APPORTIONING LIABILITY IN MASS INOCULATIONS: A COMPARISON OF TWO VIEWS AND A LOOK AT THE FUTURE

I
INTRODUCTION

In 1976, the federal government embarked on the unprecedented task of immunizing the entire adult population against the threat of one disease—Swine Flu.[1] Many of the difficulties encountered by the program planners resulted from the need for a scheme that would apportion liability for injuries associated with the inoculation program. The Swine Flu inoculations were officially halted on December 16, 1976; the socio-epidemiological and legal ramifications of this Program demonstrate the need for a permanent national scheme for ensuring the safe production and dissemination of vaccines when threats of epidemics arise in the future.

Public Law No. 94-380[2] is the congressional response to the problem of apportioning liability in mass inoculations. The judicial reaction to this problem of liability varies by jurisdiction and by theory of liability—*i.e.*, negligence, breach of warranty, and strict liability in tort.

This Note compares the common law of liability in mass inoculations, as developed by the courts, with the legislative model[3] depicted by the Swine Flu Program. Both the judicial and legislative approaches are analyzed with respect to: principles of risk allocation, the peculiar nature of mass inoculations, the actions to which liability could attach, and the public policy priorities. Finally, a model is proposed for the long term solution to the mass inoculation problem.

II
BACKGROUND TO THE SWINE FLU PROGRAM

Mass immunization campaigns typically begin with the threat of an epidemic. In the National Swine Flu Immunization Program, the controversy

1. Influenza A virus from swine were first isolated in 1931. In studying the relationships between human and swine influenza, it was found that some humans had antibodies against swine influenza. Since such antibodies seemed to be limited to persons exposed to the pandemic of 1918-1919, a hypothesis was formulated that the swine influenza virus, or a closely related strain, caused the 1918-1919 pandemic. *See* Harkness, *et al.*, *Studies on Relationships Between Human and Porcine Influenza*, 47 BULL. WORLD HEALTH ORG. 709, 716. For the purposes of this analysis, "Swine Flu" denotes the influenza virus A/New Jersey/76 (Hsw 1N1).

2. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (1976) (to be codified in 42 U.S.C. §§ 247b(j)-(*l*) [hereinafter, the "Swine Flu Program"].

3. The term "legislative model" is used as a shorthand for the legislative answer to the problems of liability in mass inoculations. Use of the word "model" in no way implies that this solution is exemplary.

began at this early stage when the scientific community was divided as to the actual existence of a threat of a Swine Flu epidemic. To understand the legislative model and its imperfections, it is necessary to appreciate the medical and legal climate which produces such legislation. The Swine Flu experience serves as the recent example.

The Swine Flu pandemic of 1918-1919 left more than 548,000 Americans dead, while worldwide fatalities totaled 20 million.[4] In January and February of 1976 when five hundred army personnel at Fort Dix, New Jersey, became ill, and antibody[5] surveys showed a virus which was antigenically similar to the virus in the 1918-1919 pandemic,[6] the Committee on Immunization Practices of the Department of Health, Education and Welfare convened to discuss the potential health threat.[7] The reported death of one recruit[8] served as a reminder that the 1918-1919 pandemic disproportionately struck the young, otherwise healthy, population. At the urging of President Ford, legislation was hurriedly passed to appropriate $135,064,000 in emergency funds for a nationwide influenza immunization program.[9]

Problems immediately developed. One of the four manufacturers of the vaccine produced the wrong strain,[10] and the timetable for inoculating the public was delayed. In mid-June, 1976, the parent company of Parke-Davis & Co. notified President Ford that its insurance carrier had withdrawn liability coverage for the Company's participation in the Swine Flu Program. The other three manufacturers indicated similar liability insurance problems.[11] Fears of having to defend countless products liability actions with potentially limitless liabilities were cited as a major justification for the insurance companies' reticence to permit the manufacturers to participate in the Program.[12] Public Law No.

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4. *Swine Flu Immunization Program, 1976: Hearings on S. 3735 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 94th Cong., 2d Sess. 111 (1976) (statement of J. Glenn Beall, Jr.) [hereinafter cited as *Hearings*].

5. Antibody is defined as "a protective or defensive material found naturally in the body or produced by the body in response to the introduction into its tissues of a foreign substance . . . ." J.E. SCHMIDT, ATTORNEYS' DICTIONARY OF MEDICINE (1962).

6. Barclay, *Editorial*, 235 J.A.M.A. 2753 (1976).

7. When this committee was convened on March 10, 1976, by the Center for Disease Control, the following data were presented: a) in 1974, one case of swine influenza was diagnosed at the Mayo Clinic in Rochester, Minnesota; b) in 1975, a case was diagnosed in Sheboygan, Wisconsin, by a rise in antibody level. There was no apparent transmission to school contacts; c) in January and mid-February of 1976, five viral cases were diagnosed in Fort Dix, New Jersey, and antibody surveys showed more than 500 Army personnel with heightened antibody levels. Seven other patients were diagnosed on the basis of increased antibody levels; d) two possible cases of pneumonia existed in Charlottesville, Virginia in December 1975; and e) one possible case of the virus was being investigated in Clarksdale, Mississippi. Seal, *et al., A Status Report on National Immunization Against Influenza*, 133 J. INFECTIOUS DISEASES 715, 716 (1976).

8. *Id.* at 716.

9. Emergency Supplemental Appropriations, 1976, Pub. L. No. 94-266, 90 Stat. 363 (1976).

10. *Hearings*, *supra* note 4, at 35 (statement of Dr. Cooper). Parke-Davis & Co. produced a vaccine which was similar, but not identical, to A/New Jersey/76. These vaccines could not be used in the National Immunization Program. The other three manufacturers of the vaccine are: Merck & Co., Richardson-Merrell Inc., and Wyeth Laboratories. *Hearings*, *supra* note 4, at 116, citing Wall Street Journal, Aug. 4, 1976, at 1, col. 1.

11. N.Y. Times, Oct. 14, 1976, at 53, col. 2. A spokesman for the pharmaceutical manufacturers also expressed concern over possible antitrust liability. *See Hearings*, *supra* note 4, at 72 (statement of C. Joseph Stetler).

12. *Hearings*, *supra* note 4, at 132 (statement of Secretary David Mathews).

94-380, which made lawsuits against the government the exclusive remedy for all actions connected with the Swine Flu Program, provided the necessary shift in liability from the manufacturers to the government[13] so that the vaccine could be disseminated.

The Swine Flu Law was a direct reaction to the legal climate which the drug manufacturers gleaned from prior vaccination and drug related cases under the judicial model.

III
LIABILITY IN MASS INOCULATIONS

A. The Peculiar Nature of Mass Inoculations

The unique character of mass inoculations poses difficult problems in the planning, implementation, and post inoculation stages of immunization programs. For example, the benefits of an immunized population accrue not only to those who take the vaccines, but also to those who do not, since the risk of an unvaccinated person contracting a communicable disease decreases as the number of inoculated persons increases.[14] This general benefit result is in marked contrast to other products liability[15] situations in which the ultimate consumer's use of a product is primarily for his immediate, personal benefit, and contagion is not usually involved.

Arguably, if the population at large benefits from a mass inoculation program, then the public, as an entity, should pay the expenses of the program and should shoulder the liability for those who assist in bringing the inoculations to the people. This "liability-to-those-who-benefit" aspect is particularly relevant to the Swine Flu Immunization Program, since the manufacturers cannot make a profit on the monovalent vaccine, A/New Jersey/76.[16] The result should be different, however, when the manufacturers "benefit" from a vaccination program by gaining profits from the venture. Thus, when the manufacturers accommodate the government by making the vaccine,[17] and when government specifications determine the testing standards, it is reasonable to shift

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13. The government retained the right to seek indemnification from the manufacturer (or other program participant) for injuries resulting from a participant's negligent conduct. 42 U.S.C.A. § 247b(k)(7) (Supp. 1977).

14. This phenomenon is sometimes referred to as the "herd effect." *Hearings*, *supra* note 4, at 9.

15. *See* text accompanying notes 51-76 *infra* for a discussion of the infusion of products liability law into suits involving mass inoculations.

16. 42 U.S.C.A. § 247b(j)(3) (Supp. 1977) states, *inter alia*:

> Any contract for procurement by the United States of swine flu vaccine from a manufacturer of such vaccine shall . . . be subject to renegotiation to eliminate any profit realized from such procurement (except that with respect to vaccine against the strain of influenza virus known as influenza A/Victoria/75 profit shall be allowed but limited to an amount not exceeding a reasonable profit) . . . .

17. The production of influenza virus vaccine is not very profitable. *Hearings*, *supra* note 4, at 41 (statement of Dr. Harry M. Meyer, Jr.). This is due largely to the fact that a unique vaccine must be prepared for each strain of influenzavirus. Subtle antigenic changes make it difficult to predict which strains of flu will strike from year to year. It is therefore doubtful that the vaccine manufacturers would have undertaken the manufacture of A/New Jersey/76 vaccine without the prodding of the federal government.

the risk of liability (which may result from vaccine related injuries) from the manufacturer of the vaccine to the entity benefiting from it, *i.e.*, the public. In this case, the public bears the cost through the medium of the federal government's sponsorship and indemnification scheme.[18]

Another concern in apportioning liability is that the government should not be discouraged from bringing preventive medicine to the population. In mass inoculations, the goal of reaching the populus with the vaccine often means that churches, schools, and public meeting halls are temporarily converted into clinics. These clinics are, for the most part, staffed by volunteers; people other than doctors and nurses are often trained to administer the vaccines.[19] Implicitly, the choice is made that the risks of improper sterile technique or mishandling of the equipment are qualitatively less than the risks associated with the spread of the disease to persons who would not be vaccinated if these satellite clinics did not exist. Accordingly, there is a strong public policy to insulate these volunteers from liability, except for the grossest negligence, when they act as good samaritans. Consistent with the basic notions of fairness and *respondeat superior*, the volunteer should not risk punishment for his participation in a program designed for the public benefit. The Swine Flu Program incorporated this concern by insulating program participants from liability resulting from negligence other than their own.[20]

In federally sponsored mass inoculations, the imprimatur of the government becomes associated with effectuating a national health priority. For example, the average American reasonably could have assumed that the Swine Flu vaccine was being "warranted" by the government as safe. Participation in the Program was given a further "seal of approval" when the President of the United States said that every man, woman, and child should be vaccinated.[21] Statements as to the vaccine's safety, which spokesman for the Center for Disease Control (CDC) gave to the press, may form the basis for a breach of warranty claim against the government. Moreover, when mass media campaigns are crucial to gaining wide acceptance of the vaccine, there is a very delicate balance which must be struck between overselling the Program, thereby "white-washing" the risks, and making the risks so specific as to frighten away potential vaccinees.

The legislative and the judicial models agree that vaccinees must have full disclosure of the risks associated with vaccination. The legislative model has dealt with this problem by insisting that vaccinees sign consent forms.[22] The courts have taken an *ad hoc* approach when presented with the defense that

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18. *See* text accompanying notes 93-109 *infra*.

19. *See, e.g.*, Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 123 (9th Cir. 1968), in which plaintiff was inoculated with Type III Sabin Oral Vaccine by a pharmacist at a clinic. The pharmacist was not sued for negligence; rather, the plaintiff sued the manufacturer for breach of warranty and for strict liability in tort. The Ninth Circuit found that strict liability instructions should have been given to the jury. *Id.* at 125-26.

20. 42 U.S.C.A. § 247b(k)(1)(A) (Supp. 1977) states: "The Congress finds that—(i) in order to achieve the participation in the program . . . it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence . . . ." *See* discussion *infra* note 100.

21. 122 CONG. REC. S14,115 (daily ed. Aug. 10, 1976) (statement of President Gerald R. Ford, introduced into the Record by Sen. Jacob Javits).

22. 42 U.S.C.A. § 247b(j)(1)(F) (Supp. 1977). *See* text accompanying notes 82-86 *infra*.

there had been informed consent. Some courts have asked the jury to determine whether the vaccinee would have refused inoculation if he had known of the risks associated with the vaccine,[23] while other courts have created a presumption that the consumer would have acted so as to minimize the risks of vaccination.[24]

Mass inoculations are also distinguished from other prescription drug situations insofar as the target of a mass inoculation program is a vast audience. In absolute terms, the planners must anticipate injury to a small proportion of those vaccinated. In products liability terms, vaccines are unreasonably dangerous.[25] Some individuals may have allergic reactions to the vaccine and others may contract the illness the vaccine was intended to prevent.[26] These risks of injury are endemic to mass inoculation programs, and must be weighed against the benefits of preventing an epidemic. The notoriety of these injuries, however, cannot overshadow their infrequency.[27]

This balancing of risks and benefits is crucial in the initial stages of deciding whether or not the inoculation should occur. Once the decision has been made to inoculate the population, there must be a policy choice as to who will bear the cost of the injuries resulting from vaccination. Thus far, the judicial

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23. In Cunningham v. Charles Pfizer & Co., Inc., 532 P.2d 1377 (Okla. 1974), the plaintiff was 15 years old when he contracted polio after ingesting oral polio vaccine. The court, after finding the manufacturer strictly liable in tort for failure to warn the plaintiff of known risks, remanded the case for a determination of whether the plaintiff would have refused to take the vaccine if adequate warning had been given.

24. In Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1281 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974), in which an infant contracted polio after ingesting Sabin Oral Vaccine, the court adopted RESTATEMENT (SECOND) OF TORTS, § 402 A, comment j (1965). The court concluded that there is a rebuttable presumption that the consumer (here, the child's parents) would have read the warning if it had been properly provided by the manufacturer, and would have acted so as to minimize the risks of injury.

25. The drafters of the Restatement recognized that products such as vaccines may be unavoidably unsafe, yet their social utility justifies their inherent risks:

> 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 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. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS, § 402 A, comment k (1965).

26. *Polio Immunization Program, 1976: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 94th Cong., 2d Sess. 6 (1976) [hereinafter cited as *Polio Hearings*]. All domestic cases of polio since 1973 (13 cases in 1973) have been caused by the vaccine. Dr. Jonas Salk concluded that at present, there is a greater risk of getting polio from the vaccine than from naturally occurring viruses. *Id.* at 5-6 (statement of Dr. Jonas Salk).

27. It is estimated that one in ten million persons receiving a polio vaccine may develop an adverse reaction that cannot be differentiated from *actual* poliomyelitis. *Polio Hearings*, *supra* note 26, at 111 (statement of James F. Dickson, III, M.D.).

model has assigned the liability for injuries resulting from vaccination to the manufacturer or the inspector of the vaccines. On the other hand, the legislative model depicted by Pub. L. No. 94-380 shifts the liability to the government, except if such liability arises from the program participant's negligence.[28]

Finally, in assessing the costs of injury[29] and the benefits from vaccination, the public health officials must also consider the impact on the public's confidence in health officials who either scare the public with threatened epidemics that do not materialize, or who fail to arm the public against potential health hazards. This element of public trust does not similarly affect the manufacturers of vaccines, for the manufacturers are rarely seen as promoting the vaccine. Rather, the government is the sponsor and endorser of the venture.

B. Fears of Liability Led to Pub. L. No. 94-380

The insurance companies' refusal to underwrite participation in the Swine Flu Program was not wholly a function of imagined liability. In the preceding decade, the drug manufacturers had paid large judgments for injuries related to polio vaccines and Quadrigen, a four-in-one vaccine against diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis.

In an early polio vaccine case, *Gottsdanker v. Cutter Laboratories*, the court awarded the families of two injured infants a total of $139,000 for the infants and $8300 for the parents, after the children received a Salk vaccine containing live virus[30] and thereafter contracted polio.

When the Sabin Oral Polio Vaccine[31] was developed, the risk of injury from defective or unsterilized needles are reduced, but injuries still resulted

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28. 42 U.S.C.A. § 247b(k)(1)(A)(i)-(ii) (Supp. 1977).

29. As part of the justification for a nationwide immunization program, the Department of Health, Education and Welfare supplied the Senate Subcommittee on Health with the following data pertaining to the costs of flu epidemic:

> In an average year, influenza causes about 17,000 deaths (9 per 100,000 people), widespread illness, and costs the Nation approximately $500 million. Severe epidemics, or pandemics, of influenza, occur at approximately 10-year intervals. In 1968-69, influenza struck 20 percent of our population, causing more than 33,000 deaths (14 per 100,000 people) and an estimated $3.2 billion.

Hearings, *supra* note 4, at 37 (statement of Dr. Cooper from information prepared by the Center for Disease Control).

30. 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (Dist. Ct. App. 1960). Since the Salk vaccine was represented as a virus inactivated with formaldehyde, the court found liability under breach of warranty theory because the vaccine actively caused the disease it was designed to prevent. *Id.* at 611, 6 Cal. Rptr. at 325-26. The court permitted recovery in the absence of privity of contract. *Id.* at 607, 6 Cal. Rptr. at 323.

31. There are three types of poliovirus: Type I, Type II, and Type III. In 1955, Dr. Jonas Salk received approval to market a vaccine made from a killed poliovirus. When the virus is injected into the body, it acts as an antigen causing the body to produce antibodies. The Salk vaccine was administered by injection. By 1960, Dr. Albert Sabin had developed an oral vaccine made from living but attenuated poliovirus (*i.e.*, the virus used is incapable of causing the disease, yet it is sufficient to induce an antibody response in the body). In addition to marketing Types I, II, and III Sabin Oral Vaccine, some companies were licensed to produce a Trivalent vaccine which would immunize the recipient from all three types of poliovirus.

For further non-technical history, *see* Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1295-98, *cert. denied*, 419 U.S. 1096 (1974); and Griffin v. United States, 351 F. Supp. 10, 23-25 (E.D. Pa. 1972), *modified*, 500 F.2d 1059 (3d Cir. 1974).

from reactions to this attenuated virus. Injury from Type I Sabin vaccine precipitated the case of *Grinnell v. Charles Pfizer & Co., Inc.*[32] in which two plaintiffs were awarded $60,000 and $80,000, respectively. The court found that the jury could properly infer a defective product once it was determined that the vaccine caused polio.[33]

In *Griffin v. United States*,[34] the government was found negligent in failing to recall a defective lot of Sabin Type III Vaccine. A woman, who became a quadriplegic as a result of the vaccine, was awarded $1,759,946.25 in damages, while her husband was awarded $300,000 for loss of consortium.[35] Trivalent Sabin Oral Vaccine also caused a forty-one year old woman to become permanently paralyzed in both legs and in her right arm. The court awarded her $130,000 because the drug manufacturer failed to warn of the risks associated with administering Type III vaccine to persons over thirty years of age.[36] In *Reyes v. Wyeth Laboratories*,[37] an eight month old female contracted polio after ingesting Trivalent Sabin Oral Vaccine. Strict liability was imposed for failure to warn of the vaccine's dangers; plaintiff received $200,000 in damages.

Apart from the mass inoculation setting, the drug manufacturers were also cognizant of the liability incurred by Parke-Davis & Co., the manufacturer of a four-in-one vaccine, Quadrigen. In one case, a damage award of $651,783.52 was sustained when a three month old male infant was permanently disabled, both physically and mentally, after being injected with Quadrigen.[38] In another Quadrigen case, damages totalling $500,000[39] were awarded for breach of the implied warranties of fitness and merchantability and for negligence in failing to warn of risks and failing to adequately test Quadrigen.[40]

Undoubtedly, the actual liability incurred by the drug companies as a result of their participation in polio inoculations caused them to become apprehensive of future mass inoculation programs.[41] It is interesting, however, that the drug companies' concerns for future liability were predicated primarily on the language from *Davis v. Wyeth Laboratories, Inc.*,[42] which the drug companies called "an exaggerated interpretation of their responsibility in a mass

32. 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (Dist. Ct. App. 1969).

33. *Id.* at 438, 79 Cal. Rptr. at 376. It is interesting to note that the trial court submitted the question to the jury based on the theories of express and implied warranty. The appellate court indicated that warranty theory was virtually superceded by strict liability, and therefore based its opinion on strict liability. *Id.* at 432-34, 79 Cal. Rptr. 373-74.

34. 500 F.2d 1059 (3d Cir. 1974). This case was brought under the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b) (1970), 2671-80 (1970 & Supp. V 1975).

35. 351 F. Supp. at 36-38 (E.D. Pa. 1972), *modified on other grounds*, 500 F.2d 1059 (3d Cir. 1974).

36. Stahlheber v. American Cyanamid Co., 451 S.W. 2d 48 (Mo. 1970).

37. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

38. Tinnerholm v. Parke, Davis & Co., 411 F.2d 48 (2d Cir. 1969). The court imposed liability on the theory that the defendant breached its implied warranty of merchantability when it marketed Quadrigen with an unstable preservative, thereby making the drug defective. *Id.* at 51-53.

39. Parke-Davis and Co. v. Stromsodt, 411 F.2d 1390, 1392 (8th Cir. 1969).

40. *Id.* at 1399.

41. In the legislative hearings, the drug manufacturers never said that their actual liabilities made it infeasible to participate in a mass immunization program. Senator Kennedy explained that the concerns of the drug companies were hard to understand since over the past 10 years, more than 20 million influenza vaccinations have been given annually, and liability suits have amounted to less than one per 10 million immunizations. *Hearings*, *supra* note 4, at 98.

42. 399 F.2d 121 (9th Cir. 1968). The damages awarded in this case are not reported.

inoculation program."[43] In *Davis*, the court found that it was the manufacturer's duty to see that warnings about a drug reach the consumer.[44] In the absence of such warnings, the Sabin Oral Vaccine was found to be unavoidably unsafe.[45] The drug manufacturers expressed concern not only with their potential liability for injuries resulting from the vaccine and its administration, but also with the cost of defending spurious lawsuits.[46] In anticipation of a problem which would be more theoretical than real, for want of a complaining party, the drug companies also feared antitrust liability from participation in the Swine Flu Program.[47]

The precedent for large judgments resulting from vaccine related injuries prompted the drug companies' insurers to insist, as a prerequisite to their clients' participation in the Program, that the government accept the burden of defending these cases. This intractable position led to Pub. L. No. 94-380.

C. Actions to Which Liability Could Attach

The imposition of liability in mass inoculations[48] could be predicated on the theories of negligence,[49] breach of warranty,[50] or strict liability in

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43. *Hearings*, *supra* note 4, at 72 (statement of C. Joseph Stetler, president, Pharmaceutical Manufacturers Association).

44. 399 F.2d at 131.

45. *Id.* at 128-29.

46. The key to this concern was the drug companies' alleged inability to predict the number of lawsuits which might arise. The companies were satisfied that there were no unusual medical risks in this Program. *Hearings*, *supra* note 4, at 132 (statement of Secretary Mathews); *see also id.* at 119.

47. *Hearings*, *supra* note 4, at 72 (statement of C. Joseph Stetler).

48. This Note is limited to a discussion of liability in the vaccination of humans. For a thorough history of liability in animal vaccinations, *see* Baynes, *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 ST. LOUIS U.L.J. 44, 46-57 (1977).

49. The generally accepted explication of this theory of action is found in the RESTATEMENT (SECOND) OF TORTS § 282 (1965): "[N]egligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm . . . ." Negligent conduct is defined as:

> 1) an act which the actor as a reasonable man should recognize as involving an unreasonable risk of causing an invasion of an interest of another, or
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> 2) a failure to do an act which is necessary for the protection of another and which the actor is under a duty to do.

Id. § 284. Thus, ascertaining whether one administering a vaccine has been negligent, the trier of fact must decide whether the person giving the inoculation acted as a reasonable person in similar circumstances would act, and whether the breach of duty of care was the cause of the plaintiff's injury. In proving negligence, it is often difficult to identify and locate the person who administered the inoculation to the plaintiff.

There is a similar duty of care which attaches to the manufacturers' actions. Thus, it would be negligent to fail to test a drug for impurities or to do so without exercising reasonable care in conducting the tests. The underlying theme of negligence theory is fault, *i.e.*, liability should attach to one who acts in an unreasonable manner which causes injury to another. The general rule is that "the seller is liable for negligence in the manufacture or sale of any product which may reasonably be expected to be capable of inflicting substantial harm if it is defective." W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 96, at 643 (4th ed. 1971).

50. It is generally believed that one who puts a product in the stream of commerce implicitly represents to the public that it is suitable and safe. This area of products liability law is borrowed

tort.[51] Since it may be difficult to isolate the person who administered the vaccine, the batch of vaccine, or the specifics of the manufacturing process, the theory of strict liability is particularly well-suited to mass inoculations.

In assessing specific acts to which liability could attach, the possibility for recovery, the difficulties of proving certain actions, and the social considerations which the courts are likely to weigh in apportioning liability are relevant concerns. For example, in viewing the above factors, satellite clinics would not make good defendants, but drug manufacturers would, and have been the most frequent defendants under the judicial model.

1. The Pre-marketing Stage: Testing and Approving

The fact that a drug appears on the market presupposes that the statutory obligation to test it was met.[52] The question arises whether or not the testing

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from contract law, and therefore the early cases required privity between the manufacturer and the injured party. The notions of privity soon expanded to encompass the "ultimate consumer."

It should be noted that warranty theory was predicated on the belief that one who manufactures a product presumably includes in the price of the product a profit for the manufacturer, and a means of covering the cost of any risks associated with the product. In the case of the Swine Flu Program, in which no profit is to accrue to the manufacturers, it is debatable whether it is reasonable to attach the liability to one who does not profit from the endeavor.

51. The clearest statement of this theory of liability is enunciated in the RESTATEMENT (SECOND) OF TORTS § 402 A (1965):

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
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> a) the seller is engaged in the business of selling such a product, and
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> b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
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> (2) The rule stated in Subsection (1) applies although
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> a) the seller has exercised all possible care in the preparation and sale of his product, and
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> b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

A "defective condition" is one which is "not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." *Id.* § 402 A, comment g.

Many products cannot possibly be made entirely safe, and there may be some risk of harm inherent in any food or drug. With this in mind, "unreasonably dangerous" is described as "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.* § 402 A, comment i.

52. This process was described as having two major divisions: animal testing and human testing. The idea for a new compound may come from a scientist's "hunch," experiments with plant extract, or any other conceivable avenue. The compound then undergoes initial screening to analyze its possible therapeutic value. This is determined from studies of pharmacological activity in animals. Lethal doses and margins of safety are then determined through acute toxicity tests in animals. The final stage of animal testing, prior to human clinical trial, is subacute toxicity testing. Animal testing continues while human trials are being conducted.

Human trials consist of: a) Phase I, in which there are limited trials and data are sent to the FDA, b) Phase II of clinical pharmacology in which the study is expanded in scope, and c) Phase III in which broad clinical trials are conducted. At the conclusion of this rigorous testing, a New Drug Application is filed with the FDA. *Subcomm. of the Comm. on Government Operations: House of Representatives*, 88th Cong., 2d Sess. 517-55 (statement of Dr. Kenneth G. Kohlstaedt). The obligation to test drugs before they are marketed is codified in 21 U.S.C. § 355 (1970).

was done properly, *i.e.*, at least non-negligently. The *Stromsodt*[53] and *Tinnerholm*[54] cases represent instances of recovery for injuries resulting from the marketing of an improperly tested drug (Quadrigen). In both of these cases, liability was predicated on breach of warranty theory.

In the *Griffin* case,[55] the Division of Biologic Standards of the National Institutes of Health (DBS) was found negligent in releasing a lot of Sabin Oral Vaccine which did not meet the standards that had been established for polio vaccines.[56] The Third Circuit, however, sought to limit the government's overall liability: "We do not hold that the Government may be liable for policy determinations made by its officials. Rather, we hold only that the Government may be liable where its employees, in carrying out their duties, fail to conform to preexisting statutory and regulatory requirements."[57] The moral of *Griffin* is clear: if the government promulgates standards for vaccines, it must ensure that they are rigorously enforced by government employees, or risk massive liability when injury occurs from a defective or otherwise substandard vaccine.

If the appearance of Guillain-Barré syndrome, the paralytic condition which led to the suspension of the Swine Flu Program, is found to be causally related to the vaccine, the trier of fact will have to determine whether the vaccine itself was impure or whether the syndrome is an unpredictable allergic reaction.[58] If the court finds the vaccine impure, the *Griffin* case will be an important precedent in determining the liability of the DBS and other government entities.

2. *Manufacturing and Inspecting*

It is axiomatic that one who puts foodstuffs into commerce impliedly warrants that they are suitable for consumption.[59] In *Gottsdanker*,[60] the court held that since vaccines were intended for human consumption, warranty theory as developed in food cases would also apply to drugs (and biologicals).[61] Applying

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53. 411 F.2d 1390 (8th Cir. 1969).

54. 411 F.2d 48 (2d Cir. 1969).

55. 500 F.2d 1059 (3d Cir. 1974).

56. These standards were enunciated in 42 C.F.R. § 73.114(b)(1)(iii), *as cited in* 500 F.2d at 1062-63 n.7.

57. 500 F.2d at 1069.

58. The United States Public Health Service Advisory Committee on Immunization Practices concluded that there was an "apparent association between influenza vaccination and neurological complication," specifically Guillain-Barré Syndrome (GBS). From September 26 through December 31, 1976, 571 cases of GBS were reported from 47 states. Of the reported cases, 287 had been vaccinated, 261 had not been vaccinated, 18 were unknown and 4 received only B vaccine. Morbidity and Mortality Weekly Report, Jan. 7, 1977, U.S. Department of Health, Education and Welfare, Center for Disease Control.

For a discussion of the physical manifestations of Guillain-Barré Syndrome, *see* Gothgen & Forster, *Guillain-Barré Syndrome*, 76 WISC. MED. J. S37 (1977).

Injuries other than Guillain-Barré Syndrome have been reported after vaccination. *See* 34 ARCH. NEUROL. 258 (1977) for a reported case of encephalomyelitis which turned out to be reversible. The patient became mute, weak in all limbs, and sustained a downward gaze. This condition remained for one month.

59. *See* PROSSER, *supra* note 49, at 651.

60. 182 Cal. App. 2d at 607, 6 Cal. Rptr. at 323.

61. "Biologicals" is defined as "[c]omplex medicinal preparations, derived from living organisms, as bacteria, animals, and human beings, used to create immunity, to overcome infection,

breach of warranty theory, the *Gottsdanker* court permitted recovery to the parents and infant plaintiffs who received Salk vaccine, a purportedly killed virus, which actually contained live virus. The production of this defective vaccine was a manufacturing error, which was not detected in the inspection stage. Nevertheless, the jury in *Gottsdanker* held Cutter Laboratories not negligent "either directly or by inference."[62] Instead, recovery was founded on breach of warranty theory since the vaccines were not suitable for the purpose for which they were intended.

The *Griffin* case exemplifies another situation in which defective vaccines were not detected in the inspection stage. In *Griffin*, however, the testing was done by the Division of Biologic Standards of the National Institutes of Health. The court held the DBS negligent in releasing the lot of vaccine which was the proximate cause of Mrs. Griffin's illness.[63] The *Griffin* court held that the District Court's finding of negligence *per se*, as predicated on the DBS's duty to see that the only vaccines released were those which complied with the federal regulations on neurovirulence, was not clearly erroneous.[64] This finding of negligence *per se* relieved the plaintiff of the duty to prove all the elements of negligence by delving into the particulars of the testing procedure.

The *Gottsdanker* and *Griffin* cases demonstrate that the manufacturer or inspector of vaccines can be held liable under negligence or breach of warranty theory for injuries caused by defective vaccines. Liability for injuries resulting from contaminated vaccines could also be predicated on the *Gottsdanker* or *Griffin* rationale.

3. *Marketing, Prescribing, and Administering the Vaccine*

In the marketing stage, unless a vaccine is accompanied by proper warnings, it will be deemed unreasonably dangerous.[65] The label and package inserts must clearly alert the user to possible contraindications and inform the consumer of proper dosages. Labels[66] and package inserts[67] which are manifestly comprehendable to the user can shield a manufacturer from liability. Although it is nearly impossible to draft a model statement that would embody all the requirements of the duty to warn, the manufacturer should be careful to reveal all that it knows about the product and its possible risks,[68] and to make

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to replace lost body fluids, etc. Vaccines, serums, antitoxins, blood plasma, etc., are examples of biologicals." SCHMIDT, *supra* note 5.

62. 182 Cal. App. 2d at 605, 6 Cal. Rptr. at 322.

63. 500 F.2d 1059 (3d Cir. 1973).

64. *Id.* at 1069, *aff'g* 351 F. Supp. at 34 (E.D. Pa. 1972).

65. *See* notes 25, 51 *supra*.

66. For example, in Nolan v. Dillon, 261 Md. 516, 276 A.2d 36 (1971), a physician was found negligent in giving an intravenous injection of Sparine (promazine hydrochloride) when the ampule and package insert clearly said intramuscular injection only. The clarity of the warning was sufficient for a directed verdict for the manufacturer.

67. In Carmen v. Eli Lilly & Co., 109 Ind. App. 76, 32 N.E.2d 729 (1941), the warning on the package insert with a rabies vaccine was found sufficient to apprise the user of the inherent risks, thereby insulating the manufacturer from liability.

68. In Grinnell v. Charles Pfizer & Co., 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (Ct. App. 1969), the court permitted the jury to infer that a package insert for Sabin Oral Vaccine was misleading as it did not contain information on studies which tended to show a risk associated with persons over the age of 30 taking Sabin vaccine.

sure that a promotional zeal similar to that used in attracting the customer is utilized in apprising consumers of contraindications as they become known.[69]

In *Davis v. Wyeth Laboratories, Inc.*,[70] the court explained the so-called "prescription drug exception" to the manufacturers' general duty to warn. Because the choice of a particular drug is largely a medical, rather than a consumer, decision as a result of the specialized knowledge of the physician, the manufacturers believed that a warning to the physician was the only effective warning that could help a patient. The prescription drug exception therefore did not require direct warnings to the consumer. The court quickly distinguished the situation in which a physician prescribed a drug from the mass inoculation setting in which:

> the drug . . . [is] dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases . . . warning by the manufacturer to its immediate purchaser [the doctor or the clinic] will not suffice. . . . But just as the responsibility for choice is not one that the manufacturer can assume for all comers, neither is it one that he can allow his immediate purchaser to assume. In such cases, then, it is the responsibility of the manufacturer to see that warnings reach the consumer.[71]

The court suggested that advertising, posters, or releases which consumers would be required to read and sign could have been used to notify and warn the vaccinees of risks inherent in the vaccine.[72] The court in *Reyes* was conscious of the burden which was placed on the public health clinics participating in mass inoculations. It therefore imposed the burden on the manufacturers to provide warnings to the ultimate consumers (*i.e.*, the vaccinees) where it was forseeable that there would be no individualized medical judgment prior to vaccination.[73]

Clearly, if it is necessary that a warning accompany a prescription drug so that it is not "unreasonably dangerous,"[74] then the warning must reach the patient either through the patient's doctor, or by information aimed directly at the patient. The duty to warn, when applied to a mass inoculation setting, is predicated on the notion that individuals do not sacrifice their rights to make

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69. *See, e.g.*, Stevens v. Parke-Davis & Co., 9 Cal. 3d 51, 107 Cal. Rptr. 45 (1973), where plaintiff was awarded $400,000 for the defendant's failure to adequately warn of the risks associated with Chloromycetin. Here, the drug was "overpromoted."

70. 399 F.2d 121 (9th Cir. 1968).

71. *Id.* at 131.

72. *Id.*

73. The court said:

> We recognize both the essential role the city health clinic and the rural county clinic play in the nation's public health scheme, and the dangers that their depersonalized medical treatment pose. We do not then, lay down an absolute duty to warn all who receive medication at public clinics. Instead, we hold that in the case of a prescription drug which is unavoidably unsafe, and as to which there is a certain, though small, risk throughout the population, there must be *either* a warning—meaningful and complete so as to be understood by the recipient—*or* an individualized medical judgment that this treatment or medication is necessary and desirable for this patient.

Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1294-95, *cert. denied*, 419 U.S. 1096 (1974).

74. *See* notes 25, 51 *supra*.

an informed choice about medication merely because they participate in a massive public health effort.

4. Miscellaneous Actions to Which Liability Could Attach

Under the Swine Flu Law, an individual may sue for any injury or death arising out of the Swine Flu Program.[75] Injuries from broken syringes or unsterilized "jet injectors,"[76] and damage to clothing would be compensable injuries. Arguably, injuries such as falling at clinic sites would "arise out of the administration of the vaccine" and would therefore be covered under the Swine Flu Law.

IV
THE SWINE FLU LAW

The Swine Flu Law was an attempt to incorporate the lessons from *Reyes*, *Davis*, *Griffin*, and the other mass inoculation cases. Schematically, the key provisions of Pub. L. No. 94-380 can be grouped within three categories: nature and scope, administration, and liability.

A. Nature and Scope

The Act limits the program to: developing, preparing, and procuring a safe and effective vaccine; making grants to the states for the administration of programs; furnishing federal health authorities with sufficient vaccine; training personnel and funding research on the nature and causes of swine influenza; preparing written consent procedures; and engaging in other activities that may become necessary to implement the program.[77]

Congress clearly stated its findings that the liability scheme in this law was necessary to ensure the participation of the drug companies and other health related personnel in the National Swine Flu Immunization Program.[78] These

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75. 42 U.S.C.A. § 247b(k)(2)(A) (Supp. 1977) states: "The United States shall be liable with respect to claims . . . for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program . . . ."

76. To expedite inoculations, some clinics used the pressurized syringes called "jet injectors." These gun-like devices do not use needles, and were therefore expected to minimize the number of injuries usually associated with faulty syringes.

77. 42 U.S.C.A. § 247b(j)(1) (Supp. 1977).

78. 42 U.S.C.A. § 247b(k)(1) (Supp. 1977) provides:

> (A) The Congress finds that—
>
> (i) in order to achieve the participation in the program of the agencies, organizations, and individuals who will manufacture, distribute, and administer the swine flu vaccine purchased and used in the swine flu program and to assure the availability of such vaccine in interstate commerce, it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of such vaccine;
>
> (ii) to provide such protection . . . it is necessary that an exclusive remedy for such claimants be provided against the United States because of its unique role in the initiation, planning, and administration of the swine flu program; and
>
> (iii) in order to be prepared to meet the potential emergency of a swine flu epidemic, it is necessary that a procedure be instituted for the handling of claims by persons alleging such injury or death until Congress develops a permanent approach for handling claims arising

findings reflect the Congressional concern that this law not be considered a prototype for other inoculation programs.[79]

B. Administrative Provisions of the Swine Flu Law

One of the key provisions of the Swine Flu Law requires the Secretary of Health, Education and Welfare to supervise the development of informed consent forms and procedures[80] to assure that "the risks and benefits from the Swine Flu vaccine are fully explained to each individual to whom the vaccine is to be administered. . . . Such procedures shall include the information necessary to advice [*sic*] individuals with respect to their rights and remedies arising out of the administration of such vaccine."[81] The experience from the polio inoculations and the trends in medical malpractice cases made the inclusion of informed consent provisions imperative. At least one Senator wanted the legislative history to reflect clearly that it was the Congressional intent "to point out to individuals, who are taking advantage of this vaccine, the rights and remedies available to them in a *clear and succinct fashion*, . . . so that it does not invite or encourage unnecessary litigation."[82]

The informed consent form that was used[83] did not explain the "rights and

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under programs of the Public Health Service Act.

(B) To—

(i) assure an orderly procedure . . . and

(ii) achieve the participation in the swine flu program of (I) the manufacturers and distributors of the swine flu vaccine, (II) public and private agencies or organizations that provide inoculations without charge for such vaccine or its administration and in compliance with the informed consent form . . . and (III) medical and other health personnel . . . it is the purpose of this subsection to establish a procedure under which all claims will be asserted directly against the United States under section 1346(b) of title 28, and chapter 171 of such title (relating to tort claims procedure) except as otherwise specifically provided in this subsection.

79. *See, e.g.*, 122 CONG. REC. S14,109 (daily ed. Aug. 10, 1976) (statement of Mr. Javits); *id.* at S14,110 (statement of Mr. Taft); *id.* at S14,116 (statement of Mr. Kennedy); *id.* at S14,121 (statement of Mr. Hathaway).

80. The Secretary of Health, Education and Welfare is instructed by the statute to consult with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. It is curious that the Justice Department was not designated to aid in preparing the form. Rather, a group which is used to dealing with experimental drugs was designated. This is not a crucial legal distinction, but symptomatic of the concern for unknown effects and unanticipated liability.

81. 42 U.S.C.A. § 247b(j)(1)(F) (Supp. 1977).

82. 122 CONG. REC. S14,113 (daily ed. Aug. 10, 1976) (statement of Mr. Beall) (emphasis added).

83. After describing the disease and the vaccine, the consent form relays, *inter alia*, the following information:

Possible Vaccine Side Effects

Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people will also have fever, chills, headache, or muscle aches within the first 48 hours.

Special Precautions

As with any vaccine or drug, the possibility of severe or potentially fatal reaction exists. However, the flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions. You should note very carefully the following pre-cautions:

— CHILDREN UNDER A CERTAIN AGE SHOULD NOT ROUTINELY RECEIVE FLU VACCINE. PLEASE ASK ABOUT AGE LIMITATIONS IF THIS INFORMATION IS NOT ATTACHED.

remedies" of injured vaccinees. The only reference to legal remedies was in a second form given to each vaccinee for his records.[84] Although the division of relevant information between two forms makes informed consent more complicated than Congress intended, the two forms together satisfy the statutory mandates for informed consent. In light of the fact that the Swine Flu Program was halted because of the incidents of Guillain-Barré syndrome, it is important to note that the consent form never mentions the word paralysis. To preclude recovery under this consent form, a court or jury would have to find that the words "the potentially fatal reaction" found in that form necessarily include the lesser reaction of paralysis. When confronted with the paralyzed plaintiff, it is unlikely that a jury would choose this interpretation. It is more probable that individuals who contracted Guillain-Barré after being vaccinated will recover damages because of the government's failure to adequately warn of the vaccine's dangers.[85]

While an informed consent provision is essential in a nonemergency, elective medical procedure, it is questionable whether a truly "informed consent" can be given by everyone, or whether there are subtle forms of duress which are associated institutionally with "assembly line medical techniques."[86] Realistically, there is a very fine line between supplying sufficient information to permit an informed choice, and supplying so much information as to scare away potential vaccinees. It is better to err on the side of supplying too much rather than too little information in an informed consent form. Having medical personnel available at clinic sites to respond to the emergencies and questions of a frightened public will ameliorate some of the problems inherent in dispensing vaccines en masse.

The Swine Flu Law also contains provisions for continued monitoring of the Program through: a) quarterly reports to Congress on the supply of the vaccine, the number of persons inoculated, the cost of the program, and the

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— PEOPLE WITH KNOWN ALLERGY TO EGGS SHOULD RECEIVE THE VACCINE ONLY UNDER SPECIAL MEDICAL SUPERVISION.

— PEOPLE WITH FEVER SHOULD DELAY GETTING VACCINATED UNTIL THE FEVER IS GONE.

— PEOPLE WHO HAVE RECEIVED ANOTHER TYPE OF VACCINE IN THE PAST 14 DAYS SHOULD CONSULT A PHYSICIAN BEFORE TAKING THE FLU VACCINE.

If you have any question about flu or flu vaccine, please ask.

U.S. Dept. of Health, Education and Welfare/Public Health Service/Center for Disease Control/Atlanta, Georgia 30333 (CDC 7.31, 7-76).

The vaccinee or guardian signed in two places that he had read the statement about swine flu and the special precautions.

84. This form, entitled "Important Information from the U.S. Public Health Service about Swine Flu and Victoria Flu Vaccines," has a space for the clinic site, the date, and the lot number of vaccine used.

In the seventh paragraph of an eight paragraph information sheet, it states:

> *While there is no reason to expect more serious reactions to this flu vaccination, persons who believe that they have been injured by this vaccination may have a claim.* The Congress recently passed a law providing that such claims, with certain exceptions, may be filed only against the United States Government. Information regarding the filing of claims may be obtained by writing to the U.S. Public Health Service Claims Office, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852.

85. Despite all efforts to gain informed consent of all vaccinees, 13% did not sign the informed consent forms. New York Post, Dec. 18, 1976, at 3, col. 2 (Final ed.).

86. M. Shapo, *Swine Flu and Legal Policy*, 63 A.B.A.J. 51, 53 (1977).

epidemiology of the disease;[87] and b) a semi-annual report to Congress on litigation under the statute.[88]

The Swine Flu Law provides that the contracts by the United States to procure the vaccine be renegotiated to eliminate any profit from the A/New Jersey/76 vaccine, although a reasonable profit is permitted from the A/Victoria/75 vaccine.[89] Public Law No. 94-380 also provides for a refund to the United States of any insurance premiums included in the price of the vaccine which are returned to the manufacturers based on retrospective experience-rating.[90]

Another administrative component of the law provides that the activities of the program cannot exceed the funds appropriated by Pub. L. No. 94-266, *i.e.*, $135,164,000.[91] This suggests that the Swine Flu Law was an emergency program which was not intended to entail future expenditures without in-depth Congressional analysis.

Finally, to emphasize the Congressional concern that this law not serve as the prototype for other laws, Pub. L. No. 94-380 provides for the Secretary of Health, Education and Welfare to coordinate a study of immunization programs and alternative liability schemes.[92]

C. Liability Under the Swine Flu Law

The United States is liable for claims submitted after September 30, 1976, for personal injury or death arising out of the administration of the vaccine and based on an act or omission of a program participant.[93] Jurisdiction is predicated on 28 U.S.C. § 1346(b), the section of the Federal Tort Claims Act dealing with the United States as defendant.[94] The Swine Flu Law gave the potential plaintiff great leeway in suing the government.[95] The government gave a broad waiver of its sovereign immunity by providing for the substitution of the United States government for any defendant who is a *bona fide* program participant.[96] There was no effort to limit government liability when a partici-

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87. 42 U.S.C.A. § 247b(j)(2) (Supp. 1977).
88. 42 U.S.C.A. § 247b(k)(8) (Supp. 1977).
89. 42 U.S.C.A. § 247b(j)(3) (Supp. 1977).
90. *Id.*
91. 42 U.S.C.A. § 247b(j)(4) (Supp. 1977).
92. 42 U.S.C.A. § 247b note (Supp. 1977). Congress suggested that a compensation scheme be considered, thereby indicating that broadly based reform would be acceptable.
93. 42 U.S.C.A. § 247b(k)(1)(A,B) (Supp. 1977).
94. 28 U.S.C. § 1346(b) (1970) states:

> Subject to the provisions of chapter 171 [Tort Claims Procedure] of this title, the district courts . . . shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages . . . for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where 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.

95. For example, 42 U.S.C.A. § 247b(k)(2)(A)(i) (Supp. 1977) provides that liability can be predicated on any theory of liability including strict liability. This was probably a reaction to Laird v. Nelms, 406 U.S. 797, *reh. denied*, 409 U.S. 902 (1972), in which strict liability was not available as a theory of action against the U.S., regardless of state law.
96. It was suggested during the Congressional debate that this procedure abrogates the Federal Rules of Civil Procedure which require that real parties in interest be joined. 122 CONG. REC. S14,119 (daily ed. Aug. 10, 1976) (statement of Mr. Hathaway). Since all program participants are

pant fully complied with the Program's prescriptions.[97] Congress specifically stated, however, that the federal government would only assume the liability for the program participants who complied with the informed consent provisions and who did not charge for the administration of the vaccine.[98]

The Swine Flu Law made suits against the government the exclusive remedy of an injured party.[99] The United States may seek indemnification from a program participant for damages which the United States paid when the government's liability was a result of the participant's negligent conduct or failure to carry out a contractual obligation under the Swine Flu Program.[100]

In general, the procedure for suit is governed by 28 U.S.C. § 1346(b)[101] which confers upon the district courts the exclusive jurisdiction over civil actions for claims against the United States for money damages for injury or loss of property. As a result of incorporating the Federal Tort Claims Procedure into the Swine Flu Law,[102] the government is not liable for punitive damages, unless the applicable state law provides only for punitive damages.[103] In addition to invoking the requirements of Federal Tort Claims Procedure, the legislature provided for other procedural rigors: a) the Attorney General defends any civil action or proceeding based on the Swine Flu Program;[104] b) after the Attorney General certifies that an action is based on a claim arising out of the administration of the vaccine under the Swine Flu Program, the action is deemed an action against the United States,[105] the United States is substituted

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required to cooperate with the U.S. Attorney in the defense of the action, it is unlikely that a plaintiff would be damaged by the mere fact that a program participant was not a named defendant.

97. Thus, the exceptions to government liability which would otherwise be applicable under 28 U.S.C. § 2680(a) specifically do not apply to the Swine Flu Program. 28 U.S.C. § 2680(a) (1970) provides:

> The provisions of this chapter and section 1346(b) of this title shall not apply to—
> Any claim based upon an action or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

98. 42 U.S.C.A. § 247b(k)(2)(B) (Supp. 1977).

99. 42 U.S.C.A. § 247b(k)(3) (Supp. 1977).

100. 42 U.S.C.A. § 247b(k)(7) (Supp. 1977) states:

> Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative settlement or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as any costs of litigation, resulting from the failure of any program participant to carry out any obligation or responsibility assumed by it under a contract with the United States in connection with the program or from any negligent conduct on the part of any program participant in carrying out any obligation or responsibility in connection with the swine flu program. The United States may maintain such action against such program participant in the district court of the United States in which such program participant resides or has its principal place of business.

101. 42 U.S.C.A. § 247(b)(2)(k)(1) (1977).

102. *Id.* The Swine Flu Law specifically invokes Ch. 171 of Title 28, Tort Claims Procedure (28 U.S.C. §§ 2671-80 (1970 & Supp. V 1975)).

103. 28 U.S.C. § 2674 (1970).

104. 42 U.S.C.A. § 247b(k)(4) (Supp. 1977).

105. 42 U.S.C.A. § 247b(k)(5)(A) (Supp. 1977).

as the party defendant,[106] and any such action which was commenced in state court may be removed to the U.S. District Court for the division in which the state suit was pending;[107] and c) the statute of limitations is tolled if an action under this law is begun but is dismissed because of available remedies under other laws.[108] The procedure for suits under this Program specifies that a program participant must cooperate in the processing or the defense of a claim. Failure to do so will result in the revocation of program participant status and the substitution of the original defendant for the United States.[109]

In light of the indemnification provision,[110] it is unclear what a program participant's liability would be for claims which the government settles out of court and which the program participant feels should be litigated. The program participant might claim that the U.S. Attorney has a conflict of interest between his role as defender of the program participant and his duty to seek indemnification. Such a defense in indemnification proceedings may lead to the relitigation of the program participant's liability, but this would have no adverse effect on the potential plaintiffs.

V
THE SWINE FLU LAW: AN EVALUATION

The Swine Flu Law must be evaluated in terms of its acceptability as both a legal and a social solution to a national health problem. Although this legislative approach may be an adequate legal solution, it is an unacceptable response to the social problem of mass inoculations.

A. The Swine Flu Law: An Acceptable Legal Solution

Since participation in this Program is voluntary and there are no sanctions for nonparticipation, any constitutional challenge to the funding and promotion of the inoculation program is likely to fail.[111] If inoculation with Swine Flu vaccine were made compulsory, an unwilling vaccinee could raise a fifth amendment due process attack on the statute which compelled inoculation. Nevertheless, a fifth amendment challenge would be likely to fail if a "compelling state interest" could be shown.[112]

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106. 42 U.S.C.A. § 247b(k)(5)(B) (Supp. 1977).

107. *Id.* The statute provides, in relevant part:

> The certification of the Attorney General with respect to program participant status shall conclusively establish such status for purposes of such initial removal. Should a district court of the United States determine on a hearing on a motion to remand held before trial on the merits that an action or proceeding is not one to which this subsection applies, the case shall be remanded to the State Court.

108. 42 U.S.C.A. § 247b(k)(5)(C) (Supp. 1977).

109. 42 U.S.C.A. § 247b(k)(6) (Supp. 1977). The revocation of such status occurs on motion by the United States to the district court after a finding by the court that the program participant failed to cooperate with the United States.

110. 42 U.S.C.A. § 247b(k)(7) (Supp. 1977). *See* note 100 *supra*.

111. The broad Congressional power to provide for the "general welfare" makes this appropriation of funds and personnel permissible. U.S. CONST. art. I, § 8.

112. A state must show a compelling state interest for infringing on an individual's due process rights. Griswold v. Connecticut, 381 U.S. 479 (1965) (concurring opinion, Justices Goldberg, War-

A more interesting case would arise if someone objected to inoculation on religious grounds, and therefore challenged the statute as a violation of his first amendment rights.[113] In such a case, an actual epidemic would provide a sufficient emergency in which the court could find that religious actions can sometimes be regulated.[114] A compulsory inoculation statute is best left to the states upon direct findings of a health threat. A national compulsory inoculation statute which provided for inoculation against diseases "that may be threatening to the public health" would likely run afoul of the first amendment.

Given the Congressional finding that it was necessary for the government to assume liability in order for this inoculation to occur, the liability scheme which was adopted is not an onerous one. This legislative model merely substitutes the federal government for the program participant for the purposes of any lawsuit. As to all other major factors (*e.g.*, theories of liability, actionable wrongs), it is indistinguishable from the judicial model.

From the point of view of potential plaintiffs, the government has waived its sovereign immunity and consented to be sued under any theory of liability that would apply to an individual. Thus, this scheme inconveniences a potential plaintiff only to the extent that the suit is subject to removal to the district court, and to the extent that the neighborhood attorney serving as plaintiff's counsel may not be as "comfortable" in federal court as in state court.

To potential defendants (*i.e.*, program participants), it is desirable for the government to bear the cost of litigation.[115] The requirement that a program participant must cooperate with the Attorney General is not too burdensome. Similarly, the possibility for indemnification for negligence or for failure to carry out an obligation under the Program puts the program participant in no worse position than it would have been if it were the defendant in the lawsuit.

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ren, and Brennan). Since the standard for due process under the fifth amendment must be at least as stringent as under the fourteenth amendment, Bolling v. Sharpe, 347 U.S. 497 (1954), it therefore follows that a government may compel inoculation when there is a threat of epidemic, Jacobson v. Massachusetts, 197 U.S. 11 (1905), yet the government does not violate equal protection when it finds some vaccination regulations appropriate for adults but not appropriate for children. *Id.* at 30. *See also* Zucht v. King, 260 U.S. 174 (1922).

In Commonwealth v. Childs, 299 Mass. 367, 12 N.E.2d 814 (1938), a statute was held not to be unconstitutionally vague where it required a certification by a physician before an unvaccinated child could be admitted to school. The court found that the term "vaccination" referred to smallpox vaccine unless otherwise specified. The statute therefore was not vague.

113. In Dalli v. Board of Education, 358 Mass. 753, 267 N.E.2d 219 (1971), the court held a mandatory vaccination statute unconstitutional. This statute violated the first and fourteenth amendments where it exempted from the vaccination requirement those children whose parent or guardian objected to the vaccination on the ground that it conflicted with "the tenets and practice of a recognized church or religious denomination of which he is an adherent or member." Proof of membership in such an organization was required to exempt the child from the requirement of vaccination against smallpox, diptheria, pertussis, tetanus, measles, poliomyelitis "and other such diseases as may be specified from time to time." *Id.* at 756, 267 N.E.2d at 221. The court held that since this exemption for organized religions was not based on a compelling state interest, there was no justification for this infringement on the rights of individuals to participate in "non-organized" religions. *Id.* at 759-60, 267 N.E.2d 222-23.

114. *See* Reynolds v. United States, 98 U.S. 145, 166 (1878), in which the Court stated, "laws are made for the government of actions and while they cannot interfere with mere religious belief and opinions, they may with practices." The Court therefore found that a Morman whose religious beliefs include polygamy could be held liable for violating a statute making polygamy a crime.

115. This is especially true in light of the concern of the drug companies' insurers that they would have to defend in spurious suits. *See* note 46 *supra*.

As previously indicated,[116] the informed consent provisions of the Swine Flu Law necessarily evolved from the duty to warn about the dangers in prescription drugs.[117] It is likely, however, that the informed consent form utilized in the Swine Flu Program will be found inadequate by virtue of its failure to warn of the possibility of paralysis.[118]

Assuming that the immunization against the threat of Swine Flu was necessary, and assuming further that the existence of the Program hinged on the government's willingness to accept the liability for the Program, then the provisions of the Swine Flu Law are legally adequate. The procedures are not particularly burdensome, plaintiffs have the same causes of action available to them as they would have had if they sued the program participants individually, and there are few,[119] if any, complications for the unwary plaintiff.

B. The Swine Flu Law: An Inadequate Social Solution

Although Congress was scathing in its criticism of the insurance industry,[120] and clear in its warnings that this law was not to be the prototype for laws in the future,[121] the precedent has nevertheless been set for the drug companies and their insurers to insist that in future immunization programs, the government bear the costs and the risks associated with the venture. It would have been preferable for the government to have permitted the drug companies to make a profit on the production of the Swine Flu Vaccine. The risks associated with this enterprise would then be reflected in the costs of production and would properly lie with the manufacturers. In theory, the cost of production would include the cost of insuring the drug companies against the risk of injury to the vaccinees resulting from the inoculation. When it became apparent that the drug companies would have to pay $1.00 for every $1.40 worth of insurance,[122] the manufacturers preferred not to make a profit on the

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116. *See* text accompanying notes 81-86 *supra*.

117. *See* RESTATEMENT sections and cases cited in notes 51, 68-74 *supra*.

118. Of course, the appearance of Guillain-Barré Syndrome would first have to be causally linked to the vaccine or vaccination.

119. In the early stage of the Program, some elderly persons died after being inoculated. Some of those deaths were attributed to the stress and strains of waiting on long lines. If it can be shown that stress caused the deaths and that this stress was attributable to the absence of rest areas for the elderly at these clinics, the question would then arise whether these injuries arose out of the "administration" of swine flu vaccine.

42 U.S.C.A. § 247b(*l*) (Supp. 1977) states:

> For the purposes of [the Swine Flu Law] . . .
> (1) the phrase "arising out of the administration" . . . includes a claim with respect to the manufacture or distribution of such vaccine in connection with the provision of an inoculation using such vaccine under the swine flu program.

Hopefully, the courts will broadly construe the "distribution" of the vaccine to include all facets of the clinic's operations and not merely the act of injecting the vaccine.

120. Senator Kennedy remarked: "I know that the Department [of HEW] has engaged in countless meetings with the vaccine producers and with the insurance industry, and that these efforts have been frustrated at every turn by the unwillingness of the insurance companies to assume a responsible posture." *Hearings*, *supra* note 4, at 98.

121. *See* note 79 *supra*.

122. In explaining some of the options considered prior to the Swine Flu Program's liability scheme, it was explained that "the price for the insurance was raised, until the [insurance] industry

vaccine but rather insisted that the government bear the cost of insurance.

As a result of the adverse publicity associated with the failure of the Swine Flu Program, the drug companies may now have reached the point where refusing to manufacture vaccines will be no worse for their public relations posture than participating in mass inoculation programs. At some point in the future, the drug companies will refuse to allocate their resources to such non-profit ventures, and general vaccine scarcity will result.[123]

The most desirable option is to retain the profit motive and allocate the risks of production to the manufacturers. When the cost to the government of buying the vaccines becomes prohibitive, as a function of the insurance component, the government should consider establishing a quasi-public drug company to manufacture the required biologicals.[124] Such a quasi-public company may also be required in light of the exodus from vaccine production.[125]

The legislative model's insistence on the informed consent of every vaccinee (or vaccinee's guardian) incorporates the now indisputable law fashioned by the judiciary. Although it is unquestionably desirable for every vaccinee to be fully informed of the risks inherent in the inoculation, the drug companies have tried to use this requirement to limit their own liability. For example, in the manufacture of polio vaccines, one company has sought to include in its contract with the government a provision that a physician must administer the vaccine after prescribing it, and that the physician or his administering agent must provide a warning.[126] Thus, there has been difficulty in closing the contracts for polio, measles, and mumps vaccines.[127]

The Swine Flu Law was hurriedly enacted in reaction to an emergency situation.[128] In this instance, only the *threat* of an epidemic existed. It is questionable whether the wheels of Congress could move fast enough to appropriate funds for an *actual* health emergency. It is wholly unacceptable to leave our national health to such ad hoc, "knee-jerk" legislation. The responsibility will

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made a proposal for $50 million in insurance, with a minimum premium of $2 million, and then a premium of $1.20 for each $1.00 paid out, up to a maximum of $40 million." 122 CONG. REC. H8648 (daily ed. Aug. 10, 1976) (statement of Mr. Rogers).

123. Vaccine scarcity was a primary motivation for convening the *Polio Hearings*, *supra* note 26, at 1 (statement of Sen. Kennedy).

124. Either the public utility or the post office models could be followed.

125. Approximately three or four years ago there were eight manufacturers of influenza vaccine. There are now four. *Hearings*, *supra* note 4, at 41 (statement of Dr. Meyer).

126. *Hearings*, *supra* note 4, at 130-31 (statement of Dr. Spencer). Another report stated, "Lederle Laboratories division of the American Cyanamid Company balked at signing a contract with the Federal Government for polio vaccine. The company insisted that health departments administering the vaccine be responsible for having parents or guardians sign statements indicating they knew the risks of the product their child was to receive." N.Y. Times, Oct. 14, 1976, at 53, col. 2. *See also Polio Hearings*, *supra* note 26, at 111-14, in which the Public Health Service implemented this request of the drug manufacturer by putting a clause in the contracts with the manufacturer that the state authorities receiving vaccines would take appropriate steps to give adequate notice to all vaccinees of risks and benefits of the vaccination.

127. *Hearings*, *supra* note 4, at 133.

128. The House of Representatives called-up the Senate Bill. The Senate considered concerns of the House in amending the Senate Bill. 122 CONG. REC. H8648 (daily ed. Aug. 10, 1976). Thus, this Bill did not get full consideration by Congress. (It was a "hurried" law and therefore not the best of all alternatives. The Bill as stated in 122 CONG. REC. S14,121 is not the Bill as stated in U.S. Code Cong. & Admin. News, 90 Stat. 1113. It is therefore questionable whether Congress actually knew what it was enacting.)

undoubtedly fall on Congress to establish, as part of a national health program, a mechanism for providing preventive medicine to an *informed* and increasingly skeptical public.

VI
AN ALTERNATIVE MODEL

Centralization of control of mass immunization programs must be vested in an agency with authority to determine the need for such programs, and with the authority to implement them. This agency should consist of consumer representatives, in addition to medical and other scientific and business personnel, who would work to find the most effective means of informing the public of the need for inoculation and of promoting an immunization program.

If the agency decided that an inoculation program were warranted, the agency would then face the problem of choosing to produce live or killed vaccine. The choice of vaccine involves a balancing of the risk of injury from vaccination with the ability of either vaccine to produce an active immunity.[129]

The proposed model must also provide a system for recovery of damages from injury arising out of the inoculation program. The possibility for an arbitration scheme for claims up to a stated amount[130] might expedite small claims and decrease litigation expenses. A national plan of this sort could complement an insurance scheme in which the government pays an insurance company to underwrite the risks of the program, although the government would agree to insure for liability above a stated amount.[131]

This alternative is desirable only if there is a conscious policy choice that individuals who are injured by vaccines must sue to recover damages. The policy adopted in Japan, Hungary, Monaco, Switzerland, Denmark, and West Germany[132] constitutes a more enlightened approach which the United States should adopt. These countries recognize that since the benefits of an immunized population accrue to all, and since vaccines have inherent risks of injury, the government should establish a system to compensate injured vaccinees for their medical costs and provide for the continued support of those injured by the vaccine. Such a system could easily be paralleled to the workers' compensation systems or the "no fault" plans enacted in numerous states.

Under a "no fault" system, there would be a rebuttable presumption that injuries sustained within a certain number of days[133] after vaccination were

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129. *See Polio Hearings*, *supra* note 26, at 4-7. Dr. Jonas Salk concluded that live virus vaccines are best for curing outbreaks of disease in small areas, while killed virus vaccines are best for mass routine immunization since live virus vaccine "blocks" the wild virus vaccine by stimulating an immunity response before the natural virus can reach the body. Dr. Salk therefore endorses the choice of live or killed vaccine as a factor within informed consent. *Id.* at 42. Dr. Spencer, on the other hand, concluded that live virus vaccines are more effective for immunizing the general population, even though live vaccine inevitably induces a few cases of the disease. *Id.* at 101.

130. Ten thousand dollars might be an acceptable ceiling on arbitrable claims.

131. *See, e.g.*, the plan proposed during debate on the Act, in which a $50 million insurance pool would be devised with the government insuring above that level. 122 CONG. REC. H8648 (daily ed. Aug. 10, 1976).

132. *Polio Hearings*, *supra* note 26, at 127.

133. This date would be determined scientifically, based on the incubation period before which the disease would be unlikely to appear.

caused by the vaccination. A schedule of benefits, as in the workers' compensation plans, would then dictate the recovery, and all medical costs would be paid by the government. The plan should also provide for long-term occupational and physical therapy when appropriate. This proposal can be modified, if required by no fault opposition, to permit damages actions for the recovery of lost earnings in excess of some legislatively determined sum. Our society must be willing to bear the costs of damages to those who submit to immunization for their own and their neighbors' benefit.[134]

A national clearinghouse for immunization related claims should be established for consumers. The effectiveness of such pooling of information and resources is documented by the MER/29 experience.[135] Such a pooling of information is important not only to a plaintiff who must sue to recover damages, but also to the government for collecting data relevant to planning future inoculations.

The Department of Health, Education and Welfare (HEW) endorsed a two tier plan in response to the manufacturers' request for indemnification: a) indemnification for manufacturers of biologicals, and b) compensation for injured persons.[136] The Department of HEW stated:

> A compensation program would require establishing a Federal mechanism to accept, review, arbitrate and settle claims arising from injuries associated with the administration of vaccines manufactured in a non-negligent manner. The program would eliminate the right of an aggrieved person to bring a lawsuit against the manufacturer. Payments would be made to an injured party on the basis of his economic loss in accordance with a benefits package.[137]

This compensation proposal left many questions unanswered; for example, whether or not an injured vaccinee can sue for negligence.

The necessity for a compensation scheme is highlighted by the irony that the Department of Agriculture has the statutory authority to reimburse the owner for the fair market value of animals which had to be destroyed as a result of disease.[138] Since animal diseases can be caused by vaccination, we arrive at the peculiar result that the government compensates farmers for injury to their livestock which may result from vaccination, but prior to the Swine Flu

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134. This conclusion is further emphasized by the finding that some of the recent cases of polio have been the result of contact with individuals receiving vaccines when the injured person was not vaccinated. *Polio Hearings*, *supra* note 26, at 40 (statement of Dr. Harold Ginzberg). In 1974, of the four cases of polio in the United States, three were vaccine induced, but these three had not been vaccinated. *Id.*

135. *See* Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CAL. L. REV. 116 (1968). This was a plan under which a group of attorneys joined forces, all of whom were participating in litigation against Richardson-Merrell, Inc. for its fraudulent marketing of MER/29, triparanol, a drug which purportedly decreased cholesterol. The manufacturer was indicted under a federal false writing statute, 18 U.S.C. § 1001 (1964) for failing to provide information in its FDA reports that laboratory rats had developed cataracts from the medication. This instance of group cooperation was successful in gaining depositions and litigation information from around the country.

136. *Polio Hearings*, *supra* note 26, at 136.

137. *Id.*

138. 21 U.S.C. § 134a (1970).

Law, there was no statutory plan to compensate individuals for injury resulting from vaccination.

The proposed model incorporates the permanence of the legislative approach with the recognition that the health of our nation cannot depend on the willingness of insurance companies to underwrite the drug manufacturers' participation in mass inoculations.

If, to ensure the availability of vaccines, the government must assume the liability associated with mass inoculations, then these costs can be, and should be, distributed among those who benefit from the immunization—the general public. The arbitration and disability schemes proposed above are suggested as the guarantee to the public that they will be cared for if injury results from vaccination.

VII
CONCLUSION

The Swine Flu Immunization Program has caused great embarrassment to the public health community. Future pleas for mass immunization to combat threatened epidemics will be scrutinized carefully, for the American public may no longer be fully receptive to the "roll up your sleeves" plea.

The marked decrease in cases of measles[139] and polio[140] in the United States is testimony to the social utility of mass immunization programs. The importance of a healthy citizenry cannot be overstated, and consequently, our national health cannot be dependent on the type of ad hoc legislation which Pub. L. No. 94-380 exemplifies. A permanent and centralized entity responsible for keeping a watchful eye on the nation's health must be created.

The proposed model provides the permanence and predictability of a legislative approach which were absent in the judicial response to liability resulting from mass inoculations. Every individual must have the assurance that he will be cared for if injury results from a program designed to prevent illness.

BONNIE L. SIBER

139. *See*, Witte & Axnick, *The Benefits From 10 Years of Measles Immunization in the U.S.*, 90 PUBLIC HEALTH REPORTS 205 (1975).

140. *See* Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1269-70 n.1 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).