs that fall in their domain and discount or forget about those that fall on others. In this case, those in government who decided to use the Sabin vaccine, or to continue using it after the danger became known, were relying on its effectiveness as well as its inexpensive administration and the ease of reaching the public without costly public relations campaigns. The costs to victims may have been considered, but they are unlikely to have been given as much weight as those costs that traditionally fell on the government in such programs. The advantage of having the full array of costs in the minds of decisionmakers has played a role in the development of strict liability theory in other contexts.[52]

One problem with this explanation is that the costs in most of the cases have fallen on the vaccine manufacturers rather than the government. This has occurred because the federal government is not subject to suit under the Federal Tort Claims Act for the discretionary decisions of its officers.[53] Thus, the costs cannot be placed directly on the decisionmakers. Nonetheless, by placing the costs on the vaccine manufacturers the courts created a vocal force that would play a powerful part in future vaccine decisions—as the flu episode demonstrates.[54]

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52. *See* Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499 (1961); Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 377 P.2d 879, 27 Cal. Rptr. 697 (1962); Escola v. Coca Cola Bottling Co., 24 Cal. 2d 453, 461, 150 P.2d 436, 440 (1944) (Traynor, J., concurring opinion).

53. The Federal Tort Claims Act imposes liability on the United States for the negligent acts or omissions of federal employees while acting within the scope of their employment in the same manner and to the same extent as a private individual under similar circumstances. 28 U.S.C. § 1346b (1970). One exception to this waiver of governmental immunity provides that the government shall not be liable for acts or omissions within the discretionary function of any federal agency or employee. 28 U.S.C. § 2680a (1970). There is general agreement that high level planning and policy decisions are within the scope of the exception but that activity at the "operational" level is not. *See, e.g.*, Driscoll v. United States, 525 F.2d 136 (9th Cir. 1975). The United States is not liable for damages caused by acts or omissions falling within the discretionary function exception even where such decisions are clearly unreasonable. *See* Eastport S.S. Corp. v. United States, 372 F.2d 1002 (Ct. Cl. 1967); United States v. Morrell, 331 F.2d 498 (10th Cir. 1964), *cert. denied sub nom.* Chournos v. United States, 379 U.S. 879 (1964).

It seems clear that the government could not be successfully sued for its decision to use Sabin rather than Salk vaccine in the public health program.

54. Because of the way these vaccines are financed, it is unlikely that a drug manufacturer can recoup its expenses from the general public or even from those who use the vaccine. With ordinary prescription drugs, costs from liability awards can be passed along in the price of that product to future users. But here there may be no large future group of users. Moreover, because of the "herd effect" the group benefitted by widespread use of a vaccine is the general public—not, as in the case of most prescription drugs, those who use it for their own individual benefit.

Imposition of liability on some participant in the program was much more likely to drive those costs home to decisionmakers than leaving the costs on the disorganized and disabled victims. Under this view, the courts are not asserting that the public health decisions have been right or wrong, but only that tort law has a role to play in trying to assure that such decisions are made with the costs fully considered.[55]

It is also possible to read the cases as "reaching" to bring each victim within tort rules because the courts have no other way to compensate these few victims whose participation benefitted others. This explanation is suggested by cases like *Davis* in which there was no outbreak of polio in the area and the plaintiff participated in the immunization program out of a sense of good citizenship.[56] The courts may have concluded that special obligations are owed citizens who participate in mass immunization programs established for the public benefit.[57]

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55. Some evidence exists that the original government choice to use Sabin rather than Salk vaccine may have been unfortunate. In testimony before the United States Senate's Subcommittee on Health, Committee on Labor and Public Welfare, given September 23, 1976, Dr. Jonas Salk stated that contrary to beliefs held in 1961, (1) the oral vaccine is not completely safe but has in fact been the principal cause of domestically arising cases of polio in the last several years; (2) the infection of contacts by those previously immunized by oral vaccine is not always harmless; (3) killed virus vaccine is effective in eliminating wild virus from the community; and (4) booster shots of killed virus vaccine are not required every couple of years for effective immunity.

Furthermore, Professor Karl Penttiten of the University of Helsinki testified that in Finland and in Sweden, where Salk vaccine is used exclusively, no polio cases have been reported since 1964 and 1963 respectively. Norway, which has used Sabin vaccine since 1965, has recorded at least eight cases. Norway's rate of vaccine-induced polio of 1 in 300,000 immunizations appears to be about 10 to 15 times higher than that of the United States. Wash. Post, Sept. 24, 1976, at A13, col. 1.

Since Dr. Penttiten's testimony, Sweden has reported its first polio case in nearly 15 years—a person who had not been vaccinated. Boffey, *supra* note 25, at 36.

56. See note 42 *supra*.

57. In a footnote, the court in *Reyes* observed:

> It can also be argued, of course, that since all society benefits from universal immunization against infectious diseases, the loss should be borne by the local, state or federal government. Unless the doctrine of sovereign immunity is significantly altered, however, such a loss distribution scheme does not appear to be likely.

498 F.2d at 1294 n.57. Yet the concept of society at large benefitting from the program may have aided the court in resolving "by a balancing process the head-on collision between the need for adequate recovery and viable enterprises" in favor of the victim. 498 F.2d at 1294 (quoting Helene Curtis Indus., Inc. v. Pruitt, 385 F.2d 841, 862 (5th Cir. 1967), *cert. denied*, 391 U.S. 913 (1968)).

The argument that victims' damages are in fact spread to the public by either health insurance or by welfare charges does not refute the main point. First, insurance and welfare do not nearly compensate the full extent of the loss suffered by a person who contracted polio or who suffered paralysis after receiving a vaccination. Beyond that, to the extent these losses are not spread by insurance, their spreading depends on the welfare structure in a particular state. Finally, even if the full cost were spread this

III

THE FLU PROGRAM

The imposition of liability in *Reyes* and in other polio cases[58] and the uncertainty surrounding the basis for liability in these cases made insurance companies reluctant to underwrite a national flu immunization program.[59] Congress responded by passing a statute under which 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].[60]

In addition the United States accepted liability in certain types of cases which normally do not give rise to liability under the Federal Tort Claims Act.[61] Liability under the Federal Tort Claims Act lies for acts of government employees under circumstances in which the United States "if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."[62] Although under the Tort Claims Act the government cannot be held on strict liability theories,[63] one of the exceptions in the flu statute provides that the liability of the United States "may 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,

way it would be hard for decisionmakers to learn the extent of these costs, and they would have little incentive to weigh these costs fully in making their decisions.

58. See note 3 *supra.*

59. *See* Zimmerly, *Legislative Boost for Swine Flu Program,* J. LEG. MED., Oct. 1976, at 20. *See also* Sparks v. Wyeth Laboratories, Inc., 431 F. Supp. 411, 415 (W.D. Okla. 1977), where the court stated that the insurance market's collapse was caused by the threat of a large number of claims, with the attendant costs of investigation and defense, and by the *Davis* and *Reyes* rulings that a manufacturer is strictly liable for failure to warn a vaccinee of the vaccine's risk. This reluctance to underwrite the flu program appears to have been justified. As of March 31, 1977, 282 claims and 14 suits had been filed totaling over $300 million. It has been estimated that 4000 to 4500 claims and suits will ultimately be filed, seeking over $1 billion. U.S. COMPTROLLER GENERAL, THE SWINE FLU PROGRAM: AN UNPRECEDENTED VENTURE IN PREVENTIVE MEDICINE, H.R. DOC. NO. 77-115, 95th Cong., 1st Sess. 83 (1977) [hereinafter cited as COMPTROLLER GENERAL'S REPORT].

60. 42 U.S.C.A. § 247b(k)(2)(A) (Supp. 1977). In Sparks v. Wyeth Laboratories, Inc., 431 F. Supp. 411 (W.D. Okla. 1977), the Swine Flu Act was upheld against a variety of constitutional challenges. Plaintiff sued Wyeth, and the United States moved to substitute itself as the sole party defendant and to dismiss the action for plaintiff's failure to file an administrative claim required by the Federal Tort Claims Act procedure, 28 U.S.C. § 2675(a) (1970). The plaintiff opposed these motions on the grounds that the Swine Flu Act denied plaintiff due process, equal protection, and the right to a jury trial, and also violated the tenth amendment. The court rejected all of plaintiff's constitutional arguments, and dismissed the action.

61. *Id.* See notes 63-65 *infra.*

62. 28 U.S.C. § 1346b (1970). See note 53 *supra.*

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

strict liability in tort, and breach of warranty."[64] The government also agreed in the flu statute not to invoke the provision of the Tort Claims Act that bars liability "based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty . . . whether or not the discretion involved be abused."[65]

The upshot of the interplay between the two statutes is that plaintiffs claiming harm from the flu program must sue the United States, which agrees to be bound by the law applicable to private persons in the particular states involved even if the liability is based on strict liability theories or the abuse of a discretionary function. The remedy against the United States is exclusive,[66] and the case is to be tried without a jury as under the Tort Claims Act.[67]

If the United States is held liable it is entitled to indemnity against any program participant whose negligence or violation of a contract with the government caused the harm.[68] The right to indemnity exists "notwithstanding any provision of State law" that might limit recourse to indemnity.[69] Leaving only strict liability awards to fall ultimately on the government would be quite consistent with the legislation's purpose—to remove from drug manufacturers and their insurers the dangers of being held strictly liable for unanticipated harms, such as Guillain-Barré syndrome paralysis.[70] Nevertheless, the government agreed to fund a total of $230 million of liability insurance obtained by vaccine manufacturers to insure against the government's right to indemnity.[71]

64. 42 U.S.C.A. § 247b(k)(2)(A)(i) (Supp. 1977).

65. 42 U.S.C.A. § 247b(k)(2)(A)(ii) (Supp. 1977) (providing that "the exceptions specified in section 2680(a) of Title 28 shall not apply").

66. 42 U.S.C.A. § 247b(k)(3) (Supp. 1977); Sparks v. Wyeth Laboratories, Inc., 431 F. Supp. 411, 420 (W.D. Okla. 1977).

67. 42 U.S.C.A. § 247b(k)(5)(A) (Supp. 1977). The Federal Tort Claims Act procedures are contained in 28 U.S.C. §§ 2671-80 (1970). The section providing for trial without a jury survived constitutional challenge in Sparks v. Wyeth Laboratories, Inc., 431 F. Supp. 411, 418-19 (W.D. Okla. 1977). See note 60, *supra.*

68. 42 U.S.C.A. § 247b(k)(7) (Supp. 1977).

69. *Id.*

70. The latest figures show that the risk of permanent injury or death from Guillain-Barré syndrome is one in one or two million vaccinations. Other evidence indicates that vaccinees were 7.5 times more likely to develop Guillain-Barré syndrome than others. Boffey, *Guillain-Barré: Rare Disease Paralyzes Swine Flu Campaign,* 195 SCIENCE 155 (1977).

Whether the theory in the cases be strict liability for "scientifically unknowable" risks in design or for non-negligent manufacturing problems, the polio experience suggests that courts may "reach" to impose liability.

71. COMPTROLLER GENERAL'S REPORT, *supra* note 59, at 19-20. The manufacturers are self-insured to $10 million; the remaining $220 million was bought from insurance companies for an $8.65 million premium. If the government pursues its right to indemnity, all litigation and settlement costs up to $10 million are charged to the self-insurance fund and paid by the government. *Id.*

Actions under the Tort Claims Act for the negligence of government officials

After the creation of the federal mass immunization program, but before passage of the liability legislation, the states realized that the federal government was going to arrange for states to receive the vaccine free of charge, but would not provide funds to help the states meet the costs of administering the vaccine. The states had reason to believe that medical personnel would be concerned about malpractice liability for their actions during the program. The states might have met this concern by purchasing insurance to cover participants or by paying participants so that they, in turn, could buy insurance. But these paths would have cost the states money.

Instead, some states, led by California, adopted legislation exempting participants in the program from liability unless their behavior involved "willful misconduct."[72] The California urgency statute asserted that:

> [S]tate and local budgets are inadequate to finance mass immunization programs unless health care providers of all categories are asked to volunteer their services, and unless local health departments can be relieved of the expense of potential liability associated with administration of the vaccine. It is evident that a sufficient number of volunteers will not be available unless statutory protection is afforded to them against potential liability.[73]

Since the California statute defined "volunteer" to exclude drug manufacturers, the protection for volunteers extended only to those involved in promotion of community immunization programs or in on-the-spot administration of such programs—such as physicians, nurses and public health facilities.[74] Either California was not concerned about the imposition of strict liability on the suppliers or it anticipated that their problems would be handled on the national level. But when

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would also presumably rest ultimately on the government, as in Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), 353 F. Supp. 324 (E.D. Pa. 1973), *aff'd in part, rev'd in part and remanded*, 500 F.2d 1059 (3d Cir. 1974).

72. CAL. GOV'T CODE § 856.6(a) (West Supp. 1977). Some states have passed similar legislation to exempt program participants from liability for damages in connection with community vaccination programs. *See, e.g.*, Pub. Act No. 202, 1976 Mich. Legis. Serv. (West) (to be codified in MICH. COMP. LAWS §§ 691.1501-02) (exempts from liability unless gross negligence or willful and wanton misconduct); 35 PA. CONS. STAT. ANN. §§ 10151-52 (Purdon Supp. 1977) (exempts from liability so long as there is no gross negligence; broadens the scope of an earlier act dealing with doctors' and nurses' liability).

Some states have long limited the personal liability of public health personnel. *See, e.g.*, N.Y. PUB. HEALTH LAW § 329 (McKinney 1971).

Some recent legislation explicitly states that vaccine manufacturers are not protected by the reduced liability standards. *See, e.g.*, the Michigan and Pennsylvania statutes.

On state reactions to the flu problem, *see generally* Ladimer, *Legal and Regulatory Perspectives in Mass Immunization Programs*, 1976 INS. L.J. 459.

73. Ch. 427, § 2, 1976 Cal. Stats.

74. CAL. GOV'T CODE § 856.6(c)(2) (West Supp. 1977).

the federal legislation took its present shape, the result was that persons hurt by a nurse's negligence in California were barred from recovery by state law, and thus the federal government was not liable.[75] In states without similar statutes, the federal government probably would be liable for such negligence but then would be entitled to indemnity from the wrongdoer. The curious result in states like California is that those injured by negligence during the administration of the program get nothing, but those injured by totally unexpected side effects may recover against the United States on a strict liability theory if state law is interpreted to allow such a recovery.[76]

Whatever may be said about the wisdom of the California approach, it was not calculated to alleviate public reluctance to get involved with the program. Presumably, those concerned about this problem could have obtained their flu shots from a private physician who would have been subject to traditional malpractice liability.[77] This alternative would undercut the philosophy of a mass immunization program—getting as many citizens as possible to participate in a single community effort. This difficulty results from an effort to avoid taking into account certain inevitable costs of the program and a willingness to let these costs fall randomly and heavily on a small number of unfortunate victims.

Both federal and state legislatures were concerned with the practical problems of getting the flu immunization program underway quickly and with avoiding objections from those concerned about the costs of the program. The federal statute accepted initial liability only because the alternative would have been no program at all. In state legislatures, however, the costs were simply avoided, because there was no powerful lobby on behalf of yet-to-be identified victims.

Congressional supporters of the flu statute argued vehemently that the bill set no precedent because it was a unique response to a pressing medical problem. That was sound politics at the time, but the federal statute contains the first glimmer of a sensible approach to the mass vaccine problem. As a matter of political philosophy, a case can be

75. The California statute precludes the imposition of liability on the federal government in cases where program participants are merely negligent, because liability can be imposed under the Federal Tort Claims Act 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." 28 U.S.C. § 1346b (1970). By limiting actions against certain program participants to those involving willful misconduct, California has denied some victims of the flu program actions against the federal government.

76. *See, e.g.*, Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1st Dist. 1960).

77. The statute creating the national swine flu immunization program imposes liability upon the United States only for acts or omissions of a "program participant." Unless the vaccine was provided without charge, a private physician would not be de-

made for the view that since citizens are asked to take part in a mass immunization program for the public benefit, the public should share in the inevitable costs of the program. As a matter of attaining public health goals, the argument can be made that public participation in immunization programs would increase if the public learned that anyone hurt by the vaccine or its administration would be compensated for the injury.

Placing liability for harm on the government would provide the additional benefit of concentrating the decisionmaking powers and the costs of the program in the same hands. Public officials would be more likely to weigh all the costs when deciding which immunization program, if any, to adopt. Thus far, where the government could not be held liable the courts have grappled with the situation by imposing costs on the manufacturers. Whether the courts realized how quickly and sharply this would work its way back into government calculations is not clear. In any event, with the advent of the swine flu program the government has taken an active role in compensating victims of immunization.

One obvious problem with the federal flu statute is its reliance on state law to determine liability. The goals of national immunization programs are necessarily national in scope, and liability for misadventures along the way should be paid for by the general public. There is no justification for allowing the peculiar features of state law to control recovery, or worse yet, to influence citizens not to be vaccinated. The federal government is attempting to achieve maximum participation in order to avoid a national health peril and should therefore use public relations campaigns that will assure all citizens of compensation in the case of injury wherever they may happen to live.[78]

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fined as a program participant and therefore would not be protected from a traditional malpractice suit. 42 U.S.C.A. § 247b(k)(2)(B) (Supp. 1977). The California law would exempt a volunteer participating in the program from liability except for acts of willful misconduct, but it seems unlikely that the statute protects a physician charging money for the vaccination. *See* CAL. GOV'T CODE § 856.6 (West. Supp. 1977).

78. One question that confronts any commentator on the utility of tort law in a specific context is whether to address only that context or to consider the argument that problems of compensating victims of personal injury should be approached without regard to the source or cause of the injury. See note 68 *infra*.

This Article is a response to a specific problem which has arisen. The mass immunization program situation arguably presents a stronger case for some non-tort system of compensation than does the general problem of accident victims, because of the role of government encouragement in the programs and because of the public benefits that flow from the socially desirable actions of the individual in this context.

Six countries—Denmark, Hungary, Japan, Monaco, Switzerland, and West Germany—have already enacted laws or issued regulations to compensate persons who experience vaccine-associated disability. *See* Ladimer, *Legal and Regulatory Perspectives in Mass Immunization Programs*, 1976 INS. L.J. 459, 469.

Two questions about any such compensation program, though important, are beyond the scope of this article. The first is by what standard the amount of compensation should be measured—tort law, workmen's compensation, or some no-fault analogy. Should the amount of the recovery depend on whether the injury was attributable to negligence? These questions implicate broader philosophical and practical disputes discussed elsewhere.[79] Second, whatever approach one adopts, a connection must be shown between the program and the onset of the disease or other injury. The proof requirement should not be too rigorous, however, or the general goal of encouraging the citizenry to participate in immunization projects will be undermined.[80]

Whatever compensation system is adopted, there should be full disclosure of the significant dangers associated with the vaccine, as Congress sought to achieve in the flu statute.[81] This disclosure should include the statement that anyone who suffered adverse reactions from the vaccine or its administration would be compensated. Although the combination of disclosure of risks and assurance of compensation might deter participation more than would lack of any warning at all, the importance of individual autonomy, stressed in *Reyes*, should not be ignored. Of course, disclosure should not serve as a defense to avoid all payment, since this would defeat the very purpose of the reassuring approach. This is particularly true when the federal and state governments have conducted public relations campaigns to encourage citizens to participate, since such campaigns greatly reduce the impact of any warning.[82]

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79. *Compare* Franklin, *Replacing the Negligence Lottery: Compensation and Selective Reimbursement*, 53 VA. L. REV. 774 (1967) *with* Blum & Kalven, *Ceilings, Costs, and Compulsion in Auto Compensation Legislation*, 1973 UTAH L. REV. 341 (1973).

80. Since a tort measure of damages would presumably be coupled with a strong showing of causation, the two questions are related. A tentative resolution would be to provide an award in the no-fault range on a causation showing as weak as that in *Reyes*.

81. 42 U.S.C.A. § 247b(j)(1)(F) (Supp. 1977). The informed consent form used between October 1 and December 16, 1976 contained no specific warning of possible neurologic disorders, although information available before the program began identified such disorders as a possible severe reaction associated with flu immunization. COMPTROLLER GENERAL'S REPORT, *supra* note 59, at 22-23. This omission may prove significant because of the incidence of Guillain-Barré syndrome.

82. In Stevens v. Parke, Davis & Co., the court upheld

> the implied finding of the jury that Parke, Davis negligently failed to provide an adequate warning as to the dangers of Chloromycetin by so "watering down" its warnings and so overpromoting such drug that members of the medical profession, including Dr. Beland, were caused to prescribe it when it was not justified.

9 Cal. 3d 51, 66, 507 P.2d 653, 662, 107 Cal. Rptr. 45, 54 (1973). Similar results were reached in Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (3d Dist. 1964), *second appeal*, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (3d Dist. 1967); Incol-

CONCLUSION

The tensions between the private and public interests in mass immunization programs lead one to question the utility of tort law in this context. The case for assuring compensation to all injured participants is uniquely strong. Although the federal flu legislation is far from ideal,[83] the polio and flu episodes suggest that the statute has virtues that should be expanded upon in any future mass immunization programs.

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lingo v. Ewing, 444 Pa. 263, 444 Pa. 299, 282 A.2d 206 (1971). *See* Cohen, *Stevens v. Parke, Davis & Co.*, 10 U.S.F. L. REV. 683 (1976).

83. Since only one case has been decided under the swine flu legislation, it is too early to know exactly how the courts will interpret this statute. It is possible that the statute will not be applied precisely as outlined in this Article.

Perhaps there will be new legislation regarding liability for injuries arising out of immunization programs, as Congress has directed the Secretary of Health, Education, and Welfare to conduct a study of alternative approaches to providing protection against such liability, including the alternative of a "compensation system." National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, § 3, 90 Stat. 1118 (1976).