presumptuous to assume the mothers' ability to recognize a "reaction", to assume their possession of thermometers with which to determine whether their children were experiencing febrile reactions, to assume the availability of telephones with which to communicate the fact that a reaction had been suffered, and hypothesizing the fact that telephones were available, to assume the dependability of the mothers to make the requested reports. To allow any implication to be derived from this study with regard to the incidence of reactions following the inoculation of the children was negligence on the part of the defendant herein.[14]

[22] Quadrigen was then made available to selected members of the medical profession who were requested to comment on their experience with the product. Enough of the "field trials" indicated a marked increase in reactions among the patients given Quadrigen over those being given the triple antigen product with a separate inoculation of the poliomyelitis vaccine to have required Parke, Davis to experiment further with their newly-developed quardruple antigen. There were some reports indicating up to 75 per cent reactions in the children tested whereas other reports indicated that no reactions whatsoever had been suffered. Some of these contrasting reports involved experiences with the same lot of vaccine. In other reports which indicated reaction rates as low as 2 per cent, the "Remarks" sections indicated that "slight fever" was not reported, "high temperature" was designated "no reaction", and "103-degree temperature" designated as a "slight reaction". In one report, only temperature of 105 degrees qualified as a "reaction". Many of the reports which indicated unrealistically low reaction rates were from doctors who, by the nature of their covering letters, seemed primarily interested in obtaining more of the free vaccine. In addition, it is most significant that the deposition testimony of Dr. John E. Gajewski, employed during 1959 in Parke-Davis' Department of Clinical Investigation and thereafter as Assistant Director of Medical Correspondence, indicated that during the period between July 1959 and September 1961 the reported incidents of febrile reactions with Quadrigen showed more frequent and higher temperature elevations. Similarly, and in the face of the testimony of Dr. Feinberg and Dr. Lapin that it was a rare instance when the triple antigen vaccine produced a fever of 104 degrees, the results of a study conducted by Dr. Sauer, the inventor of the original pertussis vaccine, submitted for publication on June 10, 1959, and published in the fall of that year, evidenced that of the large groups of infants inoculated with Quadrigen 5 per cent reacted with temperatures of 104 degrees and as much as 2 per cent reacted with temperatures of 105 degrees. All in all, it appears to this Court that there existed a sufficient number of both unrealistic and conflicting reports from the field to have required Parke-Davis to take a serious second look at its product before placing it on the market.

Of particular note was Parke-Davis' cursory attempt to investigate the cause of a reported death attributed by the treating physician to his use of Quadrigen. Although the autopsy report, received subsequently by Parke, Davis, stated that the immediate cause of death was bronchial pneumonia, the hospital record revealed that the patient had exhibited high fever, convulsions, opisthotonus, vomiting and lethargy several hours after a Quadrigen inoculation. The conclusion of the autopsy report is not necessarily inconsistent with a finding that the child experienced a pertussis encephalopathy prior to his death in that although bronchial pneumonia may have been the immediate cause of the infant's expiration, such condition can frequently be brought about by some other condition, which, in this case, in light of the small hemorrhages found in the subarachnoid portion of the brain, could well have been the vaccinal encephalopathy as was originally diagnosed. Nevertheless, there should have been an immediate and thorough investigation conducted by Parke-Davis into the possible connection between the Quadrigen inoculation and the infant's death two days subsequent thereto, especially in view of the fact that the quadruple antigen was soon to be released on the commercial market. This was not done nor did Parke-Davis attempt to notify the NIH of the possible existence of a Quadrigen-related death.[15]

[14] Although a separate study had been conducted by Dr. Barrett in 1958, using fresh experimental vaccine and employing stricter controls over the diagnostic and reporting procedures, this study showed increased febrile reactions with the use of Quadrigen, and was not the principal study relied upon in support of the license application. To the contrary, it was the Detroit study discussed in the accompanying text which Parke-Davis attached to its application and upon which it relied most heavily.

[15] See note 12, supra.