Summary of Joint Expert Witness Report on

# Baby F and L

Dr Neil Aiton MBBS MD MRCPI FRCPCH
Dr Adel Ismail, PhD FRCPath Professor Matthew Johll PhD
Professor Alan Wayne Jones BSc, PhD, DSc
Professor Charles Stanley MD
Dr Richard Taylor MBBS FRCPC
Dr Hilde Wilkinson-Herbots MSc, PhD

# BIOGRAPHIES

## Dr Neil Aiton MBBS MD MRCPI FRCPCH

Specialist in paediatrics (neonatal medicine) on the General Medical Council Register and has been a Consultant Neonatologist at Royal Sussex County Hospital, Brighton since 1998.

He is an Honorary Senior Lecturer at Brighton & Sussex Medical School.

**Relevant experience**

- 25 years' experience: regional neonatal intensive care unit with neonatal surgery and transport
- Over 20 years' experience as an expert witness (mostly in the Family Court)
- Undertaken Bond-Solon/ Cardiff University Law School Expert witness training
- Active involvement in child death review (Pan-Sussex Child Death Overview Panel, neonatal adviser)
- Experienced in teaching newborn life support course (NLS) (>20 yrs): instructor, course director
- Higher Research Doctorate and publications on cardiorespiratory physiology of adaptation at birth
- Experience managing neonatal hypoglycaemia, transient neonatal hyperinsulinism, and early diagnosis and referral of babies with congenital hyperinsulinism.

## Professor Alan Wayne Jones BSc, PhD, DSc

Retired Professor in Forensic Toxicology (The science of poisons).

**Relevant experience**

- Senior Scientist, Swedish National Laboratory of Forensic Medicine, Division of Forensic Genetics and Forensic Toxicology until retirement in 2013.
- Over 30 years of service, specialising in forensic toxicology and pharmacology of alcohol, narcotics and toxic agents.
- Guest Professor, University of Linköping, Sweden Division of Clinical Chemistry and Pharmacology and continuing to participate in research and academia.
- Published extensively in over 100 peer-reviewed journals.
- Authored multiple book chapters on the toxicology of alcohol and drugs of abuse.

- Areas of expertise include forensic toxicology, alcohol and drug-related pharmacology, and the use of insulin as a toxic agent.

- Leading international authority in forensic toxicology, specializing in the pharmacology of alcohol, drugs, and poisons.

- Provided expert witness testimony in cases related to impaired driving and drug overdose deaths in multiple countries, including the UK and USA.

- Invited speaker and lecturer at numerous international conferences and academic institutions on forensic toxicology.

- Recipient of several international awards from forensic science and toxicology organizations in recognition of career long contributions to research and scholarship

## Dr Richard Taylor MBBS FRCPC

Specialist in paediatrics (neonatal perinatal medicine) and Part Time Consultant Neonatologist at Surrey Memorial Hospital, FraserHealth Authority, Canada since 2024. Formerly consultant Neonatologist at Victoria General Hospital 2007 – 2023.

Assistant Professor University of British Columbia, Canada.

Registered as practicing specialist in BC and non- practicing specialist with General Medical Council.

**Relevant experience**

- 30 years' experience in level 3 neonatal units in Canada (Vancouver, Ottawa, Calgary & Victoria)

- Past Chair BC RSV Prophylaxis Committee Vancouver Island

- Physician representative to BC Hospital Pharmacy Committee

## Dr Adel Ismail, PhD FRCPath

Retired Consultant in Clinical Biochemistry & Chemical Endocrinology, Director of Pathology Services, member of Mid-Yorkshire trust board and Honorary Senior Lecturer, Leeds Medical School.

**Relevant experience**

- Endocrinology & Chromatography

- Extensive research and publications on endocrinology, with specialisation in chromatography techniques including gas-liquid chromatography and mass spectrometry.

**Immunoassay Development & Analytical Techniques:**

- Pioneered immunoassay methods and development before commercialisation, including antibody production, specificity evaluation, and method validation. This allowed me to have In-depth understanding of immunoassay limitations and analytical errors which is crucial in ensuring diagnostic accuracy.

**Medical Error Analysis & Publications:**

- Authored the largest (and only) prospective study assessing immunoassay errors in over 5,000 patients
- Published over 100 peer-reviewed papers
- Book: “Biochemical Investigations in Endocrinology: Methods and Interpretation”
- My contribution and publications on this subject exceeded those of many peers and are recognised internationally particularly in immunoassay error analysis and endocrine diagnostics

## Professor Matthew Johll, PhD

Professor of Chemistry and Forensic Science since 1999 at Illinois Valley Community College Doctorate in Analytical Chemistry and author of Investigating Chemistry: Introductory Chemistry from A Forensic Science Perspective, 4ed. Macmillan Publishing. Consultant for the LaSalle County Coroner since 2017.

**Relevant Experience**

- Consultant and expert witness for multiple insulin related cases over the past 15 years.
- Provided multiple submissions and was interviewed by the CCRC regarding the Dee Winzar Appeal.
- Consultant for the LaSalle County Coroner cold case investigation for 8 years.
- Provide instruction on proper methods for the collection, storage and analysis of samples in a Forensic setting and the limitations of laboratory information.

## Dr Hilde Wilkinson-Herbots MSc, PhD

Associate Professor, Department of Statistical Science, University College London

**Relevant experience**

- More than 25 years’ experience teaching Probability Theory and Statistics to undergraduate and postgraduate students
- Active in research focusing on applications of probability and statistics in genetics and epidemic modelling
- Publications in international, peer-reviewed journals (some with hundreds of citations)

- Consultancy work for the Forensic Science Service (1994-1995)

## Charles Stanley MD, Professor of Pediatrics (Emeritus)

Paediatric Endocrinologist Emeritus Professor CE of Pediatrics, Perelman School of Medicine at the University of Pennsylvania.

**Relevant experience**

- Internationally recognized expertise in hypoglycemia diseases of newborns, infants, and children including inborn errors of metabolism, hyperinsulinism, and other endocrine disorders.
- Previous service at Children's Hospital of Philadelphia as Attending Endocrinologist
- Chief of Division of Endocrinology and Diabetes, Clinical Research Center Core Laboratory Director, and Director of Hyperinsulinism Center
- Experience as Expert Witness for Medico-Legal cases for both plaintiffs and defendants testifying at depositions and trial
- Author of over 200 original articles and chapters on hypoglycemia disorders in children dealing with diagnosis and treatment, disease mechanisms, and genetics
- Co-author of Pediatric Endocrine Society guidelines for diagnosis and treatment of hypoglycemia and guidelines for diagnosis and treatment of Congenital Hyperinsulinism.
- Published original research on management of transitional neonatal hypoglycemia and perinatal stress induced hyperinsulinism and on biochemical mechanism of hyperinsulinemic-hypoglycemia in normal and high-risk newborns

# SUMMARY OF JOINT OPINION

In the report we present convincing new evidence from multiple sources that the Roche immunoassay test used can give rise to falsely high insulin results due to the presence of antibodies that can react with this type of immunoassay test. We also highlight evidence these antibodies can pass across the placenta to unborn babies and cause hypoglycaemia and apparently high insulin levels in the newborn period. Furthermore, new evidence has been published which increases our awareness and understanding about hyperinsulinism in the neonatal period. This information has provided greater insight into how adverse perinatal factors can cause hyperinsulinism in some newborn and premature infants. This is termed Perinatal Stress-Induced Hyper-Insulinism (PSIHI).

We have concluded that the Jury were misled in important areas as follows:

a) Medical facts: the evidence for sepsis, leakage of the central line into surrounding tissues, and consideration of alternative causes for the hypoglycaemia.
b) Evidential facts: errors in the glucose results presented, changes in the glucose levels in response to TPN infusion connection/disconnection, ward-based blood glucose tests presented as if they were laboratory results.
c) Testing: that the results of the immunoassay tests can be relied upon, and that the Roche immunoassay method used at the Royal Liverpool University Hospital (RLUH) was specific for identification of insulin alone (endogenous or exogenous)- neither of which are correct.
d) Background error rate: this is at least 0.5-2% despite excellent quality control for the type of insulin immunoassay test used, which the jury were not made aware of.
e) Quality Control testing information was not revealed to the Court in expert witness evidence. The results showed a quality control test with high insulin and a low C-peptide.
f) Abnormal results: it is essential requirement according to published standards to undertake confirmatory testing of the immunoassay result using a different, more specific methodology, such as liquid chromatography mass spectrometry (LC-MS).
g) Reference ranges not applicable in small preterm infants for C-peptide results and insulin/C- peptide ratios. Studies in adults and older children were quoted which are not relevant, and the limited appropriate information was not referred to.
h) The testing did not meet acceptable forensic standards at the Liverpool laboratory in terms of analytical specificity, chain of custody, control testing for interfering substances, and obtaining confirmatory result using alternative available methods or another laboratory.

The new evidence undermines the validity of the results of the insulin and C-peptide testing presented in Court and shows that these immunoassay results cannot be safely relied upon (without undertaking further confirmatory testing).

There is now evidence that:

- shows that the presence of antibodies (IAA insulin autoantibodies and other antibodies such as HAMA) can interfere with the immunoassay result and cause falsely high insulin results

- demonstrates that insulin autoantibodies can be transferred from mother to baby during pregnancy causing hypoglycaemia in the baby and falsely high insulin levels
- that IAA (insulin autoantibodies) can be found in pregnancy and in the umbilical cord blood of infants, that this is not rare, and that the prevalence can vary over time
- In the context of a falsely high insulin result the insulin/C-peptide ratio is meaningless
- demonstrates there are alternative medical explanations which explain the hypoglycaemia in both babies, such as line failure, sepsis and perinatal stress-induced hyper-Insulinism (PSIHI). These alternative possibilities were not considered.
- indicates that the testing undertaken did not meet acceptable standards of clinical, laboratory or forensic practice, and therefore cannot safely be relied upon

Our inescapable conclusion is that this evidence significantly undermines the validity of the assertions made about the insulin and C-peptide testing presented in Court.