correspondence between Parke-Davis and DBS during the year 1959 that beginning with the very first experimental lots of Quadrigen submitted to DBS for testing, i.e., Lots X–7513 and X–7514, Parke-Davis was having difficulty obtaining satisfactory potency values. On January 9, 1959, Dr. Workman of DBS wrote to Parke-Davis that:

"Our potency assays on the pertussis component of this lot (X–7514) showed values of only 7.9 and 3.8 units per total immunizing dose and thereby suggest the potency of the pertussis component is too low. In view of the extreme difference between your and our results, however, we would be willing to give further consideration to this lot if you are willing to retest. * * *" Plaintiffs' Exh. 3.

Letters of a similar nature were written concerning Lots 049033, 059294, 049032, 049034, 054044, 055961, 051639, 058836 and others, which lots initially produced test results between 2.7 and 7.25 protective units per THD. Some of these lots were re-tested and eventually withdrawn from processing.

Evidencing Parke-Davis' dilemma, on March 5, 1969, only 4 months prior to the time Quadrigen was commercially marketed, George D. Brigham, Director of the Biological Division of Parke-Davis, wrote a letter to Dr. Workman regarding Lot X–7514:

"As you know from recent reports, we have been having difficulties in obtaining satisfactory potency values in our preliminary production lots of Quadrigen. In view of these results, we are planning to increase the H. pertussis content to 20 opacity units instead of 15 opacity units as was originally intended." Plaintiffs' Exh. 3.

In a follow-up letter dated March 13, 1959, from Dr. Brigham to Dr. Workman, it was further stated:

"You indicate in your letter that you are concerned with the low values we have been obtaining in the pertussis component of our multiple antigens. As far as we are aware, *our only problem seems to be with the quadruple antigens i.e. except for an occasional lower than usual result, our other pertussis-containing products are given satisfactory potency tests.* Naturally, we have been concerned with the low pertussis test results in Quadrigen and as indicated in earlier correspondence, we plan to increase the concentration of organisms to a minimum of 20 opacity units per cc. as an immediate step to correct the situation." Plaintiffs' Exh. 3D. (Emphasis added.)

It seems significant to this Court that Parke-Davis, realizing the inherent potential of the pertusis component for causing fatal reactions, and faced with the unique problem of exceptional deficiencies in the potency values of its premarket lots, simply sought to strengthen the pertussis component without considering the possible existence of a defect in the combination itself. This proposed solution, however, also presented problems. On June 4, 1959, Dr. Brigham wrote Dr. Workman with reference to Lot 52230, the first commercial lot:

"We noted the *unusually high value obtained in the pertussis vaccine potency test.* In view of these high results we conducted a re-test on thi slot. A supplemental protocol summarizing the test is attached indicating 21.5 units per total human dose. This confirms our thought that a re-test would probably show average results within an acceptable range." Plaintiffs: Exh. 3F. (Emphasis added.)

It appears clear to this Court that Parke-Davis in its rush to commercialization of its product either overlooked or neglected to consider the possibility that Quadrigen was too unstable a vaccine and therefore too unpredictable to be released on the market at that time.

[19, 20] Parke-Davis was equally negligent in failing to test its product under market conditions. Inasmuch as it was well known that variations in temperature could have marked effects on the safety and effectiveness of a vaccine, and it was also known, as testified to by Dr. McLean of Parke-Davis, that many of the lots could not be shipped under refrigerated or storage conditions, it was incumbent upon Parke-Davis to subject their pre-release lots to those foreseeable variations in temperature to which their product would be exposed prior to the point of inoculation so as to insure that this exposure would not produce deleterious effects. This was not done. As it developed, tests taken in 1960 by the Massachusetts Department of Health and subsequently by DBS, indicated that although samples of the quadruple antigen vaccine which were held in storage under refrigerated conditions showed no perceptible loss of potency, those purchased on the market revealed a loss of potency below the minimum requirements for a pertussis vaccine. Although events subsequent to the injury herein cannot be considered in determining the manufacturer's negligence, it could not have been