

all four diseases. No clinical reactions of any serious consequence were reported or observed.

Quadrigen was then made available to selected members of the medical profession who were requested to comment on their use of the product. These "field trials" indicated a marked increase in reactions among patients given Quadrigen over those being given DPT and poliomyelitis vaccine. Of the severe reactions reported the first apparent instance in which death resulted was in March of 1959. It does not appear that Parke-Davis made any effort to determine the cause of the high incidence of reactions, and only a cursory attempt was made to investigate the cause of a death attributed to the use of Quadrigen.

[5] It appears to this Court that adequate tests performed prior to marketing would have disclosed the product's potency instability as well as the cause of greater incidence of reaction, especially in view of the number and seriousness of the reactions being reported. This was not a situation where an epidemic existed or where need justified the risk of premature marketing since products were already available to the medical profession that satisfactorily accomplished that Quadrigen was designed to do.

[6] Although all of the Government regulations and requirements had been satisfactorily met in the production and marketing of Quadrigen, the standards promulgated were minimal. The Defendant still owes a duty to warn of dangers of which it knew or should have known in the exercise of reasonable care. *Love v. Wolf*, 226 Cal.App.2d 378, 38 Cal.Rptr. 183. See also *Ebers v. General Chemical Co.*, 310 Mich. 261, 17 N.W. 2d 176; *Brown v. Globe Laboratories*, 165 Neb. 138, 84 N.W.2d 151; *Gonzalez v. Virginia-Carolina Chemical Company*, 239 F.Supp. 567 (DC, SC, 1965).

[7, 8] The danger must be reasonably foreseeable and the injury must be proximately caused by the failure to warn. *The Defendant knew or should have known that Quadrigen might cause encephalopathies in some users and to warn of the danger.*

[9] Though this may have been the first case in which encephalopathy² occurred after the administration of Quadrigen, it does not preclude the finding of foreseeability and negligence. See *Roberts v. United States*, 316 F.2d 489 (3 Cir., 1963).

The warning "Local reactions have been known to be more severe when the child is in the incubative stage of pertussis" on the insert accompanying the product, not only would not have warned members of the medical profession, but might have misled them to believe that only in cases where the child was in the incubative stage of pertussis would encephalitic symptoms occasionally occur.

There is no competent evidence in the entire record, medical or other, to show that Shane's condition arose out of or from any susceptibility or predisposition, nor that the child had any congenital disease or disorder or defect of any kind, nor that he had any allergy or idiosyncrasy, nor that heredity was a factor that might account for his present condition.

This Court being of the opinion that the Defendant is liable both for breach of an implied warranty and for negligence, it becomes unnecessary to forecast whether the Supreme Court of North Dakota would apply Sec. 402 A of the Restatement of Torts in a situation such as is here presented.

As pointed out in 2 *Frumer-Freidman*, Chapter 3, Sec. 16A [4]:

"Strict liability in tort in the products liability area is in its infancy. Therefore, the precise scope of the rule and the defenses thereto have not as yet been clearly defined. It is believed, however, that strict liability in tort is for the most part no different than strict liability in warranty, that similar results can be achieved under either theory. Comment *m* to § 402A of the Restatement of Torts seems to agree. It states:

"There is nothing in this section which would prevent any court from treating the rule stated as a matter of 'warranty' to the user or consumer."

"But in the next sentence it is pointed out that,

"if this is done, it should be recognized and understood that the 'warranty' is a very different kind of warranty from those usually found in the sale of goods, and that it is not subject to the various contract rules which have grown up to surround such sales."

"If a court does not require, *inter alia*, privity of contract, a sale, or notice of a breach of warranty, does it matter that the defendant is being held strictly liable in warranty rather than in tort? The answer seems obvious.

² Any degenerative disease of the brain.