Critique Of Toxicology Reports From Professor Frank Daly And Professor George Braitberg

The Toxic Heavy Metals Taskforce has reviewed the Toxicology Reports of Professor Frank Daly and Professor George Braitberg and due to the inadequacy of information provided to them by the DHHS from previous investigations, medical reports, data, test results and files we have found the Reports contain numerous errors of fact and incorrect assumptions.

In our Critique we explain the deficiencies in each patient's assessments by Professors Daly and Braitberg and provide a Summary of our assessment.

PATIENT A

Professor Daly's Report:

- Page 9 Failed to mention that gas sampling conducted in December 2008 showed positive results for Nitrogen Dioxide (NO2), Hydrogen Sulphide (H2S) and Carbon Monoxide (CO).
- Omitted patient A's urinary arsenic level of 0.096 µmol/mmol.
- Page 10 "Patient A has had numerous other investigations. In the period February 2008 to July 2009 the following investigations were found to be unremarkable" but failed to mention other test results and diagnosis including:

Diagnosed with Parasthesia in July 09 by GP.

Diagnosed with peripheral neuropathy in Dec 09 by GP.

Diagnosed with Myalgia in July 09 by GP

Confirmed Microalbuminuria in renal test on 23/10/08.

High creatinine at level 92 (44-80), Lcw kidney filtration rate 66 (>89), and Haemolysed blood in June 08.

Diagnosed by Specialist with neuropathy features on upper and lower limbs in September 2009.

Bone density scan showed osteopenia in February 2010.

- "Patient A was tested for 30 essential and toxic metals on 12 -11 -08. The only toxic metal reported to be in the high range was strontium." Failed to mention high levels of Copper, Cobalt, Calcium, Magnesium, and borderline level of lead and this opinion conflicts with that of Professor Braitberg. Date of test was incorrect.
- Page 11 "congenital fusion of cervical vertebrae C2-C3 and C6-C7, unfused bifid C1 cervical vertebra and Arnold Chiari malformation (downward displacement of cerebellum through foramen magnum)". The Arnold Chiari malformation was not picked up through MRI tests but a Specialist diagnosed this in September 2009.
- "Bruxism related left masseter pain". Four different diagnosis have been given for this.
- List of medications is incomplete and outdated:

Lexapro - Jan 09 - Post Traumatic Stress Disorder - patient did not take these tablets.

Temazepam - June 07 - Insomnia - patient did not take these tablets.

Alepam - October 08 - Stress - patient did not take these tablets.

Chlorsig eye drops - November 08 - For the instant eye infections that frequently developed after getting dust in eyes from the yard.

Claratyne - October 09 - Itchy skin or rash.

Panamax - April 09 - For Neuralgia - occasional use only.

Lyrica - November 09 - For neuralgia - occasional use only.

• "Patent A was reviewed by a specialist but the date of the consultation is not noted. No examination findings were documented." Examination findings were documented in September 2009:

Neuropathy features in upper and lower limbs.

Unexplained weight loss

Urinary Arsenic

Skin rash

Arnold Chiari Malformation

Fusion of cervical vertebrae C2-C3 and C6-C7,unfused bifid c C1 cervical vertebra.

- Dr Robert Parks conducted examination on November 20-08. "Dr Parks noted maculopapular lesions measuring approx 3mm on the angle of her jaw on both sides, he considered this to be secondary to her earrings." These lesions developed all over the body of patient A – the patient wears gold or silver earrings only and has no allergic reaction to these metals.
- Page 12 "The intermittent contact with small amounts of dust would have been insufficient to lead to the ingestion or inhalation of any significant dose". In addition to general airborne dust in the town and due to extensive work on house renovations and garden landscaping patient A had frequent exposure to high levels of dust.
- "the presence of multiple symptoms in multiple organ systems without any associated objective medical signs or pathological abnormalities suggest a functional somatic disorder". Patient A has numerous medical signs and pathological abnormalities.

Professor Braitberg's Report:

- Page 35 List of medications incomplete. See above for comments on Page 11 of Professor Daly's Report.
- Page 36: Incomplete list of tests. See above comments for comments on Page 11 of Professor Daly's Report.
- "Hair analysis on 20/11/08 showed high levels of calcium, cobalt, magnesium and copper". Failed to mention high level of Strontium and lead levels in hair analysis.
- Page 37 "an elevated arsenic to creatinine ratio is likely due to organic arsenic ingestion given the results of the arsenic speciation taken at the same time as the urine collection". Patient A does not eat seafood. The documents from North West Pathology and Queensland Health Clinical and Statewide Services show that the speciation was not

done on the same day. In addition, the speciation results from Queensland Health Clinical and Statewide Services are not consistent with results of tests conducted on urinary samples taken from people who have eaten seafood and shellfish. Further, the reports omitted to mention that arsenobetaine can also be excreted after exposure to inorganic arsenic and arsine gas.

- Page 38: The table does not include spot urine and hair analysis results.
- Page 39 "Metallic taste is reported in patients on lithium and iron therapy, in patients exposed to botulinum, following treatment with metronidazole, ligncaine treatment, oral candidiasis or metformin treatment for diabetics. Chemotherapy, radiation therapy, or cancer itself can cause a metallic taste in mouth. "Patient A is not taking any of these medications or undergoing any treatments.
- Page 45 "History of neurological symptoms but no examination or objective nerve conduction results". This is incorrect as on Page 35 Prof Braitberg comments on Patient A's consultation with neurologist Dr Stan Siejka and the nerve conduction test results.
- "Cadmium high, but reporting laboratory concluded that the result was a sampling error" however on page 44 Prof Braightberg contradicts this statement with "The patient has had high cadmium and needs further testing".
- Omitted the high Arsenic level of 0.096 µmol/mmol.

PATIENT B

Professor Daly's Report:

- Page 15 Incorrectly analysed patient B's biological data for arsenic and cadmium. "The cadmium elimination was high (1257nmol/L), but this is likely to be secondary to collection artifact." This figure of 1257 nmol/L is not patient B's result but is that of another patient. Patient B's result is 232 nmol/L. The normal reference range in urine for cadmium should be 0-30 nmol/d.
- Incorrectly states "A 24-hour urine collection was repeated in January 2009. The urinary arsenic elimination was 0.096 mcmol/mmolCr, which was slightly elevated (reference range 0-0.060 mcmol/mmol Cr). Speciation of urinary arsenic on the same day demonstrated that 98% of the eliminated arsenic was in the form of arsenobetaine, a non-toxic organic arsenic, a non-toxic organic arsenic compound found in seafood and shellfish". The documents from North West Pathology and Queensland Health Clinical and Statewide Services show that the speciation was not done on the same day. In addition, the speciation results from Queensland Health Clinical and Statewide Services are not consistent with results of tests conducted on urinary samples taken from people who have eaten seafood and shellfish. Further, the reports omitted to mention that arsenobetaine can also be excreted after exposure to inorganic arsenic and arsine gas.
- Page 16 Incorrectly lists medications prescribed by Drs Henshaw and Johnson and being taken by patient B - as only one out of the seven have been taken by patient B for over 18 months.
- Page 17 Refers to a report by Dr Robert Parkes from a consultation with patient B on 20th November 2008. In the Final Report released in April 2009 it states on Page 49, in reference to Dr Parkes report from patient B's one consultation "however, to date the physician has not released the report to anyone.". The information provided from Dr

Parkes was incomplete, deficient and some additional medical conditions diagnosed by Dr Parkes and previously unknown to that specific patient have never been released to her GP for follow up testing. This information should have been pursued for the purposes of any investigation for a heavy metal diagnosis.

• Page 18 - Incorrectly states that for patient B "there is no evidence of anaemia" conflicting with Prof Braitberg on Page 43 where he states "Iron deficiency anaemia – cause needs to be pursued.......Copper is necessary for iron uptake and a copper deficiency can result in iron deficiency. In this case there is iron deficiency in the setting of an excess of copper and normal zinc".

Professor Braitberg's Report:

- Page 24 In relation to patient B "Dr Johnson, from the Rosebery Medical Centre lists her medication, as of 29-11-09 as:....," but patient B has only been taking one out of the seven medications prescribed by Drs Henshaw and Johnson in the past eighteen months.
- Also refers to a report by Dr Robert Parkes from a consultation with patient B on 20th November 2008. In the Final Report released in April 2009 it states on Page 49, in reference to Dr Parkes report from patient B's one consultation "however, to date the physician has not released the report to anyone.". The information provided from Dr Parkes was incomplete, deficient and some additional medical conditions diagnosed by Dr Parkes and previously unknown to that specific patient have never been released to her GP for follow up testing. This information should have been pursued for the purposes of any investigation for a heavy metal diagnosis.
- The statement that patient B's symptoms did not include "anorexia and skin rashes" was also incorrect.
- Page 26 There is no 24 hour urinary cadmium result in the table of urinary test results.
- In January 2010 patient B had a Nuclear Medicine Whole Body Scan, Whole Body Bone Density Test, heavy metal and complete work up blood testing, chest, lung and spinal x-rays. The results of these tests have not been assessed by Profs Daly and Braitberg. The results of these tests have not been provided by the DHHS for Professors Daly and Braitbergs' assessments.
- In May 2010 patient B will be having neurological testing.

PATIENT C

Professor Daly's Report:

• Pages 19/20 - Under the heading "Social history....." he states "Dr Ernst documented that there was no history of heavy drinking. " and yet Prof Daly goes on to propose a possible diagnosis of "Dupuytrens disease".

Professor Braitberg's Report:

- Page 22/23 proposes a possible diagnosis of "Dupuytrens disease" for a patient C and goes on "I would also pursue his alcohol intake, as this may be another cause for his self reported symptoms".
- Had consultations and examinations been conducted with patient C "Dupuytrens disease" could have been excluded as a possible diagnosis especially through observation of symptoms in his hands which do not exhibit Dupytrons contracture. Evidence would have been provided that for the past 40 years he has not been a drinker at all.
- In January 2010 patient C had a Nuclear Medicine Whole Body Scan, heavy metal and complete work up blood testing, chest, lung and hand x-rays and ultrasound testing on hands and kidneys. The results of these tests have not been provided by the DHHS for Professors Daly and Braitbergs' assessments.

PATIENT D

Professor Daly's Report:

- Page 22 Incorrectly referred to the wrong GP being the general practitioner for patient D.
- Page 23 Incorrectly stated that patient D's cadmium, manganese, copper and zinc levels were within the reference ranges whereas this was not the case.

 Incorrectly states that patient D "had mildly elevated blood cadmium." and failed to mention patient D's high urinary nickel level.
- Page 30 Incorrectly assumes patient D's medication dosage level and non compliance for treatment of thyroidism.

Professor Braitberg's Report:

• Page 31 - While stating that patient D's "blood levels show persistently high cadmium." failed to mention patient D's high urinary nickel level.

PATIENT E

Professor Braitberg's Report:

• Page 43 - Incorrectly suggests that medication could be a potential cause of Patient E's "significant biochemical abnormalities" as patient E has not been prescribed any medications and does not use any.

PATIENT F

Professor Daly's Report:

• Page 33 - "There is very little documentation for Patient F with regard to any potential environmental exposures, the timing and details of symptoms and physical examination. No laboratory data is supplied". As the DHHS did not provide this information any

thorough toxicological assessment would not be possible.

Professor Braitberg's Report:

- Page 19 "I have not been given any blood tests for this patient." As there was no urinary or blood tests provided a thorough toxicological assessement would not be possible.
- Page 43 In the Summary Notes "Symptoms could be drug related." Given the omission of any biological data provided for assessment this statement is merely speculative.
- In February 2010 patient F developed further complications with a heart condition and is on additional medication and has other specialist tests pending.

PATIENT G

Prof Daly's Report:

- Page 35 "A 24 hour urinary collection for analysis of arsenic, copper, lead, manganese and zinc was also performed on January 21 2009. The urinary elimination of arsenic was slightly elevated (1.83mcomol/day; reference range 0-1.10 mcmol/day). Similarly, urinary elimination of copper was elevated (4.65mcmol/day; reference range <1,6 mcmol/day)." Given that patient G does not eat seafood, arsenic levels can not be described as normal and no speciation was performed. No alternative explanation for what has caused the elevation in urinary arsenic and copper levels is suggested.
- Page 35 Incorrect notes were provided by this patients GP which refer to him having anorexia, weight loss and generalised itch especially the shoulders.
- Page 36 Excludes arsenic results from January 2009 of 0.125 reference range is 0.060.

Prof Braitberg's Report:

- Page 16 In relation to blood test results "clearly none of these levels are elevated suggesting that no recent exposure over the two time periods has occurred", this is clearly incorrect given that arsenic results were 0.125 from 21st January 2009.
- Page 17 "The elevated arsenic and arsenic/creatinine ratio in the presence of normal arsenic blood test may indicate a degree of body burden, but given the normal excretion on the 15th, one would wonder if there had been a fish ingestion in the 2-3 days prior to the test and I would recommend repeat urinary collection after a period of fish diet abstinence or arsenic speciation". Patient G has not eaten any seafood for years therefore this high urinary arsenic excretion level can only be due to body burden and sourced from inorganic arsenic.
- Page 43 "Arsenic speciation, Copper elevated on second testing should be repeated." Arsenic speciation was not done.
- In February 2010 patient G attended Casualty at the Royal Hobart Hospital and during examination 17 lumps were found under the surface of the skin in various parts of the body. Patient G had 2 chest xrays at the Royal Hospital Four lumps are now causing this patient considerable pain, One has increased rapidly in size within one month and he is having surgery in late April. These lumps could have been detected through an

examination by Profs Daly and Braitberg and assessed in relation to other symptoms.

PATIENT H

Professor Daly's Report:

- Page 39 "There is very little documentation for patient H with regard to any potential environmental exposures, the timing and details of symptoms, and physical examination. No laboratory data is supplied." The DHHS failed to provide documentation and laboratory data for patient H which shows high biological levels of copper. Without this documentation any thorough assessment is not possible and will be incomplete.
- Patient H's infant son has been tested for thallium, zinc and copper and had elevated levels yet no mention is made of this infant's biological levels or his symptoms.

Professor Braitberg's Report:

- Page 14 "abnormal copper blood test but no level or context was provided" again indicates the lack of biological results provided by the DHHS.
- Page 43 In the Summary Notes "No blood test, nil specific symptoms. Metallic taste. List of possible causes of metallic taste provided." Without test results and documentation any thorough assessment or possible alternative diagnosis will be incomplete.
- Patient H's infant son has been tested for thallium, zinc and copper and had elevated levels yet no mention is made of this infant's biological levels or his symptoms.
- This patient was hospitalised twice in February 2010 with severe diarrhea and vomiting and these symptoms occur regularly.

SUMMARY

Professors Frank Daly and George Braitberg based their assessments on ten patients from information provided by the DHHS from previous investigations, medical reports, data, test results and files. The conclusions in their reports based on the information provided show numerous errors of fact and incorrect assumptions:

- Conclusions drawn were made from incomplete, flawed and deficient DHHS and EPA investigations.
- Assumptions on possible diagnosis were made without patient consultations or examinations.
- Assumptions on possible diagnosis were made without access to up to date medication lists, accurate medical reports, documentation, correct data and specialist/diagnostic test results
- Incorrect attribution and analysis of data
- Conflicting findings between Professor Daly's and Professor Braitbergs' Reports.

Other than problems described in our patient specific analysis of the reports there are general examples in the reports that point to inconsistencies and flawed analysis:

- Prof Braitberg states on Page 44 in relation to "methodological concerns regarding the way Dr Ernst has reached his conclusions......iii) He has not examined the patients and therefore is unable to provide objective clinical correlations with observations". This assertion also needs to be applied to Professors Daly and Braitberg regarding the conclusions they have drawn in assessing Dr Ernst's diagnosis of the ten patients especially given the paucity of additional information provided to them about patients from the DHHS.
- Professors Daly and Braitberg did not adequately assess the commonality and the patterns of symptoms in the patients. For example most patients have experienced sudden onset and severe dental problems in the past two years, yet this is not discussed in any depth except for patient C where smoking is suggested as a cause for poor dentition. All patients have experienced abnormal hair loss concurrent with dental problems and musculoskeletal problems regardless of age. Had Professors Daly and Braitberg conducted patient examinations, the pattern of the symptoms which is what casued Dr Ernst to notify the DHHS, would have been clearly apparent and could have assisted with their assessments.
- Professor Daly states in relation to patients A, B, C, F, G and H that "The presence of multiple symptoms in multiple organ systems without any associated objective medical signs or pathological abnormalities suggests a functional somatic disorder, which occurs in up to 4% of the population". Professor Braitberg states that "the first step is to overcome the currently held belief that the residents have been poisoned by heavy metals. However, belief, no matter how strong; where there is no evidence, does not serve the best interests of these patients." This diagnosis is given in the absence of any comprehensive objective clinical medical or psychological assessment or reports based on patient consultations, examinations and test results.
- Although no thallium testing was done by the EPA or DHHS, Prof Daly's comments on Page 25 on the effects of thallium poisoning refer only to effects of severe poisoning not to long term low level exposure which can in fact result in gradual loss of hair.
- Prof Braitberg on Page 43 incorrectly states that "None of the patients have had skin biopsies". Three patients have had excisions of lumps and these were tested for cancer. Although testing was requested for heavy metals on these biopsies, this testing was not done.

In Prof Braitberg's Executive Summary he states "while there is some evidence of low level soil concentration elevation of some metals" and in Professor Daly's Summary he also states "Rosebery has demonstrated elevated levels of several metals". This is incorrect when considering that properties had some very high levels including a soil lead level of 4,590 mg/kg - up to 15 times the Health Investigation Level (HILs), an arsenic level of 646 mg/kg - up to 6 times the HIL's. These levels are not just 'elevated' - they are very high.

The information provided to the toxicologists from the DHHS on data from the EPA investigations did not include critical information needed for a thorough toxicological assessment:

- No biological or environmental tests were conducted by the DHHS or the EPA for thallium or any radioactive elements.
- No roof cavity dust testing was conducted by the EPA and dust monitoring/sampling

was either not done or incomplete.

- Arsine gas testing was inadequate and conclusions drawn erroneous.
- The instruments used for Hydrogen Sulphide testing had insufficient resolution.
- The Toxic Heavy Metals Taskforce Tasmania Critique of the EPA investigation including: sampling methodologies, data interpretation and presentation and conclusions drawn were not assessed.

Because of the failures in the EPA investigation and failure of the DHHS to provide accurate information, Professors Daly and Braitberg were unable to address the major issue of potential exposure pathways for dust and gas and instead focused on those for water and soil.

The Department of Health and Professors Daly and Braitberg have failed to adequately take into account the importance of complex mixtures of toxic substances at even low levels and their effects on human health. In the context of discussion on low level exposure synergism Profs Daly and Braitberg cite the US Agency for Toxic Substances and Disease Registry (ATSDR) Interaction profiles for: arsenic, cadmium, chromium and lead; and lead manganese, zinc and copper, from 2004 There is no referencing to more recent relevant research from the the US National Institute of Environmental Health Sciences (NIES) and the National Toxicology Program. In a recent article in Environmental Health Perspectives, Linda Birnbaum, Director of NIES and NTP states "There are several recent examples of how research supported by the NIEHS is leading to a paradigm shift in understanding how environmental toxicants – even at very low-level exposures - can have significant consequences including dysfunction and disease". The conclusions from a recent survey in the US on lead exposure and kidney disease have shown "increasing epidemiologic evidence indicating an adverse effect of low-level environmental lead exposure." Blood Lead Level and Kidney Function in US Adolescents from the Third National Health and Nutrition Examination Survey by Jeffrey J. Fadrowski, MD, MHS; Ana Navas-Acien, MD, PhD; Maria Tellez-Plaza, MD, MPH; Eliseo Guallar, MD, DrPH; Virginia M. Weaver, MD, MPH; Susan L. Furth, MD, PhD Arch Intern Med.2010;170(1):75-82.

A new study published in the ejournal *evisa* on 23-2-10 by Chris Newcombe, Andrea Raab, Paul N. Williams, Claire Deacon, Parvez I. Haris, Andrew A. Meharg, Jörg Feldmann, *Accumulation or production of arsenobetaine in humans?*, J. Environ. Monit., 2010, outlines important research on inorganic sources of arsenobetaine and metabolism of arsenic by the human body. *Can humans metabolize arsenic compounds to arsenobetaine?*, by W. Goessler, C. Schlagenhaufen, D. Kuehnelt, H. Greschonig, K. J. Irgolic, Appl. Organomet. Chem., 1997, 11, 327–335. adds to this body of research and in relation to potential exposure pathways for Rosebery residents there is a need for further investigations.

The provision of comprehensive specialist assessments and data along with consultations and examinations of patients is essential for toxicological assessment relating to long term low-level exposure to complex mixtures of heavy metals. In summary, due to the serious deficiencies in the documentation provided to Professor Daly and Professor Braitberg by the Department of Health and lack of patient examinations, we are unable to accept the findings in Professor Daly and Professor Braitbergs' Reports.

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