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A REVIEW: LEGAL LIABILITY AND COMPENSATION FOR VACCINE-RELATED INJURIES

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. . . HEW carries out its contractual obligation to the manufacturers by developing an adequate informed consent statement, by requiring the State and local health agencies to use that statement, and by providing guidelines to the health agencies for obtaining informed consent from persons who are to be vaccinated. The underlying responsibility, however, to warn persons of the risks and benefits of vaccination remains upon the manufacturers.

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May *1979*

the vaccine manufacturers have now contractually shifted this [duty to warn] responsibility to the Federal Government in the vaccine supply contracts.

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BACKGROUND AND INTRODUCTION

All vaccines, even when properly manufactured and administered, can produce adverse reactions. In general, adverse reactions are mild and self-limiting, including, for example, pain, redness, or swelling at the injection site. For the vast majority of individual vaccinees, therefore, as well as for society as a whole, the benefits of vaccination greatly outweigh the risks.

For an exceedingly small number of vaccinees, however, the risks of a particular type of vaccination prove to exceed the benefits. A few vaccinees do experience severe adverse reactions that result in permanent disability or death. (See table 16.) While such reactions are rare, many are unavoidable, i.e., they are caused, not by a defective vaccine product or negligence on the part of the vaccinator, but by the inherent properties of a particular vaccine.

In order to receive compensation for vaccine-related injury, injured vaccinees must establish legal liability for their injury. In addition to proving that vaccine-related injury

Table 16.—Vaccine Risks and Adverse Reactions

Vaccine	Rate of minor side effects	Rate of serious adverse reactions	Types of serious reactions
DPT	1/5 to 1/2	1/5,000 1/12,000	Convulsions Abnormal screaming
Measles	1/4	1/1 ,000,000	Encephalitis (inflammation of the brain)
Rubella	Rare	1/10 1/10,000 1/1 ,000,000	Temporary arthritis Nerve damage Brain damage
Polio (killed virus)	0	0	
Polio (oral) (live virus)	0	1/4,000,000	Paralytic polio

SOURCE: "Fact Sheet on Immunization Initiative," Center for Disease Control, 1978. (U.S. Ex. Br., CDC. Fact, 1978.)

has occurred, a plaintiff must establish in court that the defendant (e.g., vaccine manufacturer, vaccine administrator, or both): 1) knew or should have known of the possibility of injury, and 2) had the duty either to prevent the injury or to warn the vaccinee of inherent risks.

Who receives compensation for vaccine-related injuries and who is responsible for providing it at present depend on legal theories of liability. To encourage the development of appropriate safeguards against harm, the litigation process lays fault on those in the best position to develop such safeguards. Harm by itself does not necessarily give rise to liability. One of the cornerstones of the attachment of liability is foreseeability: i.e., those in a position to prevent harm know of the dangers and know what their duty is in order to avoid liability. Some courts have explicitly forewarned that they may be basing their future reasoning on considerations, not of who is best able to avoid the risk of loss, but of who is best able to bear the risk.

Most liability issues at present revolve around the legal responsibilities for the duty to warn potential vaccine recipients about inherent vaccine risks, i.e., unavoidable risks associated with nondefective and properly administered vaccines, To date, the courts have assigned legal responsibility for the "duty to warn" to the vaccine manufacturer. In three major court cases during the past 11 years, plaintiffs have successfully sued vaccine manufacturers, because the courts decided that the manufacturer had not adequately discharged its "duty to warn" injured vaccinees about the less than 1 in 1 million to 4 million chance of developing polio from live poliovirus vaccine.

Successful discharge of the duty to warn potential vaccinees about the inherent risks of vaccination would not prevent injury, but would foreclose injured vaccinees' only avenue to compensation for injury. Following the three precedent-setting **cases of** *Davis v. Wyeth Laboratories, Reyes v. Wyeth Laboratories,* and *Givens v. Lederle,* however, it is not clear how the manufacturer's duty to warn can be discharged. The direction in which these cases seem to be leading is for the courts to hold manufacturers "strictly liable" for all unavoidable injuries resulting from use of their products. It appears, in other words, that the courts **may not** allow manufacturers and other potential defendants to escape liability for injuries associated with the unavoidable risks of vaccines.

In 1976, because of their concern over liability, vaccine manufacturers, under pressure from their insurers, refused to supply vaccines for the massive federally sponsored swine flu immunization program unless the Federal Government assumed liability for the duty to warn. To obtain the manufacturers' cooperation in producing vaccines for the program, Congress enacted legislation (Public Law 94-380), under which the Federal

Government did assume the manufacturers' liability for the duty to warn. Unexpectedly, about 1 in every 100,000 vaccinees developed Guillain-Barre Syndrome (GBS) as a serious adverse reaction to nondefective and properly administered swine flu vaccines. (See appendix 5.1.) The Federal Government (HEW) is still in the process of settling some swine flu GBS claims and lawsuits.

Experience with the 1976 swine flu immunization program has heightened general concern with vaccine liability issues among manufacturers and policy makers in the Federal Government. In part because of what happened under the swine flu program, vaccine manufacturers now require as a condition of supplying vaccines for use in public immunization programs that the Federal Government assume responsibility for the duty to warn.

Currently, therefore, the Department of Health, Education, and Welfare (HEW) is assuming the duty to warn obligation from vaccine manufacturers in Government vaccine purchase contracts. In addition, HEW is requiring, in its vaccine supply contracts, that State and local health agencies that administer federally purchased vaccines in their immunization programs use HEW-developed informed consent statements and guidelines to obtain consent from persons who are to be vaccinated.

Whether the courts will uphold the contractual transfer of the vaccine manufacturer's duty to warn remains to be seen, Will the courts uphold the legality of the transfer of duty to warn obligation from the manufacturer to the Federal Government, making the Federal Government liable for injuries associated with inherent risks? Will they uphold HEW's contract with State and local health agencies, possibly making the person administering the vaccine liable? Or instead, will the courts—under theories of strict liability—hold the manufacturer ultimately responsible for harm produced by its products? Another question that may arise is this: Will the courts judge HEW's informed consent statement and guidelines to be an adequate warning?

The uncertainties surrounding vaccine liability issues appear to be undermining support for large-scale public immunization programs both in Congress and among vaccine manufacturers. Recently, for example, Congress refused to authorize HEW to establish a large continuing influenza immunization program, basing its refusal, at least in part, on concern with liability. Some major vaccine manufacturers and their insurance companies, furthermore, have indicated that unresolved liability issues threaten their continued willingness to produce and supply vaccines for public immunization programs. In addition, heightened visibility and awareness of the risks of vaccination may be diminishing the public's willingness to participate in such programs.

From the standpoint of the injured vaccinee, whether the courts uphold the contractual transfer of the duty to warn responsibility is of less vital concern than the fact that, if the courts rule that the responsible party has adequately discharged its duty to warn, no compensation for vaccine-induced injury will be provided. Legal discharge of the duty to warn would not provide any compensation to those few vaccinees who experience severe adverse reactions or who die; in fact, it would mean that compensation would be expressly denied. Furthermore, for the childhood vaccines, mandatory State vaccination laws make the duty to warn moot. Forty-seven States, the District of Columbia, and three territories mandate certain childhood immunizations upon a child's entry into a public school. (See table 17.) Warning of the possible adverse effects of vaccines implies or is based on the assumption that the vaccinee has the choice to refuse vaccination. Mandatory State vaccination laws, however, preclude this choice.

Table 17.- immunization Requirements Prior to School Entry (September 1976)

State	Type of legislation			If no State law, are there plans pending for proposing such a law?		If yes, before September 1977?	Immunizations required for specific diseases							
	Mandatory	Permissive	None	Yes	No		Diphtheria	Pertussis	Tetanus	Measles	Mumps	Polio	Rubella	Smallpox
Alabama	X						X	X	X	X		X	X	
Alaska		X					X	X	X	X		X		
Arizona [a]			X[a]		X									
Arkansas	X						X	X	X	X		X	X	
California	X						X	X	X	X		X		
Colorado	X						X	X	X	X		X	X	
Connecticut	X	X								X		X	X	
Delaware	X						X	X	X	X		X	X	
District of Columbia,	X						X	X	X	X		X	X	
Florida	X						X	X	X	X		X	X	
Georgia	X						X	X	X	X		X	X	
Hawaii	X						X	X	X	X		X	X	
Idaho			X		X									
Illinois	X						X	X	X	X		X	X	
Indiana	X						X	X	X	X		X	X	
Iowa			X	X										
Kansas	X						X	X	X	X		X	X	
Kentucky	X						X		X	X		X		
Louisiana	X						X	X	X	X		X		
Maine		X					X	X	X	X	X	X	X	X
Maryland	X						X	X	X	X		X	X	
Massachusetts	X						X	X	X	X		X		
Michigan	X						X	X	X	X		X	X	
Minnesota	X									X			X	
Mississippi		X					X	X	X	X		X	X	
Missouri	X						X			X		X	X	
Montana		X					X	X	X	X		X	X	
Nebraska	X						X	X	X	X		X	X	
Nevada	X						X	X	X	X		X	X	
New Hampshire	X						X	X	X	X		X	X	
New Jersey	X						X	X	X	X		X	X	
New Mexico	X						X	X	X	X		X	X	
New York	X						X			X		X	X	
North Carolina	X						X	X	X	X		X		
North Dakota	X						X	X	X	X	X	X	X	
Ohio	X						X	X	X	X		X	X	
Oklahoma	X						X	X	X	X		X	X	
Oregon	X						X	X	X	X		X		
Pennsylvania	X						X		X	X		X	X	
Rhode Island	X						X		X	X		X	X	
South Carolina	X						X	X	X	X		X	X	
South Dakota	X						X		X	X		X	X	
Tennessee	X						X	X	X	X		X	X	
Texas	X						X		X	X		X	X	
Utah	X						X	X	X	X		X	X	
Vermont			X[c]		X									
Virginia	X						X	X	X	X		X	X	
Washington[a]			X[a]	X		Yes								
West Virginia	X						X	X	X	X		X	X	
Wisconsin	X						X	X	X	X		X	X	
Wyoming			X		X									
Guam			X[a]		X									
PuertoRico	X													X
Virgin Islands	X			2		1	X	X	X	X	2	X	X	X
Total	47[b]		7		5		44	37	42	46		45	39	3

[a]Arizona, Washington, and Gua[illegible] have [illegible] requirements.
[b]Connecticut: rubella and measles are mandatory; polio is permissive.
[c]Vermont has local option regulations at the school district level, establishing school entry immunization requirements.

SOURCE: "Fact Sheet on Immunization initiative:' CenterforDisease Control 1978. (U.S. Ex. Br., CDC, Fact, 1978)

In this chapter, the nature and dimensions of current vaccine liability and compensation problems are discussed in relationship to three pertinent topics: 1) developments in case law on vaccine-related injuries; 2) principles underlying insurance companies' pricing of liability insurance; and 3) recent experience with vaccine risks, adverse reactions, and liability claims arising out of federally sponsored immunization programs, including the 1976 swine flu immunization program.

Issues related to vaccine liability and compensation are discussed further in chapter 6, and possible options for congressional actions to resolve some of these issues are presented in chapter 7.

CASE LAW ON VACCINE-RELATED INJURIES[1]

Developing specific policies for liability associated with the use of vaccines is complicated by the fact that vaccine-related injuries are part of two even larger issues: 1) the availability of socially useful, but unavoidably dangerous, products that inevitably cause some harm no matter what precautions are taken (i. e., product liability), and 2) compensation for injury when the person harmed was not in control of the circumstances under which the injury occurred.

At the same time that the courts are turning toward the insurance concept of spreading the risk, they must continue to work within the legal framework of an adversary, faultfinding process. The limitations of a judicial approach to insurance for injuries can be seen in the summaries of emerging case law on vaccine-related injuries presented below.

Legal Determination of Liability by Courts of Different Jurisdictions

The jurisdiction of the legal determination of liability is as important as specific legal theories embodied in the case law. The outcome of a lawsuit for a given factual situation may not be identical across the country. There is no requirement that the common or statutory law be consistent across the United States, as our Federal/State form of government results in applicable laws being those of a particular jurisdiction. [2] In cases of conflict between different Federal jurisdictions, the U.S. Supreme Court may eventually resolve the difference, but the concept of State sovereignty means that some areas and some State laws are outside the jurisdiction of even the U.S. Supreme Court.

On the other hand, courts of highest jurisdiction (i.e., the U.S. supreme Court and State Supreme Courts) may adopt legal doctrines from other jurisdictions, and the influence of case law can continue even though it may have been legislatively repudiated in the jurisdiction where it originated. [3]

[1] This topic and the broader issue of product liability recently have been the subject of several analyses. For product liability, see *Interagency Task Force on Product Liability: Final Report (Interagency, 1977)*, described as "the most thorough analysis of problems in the product liability area that has been published in the United States." For liability in immunization programs, see *Liability Arising Out of Immunization Programs: Final Report to Congress* (U.S. Ex. Br., DHEW, May 1978); T. E. Baynes, Jr., "Liability for Vaccine-Related Injuries: Public Health Considerations" (Baynes, 1976); and G. R. Smith, "Liability in Preventive Medicine: A Review and Analysis of Trends, Primarily Those Related to Vaccination Practices" (Smith, 1976).

[2] This is a simple representation of the area of conflict of laws.

[3] The most prominent recent example is *Helling* v. *Carey*, 83 Wash. 2d 514, 519 P. 2d 981 (1974), in which the court replaced a medical standard for testing of glaucoma with a legal standard. The court was overruled legislatively by Wash. Revised Code Section 4.24.290 (1976).

It is hard to predict when a court will confine case precedents to similar factual situations or when it will extend it to other situations. Three cases arising out of the use of live, attenuated polio vaccines have received the most attention in this respect: *Davis v. Wyeth Laboratories, 399* F. 2d 121 (9th Circuit 1968), *Reyes v. Wyeth Laboratories, 498* F. 2d 1264 (5th Circuit 1974), and *Givens v. Lederle,* 556 F. 2d 1341 (5th Circuit 1977). A question that arises from these three court cases is this: Will the courts limit precedents established in these cases to future situations involving injuries from live vaccines, or will they promote social policy goals?

Causes of Action for Vaccine-Related Injuries

A cause of action for vaccine-related injuries may arise in product or personal (medical malpractice) liability and may fall on any of the actors in the chain of events from manufacture of the vaccine to dispensation to vaccination.[4] Liability may arise from the intrinsic properties of a particular vaccine coupled with the failure to warn of these potential side effects, or from conduct associated with a vaccine (e. g., faulty manufacturing, nerve damage from the injection of the vaccine), in which case, liability does not depend on the vaccine's intrinsic properties.

Vaccine manufacturers' liability includes negligence in manufacturing and disseminating of the vaccine, for breach of express or implied warranty, and strict liability in tort:

1. Negligence applies to situations in which, for example, there was a reasonably correctable defect in the vaccine (e. g., contamination with bacteria or wrong labeling on the bottle) that caused an injury.
2. Breach of warranty is a claim that a contractual relationship existed between the manufacturer and the person injured. This relationship may be based on an actual contract (i.e., express warranty, although a court may read an implied warranty in the contract) or on an unwritten contract (i. e., implied warranty, where the court interprets the facts to be a contractual relationship). These "contracts" are often legal fictions to allow the plaintiff a cause of action against the manufacturer instead of against the party from which the product was actually purchased.
3. In strict liability in tort, the seller may be liable if a product leaves the seller's control in a condition unreasonably dangerous to the user. Some products are unavoidably unsafe no matter what precautions are taken, e.g., the Pasteur rabies vaccine, dynamite. If these products are socially useful, however, they are not considered "unreasonably dangerous, " providing that they are properly manufactured and accompanied by appropriate warnings regarding their inherent dangers.

Those who administer a vaccine are liable for professional malpractice associated with the vaccination procedure. Under certain circumstances, vaccinators assume the duty to inform vaccinees of the particular vaccine's inherent foreseeable risks. In this case, theoretically, the manufacturer's duty to warn legally can be transferred to the purchaser, individual, or organization actually performing the vaccination. The latter party, in turn, must gain the informed consent of the vaccinee. How the duty to warn can be transferred to the satisfaction of a court, however, is not clear.

'The differences and convergence of these theories of legal liability, especially as the, relate to manufacturers' liability, are outgrowths of very complicated historical developments of the law. (See note 1.)

In a suit against a particular party, any or all causes of action may be alleged, although one cause of action is usually decided upon by the plaintiff or court at trial or on appeal. A particular set of facts, therefore, does not necessarily indicate what the relevant cause of action is or will be. In the 1968 case of *Davis v. Wyeth Laboratories,* for example, the plaintiff brought a claim founded on 1) negligent manufacture, 2) failure to warn of known dangers, 3) strict liability in tort, and 4) breach of an implied warranty of fitness. The trial court dismissed all save that of breach of warranty. The U.S. Court of Appeals for the Ninth Circuit found that it was error to fail to instruct the jury, either in warranty or tort, that the manufacturer was strictly liable if its vaccine product caused the plaintiff to contract polio and if plaintiff's taking of the vaccine was without knowledge of risk.

Legal Liability Theories Embodied in Recent Case Law

The liability theory that has received the most attention is that of strict liability in torts Prior to the three live polio cases discussed below, the manufacturer's duty to warn the vaccine recipient about potential adverse reactions was discharged by warning the person administering the vaccine, who in turn had to warn the vaccinee. Following these cases, however, it is not clear whether a distinction can be made between factual situations in which the manufacturer's duty to warn is discharged and assumed by the vaccinator and situations in which the manufacturer's duty to warn is retained. Manufacturers may be held "strictly liable" for all vaccine-induced injuries associated with the inherent risks of their vaccine products.

1) Davis v. Wyeth Laboratories, 399 F. 2d 121 (9th Circuit 1968)—in Davis v. Wyeth *Laboratories,* the U.S. Court of Appeals for the Ninth Circuit found that the facts of the case imposed on the manufacturer a duty to warn the consumer (or make adequate provisions for the consumer's being warned) as to the risks involved, and that strict liability attached to the sale of the vaccine in the absence of such a warning.

Plaintiff Davis had contracted polio after taking live polio vaccine in a mass immunization clinic run by a pharmacist. A salesman for Wyeth Laboratories managed the vaccination campaign for the local medical society. He arranged for delivery of the vaccine and the promotional campaign, set forth the schedules and procedures to be followed, and was reimbursed for his expenses by the medical society. Vaccination fees were used to pay the medical society's bill from Wyeth, with the remainder kept by the society.

The Association of State and Territorial Health Officers, citing the U.S. Surgeon General's report, had published information that a small but definite risk of adult vaccinee's contracting polio from the vaccine did exist, and that because of this risk, the Surgeon General's report had recommended that the vaccine be given to children and high risk adults. (Mr. Davis fell into the class of high risk adults, because the parents of young children were included). The package insert accompanying the vaccine contained

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[5]Different interpretations exist on the content of this legal duty, which in part are related to legal distinctions between products that are "unreasonably dangerous" and products that are "unavoidably dangerous." The label "unreasonably dangerous" implies a traditional negligence test, where the defect is correctable under legal standards of reasonableness. "Unavoidably dangerous" implies the possibility of harm no matter what precautions are taken. For example, in *Davis v. Wyeth* ***Laboratories (Davis, 1968),*** one of the three live polio cases, the court stated:

> We conclude that the facts of this case imposed on the manufacturer a duty to warn the consumer (or make adequate provision of his being warned) as to the risks involved, and that *failure to meet this duty rendered the drug unfit in the sense that it was thereby rendered unreasonably dangerous.* (emphasis added) 399 F. 2d at 130.

Obviously, the court was not referring to the intrinsic properties of the vaccine, which would be unchanged whether or not the warning was given. Rather, it was determining who would bear the cost of injury—the manufacturer, the vaccinator, or the vaccinee—once the risk of injury was realized.

pertinent excerpts of indications and risks, but neither the pharmacist nor Mr. Davis read it. A fact sheet put out by Wyeth, contained in a book it supplied to the clinic, was published prior to the Surgeon General's report and represented the vaccine as completely safe for all ages. No effort was made by Wyeth or the medical society to inform the c1inic pharmacist of the risk.

Finally, the Ninth Circuit Appellate Court rejected the statistical argument that a risk of less than one in a million was not unreasonable, stating that the risk of contracting polio without immunization was about the same as contracting it from the vaccine.

2) Reyes v. Wyeth Laboratories, 498 F. Zd 1264 (Sth circuit 1974)—In the 1974 case of Keyes v. Wyeth *Laboratories,* the U.S. Court of Appeals for the Fifth Circuit affirmed the lower court judgment that Wyeth was liable for polio contracted by a vaccinee, because it marketed an unavoidably unsafe vaccine and failed to provide the parents of the vaccinated infant with either a warning of risk or individualized medical judgment that the vaccination was necessary and desirable for the infant.

One issue at the trial level was whether the vaccine or a wild polio virus known to be present in the community at the time of vaccination caused the polio. This was approached as a question of fact for the jury to decide, and the appellate court would not reopen the question.

Wyeth contended that, if it had a duty to warn, this duty was discharged by the warning contained on the package insert which accompanied the vials of vaccines it sold to the Texas State Department of Health, i.e., its duty to warn was the same as that for prescription drugs. It also distinguished the facts of the case from Davis for the following reasons: 1) the infant Reyes took the vaccine at her parents' request, not as a result of a mass immunization program; 2) the vaccine was administered by a public health nurse, not a pharmacist; 3) Wyeth's role was passive, not like that of its salesman in *Davis;* and 4) it claimed no knowledge that the vaccine would not be administered as a prescription drug (and thus be accompanied by an individualized medical judgment as to its use).

The appellate court dispensed of the first two arguments by finding that the prescription drug exception required an individualized medical balancing of the risks to the vaccinee. The public health nurse had testified that she had read the package insert, but that it was not the practice of the nurses at the clinic to pass on warnings to the vaccinees or their guardians, and that she had given no warning.

As for the latter two arguments, the court found that Wyeth had ample reason to foresee the manner in which its vaccine would be distributed. Since Wyeth knew or had reason to know that the vaccine would not be administered as a prescription drug, it was required to warn foreseeable users, or to see that the vaccine purchaser, the Texas Department of Health, warned them.

3) Givens v. Lederle, 556 F. 2d 1341 (5th Circuit 1977)—In the 1977 case of *Givens v. Lederle,* the U.S. Court of Appeals for the Fifth Circuit (the same court as that in Reyes) found that a rational basis existed for the jury's verdict against Lederle on the issues of failure to give adequate warning and of such failure being the proximate cause of the vaccinee's mother contracting polio.

The proximate cause issue had arisen because the trial judge had excluded testimony that the vaccine could cause polio. The original jury had found for the manufacturer, Lederle, but the trial judge had reversed himself after the Reyes decision, in which the appellate court had expressly accepted as fact that oral polio vaccine can induce an active polio case. At the second trial, the verdict went against Lederle.

The plaintiff Givens developed polio soon after having taken her daughter to her pediatrician for oral polio vaccinations. Lederle argued that, in Reyes, a county health clinic administered the vaccine, whereas in this case a private physician did. The court's rebuttal, as extracted below, was as follows (Givens, 1977):

> [T]he difference is not nearly so great as appellant indicates. The "county health clinic" in Reyes was not involved in the same sort of "mass inoculation" as was taking place in Davis v. Wyeth *Laboratories, inc.,* the case which established the duty to warn in these "unavoidably dangerous" drug cases, like Reyes and the instant one. The administration of the vaccine by a public health nurse in Reyes is as close to the instant situation as it is to the *Davis* mass inoculation . . , There is solid evidence that the vaccine was administered here in a manner more like that at a small county health clinic, as in Reyes, than by prescription. For example, Dr. LaRue, the private pediatrician, testified that the administration in his office "really didn't differ" from that of the Public Health Center, "not in the administration at all. " If so, then Lederle is responsible for taking definite steps to get the warning directly to the consumer . . . Dr. LaRue claims that "the wording on the insert states that it is a safe and affective (sic) means of immunizing the population and that the risk, if it exists, is no more than one in three million. I felt that was a very nebulous way of putting it . . , and I did not feel there was sufficient evidence or warning to warn Mrs. Givens about them." (Citations omitted.)

Following the Givens case, a manufacturer must assume that vaccines will always be administered without individual medical attention, no matter where or how they are administered. [b]

Finally, if the duty to warn is transferred to the vaccinator, that duty becomes a part of the informed consent that must be obtained from the patient for treatment.[7]

> A claim based on lack of informed consent is essentially a claim that the physician did not disclose to a patient what the nature and risk of treatment would be, that the subsequent treatment, therefore, was, in effect, without the patient's consent, and that the plaintiff is consequently entitled to seek damages for any resulting injury. The theory is that, had the physician made a full disclosure, the patient could have refused treatment, thus avoiding the adverse outcome. Lack of informed consent is an independent theory, and thus an action based on it does not require a showing of negligent conduct butmerely a failure of disclosure.[8]

It is difficult to see, though, how the *Givens* court would approach a suit in a failure to warn case against the vaccinator, and not the manufacturer. In the *Givens* case, the court chose to use testimony by the vaccinating physician as one basis for concluding that the manufacturer's duty to warn had not been discharged. [g]The court relied on the very kinds of conclusions by the physician on the statistical risk that it would not allow

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'See pp. **27-34** in *Liability Arising out* of *Immunization Programs: Final Report To Congress* (U.S. Ex. Br., DHEW, May **1978).** Baynes, on p. 168 in "Liability for Vaccine-Related Injuries: Public Health Considerations'' (Baynes, **197** makes a distinction between private and public immunization programs, but the *Givens case* had not been decided at the time of his analysis.

'Informed consent originated in the theory of battery, where harm resulted from unconsented touching. *Mohr v. Williams, 95* Minn. **261, 104** N.W. 12 (1905). It thus has a doctrinal basis that is different from that for the duty to warn. The implications of the two, however, are the same.

'See p. **37** in *Report* of *the Special Advisory Panel on Medical Malpractice, State of* New *York (Report,* 1976). There is a difference between jurisdictions in determining the adequacy of the information given to satisfy informed consent. Some courts require expert medical testimony to show what the standard of disclosure is, the plaintiff having to provide the expert testimony in order to show that the defendant deviated from it. *Natanson v. Kline,* 187 Kan. 186, 354P. 2d 670 (1960). (Other courts, emphasizing the patient's right to know, have held that expert testimony is not needed to show inadequacy of disclosure. *Canterbury v. Spence,* 464 F. 2d 772 (D. C. Circuit 1972), *Cobbs v. Grant, 8* Cal. 3d **229, 502** P. 2d 1 (1972). This is still the minority doctrine.)

'Its other reason, that the administration of the vaccine by public health nurse in *Reyes* was as close to the private pediatrician situation as it was to the *Davis* mass inoculation, is not a particularly lucid rationale and comes close to being a non sequitur.

the manufacturer to make. It is not clear that the same legal principles govern whether a manufacturer must provide a warning (to a physician or a patient) to avoid strict liability and whether a physician must warn his patient to avoid liability under the informed consent cases. The manufacturer must warn of the risks that make its products unavoidably unsafe. The physician, however, might be permitted to omit a warning if his evaluation of the patient indicates that it would cause the patient unreasonably to forego medical treatment. The outcome would be further complicated in mandatory vaccination programs.

Finally, the Givens court, the U.S. Court of Appeals, Fifth Circuit, is the same court that decided Reyes. The Reyes decision provided manufacturers two avenues for avoiding liability: 1) a warning of risk, or 2) individualized medical judgment that the vaccination was necessary for the vaccinee. With the ruling in *Givens,* the second avenue would be effectively closed. The closing of this avenue, coupled with the continuing uncertainty as to when the warning requirement has been satisfied, may mean that the only way the manufacturer can avoid liability is to expressly transfer the duty to warn to the vaccinator in the written contract of purchase of the vaccine.

When it cited a "policy factor" at work in the Reyes case, the Fifth Circuit Court of Appeals may have been forecasting its *Givens* decision (Reyes, 1974):

> Until Americans have a comprehensive scheme of social insurance, courts must resolve by a balancing process the head-on collision between the need for adequate recovery and viable enterprises. This balancing task should be approached with a realization that the basic consideration involves a determination of the most just ***allocation of the risk of loss*** between the members of the marketing chain. Statistically predictable as are these rare cases of vaccine-induced polio, a strong argument can be advanced that the loss ought not lie where it falls (on the victim), but should be borne by the manufacturer as a foreseeable cost of doing business, and passed on to the public in the form of price increases to his customers.

PRINCIPLES UNDERLYING PRICING OF LIABILITY INSURANCE[10]

As noted in the preceding section on case law, a cause of action for vaccine-related injuries may arise in product or personal liability, and liability may fall on any of the actors in the chain of events from manufacturing to dispensation to vaccination.

Vaccine-related injuries are covered by the product and medical malpractice liability insurance policies of manufacturers and health care providers (individual physicians and other independent practitioners as well as organizations such as hospitals).[11] Premiums usually are set for groups of manufacturers or categories of products. Premiums are calculated for groups of health care providers, not for individual providers. For products liability, premium calculations may be class-rated or judgment-rated, the latter being subject to negotiations between the manufacturer and the insurance company.

The logistics of underwriting liability insurance for multiple products and multiple types of providers mean that the liability experience for any particular product (e.g., vaccines) or cause of action (e. g., informed consent) will command only cursory analysis by

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[10] For more detailed discussion of th, field and of ratemaking practices, see ch. V of *Interagency Task Force on Product* Liability; *Final Report (Interagency,* 1977), "Pricing Medical Malpractice Insurance: A Technical Discussion of Rate-Making, " in *Report of the Special Advisory Panel on Medical Malpractice, State of New York (Report, 1976),* R. S. L. Roddis and R. E. Stewart, "The Insurance of Medical Losses, " 1975 *Duke L. J.* 1281 (January 1976).

[11] ' 'The recent swine flu program was an exception because of its enormous size and lack of historic data on which to base premiums.

underwriters charged with setting premium levels. When a manufacturer has one product with large liability losses, however, either this product may be excluded or two insurance contracts may be written. Until recent events spotlighted product and medical professional liability, insurance companies usually kept no separate data on these two fields and reported only the overall results for property-casualty insurance and miscellaneous liability insurance. Thus, whenever any particular area of liability was scrutinized, the insurance data were found to be inadequate.

Coverage

The typical liability insurance policy is issued on an "occurrence" basis. Under an occurrence policy, the insured is covered for injuries that occur during the policy period, usually 1 year, regardless of when a claim is filed or a suit settled. Issuing policies on an occurrence basis has caused problems in pricing medical malpractice premiums, because as courts have extended the rule of discovery, [12] leading to the "long tail" in medical malpractice suits, insurers have had difficulty in estimating payments for claims which may be brought many years in the future.

Liability insurance policies also may be issued on a claims-made basis. In claims-made policies, the insurer is liable only for claims made during the policy period. [14] The uncertainties inherent in occurrence policies are somewhat reduced by claims-made policies, because the insurer is able to know after the end of the policy period exactly how many claims are covered by a particular claims-made policy. For retiring physicians or those who switch back to occurrence policies, coverage for future claims rising out of occurrences in the claims-made policy year can be provided by a single premium, perhaps calculated as a fixed percentage or multiple of the last annual premium on the claims-made policy .15

For product liability, the occurrence is at the time of injury, not at the time of manufacture. Uncertainties in pricing occurrence insurance policies arise in two situations:

1. Situations involving liability for old products, in which a long time may have elapsed between the time of manufacturing and sale of the product to the time of injury; and
2. Situations in which adverse results may not be known and/or may not occur for many years (e. g., cases involving 'hormonal treatment and gynecological cancers, or asbestos and cancer).

Insurance is provided in several layers of coverage. First, there may be a deductible amount assumed by the insured that has to be exceeded before insurance policies pay claims losses. Second, there is a basic insurance policy that covers a specified amount, usually stated in annual amounts per occurrence and in the aggregate. (For example, the limit may be $1 million per occurrence, $3 million in the aggregate. The insurer will not pay more than $1 million for losses arising out of an incident and no more than $3 million

[12] The prototypical case is the discovery of a sponge at the operating site in the body many years after the operation occurred. Courts have ruled that the statute of limitations did not toll from the time of operation but from the time of discovery.

[13] A recent Illinois Supreme Court decision portends additional problems in calculating future payments for acts of malpractice. In *Renslow v. Mennonite Hospital, 67* Ill.2d *348, 367* N.E.2d 1250, rehearing denied (1977), the court ruled that a child may recover damages for personal injuries sustained as a result of the negligent conduct of a physician and a hospital in giving her mother a blood transfusion 8 years before the plaintiff's birth.

[14] Claims-made policies were used by some captive insurance companies termed by physician organizations during the recent medical malpractice insurance availability crisis of the mid-1970's.

[15] This also could be overcome by a surcharge on active physicians to cover possible claims against retired physicians. Also, gaps in coverage could be a problem if physicians switched back and forth between occurrence and claims-made policies.

for all incidents occurring in the policy year.) Third, the insured may purchase excess insurance covering, up to a specified limit, losses above the basic policy. Any losses above the excess insurance limit are the liability of the insured.

Insurers providing either the basic or excess insurance policies may reinsure part of the risk themselves or may spread the policy among several companies; that is, a given insurer may itself purchase insurance from an excess insurer, or it may share the coverage (and premiums) with other insurance companies. Excess insurance usually is provided by special excess or "umbrella" insurance companies. By its very nature, excess insurance is among the most speculative types of insurance. This is the primary reason that companies providing the basic policies stay out of the market. As historic data are accumulated and ratesetting becomes more reliable, basic insurers may enter this market by raising the limits of the basic policies.

Servicing of claims usually is provided by the basic insurers. The dollar figures for the deductible and basic and excess insurance policies refer to claims paid and do not include administrative costs. In calculating premiums, the basic insurers take these servicing costs into account. Some insureds, such as large drug companies, may service their own claims, in which case their premiums would reflect this by being lowered.

The insurance arrangements that were worked out for the swine flu immunization program illustrate this layering of coverage and spreading of the risks.*' The Federal Tort Claims Act was modified to require all vaccine-related claims to be brought against the Federal Government, which in turn could recover from negligent manufacturers or vaccinators. Vaccine manufacturers and insurers providing their basic policies thus were relieved of the expense of handling swine flu liability claims, although they still incur expenses in assisting the Federal Government to process these claims.

Each of the four manufacturers of swine flu vaccine self-insured for **$2.5** million, for a total of $10 million. Each manufacturer also received a basic policy of $5 million[17] and an excess policy of **$50** million, for a total of $20 million for the basic policy and $200 million for the excess coverage. Total premiums on the $20 million basic policies were $2.4 million; the premium on the $200 **million excess** policies was **$6.25** million.

Sixteen companies insured the basic policies, with each company's share ranging from **0.5** to 10 percent of the total. Thirty-seven companies issued the excess policies, with each company's share ranging from 0.05 to 17.035 percent of the total. Twelve companies participated in underwriting both types of policies,

If the Federal Government had not assumed responsibility for defending against claims, in addition to adjusting the premium upwards, the companies would have had to agree on who would be handling claims. The most likely arrangement would have been to limit the insurers underwriting basic policies to a few (perhaps one per manufacturer), with other companies reinsuring the risk, or for manufacturers to handle the claims themselves.

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[16] See p. 39 i„ *Review and Evaluation of the Swine Flu* Immunization Program (U.S. Cong., HCIFC, 1977).

[17] This amount is the aggregate limit, apparently the same as the occurrence limit.

Ratemaking[18]

Medical malpractice and product liability ratemaking practices differ somewhat in methodology, but the basic concepts and terminology are the same.[19] The following discussion is based on the specific practices followed by the Insurance Services Office (ISO), a servicing agency for the insurance industry.

Premiums are calculated on the basis of all of the following:

1. Loss and expense data,
2. Loss development factors, and
3. Trend factors.

Loss and expense data consist of paid plus incurred (but not paid) losses and expenses. Losses are the amounts paid out in claims plus loss adjustment expenses (e.g., lawyer and court fees, etc.). Expenses equal all other items such as agents' commissions, taxes, fees, overhead, profit, etc. The reliability of the loss and expense data is a function of size. In vaccine liability, for example, the data that insurers have are inadequate to be reliable for setting premiums, because: 1) there are too few claims, and 2) most large drug companies have sizable self-insured deductibles before the insurance policy goes into effect.

Loss development factors produce estimates of what incurred losses will be when finally paid. The trend factor relates largely to expenses, not losses, and is an index that measures changes in the past with the expectation that these changes will continue at the same rate in the immediate future *(Problems, 1975).* Brief descriptions of the loss development and trend factors follow.

A loss development factor is calculated to compare premiums (and relevant income derived from premiums) for any policy year against total losses. Losses include paid claims, estimated costs of known claims, and estimated costs of potential claims (commonly known as incurred-but-not-reported, or IBNR). Insurers submit loss (and expense) reports to ISO at 15 months, then every 12 months, after the beginning of the policy year. For product liability, four subsequent annual reports **are** made. **For medical** malpractice, ISO estimates that incurred losses will not be known until 10 years after the beginning of the policy year, or after nine reports. The report does not include IBNR losses *(Problems,* 1975):

> Since the first report on a policy year basis will be quite immature, reflecting as it does only a very small portion of paid claims and no estimate at all of unknown claims, those losses must be adjusted to approximate the amount that ultimately will be paid in claims and related expenses arising from incidents which occurred in that year. This adjustment is accomplished by the use of a loss development factor which is determined by comparing the more mature loss reports for prior years with the less mature reports for those same years. By means of this calculation the actual historical development which took place in the most recent past is measured and then applied to the latest policy year's incurred losses . . .

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[18] This is a very technical subject, and the reader should refer to the references in note 10 for further discussion. Also not discussed here are the effect of insurance company investment practices on premium rates and the controversy *over* how much profits or losses from these practices should be considered by State insurance commissioners in approving or denying changes in premium rates. For some State examinations of ratemaking in the medical malpractice area, see T. A. Harnett (Commissioner of Insurance, State of New York), "Opinion and Decision in the Matter of the Medical Malpractice insurance Association and insurance Services Off ice," November 1975, and Joint Legislative Audit Committee, Office of the Auditor General, California Legislature, *Doctors' Malpractice Insurance: An Interim* ***Report,*** Sept. **10,** 1975.

[19] See ch. v of *Interagency* Task *Force on Product Liability (interagency,* 1977) and *The* ***Problems Of*** *Insuring Medical* ***Malpractice (Problems,*** 1975).

Thus, for example, if the losses in the first report were $1 million and the loss development factor to the final report were 1.5, losses would be estimated at $1.5 million for the relevant policy year.

The methodology is sound, but is limited by the reliability of the data base. The data base includes estimated costs of known claims and potential claims (IBNR), and the latter especially depend on how good early-warning reporting systems are. An almost uniform finding of the various State commissions that studied the medical malpractice problem was that these reporting systems are nonexistent .20

Other factors affecting the reliability of the data comes down to the "informed best guess" of the individual underwriter trying to price a line of insurance and are affected by such things as the competitive environment of the field, the insurer's overall capacity to provide insurance of different types, management's willingness to do business in **a par**ticular line of insurance, potential defense and claims processing costs, and many other factors including the complex legal milieu described earlier. For particular lines, there may be so little claims experience or experience of such variability that it is impossible to calculate statistically valid rates. For products such as vaccines, there may not be very many claims, but claims that are made may be very high.

Early estimates of losses for any policy year may be dramatically different from eventual actual losses, as seen in the following example:

Losses for the Policy Year Ending December 31, 1966[21]

Undeveloped losses (paid claims and case reserves) as known on 3/31/67	*Actuarial estimate of what* losses will *be* on .3/.31 /71	*Paid* claims *and case reserves as* known on **3/31/71**
$5,559,547	**$12,263,892**	**$18,185,503**

SOURCE: *The Problems of insuring Medical Malpractice, 1975,* p. **17.** *(Problems, 1975.)*

Upwards adjustments of loss estimates, as would be necessary in the example above, would have the effect of increasing the loss development factor (and vice-versa) for subsequent years. Loss development factors are used as one part of the formula for calculating future premiums. The experience of previous policy years that go into the calculation also includes that of the most recent years, for which, as noted earlier, estimates of eventual losses are most tentative.

The trend factor used by ISO is derived by multiplying the average annual percent increase in claims costs by the percent increase in claims frequency from previous years' experience. It is determined separately for each policy year.

This trend factor is then applied to incurred losses as adjusted for the loss development factor. This estimate of losses is what is expected to occur under policies written after the proposed effective date. In effect, the calculation estimates what claims would cost if the underlying occurrences were to take place in the policy year for which rates are being set and were closed sometime in the future.

These losses (which include loss development and trend factors) are then divided by the premiums at current rate levels. The quotient is the "loss ratio" and represents the percentage of premiums at present rates that would be required to pay claims and related

[20] For example, see pp. 236-237 in *Report of the* Special *Advisory Panel* on Medical Malpractice *(Report,* 1976).

[21] The first policy issued would be on Jan. 1, 1965, and the last, on Dec. 31, 1965, so that coverage on the last policy issued would end on Dec. 31, 1966. The reporting date of Mar. 31, 1967, would be 27 months after issuance of the first policy. See p. 17 in The Problems of *Insuring* Medical Malpractice *(Problems, 1975).*

expenses. In order to set a figure for premiums in the next policy year, the "loss ratio" is compared to a standard, the "expected loss ratio, " which is calculated by subtracting from 100 percent the necessary business expenses plus underwriting profits and contingencies, expressed as a percent of premium. The loss ratio divided by the expected loss ratio indicates what the premium level will be. For example, if losses are 90 percent of premiums, the loss ratio will be 0.900. If the standard for the expected loss ratio assumes 25-percent business expenses and 5 percent for underwriting profit and contingencies, the expected loss ratio will be 0.700. Dividing the loss ratio by the expected loss ratio would indicate that current premiums would have to be increased by 28.6 percent (0.900 divided by 0.700 equals 1.286).

To summarize the ratemaking process:

1. The reliability of the data base may be limited. Even if resources were applied to obtain reliable data, the diversity of the risks covered and the complexity of legal liability issues would still limit the reliability of the collected data.
2. A basic requirement of ratemaking is that events must be predictable within relatively narrow boundaries of uncertainty. Fluctuations in, or changing patterns of, claims costs and frequencies raise questions about the predictive value of historic data. If predictions begin to result consistently in losses, insurers will become more conservative and price the risks at even higher levels or withdraw from unprofitable markets.
3. "Incurred" losses necessarily include estimates of losses from known and potential claims and their associated administrative costs. Loss development and trend factors then are used to further quantify these estimated losses. Estimated losses can turn out to differ significantly from actual losses. The long lag time between policy years for which total losses are finally known and policy years about to be underwritten make even known losses for past policy years of limited usefulness in the ratemaking process.

VACCINE RISKS, ADVERSE REACTIONS, AND LIABILITY CLAIMS

The previous sections have presented developments in case law on vaccine-related injuries and insurance methods for pricing liability insurance. In this section: 1) the degree of risks from vaccines is summarized, 2) data on claims for injuries are presented, and 3) the liability experience of the recent swine flu mass immunization program is discussed in terms of compensation for injury within the present tort liability system.

Degree of Vaccine Risks and Adverse Reactions

Minor side effects such as fever, sore throat, rash, malaise, etc. maybe frequent for some vaccines, but the rate of serious adverse reactions is usually low. The rates of adverse reactions to the childhood vaccines is shown in table 16. (For rubella vaccine, temporary arthritis and perhaps transient nerve damage might be classified as minor reactions by some medical authorities.)

The now familiar Guillain-Barre Syndrome (GBS) found to be associated with the swine flu (A/New Jersey/76) vaccine is an "ascending paralysis" which begins in the legs and later involves the trunk, arms, and neck. It is a transient condition in about 90 percent of the cases, leaves a residual paralysis in about 10 percent, and is fatal in about another 5 percent. In the swine flu program, one extra case of GBS above the expected incidence was observed for each 100,000 influenza immunizations (U.S. Cong., HCIFC,

1977). Cases of GBS in the vaccinated and unvaccinated populations appear in table **18.** The risk is higher in the vaccinated than in the unvaccinated population for persons **25** years and older. Preliminary data from the Center for Disease Control's (CDC) GBS surveillance program for the 1978 flu program (which was targeted at Russian flu, not swine flu) indicate that there is no significant difference in GBS rates between the vaccinated and unvaccinated populations (Hamilton, **1979). (See** appendix 5.1.)

Table 18.—Reported Fatal and Non-Fatal Cases of Guillain-Barre Syndrome in the United States October 1, 1976–January 31,1977 (by age group and A/New Jersey vaccination status)

	Vaccinated			Unvaccinated**			Total		
Age group	Cases	Deaths	Ratio	Cases	Deaths	Ratio	Cases	Deaths	Ratio
0-17 years	2	0	00/0	120	1	0.8%	122	1	0.8%
18.24 years	36	1	2.8%	76	3	3.9%	114*	4	3.5%
25-44 years	202	4	2.0%	131	4	3.1%	333	8	2.4%
45-64 years	173	12	6.9%	137	6	4.4%	313*	18	5.8%
65+ years	118	15	12.7°10	91	12	13.2%	212*	27	12.7%
Unknown	1	0	0%	3	0	0%	4	0	0%
Total	532	32	6.0%	558	26	4.7%	1,098*	58	5.3%
18 + years	530	32	6.0%	438	25	5.7%	972	57	5.9%

*Includes one or more cases with unknown vaccination status.
**Includes cases with onset of Guillain-Barre Syndrome before vaccination.

SOURCE: *Federal High-Risk Influenza Immunization Initiative—Oversight.* Hearings before the Subcommittee on Health and Environment of the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, p. 52, 1978. (U.S. Cong., HCIFC, 1978.)

Claims and Lawsuits From Vaccine-Related Injuries

Existing information on the numbers of vaccine-related injury claims and lawsuits prior to those arising out of the swine flu program is conflicting, but the numbers are very small both in absolute terms and compared to those from the swine flu program. The number of claims is larger than the number of lawsuits, because filing for a claim is preliminary to filing for an actual lawsuit, and many claims may never progress to the lawsuit stage.

General Counsel for HEW stated that as of March **23, 1979, 3,694** claims had been filed under the swine flu immunization program; as of April **2, 1979, 464** of these claims had been filed as lawsuits (Hamilton, 1979). The U.S. General Accounting Office (GAO) cites Public Health Service (PHS) records showing total number of claims since **1963** to be **3,721.** The **27** claims other than the **3,694** arising from the swine flu program were listed by type of vaccine as follows (Bernstein, 1979):

Polio	19
Flu	3
Smallpox	3
Typhus/typhoid	1
Measles	1
Total	27

In its **1978** report to Congress, Liability Arising Out of Immunization *Programs (U.S.* Ex. Br., DHEW, May 1978), HEW provided the data in table 19 on the number of vaccine-related lawsuits filed against manufacturers of vaccines between **1967** and **1977.** Altogether there were a total of **89** lawsuits filed in this period. In comparison to the numbers of claims and lawsuits currently pending from the single swine flu program, the total numbers of claims and lawsuits filed against manufacturers between 1967 and 1977 for other alleged vaccine-related injuries are small.

Table 19.—Vaccine-Related Lawsuits (1967-77)'

By status of lawsuit

Status	Number of suits
Pending	41
Settled	33
Dismissed or discounted	14
Jury verdicts for plaintiff	1
Total	89

By year of fifing

Year	Number of suits
1967	3
1968	2
1969	11
1970	11
1971	4
1972	5
1973	9
1974	**10**
1975	**12**
1976	**9**
1977	**13**
Total	89

[a]This table indicates lawsuits, not claims. Numbers are based on data supplied by five manufacturers who now produce or in the past produced measles, mumps, rubella, DPT, polio, and flu vaccines, and reflect liability experience with respect to these vaccines. The table does not show cases filed against Lederle Laboratories, the sole present manufacturer of oral polio vaccine, which did not provide data.

SOURCE: *Liability Arising Out of Immunization Programs: Final Report to Congress,* U.S. Department of Health, Education, and Welfare, 1978. (U.S Ex. Br., DHEW, 1978.)

Liability Experience of the Swine Flu Immunization Program

Because vaccine manufacturers were initially denied liability insurance by the insurance industry, the swine flu immunization program was delayed until Congress enacted legislation providing that all tort suits had to be brought against the Federal Government through a modification of the Federal Tort Claims Act. Under the legislation enacted, the National Swine Flu Immunization Program of 1976 (Public Law 94-380), the Government has a right of subrogation only against manufacturers and program participants who were negligent.

As described earlier, each of the four manufacturers of swine flu vaccine self-insured for $2.5 million, for a total of $l0 million. Each manufacturer also received a basic policy of $5 million and an excess policy of $50 million, for a total of $20 million for the basic policy and $200 million for the excess coverage. Total premiums on the $20 million basic policies were $2.4 million; on the $200 million excess policies, the premium was $6.25 million. Sixteen companies issued the basic policies, each insurance company's share ranging from 0.5 to l0 percent of the total. Thirty-seven companies issued the excess policies, each company's share ranging from 0.05 to 17.035 percent of teetotal.

Both the self-insurance costs and the premiums are considered business expenses of producing the vaccines, so the Federal Goverment funded both for a total of $l8.65 million. The premiums cannot be recovered, because they were the cost of providing the insurance. The $l0 million self-insurance or remaining portions of it will be returned to the Government with interest, providing either that the money is not used to pay claims costs, or that the manufacturers are shown to have been negligent in causing injury. This does not include the duty to arn, which had been assumedly the Federal Government.

Since the Government would be recovering up to the first $10 million in negligently proven cases from funds that it would recover from the manufacturers anyway, even if no subrogation suits were brought, there seems little incentive to bring such suits. While the insurance companies are theoretically responsible for $220 million-of paid-out claims (at a premium price of $8.65 million), none of this money will be paid out unless the injuries to be covered by these funds were negligently caused and the $10 million self-insurance fund is exhausted.

Of the 3,694 claims filed as of March 23, 1979, 1,045 allege Guillain-Barre Syndrome (GBS). Of the $3.351 billion in damages sought, **$952.5** million arises from GBS (Hamilton, 1979). In fact, both these sets of figures greatly overstate the actual situation because, first, some allegations of GBS are not credible, and second, in a lawsuit, just about any dollar figure can be alleged. The numbers cited include: 1) claims alleging vaccine-induced GBS by individuals in whom the syndrome began long after there would have been any relationship to the vaccine; 2) claims by individuals in whom GBS occurred, but who had not received the vaccine; and 3) frivolous claims such as an **$80,000** claim by a truck driver who alleges having contracted GBS as a result of transporting the vaccine, and a $1 million claim for "hives, etc.;" and 4) claims filed because the statute of limitations was approaching by individuals who suffered no injuries.

The 464 lawsuits that have been filed seek damages totaling **$504.3** million. The kinds of vaccine-related injuries alleged by persons bringing suits are shown in table **20.** Between **40** and **50** claims and suits have been settled to date, with payments of approximately $1 million. This amount does not include expenses related to handling these claims. Through fiscal year 1977, the Department of Justice estimated costs of processing and defending these claims at **$170,000** (Staats, 1979).

Table 20.—Alleged Injuries in Filed Lawsuits Arising From the Swine Flu Immunization Program

Type of injury alleged	Number of suits
Personal injury related to GBS	251
Death from GBS	25
Personal injury from other neurological injuries	67
Death from other neurological injuries	3
Personal injury from non-neurological injuries	95
Death from non-neurological injuries	23
Total	464

SOURCE Statement of Peter B Hamilton, Deputy ic Research, 1979 (Hamilton, 1979)

Finally, two observations should be noted. First, the swine flu program essentially was in effect from October to mid-December 1976. Two and one-half years later—out of total filed claims (including frivolous ones) of 3,694 and total filed suits of 464—only 40 to 50 claims have been settled. For vaccinees suffering real harm or death, therefore, compensation was not timely, has yet to be provided, or may not be provided. Second, the most significant injury and the one for which most compensation probably will be paid, i.e., Guillain-Barre Syndrome (GBS), resulted without apparent negligence in the manufacturing of the vaccine. Thus, when viewed as a compensation approach, the $8.65 million premium costs for liability insurance in all likelihood will provide no return.