Submission to the Joint Parliamentary Committee on the National Disability Insurance Scheme

ME/CFS Legal Resources - Australia

An Organisation

ME CFS Legal Resources

Australia

13 November 2017

Acknowledgement

ME/CFS Legal Resources acknowledges the advocates, patients and carers who have provided feedback and insight into the experiences and difficulties in engaging with the NDIS application process. These experiences have informed this submission and ensured the key issues are identified.

Table of Contents

Executive Summary

ME/CFS and CFS are complex disease processes. For a person suffering either condition, there are significant psychosocial impacts in terms of illness experiences, financial devastation, social isolation, stigma and functional impairment. The National Disability Insurance Scheme (NDIS) was established to assist the lives of people who suffer a disability arising out of functional impairment. An applicant can, therefore, access the NDIS through two means:

- Meeting the disability requirements; or
- Meeting the early intervention requirements.

ME/CFS Legal submits that there are significant access issues currently being faced by applicants who have ME/CFS and CFS. It is the submission of ME/CFS Legal to the Senate Committee, that the current approach of the NDIS framework to reject the vast majority of applicants with ME/CFS or CFS (ie only one so far has gained access), hence a grave inequity surrounds the scheme.

It is our submission that such applications are being rejected for one of four specific reasons:

- The condition is not attributable to an impairment that is permanent
- The condition is not attributable to an impairment that is likely to be permanent;
- The condition is does not result in substantially reduced functional capacity;
- The condition is a chronic health condition that is most appropriately supported by other agencies within the State or Commonwealth health systems (ie health and allied services).

The first three issues pertain to the assessment of disability whilst the third and fourth conditions relate to assessment of early intervention.

ME/CFS Legal Resources submits that ME/CFS and CFS are lifelong, incurable conditions. This is not controversial – it is fact. They are considered to be permanent conditions, or likely to be permanent conditions, each cause impairment hence a disability and are not best serviced by the existing medical system. They therefore meet, for all intents and purposes of this scheme, the key criteria for the NDIS. Conversely, the early stages of the conditions and available treatments, raise the argument that the conditions are ideal for early intervention to improve function outcomes.

In addition to addressing these specific issues, this submission will respectfully submit that ME/CFS and CFS are a serious disability that falls squarely within the definition of disability under the NDIS hence recommends that the condition be promptly included under List B as a neurological condition (noting that the NDIS case study at Annexure 2 below, clearly demonstrates that the NDIS accepts it to be so), hence would alleviate the onerous task of making applicants to establish permanency on an individual basis.

ME/CFS Legal will further recommend that the NDIS commission a research paper on ME/CFS and CFS and the attendant needs of those who suffer from it. This task, it is submitted, would be appropriately attended to by knowledgeable ME/CFS researchers, in conjunction with relevant stakeholders and stakeholder organisations. Such a position paper would guide the future administration of ME/CFS and CFS within the application and administration bounds of the NDIS.

This submission will close with a generic recommendation with respect to Medicare. ME/CFS Legal Resources submits that the costs of the NDIS application process are best borne by the Medicare system, hence reports and investigations should be covered under the Medicare Benefits Schedule so as to ease the burden of all applicants, including ME/CFS and CFS patients.

Summary

Submissions

ME/CFS Legal Resources submits that ME/CFS and CFS:

1. are lifelong, incurable conditions, hence they are both a permanent condition, or are likely to be a permanent condition;
2. do cause impairment hence are a disability;
3. are, in the early stages of the condition (and at other stages) appropriate for early intervention;
4. warrant access to reasonable and necessary supports

Recommendations

ME/CFS Legal Resources makes the following recommendations:

1. the conditions should be added to List B under neurological disorders;
2. that a research paper on ME/CFS and CFS should be commissioned, and include the attendant needs of those who suffer from it;
3. reports and investigations relevant to the NDIS application process should be universally covered under the Medicare Benefits Schedule so as to ease the burden of all applicants, including ME/CFS and CFS patients.

1. Terms of Reference

The terms of reference have been expressed as follows:

> "As part of the committee's inquiry into the implementation, performance and governance of the National Disability Insurance Scheme (NDIS), the committee will inquire into and report on the transitional arrangements for the NDIS, with particular reference to:
>
> a. the boundaries and interface of NDIS service provision, and other non-NDIS service provision, with particular reference to health, education and transport services;
> b. the consistency of NDIS plans and delivery of NDIS and other services for people with disabilities across Australia;
> c. the rollout of the Information, Linkages and Capacity Building Program; and
> d. any other related matters.
>
> In considering these issues, the committee will have regard to:
>
> i. the Bilateral Agreements between the Commonwealth and State and Territory Governments;
> ii. the Operational Plans between the Commonwealth and State and Territory Governments;
> iii. the risks borne by the Commonwealth and State and Territory Governments in the rollout of the NDIS nationally;
> iv. NDIS decision-making processes, particularly in relation to the Disability Reform Council and COAG; and
> v. the impact on rural and remote areas, with particular reference to Indigenous communities." (Parliament of Australia, 2017)

2. Preamble

2.1 Standing

The following submission is grounded on the experience of a number of advocates, with substantive content from the founder and coordinator of an online legally focused resource, created to inform and meet the needs of people with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (hereinafter 'ME/CFS'). As founder, I declares that I am a person with ME/CFS and have been for 21 years. I have extensive experience in the area as a researcher and advocate. I have multiple relevant qualifications and am working towards multiple post-graduate qualifications in this area. There are over 415 members of the rapidly group, who have ME/CFS or hold an interest in the condition. The site is exposed to tens of thousands more by way of sharing on social media.

2.2 Support for the NIDIS

ME/CFS Legal Resources support the introduction of the National Disability Insurance Scheme (NDIS) and acknowledges its potential to significantly transform the disability sector.

There is, however, significant disquiet and dissatisfaction within the ME/CFS community, with respect to the inability of sufferers of the disease to obtain access to NDIS support. Compounding

the issue has been the simultaneous reduction and cessation of other available disability and support services in the wake of the NDIS being introduced.

Persons with ME/CFS are amongst the most disabled and most vulnerable in Australian society, yet the assessment of applications is regrettably far removed from of the reality of the condition.

2.3 Purpose of the NDIS

The NDIS website extolls the value of the framework and asserts the scheme exists to:

> … support a better life for hundreds of thousands of Australians with a **significant and permanent disability** and their families and carers. The NDIS will mean peace of mind for every Australian - **for anyone who has, or might acquire, a disability.** (National Disability Insurance Scheme, 2017a)

Additionally, further guidance is provided within the objects set out in section 3(1) of the *National Disability Insurance Scheme Act 2013* (Cth) which states:

> (1) The objects of this Act are to:
>
> (i) in conjunction with other laws, give effect to Australia's obligations under the Convention on the Rights of Persons with Disabilities done at New York on 13 December 2006 ([2008] ATS 12); and
> (ii) provide for the National Disability Insurance Scheme in Australia; and
> (iii) support the independence and social and economic participation of people with disability; and
> (iv) provide reasonable and necessary supports, including early intervention supports, for participants in the National Disability Insurance Scheme launch; and
> (v) enable people with disability to exercise choice and control in the pursuit of their goals and the planning and delivery of their supports; and
> (vi) facilitate the development of a nationally consistent approach to the access to, and the planning and funding of, supports for people with disability; and
> (vii) promote the provision of high quality and innovative supports that enable people with disability to maximise independent lifestyles and full inclusion in the mainstream community; and
> (viii) raise community awareness of the issues that affect the social and economic participation of people with disability, and facilitate greater community inclusion of people with disability; and
> (ix) in conjunction with other laws, give effect to certain obligations that Australia has as a party to:
>
> (i) the International Covenant on Civil and Political Rights done at New York on 16 December 1966 ([1980] ATS 23); and
>
> (ii) the International Covenant on Economic, Social and Cultural Rights done at New York on 16 December 1966 ([1976] ATS 5); and

(iii) the Convention on the Rights of the Child done at New York on 20 November 1989 ([1991] ATS 4); and

(iv) the Convention on the Elimination of All Forms of Discrimination Against Women done at New York on 18 December 1979 ([1983] ATS 9); and

(v) the International Convention on the Elimination of All Forms of Racial Discrimination done at New York on 21 December 1965 ([1975] ATS 40).

Given the NDIS seeks to achieve such life changing goals, it would be an illogical, if not somewhat perverse outcome, for the framework to deny access to disabled persons based upon fallacious beliefs about the nature of ME/CFS – or even worse, the use of information outside of the parameters of the legislative requirement to found decision in an 'appropriate evidence base'.

3. The Relevant Condition – ME/CFS

3.1 A Brief History

ME/CFS is the nomenclature of choice within the Australian community. Prior to 1988 ME was the diagnosis attributed to a specific patient cohort (Ramsay, 1986; Ramsay, 1988). ME has been classified as neurological by the World Health Organisation since 1969 (World Health Organization, 1969). In 1988, the US CDC created the Holmes criteria for CFS, in order to explain a number of significant outbreaks throughout the United States (Holmes, et al., 1988). There was no expressed intention to replace the diagnosis of ME, nor any research or evidence that the two were one and the same. Despite this fact, a small group of researchers within Australia unilaterally declared ME dead and replaced by the term CFS (Lloyd, Wakefield, Broughton, & Dwyer, 1988).

In 1994 the US Centres for Disease Control introduced a further criteria for CFS which was primarily designed for research and not a clinical setting (Fukuda, 1994). The CDC were clear in their view that ME was not CFS and expressly stated:

> **Various terms are incorrectly used interchangeably with CFS**. CFS has an internationally accepted case definition that is used in research and clinical settings. The name chronic fatigue and immune dysfunction syndrome (CFIDS) was introduced soon after CFS was defined; there is no case definition for CFIDS, and the name implies an understanding about the pathophysiology of CFS that is not fully supported in the medical literature. The name myalgic encephalomyelitis (ME) was coined in the 1950s to clarify well documented outbreaks of disease; however, **ME is accompanied by neurologic and muscular signs and has a case definition distinct from that of CFS**.(Centres for Disease Control, 2007)

More recently the US Institute of Medicine (2015), in reviewing the ME and CFS affirmed this view, stating:

> Historically, however, the diagnostic criteria for ME have required the presence of specific or different symptoms from those required by the diagnostic criteria for CFS; thus, **a diagnosis of CFS is not equivalent to a**

> **diagnosis of ME.**(Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 60)

Recent changes to the *British Medical Journal Best Practice* site for Practitioners updated their clarification of ME, stating "Myalgic encephalomyelitis (ME) is more strictly defined than CFS. ME is defined by: disabling fatigue; post-exertional malaise; sleep, pain, cognitive and autonomic dysfunction; and chemical irritant sensitivity" (BMJ Publishing Group Limited, Chronic Fatigue Syndrome, 2017).

Twisk (2016) and Jason et al (2017) reinforce this point out that the two entities share some symptoms but they are not the same (see Figure 1). The 2002 RACP Guidelines, arguably incorrectly, treats ME and CFS as one of the same – which is the preference of the authors who were involved in the 1988 unilateral declaration.

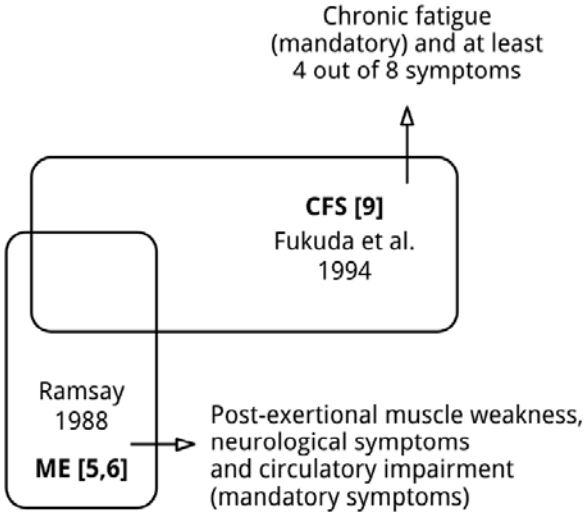


Figure 1 – ME and CFS – Two Distinct but Overlapping Diagnoses (Twisk F. M., 2016)

Following the recommendations of the Chronic Fatigue Syndrome Review Committee in 1993, the Royal Australian College of Physicians introduced 2002 CFS Guidelines (Loblay, et al., 2002). These Guidelines and the bulk of their recommendations are out of date (Senate Community Affairs Committee, 2017). In 2003 an International committee came together to create a consensus document for ME/CFS (Carruthers, et al., 2003).

Unlike the RACP Guidelines, the committee was not made up of a hand selected group in the manner the RACP Guidelines were, but rather a group of international ME/CFS clinicians and researchers who then conducted an extensive literature review to arrive at a set of evidence-based clinical guidelines to provide a general guide to best practice (Carruthers, et al., 2003). This consensus criteria has since become the foundation of numerous research papers into ME/CFS. In 2004 this criteria and treatment guideline was distributed by a South Australian Taskforce to assist medical practitioners with diagnosis and management in a community of primary care setting (South Australian Department of Health, 2004).

There are a number of other criteria that have arisen throughout the world, and Australia and each has a different patient population (see Figure 2). Within Australia ME will be occasionally diagnosed, as will CFS and ME/CFS.

Regardless of which of the three criteria is used, ME, CFS and ME/CFS remain diagnoses of exclusion. ME and ME/CFS provide a clear, objective approach to investigation and diagnosis (Carruthers, et al., 2003; Ramsay A. M., 1988; Hyde, 2010).

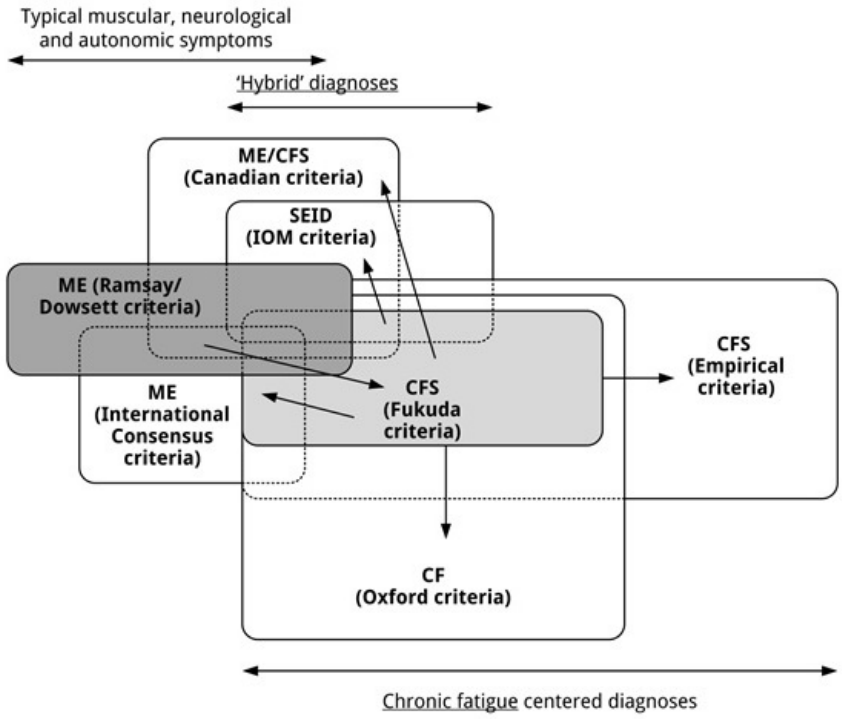


Figure 2 – Diagnostic Model for ME, CFS, ME/CFS and CF (Twisk F. N., 2017a, p. 2)

3.2 Not Mere Fatigue

It bares mention that there is a perception that ME/CFS and CFS are merely fatigue of a prolonged nature. Taylor and Jason (2001) have made this point very clear and the strength of it has not diminished:

> Chronic fatigue (CF) of 6 or more months occurs in approximately 4% to 5% of the population ... It is a key symptom of a variety of medical disorders including multiple sclerosis, systemic lupus erythematosus, and untreated hypothyroidism (CF-explained-medical), and it also accompanies a wide range of psychiatric disturbances and substance use disorders (CF-explained-psychiatric). (Taylor & Jason, 2001)

Whilst ME/CFS does have prolonged fatigue among the symptoms, it is but one of many. ME, ME/CFS and CFS are not in any way, the same as CF. This point will be borne out further in Submission 3 below.

3.3 Epidemiology

The incidence of ME/CFS within Australia has not been effectively or appropriately studied (Johnston, Brenu, Staines, & Marshall-Gradisnik, 2013). This is a direct consequence of a lack of funding in the area of ME/CFS research within Australia (Senate Community Affairs Committee, 2016), and a lack of encouragement of research by the medical fraternity (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015). Only $1.392

million has been awarded for CFS funding since 2005 by the National Health and Medical Research Council (Senate Community Affairs Committee, 2016).

The estimated community rate falls between 0.2 and 0.7 percent (Loblay, et al., 2002). The peak age of onset falls between 20 and 40 years of age(Loblay, et al., 2002).The condition impacts women more than men (Ranjith, 2005; Carruthers, et al., 2003). A number of high risk occupational groups have been identified as suffering higher rates of CFS. These include health care workers, airline pilots and shift workers (Ranjith, 2005). The ratio of women to males is 3:1 (Wyller, 2007, p. 7).

4. Terms of Reference: Point (d) – Any Other Related Matters

The purpose of this submission is to address the issue of the failure of the NDIS to adequately cater for persons with ME/CFS (and CFS). Whilst some matters clearly cross over into reference point (a) and (b), the matters are best dealt with generically and more clearly under reference point (d) (Parliament of Australia, 2017).

The issue of relevance to the committee would best be described as falling under issue (iv) being the decision-making processes (Parliament of Australia, 2017).

4.1 The Difficulty of Accessing the NDIS

4.1.1 Rejection of Applications

The feedback from within the ME/CFS patient community has been one of uniform denial by the NDIS (with the exception of just one patient that we are aware of). The foundation for denial is centred around one or all, of the following five reasons:

1. ME/CFS or CFS are not a disability because they are not a permanent condition;
2. ME/CFS or CFS are not a disability because they are not likely to be a permanent condition;
3. ME/CFS or CFS are not a disability because the condition does not result in a substantially reduced functional capacity;
4. ME/CFS or CFS are not eligible for early intervention because the condition does not result in a substantially reduced functional capacity;
5. ME/CFS or CFS are conditions that are a chronic health condition that is most appropriately supported by other agencies within the State of Commonwealth health system.

4.1.2 Insufficient Reasons Provided

Of those rejections that have been forthcoming to date, no applicants have been provided evidence or detailed reasons by the NDIA in their original decision correspondence or review, with respect to how they arrived at such conclusions. The applicants were provided no insight into the 'appropriate evidence base' used to found the above assertions, nor any expression of the policy foundation upon which it relies (if one, in fact, exists). The NDIS is a Commonwealth entity, hence subject to Model Litigant Guidelines – including the obligation to ensure applicants are accorded procedural fairness.

The only insight into the apparent source of the information informing decisions makes with respect to ME/CFS, has been thr better particulars provided by the NDIS in a current AAT matter (see: 9.1.1 Case Study). The apparent 'appropriate evidence base' is the Victorian Government's Better Health Channel's opinion piece website (Better Health Channel, 2016).

4.1.3 Apparent Flawed Evidence Base

Further compounding the issue has been the refusal of the NDIS/NDIA to confirm or deny the existence of a policy with respect to ME/CFS or CFS, and should one exist, provide the policy and/or the foundation for the policy. The refusal comes in the face of multiple formal and informal requests. In the absence of any apparent evidence base, the approach therefore appears to be one of applying an adverse public policy with respect to ME/CFS.

ME/CFS Legal speculates that decisions are therefore not related to the merits of the case and the appropriate evidence base. On the contrary, the decisions appear arbitrary and capricious, and contrary to the current state of the appropriate evidence.

4.1.4 Foundation for Submissions

The purpose of this submission if five-fold:

1. To make submissions with respect to entitlement to disability;
2. To make submissions with respect entitlement to early intervention;
3. To make submissions with respect to the evidence base, particularly with respect to interventions;
4. To make submissions with respect to the inclusion of ME/CFS and CFS in Schedule B of the NDIS Rules;
5. To make submissions with respect to Medicare assistance in providing reports

5. Merits Issues

ME/CFS Legal submits that a number of significant merit issues need to be ventilated with respect to persons with ME/CFS and CFS and their right to access the system. This merits submission is based upon the available 'appropriate evidence base' that exists with respect to the condition – and not merely a partial/negatively biased research view that appears to be influencing decisions of NDIA.

The breadth of conflicts within the history of the evidence base for ME/CFS and CFS arguably presents a significant confounder to the understanding of the true position of the condition. Whilst time has caused a significant pool of research to become redundant, ME/CFS Legal submits that the use of mismatched diagnostic criteria and the exceedingly poor quality of research that derives from it, is a significant source of the problem. This position is explored further within Submission 3 below, focusing on the United Kingdom's Oxford Criteria (1991).

In the absence of definitive NDIS position or policy (hence denial of access to the evidence base purportedly underlying the policy) with respect to ME/CFS or CFS, and no apparent NDIS assessment and reference package, ME/CFS Legal Resources has taken an educated guess as to the source of the evidence base informing the scheme.

Indeed the strength of this supposition is reflected in the references of the 2016 Better Health Channel Website (Better Health Channel, 2016).

Before engaging the deficiencies of that inappropriate evidence base, the specific issues causing denial will be addressed.

6. The Applicable Framework

6.1 The Legislative Requirements

The key to eligibility for ME/CFS applicant lies within sections 24 and 25 of the *National Disability Insurance Scheme Act 2013* (Cth) ('the Act'). Section 24 reads:

> 24 Disability requirements
>
> (1) A person meets the disability requirements if:
> (a) the person has a disability that is attributable to one or more intellectual, cognitive, neurological, sensory or physical impairments or to one or more impairments attributable to a psychiatric condition; and
> (b) the impairment or impairments are, or are likely to be, permanent; and
> (c) the impairment or impairments result in substantially reduced functional capacity to undertake, or psychosocial functioning in undertaking, one or more of the following activities:
>
> (i) communication;
> (ii) social interaction;
> (iii) learning;
> (iv) mobility;
> (v) self care;
> (vi) self management; and
> (d) the impairment or impairments affect the person's capacity for social and economic participation; and
> (e) the person is likely to require support under the National Disability Insurance Scheme for the person's lifetime.
>
> (2) For the purposes of subsection (1), an impairment or impairments that vary in intensity may be permanent, and the person is likely to require support under the National Disability Insurance Scheme for the person's lifetime, despite the variation.

Section 25 reads:

> 25 Early intervention requirements
>
> (1) A person meets the early intervention requirements if:
> (a) the person:
> (i) has one or more identified intellectual, cognitive, neurological, sensory or physical impairments that are, or are likely to be, permanent; or
> (ii) has one or more identified impairments that are attributable to a psychiatric condition and are, or are likely to be, permanent; or
> (iii) is a child who has developmental delay; and
> (b) the CEO is satisfied that provision of early intervention supports for the person is likely to benefit the person by reducing the person's future needs for supports in relation to disability; and

(c) the CEO is satisfied that provision of early intervention supports for the person is likely to benefit the person by:
  (i) mitigating or alleviating the impact of the person's impairment upon the functional capacity of the person to undertake communication, social interaction, learning, mobility, self care or self management; or
  (ii) preventing the deterioration of such functional capacity; or
  (iii) improving such functional capacity; or
  (iv) strengthening the sustainability of informal supports available to the person, including through building the capacity of the person's carer.

  Note: In certain circumstances, a person with a degenerative condition could meet the early intervention requirements and therefore become a participant.

(2) The CEO is taken to be satisfied as mentioned in paragraphs (1)(b) and (c) if one or more of the person's impairments are prescribed by the National Disability Insurance Scheme rules for the purposes of this subsection.
(3) Despite subsections (1) and (2), the person does not meet the early intervention requirements if the CEO is satisfied that early intervention support for the person is not most appropriately funded or provided through the National Disability Insurance Scheme, and is more appropriately funded or provided through other general systems of service delivery or support services offered by a person, agency or body, or through systems of service delivery or support services offered:
  (a) as part of a universal service obligation; or
  (b) in accordance with reasonable adjustments required under a law dealing with discrimination on the basis of disability.

6.2 The Applicable Rules

Accompanyin the Act are the *National Disability Insurance Scheme (Becoming a Participant) Rules 2016* (Cth) ('the Rules') made under sections 22, 23, 25, 27 and 209 of the Act. Such rules complement and inform the operation of the Act.

Part 5 of the Rules set out the preconditions for when an applicant meets the disability requirements. Part 6 sets out when the applicant meets the early intervention requirement. Part 7 sets out set out the requirements for assessment if an applicant meets the disability or early intervention requirements.

For the purposes of this submission, these rules are set out in Annexure 1 below.

Rules 2.3 to 2.7 state as follows:

> 2.3 A person becomes a participant in the NDIS on the day the CEO of the Agency decides they *meet the access criteria*.
>
> 2.4 A person meets the access criteria if the CEO is satisfied that they meet each of the following, as they apply in the area in which the person resides:
> (a) the *age requirements* (see Part 3);

(b) the *residence requirements* (see Part 4);
(c) either the *disability requirements* or the *early intervention requirements* (see Parts 5 and 6).

2.5 Generally speaking:

(a) a person will meet the disability requirements if they have a disability that is attributable to an impairment that is permanent or likely to be permanent and that results in substantially reduced functional capacity;
(b) alternatively, a person can access the NDIS through the early intervention requirements without having substantially reduced functional capacity. Instead, the early intervention requirements consider the likely trajectory and impact of a person's impairment over time and the potential benefits of early intervention on the impact of the impairment on the person's functional capacity. The CEO may consider a range of evidence in deciding the potential benefit of early intervention on a person's impairment. The CEO may consider existing evidence or information from an individual or their family or carer. Where a young child has an impairment resulting in developmental delay, or resulting from a condition on a list published by the CEO for which the benefits of early intervention have already been established, no further evidence of the benefit of early intervention supports to the child is required to meet the early intervention requirements. A young child or other person can still meet the early intervention requirements without having one of these conditions, provided there is evidence that the requirements are satisfied.

2.6 Part 7 deals with the use of assessment tools in assessing whether a person meets the disability requirements or the early intervention requirements.

The rules and Act are accompanied by various guidelines that provide insight into the operation of the Act. These will be referenced throughout.

7. Submission 1 - Disability and the NDIS

7.1 Specific Terms Under S. 24

Within section 24 of the Act, there are a variety of terms applied that have specific meaning and relevance to the submissions being made with respect to CFS and ME/CFS.

7.1.1 Disability

The characterisation of the term 'disability' as utilised by the NDIS arguably lacks clarity and definition – an issue apparently repeatedly highlighted to the Product Commission's study of NDIS costs (One Door Mental Health, 2017, p. 5).In the 2014 decision within *Mulligan v NDIA*[1], the Administrative Appeals Tribunal affirmed this position in confirming the NDIS Act and Rules had not

[1] *Mulligan and NDIA* [2014] AATA 374 per Toohey and McCallum.

defined the words 'disability' or impairment'.[2] Senior Member Toohey and Member McCallum state:

> A person may have a disability without necessarily meeting all, or even any, of the disability requirements in s 24(1)(b), (c), (d) and (e). For example, a person might have a temporary disability, or a permanent disability that has only minimal effect on functioning, or no effect on his or her social or economic participation. The fact that s 13(1) states that the NDIA may provide support to people with disability who are not participants tends to support this view.

In *Fear v NDIA*[3], the AAT affirmed the scope of the term 'disability' stating "there may be little obvious distinction between disability and chronic illness or medical conditions."[4]

The NDIS takes a "functional definition of disability"[5]and is based on Article 1 of the 2008 *United Nations Convention on the Rights of Persons with Disabilities.*[6]

In the 2014 matter of *Mulligan*, the AAT makes reference to the *Explanatory Statement to Becoming a Participant Rules 2014*. These rules focused upon disability being a lost of the ability to perform an activity that results in impairment – that "results in substantially reduced functional capacity". The rules state:

> Although the definition of "disability" under these Rules does not precisely correspond with that of the CRPD, the eligibility and assessment of need has been based on the World Health Organisation's International Classification of Functioning, Disability and Health (ICF). The narrower definition of "disability" employed by the [NDIS] is aimed at achieving a legitimate purpose by targeting those people with disability who have a significant impairment to their functional capacity. This functional definition of disability focuses on outcomes for the segment of the disability population that has the most unmet need.

In the 2015 matter of *Mulligan v NDIA*[7] made it very clear that "the NDIS was not intended to provide funded supports (as opposed to general supports) for every person with a disability" hence it is "intended to cover a subset of those affected by disability"– a much smaller cohort of those impact with a disability.[8]

The NDIS approach is slightly narrower and designed to respond to people that are in the most need (Royal Australian College of Physicians, 2017, p. 34). The focus is centred on the level of functional capacity, as it relates to deniability, and focuses on the activities set out in section 24(1)(c) of the Act.[9]

In the 2015 decision of *Mulligan v NDIA*, the tribunal found that given the intent that a subgroup of people will disabilities be included with the NDIS, the definition of disability "cannot be read

[2] Ibid, [19].
[3] *Fear by his mother Vanda Fear and NDIA* [2015] AATA 706.
[4] Ibid, [51].
[5] *Mulligan and NDIA* [2015] AATA 374 per Toohey and McCallum, [35].
[6] Ibid, [6], [37].
[7] Ibid.
[8] Ibid, [39].
[9] Ibid, [31].

down".[10] The tribunal reiterated the decision of Mortimer J in the 2015 Federal Court Decision, appealing the 2014 AAT case for *Mulligan*.[11]

A 'chronic health condition' can be classified as a disability because they can be disabling.[12] The Productivity Commission in making findings with respect to the NDIS conceded this point, stating

> The Commission does not favour a blanket 'yes' or 'no' response to the question of whether individuals with chronic health conditions would be covered by the scheme. Rather, **the answer should be informed by whether the NDIS is the most appropriate system to meet the person's needs**.[13]

In the 2015 case of *Fear v NDIA*[14], the AAT defined a health condition as:

> The term "health conditions" may also be broad. In the World Health Organisation International Classification of Functioning, Disability and Health it comprehends "diseases, disorders and injuries". **In some cases, the neurological or physical impairment that gives rise to a disability for the purposes of the disability requirements in s 24(1) of the Act might also be regarded as a chronic health condition**.[15]

It is conceded that a person can have a disability, yet possible not meet all, or indeed any, of the requirements under Section 24(1)(b)-(e) (National Disability Insurance Scheme, 2014c, p. 3). ME/CFS and CFS arguably fulfil the criteria for both.

7.1.2 Impairment

Like disability, impairment is not explicitly defined within the Act or Rules.[16]Impairment is different to the term disability in the context of Section 24(1)(a) of the Act.[17] Impairment in the context of the NDIS therefore means a loss of, or damage to, sensory, physical or mental function[18] (Royal Australian College of Physicians, 2017, p. 34). Such impairment must therefore be diagnosed by a qualified professional as a "recognised intellectual, cognitive, neurological, sensory, physical or psychiatric condition" (National Disability Insurance Scheme, 2014c, p. 3).

Rule 5.8 of the Rules also assists in understand. Under this rule an impairment must result "in substantially reduced functional capacity of a person to undertake one or more of the relevant activities—communication, social interaction, learning, mobility, self-care, self-management".

Mortimer J made it clear that impairment does not warrant a judgement as to severity:

> That being the case, no arbitrary limits are placed on access to the NDIS. No decision-maker need be satisfied a person's impairment is "serious", or more serious than another person's. No qualitative judgments in that sense

[10] Ibid, [52].
[11] *Mulligan v National Disability Insurance Agency* [2015] FCA 544, [17]-[18] per Mortimer J.
[12] *Mulligan and NDIA* [2015] AATA 374 per Toohey and McCallum, [43].
[13] Ibid.
[14] *Fear by his mother Vanda Fear and NDIA* [2015] AATA 706.
[15] Ibid, [55].
[16] *Mulligan and NDIA* [2014] AATA 374, [19] per Toohey and McCallum.
[17] *Mulligan and NDIA* [2015] AATA 374 per Toohey and McCallum, [33].
[18] *Mulligan v NDIA* [2015] FCA 544, [26]-[31] per Mortimer J; *National Disability Insurance Scheme Act 2013* (Cth) s. 24(1)(a).

> are called for. Rather, the legislative scheme is based on a functional, practical assessment of what a person can and cannot do. Critically, the scheme makes detailed provision for that assessment, and it is sufficient for a person to have substantially reduced functional capacity in relation to one activity. That, in my opinion, recognises the spectrum of impairments which can be experienced by persons with disabilities, and accommodates different abilities within one person in terms of her or his daily activities. That is why a detailed functional assessment is so important.[19]

The applicant will provide information with respect to the impairment on the Access Request Form, which requires that the applicant respond to the access criteria with information. Diagnostic information is also required for the purposes of assessing attribution of disability to an impairment. Additional information with respect to a person's reduced function can be supplemented by being provided on the Evidence of Disability form, thereby outlining other information with respect to impairments outline in section 24(1)(a) of the Act. (National Disability Insurance Scheme, 2014c, p. 4)

7.1.3 Permanent Impairment

Under section 24(1)(b) of the Act, there is a requirement that an applicant demonstrate disability by showing that the claimed "impairment or impairments are, or are likely to be permanent." The Act is assisted by the rules with respect to the assessment of permanence. Specifically Rules 5.2, and 5.4-5.7 are of significance to establishing if a applicant is, or is not, suffering a permanent impairment (National Disability Insurance Scheme, 2014c, p. 4).

7.1.3.1 Variable Intensity

Rule 5.2 establishes that an impairment "that varies in intensity (for example, because the impairment is of a chronic episodic nature) may be permanent despite the variation." (National Disability Insurance Scheme, 2014c, p. 4).

7.1.3.2 Evidence Base

Rule 5.4 establishes that an impairment "is, or is likely to be, permanent only if there are no known, available and appropriate evidence-based clinical, medical or other treatments that would be likely to remedy the impairment.(National Disability Insurance Scheme, 2014c, p. 4)"

In *Mulligan v NDIA*, the AAT affirmed Rule 5.4 "provides that an impairment is, or is likely to be, permanent only if there are no known available and appropriate evidence-based clinical, medical or other treatments that would be likely to remedy it".[20]

7.1.3.3 Fluctuating Severity

7.1.3.3.1 The Issue of Severity

Fluctuating severity is one of the key hurdles for an applicant to overcome when establishing permanence. Rule 5.5 establishes that an "impairment may be permanent notwithstanding that the severity of its impact on the functional capacity of the person, may fluctuate or there are prospects that the severity of the impact of the impairment on the person's functional capacity, including their

[19] Ibid, [56].
[20] Ibid, [69].

psychosocial functioning, may improve"(National Disability Insurance Scheme, 2014c, p. 4). The Operational Guidelines, however, provide further understanding, stating:

> 31. For NDIS purposes, where the person's impairment is fluctuating or episodic (e.g. due to a mental illness or a condition such as epilepsy), substantially reduced functional capacity is determined when the person's impairment is fully treated and stabilised, (i.e. the person's level of functional capacity due to residual and long term impairment is determined in the periods between acute episodes)(National Disability Insurance Scheme, 2014c, p. 6).

The key issues for applicants with ME/CFS and CFS is the need to demonstrate that the condition is fully treated and stabilised. This is an area that ME/CFS Legal identifies as of significant concern in terms of the approach of the NDIA to assessment. This concern derives from the issues arising from the same wording in Centrelink Disability Pensions assessments.

7.1.3.3.2 Case Law Interpretation

The phrase "fully treated and stabilised" is replicated in the assessment of the permanency in the Social Security Impairment Tables under Part 2, Paragraph 6(4)(c) and (d) respectively,[21] and defined within Paragraph 6(5) (Fully Treated) and 6(6) (Fully Stabilised) respectively.

In *Tooley v Secretary, Department of Employment and Workplace Relations*[22], the applicant was diagnosed with CFS and in considering his impairment under the applicable tables, the Member deferred to three treatment the Secretary argued were required as treatment for CFS:

> Was Mr Tooley's condition fully treated? … There were three treatment modalities suggested during the hearing, including drug therapy such as antidepressants, cognitive behaviour therapy and a graduated program of physical activity.[23]

Anecdotal evidence and experience of dealing with numerous ME/CFS and CFS applicants, affirms that the policy utilised in the Centrelink process is an expectation that GET and CBT be applied BEFORE any claim is accepted. Centrelink is clearly of the view that these are the appropriate treatments and fulfil the requirements Part 2, Paragraph 6(7) of the Impairment Tables, which defines reasonable treatment:

> (7) For the purposes of subsection 6(6), reasonable treatment is treatment that:
> (a) is available at a location reasonably accessible to the person; and
> (b) is at a reasonable cost; and
> (c) can reliably be expected to result in a substantial improvement in functional capacity; and
> (d) is regularly undertaken or performed; and
> (e) has a high success rate; and
> (f) carries a low risk to the person.

[21] *Social Security (Tables for the Assessment of Work-related Impairment for Disability Support Pension) Determination 2011*.
[22] *Tooley v Secretary, Department of Employment and Workplace Relations* [2007] AATA 1666 per Denovan M.
[23] Ibid, [134].

It is submitted that in ME/CFS and CFS in some cases, the applicant will have a history of fluctuating severity. However, it is further submitted that the use of Graded Exercise Therapy and Cognitive Behavioural therapy has been shown by the evidence base, not to provide substantial improvement in functional capacity, not have a high success rate, not be undertaken regularly and in a substantial number of cases, causes deterioration or no benefit.

7.1.3.3.3 GET and CBT are Damaging

In July of 2017, the US Centres for Disease Control removed CBT and GET from its site and ceased recommending these treatments are recommended management of CFS (Centres for Disease Control, 2017). This is no coincidence. It is the result of a change in the evidence base -particularly the identification of methodological flaws in studies that caused misrepresentations of the effectiveness of outcomes and efficacy.

Kindlon (2011) raised the adverse impacts of GET and CBT, and thoroughly examined the harms associated with exercise-related physiological abnormalities that arise from GET. Significantly, he revealed that large scale patient surveys demonstrated some 51% reported that GET cause their health to become worse, while 20% of those using CBT reported a worsening of symptoms (Kindlon T. , 2011a, p. 60). Kindlon argued strongly that the reporting of harms in ME/CFS were not being tracked by systematic methods within research trials, nor outside of the trials (Kindlon T. , 2011a, p. 84).Aside from being a flaw in the research, it was arguably and ethical breach. With patients reporting harm, and the primary research papers examining GET and CBT not properly reporting harms, Kindlon correctly calls into question the validity of such research.

At 7.3.1.1.6 and 9.2.6ME/CFS Legal outlines an extensive, evidence based review of the flaws in the largest trial of CBT and GET.

Suffice to say, PACE is founded on the Oxford (1991) criteria, hence is not generalisable to the Australian applied criteria for ME/CFS and CFS, being Carruthers (2003) and Fukuda (1994) respectively. PACE has been demonstrated as a flawed study founded in misconduct (Tuller, 2017; Various, 2017), yet it has incorrectly and inappropriately dominated the landscape of ME/CFS and CFS when it comes to providing any tangible benefit for patients (Vink M. , 2017a)

Baranuik (2017) recently pointed out the methodological flaws of PACE in rejecting the applicability of the various papers to practice"

> A meta-analysis of RCTs has suggested that exercise therapy is generally beneficial for sleep, physical function, and self-perceived general health in patients with fatigue diagnosed using the outmoded Oxford criteria of minimal fatigue. However, **this analysis did not report drop-out rates or measure the consequences of exercise therapy on immediate and delayed PEM, pain, and cognitive dysfunction**. Furthermore, no conclusions could be drawn on the effects of exercise therapy on quality of life, anxiety, depression, and use of health service resources. Exercise therapy was shown to be more effective than pacing, but similar to passive non-physical CBT. The use of the Oxford criteria in 5 of the 8 studies included in the analysis is an important limitation of the review. These criteria include patients with altered mood and depression, which will bias study outcomes because exercise has a direct beneficial effect in affective dysfunction. (Baraniuk, Chronic fatigue syndrome prevalence is grossly overestimated

> using Oxford criteria compared to Centers for Disease Control (Fukuda) criteria in a U.S. population study, 2017, p. 39)

The relevant and appropriate evidence base therefore identifies that treating patients with GET and CBT can cause deterioration, or no benefit what so ever, on the majority of occasions.

ME/CFS Legal submits that satisfaction of Part 2, Paragraph 6(7) of the impairment tables is far from achieved. If one applies the same reasoning to the NDIS decision making process, the expectation that CBT and GET be carried out first, falls away.

Putting this argument aside for one moment, there is one more flaw in the utilisation of these approaches and that is one of replication.

Even if one were to assume that CBT and GET research demonstrated effectiveness, there is an inescapable flaw in their application in Australia – the treatment regime is not conducted in the same manner in which it was carried out within research. The application of GET and CBT in Australia is that practitioners 'create' their own approach, without evidence base, and apply it as being GET or CBT. There is no protocol to follow. These practitioners do not utilise the same setting, tools, supervision, structure or approach. Calling something GET does not mean it is the same animal that was applied within a research paper. Quite frankly it is negligent to suggest that they are one and the same – yet that is the characterisation that exists under the Impairment Tables and within the NDIA assessment process.

It is dangerous and inappropriate.

7.1.3.3.4 Submission

In the absence of an effective, relevant evidence based literature on treatment, ME/CFS Legal submits that CBT and GET are not relevant to establishing if the condition is fully treated and stabilised. CBT and GET should be disregarded in the same manner as the recommendations of the US Centres for Disease Control. With respect, the UK approach is based on a symptom, being chronic fatigue, and not ME/CFS or CFS. This will be elucidated further at 9.2 below

7.1.3.4 Medical Treatment or Review

Rule 5.6 establishes that an "establishes that an impairment is, or is likely to be, permanent only if the impairment does not require further medical treatment or review in order for its permanency or likely permanency to be demonstrated (even though the impairment may continue to be treated and reviewed after this has been demonstrated). In relation to this requirement:

> a. What is required is information that is sufficient to demonstrate to a delegate that the impairment is permanent or likely to be permanent. This is matter of judgment but what the Becoming a Participant Rules are trying to do is rule out cases where the permanency or likely permanency has not been established because the person requires further medical treatment or review before the permanency or likely permanency can be demonstrated.
>
> b. This does not mean that an impairment will not be permanent or likely to be permanent if it requires further medical treatment or review. In addition to that described in paragraph 15a above, in some cases an impairment may continue to be treated and reviewed after it has been demonstrated that is permanent or likely to be permanent.(National Disability Insurance Scheme, 2014c, p. 4)

7.1.3.5 No Improvement

Rule 5.7 establishes that no improvement will be deemed were "an impairment is of a degenerative nature, the impairment is, or is likely to be, permanent if medical or other treatment would not, or would be unlikely to, improve it" (National Disability Insurance Scheme, 2014c, p. 5).

7.1.3.6 Summary

With a variety of approaches to the issues of identifying the nature of permanency, it is clear that the rules provide a variety of considerations with respect. Most significant with respect to ME/CFS and CFS, there is facility to allow for fluctuations within the intensity of the condition and the severity.

7.1.4 Substantially Reduced Functional Capacity

The issue of identifying the components that demonstrate a substantially reduced functional capacity is a complex one, however, it is submitted, not one that presents a challenge in the context of ME/CFS or CFS.

Under section 24(1)(c) of the Act, there is a requirement that an applicant demonstrate disability by showing that the claimed "impairment or impairments result in substantially reduced functional capacity to undertake, or psychosocial functioning in undertaking, one or more of the activities listed in s.24(1)(c)" (National Disability Insurance Scheme, 2014c, p. 5). The activities listed in section 24(1)(c) are "communication, social interaction, learning, mobility, self-care, self-management".

Deference to Rule 5.8(a) identifies that a substantial reduction in capacity results if the"person is unable to participate effectively in the activity, or perform tasks or actions required to undertake or participate effectively in the relevant activity due to their impairment, without assistive technology, equipment (other than commonly used items such as glasses) or home modifications" (National Disability Insurance Scheme, 2014c, p. 5).

Rule 5.8(b) further identifies that thata substantial reduction in capacity results if the "person usually requires assistance (including physical assistance, guidance, supervision or prompting), from other people to participate in the activity or to perform tasks or actions required to undertake or participate effectively in the activity. Delegates may also take into account the person's age and whether they are able to perform tasks that they would normally be expected to perform independently at their age" (National Disability Insurance Scheme, 2014c, p. 5).

Rule 5.8(c) further identifies that that a substantial reduction in capacity results if the "person is unable to participate in the activity or to perform tasks or actions required to undertake or participate in the activity, even with assistive technology, equipment, home modifications or assistance from another person" (National Disability Insurance Scheme, 2014c, p. 6).

In *Mulligan*[24] the AAT established some of the bounds of a substantial reduction:

> If it were, a person with a permanent impairment which has no effect on functioning could satisfy s 24(1) as long as he or she has another impairment which substantially reduces functioning in a relevant area even if it is only temporary.

[24]*Mulligan and NDIA* [2015] AATA 374 per Toohey and McCallum, [72].

In effect, two or more concurrent impairments can exist and amount to a substantial reduction, so long as one meets the requirements.

7.1.5 Social and Economic Participation

Section 24(1)(d) of the Act has regard to impairment that effects the applicant's capacity for social and economic participation. The applicant must demonstrate that their "impairment or impairments is affecting their capacity for social and economic participation to meet this disability requirement"(National Disability Insurance Scheme, 2014c, p. 6).

For example, the impairment may be affecting the person's capacity to look for and maintain employment.

The Applicant need not satisfy a delegate that their capacity for social and economic participation is reduced or substantially reduced - it is sufficient to demonstrate their capacity for social and economic participation to be merely affected by the impairment. This is a much lower threshold.

In the 2014 decision in *Mulligan* the AAT referenced the various domains affected by incapacity, concluding:

> We accept that Mr Mulligan retains substantial capacity for social and economic participation but the test in this requirement is only that a person's capacity for social and economic participation be affected. There is no requirement that it be affected to any particular degree. We accept that Mr Mulligan's participation in social life is reduced, mainly on account of his fear of exerting himself and bringing on a panic attack, and we accept that he has been on leave of absence from his work with the Samaritans for the past three months on account of his sciatic pain.[25]

7.1.6 Lifetime Support

Section 24(1)(e) of the Act has regard to an applicant with a disability who is likely to require support under the NDIS for the person's lifetime (National Disability Insurance Scheme, 2014c, p. 6). The applicant is required to demonstrate that:

a. they are likely to require support of a kind that is funded or provided under the NDIS; and

b. the support is likely to be required for the rest of the person's lifetime.

The 2015 decision in *Mulligan* identified that neither the rules nor the operational guidelines gave guidance on this issue. The AAT considered that:

> 146. The NDIA accepts that Mr Mulligan will need access to general supports for the rest of his life. The NDIA contends, however, that s 24(1)(e) requires consideration of whether the supports sought by an applicant are of a kind that would be reasonable and necessary within the meaning of s 34(1). We do not think that interpretation can be correct.
>
> 147. There does not appear to be any basis for reading "support" in s 24(1)(e) differently from "supports" elsewhere in the Act ... 149. It is

[25] *Mulligan and NDIA* [2014] AATA 374, [50] per Toohey and McCallum.

> clear that a person may be a participant in the NDIS without necessarily receiving general supports or reasonable and necessary supports …
>
> 153. It is difficult to know what to make of s 24(1)(e). It is easier to say what it does not mean than what it does mean. Given that it is one of the disability requirements, its purpose must be to distinguish that subset of people with serious and permanent disabilities who are intended to be the beneficiaries of funded supports.[26]

The AAT decision therefore provides some clarity on the issue to guide satisfaction of this requirement by an applicant.

7.2 Submission 1(A) - Impairment

7.2.1 Evidence of Impairment

As detailed above, section 24(a) of the Act is the first of the five elements to the assessment of disability and it centres on impairment. Impairment must consist of "one or more intellectual, cognitive, neurological, sensory or physical impairments or to one or more impairments attributable to a psychiatric condition."

It is the submission of ME/CFS Legal that ME/CFS and CFS are conditions that inherently satisfy all 6 of these impairments:

(a) *Intellectual* – There is a substantial body of evidence that the conditions cause deterioration of intellectual function. This can occur when a patient enters a post exertional state, "taking an inordinate amount of time to regain his/her pre-exertion level of function and competence" (Carruthers, et al., 2003, p. 15). Such deficiencies are measurable via psychometric testing (DeLuca J. , Johnson, Beldowicz, & Natelson, 1995, pp. 39-42; Nijhof, et al., 2016, pp. 247-250);

(b) *Cognitive* – There is a substantial body of evidence that the conditions cause deterioration of cognitive function (Twisk F. N., 2015, p. 72). The literature on the condition is consistent in demonstrating "that neurocognitive problems such as memory impairment, slowed information processing, attention deficits, and impaired psychomotor function are highly prevalent in ME/CFS patients" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 100).

Carruthers et al (2003) include an extensive list of cognitive symptoms within the Consensus Criteria, which include "confusion, impairment of concentration and short-term memory consolidation, disorientation, difficulty with information processing"(Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 97)."

Cognitive problems are objectively assessable via psychometric testing (DeLuca J. , Johnson, Beldowicz, & Natelson, 1995, p. 39; DeLuca J. , Johnson, Ellis, & Natelson, 1997, p. 154; Ickmans, et al., 2013, p. 1476; Ickmans, et al., 2015, pp. E843-E844;

[26] *Mulligan and NDIA* [2015] AATA 374 per Toohey and McCallum, [146], [147] and [153].

Nijhof, et al., 2016, pp. 247-250) as well as EEG/qEEG (Zinn, Zinn, & Jason, 2016b, pp. 1-2; Zinn, Zinn, & Jason, 2016a, pp. 283-285).

Zinn et al (2016c) affirm that neurocognitive dysfunction "are reported by nearly all (at least 90% of) patients as having a severe impact on their everyday living" (Zinn, Zinn, & Jason, Functional Neural Network Connectivity in Myalgic Encephalomyelitis, 2016c, p. 28). The authors conducted a thorough literature review on neurological and neurocognitive effects of CFS and ME, including identifying various objective measures through which the cognitive issues can be diagnosed (Zinn, Zinn, & Jason, Functional Neural Network Connectivity in Myalgic Encephalomyelitis, 2016c, pp. 39-41).

Twisk (2015) refers to "cognitive impairment ('brain fog')" as a "characteristic symptom of ME/CFS" and continues to state that "Several studies … have established a wide range of neurocognitive deficits in ME/CFS… Some findings indicate that the neurocognitive problems are induced or intensified by exercise and an upright (orthostatic) position. Cognitive impairment seems to be more severe in sudden onset-ME/CFS .... ME/CFS patients can present with moderate to large deficits in simple and complex information processing speed (attention, memory and reaction time), in tasks which require working memory over a sustained period of time, in tasks which necessitate (simultaneous) processing of complex information and in conflict-monitoring tasks (interference control). Specific cognitive deficits, reduced exercise capacity, decreased muscle power (strength and endurance) and immunological aberrations, e.g., inflammation, seem to be interrelated. Cognitive impairments can be identified, but only if the appropriate measures are used. This important observation is confirmed by a meta review of 50 studies and 79 tests. All tests for assessing attention, including attention span and working memory, showed significant deficits in ME/CFS. The effect sizes for most word list learning and recall tests were significant, but some tests seem more sensitive to memory deficits in ME/CFS than others. Reaction time is substantially impaired for responses to both simple and complex (choice) stimuli. Only two of the five tests used to assess movement times revealed significant group differences. Most tests for visuospatial ability, verbal abilities and language, cognitive reasoning and flexibility, and global functioning didn't yield significant group differences. In order to determine cognitive impairment objectively, ME/CFS patients should be subjected to neuropsychological tests aimed at the abnormalities found in ME/CFS patients, e.g., attention and memory. Cognitive deficits don't seem to be related to "fatigue" or comorbid depression. Goedendorp et al have suggested that low cognitive test scores are due to underperformance, but this view is based upon the subjective premise that ME/CFS has not proven to be a cognitive disorder. Objective measures indicate high levels of effort and an intention to do well during neurocognitive testing." (Twisk F. N., 2015, p. 72).

(c) *Neurological* – the conditions are, by the very definition at the WHO, neurological in origin (World Health Organization, 1969). Ferrero (2017) affirm this position, stating "CFS is classified as a neurological disorder and increasing evidence supports CFS as a disease of the nervous and immune systems" (Ferrero, Silver, Cocchett, Eliezer Masliah, & Langford, 2017, p. 1).

Twisk (2015) conducted a broad literature review and notes that "various studies have observed neurological aberrations, e.g., reduced white and grey matter volume, electroencephalography (EEG) abnormalities, hypoperfusion of the brain, hypometabolism, neuro-inflammation of widespread brain regions, increased fractional anisotropy in the right arcuate fasciculus and, in righthanded patients, of the right inferior longitudinal fasciculus, and spinal fluid abnormalities. A relationship between neurological anomalies and cognitive symptoms has also been observed" (Twisk F. N., 2015, p. 72)

ME/CFS and CFS cause significant neurological damage including function of parietal-occipital regions of the brain (Zinn, Zinn, & Jason, Intrinsic Functional Hypoconnectivity in Core Neurocognitive Networks Suggests Central Nervous System Pathology in Patients with Myalgic Encephalomyelitis: A Pilot Study, 2016a, pp. 7-8). Carruthers et al (2003) require neurological symptoms as part of the Consensus Criteria, including: "neurologic (perceptual and sensory disturbances, ataxia, muscle weakness, and fasciculations) manifestations" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 97).

Carruthers et al (2003) note that the "neurological/cognitive symptoms are more characteristically variable than constant and often have a distinct fatiguing component to them" (Carruthers, et al., 2003, p. 17) The committee continues, stating: "Neurological dysfunction is often seen, including hypersensitivity to vibration sense, positive Romberg test and abnormal tandem gait. Simple mental status measures are often normal, but abnormal fatiguing on serial seven subtraction testing is common. Mutual aggravation when tandem gait and serial sevens are done simultaneously, may be evident when the baseline serial sevens test and tandem gait are both normal. As more of these signs are elicited in the same patient, the diagnosis of ME/CFS is increasingly confirmed" (Carruthers, et al., 2003, p. 17). .

Neurological impairment identified within the 2011 International Consensus Criteria (an updating of the 2003 Consensus Criteria) includes "neurological impairments (which encompass neurocognitive impairments; pain; sleep disturbance; and neurosensory, perceptual, and motor disturbances)" (Carruthers, et al., 2011, p. 50).

A recent paper by Natelson et al (2017) demonstrated that poor neuropsychological performance correlated to the presence of a number of neurobiological and spinal fluid abnormalities in CFS (Natelson, et al., 2017). Similarly in Ferrero et al (2017), presented evidence that "illustrate vascular pathology, demyelination in focal areas and diffuse reactive astrogliosis, as well as the presence of Aβ plaques and axonal and neurofibrillary pathology. Robust tauopathy was also observed, with evidence of aberrant sprouting and the presence of abundant Aβ+ plaques in frontal cortex white matter" (Ferrero, Silver, Cocchett, Eliezer Masliah, & Langford, 2017, pp. 1-2).

(d) *Sensory* – the conditions impacts upon multiple sensory areas, and include issues such as "photophobia and hypersensitivity to noise – and/or emotional overload, which may lead to 'crash' periods and/or anxiety" (Carruthers, et al., 2003, p. 11). The committee further states: "Research findings suggest that there is a lower tolerance to noxious stimuli such as exposure to excessive noise, light, fast-paced and/or confusing

environments in many ME/CFS patients." (Carruthers, et al., 2003, p. 73). The recent IOM Committee outlined various sensory issues, including "sensory changes (e.g., tingling skin, increased sensitivity to noise)" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 78)

(e) *Physical* –The physical impact of ME/CFS and CFS is the most significant aspect of the condition. Jason et al (2007) have been very clear about the impact of CFS: "Patients with CFS are more functionally impaired than those suffering from type 2 diabetes mellitus, congestive heart failure, multiple sclerosis, and end-stage renal disease" (Jason & Richman, 2007, p. 86).

The IOM Committee (2015) recognise this: "Nacul and colleagues … found that scores on the role-physical (RP)1 subscale of the SF-36 were even more affected than scores on the VT subscale (version 2) but that all domains were impaired, with mental health being the best preserved. Jason and colleagues … found that impairments in physical functioning, social functioning, and role-physical had the greatest sensitivity and specificity in identifying patients who met the Fukuda definition of ME/CFS" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 76).

Symptoms	Tests
Lack of energy: physical weakness and "fatigue"	CPET 1: workload and oxygen uptake at exhaustion and at the anaerobic threshold
Cognitive impairment	Specific neuropsychological tests
Post-exertional "malaise"	
Physical effects	Repeated CPETs 1, 24 h apart
Cognitive effects	Specific neuropsychological tests before and after a CPET or before and during a tilt table test Repeated neuropsychological tests
Muscle weakness	Examination of the muscles (power, endurance, recovery)
Orthostatic intolerance	Tilt-table test
Defective stress response	Hormonal investigation (HPA axis, thyroid) in rest, at specific moments, *e.g.*, at wakening, and during the day, after provocation, *e.g.*, by adrenocorticotropic hormone and insulin, and in response to an exercise test or psychological stress test
Sleep impairment	Polysomnographic investigation (EEG) Maintenance of wakefulness test Multiple sleep latency test
Visual symptoms	Useful field of view tests Eye movement tests

Table 1 - Symptoms and Tests to Assess the Disability in ME/CFS Objectively (Twisk, 2005, 72)

Blease, Carel and Geraghty (2017)outline the physical aspects conveyed in the "biomedical model of the illness, noting the condition[which] include a wide range of theories including hypotheses that CFS/ME is a cellular level dysfunction, immune system disorder, muscular system disorder, an inflammatory condition and/or a neurological dysfunction" (Blease, Carel, & Geraghty, 2017, p. 550).

In both ME/CFS and CFS, there is an emphasis upon physical symptoms within the relevant criteria. Fatigue, joint and muscle pain, and post exertional malaise, are the primary symptoms under both applicable guidelines (Carruthers, et al., 2003; Fukuda, 1994), while the 2003 Consensus Guidelines introduce a more extensive physical symptoms such as orthostatic intolerance, sleep impairment and visual symptoms.

Twisk (2015) identifies a number of physical symptoms and provides an objective test grounded in the literature (noting many are not available in Australia or have limited availability (Table 1).

Twisk (2015) concludes that "ME/CFS has a greater negative impact on functional status and well-being than other chronic diseases, e.g., cancer or lung diseases, and is associated with a drastic decrement in physical functioning. In a comparison study ME/CFS patients scored significantly lower than patients with hypertension, congestive heart failure, acute myocardial infarction, and multiple sclerosis (MS), on all of the eight Short Form Health Survey (SF-36) subscales. As compared to patients with depression, ME/CFS patients scored significantly lower on all the scales …" (Twisk F. N., 2015, pp. 73-74)

Twisk (2015) specifically points to the "physical effects of physical exertion" and the use of a Cardiopulmonary Exercise Test (CPET) as a tool for objectively identifying the effect of exercise. He advises there is a "profound decrease in the exercise capacity at a second CPET 24h after the first CPET seems typical for ME/CFS and is neither observed in sedentary healthy controls nor in patients with other diseases. The "exercise intolerance" in ME/CFS can be reflected in significantly lower oxygen uptake and performance levels at exhaustion (VO2max and Wmax) or at the anaerobic threshold (VO2 AT and W AT) at the second CPET. In contrast, the first CPET appears to have a positive effect on the anaerobic threshold in sedentary controls at the second CPET. Due to the first CPET the anaerobic threshold can decrease to a level below 5 METS; a level at or below that which is required by many job-related activities and IADLs. Since many daily activities fall into the 3-5 MET energy range, persons with ME/CFS will exacerbate symptoms simply by completing normal daily activities. A recent study observed that VO2max at the first exercise test was reduced in ME/CFS … that all patients showed clinically significant decreases in either VO2max and/or oxygen uptake at the ventilatory threshold (VOS VT) at the second CPET, and that a classification of impairment based on the VO2max or of functional ability for 50% of the patients." (Twisk F. N., 2015, pp. 73-74)

(f) *Psychiatric* – There is a significant body of research with respect to the psychiatric issues that arise in ME/CFS and CFS. The psychosocial experience of the condition by patient has a significant role in the onset of psychiatric conditions.

The psychiatric impact of ME/CFS and CFS is an event that follows the onset of the condition. ME/CFS and CFS have previously been erroneously and mistakenly labelled a psychiatric condition (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 183). Natelson et al's (2017) recent paper affirmed this fact: "Thus, this study joins several prior others that found that the presence of psychiatric illness is not related to illness severity as reflected by illness course, cognitive processing, or physical function. This result is very important because it indicates that neither the phenomenology of CFS nor its biology is driven by psychiatric diagnosis" (Natelson, et al., 2017, p. 413).

Jason and Richman (2006) identify the impact of this mistaken belief as a source of distress for patients: "Despite its chronicity and severity, CFS remains highly controversial. A particularly high percentage of patients with this illness have experienced disrespectful treatment by the health care system … 77% of individuals with CFS reported negative experiences with health care providers … 95% of individuals seeking medical treatment for CFS reported feelings of estrangement, and 70% believed that other uniformly attributed their CFS symptoms to psychological causes, despite findings that comorbidity between CFS and psychiatric disorders is considerably, lower among patients with CFS … 66% of individuals with CFS believed that they were made worse by their doctors' care. Many health care professionals continue to doubt the scientific validity of this diagnosis. We have argued that the social construction of this disorder as a psychogenic illness of neurotic women, similar to earlier depictions of multiple sclerosis, have contributed to the negative attitudes that health care providers have toward those with this syndrome." (Jason & Richman, 2007, pp. 86-87)

Anxiety (health anxiety) and depression are common in ME/CFS and CFS, often arising out of being delegitimized, and concern over a lack of knowledge and understanding by health professionals (Daniels, Brigden, & Kacorova, 2017, pp. 1, 5). Johnstone et al (2016) asserted that "This reduced economic position adds further to the stress, anxiety, or depression that may develop with a chronic condition, particularly in those patients who are bedridden or housebound for protracted periods of time and receive limited support" (Johnson, Staines, & Marshall-Gradisnik, 2016, p. 98).

The role of mental health in ME/CFS impairment can be measured by way of a Short Form 36 questionnaire (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 77, 262). Williams (2016) identifies that patients with CFS/ME were subject to various degrees of disability and psychological distress, hence often physically dependent on other people (Williams, Christopher, & Jenkinson, 2016, p. 1). In examining the psychological impact of dependency, Williams identified that patients experienced loss of independence and self-identity, endured an invisible illness, had anxieties with respect to the present and the future, felt caught in a catch-22, internalised anger, and had issues with respect to acceptance of the condition (Williams, Christopher, & Jenkinson, 2016, pp. 5-7).

Carruthers et al (2003) states that "The chronic, incurable and poorly understood nature of this illness reduces the quality of medical and social support and may

increase the risk of suicide" (Carruthers, et al., 2003, p. 29). Suicide rates among patients with ME/CFS and CFS are many times the average of the normal population. Robert et al (2016) identified a "specific increased risk of suicide in a population of patients with chronic fatigue syndrome compared with the general population" (Roberts, Wessely, Chalder, Chang, & Hotopf, 2016, p. 1642). Roberts also found a "significant cross- sectional and prospective association exists between chronic fatigue syndrome and non-exclusionary psychiatric disorder comorbidity, with depression and anxiety disorders being strongly associated with chronic fatigue syndrome" (Roberts, Wessely, Chalder, Chang, & Hotopf, 2016, p. 1642).

7.2.2 Submission on Impairment

It is the submission of ME/CFS Legal that the very diagnosis of ME/CFS (or CFS) should be taken to satisfy one, if not all, of the conditions of section 24(a), without the need for proof of each issue. The condition, by its very nature, impacts upon most if not all 6 impairments set out in section 24(a).

Section 24(a) does not necessitate that all impairments be satisfied. It is the submission of ME/CFS Legal that by definition, ME/CFS and CFS fulfil the criteria by virtue of the fact that they are diagnosed by way of a set of symptoms and such symptoms fall within the impairments under section 24(a):

1. *Fukuda (1994) Criteria for CFS* - In the CFS criteria (see: Table 2) fatigue is a cardinal symptom (a physical and cognitive symptom under s. 24(a)) that **causes a "substantial reduction" in the activities of daily living** (hence an impairment). The patient must then satisfy at least four of eight secondary symptoms (ie physical, cognitive, or neurological);

		Criteria	
Symptom		**ME/CFS**	**CFS**
General Physical	Fatigue (> 6 Months)	X	X
	Sudden or New Onset (Not Life Long)	X	X
	Substantial reduction in previous levels of occupational, educational, social, or personal activities;	X	X
Neurological/ Neurocognitive	Joint Pain	X	X
	Muscle Pain	X	X
	Post Exertional Malaise	X	X
	New Headaches	X	X
	Arthralgias (migratory)	X	X
	Sleep Disturbances	X	X
	Neurological or Cognitive Complaints	X	
	Memory of Cognitive Impairment	X	X
Neuroendocrine/ Immune	Autonomic Dysfunction	X	
	Sore Throat		X
	Lymph Node Pain		X
	Neuroendocrine Dysfunction	X	
	Immune Manifestations	X	

Table 2 – Case Definitions – ME/CFS and CFS

2. *Carruthers (2003) Criteria for ME/CFS* - In the ME/CFS criteria (see: Table 2) fatigue is a a major symptom (a physical and cognitive symptom under s. 24(a)) that causes a "substantial reduction" in the activities of daily living (hence an impairment). The patient must meet the criteria for fatigue, post-exertional malaise and/or fatigue, sleep dysfunction, and pain; have two or more neurological/cognitive manifestations and one or more symptoms from two of the categories of autonomic, neuroendocrine and immune manifestations (ie intellectual, physical, cognitive, or neurological).

Respectfully, it would be a denial of the reality of the ME/CFS and CFS to assert that it does not satisfy the definition of impairment. If the policy of the NDIS (should any policy in fact exist) is to deny the presence of one or more of these impairments, then it would appear to be derived from a fundamentally flawed understanding of the condition and the evidence base surrounding it.

Most significantly, this organisation would direct the Committee to the recent findings of the US Institute of Medicine and their extensive literature review, prepared for the purposes of assisting the National Institutes of Health (NIH) in future funding directions. This document is now over 2 years old and represents the single most comprehensive literature review of the condition ever undertaken. It would appear that consideration of this document has been overlooked.

7.3 Submission 1(B) - Permanency

The various rejections (initial and following internal appeal) by the NDIA that have been provided to ME/CFS Legal Resources by applicants, reveal the decision makers have not supplied particulars of The various rejections (initial and following internal appeal)by the NDIA that have been provided to ME/CFS Legal Resources by applicants, reveal the decision makers have not supplied particulars of the evidence base or policy foundation for the NDIA's position that ME/CFS and CFS are not permanent. Of the bare reasons supplied, the assertion has been that the evidence demonstrates that it is treatable and recoverable. Despite various enquiries with the NDIS, "Every Australian Counts" and agencies associated with the NDIA, the evidence base for the position by the NDIA has not been provided.

A recent case[27] in which better particulars of the NDIA decision were supplied (see: 9.1.1.2), reveals that the decision maker referred to the Victoria Government's *Better Health Channel* (2016) website as the source for information and evidence about CFS (a site that was updated in November 2017).

ME/CFS Legal Resources makes the following submissions with respect to permanently.

7.3.1 Evidence of Permanency

7.3.1.1 Evidence-Based View

7.3.1.1.1 No Known Cure

There is a universal view throughout practitioner, researchers and institutions alike that there is no known cure for ME/CFS nor CFS (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 259; Carruthers, et al., 2003, p. 50; Zinn, Zinn, & Jason, 2016a, p. 2; Dantzer, Heijnen, Kavelaars, Laye, & Capuraon, 2014, p. 44; Blease, Carel, & Geraghty, 2017, p. 553; White, Sharpe, Chalder, DeCesare, & Walwyn, 2007, p. 2; Green, Cowan, Elk, O'Neil, & Rasmussen, 2015, p. 861; Centres for Disease Control, 2017; Green, Cowan, Ronit, O'Neil,

[27] Internal Review Manager JG0029 and DP0014, *Internal Review of Applicant SW*, (July 2017).

& Rasmussen, 2014, p. 1; Gibson, et al., 2006, p. 8). This view is echoed by the *Better Health Channel* – the website that the NDIA apparently accepts as the foundation for its understanding of CFS (2016).

Baraniuk (2017) affirmed the view on cure, stating: "Longitudinal studies indicate that 17% to 64% of patients improve with treatment; however, less than 10% meet criteria for full recovery, and up to 20% of patients may worsen over time" (Baraniuk, Chronic fatigue syndrome prevalence is grossly overestimated using Oxford criteria compared to Centers for Disease Control (Fukuda) criteria in a U.S. population study, 2017, p. 53).

It stands to reason that if there is no cure, there is no treatment that can be asserted to effect a cure.

7.3.1.1.2 Cure and Recovery

The English Oxford Living Dictionary defines cure as:

> Verb
> [With Object]
> 1. Relieve (a person or animal) of the symptoms of a disease or condition.
> 'he was cured of the disease'
> Synonyms: Remedy, curative, medicine, medication, medicament, restorative, corrective, antidote, antiserum.
> 1.1 Eliminate (a disease or condition) with medical treatment.
> 'this technology could be used to cure diabetes'
>
> 1.2 Solve (a problem)
> 'a bid to trace and cure the gearbox problems' (English Oxford Living Dictionaries, 2017)

The English Oxford Living Dictionary defines recovery as:

> Noun
> mass noun
> 1A. return to a normal state of health, mind, or strength.
> 'signs of recovery in the housing market'
> count noun 'it is hoped that Lawrence can make a full recovery'
> Synonyms: recuperation, convalescence, <u>return to health</u>, process of getting better, **<u>rehabilitation</u>**, healing, rallyingimprovement, rallying, picking up, betterment, amelioration. (English Oxford Living Dictionary, 2017)

In ME/CFS and CFS, the term 'recovery' means the "return to premorbid functioning" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 264), hence is the equivalent of "cure". Vink (2017) affirms this view, stating:

> … if an ordinary person was asked the meaning of recovery, the answer would be that all problems have gone and that health has returned to how it was before the illness. This was worded by Kennedy in the following manner: recovery "<u>is the elimination of...symptoms and a return to premorbid levels of functioning</u>"(Vink M. , 2017b, p. 4)

Recovery, like cure, means a "return to health" or "rehabilitation in ME/CFS and CFS - it does not mean mere improvement. It is submitted that this is an important point relevant to the understanding of the remainder of the submissions in this section.

7.3.1.1.3 Disability and Impairment

There is a very clear evidence base that affirms that ME/CFS and CFS cause disability and impairment. The IMO committee (2015), in conducting the largest literature review ever conducted, states:

> ME/CFS can cause significant impairment and disability that have negative economic consequences at both the individual and societal levels. At least one-quarter of ME/CFS patients are house or bedbound at some point in their lives. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 2, 16)

The committee (2015) continues in examining impairment:

> *Disability and Impairment*
>
> Several ME/CFS symptoms—including fatigue, cognitive dysfunction, pain, sleep disturbance, post-exertional malaise, and secondary depression or anxiety—may contribute to impairment or disability. Patients with ME/CFS have been found to be more functionally impaired than those with other disabling illnesses, including type 2 diabetes mellitus, congestive heart failure, hypertension, depression, multiple sclerosis, and end-stage renal disease. Symptoms can be severe enough to preclude patients from completing everyday tasks, and 25-29 percent of patients report being house- or bedbound by their symptoms. Many patients feel unable to meet their family responsibilities and report having to reduce their social activities. However, these data include only patients who were counted in clinics or research studies, and may underrepresent the extent of the problem by excluding those who are undiagnosed or unable to access health care. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 32)

When referring to function and measurement utilising various instrument, the Committee concluded:

> Fatigue, chronic fatigue, and particularly the impact of fatigue on function should be assessed in making a diagnosis of ME/CFS. Health care providers may use a range of questions and instruments to evaluate fatigue and its impact on function in these patients (see Chapter 7, Table 7-1). However, **ME/CFS should not be considered merely a point on the fatigue spectrum or as being simply about fatigue.** Experienced clinicians and researchers, as well as patients and their supporters, have emphasized for years that this complex illness presentation entails much more than the chronic presence of fatigue. Other factors, such as orthostatic intolerance, widespread pain, unrefreshing sleep, cognitive dysfunction, and immune dysregulation, along with secondary anxiety and depression, contribute to the burden imposed by fatigue in this illness. The challenge in understanding this acquired

> chronic debility, unfortunately named "chronic fatigue syndrome" for more than two decades, will be to unravel those complexities.
>
> *Conclusion: There is sufficient evidence that fatigue in ME/CFS is profound, not the result of ongoing excessive exertion, and not substantially alleviated by rest. This fatigue results in a substantial reduction or impairment in the ability to engage in pre-illness levels of occupational, educational, social, or personal activities and persists for more than 6 months*.(Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 77-78)

The committee also identified the disability caused by pain, and noted the significant difference between the Consensus criteria and Fukuda criteria, stating:

> Although pain symptoms are listed in all recent diagnostic criteria for ME/CFS, some of the diagnostic criteria identify patients with more frequent and more debilitating pain symptoms. In various studies, persons fulfilling the CCC, a revised definition of ME, and the ME-ICC were found to have significantly greater disability due to bodily pain (as measured by the bodily pain subscale of the SF-36) than those fulfilling the Fukuda definition. People fulfilling the CCC and the revised definition of ME also reported significantly worse (in terms of frequency and severity) headaches, chest pain, abdomen pain, eye pain, and tender/sore lymph nodes than those fulfilling the Fukuda definition. Those fulfilling the ME-ICC reported significantly worse headaches, chest pain, eye pain, muscle pain, pain in multiple joints, and tender/sore lymph nodes than those fulfilling the Fukuda definition. In one study, those fulfilling the ME-ICC also experienced significantly worse abdomen/stomach pain and bloating than those fulfilling Fukuda definition. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 144-145)

The Committee (2015) provides a more detailed account of disability at annexure 3 (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 257-265).

ME/CFS Legal submits that the evidence base, having already been thoroughly interrogated by the US Institute of Medicine demonstrate that ME/CFS can be unequivocally disabling and create significant impairment across many domains.

7.3.1.1.4 The Meaning of 'Likely'

The key issue within section 24(1)(b) for the purposes of entitlement the adjective "likely" which is the qualifier for the operative word, "permanent".

There is no case law with respect to the definition of 'likley'. In accordance with section 15AB of the *Acts Interpretation Act 1901* (Cth) the ordinary meaning can be ascertained by reference to external materials – in this case the Oxford dictionary.

The English Oxford Living Dictionary definition of likely is as follows:

> Adjective
>
> 1. Such as well might happen or be true; probable.

> 'speculation on the likely effect of opting out'
>
> with clause 'it was likely that he would make a televised statement'
>
> with infinitive 'sales are likely to drop further'(English Oxford Living Dictionary, 2017).

Likely therefore means more probable than not. In law, this would be the equivalent of the balance of probabilities. In *Re H (Minors)*[28] Lord Nicholls explained that 'balance of probabilities' is a flexible test:

> "The balance of probability standard means that a court is satisfied an event occurred if the court considers that, on the evidence, the occurrence of the event was more likely than not. When assessing the probabilities the court will have in mind as a factor, to whatever extent is appropriate in the particular case, that the more serious the allegation the less likely it is that the event occurred and, hence, the stronger should be the evidence before the court concludes that the allegation is established on the balance of probability... Built into the preponderance of probability standard is a generous degree of flexibility in respect of the seriousness of the allegation. Although the result is much the same, this does not mean that where a serious allegation is in issue the standard of proof required is higher. It means only that the inherent probability or improbability of an event is itself a matter to be taken into account when weighing the probabilities and deciding whether, on balance, the event occurred. The more improbable the event, the stronger must be the evidence that it did occur before, on the balance of probability, its occurrence will be established."

When establishing the difference between success on the balance of probabilities and failure on the balance of probabilities, Lord Denning in *Miller v Minister of Pensions*[29] effectively required the chance to be greater than *50/50.* His honour explained:

> "If the evidence is such that the tribunal can say 'we think it more probable than not' the burden is discharged, but if the probabilities are equal it is not."

On this understanding of the word 'likely' and its assessment on the balance of probabilities, ME/CFS Legal submit the following:

1. The strength of the relevant evidence base is founded in the RACP Guidelines, the 2003 ME/CFS consensus guidelines and the 2015 IOM Committee, which are firmly grounded in the relevant peer-reviewed literature;
2. The standard of the peer reviewed literature is high, hence it is strong;
3. The standard of the non-peer reviewed website is poor, being opinion and based upon 5 outdated pieces of literate (ignoring two documents had been updated and contradicted the original position);
4. Only the balance of probabilities, ME/CFS and CFS are likely to be permanent based on the relevant evidence base.

[28] *Re H (Minors)* [1996] AC 563 at 586, per Lord Nicholls.
[29] *Miller v Minister of Pensions* [1947] 2 All ER 372 per Denning J.

7.3.1.1.5 The Issue of Permanence

The other key word within section 24(1)(b) for the purposes of entitlement the requirement for the impairment to be "permanent".

ME/CFS Legal submits that ME/CFS and CFS results in permanent impairment or is likely to result in permanent impairment, when considering the relevant evidence base.

The RACP (2002) guidelines deal with the issues of recovery from the symptoms of CFS. The symptoms of CFS caused the impairments (as demonstrated in 7.2.1 above) – ergo recovery is recovery from the impairments arising from the symptoms of CFS. With respect to permanence, the RACP assert the following global position with respect to CFS:

> By contrast, full recovery in patients with established CFS is less common ... In an Australian study conducted in a specialist setting, 65 of 103 patients (63%) who had had symptoms for about five years reported abatement of symptoms and improvement in functional capacity over the next three years, **but complete recovery was uncommon** (6%) … At the more severe end of the clinical spectrum, although improvement over time can occur, the **prognosis for recovery is poor**. Patients who have had CFS for more than 10 years are more disabled than those with shorter-duration illness, and have significantly more severe symptoms (particularly cognitive impairment) and more frequent symptoms of fibromyalgia…
>
> The notion of "permanent" disability is problematic, as most people with CFS improve gradually, and some eventually recover. In people who have been severely disabled and unable to work for more than five years, the probability of substantial improvement within 10 years is less than 10%–20%. This may be regarded as "permanent disability" for medicolegal purposes. (Loblay, et al., 2002, pp. S 41-S42, S47)

Improvement in functional capacity does not mean that impairment has ceased. The key take away point of the RACP is that just 6% recovered. That means 94% of those in the study did not recover. Indeed the RACP made it even clearer with respect to the 25% of patients in the severe end of the spectrum – "prognosis for recovery is poor". Substantial improvement occur in just 10% to 20% of patients before 10 years – but again, that still means the patient has impairment.

Carruthers et al (2003) in creating the Consensus Guidelines for ME/CFS concluded from their literature review, combined with exceptional clinical experience of their committee that:

> The quality of life (QOL) of ME/CFS patients show marked diminution which is more severe than in many other chronic illnesses. ME/CFS patients were most disadvantaged in terms of vitality, recreation, social interaction, home management and work. There is a general tendency for the clinical course to plateau from between six months and six years. In a nine-year study of 177 patients, 12% of patients reported recovery. The patients with the least severe symptomology at the beginning of the study were the most likely to recover but there were no demographic characteristics associated with recovery. Patient (sic) with comorbid fibromyalgia syndrome demonstrated greater symptom severity and functional impairment than individuals with CFS alone. Other studies suggest that less than 10% ofpatients return to

> premorbid levels of functioning.As the criteria becomemore stringent the prognosis appears to worsen…
>
> While statistical studies estimate group prognosis, **the individual prognosis, which is highly variable, must remain a clinical estimate**. To estimate individual prognosis more effectively, one must have ascertained the severity and course of the patient's illness and impairments in each of their aspects, as well as the patient's circumstances and the life-world to which they are responding. The patient's progress must be followed over a course of time, within a therapeutic relationship. One must have tried to eliminate aggravating factors that worsen the illness and to encourage ameliorating factors. Only then can one give a reasonably adequate individual prognosis. Early diagnosis may lessen the impact of the illness. Generally, **if one sees deterioration in a patient's health status over an extended time, one may expect that there would be continued deterioration**, whereas if improvement was noted over an extended time period, one may hope for continued improvement. However, in the Pheley et al. study there was considerable overlap of severity of illness between those who recovered and those who did not, which suggests that accurate predictions of recovery for an individual patient may not be feasible at this time. (Carruthers, et al., 2003, pp. 29-30)

The Carruthers recommendations express the importance of the evidence contained in the individual clinical course of ME/CFS, and the clinical evaluation of prognosis. The committee concluded that more severe symptoms reduced the chance of recovery – which is consistent with most literature on the issue of prognosis.

The IOM Committee (2015) too. is adamant that there is impairment and that impairment can continue indefinitely:

> ME/CFS clearly impairs patients' ability to function on a regular basis both cognitively and physically. This impairment often confines patients to their homes or beds and may severely restrict their ability to attend to their jobs or schoolwork, among other responsibilities and basic needs. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 266)

Twisk (2015)goes further and points out that there is little difference in impairment over the longer term between CFS and ME/CFS.

> A long-term follow-up study found that people who remitted from ME/CFS had non-significant differences in impairment on 17 out of 23 outcomes compared to those who maintained a CFS diagnosis. So, **even patients who don't meet a CFS diagnosis anymore will not return to their premorbid level of functioning**. ME/CFS has a greater negative impact on functional status and well-being than other chronic diseases, e.g., cancer or lung diseases, and is associated with a drastic decrement in physical functioning. In a comparison study ME/CFS patients scored significantly lower. (Twisk F. N., 2015, p. 69)

Smith et al (2016)

> However, a recent review highlighted the variability in which studies defined recovery in adults**limiting the utility of this term as a meaningful outcome until a universal definition for recovery is accepted.** The review authors recommended using a more global assessment that captured fatigue, function, and perception of health. Regardless, economic impact is considerable with most adult patients never returning to work. (Smith, et al., 2016, p. 2)

Baraniuk (2017) echoes the views of the RACP, stating "Longitudinal studies indicate that 17% to 64% of patients improve with treatment; however, less than 10% meet criteria for full recovery, and up to 20% of patients may worsen over time" (Baraniuk, 2017, p. 53).

There is a very clear unifying position here among the most reputable of researchers and clinicians in the ME/CFS and CFS medical community. More than mere opinion, these are a rational, evidence based view that must be heeded.

ME/CFS Legal submits that the evidence base demonstrates that ME/CFS and CFS are likely to be permanent. Whilst there some assertions have been made by the NDIS about increased recovery rates in the first five years, the evidence base does not support this assertion. Indeed the evidence base defers to the medical practitioner's clinical experience of the patient across a longitudinal period, for guidance on improvement or decline. Moreover, full recovery is rare.

Dr. John Whiting, an Internal Medicine and Infectious Diseases physician with 30 years of experience working with over 5000 CFS patients, states in his submission dated 25 October 2017:

> On October 2017, a representative of the NDIS pointed to the Better Health Channel Victoria State Government website * so as to make a number of statements that are not consistent with my 30 year longitudinal experience ** with patients with Chronic Fatigue Syndrome in order to deny Ms SW's claim for assistance from the NDIS …
>
> **My experience with CFS is completely at odds with the officially made statements to an NDIS applicant** in an email to her sent on October 25, 2017 by a senior legal representative of the NDIS … **There are no longitudinal studies of value on validly diagnosed cases of CFS to support the above contentions**. I have many patients who I have a longitudinal relationship of 20-25 years standing. There are very few doctors anywhere in the world who can claim similar experiences. The functional 'improvements' referred to are not as simple as the NDIS representative claims. These patients illnesses are life long, and improvements are transitory, if and when they do occur.
>
> Thus, the NDIS position, if it does indeed hold any official position at all on CFS, is an untenable one, and old, disproven data should not be used to formulate a position currently held, as of October 25, 2017, and which suggests the direction that the NDIS is likely to take as finalised as of January 2018.
>
> **It is NOT my experience at all, that on average, that patients with ME / CFS will improve in the first five years,** and I hereby request sound data to disprove my experience, which I suggest to the committee, does not exist. It

> is my experience that if patients are initially bedbound, they may improve in the first 6 months or so, but beyond this early timeframe, no improvements can be expected to occur in the natural course of the illness, especially after the 2 year mark. Those who do improve will show improvements during this timeframe, and one can predict from the lack of significant improvements at the 6 month mark that patients are likely to remain significantly incapacitated or disabled from this point onwards. In other words, prognosis can be reliably predicted at 6 months and confirmed as certain at 2 years from the time of acute onset of illness. Those with illness of gradual onset are even more likely to remain disabled permanently.
>
> The NDIS case of Ms SW (NDIS ref: 430058059) a decision was made by the NDIS on July 19, 2017, which included [a denial that] … The impairment or impairments are, or are likely to be permanent …
>
> **This statement has no foundation in reality. This has never occurred in any of my 5,000 patients seen over 30 years.** Once a sound diagnosis has been made, using appropriate criteria (not the Oxford Criteria, for example), permanency is guaranteed once the 2 year mark post illness onset has been reached. Permanency can be predicted earlier than this in many patients. This is because the term CFS is a misnomer, and encompasses many symptoms, disabilities (many of which can be confirmed if appropriate technologies are used and accurately interpreted) and discomforts other than fatigue.(Whiting, 2017, pp. 1-4)

Recovery is global and not to be measured via a restricted domain, such as social activity, mental health or employment. Even recovery within the first five years is rare and only where the clinical history demonstrates improvement over time. Deterioration or plateauing would contraindicated improvement. Whiting affirms some of these views from the perspective of a 30 year veteran specialist and CFS practitioner:

> **Adequate definitions of recovery do not exist, and as longitudinal studies of large numbers of patients have never been performed**, I can only rely on my own large, longitudinal experience to refute the above NDIS Claim. There is no conflict (as claimed above), unless one creates one for financial purposes, or for other nefarious reasons. (Whiting, 25 October 2017, pp. 1-4, NDIS Submission 80)

ME/CFS Legal submits that the relevant evidence base should not be selectively applied and needs to be clearly understood in order to achieve a fair and appropriate understanding of full recovery.

7.3.1.1.6 Illegitimate Research

ME/CFS Legal specifically identifies the UK Pace trial (White P. D., et al., Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial, 2011) as an example of irrelevant research in the context of the Australian experience of ME/CFS and CFS (see: 9.2.6 below). The PACE research released a number of papers in which they claimed significant improvements arising from GET and CBT. This, they claimed, could be safely administered "to moderately improve outcomes for chronic fatigue syndrome" (White P. D., et al., 2011, p. 843), and later claimed the PACE study "confirms that

recovery from CFS is possible, and that CBT and GET are the therapies most likely to lead to recovery" (White P. D., Goldsmith, Johnson, Chalder, & Sharpe, 2013a, p. 2227). Geraghty (2017) outlines the impact of using the term recovery, stating:

> Confirmation biases spill over into reporting biases … Media outlets picked up the PACE trial following press briefings by the PACE authors, with headlines that 'CFS sufferers can overcome symptoms of ME with positive thinking and exercise' ... **It is arguable the PACE authors' use of the term 'recovery' contributed to a perception that CBT and GET are curative treatments** …, yet the majority of participants within the 22 per cent PACE reported recovery rate did not reach a SF-36 physical function threshold of above 85 (the level of a healthy individual). Recovery in PACE rested on subjective self-report, in a study that sought to get patients to think 'more positively', with little improvement in objective measures or secondary outcomes. (Geraghty, 2017b, p. 1213)

Blease (2017) reiterates these criticisms:

> This trial has faced a number of serious criticisms. Commentators have argued that 'recovery' did not mean return to full functional status and critics have pointed out that the positive results were not mirrored in so-called objective measures of functional ability (eg, walking tests). (Blease, Carel, & Geraghty, 2017, p. 551)

So too Shepherd (2017) expressed the existence of a deception:

> The term 'recovery' implies a sustained return towards symptom-free health along withthe ability to repeatedly and reliably participate in all aspects of normal life – employment, education, social activities and so on ... Not surprisingly, criticism of the PACE trial continued and intensified.(Shepherd C. B., 2017, p. 1189)

Aside from changing the measures for 'recovery' before analysis, White et al defined 'recovery' in such a way that did not reflect full recovery (ie cure) with no recurrence (White P. D., Goldsmith, Johnson, Chalder, & Sharpe, 2013a, p. 2230). White et al (2013b) admitted, when pressed, that their version of 'recovery' was indeed, not full recovery. They stated:

> We agree with Carter (2013) that there is a difference between sustained recovery and temporary remission; this is why we were careful to give a precise definition of recovery and to emphasize that it applied at one particular point only and **to the current episode of illness.**(White P. D., Goldsmith, Johnson, Chalder, & Sharpe, 2013b, p. 1791)

In addition the definition was based upon a self-report reduction(Geraghty, 2017b, p. 1212) in symptoms and not the complete resolving of symptoms (White P. D., et al., 2011; White, Sharpe, Chalder, DeCesare, & Walwyn, 2007).

This approach was entirely unacceptable. With respect – it scientific fraud that has effect immeasurable damage on innocent patients. The fall out of this misconduct it still yet to play out.

Geraghty (2017) identifies the deficiency of self-reporting, pointing out that the "modest improvements observed in the CBT and GET groups (contested by reanalysis) are not mirrored by

substantive changes in objective measures of walking ability on a 6-minute walking test or step test" (Geraghty, 2017b, p. 1212). Geraghty then points to other objective measures not carried out, in addition to measures of physical function that were not considered, concluding that in "addition, there is almost no change in secondary measures (employment or health care use) in CBT or GET groups. Such data suggest recovery in PACE is more a design artefact than a clinical reality" (Geraghty, 2017b, p. 1212). Vink (2017) also criticises the use of the word recovery, stating "the trial defined recovery partially on the basis of patients rating their overall health as "much better" or "very much better" which reflects improvement but not (full) recovery" (Vink M. , 2017a, p. 1136).

After a protracted legal dispute[30] with White and his colleagues by researchers, the PACE dataset was released and re-examined according to the original 2007 protocol as expressed by White et al (2007). Geraghty (2017) explains:

> The data were only released after a protracted freedom of information case brought by a patient with CFS. A tribunal ordered the lead author's institution to release their data. Upon release, re-analysis showed that the levels of improvement and recovery observed in the released data were much lower than the levels reported in the published report (White et al., 2011a) and other related publications. The released data showed that the effectiveness of cognitive behavioural therapy (CBT) and graded exercise therapy (GET), in comparison to standard medical care (SMC) and adaptive pacing therapy (APT), fell by almost two-thirds. (Geraghty, 2017a, p. 1108)

Willshire et al (2017) criticised the definition of recovery utilised by the research group in the Sharpe et al (2015)*Lancet Psychiatry* recovery paper, because the authors changed protocols to make recovery easier to achieve:

> In the Recovery paper, four criteria were used to define recovery. To be classed as 'recovered', the patient had to meet a specified threshold scoreon each of the following three self-report scales: (a) The SF-36 Physical Function subscale; (b) the Chalder Fatigue Questionnaire and (c) the Clinical Global Impression (CGI) scale, a self-rated measure of overall health change (based on Guy [11]). The fourth criterion was that participants should no longer meet a specified case definition for CFS. <u>However, the specific thresholds used to define recovery with respect to all four of these criteria were substantially modified from those specified in the original trial protocol</u>. In each instance, <u>the changes to the criteria made 'recovery' easier to achieve</u>. (Wilshire, Kindlon, Matthees, & McGrath, 2017, p. 45)

Geraghty (2017) explains that the changes to the protocol, in addition to the definition of recovery has led to multiple calls upon the Lancet to "retract [the] PACE recovery paper" and "independently verify the PACE trial's evidence" (Geraghty, 2017b, p. 1210). Tuller (2017) affirms this assessment, stating:

> In their trial protocol … the PACE investigators included four separate outcomes on which participants had to meet recovery criteria in order to be considered fully recovered. Two of them were the primary outcomes of physical function and fatigue. In the 2013 paper in Psychological Medicine,

[30]*Queen Mary University of London v Information Commissioner & Mr AlemMatthees (Dismissed : Freedom of Information Act 2000)* [2016] UKFTT 2015_0269 (GRC)

> as has been reported previously, all four of the recovery criteria were watered-down versions of the criteria listed in the protocol ... In essence, the investigators overhauled their definition of "recovery" in ways that boosted the trial's apparent success rate. (Tuller, 2017, p. 1119)

Aside from a change to the definition of recovery, the various analyses of PACE revealed significant discrepancies, such as outcome switching, undeclared conflicts of interest, questionable treatment effects, and the like (Geraghty, 2017b).

ME/CFS Legal submit that there is nothing in the PACE trial with respect to recovery that is reliable, or reflective of the ordinary meaning of the term. The outcomes of the PACE trial have been heavily criticised by academics and patients alike. I an unprecedented move, the US CDC has removed research (Centres for Disease Control, 2017) based on the major discrepancies of the study and the inappropriateness of the Oxford criteria.

7.3.1.2 Permanency Under Act

Section 24 of the NDIS refers to the term 'permanent' on two occasions at section 24(1)(a) and (2), in the context of assessing disability:

> 24 Disability requirements
>
> (1) A person meets the disability requirements if:
>
> (a) the impairment or impairments are, or are likely to be, permanent; and
> (b) the impairment or impairments result in substantially reduced functional capacity to undertake, or psychosocial functioning in undertaking, one or more of the following activities:
>
> (i) communication;
> (ii) social interaction;
> (iii) learning;
> (iv) mobility;
> (v) self care;
> (vi) self management; and
>
> (c) the impairment or impairments affect the person's capacity for social and economic participation; and
> (d) the person is likely to require support under the National Disability Insurance Scheme for the person's lifetime.
>
> (2) For the purposes of subsection (1), an impairment or impairments that vary in intensity may be permanent, and the person is likely to require support under the National Disability Insurance Scheme for the person's lifetime, despite the variation.

Rule 5.4 also comes into play. In the 2015 AAT case of *Mulligan*[31], the tribunal affirmed that permanency is assessed using "evidence-based clinical, medical or other treatments":

[31] *Mulligan and NDIA* [2015] AATA 974 at [69].

> Rule 5.4 provides that an impairment is, or is likely to be, permanent only if there are **noknown available and appropriate evidence-based clinical, medical or other treatments thatwould be likely to remedy it**.

As has been established above at 7.3.1.1, there is no cure for ME/CFS or CFS, and the PACE research, which claims 'recovery', actually misrepresents the definition of 'recovery' and changed the measurement of recovery mid-way through the study – which is an inexcusable occasion of research misconduct or researcher bias.

Part 7.2 of the NSW rules empower the CEO to specify in the guidelines, particular tools in order to assess the eligibility of a person for the disability requirements. Under Part 7.4, such tool can be unique to a particular impairment, vary between children and adults. Part 7.5 requires that such tools be fair and transparent, and reference the *WHO International Classification of Functions, Disability and Health* as in force at the time of the assessment (National Disability Insurance Scheme, 2014c, p. 7).

With respect to ME/CFS and CFS, there is no tool within the Operational Guidelines for Disability that identifies the specific impairments that occur in ME/CFS and CFS. To that end, ME/CFS Legal would direct the committee to the contents of Table 1 at 7.2.1 above.

ME/CFS Legal submits that ME/CFS and CFS satisfies the legislative criteria for permanent:

(a) being conditions which are permanent, or likely to be permanent,
(b) for which there is no treatment that is likely to remedy the condition;
(c) the conditions do vary in intensity, however the condition is still life-long.

7.3.2 Submissions on Permanency

ME/CFS Legal submits that there is a strong requirement for the NDIA to conduct a thorough review of the relevant history of the conditions in order to understand the actual position with respect to recovery, as espoused in the literature. Moreover, such literature review needs to be conducted by an experienced researcher, cognisant of the discrepancies between various criteria, issues with respect to the definition of 'recovery' and the existence of poor quality studies that can heavily slant the view of treatment and recovery.

It is not merely sufficient to take literature at face value. The legislation and rules are directive on this matter, and so is the case law. The relevant evidence base, when properly considered by a skilled researcher reveals the true position.

With respect, to date, the NDIS has failed in its obligation to comply with the legislation and rules.

8. Submission 2 – Early Intervention and the NDIS

8.1 Early Intervention in Context

Section 25 of the NDIS Act contains the criteria for the early intervention requirements and these have been provided at 6.2 above. Parts 6 and 7 of the NDIS Rules govern when a person meets the early intervention requirements and the process of assessing such eligibility. The Operational Guidelines for Intervention assist in ascertaining the process.

Section 27 bears upon Section 25, setting out the NDIS rules that related to early intervention, particularly with respect to the creation of rules involving one or more impairments relevant to

section 25(a)(i) or (ii) (see: Section 27(a)), provision of early intervention supports that are likely to mitigate, alleviate or prevent deterioration of functional capacity or improve functional capacity for the purposes of sections 25(1)(c)(i)-(iii) (see: Section 27(e)), and provision of early intervention supports that strengthen the sustaining of informal supports (see: Section 27(f)).

Section 25(1) is broken down into a series of requirements that must be satisfied in order to establish qualification for early intervention (National Disability Insurance Scheme, 2014a, p. 1).

8.1.1 Permanent Impairments

Section 25(1)(a)(i) requires that the applicant have "one or more identified intellectual, cognitive, neurological, sensory or physical impairments that are, or are likely to be, permanent". Within 7.2.1 above, the features of ME/CFS and CFS that satisfied these requirements were explored. It is submitted that ME/CFS and CFS meet these requirements. It is noted that Rules 6.4 and 6.5 are applied in a similar manner to rules 5.4 and 5.5 above, and that the Operational Guidelines for Early Intervention, at paragraph 10 to 16 apply (National Disability Insurance Scheme, 2014a, p. 2).

Rule 6.6 of the NDIS Rules state:

> An impairment may require medical treatment and review before a determination can be made about whether the impairment is permanent or likely to be permanent. The impairment is, or is likely to be, permanent only if the impairment does not require further medical treatment or review in order for its permanency or likely permanency to be demonstrated (even though the impairment may continue to be treated and reviewed after this has been demonstrated).

The operative part of Section 25(1)(a)(i) and Rule 6.6 is that the impairment be 'likely to be, permanent'. Paragraph 4 of the Operational Guidelines for Early Intervention state:

> 4. First, as a matter of fact, the person:
>   a. Has one or more identified intellectual, cognitive, neurological, sensory or physical impairments that are, or are likely to be, permanent (National Disability Insurance Scheme, 2014a, p. 1)

Permanence and the likelihood of permanence, has been established within 7.3.1.1 and 7.3.1.2 respectively. The same argument applies with respect to this section.

It is submitted that there is a significant relevant evidence base within the research to demonstrate that a patient with ME/CFS or CFS will satisfy this section as an inherent part of the condition.

8.1.2 Pscyhiatric Impairments

As an alternative to section 25(1)(a)(i), Section 25(1)(a)(ii) requires that the applicant have "has one or more identified impairments that are attributable to a psychiatric condition and are, or are likely to be, permanent". Within 7.2.1 above, the features of ME/CFS and CFS that satisfied these requirements were explored. It is submitted that ME/CFS and CFS meet these requirements. It is noted that Rules 6.4 and 6.5 are applied in a similar manner to rules 5.4 and 5.5 above, and that the Operational Guidelines for Early Intervention, at paragraph 10 to 16 apply (National Disability Insurance Scheme, 2014a, p. 2). Rule 6.6 is applied in the same manner as the section.

Paragraph 4 of the Operational Guidelines for Early Intervention require as a matter of fact that the person:

> b. Has one or more identified impairments that are attributable to a psychiatric condition and are, or are likely to be, permanent (National Disability Insurance Scheme, 2014a, p. 1)

The operative part of section 25(1)(a)(ii) is that the impairment is permanent, or likely to be permanent. Permanence has been established within 7.3.1.1 and 7.3.1.2 respectively.

It is submitted that there is a significant relevant evidence base within the research to demonstrate that a patient with ME/CFS or CFS will satisfy this section as an inherent part of the condition.

8.1.3 Reducing Future Needs for Support

Section 25(1)(b) contains the second requirement for access. For access, he applicant must ensure "the CEO is satisfied that provision of early intervention supports for the person is likely to benefit the person by reducing the person's future needs for supports in relation to disability".

Paragraph 5 of the Operation Guidelines for Early Intervention repeat the same requirements as expressed in the Act, whereas Paragraphs 19 also provide direction on the assessment considerations of the CEO and state:

> 19. In deciding whether the provision of early intervention supports is likely to benefit the person (either by reducing future support needs, mitigating or alleviating the impact on functioning, preventing deterioration of or improving functioning, or strengthening the sustainability of informal supports) the delegate should consider:
>
> a. The likely trajectory and impact of the person's impairment over time, and
> b. The potential benefits of early intervention on the impact of the impairment on the person's functional capacity and in reducing their future needs for supports, and
> c. Evidence from a range of sources, such as research or information provided by the person with disability or their family members or carers. The delegate may also in some cases seek expert opinion. (National Disability Insurance Scheme, 2014a, p. 3)

With respect, ME/CFS Legal submits that the NDIA has not properly explored the evidence with respect to early intervention, because they have not moved beyond their position that the condition is not a permanent one. To this end, this submission seeks to demonstrated that an entitlement exists for early intervention once the permanent impairment criteria is established.

With ME/CFS and CFS, the evidence base does demonstrate that patients who obtain an early diagnosis and early intervention have the potential for recover or better functioning. Carruthers et al (2003) point out the role of early intervention in ME/CFS, stating:

> The patient's progress must be followed over a course of time, within a therapeutic relationship. One must have tried to eliminate aggravating factors that worsen the illness and to encourage ameliorating factors. Only then can one give a reasonably adequate individual prognosis. Early diagnosis may lessen the impact of the illness. Generally, if one sees deterioration in a patient's health status over an extended time, one may expect that there would be continued deterioration, whereas if

> improvement was noted over an extended time period, one may hope for continued improvement. (Carruthers, et al., 2003, pp. 29-30)

The 2002 Australian Guidelines provide a number of examples of the need for early intervention:

> Where appropriate, the advice of a specialist sleep physician should be sought, either to exclude a primary sleep disorder or to manage the sleep disturbance. Sleep hygiene strategies can also be incorporated ... Clinical experience suggests that sleep interventions in people with CFS may reduce symptoms and improve functional capacity… (Loblay, et al., 2002, p. S25)

> Children and adolescents are in a dynamic developmental state, and issues such as self-concept, autonomy, body image, socialisation, sexuality and academic goals are of central importance. Early intervention in those with persistent fatigue is therefore especially important ... (Loblay, et al., 2002, p. S26)

These guidelines espouse the benefits of a number of early interventions (some of which are outdated), with a focus upon improving function and reducing impairment.

Baraniuk (2017) also points out a number of benefits to early interventions, stating:

> Fatigability' may represent an increase in this basal rate, addition of other energy demands, such as chronic inflammation, or limitations to the ability to generate the required energy levels. Greater fatigability may determine functional status by setting a lower activity limit aimed at maintaining the feeling of fatigue within a tolerable range. In this way, fatigue becomes a major determinant of sedentary behaviour. Interventions that target fatigue by increasing energy availability may reduce sedentary behaviour and disability…
>
> People with sleep disturbances felt their condition improved with exercise, increased daily activity, bright-light therapy, and cognitive behaviour therapy … Drug therapy has focused on inducing sleep rather than improving daytime function.(Baraniuk, 2017, p. 15) …
>
> There are no curative medications or treatments for chronic fatigue syndrome (CFS)/myalgic encephalomyelitis (ME). Pharmacotherapy is indicated to treat pain, migraine, sleep disturbance, and comorbid conditions, such as irritable bowel syndrome (IBS), anxiety, and depression … **Long-term management by a coordinated supportive team is beneficial to maximise functional capacity** … The primary goals of treatment are to **manage symptoms and improve functional capacity**. A possible strategy may be to provide counsel to patients every 3 months and to reassess any other health issues and treatable diseases … For some patients with CFS, their treatment regimens may be complicated and extensive. A general treatment strategy in such cases may involve a stepwise process of simplifying the treatment regimen across time (e.g., gradually reducing the number of medications). **Treatment interventions tend to be multidimensional and tailored to each patient's circumstances. The focus of treatment should be orientated toward symptom management and**

> **functional improvement, and away from repeated, extensive diagnostic procedures, or ongoing referrals to additional specialists**.(Baraniuk, 2017, p. 37).

The IOM Committee (2015) similarly suggests a number of interventions with the intent of improving function:

> Intravenous saline has been shown to improve orthostatic tolerance and to modify autonomic tone in those with neurally mediated syncope and after experimental prolonged bed rest.(Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 114)
>
> Treatment of orthostatic intolerance Open (nonblinded) treatment studies of ME/CFS subjects found improvement in function after increased sodium intake or pharmacological treatment of orthostatic intolerance. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 116).
>
> Open treatment of orthostatic intolerance has been described as being associated with improvement in ME/CFS symptoms in at least a subset of adolescents with ME/CFS … Sulheim and colleagues (2012) report on cohort study in which participants were seen at baseline and 3 to 17 months later. They confirm a correlation between improved hemodynamic variables on repeat 20-degree head-up tilt and improvement in fatigue, PEM, concentration problems, and overall function. The authors conclude that the concomitant improvement in symptoms, autonomic cardiovascular control, severity of ME/CFS-associated fatigue, and functional impairments is consistent with a possible causal relationship among these variables.(Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 188-189).
>
> The committee anticipates that use of these criteria will make it easier for clinicians to **make appropriate and timely diagnoses of ME/CFS in both children and adults, and to provide appropriate treatment and management while avoiding possibly harmful interventions** (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 210).
>
> The committee recognizes that diagnosis and treatment of comorbid conditions is necessary when caring for patients. For example, a patient with ME/CFS with a prominent history of snoring and sleep apnea may have polysomnography diagnostic of sleep apnea. Treatment with continuous positive airway pressure could improve the patient's overall condition but not resolve all the symptoms of ME/CFS, signifying that in this individual, obstructive sleep apnea is a comorbid condition rather than the cause of the patient's ME/CFS symptoms. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 224-225).

There are numerous other studies in existence that demonstrate functional improvement in ME/CFS and CFS, however none are curative.

It is submitted that there is a moderate to strong evidence base within the literature, the reviews and the guidelines with respect to treatments that are appropriate for individuals according to their symptomology and impairments. No treatment is curative.

8.1.4 Interventions Likely to Benefit

Section 25(1)(c) contains the second requirement for access, whereby the applicant must ensure "the CEO is satisfied that provision of early intervention supports for the person is likely to benefit the person by" meeting the four criteria set down (i) to (iv). The Rules add clarity and state:

> 6.7 If an impairment is of a degenerative nature, the impairment is, or is likely to be, permanent if medical or other treatment would not, or would be unlikely to, improve the condition.

The Operational Guidelines for Early Intervention at paragraph 6 merely repeat the contents of section 25(1)(c) (National Disability Insurance Scheme, 2014a, p. 1) and once again paragraph19 provides guidance on the CEO's considerations, stating:

> 19. In deciding whether the provision of early intervention supports is likely to benefit the person (either by reducing future support needs, mitigating or alleviating the impact on functioning, preventing deterioration of or improving functioning, or strengthening the sustainability of informal supports)
>
> a. The likely trajectory and impact of the person's impairment over time, and
> b. The potential benefits of early intervention on the impact of the impairment on the person's functional capacity and in reducing their future needs for supports, and
> c. Evidence from a range of sources, such as research or information provided by the person with disability or their family members or carers. The delegate may also in some cases seek expert opinion. (National Disability Insurance Scheme, 2014a, p. 3)

In ME/CFS and CFS, early intervention can assist in a better outcome according to some research. The IOM Committee asserted: "The length of recovery time and effectiveness of treatment for ME/CFS have important implications for defining the duration of disability" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 263).

Loblay et al's 2002 CFS Guidelines argue that early intervention "in those with persistent fatigue is therefore especially important" (Loblay, et al., 2002, p. S26).

The Consensus Guidelines with respect to ME/CFS by Carruthers et al (2003) emphasis the importance of early management:

> The goal of a management/treatment program is to empower the patient by encouraging them to trust their own experiences, to enhance the patients' awareness of the activities and environments in which they can cope without exacerbating symptoms and pace themselves accordingly. The program should aim at optimizing the patient's ability to maintain function in everyday activities, being as active as possible within their

> boundaries, and then gently extending those boundaries. (Carruthers, et al., 2003, p. 37)

Carruthers et al (2003) outline the approach for such interventions in the form of an individualised patient program:

> Develop an Appropriate Adaptable Approach That Is Conducive to Healing:
>
> • Assess the patient's current medical condition. Address all dimensions of the patient's impairments and their interactive nature, as well as extenuating factors and other concerns.
>
> • **Develop an appropriate individualized program.** The severity of impairments, the dynamics of activity boundaries, and unpredictable energy/activity rhythms differ from patient to patient and require different approaches.
>
> • Empower the patient through respect. The autonomy of patients is vital to their physical and psychological health.
>
> • Engage the patient in establishing a program with realistic goals. It is of utmost importance that the patients are able to set the complexity and pace of their activities, to incorporate rest intervals as needed, and control sensory exposure.
>
> - Begin a program at a level that will ensure the patient's success.
> - Pace the program to increase very gradually and thus ensure the patient's continued commitment and success.
> - Develop a plan of alternate strategies for times when the patient is having flare-ups.
>
> • The environment should be conducive to healing, i.e., be at a comfortable temperature and free from confusion, bright lights and loud music or noise.
>
> • Directions should be clear, simple, and concise. (Carruthers, et al., 2003, pp. 38-39)

The IACFSME Primer (2014) also encourages early intervention:

> Establishing the diagnosis of ME/CFS will usually give the patient much relief. **Early diagnosis with timely support and intervention (e.g., careful avoidance of over-exertion) is important as it may help to avoid deterioration and facilitate improvement.** The chronicity of the illness indicates the **need for ongoing management and periodic re-evaluation**. Regular monitoring may reveal a change in the symptoms of ME/CFS or the emergence of a new, co-existing illness that may worsen fatigue and other CFS symptoms.
>
> Given the complexities of this illness, a multidisciplinary team approach to management is desirable but rarely available. That said, patients can be successfully treated in a primary care setting, with appropriate referral to

> other health practitioners as needed. **Clinical care focuses on improving symptoms and functioning** … (Friedberg, et al., 2014, p. 7)

Baraniuk (2017) also identifies the importance of intervention to improvement of functional capacity:

> The primary goals of management are to provide a supportive healthcare environment with a team of occupational therapists, physiotherapists, and other appropriate therapists who will **manage symptoms and improve functional capacity**. (Baraniuk, 2017, p. 36)

Baraniuk (2017) also identifies the importance of intervention to improvement of functional capacity:

> **Long-term management by a coordinated supportive team is beneficial to maximise functional capacity.** Compassionate counselling by a doctor, occupational therapist, social worker, or psychotherapist can address many of the concerns of people with CFS; it can also a framework to help them restructure their lives to conserve their energy for necessary activities of daily living and gradually increase social and occupational interactions …
>
> **The primary goals of treatment are to manage symptoms and improve functional capacity.** A possible strategy may be to provide counsel to patients every 3 months and to reassess any other health issues and treatable diseases.
>
> Treatment is complicated by strong differences in opinions between patients with CFS and their support groups compared with medical specialists …
>
> Physicians are encouraged to conduct a thorough treatment history, identify all physicians and healthcare professionals (e.g., chiropractor, acupuncturist) currently involved in the patient's care, and obtain a list of prescribed medications, over-the-counter medications, vitamins, supplements, and homeopathic remedies. For some patients with CFS, their treatment regimens may be complicated and extensive. A general treatment strategy in such cases may involve a stepwise process of simplifying the treatment regimen across time (e.g., gradually reducing the number of medications).
>
> Treatment interventions tend to be multidimensional and tailored to each patient's circumstances. The focus of treatment should be orientated toward symptom management and functional improvement, and away from repeated, extensive diagnostic procedures, or ongoing referrals to additional specialists.(Baraniuk, 2017, p. 37)

ME/CFS Legal submits that there is a strong evidence base that assets that early intervention can assist in the functional experience of ME/CFS and CFS. There is no cure, but there is potential, within the early stages for some patients to obtain functional improvements.

ME/CFS Legal cautions that the evidence based research demonstrates that the default position on Graded Exercise Therapy and Cognitive Behaviour therapy are not the most appropriate approach, and can, in fact, cause deterioration (Kindlon T. , 2011a).

8.1.4.1 Mitigating or Alleviating

Section 25(1)(c) is broken into four considerations. The first relates to mitigation and alleviation. Section 25(1)(c)(i) of the NDIS Act state that treatment must be effective in "mitigating or alleviating the impact of the person's impairment upon the functional capacity of the person to undertake communication, social interaction, learning, mobility, self care or self management." This is repeated in the NDIS Rules at 6.2(c)(i).

Section 27(b) and (e) act in concert with Section 25, which empowers the rules to cover circumstance and criteria relevant to the impairments covered under section 25(1)(c)(i), as well as the provision of early interventions likely to benefit a claimant by alleviating or mitigating deterioration. For the purposes of this section, Rule 6.8 directs the CEO to consider evidence going to the issues of mitigation and alleviation. The nature of the evidence to be considered is set out in Rule 6.9 which include:

(a) the likely trajectory and impact of the person's impairment over time; and
(b) the potential benefits of early intervention on the impact of the impairment on the person's functional capacity and in reducing their future needs for supports; and
(c) evidence from a range of sources, such as information provided by the person with disability or their family members or carers. The CEO may also in some cases seek expert opinion.

There is no case law with respect to the definition of 'mitigating' or 'alleviating'. In accordance with section 15AB of the *Acts Interpretation Act 1901* (Cth) the ordinary meaning can be ascertained by reference to external materials – in this case the Oxford dictionary.

Alleviate, when given its ordinary meaning is as follows:

> verb
>
> [with object]
>
> 1. Make (suffering, deficiency, or a problem) less severe.
>
> 'he couldn't prevent her pain, only alleviate it'
>
> 'measures to alleviate unemployment' (English Oxford Living Dictionaries, 2017)

Mitigate, when given its ordinary meaning is as follows:

> verb
>
> [with object]
>
> 1. Make (something bad) less severe, serious, or painful.
>
> 'drainage schemes have helped to mitigate this problem'
>
> 1.1 Lessen the gravity of (an offence or mistake)
>
> 'he would have faced a prison sentence but for mitigating circumstances' (English Oxford Living Dictionaries, 2017)

It is fair comment to say that the two terms are synonyms and are focused upon the provision of treatment that reduces the severity of the impairment.

The case law in this area is exceptionally limited due to the short time frame in which the scheme has existed. In *YPRM and NDIA*[32], the decision maker emphasised the importance of have a "current functional assessment" when considering whether a particular treatment mitigates the impairment.

In terms of alleviation there is no specific case reference, however, being a synonym of mitigation, it is fair to assume it requires a similar degree of evidence.

With respect to ME/CFS and CFS, there are a significant number of treatment and management options that are utilised in order to alleviate and mitigate the condition for the purposes of improving function. Whilst GET and CBT have been touted as the most appropriate, the contemporary evidence has demonstrated that these approaches have little benefit for patients and in some cases, cause deterioration and adverse impacts (Kindlon T. , 2011a; Kindlon T. , 2011b; Vink M. , 2017a; Vink M. , 2017b; Geraghty, 2017a; Geraghty, 2017b; Tuller, 2017).

The evidence based research on various treatment regimens (such as those identified in 8.1.4 above) contain various levels of study quality with respect to treatment and management of ME/CFS and CFS. The purpose of such interventions is the alleviate and mitigate, in order to maintain function, hence there is a strong argument that such interventions meet the definition of Section 25(1)(c)(i).

8.1.4.2 Preventing Deterioration

The second consideration under Section 25(1)(c) relates to prevention of deterioration. Section 25(1)(c)(ii) of the NDIS Act state that the treatment must be effective in "preventing the deterioration of such functional capacity". This is repeated in the NDIS Rules at 6.2(c)(ii).

As identified above, section 27(b) and (e) act in concert with various subsections of Section 25. Section 27 empowers the rules to cover circumstance and criteria relevant to the impairments covered under section 25(1)(c)(ii), as well as the provision of early interventions likely to benefit a claimant by preventing deterioration. For the purposes of this section, Rule 6.8 directs the CEO to consider evidence going to the issue of preventing deterioration. The nature of the evidence to be considered is set out in Rule 6.9 (detailed in 8.1.4.1 above).

There is no case law available with respect to this issue within the NDIS. Extending beyond the NDIS to the area of accident compensation, the case of *Theodoulis v Transport Accident Commission (General)* [2005] VCAT 872[33] is of assistance:

> 32 … However, I regard as being perfectly reasonable his request for funding of a limited number of treatments in the future, such treatments designed to assist in the event of the deterioration of symptoms or, as described by Deputy President Macnamara in Edwards, "flare-ups". Bearing in mind his determination to remain in his present demanding occupation, it also seems to me that such limited treatment, used at his discretion, may well maintain him as what Harper J described in Russell as "a functioning member of the community". Of course, Harper J basically stated that the test was one of a much lower standard than that.

[32] *YPRM and National Disability Insurance Agency* [2016] AATA 1023 per Humphries DP, [50].
[33] *Theodoulis v Transport Accident Commission (General)* [2005] VCAT 872, Bowman J.

> 33…It may be that, upon occasions, some episodes of treatment do no more than prevent deterioration. However, as stated by Harper J, there can be situations where this is appropriate. Nevertheless, my primary reason for arriving at the conclusion which I have is that I accept the evidence of Theodoulis that the treatment is of a real benefit to him, assisting in the alleviation of pain, increasing his mobility, and enabling him to continue, without interruption, in the workforce.

Within the context of the Victorian accident compensation scheme, the treatment allowed the Applicant to maintain function and remain in employment by preventing deterioration.

The evidence based research on various treatment regimens (such as those identified in 8.1.4 above) contain various levels of study quality with respect to treatment and management of ME/CFS and CFS. The purpose of such interventions is the alleviate and mitigate, in order to maintain function, hence there is a strong argument that such interventions meet the definition of Section 25(1)(c)(ii).

8.1.4.3 Improving Functional Capacity

Section 25(1)(c) is broken into four considerations. The third relates to the improvement of functional capacity. Section 25(1)(c)(iii) of the NDIS Act state that the treatment must be effective in "improving such functional capacity." This is repeated in the NDIS Rules at 6.2(c)(iii).

Again, as identified above, section 27(b) and (e) act in concert with various subsections of Section 25. Section 27 empowers the rules to cover circumstance and criteria relevant to the impairments covered under section 25(1)(c)(iii), as well as the provision of early interventions likely to benefit a claimant by ensuring improvement in functional capacity. For the purposes of this section, Rule 6.8 directs the CEO to consider evidence going to the issue of improvement of functional capacity. The nature of the evidence to be considered is set out in Rule 6.9 (detailed in 8.1.4.1 above).

There is no case law available with respect to this particular use of the term "functional capacity" however the guidelines and case law do cover the issue in terms of disability.

Functional capacity in this context is assessed against the impairments and the impact upon "functional capacity to undertake one or more … activities" being communication, social interaction, learning, mobility, self-care, self-management and psychosocial functioning. The assessment of functional capacity is not measured as a comparative with pre disability functioning, but is a "reference to reduced functional capacity compared with what a person in the community who has not experienced the impairments of the applicant might otherwise be able to undertake."[34]

Functional capacity can be fluctuating – something that can occur in both ME/CFS and CFS. The Guidelines state that:

> 31. For NDIS purposes, where the **person's impairment is fluctuating or episodic (e.g. due to a mental illness or a condition such as epilepsy), substantially reduced functional capacity is determined when the person's impairment is fully treated and stabilised**, (i.e. the person's level of functional capacity due to residual and long term impairment is determined in the periods between acute episodes).(National Disability Insurance Scheme, 2014a, p. 6)

[34] *Kilgallin and NDIA* [2017] AATA 186, per Humphries DP and Toohey SM, [23].

Rule 6.9 allows the CEO to gather evidence where required. Evidence of functional capacity can be gathered with respect to trajectory of impairment over time (Rule 6.9(a)), potential benefits of early intervention on the impairment and need for supports (Rule 6.9(b)) and include evidence from various sources, including self-reporting, family members, carers and expert opinions (Rule 6.9(c)). In the case of the expert opinion, the expert must have "specialist expertise" must be in the condition that causes the claimed functional impairment[35].

The evidence based research on various treatment regimens (such as those identified in 8.1.4 above) contain various levels of study quality with respect to treatment and management of ME/CFS and CFS. The purpose of such interventions is also to improve function hence there is a strong argument that such interventions meet the definition of Section 25(1)(c)(iii).

8.1.4.4 Sustainability of Informal Supports

The fourth and final component of section 25(1)(c) relates to the sustainability of supports. Section 25(1)(c)(iv) of the NDIS Act state that the treatment must be effective in "strengthening the sustainability of informal supports available to the person, including through building the capacity of the person's carer." This is repeated in the NDIS Rules at 6.2(c)(iv).

The term 'informal supports' refers to "The supports participants get from the people around them, for example family, friends, neighbours" (National Disability Insurance Scheme, 2017c, p. 3).

8.1.4.4.1 Capacity Building

The concept of capacity building was originated from the United Nations programme on capacity development in 1997:

> The process by which individuals, groups, organisations, institutions, societies and countries develop their abilities, individually and collectively to perform functions, solve problems, set and achieve objectives. (United Nations Development Programme, 1997, p. 2)

The NDIS Independent Advisory Council elaborates the definition, stating:

> Capacity building was part of a process of moving from deficit 'needs based' thinking where experts fixed deficits and solved problems to a demand driven strengths based partnership approach that taps into existing knowledge, strengths, ideas and motivations to increase involvement, decision making and ownership of issues. This transformation allows decision making power to rest with those whose 'capacity is to be developed' with a change in the role of the 'capacity builder' from one of problem analyser, solution designer and implementer, to that of facilitator.
>
> Capacity building takes place over time requiring a multitude of strategies and activities at the individual, organisational and systemic levels to be sustainable. It will be most potent when multiple level strategies address the complexity of barriers in people's lives.(Independent Advisory Council of the NDIS, 2015, pp. 7-8)

In the context of carers and informal supports, the objectives within the NDIS are as follows:

[35] *Mulligan and NDIA* [2015] AATA 974, [106] per Toohey SM and McCallum M.

> Another purpose of capacity building is to assist people with disability, their families and support networks move from dependent users of services, to people who are active citizens, exercising choice and control and engaging in social, economic and civic life…
>
> Capacity building is fundamental to the sustainability of the NDIS because it assists people to build ordinary lives strengthened by relationships, not just services. Capacity building helps people understand that paid support contributes to positive lives but that an excess of paid support can drive out freely given relationships which are central to a meaningful life. In addition, capacity building strengthens people's resilience and people with greater resilience develop support solutions that are more enduring and cost effective.(Independent Advisory Council of the NDIS, 2015, p. 10)

Capacity building in the context of the NDIS is therefore centred on ensuring that that a "person with disability [is assisted to] transform from a client-hood and a life lived in services to a citizen who is actively engaged and with a sense of belonging in the economic, social, cultural and civic life of the community" (Independent Advisory Council of the NDIS, 2015, p. 7).

There is no apparent guidance on what capacity building means in practice. Carer's Australian point this out in 2013:

> There is no indication in the Bill how the need for such supports will take into account the goals, willingness and aspirations of carers ...
>
> There is no certainty that the Rules will contain the specific details on how this is likely to be assessed, the process to be used or the options available to an assessor or planner and to what extent the decision will be left to the individual planner's judgement. It is not clear why there is no similar provision for carers of people with disability who qualify under the disability requirements (cl 24). Generally, these will be the carers of people who have a disability where early intervention is unlikely to reduce the person's need for future support. This would seem to be the majority of carers. (Carers Australia, 2013, p. vi)

The current rules still provide no guidance.

8.1.4.4.2 The Role of Carers and Informal Supports

The role and issues faced by carers and informal supports in ME/CFS and CFS has been extensively studied. This experience is relevant the specific issue of "building the capacity of a person's carer".

In ME/CFS and CFS the carers and others play a significant role in the support and management of the patient. Carers are made up of husbands, wives or partners in majority of the cases, whilst a parent or child make up the remainder (Nacul, et al., 2011, p. 3).McCrone et al (2003)identify that informal carers provide an important, unremunerated contribution to the case of the patient, and this has a substantial impact upon them (McCrone, Darbishire, Ridsdale, & Seed, 2003, pp. 253-254). Nacul identified that the majority of carers were males, whilst the majority of patients were female (Nacul, et al., 2011, p. 3).

Missen et al (2012) examined the impact of CFS/ME on children, reporting that families reported significant loss of monthly income, with carers forced to give up work the care for children, whereas

siblings were impacted by the loss of their playmate, as well as playing a role in their care (Missen, Hollingworth, Eaton, & Crawley, 2012, pp. 508-509). Ax et al (2002) conversely identified that the carer often underwent a process of change, taking on breadwinner roles, parental roles or taking on the home duties (Ax, Gregg, & Jones, 2002, pp. 35-36). Carers often accompanied the patient to frequent hospital visits, medical check-ups and long waiting times, as they assisted the patient (Ax, Gregg, & Jones, 2002, p. 37).

Nacul et al (2011) identify that caring for a chronically ill patient impacts upon the health and quality life of the carers (Nacul, et al., 2011, p. 2). Carers with patients whose mental health was more impacted by the condition, place greater emotional pressures on carers and represent a great burden (Nacul, et al., 2011, p. 8). Ax et al (2002)too identified this perception of burden and identified that carers often questioned how their future would be constrained (Ax, Gregg, & Jones, 2002, p. 36).Ax et al further identify that carers suffer distress and fear for the future of the patient as the illness progresses (Ax, Gregg, & Jones, 2002, p. 37).

8.1.4.4.3 Capacity Building Carers and Informal Supports

ME/CFS Legal submits that there is a dearth of research to guide this particular section of the Act. The capacity building expectations of carers and informal supports within the NDIS framework aims to build the capacity of carers. This might well include building their ability advocate on behalf of patients, or to identify and engage with coordinated support (ie "whether or not to receive support receive individualised cross-sector service coordination support, and the timing and intensity of support received") (Centre for Disability Research and Policy, University of Sydney (CDRP) and Young People in, 2014, p. 105). At this point in the implementation of it is difficult to comment further.

8.1.4.5 Specialist Expertise

ME/CFS Legal identifies that the ability of the CEO to refer an assessment for an expert opinion under Rule 6.9(c) is a common theme that flows throughout section 25(c). In the 2005 matter of *Mulligan and National Disability Insurance Agency,* the AAT asserted that such expert must have "specialist expertise" must be in the condition that causes the claimed functional impairment.[36] Beyond this obiter statement, there is no comment on the issues within the NDIS decisions to date.

From the perspective of ME/CFS and CFS, the major concern for applicants within the Centrelink, as they are in the NDIS, is the appropriate selection of a knowledgeable expert, that is not wedded to the school of thought that CBT and GET are the only approaches to treatment and functional improvement. As has been shown in this submission – this evidence base is heavily flawed and holds more potential for harm than benefit.

Expertise is a critical factor in ME/CFS and CFS. Not all medical practitioners have sufficient knowledge. In *Makita (Australia) Pty Ltd v Sprowles*[37] Priestley, Powell and Heydon JJA gave a firm guidance on the importance of the expert opinion being provided by a witness with specialised knowledge. Their honours stated:

> In short, if evidence tendered as expert opinion evidence is to be admissible, it must be agreed or demonstrated that there is a field of "specialised knowledge"; there must be an identified aspect of that field in which the witness demonstrates that **by reason of specified training, study or experience, the witness has become an expert**; the opinion proffered

[36]Ibid.

[37]*Makita (Australia) Pty Ltd v Sprowles*[2001] NSWCA 305 Priestley, Powell and Heydon JJA, [83].

> must be "wholly or substantially based on the witness's expert knowledge"; so far as the opinion is based on facts "observed" by the expert, they must be identified and admissibly proved by the expert, and so far as the opinion is based on "assumed" or "accepted" facts, they must be identified and proved in some other way; it must be established that the facts on which the opinion is based form a proper foundation for it; and **the opinion of an expert requires demonstration or examination of the scientific or other intellectual basis of the conclusions reached**: that is, the expert's evidence must explain how the field of "specialised knowledge" in which the witness is expert by reason of "training, study or experience", and on which the opinion is "wholly or substantially based", applies to the facts assumed or observed so as to produce the opinion propounded. If all these matters are not made explicit, it is not possible to be sure whether the opinion is based wholly or substantially on the expert's specialised knowledge.

Regrettably in the context of Centrelink, the alleged medical experts to which claimants are referred, are heavily deficient with respect to the knowledge of ME/CFS and CFS. A recent joint submission to Parliament by patient support groups submitted that:

> Improved education is needed for Job Capacity Assessors and Centrelink-employed medical practitioners regarding the nature of ME/CFS, including an overview of the current scientific literature and appropriate treatment options. (#ME Action Network Australia, ME/CFS Australia (South Australia), Inc. and ME/CFS and Lyme Association of Western Australia, Inc., 2016, p. 3)

When one considers the requirements of *Makita*, it is not merely sufficient that the "expert opinion" come from a specialist within a medical disciple (eg neurology, internal medicine, immunology). The expert's "specialised knowledge" must come from the "training, study or experience". A practitioner who merely prescribes CBT and GET, without exploring other evidence-based treatments could hardly be said to have 'specialised knowledge' when such knowledge does not extends to the alternatives, nor understand or accept that CBT and GET are not appropriate treatments and have not been demonstrated to be effective.

It is the submission of ME/CFS Legal that the NDIS requires educated, appropriately knowledgeable, medical specialists that have a genuine capacity to assess and understand the needs and nature of the condition.

8.1.4.6 Evidence Required

Section 26(1) of Act provides the CEO the ability to request various reports to assist him/her in the assessment of access: reports to assist him/her in the assessment of access:

(a) that the prospective participant, or another person, provide information that is reasonably necessary for deciding whether or not the prospective participant meets the access criteria;
(b) that the prospective participant do either or both of the following:
    a. undergo an assessment and provide to the CEO the report, in the approved form, of the person who conducts the assessment;
    b. undergo, whether or not at a particular place, a medical, psychiatric, psychological or other examination, **conducted by an appropriately**

> **qualified person**, and provide to the CEO the report, in the approved form, of the person who conducts the examination

Rule 6.9 outlines the evidence that is required when specifically required to establish early intervention:

> 6.9 In deciding whether provision of early intervention supports is likely to benefit the person in the ways mentioned in paragraphs 6.2(b) and (c) above, it is expected that the CEO would consider:
>
> (a) the likely trajectory and impact of the person's impairment over time; and
> (b) the potential benefits of early intervention on the impact of the impairment on the person's functional capacity and in reducing their future needs for supports; and
> (c) evidence from a range of sources, such as information provided by the person with disability or their family members or carers. The CEO may also in some cases seek expert opinion.

The Act does not define what an "appropriately qualified person" is. In the context of a medical practitioner, *Bahonko v Moorfields Community & Ors (No 6)*[38] offers some direction.

> Having regard to the injuries and conditions relied upon by the plaintiff in this proceeding, **I am satisfied that the expert evidence of appropriately qualified medical practitioners** practising in the area of ophthalmology, orthopaedic surgery and psychiatry, may be relied upon by both the plaintiff and the defendants in providing evidence to the Court with respect to the issues which arise in this proceeding…
>
> Having regard to the injuries and conditions relied upon by the plaintiff in this proceeding, **I am satisfied that the expert evidence of appropriately qualified medical practitioners practising** in the area of ophthalmology, orthopaedic surgery and psychiatry, may be relied upon by both the plaintiff and the defendants in providing evidence to the Court with respect to the issues which arise in this proceeding.[39]

It is submitted that an appropriately qualified medical practitioner must therefore have an expertise in accordance to the submissions in 8.1.4.5, hence knowledge, education and experience in ME/CFS and CFS is essential to any report obtained by the CEO, for the reasons expressed above.

The rules offer up other considerations:

8.1.4.6.1 Trajectory

The consideration of the "likely trajectory and impact of the person's impairment over time" within Rule 6.9(a) in the context of ME/CFS and CFS requires consideration of issues of permanency and decline detailed within 7.3.1 above.

[38] *Bahonko v Moorfields Community &Ors (No 6)* [2013] VCC 873 per Saccardo, J.
[39] Ibid, [18], [20].

Severity and longevity in ME/CFS and CFS play a significant role in considerations of trajectory and impact. In severe cases, the trajectory is often one of decline over time, and increased impairment.

The unparalleled and extensive experience of the author of NDIS submission 80, Whiting (2017) as an ME/CFS and CFS specialist physician, is of direct relevance to the issue. On the issue of trajectory he states:

> It is my experience that if patients are initially bedbound, they may improve in the first 6 months or so, but beyond this early timeframe, **no improvements can be expected to occur in the natural course of the illness, especially after the 2 year mark**. Those who do improve will show improvements during this timeframe, and **one can predict from the lack of significant improvements at the 6 month mark that patients are likely to remain significantly incapacitated or disabled from this point onwards**. In other words, prognosis can be reliably predicted at 6 months and confirmed as certain at 2 years from the time of acute onset of illness. **Those with illness of gradual onset are even more likely to remain disabled permanently**. (Whiting, 2017, p. 3)

It is the submission of ME/CFS Legal that ME/CFS and CFS satisfy this requirement of the rules.

8.1.4.6.2 Benefits of Early Intervention

The second condition within Rule 6.9 requires the applicant to demonstrate the "the potential benefits of early intervention on the impact of the impairment on the person's functional capacity and in reducing their future needs for supports". The benefits are outlines within 8.1.4.

ME/CFS Legal submits that there are benefits within various interventions that can potentially assist some within the ME/CFS and CFS community, such that their need for future supports is reduced.

8.1.4.6.3 Evidence Sources

The second condition within Rule 6.9 requires the applicant to demonstrate the "evidence from a range of sources, such as information provided by the person with disability or their family members or carers. The CEO may also in some cases seek expert opinion."

Paragraph 20 of the Operational Guidelines for Early Intervention complement this section, stating:

> The Becoming a Participant Rules **allow delegates to consider evidence from a range of sources, including from the person with disability, family members, carers and from experts**. Delegates are to make judgments about the weight or value of particular pieces of evidence. The sources of the evidence and the purposes for which it is being used will have an impact on the weight or value of the evidence. For example, evidence from a doctor on a specific medical matter would be **given considerable weight** just as evidence from family members on the impact of a support on the informal support they provide would be given considerable weight. When considering if a person is likely to benefit from early intervention supports, the delegate may also wish to consider factors such as the time elapsed since the onset or diagnosis of the disability and whether there has been a recent, or there is an impending, significant change in the person's impairment or disability. As a guide, early intervention supports generally provide a greater benefit to a

> person if they commence within 2 years of onset or diagnosis of the impairment or immediately after a significant change in the impairment.(National Disability Insurance Scheme, 2014a, p. 3)

The role and importance of an expert opinion from specialist medical practitioner with expertise in ME/CFS and/or CFS is essential to the quality of the opinion garnered. The treating practitioner is regarded as the most significant because of their familiarity with the applicant. The weight of such opinion is high. The significance of an expert opinion has been outlined above at 8.1.4.5. Aside from the ability of the applicant to submit their own evidence, the CEO has the right to call his or her own expert opinion - with experience, knowledge and education in ME/CFS and/or CFS.

The value of evidence from family members and other witnesses of those with ME/CFS or CFS has been highlighted in the recent English case of *Miles v Friends Life Ltd*[40] where Turner J states:

> I take the view that, bearing in mind the extent and duration of the contact which each of these witnesses has maintained with the claimant over recent years, **it is improbable that they are primarily the victims of any persistent deceit on his part**. Even the most callid performer would struggle to fool all of these people all of the time. Furthermore, such a performance **would take such a sustained and unremitting effort of self-control on the claimant's part as to render his quality of life almost as impaired as if he were suffering from a genuine medical condition** which gave rise to such limitations.
>
> It follows that the scrutiny to which the evidence of the claimant and his witnesses have been exposed has focussed, in particular, upon their veracity as opposed to their gullibility.[41]

Applicants can therefore supplement their own evidence with evidence of carers and informal supports. The value of such statement is significant, particularly because they provided an independent view of function and impairment across a prolonged period of time.

8.1.4.7 Degenerative Conditions

A further provision flows through section 25(1)(c) with a note at the end of the section which states that in "certain circumstances, a person with a degenerative condition could meet the early intervention requirements and therefore become a participant." This is repeated at Rule 6.7. The Operational Guidelines assist somewhat more, stating:

> Under the Becoming a Participant Rules, where an impairment is of a degenerative nature, the impairment is, or is likely to be, permanent if medical or other treatment would not, or would be unlikely to, improve it. (National Disability Insurance Scheme, 2014a, p. 3)

It is submitted that ME/CFS and CFS are, in a significant proportion, within the realm of a degenerative condition – particularly the 25% or so of patients are severely ill and bedbound or housebound. The foundation for this position is outlined above at 7.3.1 above and outlined within NDIS Submission number 80 (Whiting, 2017).

[40] *Miles v Friends Life Ltd* [2017] EWHC 2415 (QB) per Turner J.
[41] Ibid, [68]-[69].

It is submitted that there are a significant number of patients with ME/CFS who would qualify under this particular section. It is noted that the IOM's (2015) statement on the seriousness of the condition:

> Patients with ME/CFS have been found to be more functionally impaired than those with other disabling illnesses, including type 2 diabetes mellitus, congestive heart failure, hypertension, depression, multiple sclerosis, and end-stage renal disease. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 31)

The severity and/or longevity of the condition can play a significant role in this assessment.

8.1.5 Prescribed Impairments

Section 25(2) states that "The CEO is taken to be satisfied as mentioned in paragraphs (1)(b) and (c) if one or more of the person's impairments are prescribed by the National Disability Insurance Scheme rules for the purposes of this subsection."

In ME/CFS and CFS, the application of this section is somewhat limited. It is noted that Intellectual Disability are List A, B and C. An intellectual disability is defined as "Intellectual disability diagnosed and assessed as moderate, severe or profound in accordance with current DSM criteria (e.g. IQ 55 points or less and severe deficits in adaptive functioning)" (National Disability Insurance Scheme, 2017b).

In ME/CFS and CFS the condition can have a significant impact upon intellectual function. Nijhof et al (2016), in examining children state, illustrate the impact upon an individual's IQ:

> We found that current IQ scores of CFS adolescents were lower than the IQ scores of healthy peers with an equivalent school level. Furthermore, there was a diminishing on cognitive functioning across time when current IQ scores were compared with pre-CFS cognitive achievement. (Nijhof, et al., 2016, p. 249)

In the context of the post-exertional impact of ME/CFS LaManca et al (1998)demonstrated "a decrease in cognitive functioning after physical exertion by CFS patients" and that "the reduction in cognitive processing in CFS patients was seen only after exercise and not at baseline, since no differences were found on any of the CTB variables before the treadmill test … CFS patients showed a deficit in the speed of information processing on the more complex and challenging cognitive tasks after the exercise challenge." (LaManca, et al., 1998, p. 63S)

There is a significant body of research that demonstrates the decline in IQ is a feature of patients with ME/CFS and CFS. Regardless of the evidence based research, the

Patients with ME/CFS and CFS could well achieve access to the scheme on the basis of their decline in intellectual capacity as a prescribed impairment.

8.1.6 Intervention Appropriately Funded Outside NDIS

8.1.6.1 Legislative Framework

The final consideration, being Section 25(3) states that "Despite subsections (1) and (2), the person does not meet the early intervention requirements if the CEO is satisfied that early intervention **support for the person is not most appropriately funded or provided** through the National Disability Insurance Scheme, and is **more appropriately funded or provided through other general**

systems of service delivery or support services offered by a person, agency or body, or through systems of service delivery or support services offered:

(a) as part of a universal service obligation; or
(b) in accordance with reasonable adjustments required under a law dealing with discrimination on the basis of disability."

Rule 6.1 works in concert with this section, and states:

> A person does not meet the early intervention requirements if the CEO is satisfied that early intervention support for the person is more appropriately funded or provided through another service system (service systems is defined in paragraph 8.4) rather than the NDIS.

The Operation Guidelines for Early Intervention, at paragraph 7, provide the fourth step of requirements for access to interventions and state:

> Fourth, there is one more step. Even if a person meets the test above, that person does not meet the early intervention requirements if the delegate is satisfied that early intervention supports for the person:
>
> a. Is not most appropriately funded or provided through the National Disability Insurance Scheme (NDIS), and
> b. Is more appropriately funded through:
> i. Other general systems of service delivery or support services offered by a person, agency or body, or
> ii. Systems of service delivery or support services offered as part of a universal service obligation or in accordance with reasonable adjustments required under a law dealing with discrimination on the basis of disability. (National Disability Insurance Scheme, 2014a, pp. 1-2)

The experience with respect to ME/CFS and CFS to date has been one of denial on the grounds that it is more appropriately provided through the health system (being health and allied health systems) to manage the symptomology of the condition. In the context of a multidisciplinary approach being suggested, these decisions have made no attempt to assess the support in terms of

8.1.6.2 Case Law on Intervention Funding

In the 2015 AAT decision in *McCutcheon*[42], Toohey SM considered this specific issue and the difficulty of discerning between the responsibilities of the NDIS and the health system.

> That said, **it is not easy to draw clear lines around what is "clinical treatment of health conditions**" for which the NDIS will not be responsible (Rule 7.5) and supports that meet the description in Rule 7.4 for which the NDIS will be responsible. Nor is it a simple matter to segregate chronic pain from the condition which is causing it…
>
> **The policy underlying the legislation is clear: that it is not for the NDIS to respond to shortfalls in mainstream services ...**

[42] *McCutcheon and NDIA*[2015] AATA 624 per Toohey SM.

> The fact that a Medicare rebate is available for a treatment **might suggest that it is more appropriately funded by the health system** than the NDIS, but not necessarily. The **Operational Guideline states that "assistance" by allied health professions including physiotherapy and occupational therapy**, both of which are covered by the Chronic Disease Management – Individual Allied Health Services under Medicare program, is more appropriately funded by the NDIS than other parties **if it is maintenance care whose primary purpose is to provide ongoing support in order to maintain a level of functioning including long-term therapy/support to prevent functional decline.** It may be that "assistance" connotes something different from "treatment" but, if so, it is not clear why the Guideline refers to "long term therapy/support"…
>
> The NDIA accepts that physiotherapy (for which the Chronic Disease Management rebate is available) may be funded as a reasonable and necessary support but says it may only be funded for a specified number of sessions aimed at assessment and assisting a person establish home-based exercise, rather than treatment. If the first part of that is correct, I cannot see why chiropractic treatment is necessarily excluded from being a reasonable and necessary support. It is not clear from the Rule and the Guideline why funding for physiotherapy is necessarily limited as described but, even if it is, I cannot see a basis for not funding chiropractic for a purpose such as proposed by Dr Sherry...
>
> Subject to the comments below, I am satisfied in all the circumstances, and taking into account the opinions of Dr Sherry, Dr Young and Ms Zahl, that chiropractic treatment for Ms McCutcheon is most appropriately funded by the NDIS and is not more appropriately funded through the general health system.[43]

According to Toohey SM, the key distinction that makes the treatment the responsibility of the the NDIS is whether "… it is maintenance care whose primary purpose is to provide ongoing support in order to maintain a level of functioning including long-term therapy/support to prevent functional decline"[44] This is in line with the early intervention requirements under section 27(a) where the provision of early intervention supports are likely to mitigate, alleviate or prevent deterioration of functional capacity or improve functional capacity for the purposes of sections 25(1)(c)(i)-(iii) (see: Section 27(e)), and provision of early intervention supports that strengthen the sustaining of informal supports (see: Section 27(f)).

It is the submission of ME/CFS Legal that assessors are not attempting to take account of whether individual components of the support are likely to mitigate, alleviate or prevent deterioration. A cart blanch denial without appropriate consideration of the legislation, rules and guidelines is capricious and arbitrary. In *Buck v Bavone*[45] Gibbs CJ espoused the requirement that an authority act in good faith:

[43] Ibid, [105]-[110].
[44] Ibid, [107].
[45] *Buck v Bavone* (1976) 135 CLR 110 per Gibbs CJ.

> …the authority must act in good faith; it cannot act merely arbitrarily or capriciously…a person affected will obtain relief from the courts if he can show that the authority has misdirected itself in law or that it **has failed to consider matters that it was required to consider** or has taken irrelevant matters into account. Even if none of these things can be established, the courts will interfere if the decision reached by the authority appears so unreasonable that no unreasonable authority could properly have arrived at it. However, where the matter of which the authority is required to be satisfied is a matter of opinion or policy or taste it may be very difficult to show that it has erred in one of these ways, or that its decision could not reasonably

It is the submission of the ME/CFS Legal that the NDIA is failing to consider matters, being issues pertaining to mitigation, alleviation and prevention of deterioration.

8.1.6.3 Supports in the Plan – Interface with Health

The Operational Guideline for Planning and Assessment deals with Supports and the interface with health(National Disability Insurance Scheme, 2014b). There are a number of supports that are arguably accessible in ME/CFS and CFS.

8.1.6.3.1 Reasonable and Necessary Defined

The key requirement for any support to be included within a plan is for the CEO to be satisfied that the support it "reasonable and necessary" (Sections 33(2)(b) and 33(5)(c)). Reasonable and necessary supports are spelled out in section 34 of the Act:

> (1) For the purposes of specifying, in a statement of participant supports, the general supports that will be provided, and the reasonable and necessary supports that will be funded, the CEO must be satisfied of all of the following in relation to the funding or provision of each such support:
>
> (a) the support will assist the participant to pursue the goals, objectives and aspirations included in the participant's statement of goals and aspirations;
>
> (b) the support will assist the participant to undertake activities, so as to facilitate the participant's social and economic participation;
>
> (c) the support represents value for money in that the costs of the support are reasonable, relative to both the benefits achieved and the cost of alternative support;
>
> (d) the support will be, or is likely to be, effective and beneficial for the participant, having **regard to current good practice**;
>
> (e) the funding or provision of the support takes account of what it is reasonable to expect families, carers, informal networks and the community to provide;
>
> (f) the support is most appropriately funded or provided through the National Disability Insurance Scheme, and is not more appropriately funded or provided through other general systems of service delivery or support services offered by a person, agency or body, or systems of service delivery or support services offered:

(i) as part of a universal service obligation; or
(ii) in accordance with reasonable adjustments required under a law dealing with discrimination on the basis of disability.

(2) The National Disability Insurance Scheme rules may prescribe methods or criteria to be applied, or matters to which the CEO is to have regard, in deciding whether or not he or she is satisfied as mentioned in any of paragraphs (1)(a) to (f).

The Rules are very clear with respect to the objects of the scheme and the provision of support:

1.3 The Act sets out a number of objects and principles for the NDIS. The following are particularly relevant to these Rules:

Objects

(a) to provide reasonable and necessary supports, including early intervention supports, for participants in the NDIS;
(b) …

Principles

(c) …
(d) …
(e) people with disability should be supported to receive reasonable and necessary supports, including early intervention supports.

The Operational Guidelines for Planning and Assessment spell out reasonable and necessary at paragraph 4, which states:

4. Reasonable and necessary supports for people with disability should:

a. Support people with disability to pursue their goals and maximise their independence
b. Support people with disability to live independently and to be included in the community as fully participating citizens, and
c. Develop and support the capacity of people with disability to undertake activities that enable them to participate in the mainstream community and in employment. (National Disability Insurance Scheme, 2014b, p. 1)

The Operational Guidelines continue at paragraph 7:

The statement of participant supports specifies the general supports (if any) and the reasonable and necessary supports (if any) that will be funded. In deciding whether to approve a statement the delegate must:

a. Have regard to the legislation and rules, participant statement, relevant assessments,
b. Be satisfied that all clauses of s.34 of the NDIS Act on reasonable and necessary are met including that the support is most appropriately funded by the NDIS and offers value for money,

> c. Have regard to the principle that a participant should manage their plan to the extent they wish and the operation and effectiveness of any previous plans of the participant. (National Disability Insurance Scheme, 2014b, pp. 1-2)

ME/CFS and CFS patients are often socially isolated and require significant care. The provision of such supports is exceptionally important to these applicants.

8.1.6.3.2 Preparation of a Plan

The Operational Guidelines for Planning and Assessment set out the approach to plans at paragraphs 5 and 6:

> The preparation, review and replacement of a participant's plan should so far as reasonably practical be individualised; directed by the participant; where relevant consider family, carers and significant others; consider availability of informal support, access to mainstream and community supports; and build individual capacity to increase participation and inclusion in community with the aim of achieving individual aspirations ...
>
> Plans should maximise choice and independence of the participant and facilitate tailored and flexible responses to individual goals and needs.(National Disability Insurance Scheme, 2014b, p. 2)

8.1.6.3.3 Reasonable and Necessary Supports

The Operational Guidelines for Planning and Assessment set out the approach to plans at paragraph 9:

> This operational guideline lists the matters that delegates are to consider under headings which refer to the paragraphs of s.34(1). For example, value for money (s.34(1)(a)) and effective and beneficial having regard to current good practice (s.34(1)(b)). Delegates are to note that the matters to be considered may fall across more than one paragraph of s.34(1) and need to be considered in relation to more than one paragraph of s.34(1).(National Disability Insurance Scheme, 2014b, p. 2)

8.1.6.3.4 Appropriate Funding of Supports Related to Health

The Operational Guidelines for Planning and Assessment set out the principles to establish the appropriateness of the NDIS funding of supports at paragraphs 10 Through to 12:

> The principles that determine whether or not the NDIS is more appropriate to fund a support for a participant are outlined in Schedule 1 of the Supports for Participants Rules …
>
> The NDIS will be responsible for necessary and reasonable supports related to a person's ongoing functional impairment and that enable the person to undertake activities of daily living, including maintenance supports delivered or supervised by clinically trained or qualified health practitioners where these are directly related to a functional impairment and integrally linked to the care and support a person requires to live in the community and participate in education and employment …

The NDIS will not be responsible for:

a. The diagnosis and clinical treatment of health conditions, including ongoing or chronic health conditions, or
b. Other activities that aim to improve the health status of Australians, including general practitioner services, medical specialist services, dental care, nursing, allied health services (including acute and post-acute services), preventive health, care in public and private hospitals and pharmaceuticals or other universal entitlements, or
c. Funding time-limited, goal-oriented services and therapies:
    i. Where the predominant purpose is treatment directly related to the person's health status, or
    ii. Provided after a recent medical or surgical event, with the aim of improving the person's functional status, including rehabilitation or post-acute care, or
d. Palliative care (National Disability Insurance Scheme, 2014b, pp. 2-3)

Within ME/CFS and CFS, the primary consideration is that of ongoing functional impairment and the provision of supports to enable the applicant to engage in activities of daily living.

8.1.6.3.5 Categories of Support

The Operational Guidelines for Planning and Assessment provide guidance on the appropriateness of a support under the NDIS at paragraph 13.

A. The NDIS is generally more appropriate to fund the following necessary and reasonable supports:

1. Assistance to coordinate supports and assistance with daily personal activities – assistance to engage with the health system such as decision making support and making appointments, (except where this is provided as part of a coordinated health care package), including a continuation of any support for complex communication needs or challenging behaviours while accessing health services, including hospitals.
2. Prosthetic limbs, orthotics or splints for ongoing functional performance (but not any medical or surgical procedures)...
3. Community re-integration – which enables the participant to live in the community such as **personal support and home modifications and delivery of routine, non-clinical care to enable activities of daily living**
4. Training - of NDIS funded support staff on a participant's individual needs by nurses or allied health professionals, including training for new service providers and retraining as the participant's needs change (with service providers being responsible for training new staff)
5. Assistance with transport – **specialist transport to and from medical appointments** required as a result of the participant's disability

(where no other transport option is appropriate and not including emergency or in patient transport or substituting for parental responsibility) (National Disability Insurance Scheme, 2014b, pp. 2-3)

The Operational Guidelines for Planning and Assessment provide a second tier supports that fall within the grey area where funding can fall upon the NDIS or other parties, dependent upon the purpose:

1. Assistance in managing life stages, transitions and supports, can be funded by the NDIS or by the health/mental health system. In determining which system is more appropriate, the system that is delivering the majority of supports is usually more appropriate to assist in the coordination of these supports.
    a. NDIS: assistance where the majority of the coordination and transition supports relate to supports funded by NDIS, or to non-clinical supports,
    b. Other parties: assistance where the majority of the coordination and transition supports relate to supports funded by the health system.
2. Therapeutic support, including assistance by allied health professions such as speech and language pathology, **physiotherapy, occupational therapy**, audiology and therapy delivered by a therapy assistant under the supervision of the therapist:
    a. NDIS:
        i. Maintenance care where the primary purpose is to provide ongoing support for a participant in order to **maintain a level of functioning including long term therapy/support required to achieve small incremental gains or to prevent functional decline**,
        ii. To improve functioning in an early intervention context
    b. Other parties: where it is a time limited intervention to improve functioning following an acute event, medical treatment or accident (e.g. to improve functioning immediately following a stroke or acquired brain injury)
3. Care and supervision by clinically trained staff, including delegated care
    a. NDIS: where this is required because of the **participant's functional impairment and integrally connected to the participant's support needs to live independently** and to participate in education and employment (e.g. supervision of delegated care for ongoing high care needs, such as PEG feeding, catheter changes, skin integrity checks or tracheostomy tube changes) (see Decision Tree below)
    b. Other parties: where the primary purpose is to treat or manage a medical condition or recovery after medical treatment
4. Assistance with daily personal activities and participation in community activities
    a. NDIS: where the assistance is **related to an ongoing functional impairment** (however not in hospitals, except where a continuation of any assistance for communication and challenging behaviours),

   b. Other parties: where the participant's need is temporary to recover from a medical condition or event through post-acute care
5. Aids and equipment
   a. NDIS: **aids and equipment which are permanent** and for the **purpose of improving functioning and related to a participant's self-care needs** (including continence aids and catheters), except for medical or surgical procedures (e.g. the NDIS would not be responsible for providing continence aids and catheters for participants undergoing treatment within hospital settings),
   b. Other parties: aids and equipment which are for the permanent or temporary purpose of regulating or treating a medical or health condition or aids and equipment associated with medical or surgical procedures and post-acute recovery(National Disability Insurance Scheme, 2014b, pp. 2-3)

The Operational Guidelines for Planning and Assessment detail a third tier of supports that fall outside the funding of the NDIS hence fall on other parties:

1. Diagnosis and assessment of health conditions, including ongoing or chronic health conditions (e.g. aged care, developmental delay)
2. Clinical treatment and supports, including:
   a. Acute and emergency services, general practitioner, medical specialists, dental care,
   b. Care as an admitted patient in public and private hospitals,
   c. Medicines and pharmaceuticals including items listed and not listed on the Pharmaceuticals Benefits Scheme (PBS) and oxygen and Botox,
   d. Services listed on the Medicare Benefits Schedule, and
   e. Temporary or interim prosthetics.
3. Subacute care services that are delivered under the management of a clinician, including:
   a. Palliative care where the primary clinical purpose or treatment goal is optimisation of the quality of life of a patient with an active and advanced life-limiting illness,
   b. Geriatric evaluation and management which aims to improve the functioning of a patient with multi-dimensional needs associated with medical conditions related to ageing, such as tendency to fall, incontinence, reduced mobility and cognitive impairment,
   c. Psychogeriatric care where the goal is improvement in the functional status, behaviour and/or quality of life for an older patient with significant psychiatric or behavioural disturbance, caused by mental illness, an age-related organic brain impairment or a physical condition
4. Post-acute care – including clinical supports that are delivered to a participant in their home following an acute episode (such as nursing care and medical supplies).
5. Assistance to increase functioning (rehabilitation) specialist allied health, rehabilitation and other therapies for people with recently

acquired conditions such as newly acquired spinal cord injury or brain injury, until the participant has achieved the maximum level of achievable functioning and the remaining allied health support is for the purpose of maintenance

6. General hearing, vision and podiatry services where these are unrelated to the participant's disability as determined in the NDIS access requirements and/or required by other Australians of a similar age without a disability (e.g. prescription glasses, orthotics to realign posture)
7. Preventive health designed to improve general health or prevent illness, injury and chronic disease through education, promotion and incentives, including addressing obesity, smoking and alcohol use.
8. Private health insurance fees
9. Medical costs normally met through disposable income such as gap fees with doctors or chemist costs or prescription medicines.(National Disability Insurance Scheme, 2014b, pp. 2-3)(National Disability Insurance Scheme, 2014b, pp. 2-3)

The net result is the provision of support via 14 categories organised into funding types being capital, core and capacity funded support.

Core funded supports meet the applicant's regular, everyday needs:

- assistance with daily life at home, in the community, education and at work
- transport to access daily activities
- supported independent living

Capital funded supports provide for an applicant's equipment, technology and modifications

- equipment and assistive technology
- house modifications
- vehicle modification

Capacity building funded supports with respect to learning and build skills

- improved daily living skills
- improved living arrangements
- increased community and social participation
- finding and keeping a job
- improved relationships
- improved health and wellbeing
- improved learning
- improved life choices

8.1.6.3.6 Application of Supports to ME/CFS

Within the context of ME/CFS and CFS there are some supports that will meet the needs of the majority, whilst consideration of the more severe end of the disease raise a need for more significant supports. Severe patients represent approximately 25% of the patient cohort, and are primarily housebound, and with a smaller proportion, bed-bound.

Some of the needs are, for example are outlined in Table 3 (Ability Options, 2017):

Support Purpose	Outcome Domain	NDIS Support Categories	Application in Practice	ME/CFS and CFS Specific Examples
CORE A support that enables a participant to complete activities of daily living and enables them to work towards their goals and meet their objectives	**Daily Living** 	*1. Assistance with daily life*	Household decision making, personal care and domestic tasks Assistance with household tasks, Meals on Wheels preparation and delivery of meals, assistance with and/or supervising tasks of daily life in independent living or shared living environment, Short term Accommodation and Assistance (e.g. Respite care).	• Assistance with Cooking • Household Assistance • Showering Assistance • Respite • Carer
		2. Transport	Transport, specialised transport to school education program, employment, community. Travel enables participants to access the community for educational, recreational and vocational purposes. Participants receive funds fortnightly in advance to pay for services of their choice.	• Transport to Doctors • Transport to Treatment • Social activities
	Social & Community Participation 	*3. Consumables*	Consumables are a support category available to assist participants with purchasing everyday items. Supports such as interpreting, translating, continence and home enteral nutrition (HEN) products are included in this category.	• Grocery Shopping • Household purchases
	Daily Living 	*4. Assistance with social and community participation*	Tuition fees, art classes, sports coaching and similar activities that build skills and independence. Camps, classes and vacation activities that have capacity building, mentoring or peer support and individual skill development.	• Social Activities • Education for Capacity Building
CAPITAL An investment, such as assistive technologies, equipment and home or vehicle modifications,	**Home** 	*5. Assistive technology*	Assistive equipment for recreation, assistive products for household tasks, assistive products for personal care and safety. Vehicle modifications including the installation or changes. Equipment in a vehicle to enable a participant to travel safely as a passenger or to drive.	• Computer/ iPad • Alter vehicle for wheelchair • Wheelchair • Mobility Scooter • Adjustable bed

funding for capital costs (e.g. to pay for Specialist Disability Accommodation).		*6. Home modifications*	Stair climber, certification or approval of home modifications, elevator-home, grab rails, modification to bathroom, toilet, laundry, kitchen, structural work, modification project manager or building certifier.	• Rails for bathroom • Stair climber • Ramp for access • Air Conditioning
CAPACITY BUILDING A support that enables a participant to build their independence and skills.	**Choice & Control** 	*7. Coordination of supports*	Support connection, coordination of supports, specialist coordination. Assistance to strengthen participant's ability to connect with informal, mainstream and funded supports, and to increase capacity to maintain support relationships. Resolve service delivery issues and points of crisis.	• Advocacy • Assistance with negotiating the scheme • Carer and other capacity building
	Home 	*8. Improved living arrangements*	Group homes, large residential settings, drop in support, individual accommodation support package, outreach program, disability housing and support initiative (DHASI). Assistance with accommodation and tenancy obligations, individual skill development and training.	• Accommodation Support • Housing • Tenancy issues
	Social & Community Participation 	*9. Increased social and community participation*	Recreation, peer support, community participation, life choices, active ageing, community access programs, vacation care, Out of School Hours Care (OOSH), weekend programs, flexible respite, centre based respite, group fitness for people with disability.	• Support Groups • Recreational Activities • Respite • Peer Support
	Work 	*10. Find and keep a job*	Transition to employment, transition to work. Work skills, workability, individual employments support, employment preparation, assistance in employment (ADE).	• Work Skills; • Employment Support
	Relationships	*11. Improved relationships*	Intensive behaviour intervention, development and monitoring of management plan. Positive behaviour management	• Management Plan

			strategies, individualised social skills development.	
	Health And Wellbeing 	*12. Improved health and wellbeing*	Exercise physiology, personal training, dietician consultation and plan development.	• Dietician • Exercise Physiologist • Plan development
	Lifelong Learning 	*13. Improved learning*	Transition through school and to further education.	• Educational Support • Advocacy
	Choice & Control 	*14. Improved life choices*	Financial intermediary- setup costs, training in planning and plan management building financial skills, organisational skills, and enhancing the participant's ability to direct their supports and/or develop self-management capabilities.	• Plan management • Organisational skills
	Daily Living 	*15. Improved daily living*	Assessment, training, development and/or therapy to assist in the development of, or increase in skills for independence and community participation and therapeutic supports.	• Increased skill development • Physiotherapy • Chiropractic

Table 3 – Funded Supports Under NDIS

Whilst not an exhaustive list, the requirements would be driven by the individual disability and functional impairments of the applicant. This does, however, provide an outline of the range of needs that occur in ME/CFS and CFS.

8.1.7 Further Considerations

ME/CFS Legal submits that the current health system is not set up to cater for the functional impairment that occurs in ME/CFS or CFS, particularly at the severe end of the spectrum. ME/CFS Legal draws upon the submissions of Scope (2017) to the Productivity Commission earlier this year:

> 4.3 Intersection with Mainstream Services
>
> Is the current split between the services agreed to be provided by the NDIS and those provided by mainstream services efficient and sufficiently clear? If not, how can arrangements be improved?
>
> No. The health service system is designed to deliver time-limited, goal directed therapeutic intervention and rehabilitation to address health needs which include:
>
> - Acute illness
> - Acute on chronic medical condition e.g. epilepsy
> - Chronic disease e.g. diabetes
> - Acquired disability e.g. acquired brain injury.
>
> **The health system is not equipped nor is it funded to deliver medium and long terms core support and capacity building for people with permanent significant functional impairment as a result of their disability.**(Scope, 2017, p. 14)

ME/CFS Legal submits that the quite apparent policy of rejecting applicants with ME/CFS and CFS is creating a significant problem. Some of those applicants have or had access to state and territory services and they are now being removed as the transition to the NDIS occurs. Scope (2017) covered this same issue in their submissions to the Productivity Commission:

> Is the way the NDIS refers people who do not qualify for support under the scheme back to mainstream services effective? If not, how can this be improved?
>
> No. In many instances **the services people with a disability were eligible for are no longer funded** by the respective state or territory government as the funds were transferred to the Commonwealth under the bilateral agreements. **The assumption that the primary, secondary and tertiary health service systems can adequately address the ongoing support needs of a cohort of people who have a diagnosed disability, but are not eligible for the NDIS, is flawed.**
>
> The focus of the health service system is rightly on the delivery of time-limited goal-directed therapeutic intervention and rehabilitation, **not on the provision of core support and the building of capacity within a social paradigm of services and support**.(Scope, 2017, p. 14)

8.2 Submissions

It is the submission of ME/CFS Legal that should an applicant not be eligible to access the NDIS on the grounds of permanent impairment, there is a strong evidence base to allow the applicant into the scheme by way of early intervention. The need for advocacy within ME/CFS and CFS is quite significant due to the crippling nature of the condition, hence the ability have someone represent their interests is crucial.

The use of CBT and GET is not the default treatment in this condition. As well be seen within 9, there are significant reasons why the evidence base does not support the CBT/GET protocol being used.

9. Submission 3 - Inappropriate Evidence Base

ME/CFS Legal has identified a number of issues with respect to the decisions that area being made by the NDIA with respect to ME/CFS and CFS, hence has some serious concerns that it wishes to raise with the committee. More specifically, given decisions that have been handed down, the reasons being cited and the evidence base relied upon by the NDIS/NDIA ME/CFS Legal wishes to bring such issues to the fore.

9.1 Inappropriate Evidence Base

ME/CFS Legal has identified that serious concerns with respect to the evidence base upon which the NDIA is basing their decisions. In addressing this issue the following submission will provide a recent actual case example, and then review the difficulties that arise with the evidence base that is being utilised.

9.1.1 A Case Study

With respect to the committee, ME/CFS Legal Resources submits to the panel for their consideration, the matter of NDIS Reference 430058059. This matter involves an application and decision of the NDIA, and more specifically, the written reasons provided with respect an internal review dated 19 July 2017. The decision was made by a Internal Review Manager JG0029 and affirmed by Internal Review Manager DP0014. For the purposes of this submission, the name of the applicant will be supressed for the purposes of a public submission and referred to as anacronym – SW. The applicant has provided written permission to reveal these details publicly.

The internal review outcome document dated 19 July 2017 is attached at annexure 2 below.

9.1.1.1 The Decision

By way of background, the applicant, SW, submitted an application in 2017 and was denied access to the NDIS. SW then availed herself of the internal review process in accordance with the legislation and rules. The claim was for the condition known as Chronic Fatigue Syndrome. The decision maker accepted that SW had the condition, being CFS, and that such condition was neurological in origin.

The application was rejected by the Internal Reviewers, and the decision of the Chief Executive Officer (CEO) was affirmed on the grounds that the applicant "did not meet the all the disability requirements of the *NDIS Act Section 24* nor the early intervention requirements of *NDIS Act Section 25*."[46]

The CEO, via their delegates, accepted that the applicant had a "disability attributable to one or more intellectual, cognitive, neurological, sensory or physical impairment" when finding that "Chronic Fatigue Syndrome is classified as a neurological condition." (Note: This finding of neurological impairment is in accordance with the submissions of this paper in Section 10 below.)

[46] Internal Review Manager JG0029 and DP0014, *Internal Review of Applicant SW*, (July 2017).

The CEO made five discrete decisions on 17 July 2017. For the purposes of illustration, the primary reasons will be repeated hereafter, and an annotated comment will be provided my ME/CFS Legal to illustrate the issues that potentially arises from each a:

1. *Permanency* – The decision maker made a number of findings in rejecting permanency. ME/CFS Legal identifies a number of concerns:

    a) Decision: "There is conflicting evidence regarding the permanency of Chronic Fatigue Syndrome. It is reported that the long term outcome varies for people who have been diagnosed with the condition. Some people completely recover after 6 months to a year. Other reports state that on average many people improve in the first five years of diagnosis but others may be bedbound or not be able to leave their home or they may suffer relapses throughout their lives. It is noted that you were diagnosed with Chronic Fatigue Syndrome in 2014."

    b) Discussion: ME/CFS Legal makes the following observations:

        (i) Evidence – The only evidence referred to was the content of a non-peer reviewed website about ME/CFS not CFS – the decision maker is confuses between the two. No attempted was made to comply with the rules or the operational guidelines with respect to identifying the "appropriate evidence base"[47] by way of peer-reviewed literature review, and no apparent medical expertise in the area of ME/CFS or CFS was obtained. There is no deference to the RACP Guidelines (2002) and its position with respect to prognosis and permanency. It is appropriate to note that from 12 November 2017, the *Better Health Channel* Website removed any reference to recovery rates and a five-year time frame (Better Health Channel, 2017);
        (ii) Conflict in Evidence – A review of the actual evidence base reveals a level of consistency in the opinion with respect to the correlation between severity and poor prognosis as illustrated above in the discussion of permanence in 7.3.1.1.5. The decision-maker does not correlate the clinical evaluation of severity expressed by the treating medical practitioner (who has a longitudinal evaluation of the progress of the illness) and the evidence base within the literature that expresses increased severity significantly reduced the chance of recovery to less than 10% (Carruthers, et al., 2003, pp. 29-30).
        (iii) Recovery – The decision maker makes no attempt to distinguish between the word 'recover' meaning complete return to pre-illness health or 'full recovery', and 'recovery' being mere improvement, or 'recovery' meaning an improvement in a specific symptom domain and not globally, or 'recovery' as measured by a specific activity, such as 'work', 'education' or social. The decision maker misrepresents what the research was actually demonstrating;
        (iv) Conflicting Evidence – The evidence, read objectively and appropriately, is not, in fact, conflicting. The role of decision maker is not to 'cherry pick' a position that suits denial of the claim, nor to change the meaning of the evidence by way of reconstruction. The NDIA and NDIA are model litigants, hence must (a) act truthfully and fairly; (b) meet valid claims; (c) not take advantage of an

[47] *Mulligan and NDIA* [2015] AATA 974 at [69].

unrepresented litigant. The NDIS Act is beneficial legislation, hence should be applied to the benefit of applicants;

(v) Literature – A simple click of the literature attached to the website would have led the decision maker to an updated piece of literature dated 31 July 2017 in which this specific issues was address – "Longitudinal studies indicate that 17% to 64% of patients improve with treatment; however, less than 10% meet criteria for full recovery, and up to 20% of patients may worsen over time" (Baraniuk, 2017, p. 53). No engagement was made with the findings of the IOM;

(vi) Severity – The decision does not engage with the severity of the applicant nor correlate that to the literature (ie more severe, more chance of life-long severity). The RACP Guidelines (2002) make it clear that a severe patient is unlikely to recover – which is permanence by definition;

(vii) Symptoms – The decision maker does not engage with the literature with respect to the symptom patterns (i.e. impairments) that correlated to absence of recovery, nor does the decision maker take account of the applicant's symptom pattern;

(viii) Duration – The decision maker does not correlate the specific symptom pattern with severity, nor the small percentages of those that recover inside five years. Nor does the decision maker correlate that to the applicants specific symptoms to severity;

(ix) Comment – The decision is devoid of evidence based literature, appropriate consideration of the applicant's specific circumstances and how they match to the literature – particularly the symptom patterns that are most likely to result in life long disability.

2. *Substantially Reduced Functional Capacity* – The decision maker made a number of findings in rejecting permanency. ME/CFS Legal identifies a number of concerns:

a) Decision: "Whilst the evidence indicates that you have some limitations due to fatigue and that symptoms do fluctuate the limitations do not constitute a significant reduction in functional capacity. There is no evidence of an Occupational Therapist or Physiotherapist assessment to verify any substantially reduced mobility or what disability equipment, if any, would be recommended. From the reviewed reports from SXXXX and your GP it is evident that your functional capacity does vary over time. Dr XXXXXXXX Consultant Occupational Therapist states in the XXXXXXX Health Plus report XXXXXXXXX 2016 that your level of fatigue varies throughout the day with your optimum function in the mornings when you are able to read, drive and go to appointments. This indicates you are still able to complete activities in an accepted time period even though you might have to go about completing the task in a different manner to what you did prior to your diagnosis. This is in line with medical advice to balance time between activity, rest and sleep and also to reduce tasks into smaller and manageable tasks and to avoid activities when feeling too tired.It is also noted you stated in this report you are able to perform all normal activities of daily living to some extent but have a housekeeper who attends every fortnight and does washing and other household chores. It is further reported you are able to perform activities such as shopping, can tolerate sitting for up to two hours, standing for up to an hour, walking for up to an hour, lifting up to 2kg depending on the time of day as this can cause palpitations , climbing and descending one flight of stairs.

The Disability Requirements as set out in the NDIA Operational Guidelines state:

> ''A person will be considered to be unable to participate effectively or completely in an activity if they cannot safely complete one or more of the tasks required to participate in an acceptable period of time. Undertaking a task more slowly or differently to others will not necessarily mean a person cannot participate effectively or completely in an activity.'

It is additionally acknowledged that Chronic Fatigue Syndrome symptoms are related to mood and can therefore, vary from day to day. Given your past medical history of Post Natal Depression and Anxiety this may impact on your symptoms and therefore, your functional capacity. However, there is no evidence that this is resulting in a substantially reduced functional capacity in your life domain areas of learning or self-management.

The prognosis for an individual with CFS cannot be predicted with certainty. Literature reviewed indicates that those who receive early and extensive rehabilitation arereported to get better. Other reports indicate that a return to premorbid function is rare. It is also reported that work status is an important predictor of recovery."

b) Discussion: ME/CFS Legal makes the following observations:

(i) Misrepresentation – The decision maker states "Literature reviewed indicates that those who receive early and extensive rehabilitation are reported to get better." This statement is misleading and false. The website actually does not state this at all. The *Better Health Channel* states: "People who receive an early diagnosis and early treatment tend to do better" (Better Health Channel, 2016). The decision-maker misrepresents this as recovery, when it merely comments about improvement. There is no cure for CFS (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 259). The decision-maker is clearly in error by representing early treatment can effect a cure;

(ii) Not Early – The decision maker makes representations about early diagnosis and early treatment, yet notes that the applicant was diagnosed in 2014. The opportunity for early intervention has come and gone, hence any assert it leads to recovery is irrelevant. The decision maker did not engage with the facts of the case. SW indicates that she did, in fact, have early diagnosis and treatment, yet declined.[48] The decision maker has not engaged with this evidence;

(iii) Evidence – No engagement is made with the evidence base hence no real intent to establish the best practice for CFS;

(iv) Focus on fatigue – The decision maker only takes account of impairment from fatigue. In CFS, the Fukuda (1994) criteria has fatigue as the primary symptom, and combines with four or more, of 8 symptoms. The IOM Committee (2015) sheeted this point home, stating "Other factors, such as orthostatic intolerance, widespread pain, unrefreshing sleep, cognitive dysfunction, and immune dysregulation, along with secondary anxiety and depression, contribute to the burden imposed by fatigue in this illness" (Committee on the Diagnostic Criteria

[48] Personal Communication with SW, 28 October 2017.

for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 78). The decision maker does not engage with these symptoms to assess their impact upon function;

(v) Impairment of Function – The decision maker alleges the applicant has"some limitations due to fatigue and that symptoms do fluctuate the limitations do not constitute a significant reduction in functional capacity." The decision maker is in error and contradicts the diagnostic criteria. The Fukuda (1994) criteria states that fatigue must "clinically evaluated, unexplained, persistent or relapsing chronic fatigue that is of new or definite onset (has not been lifelong); is not the result of ongoing exertion; is not substantially alleviated by rest; and results in **substantial reduction in previous levels of occupational, educational, social, or personal activities**" (Fukuda, 1994, p. 956). Functional capacity is assessed under section 24(1)(c) and impairment by section 24(1)(d). If the applicant meets the criteria of CFS, they have impairment of social and economic participation by definition – so how is that possible if the psychosocial functioning under 24(c) was not met? The findings are arguably against the diagnosis;

(vi) Depression – The decision maker assumes that past depressive conditions are the same as the current depressive symptoms when the two are independent events;

(vii) Comment – The decision is devoid of evidence based literature, appropriate consideration of the applicant's specific circumstances and how they match to the literature – particularly the symptom patterns that are most likely to result in life long disability. Most disturbingly, the decision maker, a Commonwealth model-litigant (obliged to act with complete propriety, fairly and in accordance with the highest professional standards), misrepresents the website relied upon, to assert treatment effects a cure – in a condition with no cure.[49]

3. *Lifetime Support* – The decision maker made a number of findings in rejecting permanency. ME/CFS Legal identifies a number of concerns:
   a) Decision: "As permanency is not confirmed neither can it be stated that you are likely to require NDIS support for your lifetime. As you do not satisfy the above disability requirements, you may still satisfy the early intervention requirements, and be able to access the NDIS under section 25 of the NDIS Act 2013. Consideration has also been given to this."
   b) Discussion: ME/CFS Legal make the following observations:

      (i) Comment– The decision maker has not made a genuine attempt to establish permanence, hence the decision is arguably invalid.

4. *Early Intervention – Reducing Future Needs* – The decision maker made a number of findings in rejecting early intervention. ME/CFS Legal identifies a number of concerns:
   a) Decision: "The predominant early intervention for your condition is directly related to your health with the aim of symptom relief and improving your functional capacity. This includes rehabilitation services, best provided through the Health system."

   b) Discussion: ME/CFS Legal makes the following observations:

[49] *Jane Doe v Australian Broadcasting Commission and Ors* [2007] VCC 281, [190].

(i) Literature: The decision maker is required by Rule 6.9 and paragraph 19 of the Operational Guidelines (Early Intervention) to refer to "range of sources, such as research or information provided by the person with disability or their family members or carers .. [or] … in some cases seek expert opinion." (National Disability Insurance Scheme, 2014a, p. 2). Reference to a website is not "research" and there was no deference to an expert;
(ii) Early Intervention: The decision maker does not identify the rehabilitation services that the applicant is purportedly requiring, hence it is not possible to gauge if such services are aimed at "symptom relief" or "improving functional capacity";
(iii) Rehabilitation Services: The decision maker doesn't appear to defer to *Fear v NDIA*[50] and the requirement"to consider the nature and purpose of the support for which funding is sought in light of the objects and purpose of the NDIS."[51]

5. *Early Intervention – Likely to Benefit* – The decision maker made a number of findings in rejecting early intervention. ME/CFS Legal identifies a number of concerns:

a) Decision: "Any intervention required, early or otherwise, is more appropriately provided through the health system to manage the symptomology of your diagnosis. Whilst it is considered that further multidisciplinary treatment would be beneficial to mitigating or alleviating the impact of Chronic Fatigue Syndrome on your functional capacity this intervention is more appropriately provided through the Health and allied health systems."

b) Discussion: ME/CFS Legal make the following observations:

(i) Literature: The decision maker is required by Rule 6.4 and paragraph 12 of the Operational Guidelines (Early Intervention) to refer to appropriate and relevant literature (National Disability Insurance Scheme, 2014a, p. 2). Reference to a website is not appropriate;
(ii) Symptomology: The decision maker refers to symptomology, yet only identified fatigue as a symptom hence has not considered the intervention in light of the actual symptoms of the condition;

9.1.1.2 Evidence Base for the Decision

In an Email between the solicitor for the applicant and the NDIS solicitor, dated October 2017 it was advised that:

> In the case plan developed following the case conference on 27 September 2017, the Respondent was requested to provide further details of material relied on by the internal review decision maker in making comments about the "permanency" of Chronic Fatigue Syndrome (CFS) on page 2 of the internal review decision. Apologies for the delay in responding to this request in the case plan.

[50] *Fear by his mother Vanda Fear and National Disability Insurance Agency* [2015] AATA 706
[51] Ibid, [56].

> We are instructed to advise that the internal review decision maker consulted with the Agency's in-house technical experts before finalising the internal review decision, who considered research on CFS published on the **Victoria State Government Better Health Channel website**, which stated that:
>
> > • On average, many people with Myalgic encephalomyelitis (ME)/CFS will improve in the first five years, but others may mainly stay at home or in bed or may suffer relapses throughout their lives; and
> >
> > • People who receive an early diagnosis and early treatment tend to do better.
>
> The internal review decision maker concluded **there was medical treatment available for CFS** that was likely to remedy the impairment or reduce the severity of the symptoms that may fluctuate, and considered when looking at the Applicant's case that there was insufficient evidence of the Applicant having explored all treatment options available and therefore, her condition could not be considered permanent.

9.1.1.3 Unacceptability of Evidence Base

The immediate issue for ME/CFS Legal is the fact that the only evidence actually considered was the Victorian government's Better Health Channel. ME/CFS makes the following submissions with respect to this particular website:

1. *Out of Date* – The Better Health Channel website, at the time of the decision, was last updated in August of 2016 (Better Health Channel, 2016). The science and environment with respect to ME/CFS and CFS has moved along significantly. The information is out of date. It is noted that the decision maker appears to have made no attempt to enquire as to the current status of the information on the site, nor the accuracy. As of 12 November 2017, the *Better Health Channel* amended its content and adopted a completely opposite stance to that expressed in August 2016 and more reflective of the 2017 literature (Better Health Channel, 2017);

2. *Disclaimer* – The PDF information sheet, like the site, caries a detailed disclaimer that reads as follows:

> > Content on this website is provided for education and information purposes only. Information about a therapy, service, product or treatment does not imply endorsement and is not intended to replace advice from your doctor or other registered health professional. Content has been prepared for Victorian residents and wider Australian audiences, and was accurate at the time of publication. Readers should note that, over time, currency and completeness of the information may change. All users are urged to always seek advice from a registered health care professional for diagnosis and answers to their medical questions.(Better Health Channel, 2016)

It is noted that the disclaimer specifically conveys that this is general information only. The decision maker has treated it as equivalent of best practice and peer reviewed advice. This is not appropriate.

The disclaimed makes a clear warning that the information may well be out of date and should not be relied upon because information changes. The decision-maker failed to heed the warning and make an evidence based enquiry, by a suitably qualified person.

The final comment is the urging to seek advice from a suitably qualified medical practitioner. The decision-maker appears to have ignored this requirement.

3. *Reference Sources* – The website outlines just 5 references (Better Health Channel, 2016). The nature of the references is exceptionally telling because it contains three types of reference: (i) Irrelevant documents (ii) non-peer reviewed documents; (ii) out of date documents. We submit that the issues with respect to these references are as follows:

    (a) Reference 1 – The first reference is a peer reviewed website for medical practitioners(BMJ Publishing Group Limited, Chronic Fatigue Syndrome, 2017). The website comes with a very clear statement that the Better Health Channel did not carry because this site was updated on 32 July 2011:

> It is inappropriate to use the 1991 Oxford criteria of fatigue as an alternative for CFS because the Oxford criteria are based on 'mild fatigue', do not require PEM, and allow inclusion of chronic idiopathic fatigue, depression, and other fatiguing conditions. Up to 30.5% of the population have chronic fatigue and would meet Oxford criteria for study inclusion. Studies that used the Oxford criteria are not representative of the more severe and restricted definitions of CFS that the CDC, Canadian Consensus, or SEID criteria define. Exercise and cognitive behavioural therapy studies that used the Oxford criteria for study inclusion are biased and misleading because people with true CFS are underrepresented, with excessive recruitment of people with chronic idiopathic fatigue and depression who are known to respond well to these modalities.(BMJ Publishing Group Limited, Chronic Fatigue Syndrome, 2017)

There was no attempt from the *Better Health Channel* to ensure it was appropriate for Australia, or to check accuracy or currency – despite the warning that the user should make sure it is regionally appropriate (BMJ Publishing Group Limited, 2017).

This new paper, which came in 11 months after the *Better Health Channel* was updated, provides an up to date insight into treatments and prognosis that the decision maker has overlooked. Prognosis in particular is more detailed than the summary on the *Better Health Channel* website.

(b) Reference 2 – This reference refers to a 2014 author, being an SJ Gluckman (Better Health Channel, 2016). The link actually takes the user through to a list of authors in which there is a new, 25 September 2017 paper on CFS and "Systemic Exertion Intolerance Disease" which the IOM Committee recommended in 2015 (Gluckman, Aronson, & Libman, 2017).A cursory review of the 5 references for this website would have revealed two papers from 2001, one from 2004 and one from 2006. These are significantly out of date. Move significantly, the fifth paper, being the 2015 IOM Committee report brief was not the complete report, and significantly differed on many points in the four older articles. Furthermore, the fact that the site claimed to be "evidence-based, physician-authored clinical decision support resource which clinicians trust to make the right point-of-care decisions" was contradicted by the fact that the reference list was out of date and far from exhaustive (Wolters Kluwer, 2017a).

The website also absolves itself of responsibility and liability "arising from any use of any information, idea, or instruction contained in the UpToDate Website" and makes it very clear "The UpToDate Website is designed to offer users general health information for educational purposes only. The general health information furnished on this site is not intended to replace personal consultation with a qualified health care professional" (Wolters Klower, 2017b).

The NDIA used the information from the *Better Health Channel* site, which had its own disclaimer that restricted use to general information and education . The Wolters Klewers site was simply not peer reviewed and not appropriate for informing a decision of the NDIA indirectly or directly.

(c) Reference 3 – This reference refers to a 2015paper within the Cochrane Review (Larun, Brurberg, Odgaard-Jensen, & Price, 2015). The quality of the reviewers was immediately apparent when the editorial group was "Cochrane Common Mental Disorders Group". ME/CFS and CFS are classified by the WHO as a neurological disorder, hence the reviewers were not of an appropriate expertise to conduct the review in the first place. Had the decision maker followed the link, they would understood that the article was updated on 25 April 2017 – hence the initial article was 2 years out of date. The review was significantly influenced by the White et al (2011) PACE trial which has been shown to be significantly flawed. A cursory examination of the paper would have demonstrated the significantly flawed nature of the study given the reliance upon the Oxford criteria and significant outcome switching that occurred. Whilst the Cochrane review is usually well accepted, the errors within this paper makes it unreliable hence recommendations of CBT and GET were inappropriate;

.

(d) Reference 4 – The fourth reference was to the US Centres for Disease Control website, from 2013. Again, a cursory review of the link would have revealed that the site was updated on 3 July 2017 (Centres for Disease Control, 2017). The updated reflected the 2015 IOM Committees literature review and findings and most significantly, removed its recommendations for CBT and GET. The

Better Health Channel website recommended CBT and GET, yet this was no longer being recommended. Additionally, the gamut of symptoms had changed along with the advice to medical practitioners. The failure to defer to the updated link resulted in a significant error.

(e) Reference 5 – This final reference deferred to by the website were the 2007 NICE Guidelines (National Institute for Health and Care Excellence, 2007). The Guidelines are based on a diagnoses for CFS/ME that utilises a modified Oxford Criteria. As this submission has clearly established, the Oxford Criteria diagnoses chronic fatigue and not ME, ME/CFS or CFS. The recommended treatment of GET and CBT is based upon the Oxford Criteria, flawed, PACE trial, hence was never an appropriate source because it examines Chronic Fatigue, not ME/CFS or CFS. It simply is not acceptable. So bad are the issues, that had the decision maker followed the link, he/she would have seen a very clear notice that the guidelines were, as of September 2017, being reviewed and updated (National Institute for Health and Care Excellence, 2017).

It is submitted that a reasonable decision maker, having noted the website was last updated in August 2016, would have

(a) Deferred to the links on the website to verify their authenticity as a peer-reviewed rouce;
(b) Deferred to the current appropriate evidence base to ensure that the information contained therein was, in fact, up to date and reflective of the current practice and accepted views

It is submitted that the failure to exercise reasonable care and competence was an act of negligence on behalf of the CEO in making this decision.

4. *Not Peer Reviewed* – Within the NDIS Act, Rules and Guidelines, great significance is placed upon the need for an "appropriate evidence-base".[52] The *Better Health Channel* Website is not peer reviewed, hance cannot possibly be accepted as falling within the definition and intent of the legislation. No better example of this can be found than in the 12 November 2017 changes to the website in which no references what so ever were provided (Better Health Channel, 2017).

9.1.1.4 Unacceptability of Reason Provided

ME/CFS Legal Resources submits that objects within Section 3 of the NDIS Act characterise this to be beneficial legislation, hence has a beneficial construction, where possible, in favour of the applicant.[53]

The original decision of was a decision that is reviewable under Section 99 of the Act. When a decision is reviewed, the CEO is obliged to given written notice in accordance with section 100 and such decision is reviewable, pursuant to section 100(2) in accordance with a request under section 100(3). The Operational Guidelines are then clear above the notice provided:

> When a reviewable decision has been made the delegate must give written notice to each person directly affected by the decision – for example, a

[52] *Mulligan and National Disability Insurance Agency* [2015] AATA 974 at [69].
[53] *Rawson v Coastal Management Group Pty Ltd* [2015] NSWWCCPD 3, [78] per Roche AP.

> letter to a person stating that a decision has been made that they do not meet the access criteria. The notice must comply with s.100(1) of the NDIS Act and tell the person that they can request the CEO to review the decision and that, if the CEO reviews the decision, the CEO's decision can then be reviewed by the Administrative Appeals Tribunal (AAT) ...**The notice is to also include the reasons for the decision and a contact officer to answer any questions the person may have**. (National Disability Insurance Scheme, 2013, p. 2).

It is acknowledged that a decision maker is not obliged to provide reasons unless the applicable legislative framework requires it.[54] On this occasion, the Rules in 5.4 and 6.4 expressly require reasons to be provided. It is further acknowledged that administrative decisions do not generally have to provide adequate or sufficient reasons.

It is the submission of ME/CFS Legal that the decision makes are failing to provide adequate or sufficient reasons for their decisions. It is certainly arguable that this particularly case lack the details necessary to understand how the decision maker arrives at their decision and that hindered the ability of the Applicant to have a fair review.

9.1.1.5 Inappropriate Within the Scheme

The NDIS is an "evidence-based" scheme and this is born out in Rules 5.4 and 6.4 of the NDIS Rules. For example, in the context of assessing permanent impairment, Rule 5.4 reads:

> An impairment is, or is likely to be, permanent (see paragraph 5.1(b)) only if there are no known, available and appropriate evidence-based clinical, medical or other treatments that would be likely to remedy the impairment.

The NDIS Rules and Act do not define "evidence-based" hence it is appropriate to be guided by case law. I would refer the Professional Standards Committee decision in the matter of*Schmuelly*:[55]

> 128. Evidence-based medicine (EBM) is the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research." It aims to increase the use of high quality clinical research in clinical decision making.[56]

The committee had regards to the words of Sacket et al (1996), who also went on to say:

> This description of what evidence based medicine is helps clarify what evidence based medicine is not. Evidence based medicine is neither old hat nor impossible to practice. The argument that "everyone already is doing it" falls before evidence of striking variations in both the integration of patient values into our clinical behaviour and in the rates with which clinicians provide interventions to their patients ...It is when asking questions about therapy that we should try to avoid the non-experimental approaches, since

[54]*Public Service Board of New South Wales v Osmond* (1986) 159 CLR 656.
[55]*Schmuelly, Dror* [2010] NSWMPSC 15.
[56] Ibidper Kiel, Ilbery, Pederson and Smith, [128].

> these routinely lead to false positive conclusions about efficacy. Because the randomised trial, and especially the systematic review of several randomised trials, is so much more likely to inform us and so much less likely to mislead us, it has become the "gold standard" for judging whether a treatment does more good than harm.However, some questions about therapy do not require randomised trials (successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. And if no randomised trial has been carried out for our patient's predicament, we must follow the trail to the next best external evidence and work from there. (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996, p. 72)

The Professional Standards Committee decision in *Schmuelly*[57] added a further comment of relevance here:

> He seemed unaware of the relevance or significance of evidence-based medicine, and as noted above, seemed to equate anecdotal evidence with evidence-based medicine.[58]

An evidence based approach involves an element of rigour and the use of scientific literature. It is not "equate [to] anecdotal evidence".

It is respectfully submitted that the utilisation of a website to formulate and evidence based approach to the assessment of what chronic fatigue syndrome is, does not accord with what a reasonable decision maker would do, nor fulfil the intent of parliament when they drafted the NDIS Act and Rules. With respect, it is junk science.

In *Mulligan*[59] the AAT affirmed this requirement for an evidence base, whereas in *McCutcheon*[60] the members had due regard to the process of evidence gathering applied by the Rehabilitation Physician with respect to ascertaining the effectiveness of a treatment for a specific claimant's disability, being spina bifida and scoliosis.[61] The process was one of:

1. *Guidelines* - Examining the guidelines for the condition;
2. *Systematic Reviews/Meta-Analyses* - "If there are no guidelines, or they are of low quality or outdated, she searches for systematic reviews or meta-analyses, such as those in the Cochrane Library";
3. *Randomised Control Studies* - "If such reviews are not available or are outdated, she searches for randomised controlled trials published since the last systematic review."[62]

The AAT, when faced with the decision noted that "It is difficult for the Tribunal to assess the weight that should be given to different studies without expert evidence explaining various research methods, the meaning of various scores and what is statistically significant as opposed to clinically significant."[63]

[57] Ibidper Kiel, Ilbery, Pederson and Smith.
[58] Ibidper Kiel, Ilbery, Pederson and Smith, [126].
[59] *Mulligan and NDIA* [2015] AATA 374 per Toohey and McCallum, [89].
[60] *McCutcheon and National Disability Insurance Agency* [2015] AATA 624.
[61] Ibid, [50].
[62] Ibid, [52].
[63] Ibid, [61]

It is noted that the CEO (in the form of the decision maker) referred the matter to "in-house experts" who then referred to a website. There is no attempt to appoint a medical expert, no attempt to conduct a thorough literature review, and no attempt to utilise an "evidence-based" approach.

With respect, ME/CFS Legal submits to the committee that this is an entirely unacceptable process, which is either (a) reflective of a "one-off" or evidence of a systematic failure within the NDIS with respect to the assessment of persons with ME/CFS and CFS.

9.1.1.6 Inappropriate Within the Law.

ME/CFS Legal argues that, at law, this type of evidence, used in decision is unacceptable. Section 20 of the NDIS Act authorises jurisdiction to the CEO and his delegates, to exercise makes decisions with respect to access requests. The CEO also exercises other powers granted under the Act. It is the submission of ME/CFS Legal that the decision maker committed a number of jurisdictional errors:

1. *Falling into Error* – It is our submission that the decision maker fell into error by not considering the relevant material – being the evidence base relevant to ME/CFS and CFS that was available to the CEO when he decided to seek out further information to assist him with his decision. It is our submission that the decision maker, in considering the "Better Health Channel" considered "irrelevant material" because it was not evidence based (Better Health Channel, 2016). The Channel is not peer-reviewed and was last updated in August 2016, hence is well out of date.

   In *Craig v South Australia*[64] the court made it patently clear that a decision maker falls into error and arrives at a mistaken conclusion when it "ignores relevant material" and it "relies on irrelevant material".

   In the *Minister for Immigration & Multicultural Affairs v Yusuf*[65]the High Court rejected the Minister's submission that such a ground should be construed narrowly in this case. The Court affirmed that ignoring relevant material or relying on irrelevant material in a way that affects the exercise of power is to make an error of law. To do so causes the decision maker to exceed the authority or powers given by the relevant statute.

   In an error of this type the decision maker does not have authority to make the decision that was made and they did not have the jurisdiction to make it;

2. *Illogical/Unreasonable* – It is the submission of ME/CFS Legal that the process of reasoning (ie that a website could be considered as an relevant evidence, being evidence that is evidence based) applied by the CEO was illogical and unreasonable.

   In *Minister for Immigration & Multicultural Affairs v Eshetu,*[66] Gleeson CJ emphasised that

   > "Someone who disagrees strongly with someone else's process of reasoning on an issue of fact may express such disagreement by describing the reasoning as 'illogical' or 'unreasonable' or even 'so unreasonable that no reasonable person could adopt it'. Ifthese are

[64]*Craig v South Australia* (1995) 184 CLR 163..
[65]*Minister for Immigration & Multicultural Affairs v Yusuf (*2001) 206 CLR 323.
[66]In Minister for Immigration & Multicultural Affairs v Eshetu (1999).

> merely emphatic ways of saying that the reasoning is wrong, then they may have no particular legal consequence".

To consider the use of a website as fulfilling the requirement to refer to "relevant evidence" is, in our submission, so unreasonable that no person could possible adopt the approach.

3. *Illogical/Misapplication* – ME/CFS Legal submits that misapplication of the evidence gathering process, by failing to obtain "evidence based" information when gathering "relevant evidence" was a misapplication of reasoning and illogical, hence resulting evidence that was not, in fact, relevant – a perversion of the criteria set down by the CEO, which is to be found in the operational guidelines.

   A review of the *Operational Guidelines for Access (Disability Requirement)* shows they state:

> 23. In some cases the available information will need to be assessed very carefully to determine whether the impairments are, or are likely to be, permanent. The Becoming a Participant Rules set out in legislation some circumstances in which an impairment is not permanent and also some guidance on when an impairment may be permanent. A delegate must apply the criteria below in assessing whether the impairments are, or are likely to be, permanent for the purposes of s.24(1)(b) of the NDIS Act.
>
> 24. An impairment is, or is likely to be, permanent only if there are no known, available and appropriate **evidence-based clinical, medical or other treatments** that would be likely to remedy the impairment. (National Disability Insurance Scheme, 2014c, p. 4)

   A review of the*Operational Guidelines for Access (Early Intervention Requirements)* shows they state:

> 12. Under the Becoming a Participant Rules an impairment is, or is likely to be, permanent only if there are no known, available and appropriate evidence-based clinical, medical or other treatments that would be likely to remedy the impairment.(National Disability Insurance Scheme, 2014a, p. 2)

   In *Taveli v Minister for Immigration & Ethnic Affairs*[67]Wilcox J explained there was "an illogicality in, or misapplication of reasoning adopted by the decision-maker; so that the factual result is perverting the decision-marker's own criteria"[68].

   ME/CFS Legal submits that the decision maker has ignored the applicable criteria, being the use of "appropriate evidence based" treatments set out in the various Operational Guidelines and opted for an poor quality, non-peer reviewed website, without out of date references and information that is not reflective of the current evidence base.

4. *Extreme Irrationality/Illogical* - ME/CFS Legal submits that the decision of the decision maker were based upon not based upon findings of fact or inferences of fact, supported by

[67]*Taveli v Minister for Immigration, Local Government and Ethnic Affairs* (1989) 86 ALR 435.
[68] Ibid, 453 per Wilcox J.

any logical grounds. In making this submission, we point to the findings with respect to the nature of CFS, the recovery rates, improvements and findings with respect to permanency. These are contrary to the current state of the evidence base and arguably do not represent a grounding in logic and are tantamount to extreme irrationality because of the failure to look at the significant body of peer reviewed literature that exists in the evidence base.

In *Re Minister for Immigration & Multicultural Affairs; Ex parte Applicant S20/2002*[69] the High Court found there to be extreme irrationality as a separate ground for the review of a decision where the grounds were that the decision maker's decision was "irrational, illogical and not based upon findings or inferences of fact supported by logicalgrounds."

5. *Irrational*–ME/CFS Legal submits that the decision to utilise a website in lieu of "appropriate evidence based" research is an astounding decision that is so outrageous that it defies logic. Moreover the decision maker had significant evidence of the specific issues being considered from the treating medical practitioners, yet the decision maker swept that aside preferred their inappropriate evidence.

   In the House of Lords decision of *Council of Civil Service Unions v Minister for the Civil Service*[70] Lord Diplock suggests identified three grounds upon which administrative action could be reviewed and one of which was irrationality, founded in *Wednesbury* unreasonableness. He asserted that it applies to a decision which is so outrageous in its defiance of logic that no sensible person considering the issue would have arrived at it.

   In *GTE (Aust) P/L v Brown*[71] the court established irrationality when an official 'simply brushes aside info specifically furnished by an interested party in respect of a central issue'.

6. *Procedural Impropriety*–ME/CFS Legal submits that the approach adopted by the decision maker with respect to the obtaining of evidence with respect to CFS represents a procedural impropriety because the decision maker acted unfairly in failing to observe the procedural rules set out in the NDIS Rules and Act. Such procedural unfairness amounts to a denial of natural justice.

   In *Council of Civil Service Unions v Minister for the Civil Service*[72]Lord Diplock made reference to procedural impropriety and asserted such impropriety represents a failure to observe basic rules of natural justice because the failure to act with procedural fairness towards the person who will be affected by the decision.

9.1.1.7Submission

ME/CFS Legal submits to the committee that the proper operation of the NDIS is the utilise a properly constructed evidence base when assessing claims with respect to ME/CFS and CFS. The approach taken in the current example represent an abrogation of the intent of the scheme and the jurisdiction of the CEO under the NDIS Act.

[69] *Re Minister for Immigration & Multicultural Affairs; Ex parte Applicant S20/2002* (2003) 198 ALR 59.
[70] *Council of Civil Service Unions v Minister for the Civil Service* (1985) AC 374.
[71] *GTE (Australia) Pty Ltd v Brown* (1986) 14 FCR 309.
[72] Ibid.

9.2Inappropriate Criteria

The process of obtaining an evidence base from the literature necessitates the consideration of the available research. It is the submission of ME/CFS Legal that the current evidence base of ME/CFS and CFS is being confounded by the existence of research that utilises the Oxford criteria (Sharpe, et. al., 1991). The following submissions are to assist the Senate to understand the issues that are influencing the policy of the NDIS. It is noted that the 'Better Health Channel' website (Better Health Channel, 2016) utilised by the decision maker, is purely influenced by the Oxford criteria – a criteria not even utilised in Australia.

9.2.1 Oxford Criteria Debunked

Within section3(a)the various criteria utilised within Australia were detailed. Within Figure 2 there is a very broad criteria illustrated in the form of the Oxford Criteria (Sharpe, et al., 1991). This criteria was created within the United Kingdom and has only been applied to limited research within a small research community in the UK. It is not a widely accepted criteria.

In 1994 the Australian group of Hickie, Lloyd and Wakefield were critical of the Oxford and other UK criteria. They asserted in relation to this criteria that:

> The difficulty in establishing a valid and reliable method for diagnosis, and the consequent lack of uniformity of patient samples studied, has been a major impediment to the development of appropriate treatment strategies … This process may increase the likelihood of patients with a somatoform disorder (primary psychiatric illness with physical symptoms) meeting these criteria." (Wilson, Hickie, Lloyd, & Wakefield, 1994, pp. 544-545)

The authors referred to the UK criteria as "broader .. a characterised by disabling mental and physical fatigue." They dismissed the Oxford criteria and were critical of the fact that the fact that it was impeding treatment strategies. The broadness of the Oxford criteria means that patients who do not meet the Fukuda (1994) criteria or the Consensus Criteria (2003) are entered into research cohorts – effectively diluting them with people who do not have the condition and yielding results that are simply incompatible with the Australian diagnosed patients and of no legitimate value to treatment.

In 2015 the NIH Pathways to Prevention Workshop concluded with respect to the Oxford criteria:

> Furthermore, the multiple case definitions for ME/CFS have hindered progress. Specifically, continuing to use the Oxford definition may **impair progress and cause harm**. Thus, for needed progress to occur we recommend (1) that the Oxford definition be retired, (2) that the ME/CFS community agree on a single case definition (even if it is not perfect), and (3) that patients, clinicians, and researchers agree on a definition for meaningful recovery.(Green, Cowan, Elk, O'Neil, & Rasmussen, 2015, p. 864)

In 2016 the US Agency for Healthcare Research and Quality (AHRQ) expressly stated:

> The Oxford (Sharpe, 1991) case definition is the least specific of the definitions and less generalizable to the broader population of patients with ME/CFS. It could identify individuals who have had 6 months of unexplained fatigue with physical and mental impairment, but no other specific features of ME/CFS such as post-exertional malaise which is considered by many to be

> a hallmark symptom of the disease. As a result, using the Oxford case definition results in a high risk of including patients who may have an alternate fatiguing illness or whose illness resolves spontaneously with time. In light of this, we recommended in our report that future intervention studies use a single agreed upon case definition, other than the Oxford (Sharpe, 1991) case definition. If a single definition could not be agreed upon, future research should retire the use of the Oxford (Sharpe, 1991) case definition.(Smith, et al., 2016, p. 1)

More recently the British Medical Journal Best Practice updated their practice recommendations for practitioners, stating outright:

> **It is inappropriate to use the 1991 Oxford criteria of fatigue as an alternative for CFS because the Oxford criteria are based on 'mild fatigue', do not require PEM, and allow inclusion of chronic idiopathic fatigue, depression, and other fatiguing conditions.** Up to 30.5% of the population have chronic fatigue and would meet Oxford criteria for study inclusion. Studies that used the **Oxford criteria are not representative of the more severe and restricted definitions of CFS** that the CDC, Canadian Consensus, or SEID criteria define. (BMJ Publishing Group Limited, Chronic Fatigue Syndrome, 2017)

The utilisation of any research that is based upon the Oxford criteria is inappropriate for the purposes of research and clinical diagnosis. It is not fit for purpose.

The AHRQ reviewed the literature with respect to Oxford based studies and concluded that such research was inherently unsafe:

> This addendum has delineated differences in treatment effectiveness and harms according to case definitions, highlighting studies that used the Oxford (Sharpe, 1991) case definition and how these studies impacted our conclusions. Additionally, results of studies evaluating CBT have been considered independently from other counseling and behavioral therapies. Our sensitivity analysis would result in a downgrading of our strength of evidence on several outcomes which can be attributed to the decrease in power, dominance of one large trial, or lack of trials using criteria other than the Oxford (Sharpe, 1991) case definition for inclusion. Blatantly missing from this body of literature are trials evaluating effectiveness of interventions in the treatment of individuals meeting case definitions for ME or ME/CFS. (Green, Cowan, Elk, O'Neil, & Rasmussen, 2015, p. 13)

The conclusions being reached by such organisations and individuals are not insignificant and, I would argue, not to be ignored. In the Australian context the issue is arguably particularly relevant because the Oxford criteria has never been applied here. Australia utilises CFS and ME/CFS – Oxford has no place here.

9.2.2 Incompatibility of Oxford Criteria

It has been submitted that within Australia there are primarily two specific criteria in effect. The Fukuda (1994) criteria for CFS (created for research purposes) and the Carruthers Consensus Criteria (2003) for ME/CFS (created specifically for clinical purposes and adapted for research purposes).

It must be made patently clear that the Oxford criteria is NOT an internationally accepted criteria (a purely research criteria applied in the United Kingdom and nowhere else in the world) has never:

- never been applied to any form of research within Australia; and
- been utilised in a clinical setting.

Reference to the RACP Guidelines (2002) provides some insight into the relevance of this issue. Loblay et al (2002) state:

> The validity of the results of clinical trials is **highly dependent on the quality of study design and analysis.** Critical methodological requirements are:
>
> ■ use of **an internationally accepted case definition**;
>
> ■ random assignment to test or comparison groups;
>
> ■ adequate sample size;
>
> ■use of well-characterised outcome measures and standardised self-report instruments for measuring fatigue, mood and other key symptoms;
>
> ■independent, blinded assessments of functional status at onset, completion of treatment, and three to six months later (to ensure durability of the treatment effect); and
>
> ■**reporting of refusal and drop-out rates, and of the type and frequency of adverse side effects**.
>
> Even with well-designed trials, positive results should be independently replicated before a new treatment is widely promoted to the general public. (Loblay, et al., 2002, p. 42)

The Oxford criteria is not internationally recognised (being UK only) and the quality of the research that attaches to it is questionable – particularly when it fails to have "well-characterised outcome measures". The PACE trial (White P. D., et al., 2011) is an example of an Oxford based study with poor outcomes and poor reporting of dropouts, that is influencing Australian management of ME/CFS and CFS. This issue is expanded upon below.

It is the submission of ME/CFS Legal that the Oxford criteria has no place here within Australia. The mere fact that the research using this criteria purports to study ME/CFS or CFS, does not make it the same disease entity. In fact, the patient cohort identified by the Oxford criteria are chalk and cheese in terms of resembling the cohorts in ME/CFS and CFS, as Figure 2 clearly demonstrates.

9.2.3 Oxford Criteria is Chronic Fatigue

The key difference between in the Oxford criteria is the fact that it identifies chronic fatigue (a separate and distinct diagnosis on its own) and not CFS nor ME(Twisk F. N., 2017a, p. 2). Wyller (2007) identifies this issue, stating the "Oxford-definition requires the presence of mental fatigue and accepts symptoms that might indicate psychiatric disorder" (Wyller, 2007, p. 7).

9.2.4 The Importance of Nomenclature

At this point, it is appropriate to acknowledge the issue of nomenclature. The term, Chronic Fatigue Syndrome is inappropriate. Fukuda et al (1994) acknowledged the inappropriateness of the name:

> The name "chronic fatigue syndrome" is the final issue that we wish to address. We sympathize with those who are concerned that this name may trivialize this illness. The impairments associated with chronic fatigue syndrome are not trivial. (Fukuda, 1994, p. 957)

CFS and ME/CFS is often conflated and mislabelled as “Chronic Fatigue” –particularly by the media

> Almost 20% (n¼42) of the headlines in the present study mislabeled the illness by only referencing the word ‘‘fatigue,’’ which patients may construe to be trivializing the condition, because there are many more debilitating symptoms aside from fatigue (Siegel, Brown, Devendorf, Collier, & Jason, 2017, p. 7)

Jason and Richman (2007) affirms this issue:

> In addition, CFS is frequently confused with chronic fatigue, which is a symptom of many illnesses, including some psychiatric disorders. The negative stigma associated with CFS may be partially due to the trivializing name that has been given to this disorder in 1988. (Jason & Richman, 2007, pp. 88-89)

ME/CFS is not mere fatigue. The US Institute of Medicine has made that patently clear in their comprehensive evaluation of the condition:

> ME/CFS should not be considered merely a point on the fatigue spectrum or as being simply about fatigue. Experienced clinicians and researchers, as well as patients and their supporters, have emphasized for years that this complex illness presentation entails much more than the chronic presence of fatigue. Other factors, such as orthostatic intolerance, widespread pain, unrefreshing sleep, cognitive dysfunction, and immune dysregulation, along with secondary anxiety and depression, contribute to the burden imposed by fatigue in this illness. The challenge in understanding this acquired chronic debility, unfortunately named “chronic fatigue syndrome” for more than two decades, will be to unravel those complexities. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 77)

The very fact that this is being stated by the IOM Committee, combined with the calls from the Pathways to Prevention Committee of Green et al (2015) to retire the Oxford criteria, lays credence to the argument that the Oxford criteria has no place because its focus is upon fatigue – one symptom in what is otherwise a complex, multi-symptom disease entity.

9.2.5 Effect of Oxford Criteria

The effect of the Oxford criteria is to dilute a patient cohort when being applied in research. Within the above examination of epidemiology, it was noted that CFS occurred at a rate of 0.2% and 0.7% (Loblay, et al., 2002). Conversely Nacul (2011) indicates the Carruthers (2003) Consensus Criteria yields a 0.10% prevalence estimate.

Brurberg (2014) recently completed a literature review with respect to prevalence, including the Oxford criteria. The Oxford Criteria identified a prevalence between 0.43% and 3.73% - the latter being a rate many fold that of the rates the RACP (2002) cited in the Australian guidelines with

respect to Fukuda (1994) and Carruthers (2003). Wessely et al (1997) assert that the overall estimated prevalence rate within the UK using the Oxford criteria was 2.2% (Wessely, Chalder, Hirsch, Wallace, & Wright, 1997, p. 1452) after adjustment for non-responders.

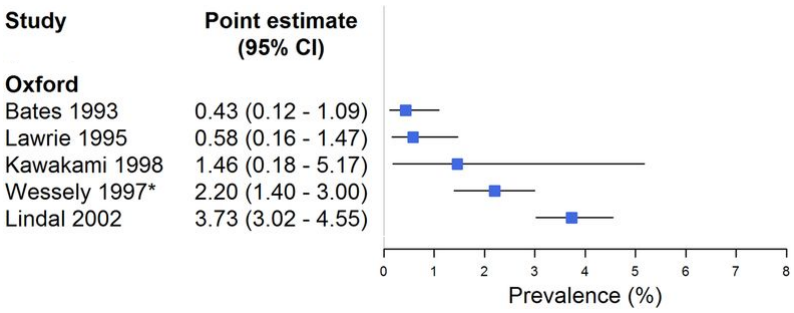


Figure 3 - Forest plot summarising prevalence estimates from Oxford case definitions(Brurberg, Fønhus, Larun, Flottorp, & Malterud, 2014, p. 9)

The Oxford criteria seeks to identify patients that "present with a principal complaint of disabling fatigue of uncertain cause" (Sharpe, et al., 1991). The authors expressly state that:

> The following guidelines were agreed. There are no clinical signs characteristic of the condition. Psychiatric disorders (including depressive illness, anxiety disorders and hyperventilation syndrome) are not necessarily reasons for exclusion(Sharpe, et al., 1991).

The Carruthers (2003) ME/CFS Consensus criteria explicitly excludes persons with any symptoms of mental illness (Wyller, 2007, p. 7).

Zdunek et al (2015)assert that the reason for the variation between the UK's significant difference in prevalence relates to the "variety of case definitions used in research studies, as well as differences in how case definitions are operationalized [which] can lead to considerable heterogeneity among individuals and different prevalence rates across study samples" (Zdunek, Jason, Evans, Jantke, & Newton, 2015, p. 98).

The authors specifically identified that cross cultural differences were having an impact upon variables such "as socio-demographic characteristics, symptoms, and impairment level" hence there samples can be significantly different (Zdunek, Jason, Evans, Jantke, & Newton, 2015, pp. 98-99). When the authors compared samples from the UK with those from the US they identified significant differences with the samples with respect to demographic characteristics, disability level, onset characteristics, activity level and symptom severity (Zdunek, Jason, Evans, Jantke, & Newton, 2015, p. 104). The UK sample was asserted to be significantly different patients with different patient experiences:

> The UK sample was significantly more impaired with regard to role emotional and mental health functioning, multiple symptoms, experienced a more gradual onset of illness, and believed the cause of the illness to be both physical and psychological. The US sample experienced more sudden onset of illness, more frequently believed their illness to be physical, and more often were on disability. (Zdunek, Jason, Evans, Jantke, & Newton, 2015, p. 104).

The UK patients were "maintaining activity" and often reported they were "working full-time" and reported "significantly worse mental health functioning impairment". In contrast "the US sample

worked significantly less hours than the UK sample, and the US sample was significantly less impaired in terms of role emotional or mental health functioning (Zdunek, Jason, Evans, Jantke, & Newton, 2015, p. 104)."

The significance of this study goes to the heart of the distinction between patients that participate in the UK studies under the Oxford criteria and the assessment of the diagnosis of CFS. The UK "version" of the condition under the Oxford criteria centres around fatigue and does not exclude mental health issues. The US Fukuda criteria specifically excludes a patient with "any past or current diagnosis of a major depressive disorder with psychotic or melancholic features; bipolar affective disorders; schizophrenia of any subtype; anorexia nervosa or bulimia nervosa … Alcohol or substance abuse within 2 years before the onset of chronic fatigue and at any time afterward (Fukuda, 1994, p. 955)" The Carruthers (2003) criteria also excludes mental health disorders.

Chronic fatigue (a single symptom distinct from ME/CFS and CFS) is commonly associated with psychiatric disorders including as mood and anxiety disorders (including posttraumatic stress disorder) (Taylor, Jason, & Jahn, 2003, p. 900). It is also associated with many medical disorders (Arnold, 2007, p. 185). In the UK the Skapinakis et al (2003) identified a point prevalence of 9% for unexplained chronic fatigue (Skapinakis, Lewis, & Meltzer, 2003, p. 61). Lawrie and Pelosi (1995) and Pawlikowska et al (1994) reported fatigue in the range of 14% to 18%.

With such a high prevalence of fatigue within the general population and the strong correlation to mental health issues, the fact that the Oxford criteria expressly includes such conditions and emphasises fatigue, it is self-evident as to why the patient cohort is diluted with patients that do not have Fukuda CFS and Carruthers ME/CFS – the primary mode of diagnosing patients in Australia.

More recently and somewhat significantly, a comparative study was conducted by Baraniuk (2017). This large-scale study compared the ability of the Oxford criteria to identify CFS in accordance with the Fukuda definition. Baraniuk identified that previous treatment studies that utilised the "low-threshold Oxford criteria for recruitment" was over-generalised in application to CFS patients with Fukuda CFS (Baraniuk, Chronic fatigue syndrome prevalence is grossly overestimated using Oxford criteria compared to Centers for Disease Control (Fukuda) criteria in a U.S. population study, 2017, pp. 1-2). In comparing the patients identified as CFS by the Oxford criteria, some "85% of Oxford-defined cases were inappropriately classified as CFS", hence he concluded that the "Oxford criteria were untenable because they inappropriately selected healthy subjects with mild fatigue and [Chronic Idiopathic Fatigue] and mislabelled them as CFS" (Baraniuk, Chronic fatigue syndrome prevalence is grossly overestimated using Oxford criteria compared to Centers for Disease Control (Fukuda) criteria in a U.S. population study, 2017, p. 1).

The position is therefore clear. Oxford is very clearly not the same animal as ME/CFS and CFS. It is, as Twisk (2017a) asserts – chronic fatigue, by definition. It is not the entity here in Australia.

9.2.6 Resources Derived from Oxford Criteria

As made clear above, the Oxford criteria does not reflect the conditions ME/CFS or CFS as diagnosed here in Australia, hence it is the submission of ME/CFS Legal that any policy that is based upon research from the Oxford criteria is incompatible and unsafe.

Such examples would include:

1. PACE Trial–The PACE trial examined, the use of Cognitive Behavioural Therapy and Graded Exercise Therapy and concluded that such therapies were more effective and safe than adaptive pacing and specialist medical care. The researchers concluded

that, at the end of the trial, patients improved or that their functioning was within normal ranges, that they had better overall health, and that therefore CBT and GET were "an effective treatment" for CFS(White P. D., et al., 2011, p. 834). It is important to note that the patients recruited for the were not representative of the spectrum of severity:

> We excluded patients unable to attend hospital. Our results apply to patients referred to secondary care. (White P. D., et al., Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial, 2011, p. 834)

Some 25% of the population with the condition are bed bound or house bound (Shepherd & Chaudhuri, 2005; Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 16, 32). These patients were not included in this research hence the study could not and did not apply to them – they could not do the treatment. Carruthers et al (2003) made this point, stating "**All studies excluded ME/CFS patients who were too ill to regularly attend treatment sessions**" (Carruthers, et al., 2003, p. 49).

In a recent special issue of the *Journal of Health Psychology*(2017), the PACE researchers were accused of serious failings in the conduct of their research in the past few years, with various eminent researchers pointing out the failure to declare conflicts of interest, the inappropriate alteration of protocols to improve the apparent effect of treatment (when the original protocols led to a null effect) (Lubet S. , 2017; Geraghty, 2017a; Vink M. , 2017a). As opposed to accepting constructive criticism of their methodological flaws, the PACE authors breached various policies on open access to publicly funded research data and spent £250,000 in a failed high court bid to prevent access to the data, falsely claiming patient threats, identification issues and vexatious requests for data (Vrijhoef & Steuten, 2016; Goldin, 2016). In short, the PACE researchers were engaged in academic and research misconduct, then set out to conceal their deception from the medical community.

The research utilised the Oxford criteria to recruit participants (White P. D., et al., Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial, 2011, p. 824), which was also criticised for being focused upon fatigue and not ME, CFS or ME/CFS (Jason L. , 2017).

More recently Baraniuk (2017) concluded that "treatment studies based on Oxford criteria for participant inclusion may be seriously flawed because they can potentially select a cross-section of the healthy general population, rather than a rigorously defined CFS group" (Baraniuk, Chronic fatigue syndrome prevalence is grossly overestimated using Oxford criteria compared to Centers for Disease Control (Fukuda) criteria in a U.S. population study, 2017, p. 13). The authors of the PACE trial themselves admit that the use of the Oxford criteria is only effective where "fatigue is the main symptom" (White P. D., et al., Comparison of adaptive pacing

therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial, 2011, p. 834)

In addition to the use of the Oxford criteria, the PACE trial has received criticism for the researchers' decision to alter the trial protocol midway through the trial. Independent reanalysis of the PACE trial data, under the original (more stringent protocol) found that there were no significant differences in recovery rates between GET, CBT and the comparison conditions of specialist medical care or adaptive pacing. (Matthees, Kindlon, Maryhew, Stark, & Levin, 2016, p. 1; Vink M. , 2017b, pp. 1-2).

In short, the PACE trial has been heavily criticised throughout the world in multiple journals as a highly flawed study, with multiple calls for its retraction (Helmfrid & Edsberg, 2017)..

It is not insignificant to note that the US Centres for Disease Control have recently removed CBT and GET from its recommended treatments in the wake of the call for retraction of PACE (National Institute of Health and Care Excellence, 2017; Centres for Disease Control, 2017). Recommendations of GET and CBT no longer have validity. They cause symptom exacerbation and relapses and the patient evidence bears this out (Vink M. , 2017b, p. 1).

2. Cochrane Review – The Cochrane database is often regarded as a reliable source of information pertaining to literature reviews on specific treatments for diseases, and in 2017 an update review of the Larun et al (2015) paper was conducted, again concluding that CBT and GET was safe and effective.

   Helmfrid and Edsberg (2017) recently argued that the Cochrane review was flawed, particularly because the authors had collaborated closely with the PACE team, had included the study in the review, and had ignored various methodological flaws. The concluded "The Cochrane review must therefore be questioned in the same way as PACE." (Helmfrid & Edsberg, 2017, p. 3)

   The Cochrane (2017) review is arguably fruit of the poisonous tree so as to speak. The authors failed to consider the flaws in the PACE trial and continue to assert its efficacy without critical evaluation of methodological flaws of this or other research it considered. For this reason, the usually high-quality review should be regarded as serious and fatally flawed, hence should not inform any policy with respect to treatment.

   A recent Cochrane review of GET and CBT for ME/CFS was conducted by Larun et al (2017), and concluded that these treatments are safe and effective for this condition. However, the Agency for Healthcare and Quality Research (AHRQ) following its 2014 review of the literature, recommended that the Oxford criteria be retired due to it being overly broad. A 2016 review of the GET and CBT literature by AHRQ, after removing all Oxford trials, resulted in the conclusion that the evidence for these treatments is insufficient. It is worth noting that the Cochrane review, mentioned above, consisted of just eight trials. Of those eight, five used the Oxford

criteria. Unfortunately, Cochrane has yet to update its review, based on the unsuitability of the Oxford criteria.

3. NICE Guidelines – The (National Institute for Health and Care Excellence, 2007, pp. 198-202). Recently NICE (in the UK) announced it will be reviewing its guideline for ME/CFS and specifically citing the fact that "Oxford criteria (used to recruit to many studies included in the guideline) and NICE criteria are too broad", the advent of the diagnostic guidelines from the IOM (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015), criticisms and flaws in the PACE trial and Cochrane Reviews (National Institute of Health and Care Excellence, 2017).

Carruthers et al (2003) called into question the appropriateness of using the Oxford criteria and claiming that it was not ?studying the same condition:

> It is unlikely that the CBT and GET studies that were included in the recent review of treatments dealt with comparable homogeneous groups since different inclusion and exclusion criteria were used in selecting the test patients and control groups. For example, in the Prins et al. CBT study on ME/CFS, patients had to meet the CDC criteria "with the exception of the criterion requiring four of eight additional symptoms to be present." If the sole CDC criterion that patients had to meet was prolonged fatigue, is not this study on chronic fatigue, rather than ME/CFS? In a study by Fulcher and White, comparing graded aerobic exercise to flexibility therapy, ME/CFS patients who had an appreciable sleep disturbance were excluded because of the effect that poor sleep has on fatigue. This is puzzling as in a study of symptom prevalence and severity by De Becker et al., 94.8% of 951 patients meeting the Holmes criteria, and 91.9% of 1,578 patients meeting the Fukuda criteria, reported sleep disturbance with an average severity of 2.5 and 2.4, respectively, out of 3. When sleep disturbance is such an integral part of ME/CFS, do the findings in the Fulcher and White study apply to ME/CFS?
>
> A systematic review of prognosis studies show that the less stringent the clinical criteria, the better the prognosis. In two of the studies reviewed, 22% and 26% of patients with chronic fatigue reported recovery, respectively, whereas none and 6% of the ME/CFS patients recovered from fatigue. **Therefore, care must be taken not to classify patients experiencing chronic fatigue as ME/CFS patients unless they meet all the criteria for ME/CFS, as the outcomes for these two patient groups are substantially different.** It is interesting to note that in the treatment review, all the CBT and GET studies that indicated improvement used the less restrictive Oxford criteria with the exception of the Prins study that used the CDC criteria for prolonged fatigue but eliminated the other CDC criteria. **All studies excluded ME/CFS patients who were too ill to regularly attend treatment sessions.**(Carruthers, et al., 2003, pp. 48-49)

It is therefore submitted that, given the significant weight of criticism of the Oxford criteria and the call for its retirement throughout the world, as well as the reliance upon the flawed PACE trial, that any of the above resources, (so far as they apply to any NDIS policy), should be discarded. Aside

from their lack of application within Australia (and the lack of any program matching the PACE treatments in any event), these sources are so inherently invalid that it would be tantamount to negligence to seek to rely upon them.

9.3 Out of Date Guidelines

ME/CFS Legal respectfully submits that the 2002 RACP Clinical Practice Guidelines are now well and truly out of date with respect to its evidence base. The National Health and Medical Research Council (NHMRC) provide a guide for the development, implementation and evaluation of Clinical Practice Guidelines(National Health and Medical Research Council, 1999). This document guides the process behind the development of clinical guidelines with respect to CFS and ME/CFS in Australia.

9.3.1 Inappropriateness of Outdated Guidelines

Guideline recommendations are based on the "systematic identification and synthesis of the best available scientific evidence". The purpose of the guidelines are to ensure health professionals improve their treatment practices and improve patient and community access to information about treatment options for ME/CFS and CFS (National Health and Medical Research Council, 1999). The document states unequivocally:

> Guidelines should be evaluated at least once every three years, although in subject areas that are prone to rapid change this may need to occur more frequently (National Health and Medical Research Council, 1999, p. 46)

Their appropriateness for use "depends on the process used to develop them, the extent to which they are evidence-based, the degree of consensus about them, and whether they are up to date" (National Health and Medical Research Council, 1999, p. 52)

The RACP guidelines for CFS are no longer fit for purpose and are very clearly 12 years beyond their review date of 2005. The science has well and truly moved on, and there has been an inherent failure in policy that has allowed them to remain unaltered. This failure, quite correctly, brings into question the validity of the currency of their evidence base with respect to matters of treatment and diagnosis.

Stern (1995) provides an insight into the consequences of applying inappropriate guidelines and affirms the dangers and legal consequences that can flow. He states:

> "…it is possible that liability in negligence might be imposed upon those who publish clinical guidelines if it is found that the clinical guideline caused a particular medical procedure to be adopted and that this in turn caused harm to the patient … [especially if] it was foreseeable that the guidelines could have the effect of modifying the care which clinicians would otherwise provide."(Stern, 1995)

9.3.2 Replacement of the Guidelines

Steps are currently underway for new guidelines to be constructedwith the potential assistance of the NHMRC. The NHMRC has acknowledged that the do not currently have a set of guidelines for ME/CFS (Senate Community Affairs References Committee, 2016).

9.3.3 Position with Respect to NDIS

As has been previously expressed, the NDIA has not been forthcoming with the policy and evidence base that it applies with respect to its assessment of ME/CFS and CFS. It is clear from the

experience of patients who are being denied access to the NDIS by the NDIA, that there are very clear beliefs (and possibly an 'evidence based' policy direction) that ME/CFS or CFS is reversible and/or not permanent. There are also perceptions that it is treatable and that treatment is currently available within the health system.

The RACP Guidelines provide various treatment and management recommendations including various pharmacological options, as well as graded exercise and cognitive behavioural therapy. There is no rational justification for this 15 year -old guideline, complete with 15 to 25 year old treatment recommendations, to have a place in a contemporary assessments for crucial entitlements under the NDIS.

The very fact that GET and CBT have been shown to be ineffective and hold potential harms for most participants (Kindlon T. , 2011b) and no place in treating the seriously ill, is reason enough that they should not be considered in 2017. The research base behind these treatments is fatally flawed, if not the product of ethical misconduct of the most extreme end (Tuller, 2017; Geraghty, 2017b; Lubet S. , 2017; Lubet S. , 2017; Stouten, 2017). Twisk (2017b) warns of iatrogenic harm from pursuing such unsafe treatment:

> As affirmed by the medical authorities in the US recently, "ME/CFS is a serious, chronic, complex, multisystem disease" [4] with "strong evidence" indicating that "immunologic and inflammatory pathologic conditions, neurotransmitter signaling disruption, microbiome perturbation, and metabolic or mitochondrial abnormalities are potentially important for the definition and treatment of ME/CFS . Exertion has (prolonged) negative effects in ME/CFS . For that reason studies and surveys indicating potential harm of CBT and GET in large subgroups of ME/CFS patients should be taken seriously. The 'safety claim' is at odds with several observations (Twisk F. N., Studies and surveys implicate potential iatrogenic harm of cognitive behavioral therapy and graded exercise therapy for myalgic encephalomyelitis and chronic fatigue syndrome patients, 2017b)

The science and evidence base with respect to ME/CFS and CFS has grown in leaps and bounds since 2002. One of the world's leading research institutions is based at Griffith University, being the National Centre for Neuroimmunology and Emerging Disease (NCNED, 2017). The NCNED engages in research utilising ME/CFS and CFS criteria. Dr. Dan Staines a researcher at the NCNED recently stated at an event on the Gold Coast that exercise in ME/CFS is bad for the patient.

The evidence based content of the RACP is clearly out of date with respect to diagnosis, treatment and management. It therefore has no place within the consideration of NDIS applications. It certainly should not be informing the assessor on issues such as treatment and management.

9.4 Updated Evidence Base

The NDIA has authority to commission a report to address specific questions with respect to a specific condition or issue, such as "develop good practice recommendations" or national guidelines (For Example: *Autism spectrum disorder: Evidence-based/evidence-informed good practice for supports provided to preschool children, their families and carers*(Roberts & Williams, 2016) and *Reviewing Assistance Animal Effectiveness*(Howell, Bennett, & Shielle, 2016)).

Given the potential for the NDIS policy to be based upon an outdated evidence base, ME/CFS Legal submits that the NDIS would be best served bycommissioning a report with respect to ME/CFS and CFS in regards to access to the system and early intervention, by creating a stakeholder group by;

1. Reaching out to the appropriately qualified and current Australian based researchers (such as the NCNED, Melbourne University research group, the Adelaide research group, Bridges and Pathways, the Canberra research group, specialist practitioners such as Dr. John Whiting or Dr. Peter Smith);
2. Reaching out to various state and national organisations such as ME/CFS Australia Ltd, #MEAction Network Australia, ME/CFS Australia (SA), ME/CFS& Lyme Association of WA, ME/CFS & FM Association of NSW, Emerge Australia, Bridges and Pathways (South Australia), ME/CFS Toowoomba);
3. Reviewing the 2015 IOM and NIH Pathways to Prevention reports;
4. Reviewing the 2003 Consensus Criteria (Carruthers, et al., 2003) and 2011 International Consensus Criteria (Carruthers, et al., 2011);
5. Referring to the CDC CFS website (Centres for Disease Control, 2017);
6. Reviewing the BMJ Best Practice document for CFS.

The purpose of an evidence base is to establish the current state of knowledge that best diagnoses and describes the condition so as to better understand where the condition fits within the NDIS legislative parameters and to assist those with a genuine disability and impairment. This arguably would assist in achieving this.

10. Submission 4 - The Case for a List B Inclusion

The final submission of ME/CFS Legal is to petition the NDIS for the inclusion of ME/CFS and CFS into its Schedule B condition under the *National Disability Insurance Scheme (Becoming a Participant) Rules 2016* (Cth). Such a move would place the condition alongside other neurological conditions and conditions of variable functional capacity thereby negate the issue of arguments alleging it is not permanent.

10.1 The Nature of List B

10.1.1 The Purpose of List B

The Operational Guidelines are clear that an applicant need not have to have a List A or List B condition in order to qualify as a participant of the NDIS (National Disability Insurance Scheme, 2014c, p. 2) The purpose of List B is to make access to the NDIS easier – an appropriate objective when the conditions involved often have significant impacts upon the ability of the applicant to engage in the necessary paperwork process that is entailed. The purpose of the List A and List B of the Guidelines is therefore simplicity and an easing of the burden of the process:

> These lists have been developed to streamline the access process for people with a condition on one of these lists. The lists are not exhaustive and in no way suggest that a person with a condition not on a list is excluded from the NDIS" (National Disability Insurance Scheme, 2014c, p. 2)

List B is for "Permanent impairment/functional capacity variable – further assessment of functional capacity required'. The Operational Guidelines (2014) state:

> This is because the nature of the conditions on List B at Appendix B is such that they are generally considered to result in a disability that is attributable to a permanent impairment. However, the severity of the resulting disability is variable and people with these conditions will not necessarily have substantially reduced functional capacity. Accordingly, a delegate would require further evidence to be satisfied that the person, as a result of that impairment. (National Disability Insurance Scheme, 2014c, p. 2)

It is the submission of ME/CFS Legal that ME/CFS is a case in point with respect to the key issues of:

- Disability attributable to permanent impairment;
- Variable severity of disability;
- Variable functional capacity.

ME/CFS and CFS operates on a spectrum of severity (Loblay, et al., 2002, pp. S32, S36; Carruthers, et al., 2003, p. 14) as does disability (Loblay, et al., 2002, p. S26).

10.1.2 The Purpose of the NDIS

The NDIS was created because "Australians deserve the peace of mind that would come with knowing that support will be there if they need it" (NDIS, 2016). The purpose is to expressly provide "targeted individual support and early intervention" so that "people with disability will be able to participate and learn more at school, go to TAFE and university and get jobs that use their skills and enable them to contribute productively to the nation" (NDIS, 2016). Moreover, it is designed to ensure that people with a disability don't "need to live on the disability support pension or beg charities to help pay for essential disability equipment. And they won't need to rely on a lifetime of unpaid support by families" (NDIS, 2016).

Persons with ME/CFS and CFS require targeted support and early intervention to accord them the best opportunity to participate in Australian society and attain a reasonable quality of life and independence. Their families need assistance with the care of these patients and the ability to live their own lives.

Peace of mind is the ultimate goal of those with ME/CFS and for very good reasons.

ME/CFS sufferers experience the effects of "stigmatization" arising from "financial instability (such as job loss or demotion), social disengagement, and feeling the need to hide their symptoms in front of others" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 30). Those who care for patients are significant affected by ME/CFS too. Nacul et al (2011) reveal that the impacts of the condition are felt:

> … by partners and family members, who may need to spend considerable time caring for their sick relatives, and therefore obliged to sacrifice work and social activities. This can not only subject them to an emotional burden but also adversely affect their own and their families" incomes. (Nacul, et al., 2011, p. 403)

Nacul et al's (2011) study concluded that the quality of life of the carers was significantly affected, and particularly highlighted the emotional burden which increased when patients where their mental health has been impacted by the condition(Nacul, et al., 2011). Nacul et al's (2011) conclusion is most significant to this submission:

> Quality of life is inversely related to distress, disability and loss of function, and is associated with the ability of individuals to remain active and perform roles in society. A major goal of people with chronic diseases is to achieve effectiveness in life and to preserve function and well-being. However, people with ME/CFS are by and large failing to achieve these goals, and their carers' emotional well being is also being affected.(Nacul, et al., 2011, p. 411)

The key reason for this failure to achieve goals is because of the fundamental failure of the "Disability assessment in [persons with ME/CFS which] remains a challenge, as the disabling nature of the condition is not always immediately apparent." (Nacul, et al., 2011, p. 411)

It is the position of ME/CFS legal that there is a strong correlation between the objectives of the NDIS and the needs of those with ME/CFS. ME/CFS Legal submits that Nacul et al's point with respect to the failure of many to understand disabling nature of ME/CFS, is an a failure repeated within the assessment policy of the NDIA. It is our submission that ME/CFS should be placed on List B in order to overcome these failures of understanding that are so prolifically present within the medical profession. This would make the task of meeting the requirements of the NDIS a great deal less onerous for people with a condition that is already a major challenge in their life.

10.2 Disease Illustration

10.2.1 Shared Classification

ME/CFS is a disease that is neuropathological in nature, more specifically a neuroimmune condition (Carruthers, et al., 2011, pp. 329-330; Morris, Berk, Galecki, Walder, & Maes, 2015; Dantzer, Heijnen, Kavelaars, Laye, & Capuraon, 2014). This is consistent with its classification as neurological in the World Health Organization's International Classification of Diseases (World Health Organization, 1969). The condition is therefore more than suitable for inclusion within List B(2), "Conditions primarily resulting in Neurological impairment" (National Disability Insurance Scheme, 2014c, p. 12) Morris and Maes (2013) affirm this argument, stating "the strong similarities between both disorders in terms of phenomenological, neurobehavior and neuroimmune characteristics further underscore that ME/CFS belongs to the spectrum of neuroimmune disorders"(Morris & Maes, 2013, p. 218).

By way of comparison, Multiple Sclerosis (MS) is included under the same heading.

10.2.2 ME/CFS and CFS as Neurological Conditions

When the term "Benign Myalgic Encephalomyelitis" was first coined in 1956 by Acheson, he did so because of the "symptoms and signs of damage to the brain and spinal cord" (Acheson, 1956, p. 790). Parish et al (1992) identify the meaning of the word encephalomyelitis as:"*Encephalo* refers to brain, *myel* to spinal cord and *itis* denotes inflammation" (Parish, Bell, Hyde, & Rubinstein, 1992, p. 4). It is this assertion of inflammation that ensured the condition was identified and subsequently included within the WHO International Classification of Diseases as a neurological condition back in 1969 (World Health Organization, 1969).

There is a significant body of evidence that demonstrates by way of cerebral spinal fluid and cytokine research that there is a definite presence of cerebral and central nervous system in ME/CFS (Morris & Maes, 2013; Morris, Berk, Galecki, Walder, & Maes, 2015; Nacul, et al., 2014; Cader, O'Donovan, Shepherd, & Chaudhuri, 2009; Ferrero, Silver, Cocchett, Eliezer Masliah, & Langford, 2017; Natelson, Weaver, Tsen, & Ottenweller, 2009; Twisk F. N., 2014; Sorenson, Furst, Mathews , & Jason, 2017; Sorenson, Jason, Peterson, Herrington, & Mathews, 2014, Glassford, 2017; Peterson, et

al., 2015; Morris, Berk, & Puri, 2017; Hornig, et al., 2016; Montoya, et al., 2017; Nakatomi, et al., 2014; Yasui, et al., 2014; Landi, et al., 2016; Khaiboullina, et al., 2015).

In view of this strong evidence base, it is the submission of ME/CFS Legal that there is ample justification to classify ME/CFS and CFS as neurological under List B.

10.2.3 A Comparative: ME/CFS and MS

MS is a neurological condition that currently has List B status (most justifiably) under the NDIS (National Disability Insurance Scheme, 2014, p. 13).

The IOM Committee (2015) sheeted home the seriousness of ME/CFS and CFS and it bears significant mention in the context of a comparison to MS:

> Patients with ME/CFS have been found to be more functionally impaired than those with other disabling illnesses, including type 2 diabetes mellitus, congestive heart failure, hypertension, depression, multiple sclerosis, and end-stage renal disease. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 31)

MS shares a significant number of symptoms with ME/CFS (sub-types) (Milo & Miller, 2014; MS Australia, 2017; Morris & Maes, 2013; Jason, et al., 2017; Sorenson, Furst, Mathews , & Jason, 2017; Jason, et al., 2017). The five most common symptoms of MS include:

- "Motor control - muscular spasms and problems with weakness, coordination, balance and functioning of the arms and legs
- Fatigue - including heat sensitivity
- Other neurological symptoms - including vertigo, pins and needles, neuralgia and visual disturbances
- Continence problems - including bladder incontinence and constipation
- Neuropsychological symptoms - including memory loss, depression and cognitive difficulties" (MS Australia, 2017)

Morris and Maes (2013) mapped out the similarities in the phenomenological experience of both conditions. The shared experiences are contained in Table 1 below.

Morries and Maes (2013) summarised:

> In summary (see Table 1), patients with ME/CFS and MS both experience severe levels of disabling fatigue and a worsening of symptoms following exercise and resort to energy conservation strategies in an attempt to meet the energy demands of day-to-day living. Debilitating autonomic symptoms are experienced by people with both illnesses. Diminished cardiac responses to exercise are a common finding as are reports of orthostatic intolerance and postural hypotension. It appears, however, that ME/CFS patients may be more sensitive to physical or cognitive activities than patients with MS. (Morris & Maes, 2013, p. 207)

Table 1 - Phenomenological similarities between MS and ME/CFS

Phenomenology	MS	ME/CFS
Disabling fatigue	✓	✓
Severe exercise intolerance	✓	✓
Mental fatigue	✓	✓
'Pacing' as an energy conservation strategy	✓	✓
Worsening of symptoms following exercise	✓	✓
Orthostatic intolerance	✓	✓
Gastrointestinal dysfunction	✓	✓
Cardiac dysrhythmias	?	✓
Postural hypotension	✓	✓
Diminished cardiac response to exercise	✓	✓
Relapsing-remitting nature	✓	✓
Chronic course	✓	✓
Disease exacerbated by infections	✓	✓
Disease exacerbated by psychological stress	✓	✓
Disease worsened or precipitated by infections	✓	✓

Other common features included oxidative and nitrosative stress, shared elevated cytokine levels within the inflammatory pathways, cell mediated immunity, autoimmunity, B cells, brain dysfunction and mitochondrial dysfunctions (Morris & Maes, 2013, pp. 208-212):

1. *Type 1* - 85% of the population with MS fall within the first phenotype and experience the relapsing- remitting form of the illness, where the patient "endures relapses of episodes of acute impairment of neurologic function. Relapses may be replaced by times of partial or complete remissions without further exacerbations" (Morris & Maes, 2013, p. 207).
2. *Type 2* - 10% of the population fall into the second phenotype, being a "primary-progressive type MS endure a continuous deterioration of their disease typically, but not exclusively, without a pattern of relative relapse or remission"(Morris & Maes, 2013, p. 207).
3. *Type 3* - The third phenotype involves patients with a "secondary-progressive type MS [who] endure an initial pattern of relapsing-remitting disease followed by a progressive deterioration of disease activity amidst a pattern of minor relapses and remissions. Around half of those with the relapsing-remitting course of disease will go on to develop secondary-progressive MS in the absence of treatment" (Morris & Maes, 2013, p. 207).
4. *Type 4* - The fourth phenotype comprises about 5% of the MS population and involves a "with progressive-relapsing type MS experience a progressive worsening of symptoms from onset coupled with acute exacerbations with or without recovery. There is no period of remission in this form of MS" (Morris & Maes, 2013, p. 207).

ME/CFS is a disease characterised by a chronic disease that is "waxing and waning of symptoms" that is either a "relapsing-remitting or progressive pattern of disease" (Morris & Maes, 2013, p. 207).

Fatigue that is disabling and ever-present is the primary joint symptom across both conditions, made worse by exercise intolerance (Morris & Maes, 2013, p. 218). Morris and Maes found that patients with ME/CFS had greater sensitivity to increases in physical and cognitive activity than MS, as well as susceptibility to infections, with a worse infection experience (Morris & Maes, 2013, p. 218).

10.2.4 Submission

It is the position of ME/CFS Legal that the very justified reasons for granting MS List B status are shared by ME/CFS and CFS. These conditions share not only a mutual symptom base, but they also share characteristics such a variability in severity, as well as advocacy, social and care needs. ME/CFS Legal petitions the Senate to urge the NDIS to revisit their evidence base and adopt a more contemporary understanding of the condition. The evidence base is broad and often it is not understood just how serious the issues are and how they cross over with other conditions – such as MS. MS was once dismissed as hysterical paralysis and psychologised accordingly. Such a view is abhorrent in modern medicine – yet we have a situation in which ME/CFS and CFS are arguably suffering the same offensive characterisation.

Like MS, ME/CFS and CFS are a serious condition. The IOM Committee (2015) brought home this point:

> Myalgic encephalomyelitis (ME) and chronic fatigue syndrome (CFS) **are serious, debilitating conditions** that impose a burden of illness on millions of people in the United States and around the world ... Seeking and receiving a diagnosis can be a frustrating process for several reasons, including skepticism of health care providers about the serious nature of ME/CFS and the misconception that it is a psychogenic illness or even a figment of the patient's imagination … ME/CFS can cause significant impairment and disability that have negative economic consequences at both the individual and societal levels. (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 2-3)

ME/CFS Legal submits, with respect, that the time to move past outdated misconceptions has come and the NDIS needs ensure such misinformed beliefs are not institutionally endorsed.

10.3 Submission for List B Inclusion

ME/CFS and CFS are conditions that hold a justifiable need for inclusion into List B of the Operational Guidelines. The purpose of a comparative to MS is not to attempt to claim in any way shape or form that they are on equal footing. The purpose is to illustrate that MS is a condition that is considered a serious illness. It brings with it expectations that it should be dealt with seriously and that no person with it should have to endure undue hardship from establishing that is it a permanent disability. That is a given.

The fact is, however, that ME/CFS and CFS have been demonstrated to be conditions where "[p]atients … have been found to be more functionally impaired than those with other disabling illnesses [such as] type 2 diabetes mellitus, congestive heart failure, hypertension, depression, multiple sclerosis and end-stage renal disease" (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, pp. 31-32; Jason & Richman, 2007, p. 80; Twisk F. N., The status of and future research into Myalgic Encephalomyelitis and Chronic Fatigue Syndrome: the need of accurate diagnosis, objective assessment, and acknowledging biological and clinical subgroups, 2014, pp. 2-3). These comparators are among those conditions included as list B – a fact that should not be ignored.

ME/CFS and CFS are permanent conditions. There is no cure (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 259). Only a small percentage of

patients recover, and almost none of those occur after the first five years. There is no magic treatment or pill that stops the process. Like MS it can be variable and it has clinical sub-groups (Twisk F. N., The status of and future research into Myalgic Encephalomyelitis and Chronic Fatigue Syndrome: the need of accurate diagnosis, objective assessment, and acknowledging biological and clinical subgroups, 2014, p. 4). It can plateau. It can have windows of improvement and relapses (Friedberg, et al., 2014, p. 44). It is, however, progressive and there is no scientific evidence that recovery or is possible for the majority (Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2015, p. 265).

It therefore the submission of ME/CFS Legal that ME/CFS and CFS have equal standing to MS and other conditions that are on the List B schedule and should included accordingly.

11. Submission 5 - NDIS and Medicare

The final submission of relevance is with respect to the cost of conducting an application for the NDIS.

11.1 The Evidentiary Burden

The NDIS requires the applicant to prove their disability or early intervention access requirements, hence they have to provide evidence of the disability – "This includes information on what your disability is, how long it will last and its impact on your life" (National Disability Insurance Scheme, 2017a).

This approach therefore requires the Applicant to provide evidence from the treating doctors or specialist via the Professional Report section of Part F of the Access Request Form or the NDIS Supporting Evidence form (National Disability Insurance Scheme, 2017a). This evidence must provide the information that the form collects.

When the condition does not fall on the existing identified conditions within List A, B, or D, the onus then falls on the applicant to "provide evidence of the impact of your condition on your life, including any impact on your mobility, communication, social interaction, learning, self-care and self-management" (National Disability Insurance Scheme, 2017a). That information comes from the medical specialist or the allied health professional (which could include a physiotherapist, an occupational therapist, speech pathologist, psychologist or a nurse) who completes the Professional report in Part F (National Disability Insurance Scheme, 2017a).

All this evidence is required at the time of submitting the access request. Without it, the access request is not considered.

11.2 Issues of Cost

The completion of the Professional Report section of Part F of the Access Request Form is conducted with the patient present and is an item recovered under normal consultation fees within the Medicare Benefits Scheme (For example, Level A – D consultations: MBS items 3, 23, 36, 44) (Health and Human Services, 2017).

The issue, however, is one of additional cost. This is often not covered within the Medicare Framework. Such expenses can include:

- *Medicare Gap* – the difference between the Medicare rebate and the amount charged for the consultation by the individual practitioner;

- *Report Fee* – the cost of a more detailed fee for a complex patient (which is more often the case in ME/CFS and CFS) is not a recoverable sum. This could run from several hundred dollars to several thousand, depending on the complexity of the report;
- *Investigations of Function*–there is a significant cost either due to the absence of Medicare funding or due to a funding gap, with respect to investigations such as psychometric testing, Cardio Pulmonary Exercise Tests, MRI's, SPECT scan, PET Scans, EEG's/qEEG's, Tilt Table with Echocardiogram, and other relevant tests of functional impairment;
- *Allied Health* – there is often no Medicare funding associated with allied health professional (although a Chronic Disease Management Plan may provide some limited access – ie 5 allied services per calendar year) to conduct investigation (Australian Government Department of Health, 2014, p. 13). Moreover, with respect to the expense of a specific report under Part F of the Access Request Form or as a separate report Part F of the Access Request Form. On some services a written report in relation to the service is provided to the referring medical practitioner, however the fee is exceptionally small (Australian Government Department of Health, 2014, pp. 18-23; Australian Governement Department of Health, 2017, p. 31);

Patients with ME/CFS and CFS are often already financially over-extended as a result of the condition, hence the ability to fund various doctor visits and produce evidence of impaired functional capacity is severely compromised.

11.3 Issues of Availability

Regrettable experience from both Workers Compensation and Centrelink experiences of patients with ME/CFS and CFS raises a number of issues:

- *Unavailable* – the ability to find an ME/CFS knowledgeable practitioner is hampered by issues such as geographical location, an absence of knowledge or absence of specialist care within the field. ME/CFS and CFS are a medically underserved population (Sunnquist, Nicholson, Jason, & Friedman, 2017, p. 33; #ME Action Network Australia, ME/CFS Australia (South Australia), Inc. and ME/CFS and Lyme Association of Western Australia, Inc., 2016; Hallmann, Hartman, & Coutts, 2014);
- *Unwillingness* – the depth of detail required to prove the issues with respect to ME/CFS or CFS, and/or produce such information on what is often a pro-bono basis, is often a burden that is beyond the capabilities of the often already over extended medical practitioner (Hallmann, Hartman, & Coutts, 2014);
- *Absence of Knowledge* – there is a dearth of medical knowledge with respect to ME/CFS among general practitioners and (#ME Action Network Australia, ME/CFS Australia (South Australia), Inc. and ME/CFS and Lyme Association of Western Australia, Inc., 2016; Sunnquist, Nicholson, Jason, & Friedman, 2017; Hallmann, Hartman, & Coutts, 2014).

The limited opportunities to obtain a report mean that persons of limited means (which is the significant majority of those with ME/CFS and CFS, if not indeed the population of those disabled, hence there is a significant issue).

11.4 Submission

With respect, ME/CFS Legal Resources submits that the NDIS, in conjunction with Medicare, might well consider putting in place, for all applicants, a service fee for report writing (such as a complex

report), for example, within the Medicare Benefits Scheme, under Category 8 – Miscellaneous Services(Australian Government Department of Health, 2017, p. 1115). This would arguably restore equity to the NDIS system for low income applicants.

12. Summary

There is little argument that ME/CFS and CFS are regarded as a controversial conditions(Blease, Carel, & Geraghty, 2017, p. 549). In the submission of ME/CFS Legal that argument arises because of a fundamental misconstruing of the condition as 'mere fatigue' and therefore not of a serious nature. Poor quality research combined with inappropriately applied mismatching research based on outdated criteria within the UK has caused this confusion. Additionally, it requires significantly experienced and appropriately qualified persons with significant understanding of the various issues within the research. The construction of a poor quality evidence base is all too easy when using research on Apples (ie the Oxford Criteria based research) and applying it to patients who are Oranges (the Fukuda CFS and Carruthers ME/CFS entities that are diagnosed here in Australia).

ME/CFS Legal Resources has provided an expert, evidence based submission for the Joint Senate Committee to consider. With respect, we submit that the current position with respect to ME/CFS is significantly flawed, hence is providing unjust outcomes that do not meet the purpose and objectives of the NDIS. To that end we submit the following recommendations:

1. Register ME/CFS, ME and CFS on List B of the Operational Guidelines;
2. Conduct a review of the evidence base (excluding all Oxford criteria derived research and guidelines) utilising experienced ME/CFS researchers and practitioners within Australia (excluding those aligned with the PACE researchers);
3. Update the NDIS policy on ME/CFS, ME and CFS, including the reference package.

ME/CFS Legal Resources extends its thanks to the Committee for their attention and consideration of the issues raised and recommendation ventilated within this submission.

13. Epilogue

Whilst the submission is detailed, ME/CFS Legal believes strongly that there was an inherent necessity to ensure that the Committee had a contemporary understanding of the condition and did not find itself inadvertently dismissing the condition based upon the poor media reporting of the past 30 years. This is a serious condition. It is not psychological. People are suffering.

Suicide is the biggest killer, (along with cancer and heart disease) in this disease (McManimen, et al., 2016). Dr John Whiting affirms this within his submission to the NDIS (Whiting, 2017, p. 2). The NDIS therefore holds the capacity to change the lives of those with the condition and help reduce burden of this disease upon patients. That is a powerful responsibility. ME/CFS Legal merely attempted to ensure a quality decision could be made.

14. References

#ME Action Network Australia, ME/CFS Australia (South Australia), Inc. and ME/CFS and Lyme Association of Western Australia, Inc. (2016, November). *Commonwealth Risk Management—Inquiry based on Auditor-General's Report 18 (2015-16): Submission 37.* Retrieved October 23, 2017, from Parliament House of Australia: http://www.aph.gov.au/DocumentStore.ashx?id=c72ebfc2-d9b0-4eec-9650-80a3066f4086&subId=460291.

Ability Options. (2017). *NDIS Support Catergories.* Retrieved November 10, 2017, from Ability Options: https://abilityoptions.org.au/ndis/ndis-supports-categories

Acheson, E. D. (1956). A New Clinical Entity? *The Lancet, 21*, 789-790.

Arnold, L. M. (2007). Understanding Fatigue in Major Depressive Disorder and Other Medical Disorders. *Pscyhosomatics, 49*(3), 185-190. doi:0.1176/appi.psy.49.3.185

Australian Governement Department of Health. (2017, February 1). *Medicare Benefits Schedule Book Category 8.* Retrieved October 24, 2017, from MBS Online: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/4A79A04857852120CA2580B1001E5978/$File/201702-Cat8.pdf

Australian Government Department of Health. (2014, November 1). *Medicare Beneftis Schedule - Allied Health Services.* Retrieved November 24, 2017, from MBS Online: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/4A79A04857852120CA2580B1001E5978/$File/201702-Allied.pdf

Australian Government Department of Health. (2017, November 1). *Medicare Benefits Schedule Book Operating from 01 November 2017.* Retrieved October 24, 2017, from MBS Online: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/AC4BB79DA21FF800CA2581A1000AE4F1/$File/201711-MBS.pdf

Ax, S., Gregg, V. H., & Jones, D. (2002). Caring for a relative with chronic fatigue syndrome: difficulties, cognition and acceptance over time. *Perspectives in Public Health, 122*(1), 35-42. doi:10.1177/146642400212200113

Baraniuk, J. N. (2017). Chronic fatigue syndrome prevalence is grossly overestimated using Oxford criteria compared to Centers for Disease Control (Fukuda) criteria in a U.S. population study. *Fatigue: Biomedicine, Health & Behavior, 5*(4), 215-230. doi:10.1080/21641846.2017.1353578

Better Health Channel. (2016, August). *Chronic Fatigue Syndrome*. Retrieved October 26, 2017, from Victorian State Government: https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/chronic-fatigue-syndrome-cfs

Better Health Channel. (2016, August). *Chronic fatigue syndrome (CFS).* Retrieved October 27, 2017, from State of Victoria: https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/chronic-fatigue-syndrome-cfs?viewAsPdf=true

Better Health Channel. (2017, November 12). Chronic Fatigue Syndrome. Retrieved November 13, 2017, from Victorian State Government:

https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/chronic-fatigue-syndrome-cfs

Blease, C., Carel, H., & Geraghty, K. (2017). Epistemic injustice in healthcare encounters: evidence from chronic fatigue syndrome. *43*(8), 549-557. doi:10.1136/medethics-2016-103691

BMJ Publishing Group Limited. (2017, July 31). *Chronic Fatigue Syndrome.* Retrieved October 27, 2017, from British Medical Journal Best Practice: http://bestpractice.bmj.com/best-practice/monograph/277.html

BMJ Publishing Group Limited. (2017). *Disclaimer*. Retrieved October 27, 2017, from British Medical Journal Best Practice: http://bestpractice.bmj.com/best-practice/marketing/disclaimer.html?button=legal

Brurberg, K. G., Fønhus, M. S., Larun, L., Flottorp, S., & Malterud, K. (2014). Forest plot summarising indirect comparisons of prevalence estimates from different case definitions (model. *BMJ Open, 4*(e003973), 1-13. doi:10.1136/bmjopen-2013-003973

Cader, S., O'Donovan, D. G., Shepherd, C., & Chaudhuri, A. (2009). FP03-MO-02 Neuropathology of Post-infectious Chronic Fatigue Syndrome. *Journal of Neurological Sciences, 285*(S1), S60-S61.

Carers Australia. (2013, February). *Carers Australia Submission to the Senate Standing Committee on Community Affairs Inquiry: National Disability Insurance Scheme Bill 2012.* Retrieved November 7, 2017, from Carers Australia: http://www.carersaustralia.com.au/storage/Carers%20Australia%20Submission%20into%20the%20Senate%20Inquiry%20on%20the%20NDIS%20Bill.pdf

Carruthers, B. M., Jain, A. K., De Meirleir, K. L., Peterson, D. L., Klimas, N. G., Lerner, A. M., . . . van de Sande, M. L. (2003). Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols. *Journal of Chronic Fatigue Syndrome, 11*(1), 7.

Carruthers, B. M., van de Sande, M. I., De Meirleir, K. L., Klimas, N. G., Broderick, G., Mitchell, T., . . . Stevens, S. (2011). Myalgic encephalomyelitis: International Consensus Criteria. *Journal of Internal Medicine, 270*(4), 327-388. doi:10.1111/j.1365-2796.2011.02428.x

Centre for Disability Research and Policy, University of Sydney (CDRP) and Young People in. (2014). *Cross sector service coordination for people with high and complex needs: Harnessing existing evidence and knowledge.* Retrieved November 8, 2017, from University of Sydney: http://sydney.edu.au/health-sciences/cdrp/discussion-paper-complexneeds-july2014.pdf

Centres for Disease Control. (2007, December 26). *Chapter One, Course WB1032*. (C. f. Control, Producer) Retrieved September 19, 2017, from Chronic Fatigue Syndrome: https://web.archive.org/web/20090314000505/www.cdc.gov/cfs/cme/wb1032/chapter1/overview.html

Centres for Disease Control. (2017, July 3). *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome*. Retrieved October 29, 2017, from Centres for Disease Control and Prevention: https://www.cdc.gov/me-cfs/treatment/index.html

Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. (2015). *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness.*

Institute of Medicine, Board on the Health of Selevt Populations. Washington: National Academy of Scientists.

Daniels, J., Brigden, A., & Kacorova, A. (2017, Feb 28). Anxiety and depression in chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME): Examining the incidence of health anxiety in CFS/ME. *Psychol Psychother, 90*(3), 502-509. doi:10.1111/papt.12118

Dantzer, R., Heijnen, C. J., Kavelaars, A., Laye, S., & Capuraon, L. (2014). The Neuroimmune Basis of Fatigue. *Trends in Neuroscience, 37*(1), 39-46. doi:10.1016/j.tins.2013.10.003

DeLuca, J., Johnson, S. K., Beldowicz, D., & Natelson, B. H. (1995). Neuropsychological impairments in chronic fatigue syndrome, multiple sclerosis, and depression. *Journal of Neurology, Neurosurgery and Psychiatry*(58), 38-43. doi:10.1136/jnnp.58.1.38

DeLuca, J., Johnson, S. K., Ellis, S. P., & Natelson, B. H. (1997). Cognitive functioning is impaired in patients with chronic fatigue syndrome devoid of psychiatric disease. *Journal of Neurology, Neurosurgey and Psychiatry, 62*(2), 151-155. doi:10.1136/jnnp.62.2.151

English Oxford Living Dictionaries. (2017). *Alleviate*. (Oxford University Press) Retrieved November 5, 2017, from https://en.oxforddictionaries.com/definition/alleviate

English Oxford Living Dictionaries. (2017). *Cure*. (Oxford University Press) Retrieved October 29, 2017, from https://en.oxforddictionaries.com/definition/cure

English Oxford Living Dictionaries. (2017). *Mitigate*. (Oxford University Press) Retrieved November 5, 2017, from https://en.oxforddictionaries.com/definition/mitigate

English Oxford Living Dictionary. (2017). *Likely*. Retrieved October 29, 2017, from Oxford University Press: https://en.oxforddictionaries.com/definition/likely

English Oxford Living Dictionary. (2017). *Recovery*. Retrieved October 29, 2017, from Oxford University Press: https://en.oxforddictionaries.com/definition/recovery

Ferrero, K., Silver, M., Cocchett, A., Eliezer Masliah, E., & Langford, D. (2017, April 6). CNS findings in chronic fatigue syndrome and a neuropathological case report. *Journal of Investigative Medicine*, 1-10. doi:10.1136/jim-2016-000390

Friedberg, F., Bateman, L., Bested, A. C., Davenport, T., Friedman, K. J., Gurwitt, A., . . . Vallings, R. (2014). *ME/CFS: A Primer for Clinical Practitioners.* Retrieved October 21, 2017, from International Association for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: http://iacfsme.org/portals/0/pdf/Primer_Post_2014_conference.pdf

Fukuda, K. S. (1994). The Chronic Fatigue Syndrome: A Comprehensive Approach to its Definition and Study. International Chronic Fatigue Syndrome Study Group. *Annals of Internal Medicine, 121*(12), 953-959.

Geraghty, K. J. (2017a). 'PACE-Gate': When clinical trial evidence meets open data access. *Journal of Health Pscyhology, 22*(9), 1106-1112. doi:10.1177/1359105316675213

Geraghty, K. J. (2017b). Further commentary on the PACE Trial: Biased Methods and Unreliable Outcomes. *Journal of Health Psychology, 22*(9), 1209-1216. doi:10.1177/1359105317714486

Gibson, I., Taylor, R., Cryer, A., Meacher, M., Turner, D., Taylor, D., . . . Cumberlege, B. (2006, November). *Inquiry into the status of CFS/M.E. and research into causes and treatment.*

Retrieved November 29, 2017, from Gibson Inquiry: http://www.erythos.com/gibsonenquiry/docs/me_inquiry_report.pdf

Glassford, J. A. (2017). The Neuroinflammatory Etiopathology of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). *Frontiers in Physiology, 8*, 1-9. doi:10.3389/fphys.2017.00088

Gluckman, S. J., Aronson, M. D., & Libman, H. (2017, 2017 October). *Patient education: Chronic fatigue syndrome (systemic exertion intolerance disease) (Beyond the Basics).* Retrieved 27, from UpToDate: http://www.uptodate.com/contents/chronic-fatigue-syndrome-systemic-exertion-intolerance-disease-beyond-the-basics?source=search_result&search=chronic+fatigue+syndrome+beyond+the+basics&selectedTitle=5~150

Goldin, R. (2016, March 21). PACE: The research that sparked a patient rebellion and challenged medicine. *Sense About Science USA*. Retrieved October 21, 2017, from http://senseaboutscienceusa.org/pace-research-sparked-patient-rebellion-challenged-medicine/

Green, C. R., Cowan, P., Ronit, E., O'Neil, K. M., & Rasmussen, A. L. (2014, December 9-10). *Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.* Retrieved December 16, 2014, from National Institutes of Health: https://prevention.nih.gov/programs-events/pathways-to-prevention/workshops/me-cfs/workshop-resources

Green, C. R., Cowan, P., Elk, R., O'Neil, K. M., & Rasmussen, A. L. (2015, June 16). National Institutes of Health: Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. *Annals of Internal Medicine, 162*(12), 860-865. doi:10.7326/M15-0338

Hallmann, G. P., Hartman, Y., & Coutts, R. (2014). ME/CFS: Social Security Accessibility and Experiences. In IACFSME (Ed.), *11th Biennial International Conference Translating Science into Clinical Care* (pp. 67-68). San Francisco: International Association for IACFS/ME. Retrieved October 23, 2017, from http://iacfsme.org/PDFS/2014Syllabus25.aspx

Health and Human Services. (2017, April). *The role of General Practitioners to support access to the NDIS.* Retrieved October 23, 2017, from State of Victoria: http://www.vic.gov.au/system/user_files/Documents/ndis/The-role-of-General-Practitioners-to-support-access-to-the-NDIS_April17.docx.

Helmfrid, S., & Edsberg, J. (2017, September). Time to Reject the PACE Study. *Lakartidningen* . Retrieved October 17, 2017, from https://www.researchgate.net/profile/Sten_Helmfrid/publication/320101462_Time_to_Reject_the_PACE_Study/links/59ce23a7aca272b0ec1a4afd/Time-to-Reject-the-PACE-Study.pdf?origin=publication_list

Holmes, G. P., Kaplan, J. E., Gantz, N. M., Komaroff, A. L., Schonberger, L. B., Straus, S. E., . . . Brus, I. (1988). Chronic Fatigue Syndrome: A Working Case Definition. *108*(3), 387-389.

Hornig, M., Gottschalk, G., Peterson, D. L., Knox, K. K., Schultz, A. F., Eddy, M. L., . . . Lipkin, W. I. (2016). Cytokine network analysis of cerebrospinal fluid in myalgic encephalomyelitis/chronic fatigue syndrome. *Molecular Psychiatry, 21*, 261–269. doi:10.1038/mp.2015.29

Howell, T., Bennett, P., & Shielle, A. (2016, September 30). *Reviewing Assistance Animal Effectiveness Literature review, provider survey, assistance animal owner interviews, health economics analysis and recommendations.* Retrieved October 27, 2017, from NDIS: https://www.ndis.gov.au/medias/documents/hf5/hc0/8799673090078/Assistance-Animals-PDF-1-MB-.pdf

Hughes, J. L. (2002). Illness Narrative and Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: a Review. *British Journal of Occupational Therapy, 65*(1), 9-14. doi:10.1177/030802260206500103

Hyde, B. (2010). *Missed Diagnoses Myalgic Encephalomyelitis & Chronic Fatigue Syndrome Second Edition* (Second Edition ed.). Ottawa, Ontario, Canada: Lulu.

Ickmans, K., Meeus, M., De Kooning, M., Lambrecht, L., Pattyn, N., & Nijs, J. (2015). Associations between cognitive performance and pain in chronic fatigue syndrome: comorbidity with fibromyalgia does matter. *Pain Physician, 18*(5), E841-E852. doi:1854/LU-6958898

Ickmans, K., Meeus, M., Kos, D., Clarys, P., Meersdom, G., Lambrecht, L., . . . Nijs, J. (2013, October). Cognitive performance is of clinical importance, but is unrelated to pain severity in women with chronic fatigue syndrome. *Clinical Rhuematology, 32*(10), 1475–1485. doi:10.1007/s10067-013-2308-1

Independent Advisory Council of the NDIS. (2015, September). *Report to the Independent Advisory Council of the National Disability Insurance Scheme: Capacity Building for People with Disability, their Families and Carers.* Retrieved November 7, 2017, from National Disability Assistance Scheme: https://www.ndis.gov.au/medias/IAC-advice-on-Capacity-Building-PDF-?context=bWFzdGVyfHJvb3R8NTg5MDU2fGFwcGxpY2F0aW9uL3BkZnxoZWYvaGFlLzg3OTc4NjQ1MjU4NTQucGRmfDE3NDEzNWIwZDM5ODUxNjRkNTA5M2FhMjQ3ZGY4YzI2MDg3OWQ4MGVjOGI2NWYwYjNjMDc2MTEzZDllOTViNjA

Jason, L. (2017). The PACE trial missteps on pacing and patient selection. *Journal of Health Psychology, 22*(9), 1141-1145. doi:10.1177/1359105317695801

Jason, L. A., & Richman, J. A. (2007). How science can stigmatize: The case of chronic fatigue syndrome. *Journal of Chronic Fatigue Syndrome, 14*(4), 85-103. doi:10.3109/10573320802092146

Jason, L. A., Ohanian, D., Brown, A., Sunnquist, M., McManimen, S., Klebek, L., . . . Sorenson, M. (2017). Differentiating Multiple Sclerosis, Myalgic Encephalomyelitis and Chronic Fatigue Syndrome. *Insights in Biomedicine, 2*(11), 1-6. doi:10.21767/2572-5610.100027

Jason, L. A., Ohanian, D., Sunnquist, M., McManimen, S., Klebek, L., Fox, P., & Sorenson, M. (2017). Differentiating Multiple Sclerosis from Myalgic Encephalomyelitis and Chronic Fatigue Syndrome. *Insights in Biomedicine, 2*(2), 11-16. doi:10.21767/2572-5610.100027

Johnson, S. C., Staines, D. R., & Marshall-Gradisnik, S. M. (2016). Epidemiological characteristics of chronic. *Clinical Epidemiology, 8*, 97-107. doi:10.2147/CLEP.S96797

Johnston, S. C., Brenu, E. W., Staines, D. R., & Marshall-Gradisnik, S. M. (2013). The prevalence of chronic fatigue syndrome/myalgic encephalomyelitis in Australian patients. *Clinical Epidemiology 2013, 5*, 105-110. doi:10.2147/CLEP.S39876

Khaiboullina, S. F., DeMeirleir, K. L., Rawat, S., Berkb, G. S., Gaynor-Berk, R. S., Mijatovic, T., . . . Lobardi, V. C. (2015). Cytokine expression provides clues to the pathophysiology of Gulf War illness and myalgic encephalomyelitis. *Cytokine, 72*(1), 1-8. doi:10.1016/j.cyto.2014.11.019

Kindlon, T. (2011a). Reporting of Harms Associated with Graded Exercise Therapy and Cognitive Behavioural Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. *Bulliten of the IACFS/ME*, 59-111.

Kindlon, T. (2011b). Harms of cognitive behaviour therapy designed to increase activity levels in chronic fatigue syndrome: questions remain. *Psychother Psychosom. 2011;80(2):110-1, 80*(2), 110-111. doi:10.1159/000320778

LaManca, J. J., Sisto, S. A., DeLuca, J., Johnson, S. K., Lange, G., Pareja, J., . . . Natelson, B. H. (1998, September 28). Influence of exhaustive treadmill exercise on cognitive functioning in chronic fatigue syndrome. *The American Journal of Medicine, 105*(3 Supplement 1), 59S-65S. doi:10.1016/S0002-9343(98)00171-5

Landi, A., Broadhurst, D., Vernon, S. D., Lorne, D., Tyrrell, J., & Houghton, M. (2016, February). Reductions in circulating levels of IL-16, IL-7 and VEGF-A in myalgic encephalomyelitis/chronic fatigue syndrome. *Cytokine, 78*, 27-36. doi:10.1016/j.cyto.2015.11.018

Larun, L., Brurberg, K. G., Odgaard-Jensen, J., & Price, J. R. (2015). Exercise therapy for chronic fatigue syndrome. *Cochrane Database Systematic Review, 2*(CD003200). doi:10.1002/14651858.CD003200.pub3

Larun, L., Brurberg, K. G., Odgaard-Jensen, J., & Price, J. R. (2017, April 25). Exercise therapy for chronic fatigue syndrome. Cochrane Database of Systematic Reviews, 4(CD003200). doi:10.1002/14651858.CD003200.pub7

Lawrie, S. M., & Pelosi, A. J. (1995). Chronic fatigue in the Community: Prevalence and Associations. *British Medical Journal, 166*, 793-797. doi:10.1192/bjp.166.6.793

Lloyd, A., Wakefield, D., Broughton, C., & Dwyer, J. (1988). What is Myalgic Encephalomyelitis? *Lancet, 1*(June 4), 1286-1287.

Loblay, R., Stewart, G., Bertouch, J., Cistulli, P., Darveniza, P., Ellis, C., . . . Toulkidis, V. (2002, May 6). Chronic Fatigue Syndrome: Clinical Practice Guidelines. *Medical Journal of Australia, 176*, S17-S56.

Lubet, S. (2017). Defense of the PACE Tiral is Based on Augmentation Fallacies. *Journal of Health Psychology, 22*(9), 1201-1206. doi:10.1177/1359105317697324

Lubet, S. (2017). Investigator Bias and the PACE Trial. *Journal of Health Psychology, 22*(9), 1123-1127. doi:10.1177/1359105317697324

Matthees, A., Kindlon, T., Maryhew, C., Stark, P., & Levin, B. (2016, September 21). A preliminary analysis of 'recovery' from chronic fatigue syndrome in the PACE trial using individual participant data. *Virology Blog.*, 1-9. Retrieved October 17, 2017, from http://www.virology.ws/wp-content/uploads/2016/09

McCrone, P., Darbishire, L., Ridsdale, L., & Seed, P. (2003, February). The economic cost of chronic fatigue and chronic fatigue syndrome in UK primary care. *Psychological Medicine, 33*(2), 253-261. doi:10.1017/S0033291702006980

McManimen, S. L., Devendorf, A. R., Brown, A. A., Moore, B. C., Moore, J. H., & Jason, L. A. (2016). Mortality in patients with myalgic encephalomyelitis and chronic fatigue syndrome. *Fatigue: Biomedicine, Health & Behavior, 4*(4), 195-207. doi:10.1080/21641846.2016.1236588

Milo, R., & Miller, A. (2014). Revised Diagnostic Criteria of Multiple Sclerosis. *Autoimmunity Reviews, 13*(405), 518-524. doi:10.1016/j.autrev.2014.01.012

Missen, A., Hollingworth, W., Eaton, N., & Crawley, E. (2012, July). The financial and psychological impacts on mothers of childrne with chronic fatigue syndrome. *Child: Care, Health and Development, 38*(4), 505-512. doi:10.1111/j.1365-2214.2011.01298.x

Montoya, J. H., Holmes, T. H., Anderson, J. N., Maecker, H. T., Rosenberg-Hasson, Y., Valenciab, I. J., . . . Davis, M. M. (2017). Cytokine signature associated with disease severity in chronic fatigue syndrome patients. *PNAS, 114*(34), E7150-E7158. doi:10.1073/pnas.1710519114

Morris, G., & Maes, M. (2013). Myalgic encephalomyelitis/chronic fatigue syndrome and encephalomyelitis disseminata/multiple sclerosis show remarkable levels of similarity in phenomenology and neuroimmune characteristics. *BMC Medicine, 11*, 205-227. doi:10.1186/1741-7015-11-205

Morris, G., Berk, M., & Puri, B. K. (2017). A Comparison of Neuroimaging Abnormalities in Multiple Sclerosis, Major Depression and Chronic Fatigue Syndrome (Myalgic Encephalomyelitis): is There a Common Cause? *Molecular Neurobiology*, 1-8. doi:10.1007/s12035-017-0598-z

Morris, G., Berk, M., Galecki, P., Walder, K., & Maes, M. (2015). The Neuro-Immune Pathophysiology of Central and Peripheral Fatigue in Systemic Immune-Inflammatory and Neuro-Immune Diseases. *Molecular Neurobiology, 53*(2), 1195-1219. doi:10.1007/s12035-015-9090-9

MS Australia. (2017). *Symptoms*. Retrieved October 20, 2017, from MS Australia: https://www.msaustralia.org.au/about-ms/symptoms

Nacul, L. C., Lacerda, E. M., Campion, P., Pheby, D., de L Drachler, M., Leite, J. C., . . . Molokhia, M. (2011). The functional status and well being of people with myalgic encephalomyelitis/chronic fatigue syndrome and their carers. *BMJ Public Health, 11*, 402-412. doi:10.1186/1471-2458-11-402

Nacul, L. C., Lacerda, E. M., Phebey, D., Campion, P., Molokhia, M., Fayyaz, S., . . . Drachler, M. L. (2011). Prevalence of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) in three regions of England: a repeated cross-sectional study in primary care. *BMC Medicine, 9*, 1-12. doi:10.1186/1741-7015-9-91

Nacul, L., O'Donovan, D. G., Lacrade, E. M., Gveric, D., Golding, K., Hall, A., . . . Pheby, D. (2014). Considerations in establishing a post-mortem brain and tissue bank for the study of myalgic encephalomyelitis/chronic fatigue syndrome: a proposed protocol. *BMC Research Notes, 7*, 370-378. doi:10.1186/1756-0500-7-370

Nakatomi, Y., Mizuno, K., Ishii, A., Wada, Y., Tanaka, M., Tazawa, S., . . . Watanabe, Y. (2014). Neuroinflammation in Patients with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: An 11C-(R)-PK11195 PET Study. *Journal of Nuclear Medicine, 55*(6), 945-950. doi:10.2967/jnumed.113.131045

Natelson, B. H., Mao, X., Stegner, A. J., Lange, G., Vu, D., Blate, M., . . . Shungu, D. C. (2017, April 15). Multimodal and simultaneous assessments of brain and spinal fluid abnormalities in chronic

fatigue syndrome and the effects of psychiatric comorbidity. *Journal of Neurological Sciences, 375*, 411-416. doi:10.1016/j.jns.2017.02.046

Natelson, B. H., Weaver, S. A., Tsen, C.-L., & Ottenweller, J. E. (2009). Spinal Fluid Abnormalities in Patients with Chronic Fatigue Syndrome. *Clinical and Diagnostic Laboratory Immunology, 12*(1), 52-55. doi:10.1128/CDLI.12.1.52-55.2005

National Disability Insurance Scheme. (2013, December 19). *Operational Guideline – General Conduct – Communicating with Participants and Others (v 1.01).* Retrieved October 26, 2017, from NDIS.

National Disability Insurance Scheme. (2014a, May 2). *Operational Guideline – Access – Early Intervention Requirements (v 2.1).* Retrieved October 26, 2017, from Australian Department of Human Services: http://www.tdsa.org.au/wp-content/uploads/2016/03/00-Op-Guidelines-all-MERGED-29-Nov-2014.pdf

National Disability Insurance Scheme. (2014b, January 16). *Operational Guideline – Planning and Assessment – Supports in the Plan – Interface with Health.* Retrieved November 9, 2017, from Australian Department of Human Services: https://www.aopa.org.au/documents/item/415

National Disability Insurance Scheme. (2014c, September 1). *Operational Guidelines - Access - Disability Requirements (V. 3.2).* Retrieved October 18, 2017, from Australian Department of Human Services: https://ndis.gov.au/html/sites/default/files/OGs-access-disability-requirements_0.docx

National Disability Insurance Scheme. (2016, November 23). *What Are Reasonable and Necessary Supports?* Retrieved November 9, 2017, from Australian Department of Human Services: https://www.ndis.gov.au/medias/documents/hf5/hae/8799191105566/Reasonable-necessary-supports-fact-sheet.pdf

National Disability Insurance Scheme. (2017a). *About Us.* Retrieved September 11, 2017, from Australian Department of Human Services: https://www.ndis.gov.au/about-us.html

National Disability Insurance Scheme. (2017a). *Evidence of your disability*. Retrieved October 23, 2017, from National Disability Insurance Scheme: https://www.ndis.gov.au/people-with-disability/access-requirements/completing-your-access-request-form/evidence-of-disability

National Disability Insurance Scheme. (2017b). *Access to the NDIS*. Retrieved November 8, 2017, from Australian Department of Human Services: https://www.ndis.gov.au/operational-guideline/access/list-a.html

National Disability Insurance Scheme. (2017c, February). *NDIS Glossary.* Retrieved November 7, 2017, from Australian Department of Human Services: https://www.ndis.gov.au/medias/documents/hbf/h21/8799946473502/Glossary-Feb-2017.pdf

National Health and Medical Research Council. (1999). *Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines.* Retrieved from NHMRC: https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cp30.pdf

National Institute for Health and Care Excellence. (2007). *Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management in Adults and Children.* London: Royal College of General Practitioners.

National Institute for Health and Care Excellence. (2017). *Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management.* Retrieved November 10, 2017, from NICE: https://www.nice.org.uk/guidance/CG53

National Institute of Health and Care Excellence. (2017, August). *Surveillance report 2017 – Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management (2007) NICE guideline CG53.* Retrieved October 17, 2017, from National Institute of Health and Care Excellence: https://www.nice.org.uk/guidance/cg53/resources/surveillance-report-2017-chronic-fatigue-syndromemyalgic-encephalomyelitis-or-encephalopathy-diagnosis-and-management-2007-nice-guideline-cg53-4602203537/chapter/how-we-made-the-decision#how-we-made-the-deci

NCNED. (2017). *National Centre for Neuroimmunology and Emerging Diseases*. Retrieved October 19, 2017, from Griffith University: https://www.griffith.edu.au/health/national-centre-neuroimmunology-emerging-diseases

NDIS. (2016). *About NDIS: Why do we need the NDIS?* Retrieved October 19, 2017, from Every Australian Counts: http://www.everyaustraliancounts.com.au/about-ndis/why-do-we-need-the-ndis/

Nijhof, L. N., Nijhof, S. L., Bleijenberg, G., Stellato, R. K., Kimpen, J. L., Pol, H. E., & van de Putte, E. M. (2016). The impact of chronic fatigue syndrome on cognitive functioning in adolescents. *European Journal of Pediatrics, 175*(2), 245-252. doi:10.1007/s00431-015-2626-1

Ohanian, D., Brown, A., Sunnquist, M., Furst, J., Nicholson, L., Klebek, L., & Jason, L. (2016, December 19). Identifying Key Symptoms Differentiating Myalgic Encephalomyelitis and Chronic Fatigue Syndrome from Multiple Sclerosis. *Neurology (E-Cronicon), 4*(1), 41-45.

One Door Mental Health. (2017). *Submission 179: Submission to the Porductivity Commission's Study into NDIS Costs.* Retrieved October 24, 2017, from Australian Govenment Productivity Commission: https://www.pc.gov.au/__data/assets/pdf_file/0005/216077/sub0179-ndis-costs.pdf

Parish, G., Bell, D., Hyde, B., & Rubinstein, H. (1992). Chapter 1: The Disease of a Thousand Names. In B. M. Hyde, J. Goldstein, & P. Levine, *The Clinical and Scientific Basis of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome* (pp. 3-4). Ottawa: The Nightingale Research Foundation.

Parliament of Australia. (2017). *Transitional Arrangements for the NDIS*. Retrieved October 17, 2018, from Joint Standing Committee on the National Disability Insurance Scheme: https://www.aph.gov.au/Parliamentary_Business/Committees/Joint/National_Disability_Insurance_Scheme/Transition

Pawlikowska, T., Chalder, T., Hirsch, S. R., Wallace, P., Wright, D. J., & Wessely, S. (1994). Population Based Study of Fatigue and Psychological Distress. *British Medical Journal, 308*(6931), 736-766. doi:10.1136/bmj.308.6931.763

Peterson, D., Brenu, E. W., Gottschalk, G., Ramos, S., Nguyen, T., Staines, D., & Marshall-Gradisni, S. (2015). Cytokines in the Cerebrospinal Fluids of Patients with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis. *Mediators of Inflammation, 2015*, 1-4. doi:10.1155/2015/929720

Ramsay, A. (1988). *Myalgic encephalomyelitis and postviral fatigue states: the saga of Royal Free disease* (2nd ed.). London: Gower Medical Publishing Corportation.

Ramsay, M. (1986). *Encephalomyelitis and Postviral Fatigue States: The saga of Royal Free Disease.* London: Gower Medical Publications.

Ranjith, G. (2005). Epidemiology of Chronic Fatigue Syndrome. *Occupational Medicine, 55*, 13-19. doi:10.1093/occmed/kqi012

Roberts, E., Wessely, S., Chalder, T., Chang, C.-K., & Hotopf, M. (2016, April 16-22). Mortality of people with chronic fatigue syndrome: a retrospective cohort study in England and Wales from the South London and Maudsley NHS Foundation Trust Biomedical Research Centre (SLaM BRC) Clinical Record Interactive Search (CRIS) Register. *The Lancet, 387*(10028). doi:10.1016/S0140-6736(15)01223-4

Roberts, J. M., & Williams, K. (2016, February). *Autism spectrum disorder: Evidence-based/evidence-informed good practice for supports provided to preschool children, their families and carers.* Retrieved October 27, 2017, from Griffith University: https://www.griffith.edu.au/__data/assets/pdf_file/0010/810784/Early-Intervention-for-Autism-research-report.pdf

Royal Australian College of Physicians. (2017, May). *NDIS Guides for Physicians and Paediatricians.* Retrieved October 23, 2017, from RACP: https://www.racp.edu.au/docs/default-source/default-document-library/racp-ndis-qa-guide-for-physicians.pdf?sfvrsn=4

Sackett, D. L., Rosenberg, W. M., Gray, J. A., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't. *The British Medical Journal, 312*, 71-72. doi:10.1136/bmj.312.7023.71

Scope. (2017, March 24). *Submission 72: Productivity Commission Issues Paper National Disability Insurance Scheme (NDIS) Costs Scope (Aust) Submission.* Retrieved November 9, 2017, from Productivity Commission: https://www.pc.gov.au/__data/assets/pdf_file/0017/215441/sub0072-ndis-costs.pdf

Senate Community Affairs Committee. (2016, February 10). *Answers to Estimates Questions of Notice: Health Portfolio.* Retrieved September 20, 2017, from Parliament of Australia: www.aph.gov.au/~/media/Committees/clac_ctte/estimates/add.../SQ16-000302.pdf

Senate Community Affairs Committee. (2017, May 29). *Answers to Estimates Questions on Notice: Health Portfolio.* Retrieved September 20, 2017, from Parliament of Australia: www.aph.gov.au/~/media/Committees/clac_ctte/estimates/sup.../SQ15-000922.pdf

Senate Community Affairs References Committee. (2016, April 20). *Topic: International Consensus Primer on ME/CFS.* Retrieved October 18, 2017, from Answers to Questions on Notice: Health Portfolio: http://www.aph.gov.au/DocumentStore.ashx?id=48c438cb-da69-4c5e-86c2-dce6c5fdedb5.

Sharpe, M. C., Archard, L. C., Banatvala, J. E., Borysiewicz, L. K., Clare, A. W., David, A., . . . Lambert, R. J. (1991). A Report - Chronic Fatigue Syndrome: Guidelines for Research. *Journal of the Royal Society of Medicine, 84*(2), 118-121.

Sharpe, M., Goldsmith, K. A., Johnson, A. L., Chalder, T., Walker, J., & White, P. D. (2015, Dec). Rehabilitative treatments for chronic fatigue syndrome: long-term follow-up from the PACE trial. *Lancet Psychiatry, 2*(12), 1067-1074. doi:10.1016/S2215-0366(15)00317-X

Shepherd, C. B. (2017). PACE trial claims for recovery in. *Journal of Health Psychology, 22*(9), 1187-1191. doi:10.1177/1359105317703786

Shepherd, C., & Chaudhuri, A. (2005). *ME/CFS/PVFS An Exploration of the Key Clinical Issues* (2nd ed.). London, England: Austin Rose Printers Pty Ltd.

Siegel, Z. A., Brown, A., Devendorf, A., Collier, J., & Jason, L. A. (2017, April 12). A content analysis of chronic fatigue syndrome and myalgic encephalomyelitis in the news from 1987 to 2013. *Chronic Illness*, 1-10. doi:10.1177/1742395317703175

Skapinakis, P., Lewis, G., & Meltzer, H. (2003). Clarifying the relationship between unexplained chronic fatigue and psychiatric morbidity: results from a community survey in Great Britain. *International Review of Psychiatry, 15*(1-2), 57-64. doi:10.1080/0954026021000045958

Smith, M. B., Nelson, H. D., Haney, E., Pappas, M., Daeges, M., Wasson, N., & McDonagh, M. (2016). *Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (July 2016 Addendum).* Evidence Reports/Technology Assessments, No. 219, Agency for Healthcare Research and Quality (US), Rockville. Retrieved October 17, 2017, from https://www.ncbi.nlm.nih.gov/books/NBK293931/

Sorenson, M., Furst, J., Mathews , H., & Jason, L. (2017). Dysregulation of Cytokine Pathways in Chronic Fatigue. *Fatigue: Biomedicine, Health & Behavior*, 1-14. doi:10.1080/21641846.2017.1335237

Sorenson, M., Jason, L., Peterson, J., Herrington, J., & Mathews, H. (2014). Brain Derived Neurotrophic Factor is Decreased in Chronic Fatigue Syndrome. *Journal of Neurology & Neurophysiology, S12*(S2-013), 1-6. doi:10.4172/2155-9562.S12-013

South Australian Department of Health. (2004). *ME/CFS Guidelines: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Management Guidelines for General Practitioners.* Retrieved September 20, 2017, from South Australian ME/CFS Association Inc: http://sacfs.asn.au/download/guidelines.pdf

Stern, K. (1995). Clinical Guidelines and the Law. In M. Deighan, & S. Hitch, *Clinical Effectiveness from Guidelines to Cost-effective Practice.* Brentwood, Essex: Earlybrave Publications.

Stouten, B. (2017). PACE GATE: An Alternative View on a Study With a Poor Trial Protocol. *Journal of Health Psychology, 22*(9), 1192-1197. doi:10.1177/1359105317707531

Sunnquist, M., Nicholson, L., Jason, L. A., & Friedman, K. J. (2017, April). Access to Medical Care for Individuals with Myalgic. *Modern Clinical Medicine Research,, 1*(1), 28-35. doi:10.22606/mcmr.2017.11005

Taylor, R. R., & Jason, L. (2001, October). Sexual Abuse, Physical Abuse, Chronic Fatigue, and Chronic Fatigue Syndrome: A Community-Based Study. *Journal of Nervous & Mental Disease, 189*(10), 709-715.

Taylor, R. R., Jason, L. A., & Jahn, S. C. (2003). Chronic Fatigue and Sociodemographic Characteristics as Predictors of Psychiatric Disorders in a Community-based Sample. *Psychosomatic Medicine, 65*(5), 896-901. doi:10.1097/01.psy.0000088580.28749.7f#

Tuller, D. (2017, June 25). *Trial by Error, Continued: Is PACE a Case of Research Misconduct?* Retrieved from Virology Blog: http://www.virology.ws/2017/06/24/trial-by-error-continued-is-pace-a-case-of-research-misconduct/

Twisk, F. M. (2016, Feb 5). Replacing Myalgic Encephalomyelitis and Chronic Fatigue Syndrome with System Exertion Intolerance Disease is Not The Way Forward. *Diagnostics (Basel), 6*(1), pii: E10. doi:10.3390/diagnostics6010010.

Twisk, F. N. (2014). The status of and future research into Myalgic Encephalomyelitis and Chronic Fatigue Syndrome: the need of accurate diagnosis, objective assessment, and acknowledging biological and clinical subgroups. *Frontiers in Physiology, 5*, 1-11. doi:10.3389/fphys-05-00109

Twisk, F. N. (2015). Accurate diagnosis of myalgic encephalomyelitis and chronic fatigue syndrome based upon objective test methods of characteristic stmptoms. *World Journal of Methodology, 5*(2), 68-87. doi:10.5662/wjm.v5.i2.68

Twisk, F. N. (2017a). An Accurate Diagnosis of Myalgic Encephalomyelitis and Chronic Fatigue Syndrome requires strict Clinical Case definitions and Objective Test Methods. *Journal of Medical Diagnostic Methods, 6*(3), 249. doi:10.4172/2168-9784.1000249

Twisk, F. N. (2017b). Studies and surveys implicate potential iatrogenic harm of cognitive behavioral therapy and graded exercise therapy for myalgic encephalomyelitis and chronic fatigue syndrome patients. *Research on Chronic Diseases, 1*(1), 13-14.

United Nations Development Programme. (1997). *Technical Adviroy Paper 2: Capacity Development.* Retrieved November 7, 2017, from Institute of Development Studies: http://www.eldis.org/vfile/upload/1/document/0803/ID2251.pdf

Various. (2017, August). Special Issue: The Pace Trial. *Journal of Health Psychology, 22*(9), 1103-1216.

Vink, M. (2017a, August 1). PACE trial authors continue to ignore their own null effect. *Journal of Health Psychology, 22*(9), 1134-1140. doi:10.1177/1359105317703785

Vink, M. (2017b). Assessment of Individual PACE Trial Data: in Myalgic. *Jounral of Neurology and Neurobiology, 3*(1), pp. 1-10. doi:10.16966/2379-7150.136

Vrijhoef, H. J., & Steuten, L. M. (2016). Can Scientific Evidence be Valid if Irrelevant to Patients? *International Journal of Care Coordination, 19*(1-2), 3–4. doi:10.1177/2053434516670209

Wessely, S., Chalder, T., Hirsch, S., Wallace, P., & Wright, D. (1997). The Prevalence and Morbidity of Chronic Fatigue and Chronic Fatigue Syndrome: A Prospective Primary Care Study. *American Journal of Public Health, 87*(9), 1449-1455.

White, P. D., Goldsmith, K. A., Johnson, A. L., Chalder, T., & Sharpe, M. (2013b). Letter to the editor: response to correspondence concerning 'recovery from chronic fatigue syndrome after treatments in the PACE trial'. *Psychological Medicine, 43*(8), 1791-1792. doi:10.1017/S0033291713001311

White, P. D., Goldsmith, K. A., Johnson, A. L., Potts, L., Walwyn, R., DeCesare, J. C., . . . Sharpe, M. (2011, March 5). Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *The Lancet, 377*(9768), 826-836.

White, P. D., Goldsmith, K., Johnson, A. L., Chalder, T., & Sharpe, T. (2013a, Oct). Recovery from chronic fatigue syndrome after treatments given in the PACE trial. *Psychological Medicine, 43*(10), 2227-2235. doi:10.1017/S0033291713000020

White, P. D., Sharpe, M. C., Chalder, T., DeCesare, J. C., & Walwyn, R. (2007). Protocol for the PACE trial: A randomised controlled trial of adaptive pacing, cognitive behaviour therapy, and graded exercise as supplements to standardised specialist medical care versus standardised specialist medical care alone for patients with the. *BMC Neurology, 7*, 6-26. doi:10.1186/1471-2377-7-6

Whiting, J. (2017, October 25). Tranitional Arrangments for the NDIS: Submission No. 80. Canberra: Parliament House of Australia. Retrieved November 6, 2017, from https://www.aph.gov.au/Parliamentary_Business/Committees/Joint/National_Disability_Insurance_Scheme/Transition/Submissions

Williams, A. M., Christopher, G., & Jenkinson, E. (2016, April 19). The psychological impact of dependency in adults with chronic fatigue syndrome/myalgic encephalomyelitis: A qualitative exploration. *Journal of Health Psychology*, 1-12. doi:10.1177/1359105316643376

Wilshire, C., Kindlon, T., Matthees, A., & McGrath, S. (2017). Can Patients With Chronic Fatigue Syndrome Really Recover After Graded Exercise or Cognitive Behavioural Therapy? A Critical Commentary and Preliminary Re-analysis of the PACE Trial. *Fatigue: Biomedicine, Health & Behavior, 5*(1), 43-56. doi:10.1080/21641846.2017.1259724

Wilson, A., Hickie, I., Lloyd, A., & Wakefield, D. (1994). The Treatment of Chronic Fatigue Syndrome: Science and Speculation. *The American Journal of Medicine, 96*(6), 544-550. doi:10.1016/0002-9343(94)90095-7

Winger, A., Kvarstein, G., Wyller, V. B., Ekstedt, M., Sulheim, D., Fagermoen, E., . . . Helseth, S. (2015). Health related quality of life in adolescents with chronic fatigue syndrome: a cross-sectional study. *Health and Quality of Life Outcomes*, 1-9. doi:10.1186/s12955-015-0288-3

Wolters Klower. (2017b). *UpToDate Terms of Use.* Retrieved November 10, 2017, from UpToDate: https://www.uptodate.com/contents/license

Wolters Kluwer. (2017a). *About Us.* Retrieved November 10, 2017, from UpToDate: https://www.uptodate.com/home/about-us

World Health Organization. (1969). WHO: International Classification of Diseases. *(ICD 8), Eighth*.

Wyller, V. B. (2007). The chronic fatigue syndrome - an update. *Acta Neurologica Scandinavica. Supplementum., 115*(S187), 7-14. doi:10.1111/j.1600-0404.2007.00840.x.

Yasui, M., Yoshimura, T., Takeuchi, S., Tokizane, K., Tsuda, M., Inoue, K., & Kiyama, H. (2014, September). A Chronic fatigue syndrome model demonstrates mechanical allodynia and muscular hyperalgesia via spinal microglial activation. *GLIA, 62*(9), 1407-1417. doi:10.1002/glia.22687

Zdunek, M., Jason, L. A., Evans, M., Jantke, R., & Newton, J. L. (2015). A Cross Cultural Comparison of Disability and Symptomatology Associated with CFS. *International Journal of Psychology and Behavioral Sciences, 5*(2), 98-107. doi:10.5923/j.ijpbs.20150502.07

Zinn, M. L., Zinn, M. A., & Jason, L. A. (2016a). Intrinsic Functional Hypoconnectivity in Core Neurocognitive Networks Suggests Central Nervous System Pathology in Patients with Myalgic Encephalomyelitis: A Pilot Study. *Applied Psychophysiology and Biofeedback, 41*(3), 283-300. doi:10.1007/s10484-016-9331-3

Zinn, M. L., Zinn, M. A., & Jason, L. A. (2016b). qEEG / LORETA in Assessment of Neurocognitive Impairment in a Patient with Chronic Fatigue Syndrome: A Case Report. *Clinical Research, 2*(1), 1-3. doi:10.16966/2469-6714.110

Zinn, M. L., Zinn, M. A., & Jason, L. A. (2016c). Functional Neural Network Connectivity in Myalgic Encephalomyelitis. *Neuroregulation, 3*(1), 28-50. doi:10.15540/nr.3.1.28

Annexure 1 – Extract of National Disability Insurance Scheme (Becoming a Participant) Rules 2016

The following are extracts of Parts 5 to 7 of the Rules.

Part 5 When does a person meet the disability requirements?

5.1 The Act sets out when a person ***meets the disability requirements***. The requirements are met if:

(a) the person has a disability that is attributable to one or more intellectual, cognitive, neurological, sensory or physical impairments, or to one or more impairments attributable to a psychiatric condition; and

(b) the person's impairment or impairments are, or are likely to be, permanent (see paragraphs 5.4 to 5.7); and

(c) the impairment or impairments result in substantially reduced functional capacity to undertake, or psychosocial functioning in undertaking, one or more of the following activities: communication, social interaction, learning, mobility, self-care, self-management (see paragraph 5.8); and

(d) the impairment or impairments affect the person's capacity for social and economic participation; and

(e) the person is likely to require support under the NDIS for the person's lifetime.

5.2 In relation to the above, an impairment that varies in intensity (for example because the impairment is of a chronic episodic nature) may be permanent, and the person is likely to require support under the NDIS for the person's lifetime, despite the variation.
Paragraphs 5.1 and 5.2 summarise section 24 of the Act.

5.3 This Part sets out rules relating to some of the elements in paragraph 5.1 above, however, in order to meet the disability requirements, all of the requirements in that paragraph need to be satisfied.

When is an impairment permanent or likely to be permanent for the disability requirements?

5.4 An impairment is, or is likely to be, permanent (see paragraph 5.1(b)) only if there are no known, available and appropriate evidence-based clinical, medical or other treatments that would be likely to remedy the impairment.

5.5 An impairment may be permanent notwithstanding that the severity of its impact on the functional capacity of the person may fluctuate or there are prospects that the severity of the impact of the impairment on the person's functional capacity, including their psychosocial functioning, may improve.

5.6 An impairment may require medical treatment and review before a determination can be made about whether the impairment is permanent or likely to be permanent. The impairment is, or is likely to be, permanent only if the impairment does not require further medical treatment or review in order for its permanency or likely permanency to be demonstrated (even though the impairment may continue to be treated and reviewed after this has been demonstrated).

5.7 If an impairment is of a degenerative nature, the impairment is, or is likely to be, permanent if medical or other treatment would not, or would be unlikely to, improve the condition.
Paragraphs 5.4 to 5.7 are made for the purposes of paragraph 27(a) of the Act.

When does an impairment result in substantially reduced functional capacity to undertake relevant activities?

5.8 An impairment results in substantially reduced functional capacity of a person to undertake one or more of the relevant activities—communication, social interaction, learning, mobility, self-care, self-management (see paragraph 5.1(c))—if its result is that:

(a) the person is unable to participate effectively or completely in the activity, or to perform tasks or actions required to undertake or participate effectively or completely in the activity, without assistive technology, equipment (other than commonly used items such as glasses) or home modifications; or
(b) the person usually requires assistance (including physical assistance, guidance, supervision or prompting) from other people to participate in the activity or to perform tasks or actions required to undertake or participate in the activity; or
(c) the person is unable to participate in the activity or to perform tasks or actions required to undertake or participate in the activity, even with assistive technology, equipment, home modifications or assistance from another person.

Paragraph 5.8 is made for the purposes of paragraph 27(b) of the Act.

Part 6 When does a person meet the early intervention requirements?

6.1 A person does not ***meet the early intervention requirements*** if the CEO is satisfied that early intervention support for the person is more appropriately funded or provided through another service system (***service systems*** is defined in paragraph 8.4) rather than the NDIS.

6.2 However, a person ***meets the early intervention requirements*** if:

(a) the person:
(i) has one or more identified intellectual, cognitive, neurological, sensory or physical impairments that are, or are likely to be, permanent (see paragraphs 6.4 to 6.7); or
(ii) has one or more identified impairments that are attributable to a psychiatric condition and are, or are likely to be, permanent (see paragraphs 6.4 to 6.7); or
(iii) is a child who has developmental delay; and
(b) the CEO is satisfied that provision of early intervention supports for the person is likely to benefit the person by reducing the person's future needs for supports in relation to disability (see paragraphs 6.8 to 6.11); and
(c) the CEO is satisfied that provision of early intervention supports for the person is likely to benefit the person by:
(i) mitigating or alleviating the impact of the person's impairment upon the functional capacity of the person to undertake communication, social interaction, learning, mobility, self-care or self-management; or
(ii) preventing the deterioration of such functional capacity; or
(iii) improving such functional capacity; or
(iv) strengthening the sustainability of informal supports available to the person, including through building the capacity of the person's carer (see paragraphs 6.8 to 6.11).

Paragraph 6.1 summarises subsection 25(3) of the Act. Paragraph 6.2 summarises subsection 25(1) of the Act.

6.3 This Part sets out rules relating to some of the elements in paragraph 6.2 above, however, in order to meet the early intervention requirements, all of the requirements in that paragraph need to be satisfied.

When is an impairment permanent or likely to be permanent for the early intervention requirements?

6.4 An impairment is, or is likely to be, permanent (see paragraphs 6.2(a)(i) and (ii)) only if there are no known, available and appropriate evidence-based clinical, medical or other treatments that would be likely to remedy the impairment.

6.5 An impairment may be permanent notwithstanding that the severity of its impact on the functional capacity of the person may fluctuate or there are prospects that the severity of the impact of the impairment on the person's functional capacity may improve.

6.6 An impairment may require medical treatment and review before a determination can be made about whether the impairment is permanent or likely to be permanent. The impairment is, or is likely to be, permanent only if the impairment does not require further medical treatment or review in order for its permanency or likely permanency to be demonstrated (even though the impairment may continue to be treated and reviewed after this has been demonstrated).

6.7 If an impairment is of a degenerative nature, the impairment is, or is likely to be, permanent if medical or other treatment would not, or would be unlikely to, improve the condition.
Paragraphs 6.4 to 6.7 are made for the purposes of paragraph 27(a) of the Act.
Deciding whether provision of early intervention supports is likely to benefit the person

6.8 Where paragraph 6.2(a) applies to a person, the main way in which the CEO can determine whether the provision of early intervention supports is likely to benefit the person in the ways set out in paragraphs 6.2(b) and (c) above is to consider evidence going to those matters, as indicated in paragraph 6.9 below. However, young children who have an impairment resulting in developmental delay (see paragraph 6.10) or resulting from a particular condition (see paragraph 6.11) will not need to provide further evidence of the matters in paragraphs 6.2(b) and (c).
Paragraph 6.8 is made for the purposes of paragraph 27(d) of the Act.

Where evidence is required
6.9 In deciding whether provision of early intervention supports is likely to benefit the person in the ways mentioned in paragraphs 6.2(b) and (c) above, it is expected that the CEO would consider:

(a) the likely trajectory and impact of the person's impairment over time; and
(b) the potential benefits of early intervention on the impact of the impairment on the person's functional capacity and in reducing their future needs for supports; and
(c) evidence from a range of sources, such as information provided by the person with disability or their family members or carers. The CEO may also in some cases seek expert opinion.

Paragraph 6.9 is made for the purposes of paragraph 27(d) of the Act. It does not compel the CEO to take the actions mentioned in that paragraph in any particular instance.

Early intervention in early childhood
6.10 The CEO is taken to be satisfied that provision of early intervention supports for a child under the age of 6 is likely to benefit the child in the ways mentioned in paragraphs 6.2(b) and (c) above if one or more of the child's impairments is a mental or physical impairment which, by itself or in combination with other mental or physical impairments, results in developmental delay.
Note: ***Developmental delay*** is defined in section 9 of the Act as a delay in the development of a child under 6 years of age that:

(a) is attributable to a mental or physical impairment or a combination of mental and physical impairments; and
(b) results in substantial reduction in functional capacity in one or more of the following areas of major life activity:
(i) self-care;
(ii) receptive and expressive language;
(iii) cognitive development;
(iv) motor development; and

(c) results in the need for a combination and sequence of special interdisciplinary or generic care, treatment or other services that are of extended duration and are individually planned and coordinated.

6.11 The provision of early intervention supports is likely to benefit a child aged 6 or under in the ways mentioned in paragraphs 6.2(b) and (c) above in the circumstance that one or more of the child's impairments results from a condition which is on a list of conditions published by the CEO for which evidence has established that early intervention supports will have these benefits.
Paragraph 6.10 is made for the purposes of subsection 25(2) of the Act. Paragraph 6.11 is made for the purposes of paragraphs 27(d), (e) and (f) of the Act.

Part 7 Assessing whether a person meets the disability or early intervention requirements
7.1 In deciding whether a prospective participant meets the disability requirements or the early intervention requirements, the CEO may, if the CEO considers it appropriate, conduct an assessment, which is to be done using an assessment tool specified in operational guidelines in accordance with this Part from time to time.

Specification of assessment tools in guidelines
7.2 The CEO may specify, in operational guidelines, assessment tools that may be used for the purposes of deciding whether a person meets the disability requirements or the early intervention requirements.

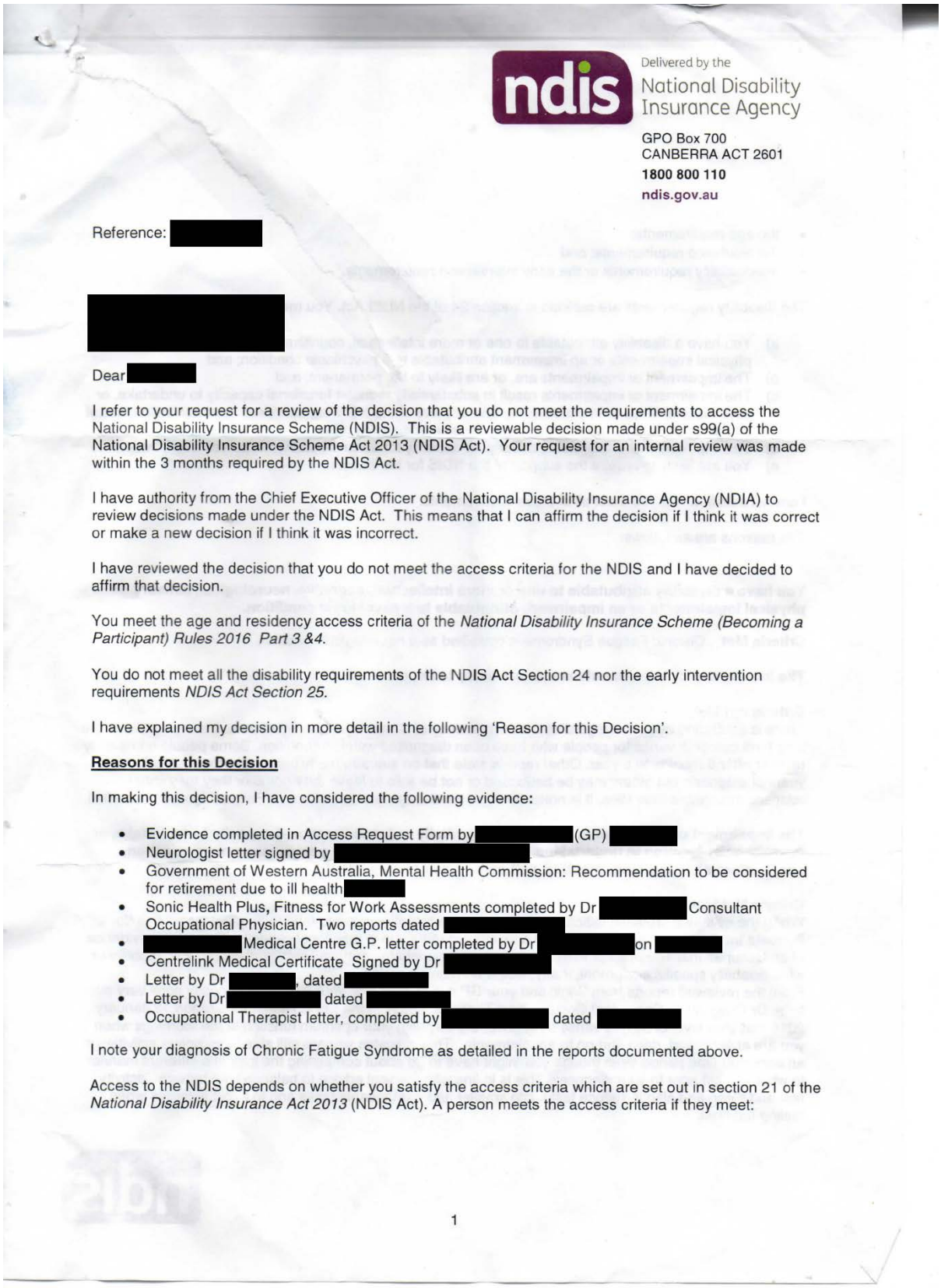
7.3 A tool specified under paragraph 7.2 may be the same as a tool specified under paragraph 4.4 of the *National Disability Insurance Scheme (Supports for Participants) Rules 2013*.

7.4 Without limitation, the CEO may specify:
(a) different tools to be used for adults and children; and
(b) tools that are specifically tailored to particular impairments.

7.5 A tool must:
(a) be designed to ensure the fair and transparent assessment of whether a person meets the disability requirements or the early intervention requirements; and
(b) have reference to areas of activity and social and economic participation identified in the World Health Organisation International Classification of Functions, Disability and Health as in force from time to time.

This Part is made for the purposes of subsection 209(2A) of the Act.

Annexure 2 – Sample Letter of Rejection



Delivered by the
National Disability Insurance Agency

GPO Box 700
CANBERRA ACT 2601
1800 800 110
ndis.gov.au

Reference: [redacted]

[redacted]

Dear [redacted]

I refer to your request for a review of the decision that you do not meet the requirements to access the National Disability Insurance Scheme (NDIS). This is a reviewable decision made under s99(a) of the National Disability Insurance Scheme Act 2013 (NDIS Act). Your request for an internal review was made within the 3 months required by the NDIS Act.

I have authority from the Chief Executive Officer of the National Disability Insurance Agency (NDIA) to review decisions made under the NDIS Act. This means that I can affirm the decision if I think it was correct or make a new decision if I think it was incorrect.

I have reviewed the decision that you do not meet the access criteria for the NDIS and I have decided to affirm that decision.

You meet the age and residency access criteria of the *National Disability Insurance Scheme (Becoming a Participant) Rules 2016 Part 3 &4.*

You do not meet all the disability requirements of the NDIS Act Section 24 nor the early intervention requirements *NDIS Act Section 25.*

I have explained my decision in more detail in the following 'Reason for this Decision'.

Reasons for this Decision

In making this decision, I have considered the following evidence:

- Evidence completed in Access Request Form by [redacted] (GP) [redacted]
- Neurologist letter signed by [redacted]
- Government of Western Australia, Mental Health Commission: Recommendation to be considered for retirement due to ill health [redacted]
- Sonic Health Plus, Fitness for Work Assessments completed by Dr [redacted] Consultant Occupational Physician. Two reports dated [redacted]
- [redacted] Medical Centre G.P. letter completed by Dr [redacted] on [redacted]
- Centrelink Medical Certificate Signed by Dr [redacted]
- Letter by Dr [redacted], dated [redacted]
- Letter by Dr [redacted] dated [redacted]
- Occupational Therapist letter, completed by [redacted] dated [redacted]

I note your diagnosis of Chronic Fatigue Syndrome as detailed in the reports documented above.

Access to the NDIS depends on whether you satisfy the access criteria which are set out in section 21 of the *National Disability Insurance Act 2013* (NDIS Act). A person meets the access criteria if they meet:

1

- the age requirements;
- the residence requirements; and
- the disability requirements or the early intervention requirements.

The disability requirements are outlined in section 24 of the NDIS Act. You meet these requirements if:

a) You have a disability attributable to one or more intellectual, cognitive, neurological, sensory or physical impairments or an impairment attributable to a psychiatric condition; and
b) The impairment or impairments are, or are likely to be, permanent; and
c) The impairment or impairments result in substantially reduced functional capacity to undertake, or psychosocial function in undertaking, one or more of the following activities: communication, social interaction, learning, mobility, self-care or self-management; and
d) The impairment or impairments affect your capacity for social or economic participation; and
e) You are likely to require the support of the NDIS for his lifetime.

I am not satisfied that you meet all of these requirements.

The reasons are as follows:

You have a disability attributable to one or more intellectual, cognitive, neurological, sensory or physical impairments or an impairment attributable to a psychiatric condition.

Criteria Met Chronic Fatigue Syndrome is classified as a neurological condition.

The impairment or impairments are, or are likely to be, permanent

Criteria not Met
There is conflicting evidence regarding the permanency of Chronic Fatigue Syndrome. It is reported that the long term outcome varies for people who have been diagnosed with the condition. Some people completely recover after 6 months to a year. Other reports state that on average many people improve in the first five years of diagnosis but others may be bedbound or not be able to leave their home or they may suffer relapses throughout their lives. It is noted that you were diagnosed with Chronic Fatigue Syndrome in 2014.

The impairment or impairments result in substantially reduced functional capacity to undertake, or psychosocial function in undertaking, one or more of the following activities: communication, social interaction, learning, mobility, self-care or self-management;

Criteria Not Met
Whilst the evidence provided indicates you have some limitations due to fatigue and that symptoms do fluctuate the limitations do not constitute a significant reduction in functional capacity. There is no evidence of an Occupational Therapist or Physiotherapist assessment to verify any substantially reduced mobility or what disability specific equipment, if any, would be recommended.
From the reviewed reports from [redacted] and your GP it is evident that your functional capacity does vary over time. Dr [redacted] Consultant Occupational Therapist states in the [redacted] report [redacted] 2016 that your level of fatigue varies throughout the day with your optimum function in the mornings when you are able to read, drive and go to appointments. This indicates you are still able to complete activities in an accepted time period even though you might have to go about completing the task in a different manner to what you did prior to your diagnosis This is in line with medical advice to balance time between activity, rest and sleep and also to reduce tasks into smaller and manageable tasks and to avoid activities when feeling too tired.

It is also noted you stated in this report you are able to perform all normal activities of daily living to some extent but have a housekeeper who attends every fortnight and does washing and other household chores. It is further reported you are able to perform activities such as shopping, can tolerate sitting for up to two hours, standing for up to an hour, walking for up to an hour, lifting up to 2kg depending on the time of day as this can cause palpitations, climbing and descending one flight of stairs.

The Disability Requirements as set out in the NDIA Operational Guidelines state

"A person will be considered to be unable to participate effectively or completely in an activity if they cannot safely complete one or more of the tasks required to participate in an acceptable period of time. Undertaking a task more slowly or differently to others will not necessarily mean a person cannot participate effectively or completely in an activity."

It is additionally acknowledged that Chronic Fatigue Syndrome symptoms are related to mood and can therefore, vary from day to day. Given your past medical history of Post Natal Depression and Anxiety this may impact on your symptoms and therefore, your functional capacity. However, there is no evidence that this is resulting in a substantially reduced functional capacity in your life domain areas of learning or self-management.

The prognosis for an individual with CFS cannot be predicted with certainty. Literature reviewed indicates that those who receive early and extensive rehabilitation are reported to get better. Other reports indicate that a return to premorbid function is rare. It is also reported that work status is an important predictor of recovery.

The impairment or impairments affect your capacity for social or economic participation;

Criteria met.
It is acknowledged that your diagnosis affects your social or economic participation. Reports provided confirm you do not have a medical clearance to return to work as you are unable to safely perform the inherent requirements of your position of Senior Human Resources Officer. It was considered unlikely that significant improvements in your health would occur in a specific timeframe and a recommendation was made to the Commissioner for retirement on the grounds of ill health.

Likely to require the support of the NDIS for her lifetime.

Criteria not met.
As permanency is not confirmed neither can it be stated that you are likely to require NDIS support for your lifetime

As you do not satisfy the above disability requirements, you may still satisfy the early intervention requirements, and be able to access the NDIS. Under section 25 of the NDIS Act 2013. Consideration has also been given to this. You will meet the early intervention requirements if:

a) You have one or more identified intellectual, cognitive, neurological, sensory or physical impairments that are, or are likely to be permanent; or

Criterion met

For the same reasons as it is not met for Access under disability as stated above.

b) The CEO is satisfied that provision of early intervention supports is likely to benefit you by reducing your future needs for supports in relation to your disability; and

Criterion not met
The predominant early intervention for your condition is directly related to your health with the aim of symptom relief and improving your functional capacity. This includes rehabilitation services, best provided through the Health system.

c) The CEO is satisfied that provision of early intervention supports are likely to benefit you by:
   i. Mitigating or alleviating the impact of his impairment upon your functional capacity to undertake communication, social interaction, learning, mobility, self-care or self-management; or
   ii. preventing the deterioration of such functional capacity; or
   iii. improving such functional capacity; or
   iv. strengthening the sustainability of informal supports available to you including through building the capacity of the person's carer.

Criteria not met
Any intervention required, early or otherwise, is more appropriately provided through the health system to manage the symptomology of your diagnosis. Whilst it is considered that further multidisciplinary treatment would be beneficial to mitigating or alleviating the impact of Chronic Fatigue Syndrome on your functional capacity this intervention is more appropriately provided through the Health and allied health systems.

On the basis of these reasons I have decided not to change the decision.

If you believe my decision is wrong you can apply for an external review by the Administrative Appeals Tribunal (AAT). You must do this within 28 calendar days of receiving this letter. Further information is available on the AAT website or you can call 1300 366 700.

Additionally, there are services that can support you in seeking a review through the National Disability Advocacy Program. More information is available on the DSS website

If you have any questions in relation to this letter, you can contact the NDIS in any of the following ways:

- Contact us on 1800 800 110
- If you are a TTY user, phone 1800 555 677 and ask for 1800 800 110
- If you are a Speak and Listen (speech-to-speech relay) user – phone 1800 555 727 and ask for 1800 800 110
- If you are an internet relay user, visit the National Relay Service website and ask for 1800 800 110
- Send an email to [redacted]@ndis.gov.au

For more information, go to the NDIS website.

Yours sincerely

[redacted]

Internal Review Manager
Delegate of Chief Executive Officer

National Disability Insurance Agency

[redacted]2017

[redacted]

Internal Review Officer
Delegate of Chief Executive Officer

National Disability Insurance Agency

5

ndis