

gen" commenced in July of 1959 with Quadrigen having an expiration dating period of twelve months after manufacture, and six months after issue.

On April 13, 1961, the Division of Biologics Standards (DBS) of the National Institutes of Health (NIH) issued a memorandum to manufacturers of multiple antigen products containing pertussis and poliomyelitis vaccines that the products could contain no less than 14 units of pertussis potency (previously 12) and be labeled with an expiration date of six months after manufacture, and four months after issue. This change was necessitated when studies indicated a significant loss of pertussis potency in quadruple antigen vaccines after marketing. No comparable loss of pertussis potency had been found in triple antigen products not containing poliomyelitis vaccine.

DBS then determined that some lots of inactivated poliomyelitis vaccine contained a live vacuolating agent (SV 40), from the monkey kidney cells on which poliomyelitis virus was grown. Resultantly, a memorandum was issued May 20th, 1961, requiring the subsequent lots of vaccines containing components grown on monkey kidney cells be free of live SV 40.

On August 23, 1961, DBS issued a regulation or letter placing a new toxicity test requirement on all products containing pertussis vaccines; and on September 21, 1961, provided a new reference vaccine for the pertussis potency test which effected an additional increase in the potency requirement. The new toxicity test required additional treatment of the pertussis component. This treatment adversely affected the pertussis potency to the extent that the potency requirement could not consistently be met. Various articles appearing in medical literature indicated that the poliomyelitis component and the preservative being used might be the cause of the instability in multiple vaccines. Production and marketing of "Quadrigen" was finally halted in November, 1962.

Shane Stromsodt was born in Grand Forks, North Dakota, May 24th, 1959. His mother's pregnancy and his birth were entirely normal and uneventful, according to her physician, Dr. John H. Graham. On August 26th, 1959, Shane was taken for examination to Dr. Graham's office; and on that date Quadrigen was administered to him intermuscularly. The infant seemed to suffer no ill effects, and his mother recalled no reaction which caused her any alarm. On October 1, 1959, some five weeks later, Shane was again taken to Dr. Graham's office, examined and once more Quadrigen was injected into the child's body, between four and five o'clock that afternoon. Mrs. Stromsodt bundled up the child and took him to the family car in which her husband, Robert, was waiting. She reached the car some five or ten minutes after Shane had received the Quadrigen, removed the blankets from about the child, and noticed a fine red rash on his face.

The Stromsodts drove to their home where Shane was undressed, and the rash was noticed on his face and the upper part of his body. Mrs. Stromsodt gave Shane his bottle immediately after the family had had their meal. Shane promptly vomited the bottle's contents, something he had never done before. Mrs. Stromsodt laid the child on the bed and testified the baby had a "seizure." She described his eyes as rolling back in his head, his heels and head dug into the bed, his back arched and his fingers grasping. Mrs. Stromsodt believes the convulsion may have lasted five minutes. Having no idea of what was happening, she watched Shane, and when the seizure was over, telephoned Dr. Graham. She described to the Doctor what had happened to Shane and added that she thought the baby had the measles. The Doctor, however, thought it was a reaction from the shot given Shane and instructed Mrs. Stromsodt to watch him and to telephone next morning if the child was no better. Shane seemed normal the next morning, and Mrs. Stromsodt did not call the Doctor nor see him again until November 4, 1959, when the baby was taken to Dr. Graham's office for a third shot. Shane slept most of the next two days following the initial seizure, but he had two more convulsive attacks after the first one, both of which were prior to November 4, 1959.

When Shane was taken to Dr. Graham's office, November 4, 1959, Mrs. Stromsodt recited his condition to the Doctor. She told him the baby had suffered from two "spells" since the last Quadrigen shot, that he had been sleeping more and "it seemed like he wasn't doing anything any more." In short, the child was not progressing normally. The Doctor concluded that Shane should not be given Quadrigen because of the severe reaction suffered by the infant following the October 1 injection of that drug, and thus, on his third trip Shane was given Triogen which contained diphtheria toxoid, pertussis vaccine and tetanus toxoid (DPT). Poliomyelitis vaccine was not given on this date.

Shane continued to have difficulties which stemmed from the October 1st introduction of Quadrigen into his body and repeatedly had seizures until January, 1960. Mrs. Stromsodt testified the baby was making no progress. On January