

## PRODUCTIVITY COMMISSION MENTAL HEALTHCARE ISSUES – June 2019

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### PROPOSITION

1. The subjective and qualitative nature of the clinically applied “Standardised Criteria” by which mental illnesses are diagnosed while the best there are, they are inadequate in time, accessibility, affordability and accuracy to improve the issues raised in the terms of reference of the Commission.
2. The critical need for objective, rapid, inexpensive diagnostic technology that enables clinicians to make earlier and more accurate diagnoses and appropriate intervention must be a primary matter for consideration by the Commission.
3. The on-going cost burdens to Government and the Community of misdiagnosis and the resulting incorrect drug therapy and delays to appropriate early intervention amounts to \$100’s of millions of lost productivity each year.
4. New objective diagnostics technologies that facilitate a more accurate and faster diagnosis are required before any globally improved and cost-effective models of mental healthcare can be developed
5. Government should be proactively facilitating policy and program initiatives to pilot innovations which have peer-reviewed evidence.
6. Dr Tom Insel, then Director of the US National Institute of Mental Health presents an example of a strategic direction in this matter in the US [NIMH Strategic Plan for Research](#) that balances urgent mental health needs with longer-term investments for basic research and piloting innovation?

In 2013, immediately prior to the release of the DSM-5 edition, [Insel quotes](#):

*“While DSM has been described as a “Bible” for the field, it is, at best, a dictionary, creating a set of labels and defining each condition. .... **The weakness is its [DSM-5] lack of validity.** Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure. In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of fever. Indeed, symptom-based diagnosis, once common in other areas of medicine, has been largely replaced in the past half century as we have understood that symptoms alone rarely indicate the best choice of treatment.”*

He ends **“Patients with mental disorders deserve better.”**

### SUMMARY

- While Clinicians do the best with the DSM-type “Standardised Criteria” as they can, early /earlier intervention in Mental Health [MH] is not possible until mental illness is de-stigmatised and that diagnosis is OBJECTIVE, affordable and equally accessible across regional and remote Australia.
- Government Innovation, Science and Health Policies, and subsequently Investment Markets appear inadequate through lack of accountability, risk aversion and under-investment in innovation, despite the Government being responsible for the growing cost burden borne by taxpayers, carers and sufferers of Mental Illness.
- There are innovative solutions available that need Government Healthcare System engagement and investment to fast-track into practice or fast-fail.

## COMMENT ON PC'S ISSUES PAPER

The words "diagnosis", "diagnostic" and "DSM" only appears twice each throughout the whole PC "Issues" document, whereas the document is silent on the words "misdiagnoses [sis]". Further, no reference is made to the World Health Organisation's International Classification of Diseases [including psychiatric conditions] Edition WHO's ICD-10 or its updated version 11 due to come into force in 2019. This ICD-10 is the European/Rest-of-World's alternate "Gold Standard" to the US Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (2013) [DSM-V], published by the American Psychiatric Association.

These two "Gold Standard" Diagnostic Manuals, DSM-5 and soon WHO's ICD-10/11, do not fully align in the wording used for the criteria by which each of the 400+ Mental Illnesses are supposed to be diagnosed. <http://journal.ahima.org/2016/08/10/dsm-5-vs-icd-10-cm/>

The above begs the questions as to how standardised the "Standardised Criteria" referred in the PC Issues paper in fact are, and are they good enough anyway, for the situation addressed by the Commission, when the chances of a correct diagnosis and appropriate safe and effective intervention at the first few clinical interviews is probably less than "coin-toss" for the majority of suffers with mental health issues.?

**INTRODUCTION** The author of this submission presents himself as having four interests and perspectives in the economic and productivity impacts of Mental Illness on the Australian Community.

1. Primarily, as an entrepreneur who together with other colleagues has dedicated the past 15 years to developing what we consider to be an Australian transformational and paradigm-changing, medical diagnostic platform technology of potential global impact, with peer-reviewed evidence of its capability to support clinicians make faster, objective and more accurate diagnostic decisions on many mental and neurological illnesses, from Major Depression to Bipolar Affective Disorder to Alzheimer's to mild Traumatic Brain Injury and Schizophrenia and Parkinson's disorders.

-See [www.neuralex.com/research](http://www.neuralex.com/research)

2. Secondly, as a broad-based industry Senior Technology and Bio-Engineering Executive, with a 40 year career covering both medical device research, regulation and manufacture, as well as multi-disciplinary research collaboration seeking funding and overcoming challenges to deliver commercialised outcomes. In this role, I note a market and government failure to effectively support, high risk investment capital policies directed towards solutions to issues with high national cost burdens borne predominantly by State and Federal Governments.
3. Next and more personally, as an individual whose family, like most, has dealt with serious mental health issues and their ongoing impacts, including the inadequacy of the diagnostic process; as well as the unaffordable cost and scarce availability of Mental Healthcare Support Services.
4. Finally, as an individual now over 65 years of age who has the one-in-eight probability of developing, to some greater or lesser level, cognitive impairment progressing to dementia – a range of neurological disorders with cognitive, emotional and behavioural symptomatic consequences over the next decade or two, knowing that my future gerontologists, despite their clinical expertise, [if I can access and afford them], will still have great difficulty determining what type of dementia I may or may not suffer from or by nature am genetically prone to have, if at all.

This statement recognises that, I have the choice of paying a costly Positron Emission Tomographic scan to confirm Alzheimer's, and/or a belated genetic scan to confirm the presence or absence of predisposing ApoE4 genes to dementia. However, even when armed with a more definitive prognosis/diagnosis, I know that any intervention will be too late or based on current therapies being too ineffective to deliver much improved quality of life, if at all, and with few and reducing new therapies now in the development pipeline, due in large part to the matters raised in this submission.

**NOTE:** My submission considers both Mental and Neurological Disorders of Brain and Central Nervous System, as both sets of pathologies have overlapping symptoms that are observed as emotional, behavioural, cognitive and/or motor impairments and aberrations to normal that prevent the sufferer effectively engaging in society. This includes the misdiagnosis of one class of disorder [say] neurological] from mental disorders, which I understand occurs with greater frequency than many clinicians desire or care to admit.

For example, complicating the clinicians diagnostic challenge is that many disorders have comorbidities that are naturally associated with each grouping; viz: a Parkinson's Sufferer [a neurological disorders] will often be severely Depressed [a mental disorder], and being generally over 65 years old may also suffer a degree of cognitive impairment which in turn maybe initiated by the Parkinson's or Alzheimer's or Depression. It is recognised faster outcomes can be achieved by first treating depression which helps alleviate cognitive impairments which in turn then facilitates better outcomes with treatment of Parkinson's.

### **CORE SUBMISSION.**

My core submission is that the underlying issue behind the increasing burden of mental illness or brain disorders, lost productivity issues from presenteeism and absenteeism, and the overall inadequate servicing of our Australian and international communities, is that the "standardised criteria" [DSM-5 or ICD-10] by which Psychiatrists and General Practitioners attempt correctly diagnose mental illness as well as many neurological disorders, while being the best there are for now for clinicians and industry to use, such criteria are not objective, nor inexpensive to apply, are slow and thus inadequate for their purpose to facilitate:

- "early intervention" with Sufferers,
- Treating to target for Pharma developing new Central Nervous System [CNS] drug therapies, which have a >98% failure rate, and >\$2 billion to bring to market over 15 years.
- State and Federal Government attempting to improve the productivity, deliver better MH services and reduce the Mental Health Cost Burden in their universal healthcare systems.

All Groups in turn have suboptimal outcomes because of these diagnostic inadequacies, with some large Pharma companies withdrawing from the marketplace of developing and delivering new and better CNS therapies, and like too many of the under-serviced sufferers, committing suicide out of hopelessness of their plight and inadequacies of the system, and finally with governments challenged each year with increasing mental healthcare budgets, now exceeding \$60 billion p.a. See MINDGARDENS Report 2019 below. <https://www.mindgardens.org.au/wp-content/uploads/2019/03/MINDGARDENS-WHITE-PAPER-FINAL-14th-March-2019.pdf>

In the absence of any alternative diagnostic techniques, the same subjective standardised criteria are applied to both selection of subjects into CNS Pharma drug trial, as well as to correlate the clinical effectiveness of each therapy on those subjects with respect to recording changes to their symptom severity, again measured subjectively using qualitative assessment rating scale scores and checklists.

While some may claim that Electro-encephalography [EEG], functional Magnetic Resonance Imaging [fMRI] or Positron Emission Spectrography [PET Scan], have a bigger future role to play in diagnosis, after over 100 years of clinical practice for EEG and 30 years for fMRI and PET, it is unlikely this will occur due to their limited utility for diagnosing mental illness, as well as their respective capital and running costs, time and accessibility constraints particularly for those sufferers living in regional and remote Australia.

## COMMENTS ON THE PC MENTAL HEALTH ENQUIRY

Three adages underpin this submission to the Productivity Commission's Enquiry on Mental Illness, in relation to its prevention; screening; early diagnosis; early intervention; targeted treatment; and on-going monitoring for relapse, recovery and/or therapy efficacy; - as well as its cost and social burden on the Australian Community:

### ***A. "While prevention is best, early diagnosis leads to early intervention to better health outcomes"***

Earlier diagnosis is currently unattainable with objective certainty for Mental Illness but this is a fundamental requirement to the reform of its diagnosis as to facilitate earlier intervention, and appropriate treatment. See B below.

### ***B. "If one always does what one has always done, one will always get what one has always got! - So with evidence do it differently to get a different and generally better outcome".***

If the PC's starting point is the tacit acceptance that the current DSM-V /ICD-10 "Standardised" criteria are essentially all that is required by way of diagnostic tools for clinical work-up of a subject, then that is an unsatisfactory basis for future planning.

For the last 50 years or more, Australia's Mental Healthcare System has relied upon the use of "Standardised Criteria" to diagnose mental illness by clinicians, with little benefit available from brain imaging technologies to improve diagnostic accuracies.

The relatively unacceptable mental healthcare outcomes leading up to the current Productivity Commission's enquiry, suggests that continued reliance on DSM type subjective diagnoses will only deliver similar outcomes unless changes are made to the quanta of mental health care personnel applied and available to facilitate earlier diagnosis and intervention. More preferably, the methods of diagnosis should be made more productive and efficient. By that, I mean, faster, objective, and more accurate, as well as more affordable and accessible, including in regional and remote Australia.

Without a drastic increase in availability and accessibility of MH support resources, and beyond that envisaged in the Federal Government \$1.5 Billion future investment in e-Mental Health Services, [even over the internet] will not improve outcomes. Such investment will probably be both unsustainable and unproductive.

A more productive solution to the social and economic burdens of Mental Health is access to evidence-based innovation that delivers affordable and accessible solutions to support the existing MH Services to make faster, earlier, more accurate diagnostic decisions so as to achieve the earlier, more effective and appropriate interventions.

Specifically, for the Australian Healthcare System to deliver better outcomes to those suffering from the societal and self-imposed stigma and burden of Mental Illness, it is essential for Governments to create innovation policies that prioritise and facilitate the pro-active search for and subsequent support of evidenced-based research and innovation in brain health, not least in objective and affordable measurement of core-brain function.

C. Management thinker Peter Drucker is quoted as saying that

**“you can’t manage what you can’t measure.”**

*Author comment*      *Mental illness is not measured, only its negative cost impacts.*

Following on from B above, I suggest that to assist clinicians make faster and more accurate diagnostic decisions and in turn initiate earlier appropriate interventions and subsequently to monitor any benefits or otherwise of those interventions, MH Innovation requires to add a truly evidence-based **OBJECTIVE** measurable dimension of brain function to the diagnostic process.

Such a dimension would ideally include domains of physiological digital biomarkers of brain/mind [dys]-function, delivered to the clinician supporting patients residing in any and all metropolitan, urban, regional or remote locations. The Objective system will need to be accessible, affordable, rapid, non-invasive, culturally and linguistically neutral, accurate, and suitable for use in all locations.

While currently an unfulfilled potential, opportunities from Australian Bio-Tech/Med-Tech Start-ups exist to deliver such outcomes over the next 2 to 5 years.

Despite the current availability of objective brain imaging Technologies, such as functional Magnetic Resonance Imaging [fMRI], and Positron Emission Tomography [PET], who’s operating and capital costs as well as their centralisation in large metropolitan centres, have a very limited utility for diagnosing Mental Disorders across the broader community. Even then such imaging technologies tends only to be capable of excluding a diagnosis, such as tumours or brain bleeds] rather than to identify one [such as schizophrenia, major depression, anxiety, or bipolar disorder].

The time consuming [>2 hours] Electro-encephalography [EEG] test while lower cost than imaging, and more accessible, has after over 100 years of use only found a routine clinical application of identifying a site and type of an epileptic seizure, depth of coma, depth of anaesthesia, and brain death. This is understandable as EEG is only capable of accurately detecting electrical function within the top few millimetres of the brain’s surface, and does not directly access the function of deep brain structures associated with behaviours and emotional drivers, such as exist in the limbic system and brain stem. Even then the signal detected is so distorted as to only provide information in the 0Hz to 100 Hz bandwidth.

**OPINION**      The author suggests that **RATHER** than drastically increasing the human and cash resources applied to better manage today’s prevalence of mental illness using today’s approaches, a more balanced approach to trial new objective diagnostic technologies that facilitate a more accurate and faster diagnosis is **FIRST** applied so that improved models of mental healthcare are possible and put into practice earlier than current possible.

## **GENERAL COMMENTS**

**PREVENTION AND EARLY INTERVENTION** are raised as the first issue for comment by the PC, where this contributor notes that logically **early intervention** per se can only occur **“early”** [in the progression of the disorder]”, if it is diagnosed earlier and ideally more reliably than is currently possible.

This highlights the as yet unasked or unconceived question for the PC Enquiry as:

if the **“standardised criteria”** [Box 1 – Page 2] for diagnosing mental illness is so good, why are so many slow/late and inaccurate misdiagnoses made for sufferers across the spectrum of mental disorders that create the physical and economic demand for the already costly and relatively scarce, yet centralised, mental healthcare resources?

## DIAGNOSIS OF MENTAL ILLNESS

The PC's starting point appears to be the tacit acceptance of "Standardised Criteria" of the DSM-V / ICD-10 defining the 450 Mental Health Disorders, as essentially all there is needed by way of tools for the diagnostic work-up of a subject, with the implication that appropriate use of those tools by sufficient numbers of trained clinicians/ healthcare workers, located close to the sufferers, or linked to sufferers over the internet, will result in correct diagnoses being made, optimal interventions implemented, and the outcome will be better.

However and as mentioned earlier, even after close to 150 years, since the foundation of the medical specialty of psychiatry by Pavlov and others, the two "Gold Standard" Diagnostic Manuals DSM-5 and soon the WHO's ICN-11 do not fully align in the quoted "Standardised Criteria" by which any Mental Illness is defined.

Both sets rely upon *qualitative subjective rating scales and checklist scoring* applied by clinicians. Ideally, such clinicians are experienced psychiatrists specialising in the diagnosis and treatment of a specific DSM/ICD disorder.

However, this is not the case and in reality General Practitioners (GPs) provide over 80% to 90% <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/general-practice/patient-characteristics#GP.1> of Mental Healthcare services in Australia, and GPs are generally the point of initial diagnosis and treatment.

Regrettably, GPs do not have the reimbursement incentive or time availability, or necessarily the expertise to deliver the intensive services and therapies required at times by the complex needs of their patients or potential patients, who are not able for the most part either to access or to afford their services.

The result for the sufferer is often misdiagnosis and costly harmful delay, attempted suicide and regrettably all too often suicide.

Further, ready accessibility of the 10% of Australians who sufferer mental health issues in any year to the 3,244 specialist psychiatrists practicing in Australia is severely restricted, as close to 90% of psychiatrists are reported by the AIHW to reside within major State Cities. However, access can be gained by those who can afford both the time of travel to as well as the gap payments to such specialists.

Overall, with one-in-4 of the population suffering from a serious mental illness in their lifetime, there is a scarcity of affordable, accessible psychiatrists particularly for those residing in regional and remote parts of Australia's 7.7 million square kilometres. Those living in these areas are particularly under-served, yet paradoxically those same areas are probably over-represented by those suffering from mental illness and their carers who are more likely to reside there because of the greater housing and living affordability of these regions relative to their generally reduced incomes of both the sufferer and their carers due to mental illness.

Finally, it is worth remembering that unlike Clinical Specialists that diagnose and treat heart, kidney, lung, muscle, gastric, and blood vessel diseases, there are no validated low-cost physical or bio-chemical, objective measurement instruments [such as blood oximeters, blood flow rate meters, Holter monitors, electrocardiogram [ECG], stethoscopes or pillcams, etc.], that Mental Healthcare practitioners can use to objectively monitor human brain [dys]-function at the cognitive, emotional or behavioural symptoms level.

There is no "*ECG for the Mind*" yet commercially available. As mentioned previously, EEG at best is effective for diagnosing brain death, depth of anaesthesia, sleep disorder or epileptic events, and fMRI / x-ray computer tomography [CT] are used to exclude diagnoses such as tumours, or brain bleeds, rather than to identify a specific psychiatric condition. PET Scanners cost \$6 Million to buy and a further \$1 Million per year to operate, and over \$1000 per scan.

## HEALTH ECONOMIC ASPECTS

The World Economic Forum<sup>1</sup> predicts that by 2030, the direct and indirect global cost burden of mental illness will reach US\$6.1 trillion.

[http://www3.weforum.org/docs/WEF\\_Harvard\\_HE\\_GlobalEconomicBurdenNonCommunicableDiseases\\_2011.pdf](http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf)

More recently [Mindgardens report 2019](#) indicates Australia's 0.33% of global population share is reported to well exceed \$60 billion p.a.

This burden is becoming unsustainable / un-supportable, and requires greater investment sooner than later in policies that support research, development, demonstration and commercialisation of innovation and into improved solutions to reduce this burden.

Re-iterating the clinical adage:- "*early diagnosis leads to early intervention, and early intervention to better health outcomes*", but looking through the 21st Century Prism at the Mental Health Issue reveals that both the Australian and Global MH Systems are broken.

Early diagnosis is not occurring, and when by chance it does the probability that first time diagnosis is correct has about a little better chance of a coin-toss [50:50].

Even then, while early intervention may be initiated, the intervention will also probably be sub-optimal or wrong as not all sufferers will respond well to all therapies, and certainly cannot respond appropriately to an un-needed pharmaceutical prescribed for a condition the sufferer does not have.

Finally, all current interventions preclude the **optimum** benefits occurring for the sufferer, their carers and the community / healthcare system supporting them, until **objective** diagnosis is possible.

### Mood Disorders [as a vignette]

Mood Disorders, including Major Depressive Disorder [MDD], Bipolar Affective Disorder [BPAD] and General Anxiety disorder, contribute to the bulk of Australia's Mental Health Burden of Disease. This group of disorder impact on over 10% of the Australian Community in any year, and contribute at least \$1billion per year to this direct and indirect cost burden of Mental Illness.

Major Depressive Disorder alone impacts about 6% to 8% of the population per year. Bipolar Affective Disorder [old Manic Depression], affects about 1.4% of the population. The latter can take over 13 years before a correct diagnosis is made, prior to which up to 4 other mis-diagnoses are likely to have been made from Major Depression to Schizophrenia to Generalised Anxiety Disorder to Attention Deficit Disorder. <https://www.ncbi.nlm.nih.gov/pubmed/17324469>.

A 2010 professionally-undertaken in-house preliminary health economics assessment estimated that Australia's health care system wastes A\$200 Million per year through the misdiagnosis of Bipolar Disorder from Major Depressive Disorder alone. The Bipolar Australia association further detailed the costs and misdiagnoses levels in their 2018 Publication: <http://www.bipolaraustralia.org.au/wp-content/uploads/2018/03/Cost-Savings-in-Bipolar-Disorder.pdf>

A study reported in the Lancet, 2009, into diagnostic accuracy of General Practitioners using "standardised criteria" for Major Depression appear to get their diagnosis of sufferers of MD wrong over 50% of the time. <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.691.781&rep=rep1&type=pdf>

## PREVENTION AND EARLY OBJECTIVE CONVENIENT DIAGNOSIS

### PREVENTION

The author fully endorses concepts of Prevention of Incidence of Mental Illness.

It is suggested that at least 1% of any State and/or Federal Departmental Health Budget should be allocated to preventative and supportive mental health services, not least to those who are statistically more vulnerable to future mental health disorders such as Combat-exposed troops, isolated workers, police and emergency personnel, as well as family and children of suicide subjects - all who compared to the general community, are reportedly twice as likely to drink excessively, take illicit substances, suffer post-traumatic stress disorder, and /or major depression and/or also suicide or attempt suicide.

## **POTENTIAL OPPORTUNITIES FOR BETTER OUTCOMES**

As alluded to on Page 1, the author of this submission is an entrepreneur who together with other colleagues and a great team of multidisciplinary Australian and Canadian Bio-engineers, Psychiatrists Researchers has dedicated the past 15 years to expend \$10 Million to develop Electrovestibulography, EVestG™. [www.neuraldx.com](http://www.neuraldx.com)

Based on our peer-reviewed publications, this technology appears to have the potential to be an Australian transformational and paradigm-changing, medical diagnostic technology capable of rapidly, objectively and accurately diagnose many of the mental and neurological illnesses contribution to the drivers of the cost burden of mental illness from Major Depression to Bipolar to Schizophrenia to Parkinson's and Alzheimer's Diseases , as well as to mild Traumatic Brain Injury and Post Concussive Syndrome.

Like any Bio-tech Start-Up, our pathway is long, slow, arduous, and perilously close to failure at any time, over a 15 year journey from idea to use.

The causes to our dilemma appear due to scarcity of high risk capital, long regulatory and clinical trialling pathways, and other circumstances beyond our control, and not by the technology or quality of management per se. Rather due to time and financial constraints required to patiently patent the concept, to win grants, to form collaborative alliances, to raise leveraging funds and to await the slow, peer-review process before acceptance of our research outputs in quality international journals.

That said, having now completed the Proof-of-Principle and Proof-of-Concept Trialling with sound peer-reviewed evidence, the start-up NeuralDx Ltd, still needs a further \$10 Million and 3 years of further risk to undertake and complete the essential multi-centre Randomised Clinical Validation Trials with Regulatory approvable equipment in order to be positioned to enter the market by 2022.

Noting the critical and costly impact on the Australian Community of Mental Illness, the Author is left wondering if a faster way of selecting, driving and incentivising investment to high risk long-term projects of strategic importance to the State and Federal Health Departments is possible.

Our choices are stark:

- To exit or To hold and hibernate or To sell, or
- To move the opportunity to the US / North America, where risk money and government incentives appear greater.

## **GOVERNMENT and MARKET OPPORTUNITY OR FAILURE?**

Over the past 20-to-30 years, State and Federal Government Research, Innovation and Health Policies seem to fail and/or are excessively passive or too distant from communicating mechanisms that specify prioritised healthcare and social systems issues for early resolution, and subsequently providing adequately resourced incentives to address those issues for fast-tracking and/or fast failing evidenced based medical technologies through Research to Practice Roll-out, including Clinical Validation for Regulatory Approval in Randomised Clinical Trials

Understandably, the Australian financial market in-turn has fundamental risk aversion to, and hence scarcity of risk investment into bio-tech start-ups focused on long-term medical issues, which from their perspective carry an expectation of >90% failure rates along the 12+ year journey from invention to the market place, before any revenue or break-even is possible for the 10% surviving the journey.

Despite generous R&D Tax incentives to Industry, most current bio-tech grant assistance tends to be restricted to and controlled by academic institutions, and contributes to the market failure of private investment into Mental Health Solutions.

These Innovation policy and program shortfalls with respect to Mental healthcare, accumulate year-by-year on the Government Budget Line, with the social and financial burdens borne most heavily by MH Sufferers and their carers, who deserve and wait for better outcomes.

**END**