STATEMENT TO CIVIL CASE REGARDING STEEN EILERT SKATVEDT BERNER (SESB)

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BACKGROUND FOR STATEMENT

Medical record from Child Department, Rikshospitalet, Oslo 24th November 2003 covering prenatal record

Conversation with Gunn Karin Skatvedt, mother to SESB, in Oslo on 24th November 2003

Conversation with Svein Erik Berner, father to SESB, in Oslo on 24th November 2003

Review of medical record on SESB from Health Centre, Asker Community, on 24th November 2003

Review of MRI performed on 5th January 2005, on 12th January 2004

Clinical examination of SESB, performed in Oslo

2.1 DESCRIPTION OF MEDICAL DATA

Predisposition, pregnancy and delivery

SESB was born on 26th July 1981 at Aker Sykehus. It was second pregnancy and first delivery. Apart from tendency to hip joint dysplasia in father's family no predispositions to disease are known, this includes epilepsy and cardiac disorders. Later mother had a new pregnancy and delivered a still healthy boy in 1986. Pregnancy with SESB was uneventful until gestational week 36, when mother delivered spontaneously. SESB was born with normal head position; he was taken with forceps due to a short period of reduced heart beats. No meconium stain. Apgar score was 6/1 (1 for breathing, 1 for muscle tone, 1 for reaction at suction and 1 for skin colour with cyanotic colour of arms and legs). Later Apgar score was rated 9/5 (1 for skin

colour). Clinical examination showed fetal development at and in accordance with 36 weeks gestational age. No malformations were detected. Birth weight was 3050 gram, length 49 cm and head circumference 36 cm. Placenta showed signs of starting partial detachment. Otherwise, placenta was normal

New born period

SESB was sucking less forcefully and was given a mixture of mothers milk and breast milk substitute. On 30th July haemoglobin was 17.9 g/l (normal 14.5-22.5); on 31st July 16.3 g/l. Bilirubin was correspondingly 180 and 181, which was normal. Due to reduced tone and insufficient sucking SESB was referred to the paediatric department at Aker Sykehus on 2nd August. Amniotic fluid with blood was suck from the ventricle and he then ate sufficiently and otherwise was found healthy. Bilirubin was 161 and haemoglobin 16.1 – 14.6 g/l. No signs of infection. SESB was discharged from hospital in good health on 4th August 1981 at an age of 9 days. No weight or length records from time of discharge

From 4th August to 29th October 1981 (day of vaccination)

By his parents SESB was perceived as a boy with normal reactions. The same opinion was held at the Health Centre where he was evaluated on the 10th of September and on the 29th of October – which was the day of vaccination. He had shown normal growth parameters – length, weight and head circumference. On 29th October length was 59 cm, weight 5720 gram and head circumference 43 cm. Both parents had good eye-contact with him, he was babbling and followed persons and objects with his eyes

CONCLUSION

Health of SESB before vaccination was quite normal. There was no sequel from birth at gestational week 36 or a slight lack of oxygen at birth

On day of vaccination 29th October 1981

Vaccine was injected in the right arm at 10.45 am. Pertussis, diphtheria and tetanus vaccine, 0.5 ml, batch 6280. Father told the medical officer, that he thought that SESB was pale and had slight common cold. From medical records at the Health Centre it was stated that SESB was awake, but a little pale. Tonsils were found increased in size. Blood percent was 71.5 (normal 62 – 82%, and as such value measured was within normal limits for age 3 months).

SESB was crying a few minutes after vaccination, but was otherwise normal. There was no swelling at or around site of injection, there was no resulting fever neither on day of vaccination nor during ensuing days.

From 29th October to 1st November on morning

According to both parents SESB had no problems. There were no periods of crying, no fever or other signs of disease. He is happy, eats well and eye contact is normal.

CONCLUSION

There were no reactions to vaccination on the first 3 days and nights (69 hours)

On 1st November 1981 (regarding description of events at home before admission see also medical report from admission on 1st November 1981)

Independent on each other the parents concurrently describe that daily routines of SESB were took place in firm pattern regarding meals every 3 hours and they therefore had a clear picture of what had happened

At 7 am father prepared a meal for SESB. SESB was happy, was without signs of disturbed functions and got his meal without problems.

He got clean clothes and a new diaper and was as usual put to sleep again. At 8 am he was placed in a prone position in his pram. The pram was positioned on a covered veranda, outside an open door to the living room. It was around +1 degree Celsius outside. According to schedule SESB should receive his next meal at 10 am. Father was in the garden, mother was inside. Nothing abnormal was heard from the pram. At 9.30 – 10 am mother got anxious for SESB and when looking to SESB in his pram she finds him silent and with blue lips. He was thus found in prone position.

Father arrives instantly and finds SESB without breathing. He has pale and blue colour of hands, face and lips and body stiffness is felt (father tells that he is especially familiar with resuscitation as he holds diving courses in connection with his diving company). Father gives SESB 3 – 4 mouth-to-mouth breaths and his breathing is resumed. Lips are still blue and pulse felt weak, but breathing continues without support. Parents call an ambulance.

The ambulance arrives after 15 minutes (but mother is uncertain on time elapsed) – according to father 45 minutes (he also is uncertain on time data). The ambulance rushes SESB to local hospital (Baerum) where, according to parents, stays for 30 – 60 minutes. According to

parents, doctors find him very sick and remit him to Rikshospitalet in Oslo where, according to parents, he arrives at 0.30 pm. There are no medical records from Baerum, only paper of refer. According to medical records from Rikshospitalet SESB at Baerum is described as very pale and with fast breathing. There are no convulsions.

There is no precise marking of time of arrival at Rikshospitalet. But it is stated that SESB is examined by a medical doctor at 1.30 pm and that he is treated with Fenemal (Phenobarbital) 50 mg intravenously at 2 pm.

At 1.30 pm he is noticed to be very pale. Lips are cyanotic and the fingers of SESB have bad colour too. The anterior fontanels is found without increased tension and thus normal. His breathing is increased and laboured as intercostals retractions are seen, however at auscultation no abnormal sounds are heard. His body is limp, reflexes of lower extremities are increased. He is shivering and irritable. On suspicion of sepsis/meningitis a lumbar puncture is immediately performed. Spinal fluid contains increased amount of protein, there are no inflammatory cells found and meningitis was thus quickly excluded. From blood specimen, urine culture, stool culture blood culture no signs of infection were detected. Body temperature was 37.5 degrees Celsius, which is normal. At arrival to Rikshospitalet a metabolic acidosis was detected, which means increased acidosis of blood.

Ensuing days at Rikshospitalet

Upon arrival a metabolic acidosis was detected. The metabolic acidosis remained for some days (at measurement on 3rd November, but not on 9th of November). According to blood specimen a temporary affection of liver and kidneys with increased metabolic products were detected. A microscopy blood in urine was found together with blood in stool as examined by Ham's test.

From nurse records a description of the condition of SESB is available. He was very limb on the first days after admission and one had no eye contact with him. Periods in a limb condition were interrupted by long periods with screaming with high sounds. On the 3rd of November SESB had 19 seizures lasting up to 30 minutes at a time – seizures were primary located to left arm and left side of face. Seizures disappeared after around 24 hours and after administering 2 anticonvulsive medications intravenously - Fenemal (Phenobarbital) and Rivotril (Clonazepam). From the 4th November and onward no seizures were observed. On the 4th of November SESB is continuously very limb, but from the 5th November he is shortly more awake and during ensuing days he is able to babble and smile a little. From 6th November he is able to eat himself (bottle fed).

On 3rd November EEG showed continuous epileptic activity over right hemisphere, especially over right temporal region. On 9th November EEG was significantly better as epileptic activity

was no longer registered. However, there still was slight asymmetry of EEG recordings and the electric activity over the right side of the brain was still not quite normal. At 17th November EEG was normal.

Screenings for metabolic disorders were normal and no signs of congenital infections were found. X-rays of lungs were normal (1st November). X-rays of kidneys (6th November) showed slight increase in seize (probably due to fluid accumulation) and reduced function was detected.

During stay at Rikshospitalet his condition got better and he was discharged 19th November to his home. However, he still was limb to some extend, but doctors found good eye contact, he was smiling and bubbling. New spinal fluid examination showed normal values at 13th November – accordingly spinal fluid protein was now normal. All blood analyses related to kidney and liver functions were likewise normalized. CT of the brain performed 12th November increased size of posterior parts of lateral ventricles (CT was not available any longer due to age)

According to medical record on discharge at 20th November 1981 the following was concluded:

We interpreted the disease as encephalitis, most likely do to triple vaccination given 2 days before admission. When the parents found him sick at home, we believe that he had a postictal phase, most likely following a seizure of long duration. The findings of temporarily changed EEG and temporarily increased spinal fluid protein could fit the interpretation of encephalitis. Also he had affection of multiple organs with pathologic hepatic and renal analyses, together with a moderate metabolic acidosis. Diagnosis: 323 Encephalitis

First month following discharge

SESB was seen by doctors at 7th December. He then had good contact, he was sparkling and smiling. He used both arms and again was able to hold head himself. At 7th December doctors at Rikshospitalet found that SESB had normal motor and mental development. Parents however felt differently and said by common assent that he had marked changes compared to his condition before admission to hospital, especially with regard to vision. Previously it was easy gain eye contact with him, now it was almost impossible to gain eye contact. His eye movements were rough and he quickly had squint. Eye axes were parallel no longer (we have seen photographs of SESB before and after hospital stay, and changes as declared by parents are confirmed by us)

Development the ensuing years

SESB was followed in an out-patient setting at Rikshospitalet and the doctor found normal development during his first year of living. He was thus able to walk alone by 13 months of age and also started talking in time. At all times parents were suspicious of reduced vision but

some years elapsed before the suspicion was taken seriously. In many years the symptoms were interpreted as a reduced ability to analyse vision input. But later it was found that SESB had a marked reduced vision with an ability of 1/60. As time passed it was also detected that SESB had difficulties of perception in various fields, as well as delayed development of social and language abilities together with difficulties of balance. Previous normal development of head circumference was exchanged with a reduced rate of growth of head circumference.
Parents tells, that SESB had need of extra support during preschool years, that he later attended special school program and to-day works in sheltered facilities

Other diseases

On 3rd September 1984 SESB fell onto a playground rack and he had a temporary palsy of left face. This was interpreted as a direct trauma to the facial nerve in the cheek. CT 6th September 1984 showed no acute changes. But marked increased seize of ventricles (as an expression of atrophy) and changes in grey matter, most pronounced in hindbrain where centre for vision is localized (pictures could not be seen as they were destroyed due to age).

On 30th September 1993 SESB is passenger in a car run into from behind. SESB had neck pain and temporary tilting of head. X-ray examinations revealed no fractures. Actually, SESB has no complains related to the event in mention.

CONCLUSION

Traumas and diseases following the initial event has had no influence on actual level of function

MEDICAL REPORT ON STEN EILERT SKATVEDT BERNER (SESB) AND CLINICAL OBSERVATION IN HIS FATHER'S HOME ON THE 24th NOVEMBER 2003 AND CLINICAL EXAMINATION AT RIKSHOSPITALET, OSLO, ON THE 12th JANUARY 2004.

SESB is working 5 – 6 hours daily in sheltered workshop facilities. During a time period of 4 weeks SESB Is living one week with his father, one week with his mother, one week in relief home facilities and one week with his father's sister. SESB needs adult support for toilet visits. He is not always noticing adults around him. He needs support for undressing and dressing. SESB is not able to care for himself in traffic situations and needs adult accompany. When eating, food is served and he is able to eat with a spoon in one hand. He is not able to use fork and knife. Thus, SESB needs constant adult support and he is not able to go about alone.

While observed in his father's home on the 24th November 2003 he is listening to music from a record player and he tries to sing along. SESB expresses himself in the Norwegian language on one is able to communicate with him as long as factual data are communicated. It is however difficult to communicate abstract data

SESB helps setting the table, however performed in slow and unsteady motion guided by his slim and peripheral vision. His movements are stereotypic while at times hopping along laughing. His father tries to get him add numbers without success

SESB appears cared for well, he is harmonious and happy while at the same time being childish in his behaviour. SESB does not show signs of psychosis

SESB is also examined on the 24th November 2003 at Rikshospitalet, Oslo. SESB had no signs of malformation or dysmorphic features resembling a chromosomal abnormality or a genetic syndrome. Head circumference was 55.5 cm, height 170 cm and weight 76.5 kg. He seems healthy. He suffers from acne on the face, breast and back

Examination of the cranial nerves showed parallel eye positions. He was not able to focus and one could not obtain eye contact with him. Continuous nystagmus was observed. Pupils reacted normally to light. All other cranial nerve functions were normal

His palate was high-arched and narrow. Teeth were irregular and crowded. He had no caries. Clinical examination of neck, ears, lungs, heart, abdomen, and genitals was unremarkable
He had an asymmetric posture and had a minor convex scoliosis. Muscle mass was slightly reduced on right side of thorax, neck and back. Muscle strength was normal and equal on both sides with regard to shoulders and elbows. Muscle strength was reduced to a moderate degree in hands. This reduction was most pronounced on the right side. Slightly dyscordinated movements of right hand were observed. Senses to touch were normal. It was not possible to elicit tendon reflexes on the arms

Right leg and foot likewise had slight less muscle mass. Circumference of fibula was 39 cm on right side and 40 cm on the left. Right food was ½ cm shorter than the opposite. Right foot had a slight adducted position while walking and standing. Muscle strength was good related to hips, knees and ankles. Right patellar and Achilles tendon reflexes were increased. Areas for eliciting tendon reflexes were not expanded. Babinski reflex was present on right side. Movements of walking were normal, however with slight asymmetry right side. SESB was

capable of walking on toe and heel positions and to jump on one leg at a time. While exercising on the movements in mention his right elbow was held in a flexed position. Running was slow and again with right elbow flexed

All exercises took time for him to perform and were in slow motion. SESB had difficulties planning motor movements – like dyspraxic performance. He was initiating movements upon instructions with latency. SESB was not able to initiate himself but had to be guided step by step

SESB performed activities in a less spontaneous fashion and he had long latency initiating and performing tasks. Likewise he showed great difficulties planning motor movements. Added to difficulties were signs of slight palsy on right (slight right hemiparesis)

MRI on 5th January 2004 shows a global substance reduction, especially in paritooccipital areas and frontal areas bilaterally. Both side ventricles are increased in size, especially posterior parts. According to T2 and flair sequences high resolution changes are seen in parenchyma close to coarse sulci as an expression of gliosis. Cerebellum is likewise of rough structure but much less as seen supratentorially. Brain stem is normal. Corpus callosum I formet in its full length, but is slightly slim. Tectum and aqueduct are normal. Cisterna magna are increased in size, there is no hernitation of tonsils. No signs of malformations.

MRI diagnosis: Encephalomalasia with pronounced loss of substance, especially at bilateral parietooccipital areas (signed Baard Nedregaard)

MRI thus shows that the brain is reduced in size in a global manner, but most pronounced at posterior parts (where centre of vision is situated) and at frontal parts (where among others centres for initiative and motor planning are localized). In remaining nervous tissue scar tissue (gliosis) has been formed. The cerebellum is not affected and medulla oblongata is almost normal. No congenital abnormalities are detected

CONCLUSION ON ACTUAL HEALTH CONDITION OF STEN EILERT SKATVEDT BERNER

Sten Eilert Skatvedt Berner suffers from a moderate to severe generalised developmental retardation. He is in need of constant support from adults around him. His vision is severely reduced, primarily due to damage to visual cortical areas of the brain. His movements are performed with reduced spontaneity and he has great difficulty planning motor activities.

2.2 QUESTIONS ON CAUSAL CONNECTIONS

REVIEW AND CONCLUSION ON EVENTS CONNECTED TO VACCINATION

There were no reactions during three 24 hour periods (69 hours) after vaccination and no sign of disease or affection from vaccination when SESB was put to sleep on the 1st November 1981 at 8 am. 1½ hours later SESB was found and had no respiration, he was pale, stiff, and had bluish colour of nails and lips. Respiration resumed quickly due to active and quick intervention by the father, but for some hours afterwards SESB is pale and has bluish colour of lips.

Blood specimen taken at arrival to hospital and the ensuing days showed that, prior to admission, a considerable reduced oxygenation of blood (affected acid base, prolonged affection of liver, kidneys and bowel functions together with increased protein in spinal fluid). Prior to admission or in connection with admission to hospital no fever was detected, apart from a temperature of 38.0 degrees Celsius on the day (3rd November 1981) where SESB had longstanding seizures (a slight increased temperature might be caused by seizures). EEG (continuous right-sided epileptic activity) on 3rd November 1981 is in accordance with the finding that, at the same day, SESB had almost constant left-sided seizures. Later EEG normalized and later SESB had no seizures

In connection with the examinations no signs of meningitis could be detected or other infection, metabolic disorder or signs of some hidden congenital disorder such as congenital malformation of the brain

Changes of consciousness, increased protein in spinal fluid and convulsions, which SESB had initially, might be seen in connection with encephalitis, but EEG changes were not in accordance herewith because both hemisphere then should have been engaged and not only changes in the right hemisphere. Nor had SESB increased temperature or inflammatory cells in spinal fluid, which otherwise is common in connection with encephalitis, especially so if encephalitis should have been responsible for a disorder of such a degree of seriousness as observed in the case of SESB

Clinical course, laboratory data and CT are fully in accordance with the fact that on 1st November 1981 SESB had what could have resulted in sudden death of infancy (idiopathic ALTE (Kahn A. Recommended clinical evaluation of infants with apparent life-threatening event (Consensus document of the European Society for the study and prevention of infant death 2003. Eur J Pediatr 2004; 163: 108-15) if not the father had done resuscitation as described. In that connection special weight is placed on laboratory data from the first days at

Rikshospitalet that indicate the presence of a considerable hypoxia prior to admission (affected oxygenation and circulation of blood). CT and, most clearly, recent MRI in accordance herewith shows changes that might be interpreted as changes following asphyxia diffusely in the brain, and to a special high degree related to visual centre at posterior part of brain and frontal lobes

Moreover, according to laboratory data and EEG and CT and MRI, there have been no signs of other competing or causative disorders. In that connection it is important to underline, that neither before nor after admission in November 1981 SESB showed signs of congenital disorder of airways, heart, brain or metabolic systems

In spite of the fact that in medical records, in connection with discharge from hospital in November 1981, it is stated that: “We have perceived the condition as encephalitis most likely due to triple vaccination” the clinical course is not compatible with the condition connected to pertussis, called encephalopathy, that occurs from 1 to 24 hours after vaccination

This evaluation is done with a background in present knowledge of side effects after pertussis vaccination as compared to knowledge gained in 1981

As background for the statement we present

- A short review of report from Division of Health Promotion and Disease Prevention, Institute of Medicine, published by National Academy Press, Washington DC 1981: Adverse effects of pertussis and rubella vaccines. A report of the Committee to review the adverse consequences of pertussis and rubella vaccines. Edited by Howson CP, Howe CJ, Fineberg HV. The report is hereafter named IOM 1991

- An updated review of studies performed during the years 1991 – 2003, a time period when one of the specialists had a continuous view on the actual field together with major Swedish tests of pertussis vaccines, performed in cooperation with American health authorities (attached is: Olin P. Efficacy trial of acellular pertussis vaccines. Final report 14th January 2004)

SHORT HISTORY REGARDING THE DEBATE ON SERIOUS EVENTS FOLLOWING PERTUSSIS VACCINATION – FROM IOM PAGE 18 - 19

The Danish medical doctor Madsen, Statens Seruminstitut, Copenhagen was the first person to describe the use of whole cell pertussis vaccination on a large scale (Madsen T. Whooping cough: its bacteriology, diagnosis, prevention and treatment. Boston Med Surg J 1925;192:50-60). Due to his vaccine, two epidemics of whooping cough on Faroe Island could be controlled.

He reported on two deaths within 48 hours after vaccination (Madsen T. Vaccination against whooping cough. JAMA 1933101:187-8). This was the first report on serious events following pertussis vaccination

To the end of the 1940 period the first reports on irreversible or chronic damages following pertussis vaccination were published (Brody M, Sorley RG. Neurological complications following administration of pertussis vaccines, Byers RK, Moll FC. Encephalopathies following profylactic pertussis vaccination. Pediatrics 1948;1:437-57). Brody ach Sorley described only one case – which however led to the recommendation that pertussis vaccine was not given to children with known chronic disorder

In year 1974 the safety of pertussis vaccine was questioned in the British popular press following review of a study which hinted to reactions to vaccination (Kulenkampff M, Schwartzman JS, Wilson J. Neurological complications of pertussis inocculation. Arch Dis Child 1974;49:46-9) and an association of parents who had children suffering from brain damage was formed (Alderslade R, Bellman MH, Rawson NSB, Ross EM, Miller DL. The National Childhood Encephalopathy Study: a report on 1000 cases of serious neurological in infants and young children from the NCES research team. In: Whooping Cough: Reports from the committee on the safety of medicines and the joint commitee on vaccination and immunisation. Department of Health and Social Security. London: Her Majesty's Stationary Office, 1981). Between 1974 and 1978 the number of children vaccinated in Great Britain was reduced from 80 to 30 percent. In certain areas even down to 9 percent (Pertussis vaccine (editorial) Brit Med J 1981,282:1563-4). An epidemic of whooping cough followed in 1997 to 79 with more than 100 000 reported cases of whooping cough and 36 deaths

The debate on the safety of pertussis vaccine reached the US in 1982 when the TV programme "DPT: Vaccine roulette" was shown the first time by a NBC local programme WRC-TV in Washington DC. The program showed children with severe damages that were told to be caused by pertussis vaccine (Permanent brain damage and pertussis vaccination: is the end of the saga in sight? Vaccine 1989;7:199-210; Koplan JP, Hinman AH. Decision analysis, public policy, and pertussis: are they compatible? Medical Decision Making 1987;7:72-3). Following that programme an interest group was founded: Dissatisfied Parents Together. The interest group demanded research to develop a safer pertussis vaccine and mandatory registration on serious events. Some in the interest group demanded whole cell vaccine to be taken out of use (Coulter HL, Fischer BL. DPT. A shot in the dark. San Diego: Harcourt Brace Jovanovich 1985)

The American government gave Institute of Medicine the task to go through all scientific literature and other sources on possible events following vaccination with whooping cough and rubella – both vaccines were mandatory according to an agreement between American states. In 1989 IOM added the committee (Committee to review the adverse consequences of pertussis and rubella vaccines) that in 1991 published the IOM 1991 report

Chapter 4 in IOM 1991 penetrates in detail neurological damages following pertussis vaccination. On page 86 - 124 encephalopathy was dealt with. First, the report is considering what is meant by the term encephalopathy:

Encephalopathy has been used in literature to characterize a set of symptoms and findings that point to generalised disturbance of brain functions. The concept of encephalopathy is used in broad terms to describe a disorder located to the brain. A more precise medical definition of encephalopathy is “a diffuse disturbance of brain function due to a generalized or multi focal damage that leads to a global disturbance of neurological functions”. In the British study mentioned above NCES (Adlerslade et al 1981) the terms acute or subacute encephalitis, encephalomyelitis and encephalopathy are used to describe a broad spectrum of clinical symptoms which include ”changes of consciousness, confusion, irritability, changes of behaviour, periods of screaming, neck stiffness, seizures, disturbances of seeing, hearing speech together with disruption of motor and sensor functions. The term encephalopathy is used in NCES when the cause of cerebral disturbance is not clear from the beginning. Thus, the term encephalopathy is a vague one which has been used to describe some form of neurological disturbance of the brain. Acute encephalopathy is used when a clinical picture of sudden seizures, disturbance of consciousness occur together with disruption of motor and sensor functions (IOM 1991 page 86). The IOM report defined encephalopathy as a united term of encephalopathy, encephalitis or encephalomyelitis. In case a child had not recovered from an acute condition the terms chronic or irreversible encephalitis are used

IOM 1991 points to the fact (same issue page 87) that a considerable variation in clinical picture which doctors had described as “encephalopathy induced by pertussis vaccination” or encephalopathy following pertussis vaccination”. A clinical picture perceived as “typical” (“most classic”) contains a major grand mal seizure (generalized tonic and clonic seizures), usually in connection with fever and occurring within 48 hours after the first, second or third dose of pertussis vaccination has been given (Cherry JD, Brunell PA, Golden GS, Karzon DT. Report of the task force on pertussis and pertussis immunization. Pediatrics 1988;81:939-984)

The definitions in mention are related to the picture of encephalopathy that was build up on the basis of reports on one or some cases that were published in 1947 to 1980 (IOM 1991 page 91-95). During 1980 – 1990 a number of population based studies were undertaken in USA and England (IOM 1991, Table 4.2, page 96) reporting 5 cases that had temporary or permanent neurological disturbances beginning within 48 hours following vaccination

In major English case-control studies NCES (Alderslade et al 1981) a risk period of 7 days after vaccination was studied (Miller DL, Ross EM, Alderslade R, Bellman MH, Rawson NSB. In IOM 1991, page 101 & tables 4.3 & 4.4. An increased risk of developing encephalopathy was found. The relative risk was 3.3 (95% confidence interval 1.4-8.2)

The NCES studies have been object for in depth critical analyses that to a great extend are dealt with in the IOM report from 1991. The IOM report concludes that data are in accordance with the fact that there exists a relationship between DTP vaccine and acute encephalitis* and that risk is in accordance with what NCES mentions: 0.0 to 10.5 per million vaccinations. According to the IOM report there is no sufficient data to document a causal relationship between DTP and lasting neurological damage

* It was not the purpose of the IOM committee to evaluate febrile convulsions or seizures without fever. But they did evaluate these factors due to the fact, that the conditions in mention were connected to the term encephalopathy according to some researchers. IOM concluded, that a causal relationship between DTP and febrile seizures was found. But that no relationship to seizures without fever could be documented

NCES was completed with a long term follow-up study (Miller D, Madge N, Daimond J, Wadsworth J, Ross E. Pertussis immunisation and serious acute neurological illness in children. Brit Med J 1993;307:1171-6). Miller et al. concluded in 1993: A child that died or had a lasting state of neurological dysfunction had a relative risk of 5.5 (95% confidence interval 1.6 – 23.7) that it had received a recent DTP vaccination (0 to 7 days), compared to children not having received vaccination within the time period in mention. They also concluded, that the number of cases associated to vaccination was extremely low (12 cases) and was uncertain from a statistical point of view and that other possible causes or dispositions could not be excluded. The authors concluded saying that DTP vaccine in rare cases might be linked to the development of severe neurological disorders causing lasting handicap. Some cases occur by random, others might be caused by other and unrelated conditions. The role of pertussis vaccine as the only or contributing factor related to the etiology of those disorders cannot be proved in the single case. Miller et al. documented, that the balance between possible risks

and known advantages of administering pertussis vaccine supports a continuous use of the vaccine in mention

The NCES studies did not include analyses of a shorter interval of risk than 0 – 7 days. In comprehensive American studies on relationship between DTP vaccine and seizures performed later (Barlow WE, Davis RL, Glasser JW, Rhodes PH, Thompson RS, Mullooly JP, et al. The risk of seizures after receipt of whole-cell pertussis or measles, mumps, and rubella vaccine. N Engl J Med 2001;345:656-61) an increased risk of febrile convulsions was only found to be present during the first 24 hours. But there was no increased risk after day 1 and onwards to 7 following vaccination with DTP. There was no increased risk of seizures without accompanying fever at any risk interval following vaccination with DTP. The weak point was that no examination of possible encephalopathy was done. In a review of hypotonic hyporesponsive episodes (HHE) an increased risk of HHE within 48 hours is pointed at, especially so within the first 24 hours (DuVernoy et al. Pediatrics 2000;106/4/e52:1-9)

SIDS is not related to DTP vaccination according to IOM report 1991 pages 125 - 143 and according to Jonville-Béra A.P, Autret-Leca E, Barbeillon F, Paris-Llado J & the French reference centers for SIDS. J Clin Pharmacol 2001;51:271-6

According to major controlled studies of pertussis vaccines performed in most European countries in 1990 – 2000 confirm that an increased risk of febrile seizures is present between 24 and 48 hours following receipt of whole cell DTP vaccine and that HHE might occur within 24 hours following receipt of different combinations of vaccines given at child ages of 2 to 3 years (see Pertussis Vaccine Trials. Eds Brown, Greco, Mastrantonio, Salmaso, Wassilak. Devel Biol Stand 1997;89:77-81, 101-103)

Studies performed in years 1990 – 2000 including long term follow-up of major English NCES studies creates a ground for a clear demarcation of the risk period to be the first 24 hours following receipt whole cell DTP vaccine and with a confidence margin of a further 24 hour period thus added to be 48 hours

The long and complete symptom free interval between vaccination and first symptoms of the life-threatening acute condition, which in accordance with well-documented medical records, are in accordance with the so called idiopathic ALTE or near missed SIDS leads to the fact, that we consider the diagnosis made in the medical record at discharge from hospital as the wrong diagnosis

From a medical point of view <u>there is no fair chance</u> that there is a causative relationship between vaccination on 29th October 1981 and the acute disease SESB suffered from.

3.2 DEGREE OF INVALIDITY

Lasting injury is 100%

Aarhus, Denmark and Solna, Sweden 20th February 2004

John Oestergaard Patric Olin