

NEGLIGENCE

[4] The finding that Parke, Davis breached the implied warranty of merchantability and that Plaintiff's injuries were caused thereby does not preclude a finding that the Defendant is also chargeable with negligence in failing adequately to test the product and adequately to warn of the dangers inherent in its use.

The insert,¹ under "Reactions", reads:

"When given in accordance with suggested methods, local and systemic reactions following the administration of Quadrigen are usually mild. The incidence is usually no greater than is normally experienced with trivalent vaccine. Local reactions and fever of short duration may occur, however, and parents should be cautioned not to apply local treatment, such as wet dressings or heat. Any child who shows a febrile reaction should be kept quiet, should be offered water repeatedly and may be given one or more doses of aspirin as indicated. Occasionally, a residual induration or circumscribed nodule may persist for a week or more.

"In instances of more marked reaction, the immunization may be completed with monovalent antigens or other combinations of antigens.

"Local reactions have been known to be more severe when the child is in the incubative stage of pertussis. Encephalitic symptoms occasionally occur with acute pertussis though rarely with the use of the prophylactic vaccine. Such severe symptoms of the central nervous system include convulsions and lethargy. They may be followed by mental or physical manifestations, sometimes permanent, or even by death; but fortunately such reactions are extremely rare.

"The poliomyelitis vaccine components of Quadrigen contains small amounts of penicillin and streptomycin used in culturing the virus. During the adsorption process most of the antibiotic content is removed. In fact, residual antibiotics in the adsorbed product are usually not demonstrable by ordinary laboratory techniques. However, consideration should be given to the possibility of allergic reactions in individuals sensitive to these antibiotics and they should be tested for sensitivity where this possibility exists.

"The value and importance of maintaining continuing antibody levels in the infant in relation to the possibility of provocation of paralytic poliomyelitis by injection are self-evident. In modern clinical practice the administration of medication by hypodermic injection is generally accepted, and the hazard of thereby provoking poliomyelitis is increasing. If, however, basic immunity against poliomyelitis as evidenced by circulating antibody has been achieved, provocation is quite unlikely. Also, it should be noted that Quadrigen is considered *less* likely to provoke paralysis than is the trivalent product not containing poliomyelitis vaccine. With products not containing poliomyelitis antigen the patient is at some risk following each injection. With Quadrigen, on the other hand, after the first injection, basic immunity is developing and risk is greatly decreased for subsequent inoculations. Furthermore, if current recommendations are followed, the course of immunization will be started during the first 6 months of life under the protection of passive maternal antibody. However, the hazard of provocation in the face of an epidemic, particularly with the first dose of Quadrigen, cannot be ignored and the physician should exercise discretion, as with any injectable."

Clinical trials of Quadrigen prior to marketing were conducted by Dr. Clarence D. Barrett of Detroit beginning in 1956 and terminating in 1959. These tests used Quadrigen considered "fresh" in that the product was less than six months of age from the date of "pooling" of the poliomyelitis component with the DPT fraction. The trials were designed to determine antibody response and the earliest age in infancy at which immunization against poliomyelitis, diphtheria, tetanus and pertussis would be started, using a multiple antigen against

¹ Exhibit 46 is a tiny bottle of Quadrigen contained in a small cardboard box which included also Parke-Davis' insert showing what the product was designed to do. It is observed that the bottle itself contained no warning whatever, the cardboard box in which it was enclosed contained no warning whatever. The insert itself, a single sheet of paper containing in the main very small print, showed the nature of the product, when to immunize, dosage and administration, recall or booster doses, reactions and storage instructions, and was printed on a sheet measuring approximately four by seven inches, in which were compressed approximately 1,444 words, excluding the reference list on the bottom of the reverse side.