Extracts from Professor Leonard Jason's Presentation at the NIH State of the Knowledge Workshop on ME/CFS Bethesda, Maryland, 7th-8th April 2011

Margaret Williams **9th April 2011**

At the National Institutes of Health "State of the Knowledge" (SOK) Workshop on ME/CFS held in Bethesda, Maryland on 7th-8th April 2011, Professor Leonard Jason from DePaul University, Chicago, gave a hard-hitting presentation, repeatedly emphasising the absolute necessity for researchers to be looking at the same disorder.

He specifically mentioned the UK PACE Trial (carried out by Wessely School psychiatrists) and noted the controversy flowing from that trial.

The PACE Trial Principal Investigators (PIs) intentionally sought as heterogeneous a cohort of "fatigued" people as possible in order to enhance both recruitment to the trial and the alleged "*generalisability"* of the Wessely School's cognitive re-structuring and aerobic exercise programme to as many "fatigued" people as possible (Trial Identifier:3.6).

Such intentional heterogeneity obviously captured people with affective disorders in which "fatigue" is a prominent feature, yet the PIs assert that they were studying patients with "CFS/ME" (which they insist is the same disorder as ME/CFS, a complex neuroimmune disorder) when their definition of "CFS/ME" has few of the features of classic ME/CFS. Indeed, the pathognomonic feature of ME/CFS -- post-exertional fatigability with malaise -- is not required in their definition of "CFS/ME" which has on-going "fatigue" as the primary symptom.

This deliberate conflating of different disorders by the Wessely School has caused dismay amongst international scientists studying classic ME/CFS, who at the SOK Workshop emphasised the near-impossibility of validating the existing biomarkers when such divergent cohorts of subjects are used (for example, by psychiatrists with fixed beliefs about the nature of "CFS/ME" who continue to disregard the biomedical evidence and the key diagnostic criteria contained in the 2003 Canadian Guidelines).

Despite the fact that the UK Department of Health accepts ME/CFS as a neurological disorder of unknown origin, in its recent submission to the NICE "consultation" process regarding any necessity to update the NICE Clinical Guideline 53 on "CFS/ME" that recommends only CBT/GET for people with "CFS/ME", The Royal College of Paediatrics and Child Health referred to the disorder as: ***"a psychological illness with physical manifestations"*** (http://bit.ly.gpdove) and on the Great Ormond Street (childrens) Hospital website, "CFS" is categorised as a somatic problem: it is placed in "**Department of Child and Adolescent Mental Health"** section and then under **"Feeding & Eating Disorders Service"** is to be found the following: "***emotional eating difficulties (e.g. food phobias) or in the context of somatic problems such as chronic fatigue syndrome"*** (http://www.gosh.nhs.uk/website/gosh/clinicalservices/DCAMH/Homepage?forumid=331851).

In the UK, NHS staff are likely to obtain their knowledge about the PACE Trial from the "NHS Choices" Information page on its website (http://www.nhs.uk/news/2011/02February/Pages/therapies-moderately-improve-CFS.aspx).

Perhaps unsurprisingly, this website contains frank misinformation about the results of the PACE Trial; for example, the PACE Trial was not a "*controlled*" trial as claimed; the Oxford criteria are not "*standard diagnostic criteria for CFS*" when "CFS" is deemed to include ME -- they are used only by the Wessely School who produced them in 1991; PACE participants were not "*confirmed as free of mental health problems such as depression and anxiety*"; participants did not meet the (proposed) *"London Criteria*" for myalgic encephlaomyleitis, but a version compiled by the Chief PI (Professor Peter White) himself, which was basically the Oxford criteria without psychiatric illness; SMC (specialist medical care) was not universally provided by a doctor "*with specialist experience in CFS"*; 22 of these "experienced specialists" were in fact trainees (all from the same centre) who, by virtue of being trainees, could not be called experts experienced in the medical care of people with CFS.

Thus despite hollow assurances from the Department of Health, the grass roots situation in the UK remains dire for people with ME/CFS, so the following quotations from Professor Jason at the SOK Workshop are of particular relevance to patients themselves and to the various agencies of State to which the Wessely School are advisors on "CFS/ME":

"If investigators select samples of patients who are different in fundamental aspects of this illness because of ambiguities with the case definition, then it would be exceedingly difficult for investigators to consistently identify biomarkers".

"In summary, any scientific enterprise depends on reliable and valid ways of classifying patients into diagnostic categories. When diagnostic categories lack reliability and accuracy, the quality of the treatment and clinical research can be significantly compromised".

"If CFS is to be diagnosed reliably across health care professionals, it is imperative to deal with criterion variance issues and provide specific thresholds in scoring rules for the selected symptomatic criteria".

In the discussion that followed his presentation Jason was emphatic:

"Those folks who have primarily affective disorder need to be differentiated".

"*I think the key issue is the defining of the sample and in our current scientific publications, the basic description of who these samples are is completely inadequate, and we've got to do something to change that….if we don't tackle that issue…our foundation is just going to be shaky".*

During this discussion, Professor Nancy Klimas commented cogently: "*Here we are, quite some 20 years into this, still talking about the bloomin' case definition"*; she registered her frustration and pointed out that lack of a unified case definition prevents the existing biomarkers for neuroimmune disorders being utilised.

Professor Jason responded:

"*There needs to be a decision as to which are the symptoms and which are the tests that we want to use (so that) everybody uses those particular symptoms and asks questions the same way – standardised questionnaires, and if we can get that accomplished by everybody being on the same page with that, I think we would do enormous benefit for our field".*

"What I'm really suggesting, because a lot of what we're talking about here is biological markers, is that ultimately, if we have samples that are different in different labs and have different characteristics, it's going to be very difficult for us to get the types of consistency of the biological markers…The problem we're all faced with is that when we don't get common findings across labs, it's very easy for the media – and others – to look at those results and not understand the complexities that we're faced with and (they) say – oh, you don't find the same abnormalities, you don't find the same lab findings, it's not like HIV (where) you find it everywhere…. ultimately you end up (with it) being thought of as a psychogenic illness, and that's the problem. It's the consequence of …attributions being made that I think are not correct".

At this point, the Editor of the journal "Brain, Behaviour and Immunity" asked a question and then agreed to publish such standardised criteria in his journal, an undertaking that was well-received.

Professor Jason ended the discussion by referring to the UK PACE Trial:

"*There's tremendous confusion about who's in particular samples. Those of you who have been reading about the PACE trial….one of the big issues was, was it the Oxford criteria, was it the Fukuda criteria, or the international, or the Reeves empiric case definition, and I think a lot of controversy came out of that trial in part because people were trying to figure out who were their patients, and I know that they did some subgroup analyses in that study, but I think it's absolutely critical for this diagnostic issue to be tackled head-on".*

Will the Wessely School psychiatrists pay any attention to this critical issue of diagnostic criteria for ME/CFS or will they persist in ignoring the international scientific research community and implacably insist that "CFS/ME" is a somatoform disorder that is reversible, if not curable, by their own brand of directive psychotherapy as they have done for the last 25 years, to the serious detriment of both patients and progress in medical science?