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Submission to the Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia

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1.0 About Applied Cannabis Research

Applied Cannabis Research, a division of Southern Cannabis Holdings, is Australia's leading contract research organisation in medicinal cannabis. Because of our experience we understand that in cannabis research, intellectual property positions are different, budgets are smaller and timescales are shorter. Accordingly, we provide an alternative research partner with hands-on experience in medicinal cannabis research.

We have direct access to the largest pool of patients undergoing cannabis therapy in Australia, multiple treatment sites and data collection platforms that are compliant and tailored to the medicinal cannabis sector.

Our goal is to assist medicinal cannabis companies guide their products through the clinical development stage leading to effective therapeutic application of these promising new drugs.

2.0 Executive Summary

We recommend the following actions be implemented to improve access to medicinal cannabis in Australia:

1. We recognise that the major barrier to access to prescription cannabis is lack of knowledge, particularly among medical practitioners
2. We recommend development of a program of observational research using large high quality data sets obtained from cannabis prescribing clinics around Australia
3. We recommend that findings from the research are widely disseminated to medical practitioners in a structured educational program
4. We recognise that a considerable barrier to access to prescription cannabis is cost
5. We recommend that the results from observational research are used to develop standard of care protocols that will allow cannabinoids to be listed on the PBS or be subsidised using Medicare
6. We recognise a subsidy scheme will reduce cost to the consumer as well as reducing the costs associated with inappropriate prescribing
7. We recognise that findings from observational studies may reveal unexpected side effects of cannabinoids as well as providing a vehicle to challenge perceived wisdoms, particularly those concerning driving a car or operating machinery while on cannabis therapy

3.0 Knowledge barriers



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While most medical practitioners are aware of medicinal cannabis, they are faced with a number of knowledge gaps that limit their ability to prescribe cannabinoid drugs with confidence. These include:

1. A lack of understanding of cannabinoids as drugs and their different formulations
2. Limited knowledge of how cannabinoids alleviate disease and how they should be prescribed
3. Limited knowledge of the long term effects and side effects of medicinal cannabis
4. Lack of awareness of the diseases that can be treated with medicinal cannabis
5. Reluctance to prescribe because of a lack of understanding of the regulatory processes surrounding cannabinoids

Our understanding of cannabinoid medications is complex and confusing. Endocannabinoids, cannabis derived compounds and synthetic cannabinoids have been implicated in effective treatments for chronic pain, chemotherapy-induced nausea and vomiting, multiple sclerosis, epilepsy and palliative care. Despite their broad applicability, the appropriate cannabinoid and the correct dose regimen are not well defined.

Clearly, there is considerable scope for research that will give medical practitioners the knowledge they require to administer cannabinoid-based drugs. At Applied Cannabis Research, we have access to clinics Australia-wide that collect large volumes of specialised, high quality data that we have used to determine cannabinoid efficacy. We have designed a series of observational studies that provide key evidence of drug effect in a process that essentially circumvents early phase clinical trials. We recommend that our approach be used to identify physiologic responses to defined cannabinoids that will provide clinical evidence that can inform more structured clinical trials. Importantly, our observational studies are expected to identify those cannabinoids that do not have the expected therapeutic effect and can thus be eliminated from further study.

Next, we recommend that new knowledge is disseminated to the community through seminars, workshops and conferences by the researchers and ultimately incorporated into standard of care protocols. The educational process should be coordinated and managed by organisations with strong protocols, broad patient bases and a profound understanding of the therapeutic efficacy of different prescribed cannabis formulations.

4.0 Cost barriers

A major stumbling block for access to cannabinoid compounds is cost, with medication costing the consumer as much as \$50 per day for treatment. Of the



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options for reducing the cost to the consumer, listing cannabis-based compounds on the PBS or offering subsidy via Medicare are some of the most effective. The very function of the PBS and Medicare is to make the healthcare Australians need affordable, while imposing a responsible cost on the community.

Listing cannabinoids on the PBS or offering subsidies through Medicare will both reduce the cost of the drug to the consumer and stimulate savings in the use of other health-care and related resources. Understanding the therapeutic properties of medicinal cannabis is likely to have flow-on effects in the healthcare system and in the community through outcomes such as a reduction in GP visits, reduced or eliminated hospitalisation and increased productivity because of reduced sick days.

To list on the PBS or Medicare requires base knowledge that can be acquired through observational studies as detailed above. The current approach to increasing our knowledge of the therapeutic benefit of cannabis compounds is through clinical trials. This lengthy approach requires detailed pre-clinical evidence and ideally a description of the molecular mechanisms of drug effect. The field of cannabis research is clouded with an array of compounds, both naturally derived and synthetic with overlapping therapeutic effects, making for a difficult choice of drug to subject to the expensive clinical trials process. Targeted observational studies can identify cannabinoids that have therapeutic potential and those that don't with significant savings in development costs.

5.0 Knowing What to Prescribe

Another advantage of listing a new therapeutic on the PBS or giving a detailed Medicare schedule is to provide medical practitioners with the correct guidelines for prescribing new drugs. Inappropriate prescribing is primarily due to a lack of clear, accurate and timely information about cost-effective uses of new drugs, and misleading information and promotional incentives from manufacturers.

Our observational approach has the potential to inform guidelines concerning appropriate prescribing of medicinal cannabis as well as providing manufacturers with sufficient information to conduct a clinical trial that is specific for their product.

6.0 Understanding the Side Effects

There are unexpected benefits of an observational approach to cannabis research. A key issue in the effective therapeutic use of medicinal cannabis is the half-life of the drug in individuals taking THC. With drug still detectable even after four days without medication, patient's ability to drive a car or operate machinery is severely compromised. Our observational studies are perfectly placed to assess driving ability in a real-world situation and formulate evidence-based guidelines concerning cannabis therapy and driving capability.



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7.0 Recommendations

1. To break down knowledge barriers, we recommend development of a program of observational research using large high quality data sets obtained from cannabis prescribing clinics around Australia
2. We recommend that findings from the research are widely disseminated to medical practitioners in a structured educational program
3. To reduce costs to the consumer as well as the community, we recommend that the results from observational research are used to develop standard of care protocols that will allow cannabinoids to be listed on the PBS or funded through Medicare
4. We recommend using observational studies to reveal unexpected side effects of cannabinoids as well as providing a vehicle to challenge perceived wisdoms, particularly those concerning driving a car or operating machinery while on cannabis therapy