From: s22(1) Jacalyn on behalf of s22(1)(a Chris
To: Geoffrey s47F
Subject: RE: INVITATION TO MEET WITH NDIA [SEC=UNOFFICIAL]
Date: Tuesday, 21 April 2020 5:10:00 PM
Attachments: image001.png

Hi Geoffrey
On behalf of Chris, I would like to acknowledge receipt of your email below.
Kind regards,
Jacalyns22(1)(a)(
Executive Assistant to Chris Faulkner
Operations and Support Division
National Disability Insurance Agency
Phones22(1)(a)(ii) - ir
Mobiles22(1)(a)(ii) - ir
Email jacalyns22(1)(a)(@ndis.gov.au

From: Geoffreys47F - pe <geoffreys47F - pe@mecfs.org.au>
Sent: Tuesday, 21 April 2020 1:37 PM
To: FAULKNER, Chris <.@..>
Cc: ME/CFS Australia Ltd Info <@..>; Joh s47F - personal priv @gmail.com>
Subject: INVITATION TO MEET WITH NDIA
cc: Dr. Johns47F - pe (ME/CFS Australia Specialist Medical Advisor)
Dear Chris
Please find attached the following:

1. Correspondence of today's date;

2. ME/CFS Australia submission with respect to the current NDIS ME/CFS assessment policy;

Kind regards
Geoffreys47F - personal privacy
Chair - ME/CFS Australia

ME/CFS Australia Ltd
ABN: 23 088 896 299
ACN: 088 896 299
Ph: s22(1)(a)(ii) - Irrelevant material Chair)
Postal: PO Box 6176, Upper Mount Gravatt QLD 4122
Registered Office: 13 Forestoak Way Goonellabah NSW 2480
Email: info@mecfs.org.au **Website:** www.mecfs.org.au

21 April 2020

Ms. Chris Faulkner
General Manager
Operations Division
National Disability Insurance Agency
GPO Box 700
CANBERRA ACT 2601

Via Email: chris.faulkner@ndis.gov.au

Dear Ms. Faulkner,

Re: Invitation for Meeting

I am writing to you to request a meeting to discuss significant issues with the current exclusion of ME/CFS from the NDIS. While we appreciate that the COVID-19 pandemic will be a current priority for the NDIA, the pandemic is exacerbating the urgency of need for people who are severely disabled by ME/CFS.

On 11 July 2018 ME/CFS Australia Ltd received your invitation to attend a meeting with yourself, to discuss the issues of the NDIS. Following that invitation, ME/CFS Australia corresponded with Kate s47F - persona Director A/G, Advisory Team, Technical Advisory and Complaints Branch. Through this correspondence Ms. s47F - perso kindly outlined the foundation upon which claims were being assessed at the NDIA.

Once we reviewed the foundation, we committed to responding with a detailed, appropriately researched response. This process has taken time, and given the fluid environment in which ME/CFS operates, we have had to adjust to new information and events.

Following the instigation of the NHMRC's ME/CFS Advisory Committee and its review of the literature, it was anticipated that the appropriateness of available clinical guidelines would be examined, and subsequent recommendations made. Also, we had reason to anticipate expression of a position with respect to ME/CFS access under the NDIS. We operated on the belief that the Advisory Committee's report was imminent, thus did not pursue our meeting with you at that stage.

The NHMRC ME/CFS Advisory Committee's report was released on 18 July 2019. The report highlights significant issues with the evidence base relied upon by the NDIA, particularly in regard to treatment and prognosis of ME/CFS. In light of the Report's findings, and with reference to feedback received from our members, ME/CFS Australia has prepared a comprehensive submission for your consideration.

I have enclosed a copy of correspondence from the NHMRC's CEO, Professor Anne s47F - person, dated 18 October 2019 for your reference. This correspondence confirms that the CEO has accepted the Committee's recommendations in April 2019. These recommendations, which are summarised on page vi of the Report, incorporate reference to clinical guidance and an undertaking in regard to access to the NDIS.

I appreciate that our submission is detailed and may take some time to review. The Executive Summary of the attached document outlines our key concerns and the matters we wish to discuss.

I look forward to discussing a mutually agreeable date to meet with you. As per your request, we anticipate the attendees would be: Ms. Penelope s47F - personal privacy (Board Director, Chair of ME/CFS South Australia, and member of the NHMRC ME/CFS Advisory Committee); Dr. John s47F - personal priva (Specialist Physician and Medical Advisor to ME/CFS Australia); and myself. In light of the COVID-19 situation, we would be happy to achieve this via Skype, Zoom or a conference call.

Yours sincerely,

Geoffrey s47F - personal privacy
Chair, ME/CFS Australia Ltd

ME/CFS Australia

submission to

ndia National Disability Insurance Agency

21 April 2020

Table of Contents

Executive Summary

What is ME/CFS Australia?

ME/CFS Australia Ltd. is a registered charity which has been the peak body for ME/CFS within Australia since 1999. ME/CFS Australia is made up of member States and other organisations representing the majority of people with ME/CFS throughout Australia. ME/CFS Australia is the national advocate for those member organisations and together, form a collaborative network and voice.

Definitions

ME refers to Myalgic Encephalomyelitis. CFS refers to Chronic Fatigue Syndrome. The organisation utilises the combined acronym of ME/CFS to include patients diagnosed under the various criteria for ME, CFS and ME/CFS.

NHMRC Recommendations

On 18 July 2019, the NHMRC ME/CFS Advisory Committee ('the Committee') provided a detailed report to the NHMRC CEO, Professor Anne Kelso. The report included a number of specific recommendations to the CEO, including recommendations to support research and treatment options for ME/CFS. The Committee was composed of ME/CFS stakeholders, clinicians and patient advocates – a diverse group representing the medical complexities of ME/CFS.

The national organisation received confirmation on 18 October 2019 that the Committee's recommendations of April 2019 had been accepted by the NHMRC CEO, Professor Anne Kelso (encl.).

ME/CFS Australia is of the view that the Committee's report represents a broad understanding of the needs of patients, including identifying the fact that the current Australian treatment guidelines are not fit for purpose and the inappropriateness of current NDIA assessment policy. The recommendations acknowledged the change in the global ME/CFS research conversation and captured the disconnect between Australian biopsychosocial treatments and the lived experience of patients with ME/CFS.

On the specific issue of NDIS access, the Committee expressed their views under point 4.5.3 entitled National Disability Insurance Scheme and access to supportive services. The report is succinct in its description of the difficulties ME/CFS patients experience to gain access to the scheme. To quote the document:-

> *Advocates have raised concern about the lack of understanding of the condition by National Disability Insurance Agency (NDIA) assessors, and the rejection of claims of people who are significantly impaired. Patients have indicated that a requirement of NDIS is that ME/CFS patients undergo graded exercise therapy and/or cognitive behavioural therapy before they can access NDIS, DSP or supportive services. To access care through the NDIS and DSP patients need to show they have a significant disability. For these ME/CFS patients, graded exercise therapy may not be appropriate. The following summarises the submissions' proposed recommendations to NDIS:*

- *recognition of ME/CFS as a serious debilitating condition*
- *the condition should be listed on the NDIS under list B: neurological disorders*
- *that assessment guidelines for NDIA assessors be developed in collaboration with clinicians with expertise in management of ME/CFS and the ME/CFS community.*

We would also like to draw your attention to point 5.3.3.1 of the NHRMC report entitled "Australian ME/CFS Clinical Practice Guidelines". The report states that the 2002 RACP CFS Guidelines are to be updated and/or replaced by NHMRC developed clinical guidelines, which better represent clinical pathways for ME/CFS. Please note that the report supports the use of a consistent diagnostic criteria for clinical use and research.

ME/CFS Australia supports this recommendation and sees it as one of the key underlying issues in the ongoing disconnect between the symptoms of chronic fatigue and the disabling condition, ME/CFS. Older research outcomes, such as the The Dubbo Study and the Cochrane – In reviewing psychotherapies for functional syndrome (including CFS), the authors identified multiple methodological concerns in psychotherapy trials, including the high drop out rates and the selection bias in sampling.. This criticism from Cochrane raises the credibility of ME/CFS Australia's assertions that studies with respect to ME/CFS are inherently flawed, particularly PACE; are in question due to the limited applicability of the studies to more recent diagnostic criteria which include Post Exertional Malaise as a defining symptom. The NHMRC ME/CFS Advisory Committee report recommended the use of an adaption of the Canadian Consensus Criteria or International Consensus Criteria.

Current Policy Concerns

In the correspondence dated 15 August 2018, the writer stated that the NDIA had consulted with Professor Andrew Lloyd from the University of New South Wales. ME/CFS Australia is well versed with Professor Lloyd's background and research portfolio.

It was indicated that Professor Lloyd NDIA Policy across various key points, including the aetiology of ME/CFS, medical and allied health specialities involved in diagnosis and treatment, clinically indicated treatment options for the condition, likelihood of permanency, and the prevalence of ME/CFS being diagnosed as a stand-alone condition as opposed to being part of a comorbidity. He additionally provided information "regarding the evidence and research regarding Graded Exercise Therapy (GET) and Cognitive Behavioural Therapy (CBT)".

ME/CFS Australia has devoted significant time and efforts to reviewing the literature upon which Professor Lloyd bases his opinion. It was noted that a significant portion of this comes from his own research (approximately 30%), and much of which was outdated, and most of which was grounded in the biopsychosocial model. A number of articles were in the process of review because the approach to treatment and the evidence base surrounding it was called into question. We also found significant contradictions and discrepancies within the evidence base provided, which we believe the NDIA needs to be aware of.

With respect to Professor Lloyd's opinion as to treatment requirements for ME/CFS and the efficacy of those approaches, ME/CFS Australia, along with all patient organisations throughout Australia, stand at odds with the view. Moreover, it is contrary to the current, established biomedical research findings. It stands contrary to the position of the US Centres for Disease Control which has expressly dropped the program put forward by Professor Lloyd and unequivocally stated "Exercise is

not a cure for ME/CFS". Most significantly, ME/CFS Australia asserts that the research relied upon does not claim cure, nor indicate any significant indicators that the proposed treatment provide any significant benefits, and certainly does not demonstrate any long term resolution to the condition.

Respectfully, Professor Lloyd's opinion is fatigue centric. It is based on a broader definition of CFS in which fatigue is the primary focus without due regard for the other symptoms of the condition - particularly the cardinal symptom of Post-Exertional Malaise. This approach does not accord with the generally accepted definitions applied by ME/CFS biomedical researchers - especially here in Australia and as endorsed by the NHMRC report. The detailed explanation of our concerns can be found in our attached PRELIMINARY MATTERS.

ME/CFS Australia does take particular umbrage with Professor Lloyd's specific requirements expressed as follows:

> *[ME/CFS must have] been present in a stable, non-improving pattern, despite evidence-based management (such as … CBT … GET … and cognitive remediation) for 5 years the Australian expert guidelines indicate that the condition should be regarded as permanent for medico-legal purposes.*

To the knowledge of this organisation, cognitive remediation is not offered by any other clinic in Australia or the world. It is only offered within Professor Lloyd's Fatigue Clinic in NSW. There have been no replication studies for his work, and the only large study on it is his own, and it includes patients with cancer related fatigue - hence is a fatigue focused study - not an ME/CFS study. The treatment does not appear in the RACP 2002 guidelines nor any other guideline anywhere in the world. It is certainly not an NHMRC ME/CFS Advisory Committee recommendation - a body upon which Professor Lloyd was a member. Pragmatically with a small clinic of limited resources located only in Sydney, It is simply impossible for the vast majority of patients to *No Centres* – The Fatigue Clinic is based in Sydney. There is a facility in Melbourne that purports to deliver CBT, not uniform in approach with Sydney. Outside of these locations, there is nothing, hence it is impossible for people to access. Again, Rule 5.4. of the *Rules* requires that the treatment be available. For the majority of Australians, there is no availability;, let alone comply with in order to access the NDIS.

Based on its review and consideration of external research, ME/CFS Australia are very concerned that the NDIA has only sought the view of one practitioner with experience in ME/CFS - a practitioner with a very narrow, polarised view of the condition. There is simply no patient organisation that supports his views, let alone his research. He and his researchers have never involved a consumer organisation in that research. That, in our view, is a telling sign here, as to the inappropriateness of the approach.

ME/CFS Australia is of the view that any policy approach should be drawn from consultation with clinical and other experts across the biomedical field who address ME/CFS. .Most importantly, a diverse clinical understanding of the condition can provide an expert opinion of the viability of any potential treatments, identify potential limitations, as well as potential harms that might limit their viability or general application.

<u>Guidelines Concerns</u>

ME/CFS Australia also holds concerns that the NDIA have relied upon the RACP 2002 and 2007 NICE CFS Guides. The criteria deferred to in the NICE Guides do not reflect that used in Australia, and are

13 years old. The medical and health framework in which they are set simply Lack of Available Resources, hence they have no practical application even if they were valid. Due to their age, and questions as to their fitness for purpose, these guidelines have been undergoing review for over two years now.

The RACP Guidelines are 18 years old and defer to literature in the realm of 20 to 30 years old. Both documents defer to criteria which apply to broader chronically fatiguing conditions - not ME/CFS. The NICE Guides are simply not compatible with Australian medical framework - the care provided in the guidelines is not available in Australia.

The NHMRC report discussed the review of CBT/GET efficacy outcomes, such as the Cochrane Review - a commonly cited publication in ME/CFS literature which has been translationally applied to ME/CFS clinical guidelines. This review is now complete and amendments made, but the editor-in-chief of Cochrane conditioned those changes, stating "This amended review is still based on a research question and a set of methods from 2002, and reflects evidence from studies that applied definitions of ME/CFS from the 1990s." Again, the Cochrane review is grossly outdated, and based on unsafe criteria and research methodology, hence it is not appropriate to apply here in Australia today.

Patient Concerns

Within the ME/CFS community, many have expressed concerns with respect to the NDIS application and administration across a variety of issues. Reports include rejected applications, communication channel difficulties and unknown expectations. Those few who have access have identified that the planners are not listening to their needs, nor addressing them with appropriate solutions. The net result of these engagements is the further deterioration in the condition itself, resulting in lower capacity and an exacerbation of impairments. Adding to patient concern, is the lack of understanding of ME/CFS by the NDIA leading to inconsistent decision making across Australia.

Three common reasons cited by our community for exclusion from the scheme include;

- that ME/CFS is a medical condition and not a disability;
- that the condition is not a disability because it is not permanent; and
- that the condition does not result in a substantial reduction of the various activities, hence it is does not raise an impairment;

The NDIA correspondence makes it clear that applications are being assessed against the criteria provided by Professor Lloyd. It is inherently apparent that the requirements set out by Professor Lloyd are creating hurdles that are leading to the denial of applications on the above grounds.

ME/CFS Australia is firmly of the view that these requirements are flawed and causing unnecessary delay in otherwise valid applications.

Discussion Points

ME/CFS Australia therefore see the key discussion points for our meeting as:

1. Discussion of the inclusion of ME/CFS into List B as recommended by the NHMRC ME/CFS Advisory Committee – linking the NHMRC's recommendations to current patient requirements under the NDIS;

2. Formation of an ME/CFS advisory group with the aim to establish NDIS policy which supports our ME/CFS cohort based on contemporary research and clinical experience;

3. Discussion of how ME/CFS Australia can best support our community to successfully apply for the NDIS, particularly the moderate to severely ill;

4. Discussion of the provision of services by ME/CFS Australia to those not covered by the NDIS

1. PRELIMINARY MATTERS

1.1. Definitions

For clarity, a reference to ME is a reference to Myalgic Encephalomyelitis and a reference to CFS refers to Chronic Fatigue Syndrome.

1.2. Nomenclature

For the purpose of clarity, the ME/CFS in our organisation's name represents an 'all-inclusive' term, encompassing CFS (as set out in the 1994 criteria), ME/CFS (as set out in the 2003 Carruthers, et al consensus criteria) and ME (as set out in the criteria of 1988 Ramsay and the distinct ICC criteria of the 2011 Carruthers, et al documents).

1.3. Brief Background

In approximately May 2017, ME/CFS Australia Ltd initiated contact with the NDIS and attempted to engage the NDIA/NDIS on the specific issue of ME/CFS given significant feedback from individuals indicating that their applications had been rejected on the basis that ME/CFS was a medical condition not a disability. Most significantly, the members were reporting that the NDIA was stating that ME/CFS was not permanent.

Multiple contacts were made with the NDIS with a view to discussing the potential for a List B categorisation and clarification of the NDIA policy with respect to ME/CFS. Ultimately via contact with the CEO in 2018, the NDIA began engagement with ME/CFS Australia. Discussions were held with Ms. Faulkner around the ME/CFS issue, and access to the NDIA policy.

ME/CFS Australia was provided an insight into NDIA policy considerations with respect to ME/CFS via Ms. Kate s47F - persona Director A/G, Advisory Team, Technical Advisory and Complaints Branch, who was kind enough to outline the foundation of the policy in her correspondence of 15 August 2018.

2. OPERATIONAL POSITION

Feedback to ME/CFS Australia from applicants to the NDIS have indicated that there is a consistent position being expressed that ME/CFS, CFS and ME are not permanent conditions and most significantly, the NDIA has expressed a position that most people recover. This appears to be the default position.

3. THE TOPIC OF DISCUSSION

3.1. NDIA Policy

Ms. Agus had confirmed the following:

1. The NDIS does not have any policy/guidelines regarding determination of ME/CFS NDIS applications and each case is assessed on a case by case basis in accordance with the legislation;
2. The NDIS consulted with Professor Andrew Lloyd of the University of New South Wales;
3. Professor Lloyd was utilised because of his "credentials and experience";
4. Professor Lloyd provided "information on the aetiology of ME/CFS, medical and allied health specialities involved in diagnosis and treatment, treatment options clinically indicated for the condition, likelihood of permanency, and prevalence of being diagnosis as a stand-alone condition as opposed to being part of a co-morbidity." He additionally provided information

"regarding the evidence and research regarding Graded Exercise Therapy (GET) and Cognitive Behavioural Therapy (CBT)".

5. Professor Lloyd has purportedly advised the NDIA that:
   (a) The evidence on permanency for ME/CFS is "conflicting";
   (b) "Information indicates that many individuals recover without intervention over weeks to months";
   (c) "… approximately 10% will meet diagnostic criteria for ME/chronic fatigue syndrome at six months";
   (d) Of that 10%, "a small subset may go on to suffer from both severe disabling and very prolonged (greater than 5 years) ME/chronic fatigue syndrome" and "these patients may be housebound or even bed-bound as a result of the illness and despite best available evidence-based treatment";
   (e) When ME/CFS has "been present in a stable, non-improving pattern, despite evidence-based management (such as … CBT … GET … and cognitive remediation) for 5 years, the Australian expert guidelines indicate that the condition should be regarded as permanent for medico-legal purposes";
6. The NDIA considers the individual's participation in the above alleged "evidence-based treatments" so that permanency can be assessed. Without it, eligibility cannot be assessed;
7. The Australian Guidelines are the accepted guidelines for diagnosis and management and the United Kingdom's NICE Guides are also being used as a source of reference;
8. A list of references from Professor Lloyd was provided – with no context as to their use.

I do note, that Ms. Agus did not actually provide a copy of the document from Professor Lloyd, in which he sets out his position.

4. KEY POINTS OF CONTENTION

4.1. Policy

It is noted that the NDIA deny the existence of a policy or a guideline with respect to ME/CFS.

However, the NDIA's Ms. Agus has clearly stated that the NDIA are referencing advice of Professor Lloyd when the NDIA "assess the potential permanency of the impairment".

Respectfully, the dictionary definition of the word policy is "a course or principle of action adopted or proposed by an organization or individual". This definition appears to cover the characteristics of the method by which the NDIA has applied the Lloyd advice. Claimants are clearly being rejected on the basis of not being able to meet his requirement – hence a course of action is being taken, being a denial of access to the NDIS.

Hereinafter, for ease of communication and consistency of understanding, we shall refer to the Lloyd advice as the 'policy'.

4.2. Literature – General Comments

By way of observation, we do note, with some concern, the age of the literature being cited by Professor Lloyd, and the weight accorded to his own work, the work of his colleagues, or the work of groups that he has affiliations with.

For what is a significant policy, we would have expected a much broader representation of the literature that is available.

4.3. Guidelines

Ms. Agus advises that the NDIA are referencing two sets of guidelines, being the 2002 RACP Guidelines[1] and the 2007 NICE Guides.[2] We make three significant submissions:

4.3.1. NHMRC ME/CFS Advisory Committee

The Committee released its Draft report for consultation in December 2018, with submissions closing on 18 February 2019.[3] The final report was released on 18 July 2019.[4] In this final report, the committee (which included Professor Lloyd) made the following statements with respect to the Guidelines issue:

1. The 2002 RACP Guidelines "…were developed at a time when not much was known about ME/CFS"[5];
2. "There has been considerable debate and concern about the 2002 RACP guidelines, including that they recommend diagnostic criteria that could be seen to be too inclusive, not considering post exertional malaise (PEM) as a mandatory symptom, as well as recommending treatments such as graded exercise therapy and cognitive behavioural therapy."[6];
3. "… they were not well received by all clinicians."[7];
4. "ME/CFS Australia was concerned that the guidelines would result in "further cases of misdiagnosis, inappropriate and inadequate medical care, and the promotion of widespread misconceptions about the illness."[8]
5. "These guidelines, however, have been criticised by some patients, advocacy groups, academics, some clinicians and some Australian and international researchers."[9]
6. "The Committee advises updating or developing new Australian ME/CFS clinical practice guidelines as well as developing General Practitioner educational material and patient engagement strategies. The currency of these resources should be maintained to reflect the latest high quality evidence; this may help to re-establish patient trust and confidence in health care practitioners."[10];
7. "In the interim, the Committee recommends a range of resources for clinical use, currently available on the NHMRC webpage for this project."[11];

We submit that the net effect of the NHMRC report is the retirement of the 2002 Guidelines in terms of their clinical recommendations.

[1] RACP Working Group, 'Chronic Fatigue Syndrome - Clinical Practice Gudelines' *Med J Aust*. 2002; 176: S17-55;
[2] NICE, 'Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management (22 August 2007) < https://www.nice.org.uk/guidance/cg53>.
[3] NHMRC ME/CFS Committee, 'Consultation on the Myalgic encephalomyelitis and Chronic fatigue syndrome Advisory Committee Report to the NHMRC Chief Executive Officer: Draft for Public Consultation', (December 2018) <https://consultations.nhmrc.gov.au/public_consultations/mecfs-2019a>.
[4] NHMRC ME/CFS Committee, 'Consultation on the Myalgic encephalomyelitis and Chronic fatigue syndrome Advisory Committee Report to the NHMRC Chief Executive Officer', (30 April 2019) <https://www.nhmrc.gov.au/file/14332/download?token=8q3RRIz6>.
[5] Ibid, p. 5.
[6] Ibid.
[7] Ibid.
[8] Ibid.
[9] Ibid, p. 19.
[10] Ibid, p. 20
[11] Ibid.

4.3.2. 2002 RACP GUIDELINES

With respect to the submissions of ME/CFS Australia, we put forward the following position with respect to the 2002 Guidelines.

The RACP Guidelines were first drafted in 1997. 2002 was the final version that was ultimately published. We make the following points:

1. the RACP Guidelines are 18 years old;
2. the RACP Guidelines have never updated;
3. no formal process of review has ever been conducted - at one point, only Professor Lloyd was deferred to on the matter of updating the RACP Guidelines and his opinion was that they were still fit for purpose. This is far from a formal or appropriate review process;
4. the science and knowledge base has moved forward significantly since the publishing of the 2002 RACP Guidelines, which were themselves based upon the bulk of journal articles up to 1997 (for the original draft), with very few from the period of 1998 to 2001 which preceded the 2002 publication. In short – the weight of evidence is in the vicinity of 20 to 30 years old – which is entirely unreasonable;
5. the NHMRC's site on updated Guidelines is currently under development.[12] In 1998 however, the relevant policy on *Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines Development*[13] was very clear:

> "A ***date should be set for revision*** of the guidelines. The National Health and Medical Research Council recommends that this ***occur every three to five years and more often*** where the subject matter or circumstances are ***prone to rapid change***…
>
> The potential for guidelines to be used as evidence in court 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***…
>
> In general, guidelines should be summaries of the evidence, should have an expiry date, should not be unduly prescriptive, and should acknowledge areas where there is disagreement. An ***independent review of the guideline development process is recommended***."[14] (Emphasis added)

It is also noted that the current NRMRC site does state:

> "Guidelines issued by NHMRC **have a limited life**. They are ***regularly reviewed and will be updated or withdrawn in light of important new evidence that may emerge***."[15]

Whilst the RACP Guidelines were not endorsed by the NHMRC, there are a number of very appropriate points to be made:

[12] NHMRC, 'Guideline for Guidelines' (2019) <https://www.nhmrc.gov.au/guidelinesforguidelines/update>.
[13] NHMRC, 'A Guide to the Development, Implementations and Evaluation of Clinical Practice Guidelines' (16 November 1998), <https://www.nhmrc.gov.au/sites/default/files/images/a-guide-to-the-development-and-evaluation-of-clinical-practice-guidelines.pdf>.
[14] Ibid, pp. 5-6.
[15] NRMRC, Guideline, (2019), <https://www.nhmrc.gov.au/health-advice/guidelines>.

- The limited life of these guidelines has been exceeded for quite some time – a fact acknowledged by the NHMRC ME/CFS Advisory Committee (see above at 4.3.2.);
- 18 years is not 3 to 5 years;
- No date was ever set down for a revision of the guidelines;
- They are not up to date, hence not fit for use in court or other settings;
- No independent review of the guidelines ever took place.

The NHMRC process demonstrates the prudent practice that existed in 1998 when the 1997 draft guidelines were released. In the case of the RACP Guidelines this course of action has not taken place. No revision policy or independent review was put into place. There has been a clear breakdown in what ethical medicine would consider the prudent practice of guideline revision to be.

ME/CFS Australia submit that the 2002 RACP Guidelines are not fit for the purpose to which the NDIA has put them. Respectfully, there is no rational foundation to assert that such guidelines could possibly represent best-practice, let alone reflect current knowledge;

4.3.3. NICE Guides

The use of the NICE Guides by the NDIA is particularly perplexing for ME/CFS Australia and we were somewhat surprised that the NDIA would defer to such a document. We would make the following points:

4.3.3.1. NHMRC ME/CFS Advisory Committee Views

The NHRMC ME/CFS Advisory Committee's report reviewed the NICE Guidelines and noted the following:

1. "Some patient groups have expressed concerns over the broad diagnostic criteria and some treatment options suggested in the 2007 guidelines, including graded exercise therapy."[16]

2. "Patient mistrust and lack of confidence have also been observed in the UK and have stimulated the revision of the NICE 2007 ME/CFS clinical guidelines, with patient/ consumer engagement a priority."[17];

ME/CFS Australia submits that the NHMRC's observations of the 13 year old NICE Guide echo similar concerns to that which exists with respect to the 2002 RACP Guidelines. The fact that the NHMRC expressed such concerns, combined with the revision that is currently being undertaken, makes them inappropriate for the NDIA to follow.

4.3.3.2. *UK Document*

ME/CFS Australia makes a number of observations and submissions with respect to the NICE Guides.

Firstly, the NICE Guidelines were not created by an international panel of experts with experience in ME/CFS, ME or CFS. They are a domestic guideline for the United Kingdom that was created by way of consensus committee whereby the majority of members were proponents of the biopsychosocial view of ME/CFS. Significantly, one of the two patient representatives resigned from the Guideline

[16] NHMRC, above n. 4, p. 6.
[17] NHMRC, above n. 4, pp. 19-20.

Development Group because she could not, as a patient representative who purported witnessed bias and flaws in the process, support the NICE Guidelines as fit for purpose.[18]

Secondly, the literature review utilised the flawed York review methodology and excluded the vast majority of biomedical evidence, including evidence of harms from exercise and focused upon the psychosocial hypothesis, particularly that of one UK research group with a strong psychological bias.

Respectfully, the document is not fit for current usage in the health sector and has no relevance to contemporary disability services.

4.3.3.3. Out of Date

Like the 2002 Australian Guidelines, the 2007 NICE Guide being 13 years old, and clearly out of date. The NICE Guide acknowledges a review of evidence was to occur every 2 to 4 years – yet that did not happen.[19] A review occurred in September 2017, and concluded "there was no clear signal that identified new evidence would result in changes to the recommendations".[20] Following stakeholder consultation and evidence provided, NICE concluded "broader issues with the guideline were highlighted that called into question the guideline scope and its current relevance."[21]

A decision has been taken to "fully update the guidelines"[22] and that is expected to be concluded by 14 October 2020.[23]

4.3.3.4. Apples and Oranges

Whilst the NICE Guide may well utilise the term CFS/ME. this is not the same condition that is diagnosed here in Australia. We point out the following:

1. The definition utilised is not an internationally recognised criteria and is not utilised in clinical practice here in Australia, hence it is incompatible;
2. The patient cohort that this specific criteria defines are not the same type of patient as experienced here in Australia because of the over-inclusivity of the criteria - ergo their requirements are different and more chronic fatigue patients are identified, as opposed to CFS or ME/CFS;
3. The literature review considered and utilised numerous pieces of research that were conducted using the Oxford Criteria, a criteria used only in the UK. Biomedical research was largely not considered;
4. The Oxford Criteria is considered by contemporary health practitioners and researchers to be overly inclusive because it only focused on fatigue and does not require the presence of other symptoms. It is not used within the international research community and never

[18] Tanya s47F - personal privac 'Personal Response to the NICE Guidelines on ME/CFS' (22 August 2007) <http://www.brame.org/contact2.html>.
[19] NICE, above n. 2, p. 41.
[20] NICE, 'Surveillance report 2017 – Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management (2007) NICE guideline CG53', (20 September 2017) <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/Surveillance-decision>.
[21] Ibid.
[22] Ibid.
[23] NICE, 'Myalgic Encephalomyelitis (or Encephalopathy)/Chronic Fatigue Syndrome: Diagnosis and Management: In Development [GID-NG10091]' (2019) <https://www.nice.org.uk/guidance/indevelopment/gid-ng10091/documents>.

utilised in Australia. Indeed, Lloyd and his colleagues were critical of the Oxford and London criteria as far back as 1994[24];

5. The US National Institute of Health commissioned Pathways to Prevention review of ME/CFS concluded:[25]

> "Furthermore, the multiple case definitions for ME/CFS have hindered progress. In particular, continuing to use the Oxford definition **may impair progress and cause harm**. Therefore, for progress to occur, **we recommend that this definition be retired** …"[26] (Emphasis added)

The mere fact that the acronyms CFS and ME are utilised in the NICE Guidelines title, does not accord them standing as equivalent or relevant to that which exists in Australia.

4.3.3.5. Lack of Available Resources

The NICE Guidelines are premised on the basis that the UK has various resources available within the NIH framework. They have no application in Australia because:

1. The assumed knowledge of the GP community in the UK is significantly greater[27];
2. There is an expectation of support for the guidelines from UK healthcare practitioners;[28]
3. There are National Health Services Specialist Services for people with CFS/ME in the UK that can deliver services tailored to the condition and the individual;[29]

With respect, none of this framework exists in Australia. Even if the NICE Guidelines were fit for the Australian experience, the fact is that their framework simply does not exist here. The NDIA is holding applicants to an unachievable standard for the vast majority, simply because it has not grasped that the infrastructure of the UK does not exist here.

4.3.3.6. CBT/GET

If the NDIA are taking on board the NICE Guidelines, there does appear to be some disparity in the expectations by the NDIA, that the severely ill must have attempted CBT/GET, when the Guidelines state

> 1.6.2.4. - Cognitive behavioural therapy (CBT) and/or graded exercise therapy (GET) should be ***offered to people with mild or moderate CFS/ME*** and provided to those who choose these approaches, because currently these are the interventions for which there is the clearest research evidence of benefit.[30] (Emphasis added)

[24] A. Wilson, I. Hickie, A. Lloyd, and D. Wakefield. 'The Treatment of Chronic Fatigue Syndrome: Science and Speculation' *The American Journal of Medicine* 1994: 96(6); 544–550 at 544-545).
[25] C.R. Green, P. Cowan, R. Elk., et al, 'National Institutes of Health Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome' *Annals of Internal Medicine*. 2015; 162: 860-865, p. 864.
[26] NICE, above n. 2, p. 25.
[27] Ibid, p. 2.
[28] Ibid, p. 2.
[29] MEAction, 'National Health Service', (13 February 2019) <https://me-pedia.org/wiki/National_Health_Service>; NICE, 'Specialist CFS/ME Care' (August 2007) <https://www.nice.org.uk/guidance/cg53/ifp/chapter/Specialist-CFSME-care>.
[30] NICE, above n. 2, p. 25.

We will come back to the relevance of this at a later point.

4.3.4. *Position with Respect to Guidelines*

In light of the above review, ME/CFS Australia are of the view that the NDIA's reliance on the 2002 Australian and UK NICE Guidelines is, for the majority of applicants, inappropriate and unsupported by the current scientific and medical community. This cannot be emphasised more clearly than the comments of the NHMRC.

ME/CFS Australia again defers to the NHMRC ME/CFS Advisory Committee's final position on the issue:

> "These guidelines, however, ***have been criticised*** by some patients, advocacy groups, academics, some clinicians and some Australian and international researchers. The treatment recommendations made in the RACP guidelines, including graded exercise therapy and cognitive behavioural therapy, as well as the ambiguity around the management of the condition ***have led to some patient mistrust, and a lowering of patient confidence in the guidelines and health care services more generally***. Patient ***mistrust and lack of confidence have also been observed in the UK*** and have ***stimulated the re-development*** of the NICE 2007 ME/CFS clinical guidelines, with patient/consumer engagement a priority."[31] (Emphasis Added)

Given this position, but for a few potentially useful sections on medicolegal in the Australian Guidelines, both should be abandoned by the NDIA altogether as unsafe.

The NHMRC ME/CFS Advisory Committee concluded that there was a strong need to re-establish patient trust and confidence in clinical practice guidelines, and recommended that guidelines be constructed internally by the NHMRC. In the interim, the NHRMC has adopted the 2003 Consensus Criteria[32] or the 2011 International Consensus Criteria[33] (the ICC having been constructed here in Australia with an international committee) and the 2017 Paediatric Primer[34]. The 2003 Consensus Document contains an extensive clinical guideline which provides objective evidence to establish the condition, and the criteria focuses upon the key symptoms that the 1994 Fukuda criteria omit.

It is noted that Professor Lloyd has provided the 2011 ICC Criteria paper to the NDIA, yet omitted the three most significant documents, being the 2003 ME/CFS Consensus Guidelines[35], the 2015 Institute of Medicine's redefinition of ME/CFS[36] and the 2017 Paediatric Primer. The IOM paper draws heavily of the 2003 and 2011 documents, as does the Paediatric Primer.

The 2003 criteria and guidelines are commonly utilised throughout Australia. In 2004, for example, the South Australian government distributed a set of clinical guidelines based on the 2003 Consensus

[31] NHRMC, above at n. 4, p. 19.
[32] B.M. Carruthers, A.K. Jain, K.L. De Meirleir, et al, 'Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical working Case Definition'. *Journal of Chronic Fatigue Syndrome*, 2003; 11(1): 7-117.
[33] B.M. Carruthers, M.I. van de Sande, K.L. De Meirleir, et al, 'Myalgic Encephalomyelitis: International Consensus Criteria'. *Journal of Internal Medicine*, 2011; 279(4): 327-328.
[34] Rowe PC, Underhill RA, Friedman KJ, Gurwitt A, Medow MS, Schwartz MS et al. Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome Diagnosis and Management in Young People: A Primer. *Front Pediatr* 2017; 5(121).
[35] Carruthers et al, above n. 32.
[36] IOM (Institute of Medicine). 2015. *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness*. Washington, DC: The National Academies Press.

Guidelines, to all GPs in the state.[37] Since then, a summary document has enabled practitioners to implement the Guidelines in clinical practice.[38]

Respectfully, ME/CFS Australia submits that the NDIA's reliance on the two nominated guidelines, that are acknowledges as outdated, to the exclusion of the 2003 Guidelines and/or the 2011 ICC criteria and 2017 Primer, has now been clearly signalled as inappropriate.

5. PROFESSOR LLOYD

5.1. No Consumer Support

We understand that the NDIA perceives that Professor Lloyd would be considered an 'expert' in the area of ME/CFS. ME/CFS Australia would, however, make the following points:

1. Professor Lloyd's research background is in CFS – not ME/CFS, nor ICC ME. His C.V. contains his research portfolio and he does not research in either area. Respectfully, there is a distinction;
2. Professor Lloyd and his work does not enjoy the support of any State or National organisation or support group within the ME/CFS community and his research with respect to GET and CBT is not held in high esteem by the majority of patients within Australia for over a decade now;
3. There are multiple ME/CFS research programs throughout Australia, with equally credentialled, if not better credentialled, research programs which study ICC ME and/or 2003 ME/CFS, as well as 1994 Fukuda CFS, and their views differ significantly on key issues addressed by Professor Lloyd;
4. Professor Lloyd is out of step with the current prevailing views with respect to ME/CFS here in Australia;
5. Professor Lloyd holds a significant perceived, if not actual, conflict of interest (pecuniary and non-pecuniary) given he holds a key position within the Fatigue Clinic at the University of New South Wales, where he is actively involved in the prescription of the highly contentious treatments of CBT and GET. His conflict arises out the benefits derived from continuation of these treatment recommendations, particularly when he holds a substantial part of the market;
6. Professor Lloyd is a member of the NHMRC ME/CFS Advisory Committee and was fully aware of the Committee's preference for the 2003 Guidelines or 2011 ICC criteria and 2017 Paediatric Primer, yet had apparently not provided the 2003 Guideline, 2005 Summary documents nor 2017 Paediatric Primer to the NDIA;
7. Professor Lloyd is regarded as a proponent of the psychosocial school of thought and his literature provided to the NDIA reflects that approach in the weight of documents provided.

[37] Government of South Australian, Human Services. Metropolitan Division., *Myalgic Encephelopathy/Chronic Fatigue Syndrome (CFS): Management Guidelines for General Practitioners* (2004) <https://sacfs.asn.au/download/guidelines.pdf>.

[38] B.M. Carruthers and M.I. van de Sande, *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Clinical Case Definition and Guidelines for Medical Practitioners: An Overview of the Canadian Consensus Document*, (2005) <http://sacfs.asn.au/download/consensus_overview_me_cfs.pdf>.

ME/CFS Australia does not endorse, nor would it recommend, the views of Professor Lloyd. Respectfully, it would be inappropriate of the NDIA to dismiss the view of the consumers, the national representative body and its member states organisations, particularly when those views are shared by the NHMRC ME/CFS Advisory Committee in its report to the CEO of the NHMRC.

ME/CFS Australia's view are by no means intended to disparage or disrespect Professor Lloyd or his work. ME/CFS Australia is a patient organisation which is well versed in the views of its members. We are therefore reflecting the views of the patient community when stating that Professor Lloyd does not represent the contemporary views of the wider Australian ME/CFS consumer and research community. We would submit that the NDIA should not be deferring to a minority view, particularly when the weight of evidence supports alternative views.

5.2. Views of Professor Lloyd

We note that the NDIA have outlined a series of views put forward by Professor Lloyd that have fuelled the NDIA's policy with respect to ME/CFS. ME/CFS Australia will address each in succession.

5.2.1. Conflicting Evidence

The NDIA have stated that Professor Lloyd reports that the evidence as to whether ME/CFS is permanent is 'conflicting'. The NDIA do not elaborate upon the details of those comments, the literature upon which Professor Lloyd bases his opinion, nor how he arrives at his conclusion that the evidence is conflicting.

5.2.1.1. NHMRC ME/CFS Advisory Committee's View

The NHMRC ME/CFS Advisory Committee provided a cursory examination of the literature with respect to the issue of recovery, reliant primarily upon the 1993 and 2003 Australian Burden of Disease ('ABD') data.[39] With no disrespect to the NHMRC ME/CFS Advisory Committee, the Committee failed to check the references behind the position of the 2003 ABD figures.[40]

Respectfully the ADB authors commit the same error that the NDIA has with respect to the 'Dubbo Study' (see: below at 5.2.2) and fail to distinguish between the research team's identification of provisional cases of Post Viral Fatigue Syndrome (89% of cases) and actual PVFS (11% of cases). To this end, the NHMRC's comments with respect to the ADB are unreliable.

The NHMRC Advisory Committee's report indicates that there are broad range of:

> "In comparison, international estimates for recovery indicate 17-64% of patients improve with treatment, but less than 10% of patients have full recovery to pre-morbid levels of functioning, and approximately 20% of patients may worsen overtime.
>
> This is in contrast to recent paediatric data, which indicate that the majority of young people (who seemed to be more likely to have infection as a trigger)

[39] NHMRC, above n. 4, p. 9.

[40] S. Begg, T. Vos, B. Barker, C. Stephenson, L. Stanley, and A.D. Lopez, 'The Burden of Disease and Injury in Australia 2002', (May 2007) https://www.aihw.gov.au/getmedia/f81b92b3-18a2-4669-aad3-653aa3a9f0f2/bodaiia03.pdf.aspx, pp 178-179.

> had a mean duration of illness of five years with a range of 1-15 years. By five years, 38% reported recovery and by 10 years 68% reported full recovery.
>
> In the 2011 ABDS study, however, ME/CFS was excluded as a separate disease given the then outdated prevalence estimates used in the 2003 ABDS. Instead ME/CFS was included under 'other neurological diseases'.38 These 'other neurological conditions' (including ME/CFS) were responsible for 9.8% of the total DALYs for neurological conditions in 2011."[41] (Footnotes Omitted)

ME/CFS Australia observes that whilst the NHMRC indicates that there has been a wide range of estimates for recovery, the committee did not distinguish between the measures used to assess recovery, nor how many measurers were utilised. It is our view that the issue of recover warrants a more thorough examination.

5.2.1.2. ME/CFS Australia's View
ME/CFS Australia submits that:

1. The assertion that evidence is conflicting is correct to the extent that issues with respect to defining recovery, and/or measuring recovery with subjective measures has caused conflicting outcomes;
2. The NIH Pathways to Prevention committee "recommend … the ME/CFS community … patients, clinicians, and researchers agree on a definition for meaningful recovery."[42]
3. The IOM review of ME/CFS literature showed an equivocality of evidence with respect to prognosis and recovery.[43] Specifically, the IOM noted:
   (a) that "[s]everal studies found that 20 to 48 percent of pediatric patients diagnosed using the Fukuda definition showed no improvement or actually had worse fatigue and physical impairment at follow-up times ranging from 2 to 13 years"[44];
   (b) identified that the research on recovery is impacted by the fact that the 1994 Fukuda CFS definition does not require post-exertional malaise ('PEM"), which is a hallmark of the condition, hence the 2003 and 2011 Carruther's criteria diagnose a more defined patient population[45];
   (c) "… studies of recovery from ME/CFS vary widely as a result of the use of different case definitions in the study samples; differing definitions of "recovery"; the lack of temporal metrics of function obtained before, during, and after treatment; and the use of patients' subjective assessment of their own progression of illness and recovery"[46];
   (d) that a 2014 systematic review of 22 studies on recovery, revealed that studies where a single domain was measured tended to show high recovery rates, whereas those with multiple domains measured significantly lower rates of recovery. The study also identified that "the term 'recovery' often included less than full restoration of health as reported by the patients, and typically was based on limited assessment."[47] The study

[41] NHRMC, above at n. 4, p. 9.
[42] Green et al, above n. 25, p. 864.
[43] IOM, above n. 35, p. 183.
[44] Ibid.
[45] Ibid, pp. 259-260.
[46] Ibid.
[47] Ibid, pp. 263-264.

also noted that the majority of studies into recovery failed to utilise objective measures of recovery, making it impossible to determine if recovery actually occurred;

(e) various other systematic reviews that utilised objective measures of recovery demonstrate that whilst some patients improved, the majority did not fully recover and remained symptomatic.[48]

With respect, what Professor Lloyd has not presented to the NDIA is the fact that objective measures of recovery tended to show that patients did not fully recover and stayed symptomatic. Studies using subjective data, or using single domains to define recovery, created the perception of recovery.

ME/CFS Australia submits that the key issue that the NDIA is focused upon is whether the individual returns to health or maintains symptoms of the condition. The fact is, the IOM demonstrated that studies which focused on objective measures did not reveal recovery. This is significant and is congruent with our experience of our membership and the patient community.

5.2.2. <u>The Dubbo Study</u>

The NDIA have asserted, based on Professor Lloyd's opinion, that

1. "Information indicates that many individuals recover without intervention over weeks to months";
2. "… approximately 10% will meet diagnostic criteria for ME/chronic fatigue syndrome at six months";
3. Of that 10%, "a small subset may go on to suffer from both severe disabling and very prolonged (greater than 5 years) ME/chronic fatigue syndrome" and "these patients may be housebound or even-bed bound as a result of the illness and despite best available evidence-based treatment";

With respect, the outcomes of the Dubbo study have been misconstrued. ME/CFS Australia submits as follows:

5.2.2.1. Recovery Without Intervention

The 2006 study by Lloyd and his colleagues ('the Dubbo study') followed the patients of 94 practitioners who had acute Epstein-Barr virus, Q-fever or Ross River Fever.[49] Before progressing, ME/CFS Australia will make four very clear points with respect to the limitations of the study:

1. *<u>Infections</u>* - The study clearly outlines that CFS can result from "acute infectious illness" and outlines that "post-infective fatigue states have been linked to a diverse spectrum of infections"[50]. The study outlines the numerous infections that can occur, but then focus in on just three.[51] This therefore makes the study an exceptionally limited one in the scheme of CFS. It is not a study that can be generalised as reflective of all CFS. The 2007 Burden of

[48] Ibid, p. 264.
[49] I. Hickie, T. Davenport, D. Wakefield, U. Vollmer-Conna, B. Cameron, S.D. Vernon, W.C. Reeves, and A. Lloyd, 'Post-infective and Chronic Fatigue Syndromes Precipitated by Viral and Non-Viral Pathogens: Prospective Cohort Study' *BMJ* 2006; 333(75688): 575-581, 575.
[50] Ibid.
[51] Ibid.

Disease report claims that "post-infective fatigue syndrome … constitutes between 30%-40% of cases"[52]. The study only refers to three infectious agents – hence in the scheme of CFS, it represents less than 10% of the cases;

2. *Recovery* - The study does not, at any time, define recovery, nor deal or purport to deal with the issues of recovery. The NDIA is extrapolating something which is not present. There is nothing in the study that allows the NDIA to claim that recovery without intervention has occurred[53];

3. *No Follow-up* – The study followed patients with CFS for one year. All participants enrolled were assessed at 12 months, but there has never been a follow-up study beyond 12 months. The onset of CFS can be gradual. That means that the onset of CFS in those who did not initially quality at 6 months or those who 'recovered' from CFS within two years, were never checked to see if the condition subsequently occurred, or if it returned to those previously diagnosed. This is an exceptionally significant weakness in the study in a condition where onset can be delayed or recurrent.

On the basis of these issues alone, the NDIA's elevation of the study to a position in which all sufferers of ME, ME/CFS or CFS are to be assessed, is simply scientifically unconscionable, medically incorrect and morally wrong.

5.2.2.2. Misconstrued Case Definitions

The NDIA has clearly misconstrued 89% of the participants as having CFS, when the study did not claim that this was the position. This is a major oversight by the NDIA.

The study set down the case definitions very clearly:

> "**Case definitions**
>
> We classified participants as ***provisional cases of post-infective fatigue syndrome*** if their SOMA scores at all time points ***up to and including three*** **months** exceeded the established threshold score. We invited these cases, and control participants matched by age and sex ***who had recovered promptly from the same infection, at six months for a medical interview,*** examination by a physician (AL), and laboratory investigation to exclude alternative medical explanations for ongoing symptoms, such as hypothyroidism or primary sleep disorder. A psychiatrist (IH) also assessed them, to ensure that no exclusionary psychiatric diagnosis was evident and to allocate comorbid diagnoses according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV). ***Where appropriate, AL and IH diagnosed the chronic fatigue syndrome (termed here confirmed post-infective fatigue syndrome) by consensus at six months after the onset***

[52] Begg et al, above n. 40, p. 178.
[53] Hickie et al, above n, 49, p. 575.

> ***of symptoms, according to the international diagnostic criteria.***"[54]
> (Footnotes omitted, Emphasis Added)

For absolute clarity – only those patients who had persisting fatigue symptoms at the end of 6 months were able to be accorded a diagnosis of Chronic Fatigue Syndrome (or Post Viral Fatigue Syndrome – 'PVFS') as the authors called it.

The study clearly showed that of the 250 cases of **provisional** PVFS, only 28 went on to receive a diagnosis of Chronic Fatigue Syndrome (i.e. the other 89% that did not make it to the 6 month mark did not, at any stage, achieve PVFS, hence were never CFS).[55] Again – the word provisional is used deliberately. These remaining 28 patients had more than simple fatigue, and met the Fukuda 1994 criteria.

Whomever reached the conclusion that the majority of participants recovered from CFS without intervention is grossly in error.

Whilst PVFS comes under the category of a CFS diagnosis, the patients prior to end of 6 months only had a provisional diagnosis of PVFS. Until their fatigue (and other) symptoms reached 6 months and 1 day, they did not have PVFS – they were merely potential candidates for the diagnosis. Only 28 of 250 reached that point.

Given this is the case, the NDIA statement that the majority recover without intervention is patently false. They never had the diagnosis of CFS to recover from in the first place.

It must be reiterated again that the Dubbo study was a very limited study, in that it only followed the patients who experienced one of three viruses. There are numerous causal associations as well as unknown causes for CFS.[56]

5.2.2.3. Meeting Diagnostic Criteria

The statement by the NDIA that "… approximately 10% will meet diagnostic criteria for ME/chronic fatigue syndrome at six months" – is completely incorrect.

Yes, in the study of PVFS there was a result of 12% of participants meeting the criteria for PVFS at 6 months – this is fact (n=29/250).[57] At 12 months, 9% (n=22/250) of the original cohort had a diagnosis of PVFS. This a study of PVFS specifically. That means at 12 months, 75% of patients who acquired a diagnosis of PVFS at the 6 month point, still held the diagnosis.

As stated above at 5.2.2.1. this is a study of a limited number of infectious agents causing PVFS. PVFS accounts for 30-40% of cases. These infectious agents account for less than 10% of CFS cases.

[54] Ibid, p. 576.
[55] Ibid, p. 577.
[56] IOM, above n. 35, p. 192.
[57] Hickie et al, above n. 49, p. 577.

There was nothing in the study that suggested that there was no intervention in the cases that did not meet the criteria at 12 months.[58]

5.2.2.4. Severe Cases

ME/CFS Australia asserts that there is nothing in the Dubbo study that equates to 10% of CFS patients going on to be severe. This is factually apparent in the text.

A cursory literature review of Professor Lloyd's work reveals that there is no study by Lloyd that indicates that 10% go onto be severe. Most significantly, this figure stands contrary to the comprehensive IOM literature review and findings encompassed under the heading of "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 (Andersen et al., 2004; Tiersky et al., 2001). ***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 (Jason and Richman, 2008; Twisk, 2014). ***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 (NIH, 2011). 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 (Wiborg et al., 2010). More information on disability in ME/CFS can be found in Appendix C."[59] (Emphasis Added)

Respectfully, the unsubstantiated and unreferenced opinion of Professor Lloyd should not be preferred over that of the detailed IOM literature review.

For the purposes of clarity, the figure of 25% is often cited. More often than not these most serious cases are omitted from studies because the condition prevents the severe and very severe from participation in the majority of studies.[60] Those who do undertake research into ME/CFS rarely take the studies to participants at the severe end of the spectrum, in their residences. Most significantly, the IOM suggests that limitations on the cited studies mean that the figure of house-bound patients is likely to be higher.

5.2.3. The Guidelines

The NDIA have asserted, based on Professor Lloyd's opinion, that when ME/CFS has "been present in a stable, non-improving pattern, despite evidence-based management (such as … CBT … GET … and cognitive remediation) for 5 years, the Australian expert guidelines indicate that the condition

[58] Ibid.
[59] IOM, above n. 35, pp. 31-32.
[60] Ibid, p. 72.

should be regarded as permanent for medico-legal purposes".

6. EVIDENCE BASED TREATMENTS

The NDIA states that it considers the individual's participation in "evidence-based treatments" (being CBT and GET) is required before permanency can be assessed. ME/CFS Australia wishes to express its concern on this specific issue from a number of perspectives.

6.1. Absence of Notification

The NDIS provides information about accessing the NDIS on its website. Under the "Providing Evidence"[61] tab, there is no information provided which indicates that the NDIA will be assessing the application by way of reference to a policy. It does notify that additional evidence might be required. There is nothing at any point in the Guidelines that indicates that the NDIA will reference an undisclosed policy.

ME/CFS Australia wishes to register its concern that the NDIA holds and is applying a policy to applicants without revealing:

(a) that the policy exists;
(b) that a discrete decision process is occurring in which that policy is being applied; and
(c) without having provided applicants a copy of the policy so that procedural fairness is accorded and more information provided to address the policy requirements.

We are particularly concerned that those who have applied for information under a Freedom of Information request were not provided with, nor made aware of, the existence of the policy, nor provided a copy.

In our view, the NDIS application process should be transparent. As it currently stands, that is not the case.

6.2. CBT, CET and GET

The NDIA has apparently been provided evidence and recommendations from Professor Lloyd that held CBT, Cognitive Remediation ('CET') and GET to be essential requirements in the treatment of ME/CFS. In relying upon those representations, the NDIA has subsequently elevated such treatments to a status whereby an application is denied if the applicant has not engaged in these treatments and demonstrated no benefit.

ME/CFS Australia holds grave concerns for this position and the evidence base upon which it is founded. The organisation therefore makes the following submissions.

6.2.1. NHMRC ME/CFS Advisory Committee's Position

The NHMRC ME/CFS Advisory Committee expressed the following:

[61] NDIS, 'Providing Evidence' (16 January 2019) <https://www.ndis.gov.au/applying-access-ndis/how-apply/information-support-your-request/providing-evidence-your-disability>.

1. When addressing the 2002 RACP Guidelines and their recommendations of GET/CBT as the treatment option of preference, the NHRMC ME/CFS Advisory Committee stated:

> "There has been considerable debate and concern about the 2002 RACP guidelines, including that they recommend diagnostic criteria that could be seen to be too inclusive, ***not considering post exertional malaise*** (PEM) as a mandatory symptom, as well as ***recommending treatments such as graded exercise therapy and cognitive behavioural therapy***. However, the historical context of these guidelines must be noted, as they were ***developed at a time when not much was known about ME/CFS***. They provided some guidance for clinicians on a poorly recognised condition that did not have much evidence on causation, including ***guidance on ways to manage ME/CFS***. Although the guidelines were well received by some clinicians in 2002, they were **not well received by all clinicians or by ME/CFS Australia** (a national organisation representing patients). ME/CFS Australia was concerned that the guidelines would result in "further cases of misdiagnosis, ***inappropriate and inadequate medical care***, and the promotion of widespread misconceptions about the illness."[62] (Footnotes omitted; Emphasis Added)

The submissions of this organisation were ignored. Without placing too fine a point on it, the concerns raised were accurate and well founded.

2. With respect to the NICE guidelines, the NHMRC Report states:

> "Some ***patient groups have expressed concerns*** over the broad diagnostic criteria and some treatment options suggested in the 2007 guidelines, ***including graded exercise therapy***."[63] (Emphasis added)

Once again it is the end users, being the patient groups, that are expressing concerns over GET, and once again, the guideline is under review.

3. The NHMRC Advisory Committee has recognised that GET is particularly controversial:

> "***Controversial treatments such as graded exercise therapy*** have contributed to a disparity in approaches and some disengagement between patients and clinicians."[64] (Emphasis added)

4. The Committee then stated:

[62] NHMRC, above n. 4, p. 5.
[63] Ibid, p. 6.
[64] Ibid, p. 8.

"Physical activity and exercise therapy treatments have received significant attention in the media, amongst ME/CFS research sectors and the wider community. ***Patients and advocates have a real concern about the harm caused by some exercise modalities***. These options for physical activity are of interest and a controversial topic of debate within all sectors (research, patients and clinicians), given the variety of responses to this form of management, and its effectiveness...

Graded Exercise Therapy is considered a controversial treatment and there is some ambiguity in its application in the clinical care setting. The primary reported concern with recommending graded exercise therapy for ME/CFS patients is it ***causing post-exertional malaise (PEM), exacerbation of symptoms and unintended harm.*** Many public consultation submissions ***expressed concern about the potential for harm from graded exercise therapy***.

Some specialist clinicians and researchers maintain that graded exercise therapy is effective ***when correctly administered*** as a patient-centred management strategy, and substantiate this with a number of clinical trials. However, these trials have been questioned by some patients, advocacy groups, academics, clinicians and Australian and international researchers. For example, the United States Agency for Healthcare Research and Quality stated in their 2016 Addendum on the diagnosis and treatment evidence for ME/CFS.

"*…By excluding the three trials using the Oxford (Sharpe, 1991) case definition for inclusion,* ***there would be insufficient evidence of the effectiveness of graded exercise therapy on any outcome****…missing from this body of literature are trials evaluating effectiveness of interventions in the treatment of individuals meeting case definitions for … ME/CFS.*" - Smith et al (2016) pp. 11-1348

A Cochrane review of exercise therapy for ME/CFS is currently the subject of ongoing review, with an update posted on Cochrane's website in March 2019:

"*Cochrane's editors and the review author team have jointly agreed that there will be a further period up to the end of May 2019, in which time the [review] author team will amend the review to address changes aimed at improving the quality of reporting of the review and ensuring that the conclusions are fully defensible and valid to inform health care decision making. The changes will also address concerns raised in feedback since the …complaint. The amendment will not include a full update, but a decision about this will [be] made subsequently.*"

> ***Concern about the potential for harm from graded exercise therapy was a common theme expressed in public consultation submissions,*** and the Committee acknowledged this as a reality for many patients. The Committee noted that ***GET should not be offered as a cure for ME/CFS*** but that it might have a role in a patient's overall management strategy, helping with any secondary anxiety, de-conditioning and stress."[65] (Footnotes omitted; Emphasis added)

The key reason for the NHMRC Advisory Committee's attention to these issues was the feedback of the end users of these treatments and the users' reporting of harms.

A recent English study into the reporting of harms and adverse outcomes during or after rehabilitative therapies by NIH specialist centres demonstrated that "there was an almost universal absence of criteria for detecting harm, and that no clinic reported any harm as having occurred in their patients." [66] Most strikingly the paper reported that "clinics mainly reported providing little information to patients about the possibility of harm, although several advised patients that setbacks or relapses could happen"[67]: Within Australia there are a few of clinics scattered throughout the country and it is clear from our experience that:

(a) They have no formal, ongoing patient follow up;
(b) They do not follow up those who drop out to identify reasons for their drop-out, such as harms;
(c) No longitudinal studies have been undertaken to see the impact of GET over the long term.

There are of course, various providers that purport to provide GET, yet they do so with no real understanding of the condition, no appreciation of the potential harms, nor any structure to report harms. In their 2018 survey, Emerge Australia noted:

> "The findings clearly show that ***increased activity/exercise makes most people feel worse***. A total of 89% reported feeling worse after increasing their level of exercise/activity, comprised of 54% reporting they feel worse straight away and 35% reporting that they initially feel better, but then feel worse later. ***Only 5% report that exercise/activity makes them feel better***. For those with severe symptoms, the incidence of ***gaining any benefit from increased activity/exercise is much lower*** (26% better at first then worse, 3% better), the majority just feel worse (68%).

[65] Ibid, pp. 11-12.
[66] G. McPhee, A. Baldwin, T. Kindlon and B.M. Hughes 'Monitoring Treatment Harm in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Freedom-of-Information Study of National Health Service Specialist Centres in England.' *J Health Psychol*. 2019 Jun 24: 135910531985453, p. 8.
[67] Ibid.

> Of those who said they feel worse after increased activity/exercise, for a quarter of people it is immediate (28%), with around a third (37%) saying it takes a few days. ***Recovery from feeling worse after increased activity/exercise mostly takes some time, with 69% reporting the recovery period as days, and 27% saying it can take weeks. …***
>
> ***The treatments most often reported as making people feel worse were:***
> - ***Graded exercise therapy (47%);***
> - ***Graded activity therapy (38%); and***
> - ***Hydrotherapy (28%)***."[68] (Emphasis added)

Emerge Australia particularly noted that there was a higher reporting of deterioration caused by the various exercise regimens among the severely affected, compared to those with mild/moderate symptoms.

5. The NHMRC Advisory Committee then reviewed the key study unpinning the majority of the evidence base that Professor Lloyd presented with respect to Graded Exercise.[69] The PACE Trial utilised the now retired Oxford Criteria. The NHMRC specifically noted that if the PACE trial was taken on face value, the best that the study demonstrated was that "the use of cognitive behavioural therapy and graded exercise therapy in treating ME/CFS as the results implied a moderate improvement of outcome measures."[70] There was no evidence that the effect was permanent or sustained.

   The committee noted the sustained criticism of the study, the sustained attempt by the researchers to prevent access to data, and ultimately the fact that reanalysis of the eventually released data showed the authors "overstated claims of benefit for cognitive behavioural therapy and graded exercise therapy through methodological alterations made throughout the study that skewed outcomes".[71] The NHMRC also criticised the trial because it specifically omitted those who had severe CFS, and likely included those with fatiguing conditions that were not ME/CFS.[72]

6. The NHMRC Advisory Committee specifically address the issue of the NDIS requiring patients to undergo GET[73], stating:

> "Advocates have raised concern about the ***lack of understanding of the condition by National Disability Insurance Agency (NDIA)***

[68] Emerge, 'Emerge Australia Health and Wellbeing Survey of Australians with ME/CFS: Report of key findings' (September 2018), <https://emerge.org.au/wp-content/uploads/2018/09/Emerge-Australia-Health-and-Wellbeing-Survey-of-Australians-with-MECFS-2018.pdf>, p. 2.
[69] NHMRC, above n. 4, p. 11.
[70] Ibid.
[71] Ibid.
[72] Ibid, p. 12.
[73] ibid.

> ***assessors***, and the rejection of claims of people who are significantly impaired. Patients have indicated that a requirement of NDIS is that ME/CFS patients ***undergo graded exercise therapy and/or cognitive behavioural therapy before they can access NDIS***, DSP or supportive services. To access care through the NDIS and DSP patients need to show they have a significant disability. ***For these ME/CFS patients, graded exercise therapy may not be appropriate***."[74] (Emphasis added)

The NHMRC identify that severity is a factor that is not being recognised by the NDIA when assessors are rejecting claims because they require GET. GET is not appropriate for such people. The risk of harm is far too high.

6.2.2. ME/CFS Australia's Position

6.2.2.1. The NDIA Rules

Rule 5.4. of the *National Disability Insurance Scheme (Becoming a Participant) Rules 2016* ('the Rules') states:

> "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.***" (Emphasis Added)

Respectfully – the NDIA is required to apply the rules as it is written and intended, and not merely apply a policy without due regard for how it acquits the requirement of that rules.

There is an apparent disconnect between the outline provided by the NDIA, and the requirement under the Rules.

6.2.2.2. Submissions of Specific Treatments

Whilst ME/CFS Australia is in substantial agreement with the views of the NHMC Advisory Committee identified above, ME/CFS Australia would submit the following on the specific treatments put forward:

- CBT and GET have been expressly removed by the Centres for Disease Control from its recommended treatments since 2018, and Cognitive Remediation is not and has never been recommended;[75]
- CBT, Cognitive Remediation or GET has not been utilised in those with severe ME/CFS at any time, hence there is no evidence base for this group;
- Neither CBT, Cognitive Remediation nor GET is curative (i.e. not likely to remedy);
- Neither CBT, Cognitive Remediation nor GET has been shown in any study to demonstrate a sustained improvement in symptoms;

[74] NHMRC, above n. 4, p. 11.

[75] Centres for Disease Control and Prevention, 'Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Treatment' (12 July 2018) < https://www.cdc.gov/me-cfs/treatment/index.html>.

- Neither CBT, Cognitive Remediation nor GET that is provided in Australia, is the same as what was studied in the PACE trial and is therefore not compatible with that research;
- There is no evidence-base to recommend either treatment.[76]

On specific matters, ME/CFS Australia submits as follows:

6.2.2.2.1. ME/CFS Has No Cure

First and foremost, we make it clear to the NDIA that it is the position of ME/CFS Australia, and indeed every patient organisation and/or advocate in Australia, the NHMRC, the US NIH and CDC, the UK NICE, advocates, researchers and the like, that there is no treatment or management available anywhere in the world that 'cures' ME/CFS.[77,78,79]

ME/CFS Australia is confident that Professor Lloyd would not and did not claim that CBT would cure ME/CFS. We make this statement because it not apparent what the NDIA itself had interpreted his advice to mean.

6.2.2.2.2. Likely to Remedy

Secondly, it is ME/CFS Australia's position that the three treatment options that the NDIA are reliant upon are not, in fact, likely to remedy the impairments outlined in Section 24(a) of the *NDIS Act* – being intellectual, cognitive, neurological, sensory, physical or psychiatric. The NDIS *Operational Guidelines* at 9.2. explains the meaning of "likely to remedy" as "cure or substantially relieve"[80] We have reviewed the relevant case law within the AAT and Federal Court jurisdictions, and the phrase is given its ordinary meaning, consistent with the guideline.

6.2.2.2.2.1. No Appropriate Evidence Base

Rule 5.4 expressly requires there to be an appropriate evidence base with respect to a remedy for an impairment.

ME/CFS Australia submit on a global basis encompassing all three treatments, that even at its strongest, there simply is no satisfaction of Rule 5.4. of the *Rules*, being no appropriate evidence base within the literature provided by Professor Lloyd, or indeed any literature that achieves the bar set by the legislation: that being a remedy for an impairment or impairments arising from ME/CFS.

This position is not simply a self-serving statement of ME/CFS Australia. Self-evidently it is in the interests of the patient community that there be remedies for the condition and that if this were so, it would be embraced accordingly. This position is based upon experience and constant literature review by our Medical Consultant, as well as the decades of experience and monitoring of literature

[76] IOM, above n. 36, pp. 264-265.
[77] Carruthers et al, above n. 32, p. 50.
[78] IOM Committee, above n. 36, p. 10.
[79] NICE, above n. 2, p. 19.
[80] NDIS, 'Access to the NDIS - Early intervention requirements', (16 July 2019) <https://www.ndis.gov.au/about-us/operational-guidelines/access-ndis-operational-guideline/access-ndis-early-intervention-requirements>.

by our directors (several of whom have the skills and experience in research required to conduct such reviews).

Professor Lloyd does, however, provide the 2015 IOM report. Within Chapter 4 of the report, the IOM Committee expressly reviewed the evidence base with respect to treatments for ME/CFS and CFS and drew the following conclusion:

> "Similar to the literature on treatment in ME/CFS patients, ***there is little evidence on the efficacy of interventions in ME/CFS patients with respect to function and disability.***
>
> ***The efficacy of cognitive-behavioral therapy (CBT) in improving cognitive function in ME/CFS patients is unclear.*** Knoop and colleagues (2007) found a decrease in self-reported cognitive impairment following CBT, yet ME/CFS patients did not differ from a support control group on results of the subscale of alertness behavior of the Sickness Impact Profile (SIP-ab).
>
> These results do not preclude the use of CBT to mitigate cognitive impairment in ME/CFS, but do suggest that any effects of CBT may not be measurable by a single scale such as the SIP-ab.
>
> A systematic review showed that while a few studies found improvement in symptoms over time, ***no variables, including gender or length of illness, predicted improvement or positive work or functional outcomes*** (Ross et al., 2002). Furthermore, analysis of existing studies revealed ***no evidence of treatments effective at restoring the ability to work***. Another systematic review found that the placebo response is lower in behavioural intervention studies than in medical intervention studies of patients with ME/CFS (Cho et al., 2005).
>
> Consistent with the findings of the systematic review of Ross and colleagues (2002, 2004), studies reviewed by Taylor and Kielhofner (2005) provided no evidence regarding the efficacy of employment rehabilitation, such as CBT and/or graded exercise therapy. Variation in methodologies, outcome measures, subject selection criteria, and other factors precluded drawing conclusions about the efficacy of interventions designed to enable ME/CFS patients to return to work."[81] (Emphasis Added)

It bears noting that following the IOM report and its position with respect to the retirement of the Oxford criteria, and following the criticism of the methodological flaws in the UK's PACE trial, the US Centres for Disease Control expressly dropped its recommendations for CBT and GET and specifically states that exercise cannot cure ME/CFS.

[81] IOM, above n. 36, pp. 264-265.

ME/CFS Australia therefore defers to the independence of the IOM report and its independent review of the available literature. The IOM committee affirms the position of ME/CFS Australia and was unable to identify any appropriate evidence base for treatments of ME/CFS that could be considered to remedy or be likely to remedy ME/CFS, let alone restore function or impairments.

6.2.2.2.2.2. The Severely Ill

6.2.2.2.2.2.1. Evidence Base

With respect to the severely ill, ME/CFS Australia submits that the NDIA have no basis for rejecting applications from this applicant cohort. Rule 5.4 of the *Rules* expressly requires there to an appropriate evidence base with respect to a likely remedy for an impairment.

That evidence base simply does not exist. Indeed we would argue that Professor Lloyd's own cache of papers upon which the NDIA relies, represents an empirical foundation for that position.

ME/CFS Australia reiterates the NHMRC's Committee's specific point with respect to the severely ill – there is no appropriate evidence base with respect to treatments (particularly those that the NDIA have required). They simply have not been the subject of research papers with respect to treatments.

Professor Lloyd provides the 2015 IOM report – an independent and arguably thorough review of the available literature up until 2015. Within Chapter 4 of the IOM report, the committee expressly reviewed the evidence base with respect to ME/CFS and CFS and its symptoms and manifestations. The committee reported:

> "Studies on ME/CFS used different inclusion criteria and different sources of ME/CFS patients and control participants. The end result is heterogeneity in both patient and control cohorts, ***creating an unclear picture of the symptoms and signs of the disorder and its outcomes***. Findings are based on samples with a large majority of middle-aged women (late 40s to early 50s) who are Caucasian and of higher educational status, perhaps limiting the generalizability of the studies. Very few stuadies focused on other population subsets, such as pediatric or geriatric patients, or included ethnic and racial minority patients. Some studies recruited patients from specialized ME/CFS treatment centers, while others used community-based samples. These different sampling methods may result in patient groups that differ in demographic characteristics and symptom type and severity. ***Furthermore, those most severely affected by ME/CFS may be bedridden or homebound and may not have been included in any of these studies*** (Wiborg et al., 2010). Thus, there are selection biases in the studies' sample composition."[82] (Emphasis Added)

Similarly the Full NICE Guide acknowledge the deficiency in research, stating:

[82] IOM, above n. 36, pp. 71-72.

> "***Randomised controlled trials, with adequate power, are needed*** to compare different methods of delivering standard methods of care, and whether outcomes differ depending on whether they are delivered in primary or secondary care. Subgroup analysis may clarify which approach is most efficient (that is, cost effective without decreasing efficacy) in different groups of people with CFS/ME (***for example, people who are severely affected***)."[83] (Emphasis Added)

6.2.2.2.2.2.2. Acceptance of the Severely Ill

ME/CFS submits that in the complete absence of any evidence base, let alone an appropriate evidence base with respect to treatment, the NDIA needs to put in place a policy that automatically accepts the severely ill (refer to 7.2 below for the full submissions).

In summary, ME/CFS Australia asserts this position on the basis that:

(a) ME/CFS is classified as a neurological condition by the World Health Organisation hence the condition meets the requirement under Section 24(1)(a) of the *NDIS Act* which requires that an applicant's disability be due to one of six categories of impairment – namely neurological;
(b) ME/CFS holds symptoms that create intellectual, cognitive, sensory or physical impairments, as well as comorbid psychiatric conditions that can impair. Such impairments are identified within Section 24(1)(a). Those who fall within the severe category and are bed bound have a physical impairment. Those who are housebound also have a physical impairment. The broad variety of symptoms outlined in the 2003 Consensus Guideline, the 2011 ICC Guidelines, the 2017 Paediatric Guidelines and the IOM Committee's report, indicate that intellectual, cognitive, sensory and psychiatric impairments (e.g. depression), are inherent to the condition;
(c) The absence of an appropriate evidence base with respect to the severely ill demonstrates that no treatment has been identified that is likely to remedy the impairments associated with ME/CFS. Given this is the case, the condition fulfils the requirements of Section 24(1)(b) of the *NDIS Act* in establishing the condition to be permanent or likely to be permanent;
(d) The severely ill have substantially reduced functional capacity and psychosocial capacity to undertake activities such as communication, social interaction, learning, mobility, self-care and/or self-management, and cannot work or engage in social participation. This therefore satisfies the requirements of Section 24(1)(c) and (d) of the *NDIS Act*;
(e) The evidence base simply does not demonstrate that the majority of those affected by ME/CFS are likely to recover. As demonstrated above, the Dubbo study upon which the NDIA has relied, has been grossly misconstrued. Whilst the study merely covered a small percentage of those with PVFS mediated CFS, it did demonstrate that 75% of those diagnosed with PVFS still had the condition at 12 months. This study did not represent the severely ill patient cohort. The severely ill are likely to require support from the NDIS throughout their lifetime, hence they satisfy the requirements of Section 24(1)(e) of the *NDIS Act*.

[83] NICE, above n. 2, p. 39.

6.2.2.2.3. The Treatments

ME/CFS Australia has reviewed the literature provided to use by Ms. Agus, which was purportedly provided by Professor Lloyd. ME/CFS Australia has reviewed this literature and submits as follows:

6.2.2.2.3.1. Cognitive Remediation Therapy

The NDIA has asserted that cognitive remediation therapy (called Cognitive Exercise Therapy or CET) is a treatment that must be attempted by applicants. ME/CFS Australia is particularly perplexed at why the NDIA is relying upon such a treatment. Professor Lloyd has put forward a treatment from his own research group, and the evidence base for that treatment made up of two papers he provides in the literature list, of which he is an author (albeit, his name is omitted on the documents provided to us by Ms. Agus).[84,85]

Putting aside the apparent self-serving nature of the treatment advice provided by Professor Lloyd, ME/CFS Australia submits the following very serious issues:

1. *Single Study* – This is a single study. It has not been replicated;

2. *Level III-3 Evidence* – When deferring to the "Quality of Evidence Ratings" applied by Professor Lloyd in the 2002 RACP Guidelines, this ranks as Level III-3 evidence.[86] This level of evidence was rarely relied upon as an evidence base in those guidelines;

3. *Small Sample Size* – The study involved only 36 patients with CFS[87];

4. *Not Randomised* – The study acknowledges it was not a randomised control study ('RCT')[88];

5. *No Severe Cases* – The study did not include any participants that represent a severe case of ME/CFS. Note that the study examined only those who were able to attend the UNSW Fatigue Clinic, hence no person who was house-bound or bed-bound could participate;

6. *Selection Bias* – The participants were obtained from "an academic, a tertiary referral clinic specializing in the management of chronic fatigue states". The clinic was acknowledged as "UNSW Fatigue Clinic" and it provided "assistance in recruiting participants for the study."[89] Professor Lloyd is a director and his wife is a practice

[84] R.L. McBride, S. Horsfield, C.X. Sandler, J. Cassar, S. Casson, E., Cvejic, U. Vollmer-Conna and A.R. Lloyd, 'Cognitive remediation training improves performance in patients with chronic fatigue syndrome' *Psychiatry Research*. 2017 Nov; 257: 400-405.
[85] C.X. Sandler, B.A. Hamilton, S. Horsfield, B.K. Bennett, U. Vollmer-Conna, C. Tzarminas and A.R. Lloyd, 'Outcomes and predictors of response from an optimised, multidisciplinary intervention for chronic fatigue states' *Intern Med J*. 2016 Dec; 46(12): 1421-1429.
[86] RACP, above n. 1, p. S21.
[87] McBride et al, above n. 83, p. 401.
[88] Ibid, p. 404.
[89] Ibid, p. 404.

manager.[90] There was no community based participant selection;

7. *No Conflict of Interest Declared* – The UNSW Fatigue Clinic is run by Professor Lloyd[91] and his wife, Andrea Lloyd, is the practice manager. The clinic is the only facility in the world offering the treatment and stands to benefit financially from validation of the treatment. Despite these factors, no conflict of interest declaration was made in the publication;

8. *Short Time Period* – The participants received 11 weeks of treatment, and were followed up at 24-weeks post-baseline. Beyond that, they study does not examine the longitudinal effect to see if those obtaining benefit sustained it, or if those who suffered harms from participation recovered their pre-treatment levels[92];

9. *Harms* – The study acknowledges that it did not measure "the impact on fatigue and other symptoms immediately after the training sessions and in the program at all"[93];

10. *No Likely Remedy* – The study purports to show "improvements on a number of objective cognitive performance domains when tested formally"[94] but there is no evidence of a curative effect on cognitive function, hence this does not reach the bar within Rule 5.4 of the *Rules* – "likely to remedy";

11. *No Post-Exertional Testing* – The study at no point tested participants in a post-exertional state, i.e. 24-48 hours post exercise;

12. *Preliminary* – The study is preliminary in nature, and acknowledges this, stating "subjective and objective performance improvements suggest that a computerized, home-based cognitive training program may be an effective intervention for patients with CFS, warranting RCT's."[95]

13. *Not Generalizable* – The study is small scale, does not represent the cross section of ME/CFS subgroups, ethnic backgrounds, or other demographic characteristics, is not randomized, is subject to multiple limitations and very basic. It cannot be generalised as applicable to all persons with ME/CFS.

ME/CFS Australia is exceptionally disappointed that the NDIA would take a preliminary small scale one-off study with no validation, no replication and a number of self-acknowledged limitations, and elevate it to the status of an "evidence-based" treatment.

[90] UNSW Fatigue Clinic, 'About the Clinic' (2019), < https://www.fatigueclinic.unsw.edu.au/about-us/about-the-clinic>.
[91] Ibid.
[92] McBride et al, above n. 84, p. 402.
[93] Ibid, p. 404.
[94] Ibid, p. 403.
[95] Ibid, p. 400.

Aside from the fact that the treatment completely ignored potential harms, it has not been shown to be safe, let alone sustainably effective, and the study is limited to the Fatigue Clinic in Sydney as a research treatment only. It does not show any cure of cognitive or other impairments at any point in the study.

This treatment cannot possibly be held out as a requirement for applicants. It simply does not come close to meeting the requirements of Rule 5.4 of the Rules. It is acknowledged that CET was used in a larger scale study in 2017 and this is examined below in 6.2.2.3.3.3.

6.2.2.2.3.2. Cognitive Behavioural Therapy

The NDIA appears to be asserting that CBT is an appropriate "evidence-based management" in accordance with the *Rules* – ergo it is "likely to remedy" the impairments associated with the claimed condition.

We therefore conclude that the NDIA therefore requires an applicant to engage in CBT prior to obtaining access to the NDIA.

ME/CFS Australia have noted that the policy outlined to this organisation does not actually state that Professor Lloyd has represented that CBT is "likely to remedy" the impairments that arise in ME/CFS. We can only infer that the NDIA is representing that the use of CBT remedies ME/CFS.

ME/CFS Australia therefore submits as follows:

6.2.2.2.3.2.1. Evidence Base

As outlined in Section 6.2.2.2.2.1. the IOM found no literature to support the view that CBT improves function.

6.2.2.2.3.2.2. CBT Not Uniform

The NDIA has been provided a variety of papers in which CBT has been studied or recommended. ME/CFS Australia makes the following points:

1. *CBT Not Compatible* - The mere fact that a treatment is referred to as CBT, does not equate to uniformity of treatment protocol – they are superficially similar only. In short – the various studies and meta-analyses do not actually examine the same type of protocol applied within CBT;

2. *Criteria Not Compatible* – The literature that Professor Lloyd provides contains various reviews, including a mish-mash of criteria including the 1994 Fukuda criteria, the 1991 Oxford Criteria and 1994 London Criteria. The latter two focus on fatigue and have been rejected from use in research by the IOM and NHMRC. Respectfully, any research from the UK utilises the latter two criteria – hence any papers from White, Chalder, Wessely, Cleare, Sharpe et al, or utilising such papers (e.g. the two Cochrane Reviews, the NICE Guides, the 2002 RACP Guidelines and the work of Prins, et al.) also incorporate those criteria. In short, almost half of Professor Lloyd's literature is tainted with these criteria;

3. *Not Transferrable* – The CBT utilised in the UK within their CFS centres within the National Health Service (NHS, cannot be transferred to an Australian context – there simply is not that trained infrastructure. It is noted that Rule 5.4. of the *Rules* requires that the "appropriate evidence-based" treatment be "available" – clearly that is not the case;

4. *No Training* – There is no training of any psychologists throughout Australia in the application of CBT for ME/CFS, hence the expectation that CBT could be delivered by any psychologist without experience, or with the pretence of some knowledge, or an approach that is not informed by an actual evidence-based program, is arguably dangerous and/or ineffective. The NHMRC ME/CFS Advisory Committee highlights in its report that the knowledge of allied health staff is quite poor to non-existent. The NICE Guides actually make the point quite firmly:

> "A course of CBT should be delivered only by a healthcare ***professional with appropriate training in CBT and experience in CFS/ME***, under clinical supervision. ***The therapist should adhere closely to empirically grounded therapy protocols.***"[96]

   The NHMRC ME/CFS Advisory Committee made the point repeatedly that training of medical and allied health staff is a priority given there are very few knowledgeable or experienced practitioners in Australia;

5. *No Centres* – The Fatigue Clinic is based in Sydney. There is a facility in Melbourne that purports to deliver CBT, not uniform in approach with Sydney. Outside of these locations, there is nothing, hence it is impossible for people to access. Again, Rule 5.4. of the *Rules* requires that the treatment be available. For the majority of Australians, there is no availability;

ME/CFS Australia submits that the NDIA is operating under a false belief that the literature provided by Professor Lloyd provides an appropriate evidence base that complies with Rule 5.4. of the *Rules*. The NDIA erroneously makes the following assumptions about the literature provided by Professor Lloyd:

(a) the criteria and condition examined within each paper or guidelines is uniformly compatible;
(b) treatment protocols are the same and are delivered in uniform approach;
(c) there exists an available and knowledgeable infrastructure to deliver treatment throughout Australia.

Respectfully, what might be represented in those articles and guidelines is not what is being delivered in reality. The reality is there is no uniform protocol and no infrastructure throughout the majority of the country. Additionally, the reality is that poor delivery of CBT could do more harm than good.

[96] NICE, above n. 2, p. 26.

6.2.2.2.3.2.3. Access

The NDIA is under the false assumption that CBT is accessible to one an all, uniformly throughout Australia. ME/CFS Australia submits:

1. *Two Centres* – As outlined above there are two centres that formally deliver what they assert is "evidence based" CBT for ME/CFS. There is no evidence that the protocol of CBT delivered is consistent with any evidence-based protocol, or that there is a consistency in such protocol between the two centres. There is no evidence that these centres are effective in their delivery of CBT when applied to patients with 1994 Fukuda CFS or 2003 Consensus Criteria ME/CFS – because there has never been a properly conducted RCT of these patients, using effective, objective measures and inclusive of the reporting of harms and drop outs;

2. *Accessibility* – Even if an applicant were located in a city where there was a facility, there are numerous limitations that can prevent access:
   (a) Affordability – Most people with ME/CFS struggle financially, hence cannot necessarily afford access to delivery of the treatment;

   (b) Transport – Assuming an applicant has access to a vehicle, they may not be able to drive themselves because of the symptoms of the condition, may not have someone to drive them, or may not be able to afford to drive to the centre. Those who have access to public transport may not be able to use it because the trip exposes them to exacerbators of their symptoms, e.g. smells, chemicals, sensory overload, PEM, orthostatic intolerance, photophobia, etc.;

   (c) Post-Exertional Malaise – Assuming a person is able to travel and attend, the process of travel and engaging in the CBT can cause the applicant to enter a crash state, or suffer PEM;

3. *Severe Patients* – Attendance at a centre and/or participation in CBT simply is not feasible for the majority, if not all, that fall within the severe group of applicants;

6.2.2.2.3.2.4. Efficacy

The NDIA is under the false assumption that CBT provides a remedy for one or more of the impairments outlined within Section 24 the *Act*. ME/CFS Australia submits:

1. *PACE Trial* – The PACE trial (which utilises the retired Oxford Criteria and focuses on a fatigue cohort), if one accepts the validity of its results from subjective measures, at their best reveals that CBT will only deliver "moderately improve[d] outcomes".[97] The PACE trial was conducted on the basis of the behavioural/deconditioning model of CFS in which it is

[97] P.D. White, K.A. Goldsmith, A.L. Johnson, 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' *Lancet* 2011; 377: 823–36, 823.

believed that patients are deconditioned and this is being perpetuated by a fear of worsening the symptoms through doing activity. CBT purportedly did little to improve walking, the only objective measure of activity used, but purportedly improved depression.[98]

The authors declared CBT to be a "moderately effective outpatient treatment".[99] The authors claim that 30% of CBT participants fell with the "normal range" after treatment.[100] In arriving at these conclusions, the authors acknowledge that "recovery" does not mean recovery of all symptoms of the condition. The authors also make it very clear that results do not apply to patients satisfying the 1994 Fukuda criteria or the 2003 Canadian Criteria or other international criteria except where the primary symptom is fatigue. Note that this is a small subset of these latter patients. Follow up reviews of the participants at two years showed little evidence of improvements in physical function.[101,102]

2. *PACE Trial Review* – Following critical review of the PACE trial[103,104,105,106,107] and a legal case initiated by Australian, Alan Matthees, in the UK High Court, the PACE data was released, with the authors proffering multiple reasons and allegations that the Court rejected as baseless.[108] The PACE Trial authors originally released the protocol for the study in 2007 and this differed substantially from the final study.[109] Tuller[110], Coyne[111], and indeed numerous eminent authors[112] have revealed that the PACE authors engaged in post-hoc outcome

[98] Ibid, p. 834.
[99] Ibid, p. 831.
[100] NB – The major criticism of the PACE trial is the fact that the normal range was altered downwards significant from the pilot study, to a level that is below was an c. 80 year old person's physical function is – a range that simply is not consistent with the ordinary meaning of recovery
[101] T. Chalder, K.A. Goldsmith, P.D. White, et al., 'Rehabilitative Therapies for Chronic Fatigue Syndrome: A Secondary Mediation Analysis of the PACE Trial' *The Lancet Psychiatry* 2015; 2(2): 144-152.
[102] M.C. Sharpe, K.A. Goldsmith, A.L. Johnson, et al., 'Rehabilitative Therapies for Chronic Fatigue Syndrome: A Secondary Mediation Analysis of the PACE Trial' *The Lancet Psychiatry* 2015; 2(12): 1067-1074.
[103] D. Tuller, 'Trial by Error: The Troubling Case of the PACE Chronic Fatigue Syndrome, (21 October 2015), <http://www.virology.ws/2015/10/21/trial-by-error-i/>.
[104] D. Tuller, 'Trial by Error: The Troubling Case of the PACE Chronic Fatigue Syndrome (Second Instalment), (22 October 2015), <http://www.virology.ws/2015/10/22/trial-by-error-ii/>.
[105] D. Tuller, 'Trial by Error: The Troubling Case of the PACE Chronic Fatigue Syndrome (Final Instalment), (23 October 2015), <http://www.virology.ws/2015/10/23/trial-by-error-iii/>.
[106] J. Coyne, 'Uninterpretable: Fatal flaws in PACE Chronic Fatigue Syndrome follow-up study', (29 October 2015) PLOS Blogs Network <https://blogs.plos.org/blog/2015/10/29/uninterpretable-fatal-flaws-in-pace-chronic-fatigue-syndrome-follow-up-study/>.
[107] J.C. Coyne and J.R. Laws, 'Results of the PACE follow-up study are uninterpretable' *Lancet Psychiatry* 2016 Feb 1; 3(2): e6-e7.
[108] *Queen Mary University of London v The Information Commissioner and Alem Matthees* [2016] UKFTT 2015_0269 (GRC).
[109] P.D. White, M.C. Sharpe, T. Chalder, et al., '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 chronic fatigue syndrome/myalgic encephalomyelitis or encephalopathy.' *BMC Neurol* 2007 Mar 8; 7: 6.
[110] Tuller, above n. 103-105.
[111] Coyne, above n. 106-107.
[112] 'Special Issue: The PACE Trial', *Journal of Health Psychology*, 2017; 22(9), 1103-1216 – this issues contained 19 articles from a variety of authors, addressing various issues with respect to the PACE trial, including investigator bias, null effect, patient selection errors, harms, disregards for principles of science, bias methods, unreliable outcomes, misleading information, and lack of objective measures.

switching, alteration of entry and recovery criteria, failure to declare conflicts of interest and various other misdeeds that overinflated the results to make the effect of CBT and GET seem to be much better than it was. The recovery criteria came under significant criticism because:

- The definition of recovery was "loosely defined" and did not reflect the "commonly understood" definition [113] and fails to "capture the core meaning of recover – that is, a return to good health"[114];
- The recovery criteria was "substantially modified after the publication of the trial process"[115];
- The claims that the symptoms of CFS were fully reversible were not justified[116];
- On the objective criteria "none of the 'recovered' patients achieved a normal walking distance in the six-minute walking test"[117];

Following the release of the data, the PACE trial authors released a revised analysis of the data which employed the original protocol.[118] The effect of the revision was a reduction in the significance of various measures. The authors concluded that little had changed. In contrast, Wilshire et al summarise the issues and then apply the original protocol to the data.[119] The authors reveal that their figures were similar in outcome to the revision of the PACE trial authors. However, when the original protocol for recovery was restored, the recovery rate from CBT dropped from 30% to 7%, hence there was no longer a statistically significant effect of treatment on recovery rates.[120]

The long-term outcomes of CBT, GET, Adaptive Pacing and specialist medical care showed none were effective, hence the null effect invalidates the use of CBT and GET in ME/CFS.[121,122]

What is significant, in our submission, is that the study does not provide some form of reference point by which the NDIA can deduce that the impairments under the Act are able to be remedied.

[113] S. Wilshire, T. Kindlon and S. McGrath, 'PACE Trial Claims of Recovery are Not Justified by the Data: A Rejoinder to Sharpe, Chalder, Johnson, Goldsmith and White (2017)', *Fatigue: Biomedicine, Health & Behavior* 2017; 5(1): 62-67, 62.
[114] Ibid, p. 63.
[115] Ibid, p. 62.
[116] Ibid, p. 63.
[117] Ibid, p. 65.
[118] K.A. Goldsmith, P.D. White, T. Chalder, et al. 'The PACE Trial: Analysis of Primary Outcomes Using Composite Measures of Improvement: Unpublished Report', (8 September 2016) Queen Mary University of London <https://www.qmul.ac.uk/wolfson/media/wolfson/current-projects/PACE_published_protocol_based_analysis_final_8th_Sept_2016(1).pdf>.
[119] C.E. Wilshire, T. Kindlon, R. Courtney, et al., 'Rethinking the Treatment of Chronic Fatigue Syndrome—A Reanalysis and Evaluation of Findings From a Recent Major Trial of Graded Exercise and CBT' *BMC Psychology* 2018; 6(6).
[120] Ibid, p. 6.
[121] M. Vink, 'The PACE Trial Invalidates the Use of Cognitive Behavioral and Graded Exercise Therapy in Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome: A Review' *Journal of Neurology and Neurbiology* 2016; 2(3), 10.
[122] K.J. Geraghty and C. Blease, 'Cognitive behavioural therapy in the treatment of chronic fatigue syndrome: A narrative review on efficacy and informed consent' *Journal of Health Psychology* 2016 Sep 15; 23(1): 127-138.

3. *Cochrane* – In reviewing psychotherapies for functional syndrome (including CFS), the authors identified multiple methodological concerns in psychotherapy trials, including the high drop out rates and the selection bias in sampling.[123]. This criticism from Cochrane raises the credibility of ME/CFS Australia's assertions that studies with respect to ME/CFS are inherently flawed, particularly PACE;

4. *Fatigue Clinic Study* – Professor Lloyd's UNSW Fatigue Clinic team conducted a study which examined and mixed in participants with Post-Cancer Fatigue and CFS, which the authors categorise as medically unexplained fatigue states, hence this is not a CFS study.[124] The study, which is not a RCT, incorporates two arms: one which integrates CBT treatment; and the other being CBT and GET.[125] This study clearly defers to the construction and outcomes of the PACE trial and is identified as such.[126]

   As per point 1 above, the PACE study focused on participants who fulfilled to Oxford criteria where the primary symptom was chronic fatigue, and the study was only comparable to 1994 Fukuda where fatigue was the primary symptom. Participants were selected on the basis of prolonged fatigue. This UNSW study's primary measure was an improvement in fatigue, with secondary measures focused on functional outcomes, mood and sleep.[127] The study purported to report harms and identified only three adverse events. There was no follow-up of participants beyond 12 months, hence there is no validity for this study to purport to remedy impairments. There is nothing in the study that indicates that it purports to remedy the condition or remedy impairments.

   Despite purporting to report on CBT alone, the study actually contains no outcomes with respect to CBT alone. The authors do not report any conflicts of interest, despite Professor Lloyd being a director of the Fatigue Clinic, his wife being the practice manager[128] or the fact that he receives a pecuniary and/or non-pecuniary benefit from the validation of protocols utilised in the clinic. The study does not reveal the severity of participants' sympyoms, however it is self-evident that participants who fall into the severe end of the spectrum of the condition are not studied. There is nothing in the study that purports to help participants achieve recovery, and nothing to indicate that the effects last long term.

5. *UK Survey for NICE* – In responding to a request for evidence from the NICE Guidelines Review Committee[129], the patient organisations collected data and a report was produced by

[123] N. Van Dessel, M. den Boeft, J.C. van der Wouden, 'Non-pharmacological interventions for somatoform disorders and medically unexplained physical symptoms (MUPS) in adults' *Cochrane Database of Systematic Reviews* 2014; 11: CD011142.
[124] Sandler et al, above n. 103, pp. 1421-1422.
[125] Ibid, p. 1421.
[126] Ibid, p. 1422.
[127] Ibid, p. 1425.
[128] UNSW Fatigue Clinic, above n. 89.
[129] Forward ME Group, 'CBT and GET Survey Results Published by Forward-ME Group', (3 April 2019) <https://www.meaction.net/2019/04/03/cbt-and-get-survey-results-published-by-forward-me-group/?fbclid=IwAR3sEJmAbYjfnOW0acxDTQ0gVYxOjLBbDAuyFIIDLxnLp1bsXB2fYfXUFOQ>.

Oxford Brookes University.[130] The large survey of patients (n = 670) reveal with respect to CBT that 16.2% experienced improvement in physical health, 53% reported no change and 24.6% experienced deterioration in their physical health. With respect to mental health, 41.5% reported improvement in mental health, 28.1% experienced no change and 26.9% experienced deterioration.[131]

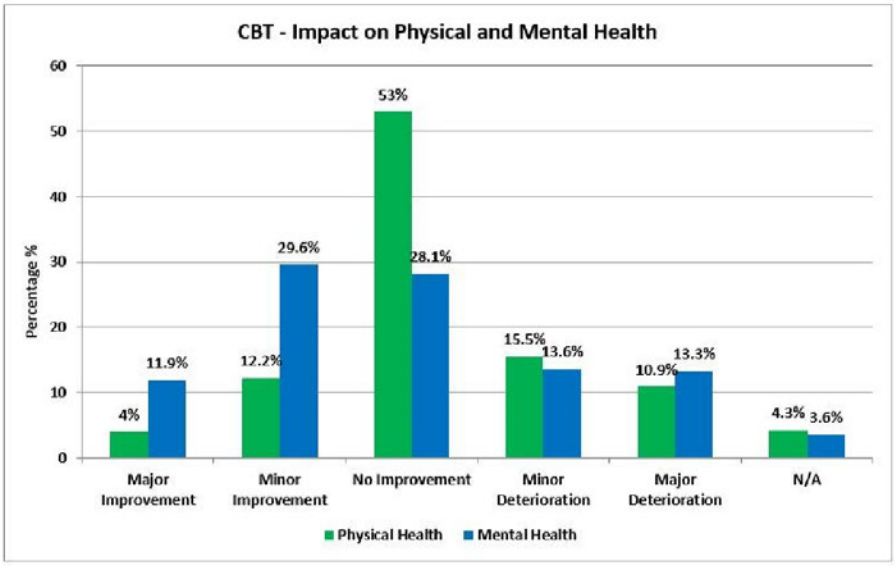

Figure 7. Impact of CBT treatment on physical and mental health

6. *Other Surveys* – Prior to the above study, Action for ME in UK conducted a patient health and well-being survey. The survey had over 2000 respondents, hence was a significant study. When indicating the impact of CBT, 54% reported that CBT was a little or very helpful, while 34% indicated no change and 12% reported that the treatment made them a little bit or a lot worse.[132]

6.2.2.2.3.2.5. Submission

ME/CFS Australia submits the following with respect to CBT:

- *Not Recommended by CDC* - The US Centres for Disease Control and Prevention removed CBT from its recommended treatments in mid-2018 and it is no longer included on their website. This removal coincided with their retirement of the 1994 Fukuda Criteria in favour of the IOM's emphasis on systemic exertion. The inference has to be drawn that this removal clearly signals that CBT is not regarded as an effective treatment[133];

[130] H. Dawes, 'Evaluation of a survey exploring the experiences of adults and children with ME/CFS who have participated in CBT and GET interventional programmes' (27 February 2019) < http://www.meaction.net/wp-content/uploads/2019/04/NICE-Patient-Survey-Outcomes-CBT-and-GET-Oxford-Brookes-Full-Report-03.04.19.pdf>.
[131] Ibid, pp. 6-7.
[132] Action for ME, 'M.E. Time to Deliver' (12 May 2014) < https://www.actionforme.org.uk/uploads/pdfs/me-time-to-deliver-survey-report.pdf>, p. 19.
[133] CDC, above, n. 75.

- *Severe Not Included* - Nothing in the alleged "evidence-base" purports to research the use of CBT on patients who fall within the severe category of ME/CFS, hence there simply is no justification to argue that this literature forms an evidence base for this patient cohort. It therefore fails the requirement under Rule 5.4. The evidence base provided is not appropriate;
- *Retired Oxford Criteria* - The evidence-base provided by Professor Lloyd is primarily based upon the now retired Oxford criteria, which focuses on fatigue;
- *Oxford Criteria Focused on Fatigue* - Research utilising the Oxford criteria simply does not represent the majority of patients diagnosed under the 1994 Fukuda criteria or the 2003 Consensus Criteria. This criteria is focused on patients who have fatigue as their primary symptom and requires no other symptoms, unlike Fukuda and the Consensus Criteria. This evidence base therefore does not satisfy the requirement that evidence be "appropriate" within Rule 5.4 of the *Rules*;
- *Treatments Do Not Remedy* - Even if the evidence base provided by Professor Lloyd was accepted, the studies do not show that a person receiving the treatment is likely (i.e. high probability of occurring or being true[134]) to have their impairments remedied, because the effect is moderate at best;
- *Significant Harms Reported* -The most recent evidence from the UK provided to the current NICE review committee at the committee's request, sourced from over 2000 patients, clearly shows that the majority of survey respondents derived no benefit from CBT, whilst most concerningly, there were significant rates of minor to major harms to patients that arose from the CBT they received;
- *Evidence Base Not Appropriate* -The evidence base provided by Professor Lloyd is exceptionally limited and highly contentious – hence does not fulfil the criteria of "appropriate" within the meaning of Rule 5.4. of the *Rules*;
- *Evidence Base Focused on Fatigue* - The evidence base provided by Professor Lloyd, even if accepted, is focused upon those patients for whom fatigue is the primary symptom. The PACE trial authors make it clear that the treatments are suitable for those patients who meet the Fukuda and Consensus criteria "ONLY if fatigue is their main symptom".[135] For the vast majority of patients who do not experience fatigue as their primary symptom, the evidence base provided by Professor Lloyd does not address their symptoms. The evidence base is therefore does not meet the definition of appropriate within the meaning of Rule 5.4. of the *Rules*.

6.2.2.2.3.3. Graded Exercise Therapy

The NDIA appears to be asserting that GET is an "evidence-based management" in accordance with the rules, ergo it is "likely to remedy" the impairments associated with the claimed condition. The NDIA therefore requires an applicant to engage in GET prior to obtaining access to the NDIA.

[134] Merrium-Webster, 'Likely", (2019) <https://www.merriam-webster.com/dictionary/likely>.
[135] White et al, above n. 97, p. 834.

ME/CFS Australia have noted that the policy outlined to this organisation does not actually state that Professor Lloyd has represented that GET is "likely to remedy" the impairments that arise in ME/CFS. We can only infer that the NDIA is representing that the use of GET remedies ME/CFS.

ME/CFS Australia therefore submits as follows:

6.2.2.2.3.3.1. Evidence Base

As outlined in Section 6.2.2.2.2.1. the IOM found no literature to support the view that GET improves function.

6.2.2.2.3.3.2. GET Not Uniform

The NDIA has been provided a variety of papers in which GET has been studied or recommended. ME/CFS Australia makes the following points:

1. *GET Not Compatible* – As submitted above with respect to CBT, the mere fact that a treatment is referred to as GET, does not equate to uniformity of treatment protocol. They are superficially similar only. In short, the various studies and meta-analyses do not actually examine the same type of protocol applied as GET. The Cochrane review of GET in CFS acknowledges this issue within studies, stating:

> "Exercise therapy lasted from 12 to 26 weeks. Seven studies used variations of aerobic exercise therapy such as walking, swimming, cycling or dancing provided at mixed levels of intensity of the aerobic exercise from very low to quite vigorous, whist one study used anaerobic exercise."[136]

2. *Criteria Not Compatible* – As submitted above with respect to CBT, the literature that Professor Lloyd provides is tainted with a mismatch of various incompatible criteria for participant selection;

3. *Not Transferrable* – The form of GET utilised in the UK within their CFS centres within the National Health Service (NHS), cannot be transferred to an Australian context. There simply is not that trained infrastructure. It is noted that Rule 5.4. of the *Rules* requires that the "appropriate evidence-based" treatment be "available". Clearly that is not the case;

4. *No Training* – There is no training of any exercise physiologist or physiotherapist throughout the country with respect to GET in the context of ME/CFS, hence the expectation that it can be delivered by any practitioner, without experience, or with the pretence of some knowledge, or an approach that is not informed by an actual evidence-based program, is arguably dangerous and/or ineffective. The NHMRC ME/CFS Advisory Committee highlights in its report that the knowledge of allied health staff is quite poor to non-existent. As with CBT, the NICE Guides made the same point with respect to GET:

[136] L. Larun, K.G. Bruberg, J. Odgaard-Jensen, and J.R. Price, 'Exercise Therapy for Chronic Fatigue Syndrome', *Cochrane Database Sys Rev* 2017; 4; CD 003200, 6.

> "GET should be ***delivered only by a suitably trained GET therapist with experience in CFS/ME***, under appropriate ***clinical supervision***."[137] (Emphasis Added)

The NHMRC ME/CFS Advisory Committee made the point repeatedly that training of medical and allied health staff is a priority given there are very few knowledgeable or experienced practitioners in Australia;

5. *No Centres* – The Fatigue Clinic is based in Sydney. There is a facility in Melbourne that purports to deliver GET, although not uniform with Sydney. Outside of these locations, there is nothing, hence it is impossible for people to access a structured, purportedly "evidence-based" program. Again, Rule 5.4. of the *Rules* requires that the treatment be available. For the majority of Australians, there is no availability;

ME/CFS Australia submits that the NDIA is operating under a false belief that the literature provided by Professor Lloyd provides an appropriate evidence base that complies with Rule 5.4. of the *Rules*. The NDIA erroneously makes assumptions about the literature provided by Professor Lloyd, that:

(a) the criteria and condition examined within each paper or guidelines is uniformly compatible;
(b) treatment protocols are the same and are delivered in uniform approach;
(c) there exists an available and knowledgeable infrastructure to deliver treatment throughout Australia.

ME/CFS Australia repeats the point raised with respect to CBT: what might be represented in those articles and guidelines is not what is being delivered in reality. The reality is there is no uniform protocol and no infrastructure throughout most of the country. Additionally, the reality is that poor delivery of GET can do more harm than good.

6.2.2.2.3.3.3. Access

The NDIA is under the false assumption that GET is accessible to one an all, uniformly throughout Australia. ME/CFS Australia submits:

1. *Two Centres* – As outlined above there are two centres that formally deliver what they assert is "evidence based" GET. There is no evidence that the protocol of GET delivered is consistent with any evidence-based protocol, or that there is a consistency in such protocol between the two centres. There is no evidence that these centres are effective in their delivery of GET when applied to patients with 1994 Fukuda CFS or 2003 Consensus Criteria ME/CFS, because there has never been a properly conducted RCT of these patients, using meaningful, objective measures and inclusive of the reporting of harms and drop outs;

2. *Accessibility* – Even if an applicant was located in a city where there was a facility, there are numerous limitations that can prevent access:
   (a) Affordability – Most people with ME/CFS struggle financially, hence cannot necessarily afford access to delivery of the treatment;

[137] NICE, above n. 2, p. 28.

(b) Transport – Assuming an applicant has access to a vehicle, they may not be able to drive themselves because of the symptoms of the condition, may not have someone to drive them, or be able to afford to drive to the centre. Those who have access to public transport may not be able to use it because the trip exposes them to exacerbators of their symptoms, e.g. smells, chemicals, sensory overload, PEM, orthostatic intolerance, photophobia, etc.;

(c) Post-Exertional Malaise – Assuming a person is able to travel and attend, the process of travel and engaging in the GET can caused the applicant to enter a crash state, or suffer PEM;

3. *Severe Patients* – Attendance at a centre and/or participation in GET simply is not feasible for the majority, if not all, that fall within the severe group of applicants;

6.2.2.2.3.3.4. Efficacy

The NDIA is under the false assumption that GET provides a remedy for one or more of the impairments outlined within Section 24 the *Act*. ME/CFS Australia submits:

1. *PACE Trial* – ME/CFS Australia defers to its position with respect to the criteria, fatigue focus and subjective measures identified above with respect to CBT (at 6.2.2.2.3.2.4). The PACE trial, if one accepts the validity of its results with respect to GET and subjective measures, only delivered "moderately improve[d] outcomes".[138] GET purportedly improved walking, the only objective measure of activity used, slightly more than CBT, but did not improve depression.[139] The authors claimed GET to be "moderately effective outpatients treatments".[140] The authors claim that 28% of GET participants fell with normal ranges after treatment.[141] In arriving at these conclusions, the authors acknowledge that "recovery" does not mean recovery of all symptoms of the condition. The authors also make it very clear that results do not apply to patients satisfying the 1994 Fukuda criteria or the 2003 Canadian Criteria or other international criteria, except where the main symptom is fatigue. Note that this is a small subset of these latter patients. Follow up reviews of the participants at two years showed little evidence of improvements in physical function.[142,143]

2. *PACE Trial Review* – Following critical review of the PACE trial[144,145,] and the Freedom of Information legal case mentioned above[146], the PACE trial's original 2007 protocol[147] was

[138] White, et al, above n. 97, 823.
[139] Ibid, p. 834.
[140] Ibid, p. 831.
[141] NB – The major criticism of the PACE trial is the fact that the normal range was altered downwards significant from the pilot study, to a level that is below was an c. 80 year old person's physical function is – a range that simply is not consistent with the ordinary meaning of recovery
[142] Chalder et al, above n. 100.
[143] Sharpe, et al, above n. 101.
[144] Tuller, above n. 103-105.
[145] Coyne, above, n. 106-107.
[146] *Queen Mary University of London v The Information Commissioner and Alem Matthees* [2016] UKFTT 2015_0269 (GRC).
[147] White et al, above n. 109.

applied to the data by Wilshire et al and revealed a lower rate of 'recovery'.[148] The GET arm of the PACE trial was, like the CBT arm, the subject of numerous serious anomalies that overinflated the effectiveness of the treatment.[149,150,151]

The PACE authors revised their data analysis in 2013 using their original protocol, concluding that little changed, with recovery from GET falling from the claimed 30% recovery rate, to a statistically significant 22%.[152] Wilshire et al analysed the data with the original protocol[153] revealing a similar outcome. However, when the original parameters for ascertaining recovery were restored, the recovery rate from GET dropped from the originally reported rate of 30% recovery to a statistically insignificant 4%, hence there was no longer a statistically significant effect of treatment on recovery rates.[154]

The long-term outcomes of CBT, GET, Adaptive Pacing and specialist medical care showed a null effect, hence the original protocols invalidated the use of GET and CBT in ME/CFS.[155,156]

Consistent with our submission with respect to CBT, ME/CFS Australia reiterates that the study does not provide some form of reference point by which the NDIA can deduce that the impairments under the Act are able to be remedied.

3. *Cochrane* – There are a number of Cochrane reviews with respect to CFS referred to in the literature list from Professor Lloyd, however the reference is duplication.[157] The NDIA have not stated when Professor Lloyd provided his evidence base, but it does not appear to be post May 2017. The NDIA were therefore been made aware that an editor's note was published on 25 October 2018 advising that a formal complaint had been received about the Cochrane publication.[158] On 8 March 2019, the editor in chief published the following note:

> "Cochrane's editors and the review author team have jointly agreed that there will be a further period up to the end of May 2019, in which time the author team will amend the review to address changes aimed at improving the quality of reporting of the review and ensuring that the conclusions are fully defensible and valid to inform health care decision

[148] Wilshire et al, above n. 118.
[149] Tuller, above n. 103-105.
[150] Coyne, above n. 106-107.
[151] 'Special Issue: The PACE Trial', *Journal of Health Psychology*, 2017; 22(9), 1103-1216 – this issues contained 19 articles from a variety of authors, addressing various issues with respect to the PACE trial, including investigator bias, null effect, patient selection errors, harms, disregards for principles of science, bias methods, unreliable outcomes, misleading information, and lack of objective measures.
[152] Goldsmith et al, above n. 119.
[153] Wilshire, above n. 118, p. 6.
[154] Ibid, p. 6.
[155] M. Vink, 'The PACE Trial Invalidates the Use of Cognitive Behavioral and Graded Exercise Therapy in Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome: A Review' *Journal of Neurology and Neurbiology* 2016; 2(3), 10.
[156] K.J. Geraghty and C. Blease, 'Cognitive behavioural therapy in the treatment of chronic fatigue syndrome: A narrative review on efficacy and informed consent' *Journal of Health Psychology* 2016 Sep 15; 23(1): 127-138.
[157] Larun et al, above n. 136.
[158] Ibid – see 'Notes' <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003200.pub7/information>.

making. The changes will also address concerns raised in feedback since the Robert Courtney complaint. The amendment will not include a full update, but a decision about this will made subsequently" [159]

The complaint of Robert Courtney[160] focused upon the fact that the Cochrane review failed to publish a "rigorous, unbiased, transparent and independent analysis", having included the technically and methodologically flawed PACE trial within the studies accepted for review, without having adequately considered these flaws. Courtney also noted that three of the Cochrane authors were working with members of the PACE trial authors on other projects, hence a significant conflict of interest existed.

Putting aside these issues and examining the study on face value, the Cochrane authors:

- relied on five studies that selected patients based on the retired Oxford criteria.[161] These studies are focused on fatigue only. Only eight studies were included in total;
- identify that there was no uniformity to the delivery mode or duration of the GET utilised[162];
- claimed the "seven studies consistently showed a reduction in fatigue following exercise therapy at end of treatment"[163];
- assert "serious adverse reactions were rare" in the two studies that made an attempt to measure such events[164];
- concluded that "[p]atients with CFS ***may generally benefit and feel less fatigued*** following exercise therapy, and ***no evidence suggests*** that exercise therapy may ***worsen outcomes***. A positive effect with respect to ***sleep, physical function and self-perceived general health has been observed***, but ***no conclusions for the outcomes of pain, quality of life, anxiety, depression***, drop-out rate and health service resources were possible … ***Randomised trials with low risk of bias are needed*** to investigate the type, duration and intensity of the most beneficial exercise intervention."[165]

ME/CFS Australia submits that were the Cochrane review taken at face value as reliable and unfettered by the criticisms currently levelled against it, the study still falls well short of purporting to remedy impairments or the condition as a whole.

No studies examined included the severely ill patients that make up approximately 25% of the ME/CFS population, hence there is no evidence base for this group..

[159] Ibid.
[160] R. Courtnery, 'Formal Complaint – Cochrane review CD003200' (18 February 2018) <https://www.dropbox.com/s/uhy95caezsmcue7/Robert%20Courtney%20Cochrane%20complaint(1).zip?dl=0&file_subpath=%2FRobert+Courtney+Cochrane+complaint.pdf>.
[161] Larun et al, above n. 136.
[162] Ibid, p. 2.
[163] Ibid.
[164] Ibid.
[165] Ibid.

The key point made was a purported "reduction in fatigue", hence not "likely to remedy", ergo falls well short of the bar required under the Rules. This submission is strengthened by the fact that the authors qualified their position heavily when stating patients "may generally benefit and feel less fatigued". This degree of uncertainty does not fulfil the requirement of rule 5.4. of the *Rules* which requires that it be "likely to remedy". The Cochrane review asserts possible benefits, not probable benefits, with respect to fatigue. With respect to other symptoms, the review finds "no conclusions for the outcomes of pain, quality of life, anxiety, depression".

4. *Cochrane Review* – The Cochrane paper was reviewed following multiple criticisms of its approach to conflicts of interest and particularly its handling of the PACE trial.[166] A recent article by Vink and Vink-Niese identified seven key areas of concern with respect to the paper:

    - *Conflicts of Interest* – The Cochrane authors held an allegiance to the CBT and GET model, and were proponents of the biopsychosocial approach to CFS. ME and CFS are classified as a neurological condition by the World Health Organisation. Seven of the eight papers reviewed came from the biopsychosocial approach to the condition, whilst the eighth did not and concluded that no treatment strategy was superior to another in all areas[167];
    - *Exclusion of Study* – The authors excluded a study that found no intervention improved health-related quality of life scores, and led to worse physical function and bodily pain scores. CBT and GET were found to be ineffective and potentially harmful[168];
    - *Broad Criteria* – The authors included five studies that utilised the Oxford criteria, which only requires six months of unexplained fatigue and no other symptoms. This criteria allows the selection of participants with mild fatigue and chronic idiopathic fatigue, and mislabels them as CFS. The inclusion of such participants confounds the ability to interpret the results for people with ME/CFS. It was noted that the US IOM and the Agency for Healthcare Research recommended retirement of the criteria because of this potential for inaccuracy. Additionally, 40% of participants within the studies selected had comorbid psychiatric disorders, which can explain a chronic fatigue state and excludes classification as CFS. The erroneous inclusion of people who do not have CFS may mean they are susceptible to the interventions, hence confounding the results[169];
    - *Entry Score Requirements Not Sufficiently Strict* – Five studies had entry requirements that potentially allowed high-functioning participants to enter the studies. Three of these studies had no entry score requirements. These

[166] M. Vink and A. Vink-Niese, 'Graded Exercise Therapy for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome is Not Effective and Unsafe. Re-analysis of a Cochrane Review' *Health Psychology Open* 2018 Jul-Dec: 1–12.
[167] Ibid, pp. 1-2.
[168] Ibid.
[169] Ibid.

weaknesses potentially allowed participants into the study who did not have CFS[170];

- *Primary Outcome was Subjective Fatigue Measured by Self Report* – Whilst the eight studies claimed to be blind, they used two subjective primary outcomes being fatigue and adverse outcomes. Participant self-report is unreliable as a measure and leads to pronounced bias as participants are open to outside influence. Efficacy can thus be misreported and the outcome assessed is unreliable. The Cochrane authors recognised this potential for bias. All but one study used objective outcomes, but the Cochrane review did not use these objective measures. The measures used were unreliable[171];
- *Chalder Fatigue Scale Flawed* – The scale employed in most of the studies has four specific flaws: not a comprehensive reflection of fatigue severity, symptomology or functional disability in CFS; ceiling effect, because maximum score at baseline cannot increase; inability to distinguish healthy controls and fatigue; the focus is on fatigue, not intensity. Its use to measure subjective fatigue, being the primary outcome measure on each study, casts doubts on reported outcomes from those studies utilising it[172];
- *Dropout Concerns* – Dropout percentages varied between studies. Those participants adversely affected are likely to drop out or be lost to follow-up. This potentially causes inflation of improvements because the dropouts were excluded, hence raising doubts about the reliability of each study.[173]

Vink and Vink-Niese reviewed each paper and identified various flaws within the papers, particularly the PACE trial. The authors noted the reporting of harms was omitted from six of the eight studies, and those reports were questionable in their measures. The Cochrane review acknowledged the limitations, yet confidently declared there was no evidence that exercise therapy would cause symptoms to worsen.[174] Vink and Vink-Niese concluded that the bias within the trials examined was high. Across two decades of studies, the authors conclude that the objective evidence generated did not show any improvement from the GET interventions. The authors pointed out that PEM is a cardinal symptom of ME, and would be triggered by GET, hence an adverse impact should have resulted in such patients. This suggests that no participants had ME and the participants were unlikely to have issues with exercising.[175] Additionally the severely ill were excluded from these studies.

The criticisms of the Cochrane review called into question the reliability of the review and the conclusions with respect to the effectiveness of GET.

[170] Ibid, pp. 2-3.
[171] Ibid, p.3.
[172] Ibid.
[173] Ibid.
[174] Ibid, p. 7.
[175] Ibid, pp. 8-9.

5. *Cochrane Revision*– Following its completion of the review of the Cochrane Review's approach to ME/CFS with respect to exercise therapy, the authors released the amended document on 2 October 2019.[176] The key amendments were:

    - *Bias* – The Cochrane authors identified a high risk of performance and detection bias in every study included;
    - *Adverse Effects* – The Cochrane authors acknowledged that the evidence in regards to serious adverse reactions caused by GET was uncertain due to the fact that the certainty of evidence was very low;
    - *CBT* – The authors admitted that the evidence with respect to CBT did make the drawing of conclusions as the comparative effectiveness of CBT, with respect to GET, impossible;
    - *Criteria* – The authors acknowledged that the primary studies were drawn from the 1991 Oxford Criteria and 1994 Fukuda criteria. The authors admitted that if a patient was diagnosed by way of another criteria (such as the 1988 Ramsay ME Criteria, 2011 ME criteria or 2003 Consensus criteria) the impact of GET may well be different;
    - *Certainty of Evidence* – The authors acknowledged that the grades for each study with respect to certainty of evidence, was low to very low across the papers;

    The Editor in Chief provided a statement[177] outlining Cochrane plans to undertake a new review of the ME/CFS evidence in 2020, with a view to a protocol being developed in consultation with an Independent Advisory Group inclusive of patient-advocacy groups. ME/CFS Australia are seeking to have a nominee participating in this process.

6. *Fatigue Clinic Study* – As examined in the CBT section above, Professor Lloyd's UNSW Fatigue Clinic study on fatigue states, not on CFS alone, examined the combined use of CBT/GET within one arm of the study and CBT in the other.[178] CET was used at intervals but was not a major component of the study.[179] This study clearly defers to the construction and outcomes of the PACE trial and this is identified.[180] We reiterate our position with respect to the PACE study and the criteria used, as made above.

    Participants within the Fatigue Clinic study were selected on the basis of prolonged fatigue and fatigue was the primary measure, whilst secondary measures focused on functional outcomes, mood and sleep.[181] The study purported to report harms and identified only three adverse events. There was no follow-up of participants beyond 12 months, hence there is no validity for this study to purport to remedy impairments.

[176] L. Larun, K.G. Bruberg, J. Odgaard-Jensen, and J.R. Price, 'Exercise Therapy for Chronic Fatigue Syndrome', *Cochrane Database Sys Rev* 2019; 4; CD 003200.
[177] Cochrane, 'Publication of Cochrane Review: 'Exercise therapy for chronic fatigue syndrome' (2 October 2019) < https://www.cochrane.org/news/publication-cochrane-review-exercise-therapy-chronic-fatigue-syndrome?fbclid=IwAR3C5yukjNA8b4MOw1bBZGHz-_GrASAtAxJ2_dUbZO1lc9HaqPhc9k0ppH0>.
[178] Sandler et al, above n. 103, p. 1421.
[179] Ibid, p. 1423.
[180] Ibid, p. 1422.
[181] Ibid, p. 1423.

The study did not have participants that fell within the severe category of patients.

The authors do not report any conflicts of interest as identified above, despite apparent pecuniary and non-pecuniary benefits and other identified issues.

The key outcome measures, being fatigue severity and cognitive complaints, were measured by way of self-report, i.e. subjective measures. Multiple instruments were employed.[182]

With respect to the use of GET with CBT, the primary measure was fatigue. The study reported that "the severity of self-reported fatigue improved significantly between baseline and end-of-treatment" and at the 24 week follow up, purporting that the improvement was "generally sustained" with some deterioration.[183] The authors claimed physical function showed "consistent improvements" at the conclusion of the study and at the 24 week follow-up.[184] Mood and social functioning improved from base-line to the end of treatment, and social functioning increased from end of treatment to follow-up. These improvements applied to 34.5% of patients at the end of treatment and dropped to 20.5% at follow-up.[185] This study does not show any outcomes beyond 24 weeks, hence is not longitudinal and cannot be generalised as sustaining a long term or permanent effect.

Putting aside the inherent flaws in the study, the fact that it is not a CFS study, and the fact, as its title states, this is a study on "fatigue states", ME/CFS Australia submits that the key issues relevant to the *Rules* and the *Act* are not met.

First and foremost this study omits the severely ill. Secondly, the study ends at follow-up, some 24 weeks after commencement. It does not and cannot claim to demonstrate that the purported benefits are permanent. Thirdly, the study does not address the majority of specific impairments outlined in the *Act* and no amount of extrapolation between its effect on symptoms can give it application. Fourthly, the study is, yet again, focused on fatigue as the primary measure, and this is not reflective of the condition for the majority. Finally, the study does not, at any point, demonstrate that the treatments are "likely to remedy" the impairments. There is no claim of a cure, to be utilised to deny permanency.

7. *UK Survey for NICE* – As with CBT, the recent survey in the UK by patient organisations conducted by Oxford Brookes University[186] at the request of NICE Guidelines Review Committee[187] demonstrates that GET is associated with significant harms:

   Of the respondents, some 67% reported deterioration in physical health following GET, while 13.3% reported an improvement, and 11.7% reported no improvement. GET also caused the

[182] Ibid.
[183] Ibid, p. 1435.
[184] Ibid.
[185] Ibid, p. 1426.
[186] Forward ME Group, above n. 129, p. 11.
[187] Dawes, above n. 130.

mental health of 53% of respondents to deteriorate, whilst 25.5% reported no improvement and 12.8% reported improvement.[188]

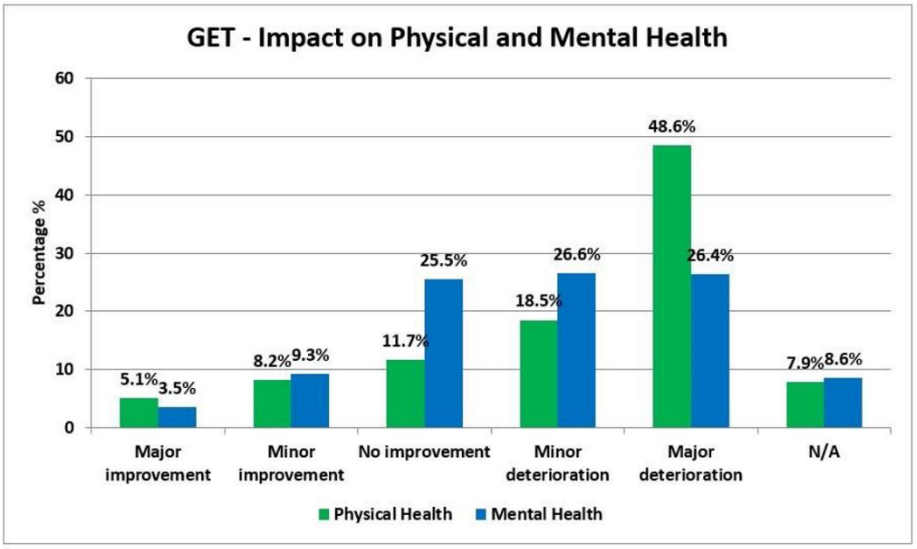

Figure 13. Impact of GET treatment on physical and mental health

When CBT and GET were combined, 48.4% reported that CBT did not improve physical health, whilst 11.8% reported an improvement in physical health. 35.5% of respondents reported that their physical health deteriorated with CBT. Mental health improved in 29.4% of respondents, whilst 32.7% reported no improvement and 34.3% reported deterioration. The report also found that some 58.4% reported a worsening of symptoms.[189]

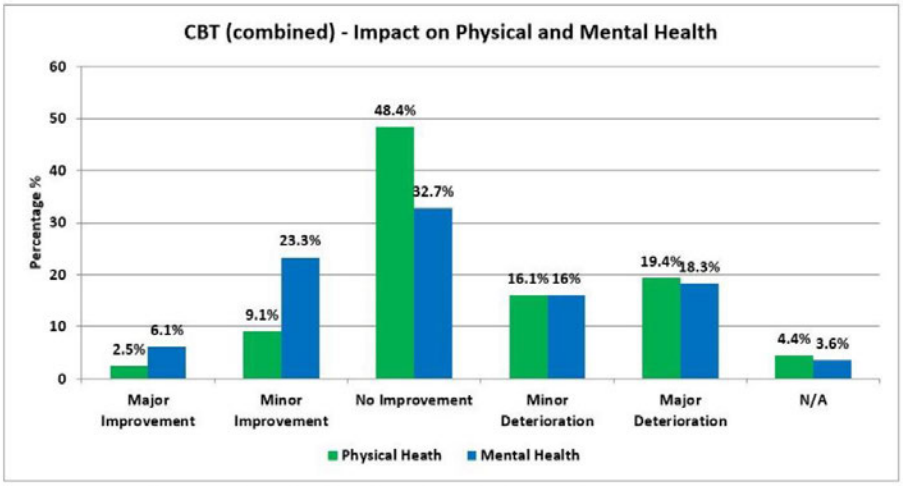

Figure 19. Impact of CBT (combined with GET) on physical and mental health

8. *Other Surveys* – The 2014 Action for ME in UK's 2014 patient health and well-being survey reported that 35% of respondents identified GET was a little or very

[188] Forward ME Group, above n. 129, p. 11.
[189] Ibid, p. 13.

helpful, while 18% indicated no change and 47% reported that the treatment made them a little bit or a lot worse.[190] The 2019 Emerge Australia survey reported 47% of respondents deteriorated after GET."[191]

6.2.2.2.3.3.5. Submission

ME/CFS Australia submits the following with respect to GET:

- *Not Recommended by CDC* - The US Centres for Disease Control and Prevention removed GET from its recommended treatments in mid-2018 and it is no longer included on their website. This removal coincided with their retirement of the 1994 Fukuda Criteria in favour of the IOM's emphasis on systemic exertion. The inference has to be drawn that this removal clearly signals that GET is not regarded as an effective treatment[192];
- *Severe Not Included* - Nothing in the alleged "evidence-base" purports to research the use of GET on patients who fall within the severe category of ME/CFS, hence there simply is no justification to argue that this literature forms an evidence base for this patient cohort. It therefore fails the requirement under Rule 5.4. The evidence base provided is therefore not appropriate;
- *Retired Oxford Criteria* - The evidence-base provided by Professor Lloyd is primarily based upon the now retired Oxford criteria, i.e. it is focused on fatigue;
- *Oxford Criteria Focused on Fatigue* - Research utilising the Oxford criteria simply does not represent the majority of patients diagnosed under the 1994 Fukuda criteria or the 2003 Consensus Criteria. The Oxford criteria is focused on patients who have fatigue as their primary symptom and requires no other symptoms, unlike Fukuda and the Consensus Criteria. This evidence base therefore does not satisfy the requirement that evidence be "appropriate" within Rule 5.4 of the *Rules*;
- *Treatments Do Not Remedy* - Even if the evidence base provided by Professor Lloyd was accepted, the studies do not show that a person receiving the treatment is likely (i.e. high probability of occurring or being true) to have their impairments remedied because the effect is moderate at best;
- *Significant Harms Reported* - The most recent evidence from the UK provided to the current NICE review committee, at the committee's request, sourced from on over 2000 patients clearly shows that the majority of survey respondents derived no benefit from GET, whilst most concerningly, there were significant rates of minor to major harms to patients that arose from the GET they received;
- *Evidence Base Not Appropriate* - The evidence base provided by Professor Lloyd is exceptionally limited and highly contentious – hence does not fulfil the criteria of "appropriate" within the meaning of Rule 5.4. of the *Rules*;
- *Evidence Base Focused on Fatigue* - The evidence base provided by Professor Lloyd, even if accepted, is focused upon those patients for whom fatigue is the primary symptom. The PACE trial authors make it clear that the treatments are suitable for those patients who meet the Fukuda and Consensus Criteria only if fatigue is the primary symptom. For the vast majority of patients who do not experience fatigue as their primary symptom, the

[190] Action for ME, above n. 132, p. 19.
[191] Emerge, above n. 68, p. 2.
[192] CDC, above, n. 75.

evidence base provided by Professor Lloyd does not address their symptoms. The evidence base therefore does not meet the definition of appropriate within the meaning of Rule 5.4. of the *Rules*.

6.3. Risk of Harms

ME/CFS Australia holds serious concerns that the current policy of the NDIA. As it stands, the scheme requires applicants to place themselves at risk of harm from potentially harmful treatments in order to meet the entry criteria of the NDIS under the policy that the NDIA is enforcing. It is our position, based upon the above, that CBT, CET and GET will not and cannot remedy the impairments in circumstances where it is a well-established fact that such treatments can, and do, cause harm for a significant percentage of the patient population.

6.3.1. Public Health Context

Public health is the science of ensuring the safety and improving the health of people within the community, through education, policy making, research and injury prevention. ME/CFS impacts up to 1% of the population. By its very definition ME/CFS is classified as a public health issue.

At the Commonwealth level[193] and within each state jurisdiction there is an enactment with respect to public health.[194]

6.3.2. Precautionary Principle

6.3.2.1. Role Within Public Health

Whilst more commonly enshrined in legislation within the sphere of environmental law, the precautionary principle also has application within the context of public health. Shirlow and Faunce explain that "[t]he precautionary principle is a risk management tool which justifies action taken to prevent potential risks, even where the existence of such risks has not been conclusively ascertained."[195]

Within the United States, the precautionary principle was instituted within public health in 1990s. Goldstein explains:

> "The precautionary principle has been advocated for public health because of the ***importance of anticipating unintended health consequences of well-intentioned public health interventions***. Seeking to ***avoid creating new problems while solving existing ones*** is an important aspect of the precautionary principle, but it is not the ***only way in which precaution can benefit public health***."[196] (Emphasis Added)

[193] *National Health Act 1953* (Cth).
[194] *Public Health Act 2010* (NSW), *Public Health Act 2005* (Qld), *South Australian Public Health Act 2011* (SA), *Public Health and Wellbeing Act 2008* (Vic), *Public Health Act 1997* (Tas), *Public Health Act 1997* (ACT), *Public Health Act 2016* (WA), *Public and Environmental Health Act 2011* (NT).
[195] E. Shirlow and T. Faunce, 'Recent Legal Developments and the Authority of the Australian Therapeutic Goods Administration'. *Journal of Law and Medicine* 2009 June; 16: 764, 767.
[196] B.D. Goldstein, 'The precautionary principle also applies to public health actions.' *American Journal of Public Health*. 2001; 91(9): 1358-1361, 1359.

The principle is, for example, encompassed within Section 6 of the South Australian and Victorian legislation, albeit different definitions. Within the Northern Territory legislation it appears at Section 5 and is similarly worded to the South Australian Act.

Within these jurisdictions, stakeholder involvement in policy development is required in order to balance the interests of stakeholders, and arrive at a solution to issues addressed.[197] The application of the precautionary principle plays a significant role in that process, allowing a calculation of risk to be made with respect to imperfect literature. Within other jurisdictions, there is a role for the precautionary principle in creating policy.

6.3.2.2. Definition

There are variations to the definition of the precautionary principle. The *Wingspread Statement* on the precautionary principle developed at the Wingspread Conference in 1998 defined the principle as:

> "… it is ***necessary to implement the Precautionary Principle***: When an ***activity raises threats of harm to human health*** or the environment, precautionary measures should be taken ***even if some cause and effect relationships are not fully established*** scientifically. In this context the ***proponent of an activity***, rather than the public, should ***bear the burden of proof***. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an ***examination of the full range of alternatives, including no action***."[198]

Judicially, Sackville J in the *Matter of the Friends of the Hinchinbrook Society Inc v Minister of Environment* (1997) 93 LGERA 249, provides an element of relevant direction to the principle, when stating:

> "The commonsense (sic) principle that caution should be exercised ***where scientific opinion or scientific information is incomplete***."

It is in this context that we believe ME/CFS and the precautionary principle meet.

6.3.3. Harms and Treatment

6.3.3.1. Applying the Precautionary Principle

ME/CFS Australia has critiqued the literature provided by Professor Lloyd to the NDIA, and offered literature which indicates that there are significant flaws within these studies. It is our submission that the NDIA literature itself demonstrates clearly that the scientific information is incomplete. Within those documents there are a variety of qualifications, and encouragement for further research. We would argue such statements are indication of an evidence base that is incomplete.

[197] L.A.J. Kruck, 'A Values Analysis of Attitudes Towards the Use of Law to Prevent Obesity. How Might These Values Inform Public Health Law Theory and Practice?', (PhD Thesis, Queensland University of Technology, 2015), 144.

[198] N. Ashford, K. Barrett, A. Bernstein, et al, 'The Precautionary principle'. *Rachel's Environment and Health Weekly*, 1998 Feb 19; 586: <http://www.psrast.org/precaut.htm>, 586

Additionally, we have presented evidence that demonstrates that the application of the various treatments lead to harms being visited upon patients, when such treatments are taken out of the controlled environment of a study, into the real world. The "threats of harm to human health" trigger precautionary measures, even when the "cause and effect relationships are unknown."

6.3.3.2. Harms and ME/CFS

At various points throughout this submission, ME/CFS Australia has consistently raised the issue of harms arising from the recommended treatments. At 6.2.2.2.3.2.4. and 6.2.2.2.3.3.4. above, we specifically reference various surveys of patients in the UK and Australia and the common theme was the large percentage of the respondent cohorts who reported deterioration. What stood out in contrast, was the fact that the studies provided by Professor Lloyd either didn't have reporting of harms, or handled the reporting of harms poorly.

The Cochrane review identified that only two of the eight studies examined serious harms, and noted one of the studies provided "moderate-quality evidence". They stated the "sparse data made it impossible for review authors to draw conclusions".[199]

In his 2011 paper Kindlon drew upon survey evidence and studies published around that time.[200] Kindlon reviewed the literature, noting that various studies identified physiological abnormalities when study participants engaged in exercise.[201] Such studies included gene expression testing, Cardiopulmonary Exercise Tests, immune dysfunction and impaired ion channels. Kindlon reviewed survey data from multiple surveys and identified that "[h]igh rates of adverse reactions following [graded activity/exercise] programs have been reported in large patient surveys in various countries over the last two decades". Indeed, Kindlon reported 51.24% of exercise programs resulted in an adverse impact, while CBT resulted in deterioration in 19.91%.[202] Kindlon identified that the reporting of harms from CBT and GET was lacking in quality, while those who did not adhere to treatment and those lost to follow-up may well have been adverse events, yet the studies had failed to obtain the information.[203]

In is 2017 paper, Kindlon examined the reporting of harms in the PACE trial. Kindlon noted that historically the reporting of adverse events in clinical trials is poor.[204] The author complimented the PACE trial on some elements of reporting harms and noted that the majority of clinical trial evidence on harms comes from the PACE trial.[205] Kindlon identified that the CONSORT statement requires reporting of non-adherent participants who are followed up or lost to follow-up, because this may well be indicative of an inability to tolerate the intervention. Kindlon was critical of the PACE trial which had a primary measure of attendance of an appointment as a compliance measure. He was also critical of definition of harms within the trial as unrealistic. He suggested the minimal changes

[199] Larun et al, above n. 136, p. 2.
[200] T. Kindlon, 'Reporting of Harms Associated With Graded Exercise Therapy and Cognitive Behavioural Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.' *Bull IACFS ME*. 2011; 19(2): 59–111.
[201] Ibid, p. 62.
[202] Ibid, p. 64.
[203] Ibid, p. 68.
[204] T. Kindlon, 'Do Graded Activity Therapies Cause Harm in Chronic Fatigue Syndrome'. *Journal of Health Psychology* 2017; 22(9): 1146-1154, 1146.
[205] Ibid, p. 1147.

in fitness across the 12 months indicate non-compliance by participants.[206] Kindlon recommended future studies utilise objective measures such as heart rate monitors and actometers to help establish what the authors are testing when using CBT and GET. In the absence of such data, and the survey reports indicating high rates of harms, he urged caution with respect to the safety of using CBT or GET.[207]

In their 2018 paper on the reanalysis of the PACE data, Wilshire et al considered the safety issues that arose in the study.[208] The authors noted the significant difference between the small number of adverse reports measured in the PACE trial and the significant percentages of adverse effects reported in multiple very large informal surveys.[209] The authors questioned participant selection and the fact that despite the PACE authors collecting objective evidence by way of actigraphy. this data was excluded from their papers.[210]

Most recently, McPhee et al conducted an examination of the quality of reporting with respect to harms arising from treatments for ME/CFS within the NHS specialist centres in England.[211] The authors obtained data from the centres by way of a freedom of information request. The authors identified that a significant number of clinics (47%) had not provided guidance to its staff with respect to identifying whether a patient had, or might have been, harmed[212]. Half of the centres did not even address the question as asked. No clinic reported any harm to any patient. The authors concluded that "such clinics place little focus on dealing with such [treatment related] harms", but noted that 18% of the clinics did, however, report drop outs without identifying the reasons why[213]. The authors concluded that the assessment of zero-harm was overly optimistic. They expressed significant reservations with respect to the manner in which NHS ME/CFS clinics handled adverse outcomes during or after therapies. The universal absence of a criteria for detecting harm and the absence of any report of harm accorded the authors particular concern. The authors viewed such information as especially important for the acquiring of informed consent from patients prior to treatment.

6.3.3.3. Unreasonable Risk

ME/CFS Australia submit that a fair review of the literature reveals that there are serious deficiencies within the research provided by Professor Lloyd with respect to the reporting of harms. Indeed, the Cochrane review provided by Professor Lloyd confirms this view. A review of the significant papers published with respect to harms reveals significant points of weakness within the existing reporting within the studies provided to the NDIA.

[206] Ibid, p. 1149.
[207] Ibid, p. 1151.
[208] Wilshire et al, above n. 119, p. 10.
[209] Ibid.
[210] Ibid.
[211] G. McPhee, A. Baldwin, T. Kindlon and B.M. Hughes, 'Monitoring treatment harm in myalgic encephalomyelitis/chronic fatigue syndrome: A freedom-of-information study of National Health Service specialist centres in England'. *Journal of Health Psychology* 2019 Jun 24; 135910531985453.
[212] Ibid, p. 5
[213] Ibid, pp. 5-6

ME/CFS Australia also considers that there is a disconcerting disconnect between the harms reported within large scale, multisite patient surveys and those reported within the limited papers utilising an instrument, including that of Professor Lloyd's fatigue states paper.

ME/CFS Australia submits that the absence of reliable research with respect to harms, combined with the strong indicators of harms from the large scale surveys, strongly suggests that there is an unreasonable risk involved in engaging in GET and CBT. In our view the NDIS legislation, Rules and Guidelines, combined with the current state of the case law, do not require that an applicant engage in an intervention with an inherently unreasonable risk attached to it, in order to achieve a possible improvement. This, we submit, is not appropriate.

6.3.4. Submission

ME/CFS strongly submits that a public health issue of the nature of ME/CFS warrants the application of the precautionary principle by the NDIA. The NDIA's policy currently requires that patients demonstrate engagement in the three interventions in order to attempt to remedy the impairments arising out of the condition.

ME/CFS Australia submits that:

- there is conflicting literature with respect to interventions;
- the literature forming the basis of the policy employed by the NDIA does not, even at its best, indicate that the interventions are "likely to remedy" the impairments outlined within the act, regardless of severity or duration;
- there is an inherent unreasonable risk of harm attached to engaging in the interventions, which at worst can render someone bed bound permanently.

Given this is the case, and taking account of central tenets of the precautionary principle:

- the interventions raise "threats of harm to human health";
- the "cause and effect relationships are not fully established scientifically";
- "precautionary measures should be taken";
- the onus of proof falls on the NDIA to prove otherwise, and the literature of Professor Lloyd falls well short;
- no action should be taken, i.e. no intervention should be required, because no alternatives exist.[214]

7. ADDRESSING THE LEGISLATION

7.1. Operative Legislation

ME/CFS Australia acknowledge that access to the NDIS is by way of demonstrating a person meets the disability requirements contained within Section 24 of the *NDIS Act*. Section 24 states:

[214] N. Ashford, K. Barrett, A. Bernstein, et al, 'The Precautionary principle'. *Rachel's Environment and Health Weekly*, 1998 Feb 19; 586: <http://www.psrast.org/precaut.htm>, 586

"Section 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 or 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."

7.2. Addressing the Legislative Requirements

ME/CFS Australia respects that the NDIA, as an inherent component of its claims process, is required to address Section 24 of the *NDIS Act* so that it might satisfy itself as to the eligibility of each individual applicant to the scheme. We do not in anyway assert that this process requires abrogation. We do raise concerns about the evidence provided by Professor Lloyd with respect to specific elements of the legislation.

We therefore address each specific element of the Section 24 requirements.

7.2.1. Meaning of Disability

Before proceeding to each element in turn, we do wish to confirm our understanding of the term, disability, as it pertains to the *NDIS Act*. In doing so, we take account of the case law, the *NDIS Act*, *NDIS Rules* and the NDIS *Access to the NDIS Operational Guidelines*.[215]

[215] NDIS, 'Access to the NDIS Operational Guidelines' (16 July 2019) <https://www.ndis.gov.au/about-us/operational-guidelines/access-ndis-operational-guideline>.

7.2.1.1. The Decision in Mulligan

ME/CFS Australia is familiar with the seminal case of *Mulligan*[216] in 2014 where the Senior Member Toohey and Member McCallum made 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."[217] (Emphasis Added)

We are also aware the tribunal affirmed that the NDIS Act and Rules had not defined the words 'disability' or 'impairment'.[218] In the 2014 case, Senior Member Toohey and Member McCallum state at [24]:

> "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***." (Emphasis Added)

The Tribunal in *Mulligan* found that given the intent that a subgroup of people with disabilities will be included with the NDIS, the definition of disability "cannot be read down".[219] When the matter proceeded to the Federal Court in 2015, Mortimer J affirmed this position, stating "s 13 of the Act indicates the Act intends a wide concept of 'disability' and "is not to be construed as limited to people who meet the access criteria in Ch 3 of the Act".[220]

7.2.1.2. The Decision in Fear

In *Fear v NDIA*[221], the AAT affirmed the scope of the term 'disability' stating "there may be little obvious distinction between disability and chronic illness or medical conditions."[222] A 'chronic health condition' can be classified as a disability because it can be disabling.[223] In *Fear*[224], 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

[216] *Mulligan and NDIA* [2014] AATA 374 per Toohey and McCallum, [52].
[217] Ibid, [39].
[218] Ibid, [19].
[219] Ibid, [52].
[220] *Mulligan v National Disability Insurance Agency* [2015] FCA 544, [17]-[18] per Mortimer J.
[221] *Fear by his mother Vanda Fear and NDIA* [2015] AATA 706.
[222] Ibid, [51].
[223] *Mulligan and NDIA* [2014] AATA 374 per Toohey and McCallum, [43].
[224] *Fear by his mother Vanda Fear and NDIA* [2015] AATA 706.

> purposes of the disability requirements in s 24(1) of the Act might also be regarded as a chronic health condition."[225] (Emphasis Added)

It is conceded that a person can have a disability, yet possibly not meet all, or indeed any, of the requirements under Section 24(1)(b)-(e) (National Disability Insurance Scheme, 2014c, p. 3). ME/CFS, therefore, need arguably not satisfy the criteria within Section 24 in any event because it is a chronic health condition, in that ME/CFS and CFS arguably fulfil the criteria for both.

7.2.1.3. Locating ME/CFS

In speaking to its views with respect to chronic health conditions, the Productivity Commission stated:

> "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***."[226] (Emphasis Added)

McCallum stands as precedent for the NDIA's position that a 'chronic health condition' can be classified as a disability because they can be disabling.[227] *Fear* has reinforced that understanding.

ME/CFS is, by definition, a chronic health condition. ME/CFS is, by definition, disabling because the diagnostic criteria requires a substantial reduction in activities in order to obtain a diagnosis. It is the position of ME/CFS Australia, that ME/CFS is a disability within the scope of the legislation.

7.2.2. Element 1 - Impairments

Section 24(1)(a) of the *NDIS Act* enables the establishment of a disability, in part, by demonstrating that the applicant has "one or more intellectual, cognitive, neurological, sensory or physical impairments or to one or more impairments attributable to a psychiatric condition".

When considering Ms Agus' correspondence of 15 August 2018, there is no assertion that the NDIA considers ME/CFS fails to meet this element. ME/CFS Australia will address this point for clarity.

7.2.2.1. Impairment Defined

As explained in the 2014 *Mulligan* case – ""Impairment" commonly refers to a loss of, or damage to, a physical, sensory or mental function. "[228] This concurs with the *NDIS Operational Guidelines*.[229]

7.2.2.2. ME/CFS and Impairment

ME/CFS Australia submits that ME/CFS is an impairment on the basis of several heads under Section 24(1)(a):

[225] Ibid, [55].
[226] Ibid.
[227] *Mulligan and NDIA* [2014] AATA 374 per Toohey and McCallum, [43].
[228] Ibid, [19].
[229] NDIS, 'Access to the NDIS – The Disability Requirements' (16 July 2019) < https://www.ndis.gov.au/about-us/operational-guidelines/access-ndis-operational-guideline/access-ndis-disability-requirements#8.1>.

(a) *Neurological* – First and foremost, ME was initially classified as a neurological condition in 1969 when it was first included in the International Classification of Diseases (ICD)[230]. It remains classified under G.93.3 in the current ICD-10.[231] The NHMRC ME/CFS Advisory Committee recently adopted the International Consensus Criteria.[232] Carruthers et al reviewed the literature and stated that "Myalgic encephalomyelitis is an acquired neurological disease with complex global dysfunctions. Pathological dysregulation of the nervous, immune and endocrine systems, with impaired cellular energy metabolism and ion transport are prominent features."[233]. The authors set out the various neurological impairments, including:

- Neurocognitive impairments – difficulty processing information, short-term memory loss;
- Pain – Headaches, Significant pain;
- Sleep Disturbance – Disturbed sleep patterns, unrefreshed sleep;
- Neurosensory, Perceptual and Motor Disturbances;[234]

On this basis alone, ME/CFS meets the requirements of an impairment;

(b) *Physical* – ME/CFS is a physical condition. Carruthers et al specifically identify the physical issues within the 2003 Consensus Criteria, including:

(i) Fatigue – "The patient must have a significant degree of new onset, unexplained, persistent, or recurrent ***physical*** and mental fatigue that substantially reduces activity level."[235]

(ii) PEM and/or Fatigue – "There is an inappropriate loss of ***physical*** and mental stamina, rapid muscular and cognitive fatigability, post exertional malaise and/or fatigue and/or pain and a tendency for other associated symptoms within the patient's cluster of symptoms to worsen. There is a pathologically slow recovery period – usually 24 hours or longer."[236]

(iii) Other Physical Impairments – The criteria also sets out other physical attributes that feature in the condition, including sleep dysfunction, pain, neurological/cognitive manifestations, autonomic manifestations, neuroendocrine manifestations, and immune manifestations[237];

The physical symptoms of the condition are the cardinal features of the condition.

(c) *Cognitive* – Neurocognitive symptoms are inherent symptoms of the condition.[238] Carruthers et al outlines the issues in the 2011 International Consensus Criteria, stating it impacts as follows:

[230] World Health Organization, 'WHO: International Classification of Diseases. (ICD 8), Eighth' (1969).
[231] World Health Organization, 'WHO: International Classification of Diseases. (ICD 8), Tenth' (1990).
[232] NHMRC, above n. 4, p. 15.
[233] Carruthers, above n. 33, pp. 327, 329.
[234] Ibid, 130.
[235] Carruthers, et al, above n. 32, p. 11.
[236] Ibid.
[237] Ibid, pp. 11-12.
[238] Ibid, p. 34

> "a. Difficulty processing information: slowed thought, impaired concentration e.g. confusion, disorientation, cognitive overload, difficulty with making decisions, slowed speech, acquired or exertional dyslexia;
> b. Short-term memory loss: e.g. difficulty remembering what one wanted to say, what one was saying, retrieving words, recalling information, poor working memory."[239]

(d) *Intellectual* – Intellectual impairment relates to intellectual functioning such as reasoning, learning and problem solving, and adaptive behaviour. The 2002 Clinical CFS Guidelines specifically note "reduced … intellectual capacity" and "loss of … intellectual performance".[240] For the most severely ill, a diagnosis of an acquired brain injury can occur. Their function is so severely impacted that it affects communication, speech and thought[241,242,243,244];

(e) *Psychiatric* – Depression is a secondary consequence of ME/CFS because of the situation that patients find themselves in.[245] Other conditions such as Post Traumatic Stress Disorder can also arise from post illness onset issues that impact the individual.

ME/CFS Australia submit that the condition inherently satisfies Section 24(1)(a) if only by virtue of the fact that it is classified as a neurological condition by WHO and the ICD-10 which is adopted within Australia. The remaining heads merely reinforce the satisfaction of Section 24(1)(a).

7.2.3. Element 2 - Permanency

The key wording within Section 24(1)(b) centres not only on actual permanency but also "likely" permanency. ME/CFS Australia is of the view that ME/CFS is more likely than not to be permanent. The NDIA has, respectfully, been provided a very limited view of the issue of permanency. Moreover, there has been a misconstruing of the Dubbo study, and indeed the meaning of recovery per se. We feel that it is exceptionally important for the NDA to comprehend the inherent nature of the condition and the limitations of various studies that have narrow meanings for the term 'recovery', issued within studies that are not significantly longitudinal in nature, nor appropriately followed up. We therefore submit as follows:

[239] Carruthers, above n. 33, p. 329.
[240] RACP Working Group, above n, 1, p. S29.
[241] F. Friedberg, L. Bateman, L.A . Jason et al, 'ME/CFS: A Primer for Clinical Practitioners' (2014) <http://iacfsme.org/portals/0/pdf/Primer_Post_2014_conference.pdf>, p. 27.
[242] G. Crowhurst, 'Supporting People With Severe Myalgic Encephalomyelitis' *Nursing Standard* 2005 Feb 2; 19(21): 38-43, 40.
[243] V. Strassheim, R. Lambson, K.L. Hackett & J.L. Newton 'What is known about severe and very severe chronic fatigue syndrome? A scoping review' *Fatigue: Biomedicine, Health & Behavior*, 2017 Jun 19: DOI: 10.1080/21641846.2017.1333185, 11.
[244] T. Pendergrast, A. Brown, M. Sunnquist, et al, 'Housebound Versus Nonhousebound Patients with Myalgic Encephalomyelitis and Chronic Fatigue Syndrome' Chronic Illness, 2016; 12(4); 1-16, 11.
[245] Carruthers, et al, above n. 32, p. 27.

7.2.3.1. The NDIA Position

The NDIA position with respect to permanency has been based upon the evidence base provided by Professor Lloyd. ME/CFS Australia have clearly and accurately addressed the foundation of the NDIA's position with respect to its misconception that the majority of patients with ME/CFS recover without intervention. Clearly the NDIA was in serious error (see: 5.2.2. above).

The 2002 RACP Guidelines clearly highlight the inaccuracy of the NDIA position, when the committee clearly state "***most*** people with CFS improve gradually, and ***some*** eventually recover."[246] With only some recovering, the majority do not, ergo they are most likely to have it for life. It is for this reason that ME/CFS Australia asserts that the evidence base supports permanency.

7.2.3.2. Concessions of the NDIA

The correspondence from Ms. Agus does, however, concede that 2002 RACP Guidelines, of which Professor Lloyd was the primary author, considered that permanency can be assumed where ME/CFS has "been present in a stable, non-improving pattern, despite evidence-based management (such as … CBT … GET … and cognitive remediation) for 5 years."

ME/CFS Australia has clearly demonstrated that there is no "appropriate evidence base" that demonstrates that CBT/GET/Cognitive Remediation is "likely to remedy" ME/CFS, thereby triggering Rule 5.4 of the *Rules* (see: 6. above).

7.2.3.3. Prognosis

ME/CFS Australia has already addressed the issue of recovery (see: above at 5.2). We draw your attention to the IACFSME Primer and its position with respect to prognosis. The Committee states:

> "Patients may be very ill at the onset of the illness, but the majority of patients report improvement, ***reaching a plateau***, within five years of becoming ill. The ***severity of illness varies between the extremes*** of some patients who are completely bedbound and others who are able to go out to work. ***Remissions and relapses are common***. Over time, many patients improve enough so that they no longer keep their ME/CFS diagnosis, but ***they also DO NOT RETURN TO THEIR PREMORBID LEVEL of functioning***. ***Restoration of full premorbid health is rare in adults***, but more common in children. Patients who do recover often need more rest than their contemporaries. Some patients may slowly get worse. ***Patients with ME/CFS who also have FM are less likely to improve than patients with ME/CFS alone***.
>
> A review of 14 studies found on average that ***5% of patients recovered*** (range 0–31%); ***40% of patients improved during follow-up*** (range 8–63%); 8-30% returned to work; ***5-20% of patients reported worsening***.

[246] RACP, above n. 1, p. S46.

> Risk factors for severity of the illness are:
> * The ***severity of the illness at onset***;
> * The ***standard of early management*** of the illness, e.g., late diagnosis or overexertion in the early stages of the illness are ***likely to lead to deterioration***;
> * Having a ***mother with the illness***"[247] (Footnotes Omitted; Emphasis Added)

The 2002 RACP Guidelines reveal similar findings. The committee state that some 22% of patients meet the criteria for Fibromyalgia[248], which is significant in terms of prognosis as the IACFSME Committee indicated. The committee also noted patients "reported improved functioning rather than return to completely normal health was a relatively common outcome."[249] The RACP Guidelines also points to severity as a key indicator, stating:

> "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***."[250] (Footnotes Omitted; Emphasis Added)

The 2003 Consensus Criteria identify that the criteria used to clinically diagnose the condition play a significant role in the prognosis cited for recovery. Specifically, it states:

> "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."[251] (Footnotes Omitted; Emphasis Added)

Like the RACP, the Consensus committee found severity, the criteria and the presence of Fibromyalgia was an indicator of prognosis, stating:

> "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. Patients with ***comorbid fibromyalgia syndrome demonstrated greater symptom severity***

[247] Friedberg et al, above n. 239, p. 26.
[248] RACP, above n. 1, p. S43.
[249] Ibid, S. 44.
[250] Ibid, p. S32.
[251] Carruthers, above n. 32, p. 48.

> ***and functional impairment*** than individuals with CFS alone. Other studies suggest that less than 10% of patients return to premorbid levels of functioning. ***As the criteria become more stringent the prognosis appears to worsen***."[252] (Footnotes Omitted; Emphasis Added)

7.2.3.4. Key Indicators as to Permanency

ME/CFS Australia submits that the appropriate evidence base demonstrates a number of key points:

1. *Severity* – The appropriate evidence base demonstrates that where the severity at onset is higher, the more likely the prognosis will be poor;

2. *Fibromyalgia* – The appropriate evidence base demonstrates that where there is comorbid Fibromyalgia, the greater the symptom severity and functional impairment;

3. *Criteria* – The appropriate evidence base demonstrates that where the diagnostic criteria is more stringent, the more the prognosis is likely to be poor. The Oxford criteria is the least stringent and is not used in Australia. The 1994 Fukuda criteria is less stringent that the 2003 Consensus Criteria. The 1988 Ramsay ME criteria is more strict again and the 2011 International Consensus Criteria is the strictest. It is noted that the 2003 Consensus Criteria and 2011 Consensus Criteria have been adopted for research in Australia by the NHMRC.

4. *Recurring* – One of the key limitations raised with respect to the various studies cited above was the fact that follow-up of so-called 'recovered' patients simply did not occur. ME/CFS is a fluctuating condition. The RACP Guidelines state "The course of the illness also varies. About two-thirds of individuals report continuous symptoms with fluctuating levels of severity, and 15% have a relapsing-and-remitting course."[253] The appropriate evidence base therefore fails to seek evidence of relapse and cannot be claimed to indicate recovery.

5. *5 Years Requirement* – The NDIA accepts the RACP Guidelines position that an applicant who has had the condition for 5 years or more, is likely to permanently have the condition.

On the basis of these points, and the appropriate evidence base, ME/CFS Australia submits the following:

(a) Likely to be Permanent – a return to pre-morbid function is "rare". The condition is life-long for the majority of patients, whether they be severe and continuous, or remitting with relapse;

(b) Criteria – in the alternative, those who meet one of the following criteria can be considered to be permanent:

- those who have a severe onset can be assumed to be likely to be permanent; and/or

[252] Carruthers, above n. 32, p. 48.
[253] RACP, above n. 1, p. S43-S44.

- those who have fibromyalgia can be assumed to be likely to be permanent; and/or
- those who fulfil the stringent diagnostic criteria, i.e. the ME or ME/CFS criteria, can be assumed to be likely to be permanent; and/or
- those who have had the condition for 5 or more years are likely to be permanent.

ME/CFS Australia believes that the evidence base that Professor Lloyd has provided, being the 2002 RACP Guidelines and 2011 International Consensus Criteria, and the NHMRC Report's accepted criteria, being the 2003 Consensus Criteria, support the contention that ME/CFS is likely to be permanent.

7.2.3.5. Addressing the Principles

Section 8.2 of the *Operational Guidelines* outline the principles for guidance with respect to impairment.[254] We will address these principles briefly:

1. *Likely to Remedy* - ME/CFS Australia has addressed the requirements of Rule 5.4. above at 6.2.2.2.. It is our position that the treatment recommendations of Professor Lloyd are not likely to remedy the condition;

2. *Variability* – ME/CFS can be a variable condition, and result in impairment that varies in intensity. The fluctuating nature of the condition has been covered above at 7.2.3.3. and 7.2.3.4.;

3. *Potential Improvement* – In accordance with Rule 5.5 of the *Rules*, ME/CFS can be considered a variable condition in which the severity of its impact on function can fluctuate and potentially improve in some cases. The fluctuating nature of the condition has been covered above at 7.2.3.3. and 7.2.3.4.. In the cases of severe ME/CFS, there can be ongoing deterioration;

4. *Medical Treatment/Review* – Rule 5.6 of the *Rules* consider a condition to be permanent where a condition does not require further medical treatment or review. ME/CFS can reach a point, as described in 7.2.3.4., where further review is not required to regard the condition as permanent. The evidence within this submission demonstrates that permanency is medically demonstrated. With respect, the evidence with respect to CBT/CET/GET does not provide some prospect of success.

   The appropriate evidence base deferred to above demonstrates that CBT/CET/GET are not treatments that provide some prospect of success because the research is significantly deficient as described and is not longitudinal, hence cannot claim to remedy or be likely to remedy.[255]

7.2.4. <u>Element 3 - Activities</u>

[254] NDIS, above n. 227.
[255] cf. *Mulligan and NDIA* [2014] AATA 974 at [71].

The third element is Section 24(1)(c) which requires that the impairments cause a reduction in function with respect to one or more of the six specific activities outlined from Section 24(1)(c)(i)-(vi): communication, social interaction, learning, mobility, self-care and self-management.

It is apparent, however, that the NDIA has potentially received advice from Professor Lloyd that the treatments that he recommended rectify the impairments to activities. The NDIA have not specified or outlined how such representations were made. ME/CFS Australia makes the following submissions.

7.2.4.1. The Diagnostic Requirements

In order to have a diagnosis of ME/CFS or CFS, a patient must meet the criteria under the 2003 Consensus Criteria or the 1994 Fukuda Criteria or the 2011 International Consensus Criteria. On rare occasions the 1988 Ramsay ME criteria may be utilised.

The relevant operative condition of the 1994 criteria is the requirement that condition fatigue "results in ***substantial reduction in previous levels*** of occupational, educational, social or personal activities."[256] It must be noted that this is a research criteria and strict compliance is required in research. In clinical practice the criteria is relaxed in the 2002 RACP Guidelines.[257] The 2003 Consensus Criteria states that: "The patient must have a significant degree of new onset, unexplained, persistent, or recurrent physical and mental fatigue that ***substantially reduces activity level***."[258] The Guidelines further state:

> "A symptom has ***significant severity if it substantially impacts (approximately a 50% reduction) on the patient's life experience and activities***. In *assessing severity and impact*, compare the patient's activity level to their ***premorbid activity level***. Establishing the severity score of symptoms is ***important in the diagnostic procedure***, and should be repeated periodically."[259] (Footnotes Omitted; Emphasis Added)

The Fukuda criteria forms the basis of much of Professor Lloyd's evidence base. The Oxford Criteria also requires substantial reductions in activities due to fatigue. He completely omitted the 2003 Consensus Criteria from the evidence base when clearly it is a significant document as the NHMRC Report, to which he was a signatory, has identified.

ME/CFS Australia makes a number of relevant submissions:

7.2.4.1.1. Relevant Activities

ME/CFS Australia accepts that there is a loose correlation between the criteria for 1994 Fukuda CFS and the activities in Section 24(1)(c) being (ii) social interaction (iii) learning and potential personal

[256] K. Fukuda, S.E. Straus, I. Hickie, et al, 'The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study'. *Annals of Internal Medicine* 1994; 121(12): 953-959, 956.
[257] RACP, above n.1, p. S27.
[258] Carruthers et al, above n. 32, p. 11.
[259] Ibid, p. 14.

activities and would encompass (i) communication, (iv) mobility, (v) self-care; and (vi) self-management, although this is unclear. We will err on the side of inclusion.

With respect to the 2003 Consensus Criteria, it is arguable that the criteria encompasses activities in general and as such all activities within Section 24(1)(c) are inclusive.

7.2.4.1.2. Focus on Fatigue

ME/CFS Australia made the point that studies selected by Professor Lloyd focus on studies that involved the Oxford Criteria, e.g. PACE and Cochrane, and as such were focused on fatigue. At 6.2.2.2.3.2.4. above it was made clear that Professor Lloyd's research group also focused on fatigue.

Whilst the criteria under the 1994 Fukuda and 2003 Consensus Criteria have fatigue as a primary symptom, and such symptom related to activities, there are issues of exceptional importance to be considered if one accepts those studies:

1. *No Removal of CFS Condition* – A fair review of the studies within the Lloyd evidence base do not claim that treatment results in patients no longer satisfying the CFS criteria. They do, however, claim to improve the primary symptom, which is fatigue. The participants still fulfilled the criteria for CFS, being Oxford or Fukuda. Even the PACE trial's Oxford Criteria cohort has best claims for moderate improvement for about 30%, which again does not reverse the diagnosis. Under reanalysis using the original published protocol it was much less and not statistically significant at all;

2. *Substantial Reduction* – The criteria for 1994 Fukuda CFS requires a substantial reduction in activities as a result of fatigue in order for the diagnosis to persist. As pointed out above, the treatments did not remedy the impairments. Even if a person had a positive response to the treatment, they still had a diagnosis of CFS;

3. *Meets Legislation* – No matter what the generalised view of Professor Lloyd or the NDIA might be with respect to the effect of the treatments, it is the words and effect of the legislation that is the paramount consideration.

   Within each study contained in the evidence base, the research participants still met the requirements of this subsection, regardless of purported treatment used or outcome concluded. The legislation requires a substantial impairment of activities.

   The word 'substantial' can be taken to have its ordinary meaning, in the absence of any evidence to the contrary. The word 'substantial' is also used when assessing the impact of fatigue upon activities in the Fukuda and Oxford definitions of CFS. The meanings are therefore one and the same.

   Even if one were to accept that the claimed evidence base was untainted and accepted that it showed treatments had an effect as significantly as claimed, there is nothing within the literature that states or demonstrates that patients no longer met the fatigue criteria for CFS. Given the participants still met the criteria, it can be concluded that they must

> therefore still have substantial reduction in one or more activities. Without a substantial reduction in activities, a patient cannot sustain the key component of the research criteria. Even if they did not, the evidence above demonstrates that the result would not be a full recovery, but a remission. At some point in time, symptoms were likely to recur;

ME/CFS Australia submits that even if the NDIA accepted the papers on face value and accepted that participants with CFS improved, patients still had the diagnosis of CFS (Fukuda or Oxford) and still had a substantial reduction in functional capacity to engage in activities.

7.2.4.1.3. No Focus on Other Symptoms

ME/CFS Australia makes the point that whilst some of the alleged evidence based treatments claimed to improve some physical symptoms, such as pain for example, they did not address the specific symptom matrix that make up 1994 Fukuda CFS or 2003 Carruthers ME/CFS.

The other physical symptoms of ME/CFS impact upon the ability of a patient to carry out activities and cause substantial reduction in pre-illness activities, including those within Section 24(1)(c). The 2003 Carruthers criteria, as identified in 7.2.4.1. above, also considers severity of the other symptoms, hence it can be presumed that a diagnosis of ME/CFS meets the criteria of substantial.

7.2.4.1.4. No Requirement for Diagnosis

ME/CFS Australia also submits that even if a person failed to continue to meet the criteria for ME/CFS or CFS, they can still meet the requirements for a disability under Section 24, by virtue of their remaining symptoms (a) being permanent (b) causing a substantial reduction in activities.

7.2.4.1.5. Summary Submission

It is submitted by ME/CFS Australia that the evidence base provided by Professor Lloyd does not provide any evidence in the literature to suggest that applicants who have undertaken treatment have reversed the substantial reduction in activities set out in the legislation.

7.2.4.2. Addressing the Activities

Section 8.3 of the *Operational Guidelines* outline the functional capacity of an applicant to undertake activities.[260] The guidelines reiterate the position of the Federal Court in *Mulligan*[261], that it is unnecessary for the NDIA to be satisfied that an applicant's impairment is as serious, or more serious than, another. The NDIS assessment is based upon a functional, practical assessment of what the person can and cannot do.

7.2.4.2.1. Assessing Functional Capacity

Section 8.3.1. of the Operational Guidelines outline the considerations when assessing functional capacity to perform one of more activities,[262] deferring to Rule 5.8(a)-(c) of the *Being a Participant Rules*. ME/CFS Australia recognises that the use of assistance (technology, equipment, home modifications, aids, etc.) in order to participate is a consideration when establishing whether an applicant can participate effectively or completely in an activity. Additional considerations including

[260] NDIS, above n. 227.
[261] *Mulligan and NDIA* [2015] FCA 44 at [56].
[262] NDIS, above n. 227.

regard to the normal expectations of persons of similar age, safe completion of tasks and speed of tasks are considered. With respect to ME/CFS specifically such considerations are an individual assessment. ME/CFS Australia is of the view that the evidence base from Professor Lloyd does not inform this assessment.

7.2.5. Element 4 - Participation

The fourth element under Section 24(1)(d) is consideration of whether the impact of impairment(s) affect the person's capacity for social or economic participation.

7.2.5.1. Relevant Case Law

ME/CFS Australia draws your attention to *Mulligan*[263] in 2014 where the Senior Member Toohey and Member McCallum made clear that:

> "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."[264] (Emphasis Added)

7.2.5.2. Operational Guidelines

The Operational Guidelines further clarify this position. Stating:

> "The NDIA is required to only consider whether ***any permanent impairment, or permanent impairments when considered together***, affect a person's social or economic participation.
>
> For example, the NDIA must be satisfied that a prospective participant's permanent impairment/s ***affect their capacity to find or maintain work, play sport, go to the movies, perform voluntary work or travel***.
>
> This disability requirement does not require a person's impairment to reduce, substantially reduce or affect to any particular degree their social or economic participation. Rather, ***the impairment merely needs to affect the person's social or economic participation***."[265] (Emphasis Added)

7.2.5.3. The Evidence Base

ME/CFS Australia acknowledges that some aspects of the evidence base provided by Professor Lloyd include general references to social activities and employment.

[263] *Mulligan and NDIA* [2014] AATA 374 per Toohey and McCallum, [52].
[264] Ibid, [50].
[265] NDIS, above n. 227.

7.2.5.3.1. RACP Guidelines

The 2002 RACP Guidelines included a number of references of relevance including:

- "Social isolation"[266];
- "Loss of social contacts and access to social learning"[267];
- "Activities should be undertaken in a 'paced' fashion'"[268];
- Severely affected are "confined to bed or wheelchair"[269];
- "At the severe end of the spectrum of CFS, people may be housebound and experience profound fatigue simply from the necessities of self-care, such as showering or dressing"[270];
- "Many people with CFS struggle to continue working"[271];
- "Many patients choose to stop working, or unable to continue, either temporarily or permanently"[272];
- "Unpredictability resulting from the fluctuating nature of fatigue symptoms is a significant problem in conforming to a work routine"[273];
- "People with CFS are commonly in crisis with their school or workplace because of the accumulated time lost as a result of the illness"[274];
- "Limited energy, cognitive impairment and memory lapses can impair work effectiveness, placing jobs in jeopardy"[275];
- "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"[276];

The 2002 Guidelines encourage return to social and employment activities[277] and recommend CBT to overcome what it asserts was a "belief that complete withdrawal from work, school and social activities is necessary"[278], noting that ME/CFS Australia disagree that beliefs drive withdrawal, as opposed to the obvious ill health and associated impairments.

The 2002 Guidelines provide a number of references that assist in comprehending that social and work issues are significant problems. The inference can be drawn that the ability for social and economic participation is impacted. For the severely ill, their inherent inability to leave the house at all, or to any degree, creates an obvious impact.

7.2.5.3.2. International Consensus Criteria Paper

[266] RACP, above n. 1, p. S36.
[267] Ibid, p. S44.
[268] Ibid.
[269] Ibid, p. S45.
[270] Ibid, p. S36.
[271] Ibid, p. S45.
[272] Ibid.
[273] Ibid.
[274] Ibid, p. S36.
[275] Ibid, p. S45.
[276] Ibid, p. S46
[277] Ibid, p. S39.
[278] Ibid, p, S40.

The 2011 ICC included a number of references of relevance to social and economic participation, including:

- The operative parts of the criteria are similar to other criteria. The ICC states:

  > "A. Postexertional neuroimmune exhaustion (PENE pen'-e): Compulsory
  >
  > This cardinal feature is a pathological inability to produce sufficient energy on demand with prominent symptoms primarily in the neuroimmune regions. Characteristics are as follows:
  > 1. Marked, rapid physical and/or cognitive fatigability in response to exertion, which may be minimal, such as ***activities of daily living or simple mental tasks, can be debilitating and cause a relapse***.
  > 2. Postexertional symptom exacerbation: e.g. acute flu-like symptoms, pain and worsening of other symptoms.
  > 3. Postexertional ***exhaustion may occur immediately after activity or be delayed by hours or days***.
  > 4. Recovery period is prolonged, usually taking 24 h or longer. A relapse can last days, weeks or longer.
  > 5. ***Low threshold of physical and mental fatigability (lack of stamina) results in a substantial reduction in pre-illness activity level…***
  > Operational Notes … "***Consider activity, context and interactive effects***. Recovery time: e.g. Regardless of a patient's recovery time from reading for ½ hour, it will take ***much longer to recover from grocery shopping*** for ½ hour and even longer if repeated the next day – if able. ***Those who rest before an activity or have adjusted their activity level to their limited energy may have shorter recovery periods*** than those who ***do not pace their activities adequately***. Impact: e.g. An outstanding athlete could have a 50% reduction in his/her pre-illness activity level and is still more active than a sedentary person."

  Activities of daily living include employment and social activities.[279]
- "Determine total illness burden by assessing symptom severity interaction and overall impact. Consider all aspects of the patient's life – physical, ***occupational, educational, social and personal activities of daily living***. Patients who prioritize their activities ***may be able to do one important activity by eliminating or severely reducing activities in other aspects of their life***."[280];
- "Children cannot be expected to judge pre-illness function with current function. Assess impact by comparing hobbies, educational, ***social and sport activities the child participated in before illness with present activity level***."[281];

[279] Carruthers et al, above n. 33, p. 129.
[280] Ibid, p. 333.
[281] Ibid.

Whilst the ICC paper is not as comprehensive as the IOM Report (to follow), it does offer up an insight into the impact of ME/CFS on the ability to participate in social and economic activities. With PENE the cardinal symptom of the condition, the ability to repeat an activity declines, hence the activity is impacted.

7.2.5.3.3. IOM Report

The 2015 IOM Report included a significant number of references of relevance to social and economic participation, including:

- The proposed criteria includes the requirement that "A substantial reduction or impairment in the ability to engage in preillness levels of ***occupational, educational, social, or personal activities***,"[282];
- "… patients have reported several other ways in which the stigmatization of ME/CFS affects them, including ***financial instability (such as job loss or demotion), social disengagement*** …"[283];
- "Many patients feel unable to meet their family responsibilities and report ***having to reduce their social activities***."[284];
- "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."[285];
- "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."[286];
- "There is sufficient evidence that slowed information processing is common in patients with ME/CFS, and a growing body of evidence shows that it may play a central role in overall neurocognitive impairment associated with the disease. Such a deficit may be ***responsible for the disability that results in loss of employment and loss of functional capacity in social environments***."[287];
- "There is clear evidence of the impact of ME/CFS on the ***education and social development*** of these young people ... The stigma and ***social effects of pediatric ME/CFS*** include the ***loss of normal childhood activities and in some extreme instances, inappropriate forcible separation of children*** from their parents."[288];
- "Impact on Daily Activities, Responsibilities, and Social Interaction … Daily activities, responsibilities, and ***social interactions***—perhaps the most important of which are adults' ability to work and children's attendance and performance in school—can be an important indicator of disability and impairment (Schweitzer et al., 1995). Patients coping with the burden of disease will often ***reduce certain activities such as***

[282] IOM, above n. 32, p. 6.
[283] Ibid, p. 30.
[284] Ibid, p. 32.
[285] Ibid, p. 76.
[286] Ibid, p. 78.
[287] Ibid, p. 107.
[288] Ibid, p. 183.

extracurricular school activities or social gatherings in order to fulfil these essential responsibilities."[289];

- "Upon follow-up, 66 percent believed that their ***illness had an overall social effect on their life that varied from mild to severe***."[290];
- "Children with ME/CFS scored substantially lower than controls on the global health item of the Child Health Questionnaire (CHQ), as well as most other items, ***including physical functioning, social limitations due to emotional and health limitations, pain and discomfort, mental health, self-esteem, general health perceptions, and family activities***. Most notably, a comparison of scores on nine items of the CHQ revealed that the ***ME/CFS children scored lower than children with type 1 diabetes and asthma***, as well as healthy controls."[291];
- "***Reductions in employment and productivity per hour*** resulted in a 37 percent reduction in household productivity and a ***54 percent reduction in labor force productivity***."[292];
- "ME/CFS often lasts for many years, and beyond lost income, inflicts substantial economic costs at both the individual and societal levels."[293];
- "Regarding work-related impairment, unemployment rates in 13 of 15 studies ***varied from 35 to 69 percent***. ***Job loss ranged from 26 to 89 percent***, which was consistent with job loss among those with other chronic illnesses. ***Decreased work performance also was consistently reported in the literature*** and was attributed to impairments of short-term memory and learning, decision making, attendance, and communication skills and increased dependence on coworkers to perform work duties, among other reasons. Studies in this review were based primarily on unstandardized self-report, and some data ***indicated that symptom severity was associated with inability to work***."[294];

The IOM Report also considered employment as an indicator of recovery, including from interventions, stating:

- "A systematic review by Taylor and Kielhofner (2005) examined employment status as an indicator of recovery. The ***review included three longitudinal studies that found little change in employment status over time*** ... A 5-year follow-up study by Andersen and colleagues (2004) found that work disability of ME/CFS patients, identified in accordance with the Fukuda definition, ***increased from 77 to 91 percent, indicating no evidence of recovery***."[295];
- "A systematic review showed that while a few studies found improvement in symptoms over time, no variables, including gender or length of illness, predicted improvement or positive work or functional outcomes ... Furthermore, ***analysis of existing studies revealed no evidence of treatments effective at restoring the ability to work***. Another

[289] Ibid, p. 260.
[290] Ibid, p. 261.
[291] Ibid, p. 262.
[292] Ibid, p. 32.
[293] Ibid.
[294] Ibid, p. 260.
[295] Ibid, p. 264.

systematic review found that the placebo response is lower in behavioural intervention studies than in medical intervention studies of patients with ME/CFS..."[296];

- "Consistent with the findings of the systematic review of Ross and colleagues…, studies reviewed by Taylor and Kielhofner … ***provided no evidence regarding the efficacy of employment rehabilitation***, such as CBT and/or graded exercise therapy. Variation in methodologies, outcome measures, subject selection criteria, and other factors ***precluded drawing conclusions about the efficacy of interventions designed to enable ME/CFS patients to return to work***."[297];

The IOM report lends significant weight to the view of ME/CFS Australia that the condition invariably has an impact upon the social and/or economic activities of applicants at some point throughout their lifetime. The fact that there is no weighting as to the degree of impact within the legislation means that the NDIA can be satisfied that for the majority, if not all, the assumption of impact under this element is appropriate. Most significantly, the IOM report identifies no interventions that demonstrate that the impact is removed completely at any point in the lifetime of a patient.

7.2.5.3.4. Summary Submission

The evidence base provided by Professor Lloyd sets out the significant impacts of ME/CFS upon applicants. There is a consistency in regards to the criteria where there is a requirement that there is an impact upon activities which include social and economic. There are also clear indications that there is no effective treatment that will restore social or economic participation completely, i.e. a cure for all symptoms throughout an applicant's lifetime.

The condition is, as demonstrated above, one that can be consistent throughout a patient's lifetime, whereas some will have a period of remission and relapse. Regardless the variations, there is satisfaction of Section 24(1)(e).

It is acknowledged that Professor Lloyd provides an evidence base that suggests that treatments lead to improvements in various domains, including social and economic participation. Again, if we take those studies at face value, they are not significantly longitudinal to be extrapolated to a life time (noting the chronic recurrent nature of the condition is either ongoing, or fluctuation of remission/relapse) and they do not demonstrate a complete recovery to pre-illness health, hence the impact upon social and economic activities, even minor impacts, are sufficient to meet the criteria within Section 24(1)(e).

7.2.6. Element 5 – Lifetime Support

ME/CFS Australia have demonstrated that the condition is permanent or is likely to be permanent. Given this is the case, an applicant is inherently "likely to require support under the National Disability Insurance Scheme for the person's lifetime".

7.2.7. Element 6 - Variation

The final element is that of variation contained within Section 24(2) of that pertaining to variation. ME/CFS Australia defer to its submissions above at 7.2.3.3. to 7.2.3.5. Given the inherent nature of

[296] Ibid, p. 265.
[297] Ibid.

the condition is one of fluctuation for many, and for some others it is a progressive deterioration, the condition meets the requirements of this section.

8. SUMMARY SUBMISSION

The purpose of this submission is to present to the NDIA an alternative and balanced perspective regarding the policy with respect to applicants to the NDIS. Whilst ME/CFS Australia appreciates that the NDIA is not an expert with respect to its comprehension and appreciation of the finer nuances of the literature and the condition, it made attempts to inform itself of the current state of the literature when seeking out an opinion from Professor Lloyd.

ME/CFS Australia has informed itself of the applicable legislation and rules and, via a balanced consideration of the literature provided by Professor Lloyd, considered what the evidence base demonstrates and how that information relates to the requirements of the *Act* and *Rules*.

ME/CFS Australia submits that when the legislature contemplated the construction of Section 24, and Rule 5.4, it had in mind that the evidence base gathered by the NDIA would speak directly to the requirements it set down. To this end, the operative word "likely" stands out as a critical requirement for assessing the permanency of impairments and the probability of success of remedies. Specifically, it requires that the NDIA undertake a weighting of the information with respect the evidence based interventions in order to satisfy itself that the intervention will likely remedy the impairment, or not remedy the impairment.

ME/CFS Australia submits that the NDIA has not appreciated that:

- It has grossly misconstrued the recovery rates with respect to CFS due to a misunderstanding of the Dubbo study;
- the evidence base does not, at any point, consider those who fall within the severe category of ME/CFS, hence there is no grounds upon which to conclude that any intervention would remedy the condition;
- the evidence base contains outdated information (e.g. studies utilising the retired Oxford criteria; the deference to outdated guidelines);
- the evidence base contains mismatched information (e.g. significantly different criteria; incompatible delivery of the same treatment label);
- the evidence base focuses on interventions for fatigue, which is not the primary symptom in ME/CFS;
- the evidence base does not speak to the majority of impairments and cannot be extrapolated to do so on the basis of the evidence base provided;
- the evidence base, if taken at face value, does not demonstrate at any point that the symptoms of ME/CFS are remedied;
- the evidence base, if taken at face value, does not achieve the threshold of "likely to remedy" at any point;

- in accepting the evidence base uncritically, it has been made aware that the evidence base is far from settled, the interventions are highly contentious, and there existed a significant base of evidence identifying numerous critical flaws in key documents within the evidence base;
- critical aspects of the evidence base, particularly with respect to guidelines and criteria, have moved forward to the exclusion of past such documents;

ME/CFS Australia has, in providing a balanced critique, attempted to provide sufficient evidence base to the NDIA to allow it to arrive at an informed decision with respect to policy. In assisting the NDIA to that policy, ME/CFS Australia, as the peak body encapsulating the consumer voice, has offered to discuss the matter with and assist the NDIA in considering relevant issues.

ME/CFS Australia has urged the NDIA to adopt the precautionary principle that applies with respect to matters of public health, which ME/CFS is, in order to avoid potential and actual harms to applicants who will likely subject themselves to the dangers of the interventions in an attempt to access the NDIA.

ME/CFS Australia therefore urges the NDIA to amend its current policy for the protection of the applicants from harms and to allow full and fair consideration of the impairments of the applicants against the requirements of the scheme.

9. LIST B-INCLUSION

The final issue that ME/CFS Australia wishes to address within this submission is the matter of List B inclusion. ME/CFS Australia submits that the NDIA holds the discretion to relieve claimants of the controversy and hurdles that have arisen on almost every ME/CFS claim to date (noting some have moved through to acceptance where another condition was accepted as the primary issue).

The NHMRC Report recently supported this position, stating:

> "To date, there have been three submissions to the Joint Parliamentary Committee on the NDIS (by Emerge Australia, ME/CFS Legal Resources Australia and ME/CFS & the NDIS Facebook group), as well as a national #MillionsMissing advocacy campaign. ***Advocates have raised concern about the lack of understanding of the condition by National Disability Insurance Agency (NDIA) assessors, and the rejection of claims of people who are significantly impaired***. Patients have indicated that a ***requirement of NDIS is that ME/CFS patients undergo graded exercise therapy and/or cognitive behavioural therapy before they can access NDIS, DSP or supportive services***. To access care through the NDIS and DSP patients need to show they have a significant disability. ***For these ME/CFS patients, graded exercise therapy may not be appropriate***. The following summarises the submissions' proposed recommendations to NDIS:

• recognition of ME/CFS as a ***serious debilitating condition***
• the condition should be ***listed on the NDIS under list B: neurological disorders***
• that ***assessment guidelines for NDIA assessors be developed in collaboration with clinicians with expertise in management of ME/CFS and the ME/CFS community***."[298]

ME/CFS Australia submits that the evidence before you, whilst not an exhaustive account of the literature, is a persuasive and sufficient justification for the inclusion of ME/CFS under List B with other Neurological Conditions.

10. ME/CFS ADVISORY GROUP

ME/CFS Australia is aware that the NDIA has a number of reference groups with whom it consults and works to improve the process and supports under the scheme.[299] ME/CFS Australia seeks to partner with the NDIA to improve the current situation. We would be happy to assist with the sourcing of experts and consumers, and use our best endeavours to source appropriate service providers.

We have reviewed the Autism Advisory Group and believe that this is an excellent template to work from should such a Group commence.[300]

[298] NHMRC, above n. 4, p. 12.
[299] NDIA, 'Reference Groups', (31 July 2019) <https://www.ndis.gov.au/about-us/reference-group-updates>.
[300] NDIA, 'Autism Advisory Group' (5 December 2018) <https://www.ndis.gov.au/about-us/reference-group-updates/autism-advisory-group>.