

# Medical Cannabis in Tasmania

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## **A submission on the Industry Background, Market Potential, Policy Considerations and Implementation Options**

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**Government Administration Committee A**

**Inquiry into Medicinal Cannabis**

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## Executive Summary

As the public awareness of the subject grows, the broad gamut of commentators approaching the topic in the media ask: When will Tasmania get the opportunity to be a part of the growing world-wide movement that recognises and appreciates the benefits that Medical Cannabis can bring to society?; Why do we have no action on Industrial Hemp, Medical Cannabis or even taxing and regulating Recreational Cannabis like alcohol and tobacco? These are questions that only the Parliament of Tasmania can give definitive answers to with policy responses, and the Legislative Council is commended in allowing public submissions through the Government Administration Committee A – in order that stakeholders can help to inform, and show the way forward for the government of the day towards a robust, effective and prosperous Medical Cannabis Sector.

The literature on Cannabis in the broader context is significant, but tends to focus on the narratives dictated by the current policies – i.e., legislative incursions and statistics on recreational usage and markets. There are many formal and anecdotal references that try and define the causal relationships between production, control and use. These vary from the conservative version that the users of Cannabis are the problem - to the more liberal versions that the regulatory model is to blame and the root cause of failure is human intervention in this area. There are the more radical notions, based on the political and economic realities of various entrenched actors and agenda setters, that big corporations such as Pharmacological companies and 'other drug' groups such as Alcohol and Tobacco, as well as medical associations prefer, and directly lobby to maintain, the status quo of Cannabis prohibition.

Stone (1989) observes that there are legal and scientific theories and models that can be used to inform policy, but they are currently used in a limited manner when looking at the bigger picture of affective Cannabis policy responses. Within the current bank of knowledge of Cannabis in society, there is less literature that concentrates solely on the Medical Cannabis sector. The knowledge is growing fast, and the most important to consider in developing policies is the scientific studies that are emerging that show the fuller potential of cannabinoids as medically viable and effective treatments to be used as intervention against a wide range of conditions.

The first part of this submission gives a broad outline of some of the issues and the scope of the situation, and in building a bigger picture, we have, at times, relied upon expert opinion in the areas that lie outside the author's expertise. The latter part of this submission looks more closely at the potential policy responses to various issues, and offers recommendations to government and bureaucrats as to the possible and preferred pathways in developing a Medical Cannabis industry In Tasmania.

As a note on naming conventions, the author considers that the modern and acceptable terminology is Medical Cannabis, Industrial Hemp, and recreational Cannabis. There are references included in this submission from third party sources that mention 'Marijuana', 'pot' and 'weed' - the author wishes it known that such terminology is becoming redundant, but includes, as such, unedited, authentic and otherwise useful sources, despite such terminology.

# 1. Medical Cannabis – Forms and products

## **The cannabinoid receptor opportunity**

Mather et al., (2013) surmise that 'The benefits of cannabinoid pharmacotherapy can be substantial. The risks are generally modest and must be weighed against those of not treating the symptoms or of alternative treatments.'

Medical Cannabis is derived from the Cannabis plant. There are two main cultivars that are used in most medical preparations – Cannabis Indica, and Cannabis Sativa. There is a wide variety of hybrids and crosses derived from these two main varieties that have been developed for specific Cannabinoid profiles and therapeutic effects. The author of this submission can provide further detailed and comprehensive material and links to scientific studies, medical data and historical research upon request.

With the wide many variations of these hybrids, users have found that selection of particular strains have a clearly defined and repeatable effect. For instance, some varieties will induce sleep, some varieties will offer a cerebral experience of lucidity and high motivation, other varieties will help to ease anxiety or symptoms of stress, and other varieties will help directly with pain control or appetite stimulation. As growers and plant breeders develop newer strains, so to the variety of conditions that can be effectively treated with Medical Cannabis increases. There is a maturity in the development of hybrids that has allowed targeted symptomatic relief with little, or no, unwanted side effects. There are non-psychoactive strains that do not create a conventional 'high', and these are suitable for patients such as children and the mentally vulnerable.

The cannabinoid system, only discovered in the past forty or so years ago, and becoming more and more understood medically and scientifically in the past 10 or so years, is an essential part of a healthy, functioning mammal. There are many compounds in the Cannabis plant varieties that have been found useful for humans and even animals such as dogs and horses.

Although the most recent research is starting to show that some compounds are more useful at higher concentrations, or are required in various combinations to be effective, the main focus of medical use has been on the high concentrations of THC and CBD that can be found in the flowering tops of Cannabis plants. These compounds are extracted readily, in useful quantities and processed and used in their acid or carboxylated states.

The definition of medical uses can stretch from anti-nausea treatments for terminally ill patients and anti-epileptic medication to treatments for non-terminal conditions such as eczema and glaucoma, through to the preventative cardiovascular and brain-protective treatment of the Omega 3 oils in hemp seed. The potential is huge in that the compounds in the Cannabis plant be applied to a startling variety of conditions with effective, safe and relatively cheap preparations derived from C. Sativa and C. Indica, and hybrids.

Some compounds are also found in useable amounts in the sun leaves, the stalk, and in the roots of the Cannabis plant. Although these Cannabinoids are not the ones that have been subject to the most anecdotal or recent scientific study such as THC or CBD - CBC, CBG, CBA, CBV and other compounds that are found in the roots are being used in therapeutic preparations today with promising results.

Cannabis plant material from Industrial hemp crops can be used to create therapeutic compounds, even though they may have and test for a very low THC concentration. As will be argued later in this submission, there is a crossover between the definition and practicalities, and thus the required policy responses, between varieties grown for as Industrial Hemp, varieties that are cultivated for Medical Cannabis, and those that are used for recreational usage.

There is further blurring of the boundaries when it comes to defining medical use and therapeutic effects. A cram prepared from the roots of an Industrial Hemp plants is very effective at helping sooth arthritics and muscular aches. The same roots from a Medical variety will also have the same potential in that application. A medical Cannabis variety grown and processed for use with cancer patients may have no, or some, psychoactive effect from the THC content.

That same THC effect, when consumed recreationally, may also have a positive effect on a person's demeanour, and thus can be argued that it is therapeutic, and if it reduces road rage, or anger leading to domestic violence or assaults, or animal cruelty, then it is a very good thing for society in general.

Many people choose to self medicate, consciously or not, with alcohol, and although that is not prescribed by their doctors, the users know it has a therapeutic effect. Aside from presenting to a GP with a set of symptoms and seeking or being prescribed pharmacy medication, alcohol is the only real alternative for people who do not want to break the law and consume Cannabis, or who are ignorant of the effects of Cannabis. The damage done to society by casual abuse or misguided self-medication with alcohol is apparent each day in hospitals and in the media.

The casual use of Cannabis is being acknowledged as a much better and safer alternative to other non-prescription drugs such as alcohol and amphetamines, and offers a non-toxic alternative with sedative effects – it can be seen that the alcohol industry is very concerned at the possibility that their ethanol product would be significantly displaced in favour of Cannabis as the social / recreational drug of choice, as Cannabis offers many benefits and few, if any of the disadvantages that are related to alcohol use.

Alcohol is, like tobacco, a poison to the human body, and has unwanted, potentially toxic effects. Cannabis is a symbiotic drug with the human endocannabinoid system, and it is impossible to die from an overdose. Cannabis users are relaxed and creative, and will usually just fall asleep with a heavy dose – some medical users rely on the ability to bring sound sleep and rest to an otherwise disquieted mind or a body in constant pain. Alcohol users become increasingly agitated and socially and self-destructive, with the attendant loss of control and inability to keep make sound judgements that is well known to be symptomatic of alcohol use and prolonged abuse will lead to an early death.

It is being shown that THC is a vital co-component in the compounds which also include CBA or CBD. Either of those Cannabinoids in isolation, as we have seen with the Sativex or Marinol type synthetics, are less effective without the THC (or THCa) component acting as a synergistic agent. The same problem arises in the extraction and production of single Cannabinoids to be able to develop a commercial (and patentable) product – without the terpenes in the preparation, the efficacy seems to be diminished or even ineffective.

There is some research into such single Cannabinoid compounds, and to date, it has been limited, and not as successful as the researchers had hoped. That is not a reflection of the potential of Cannabinoids to be effective, it is a symptom of the limited scope and faulty or presumptuous research being undertaken by those who seek a legal monopoly on what is basically a complex and still not well understood biological agent that interacts on a fundamental cellular level with humans.

Cannabis medications come in a variety of formats, depending on the application usage, the Cannabinoid profile, and the user preference for ingestion. Traditionally, dried Cannabis flowers and leaf can be smoked, or made into a tea, or integrated into edible products. Active Cannabis compounds can be extracted using a variety of methods and made into a resin or an oil to be smoked, or an oil, tincture, salve or resin for oral or external application.

The broad spectrum of cannabinoids that can be extracted from Cannabis flowers and leaves using water, butane or alcohol extraction methods is often referred to as Full Extract Cannabis Oil (FECO). This extraction of compounds into concentrated oil has been popularised and is euphemistically known as Rick Simpson Oil (RSO), after the person who originally popularised the technique and disseminated the information a number of years ago. This extracted compound can be smoked, but is usually consumed orally in minute quantities as it is very concentrated. It can be diluted or integrated into edible products.

Medical Cannabis preparations have been developed to be consumed in a variety of ways. The traditional image of smoking Cannabis is, unless the user wants to take advantage of the quick onset of THC compounds, a somewhat inefficient way to introduce Cannabinoids into the complete systems of the body. Conventional smoking can destroy many of the medically useful compounds with excessive heat. Smoking distributes the active ingredients directly into the bloodstream.

In jurisdictions where both medical and recreational Cannabis use is legal, the trend is that smoking water pipes (bongs) or hand rolled 'joints' is being replaced by vapourisers and e-cigarettes, which allow the consumption of controlled doses, without the need for potentially harmful additives to the conventional smoking process. The vapouriser technology allows precise temperature control for effective utilisation of the therapeutic compounds in dried Cannabis plant matter preparations.

Inhalation is the preferred method for an almost instant relief of symptoms. Other ingestion methods rely on the continual levels of the cannabinoid compounds to be maintained with daily, or twice daily dosages. Patients learn to manage their own dosage times and to adjust the rates for maximum effectiveness. Patients are also the best placed to make informed choices in selecting a suitable strain to work with their condition(s), with regard to their daily routines and life obligations. Some conditions require intensive initial or short term dosages, and a maintenance dose, where other conditions require a daily low level dosage regime to keep the human endo-cannabinoid system 'topped up'

Eating Cannabis allows more of the compound to be absorbed, but there is still the difficulty of delayed onset and the potential of loss of therapeutic efficacy through both the digestive process (mainly the stomach acid and the filtering effects of the liver), and the dispersion of the active compounds throughout the body, rather than localised application. Cannabis consumed in an edible way can be a highly concentrated oil alone, or infused into an inert carrier compound such as coconut oil, a capsule with a similar concentrated or diffused compound, the oil can be added to edible products, such products are commonly referred to as 'edibles' and they range from drinks, to sweets to baked goods and other culinary facsimiles that are dosed with the specific compounds required to treat the reported conditions.

Capsules can be prepared to be used as suppositories, and these bypass the digestive tract and are more effective in conditions such as prostate or colon and rectal cancers, as the medication is delivered directly to the site, rather than through the blood via digestion.

Medical Cannabis cannot be injected - either intramuscularly or intravenously. GW pharmaceuticals has trialled an atomised spray delivery method, but Cannabis is not commonly applied directly to mucous membranes due to the taste, although it would be effective if rubbed on the gums, the nose or other areas such as the rectum or vagina. Future developments may see a patch made available to facilitate dermal absorption.

Some preparations are made for topical application, such as creams or lotions (i.e. active ingredients diffused into an inert or complementary carrier) to be rubbed into skin, or applied as therapeutic or alternative body and skin care products. In the case of melanomas, eczema, infections and other external conditions, a more concentrated form is usually applied directly to the problem area or condition, depending on the nature of the issue.

Note that similar methods have been applied to animals as well, with edible concentrates and external preparations being employed to beneficially treat specific and more general conditions in domestic animals such as dogs, cats, horses and other livestock. This is an area that there is huge potential for further research and product development, allowing research partners such as UTas to become world leaders in the veterinary aspects of Medical Cannabis. Not only will such research lead to a worldwide non-human market with high demand and huge economic potential, but that research will also inform the human trials in a more timely way, potentially offering an advantage in bringing more effective products to market more quickly. It is this intermixing of potentialities that would be the responsibility of steering committees under the guidance of the Cannabis Commission.

## 2. Growing, processing and supply operations

To gain approval to supply a medicine in Australia, the sponsor of a product would need to submit an application together with supporting data on the safety, quality and efficacy of the product to the TGA for evaluation. The TGA is unable to compel a sponsor to submit an application to register a medicine in Australia. Approval for marketing in Australia cannot be given in the absence of an application.

In addition, the Act requires, with certain exceptions, that manufacturers of therapeutic goods in Australia hold a licence. It is an offence, carrying heavy penalties, to manufacture therapeutic goods for human use without a licence unless the manufacturer or goods are exempt from this requirement. The TGA website provides further information regarding manufacturing therapeutic goods in Australia.

The TGA is not involved in issuing medicinal Cannabis growers/cultivation licences. The issuing of a licence for cultivation would be a state and territory responsibility.

### **Cultivar and varietal development**

It is envisaged that University of Tasmania would be an ideal partner in developing the various strains. They have a agricultural research division that could be expanded and tasked with the development of the required varieties with the preferred Cannabinoid profiles that are matched Tasmanian specific conditions. This would be a beneficial partnership if the GBE social enterprise model explained below is adopted as this agricultural research, as well as the medical application research, would be a big source of income for UTas, as well as proving Intellectual Property that can be commercialised in the future.

### **Production Growing**

As suggested below, and in section 4 (agricultural considerations) Production would be ideally undertaken in Greenhouses and i other controlled environments with carefully managed conditions to optimise both the yield and the efficiency of processes and methods. Expansion is an easily scalable consideration, and other sites can be bought on-line at future points for differing reasons.

### **Processing and Certification**

Processing can be undertaken using relatively straightforward commercial processes and with non-toxic chemical, and produce little id any waste. Any wastes can be returned to the natural cycle or processed further into simple, benign products such as compost and potting mixes. In conjunction with the University of Tasmania, a quality certified laboratory would be charged with the management and data collection over the lifecycle of the plant. At the final processing stage, the cannabinoid profiles and strengths would be ascertained in order to certify the product as fit-for-purpose.

### **Wholesale supply and security**

Once processed and graded, the product would be packed, according to the required formats such as dried plant material, oils tinctures, capsules etc, and managed with readily available commercial processes, procedures and inventory control protocols already available for products of a similar nature.

Standard ordering and shipping procedures would be followed to distribute the product to agents, facilities and individuals with legitimate requirements and commercial arrangements, and the product can be treated in every respect just as any other high-value restricted-supply product such as pharmaceutical drugs.

### **Retail operations and dispensing**

There are a number of model that have been adopted in overseas jurisdictions in regard to retail outlets and supply chains. It is suggested that working relationships are formed with hospitals, medical surgeries, and pharmacy outlets to closely align with the current practices, protocols and safeguards that are in place for other prescription medication.

There is a good and valid case for direct supply to patients, or for Medical Cannabis specific outlets to be put in to regional centres, and the format and role of these can be explored further - these centres may provide education, referrals or specialist medical staff, or may also be a licensed outlet for edibles or other implements required to take the doses in the formats required.

### Overview of the Potential Market

There is no intention to make a business case, or to provide detailed financial scenarios in this submission. It is however, appropriate to ask the committee to see the potential of a Medical Cannabis industry in Tasmania. The potential is there for Tasmania to become the supplier of Medical Cannabis to the entire mainland of Australia, and this offers huge potential. The revenues returned to the State of Tasmania in such a scenario move from hundreds of millions into billions annually.

It should also be noted that there is potential to supply other Pacific jurisdictions in the future, with New Zealand being the most ready to accept Medical Cannabis. The Medical Cannabis treatments would also show great promise for some of the health issues faced by Pacific Island nations, but until they are in a position to consider such legislation, they remain only on record as a future potential market for Tasmanian grown and processed Medical Cannabis.

Further exploration will also find that export markets exist world-wide, especially if unique cultivars, highly effective compounds or novel packaging or dose delivery systems are developed. There is also the attendant industries that offer saleable, exportable expertise in knowledge, growing and harvesting systems and processes, and other areas such as genetics such as seeds and extraction techniques.

### Social Enterprise Model

It is this author's assertion that the potential of Medical Cannabis is of such significance that it is the equivalent to the mining boom seen in WA or QLD in the ability to generate revenue for the state. This preferred model is not a political theory attempt at socialism, it is a genuine economic opportunity for Tasmania, and the revenue available is potentially billions of dollars. If the full economic potential is to be realised for Tasmania, then the state must be able to participate in the market to the largest degree possible. It is suggested that a Government Business Enterprise (GBE) is established, in partnership with key stakeholders and service providers, to allow Tasmania to derive maximum benefit from Medical Cannabis. A simplified outline of such a structure is tabled below.

Medical Cannabis Growing GBE			
Shareholder	Shares	Responsibilities	Notes
Tasmanian Government	49%	Finance, Oversight	Main shareholder, main dividend recipient.
UTAS	16%	Research, Trials	Research into cultivation, processing, medical trials and IP management, education, QC etc
Cannabis Council	10%	Policy, Governance	New peak body initiated to deal with all Cannabis industries, including Industrial Hemp
State Investors	25%	Finance	Investors into the Enterprise such as State Super funds and other GBE who currently seek to diversify into high-return investments.
Note: Distribution of dividends and responsibilities is to be developed further.			



### 3. The legal implications and barriers

Alex Walsh, Senior Pharmacist Experimental Products Office of Scientific Evaluation at the Therapeutic Goods Administration (TGA) Commonwealth Department of Health states "Regarding the current commonwealth position, the TGA is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods for human use including medicines, medical devices and biological products under the Therapeutic Goods Act 1989 (the Act). The information provided below relates to the role of the TGA in the regulatory process for medicines under the Act only.

Broader decisions about decriminalisation and access to Cannabis are the subject of other Commonwealth and state and territory laws that apply to possession, use, trade in, distribution, import, export, manufacture, cultivation and production of Cannabis.

The term 'medicinal Cannabis' may be used in reference to a range of preparations including raw Cannabis, hashish and pharmaceutical Cannabis preparations such as tinctures and other extracts.

In relation to the TGA approval of medicines for supply in Australia, unless exempt or otherwise authorised by the TGA, therapeutic goods lawfully supplied in Australia must appear as an entry in the Australian Register of Therapeutic Goods (ARTG). On the TGA website you can search the ARTG using product details or sponsor details.

Note that Cannabis is currently listed in the SUSMP as a schedule 9 substance. Scheduling is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety. In Australia, medicine schedules are legislated in the Poisons Standard (the SUSMP).

As stated in the SUSMP, schedule 9 classification is: "Prohibited Substance - Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."

It is imperative that Tasmanian politicians take a proactive role in pushing forward the issues and in resolving the blockages. As an example, the Tasmanian parliamentary report on Industrial hemp made strong and clear recommendations that the Industrial Hemp Industry would be a beneficial one for the state. However, at a Federal level, the approval for something as simple as allowing human consumption of Hemp seed (Which would unlock a huge market place for Tasmanian growers and processors) has been held up with the Police and emergency services standing committee. The TGA has basically approved it, and they are the main body that needs to sign off on the changes. The Police standing committee seeks to resolve some issues they have with roadside drug testing, even though credible evidence is available that answers their questions and clarifies the issue.

Industrial Hemp in Tasmania, and Australia, is stagnant simply because of bureaucratic machinations. This summary is a general description of the schedule and further information can be provided by the Author in that regard.

## 4. Agricultural and production considerations

### **Quality control**

It is suggested that the quality control and cultivar requirements, along with the required growing conditions will preclude Medical cannabis from being a broad acre crop, grown in the open. At a minimum, greenhouse growing, and potentially full hydroponic growing will be required to achieve the consistency and quality required in order to provide a full range of medicinal preparations and a guaranteed concentration with repeatability between crops, and traceability of plant material. This closed style of growing is advantageous from a security perspective as well.

The preferred and suggested model of one GBE entity growing the commercial crops does not preclude a range of different sites upon which to grow crops. Research crops will be grown by UTas at their preferred sites, and those may coincide with the commercial growing operations, or be maintained as separate facilities.

### **Consistency**

Processing can be done to varying degrees at each grow site, or all step in processing can be concentrated at a dedicated facility, one that would include a testing laboratory, ISO accredited grading, processing, packaging and labelling operations. Again, with the potential size of the industry, this could be initially established at one location and based on future markets and growth in demand, business planning and decisions would be made, as the need arose, for expansion.

### **Reliability of supply**

It is suggested that there be a buffer of material maintained of at least one crop cycle equivalent in supply. The crop cycle is between 12 and 16 weeks, depending on cultivars, and processing can add a further week or so. Contingency planning would suggest that this buffer be built up to ensure continuity of medicine in the event of a natural or man-made crop failure. The natural plant material, well stored in a harvested and dried state, will keep for relatively long periods. If the material is processed and packaged, it will have a very good shelf life, with little or no loss of efficacy.

### **Ongoing research and development of Cannabinoid based medicines**

There is a major opportunity for the University of Tasmania to become a world leading research facility, and there is a strong alignment in place for such a future. The Menzies institute is well paced and well respected to move into this area of research, and the University will benefit long term from knowledge transfer, by attracting a high quality of academic and student population, and with IP options that can be commercialised world-wide. Further discussion and the exploration of the potential and partnership opportunities are suggested.

## 5. Policy Perspectives

### 5. 1. Scope and severity of the problem

As evidence comes to light, studies are undertaken and official data is released, we can begin to conclusively conclude that the biggest problem - regarding Cannabis - faced by society is the way that current policies deal with this seemingly wicked problem.

There are myriad (50,000+) documented (reference date) uses for products derived from the Cannabis plant (Sativa, Indica or Ruderalis varieties). Broadly speaking, there are three main sectors of use, and separate, but interlinked policy responses based on evidence and productive capacity is required. Aside from formalised and regulated medical usage outlined in this policy brief, there are two other sectors: Industrial and recreational.

These are the Industrial Hemp sector which utilises the purely physical nature of the plant and its component parts such as fibre, pith and seed, leaves & roots, for many purposes. The Industrial Hemp sector has regulatory instruments that control the growing, distribution, processing and sale of products derived from non-drug grade Cannabis.

Cannabis is perhaps most commonly known as a psychoactive drug usually smoked to induce a high or euphoric feeling. This relies distinctly on one active ingredient in the Cannabis plant, namely THC, and the right strains grown under the right conditions can produce a powerful yet ultimately benign recreational drug. Recreational use of Cannabis is seen as a wicked problem, with many instruments based on legislation attached to recreational use, not limited to growing, possession, distribution, use and related problems such as paraphernalia and impairment whilst driving.

In developing a policy for medical Cannabis, these other two sectors also need to be considered, as there are important overlaps between the three uses, and they cannot be managed in isolation from each other. The author respects that this enquiry has been formed to look into the Medical Cannabis sector, and acknowledges the work of past committees and the final report on Industrial Hemp (reference 2013) – but as this document is considering the situation from a policy perspective, it is the authors assertion that the other sectors must be considered during the policy development cycle.

Phil Reader, is quoted in ABC country hour on 29 July 2013 as saying "The Industrial Hemp Association says it has found anomalies in the way Tasmanian departments of health, justice, primary industry and police have been applying industrial hemp growing guidelines.". There is already an administrative burden on growing Industrial Hemp, and Medical Cannabis industry does not want to see itself embroiled in such a quagmire that has held back Industrial growers.

The Tasmanian Poppy Industry has a regulatory regime attached to it that is perhaps cumbersome at times, but offers an insight into the bio-security and policing requirements of the Alkaloids industry and thus the policy instruments applied in those areas. Many of the same questions arise in any discussion of medical Cannabis policy.

Whilst there is an enormous amount of material written about the war on drugs and commentary on the realisation that the War on drugs has failed, we can look to the historical inter-generational policy failure as a result of a purely political analysis (Kraft & Furlong 2010) of the problems, and thus see it as based on ideology, not objective and certainly based on agendas from a past era. This failure is knowingly accepted as a 'work-in-progress' because 'consistent with our cultural norm that responsibility presupposes control' (Stone 1989) the response to the problem has always been to attempt increased control. Society as a 'victim' means that the law and order agenda continues to have political traction in the electorate.

Considering how conservative the US is on some policy issues, and the huge vested interests that operate within the current prohibition status quo, the fact that 22 states have changed is very meaningful. In Australia, medicinal Cannabis currently has strong community support (69%), with research into its use

being even more strongly supported (74%). (Australian Institute of Health and Welfare. 2010). This presents numerous very large opportunities for Tasmania. These opportunities apply to the state government position on creating employment, attracting investment, funding other programs, better service delivery and a more socially and environmentally cohesive society.

With the announcement of the \$20 Billion Medical Research Endowment fund by the Federal government in the 2014 Budget, there are huge opportunities for Tasmania to develop the policies that can both build an industry around medical cannabinoids, and also deal with the other two sectors in an informed and mature way.

Tasmania can capitalise on this new 'evidence-based' way of thinking and either take the initiative, or be stuck back in the prohibitionist, racist era that was America in the 1930's – an agenda that still overshadows Cannabis policy today throughout the world. Taxing and regulating Cannabis, in all forms, is the sensible progression to make. Economist Allison Schrager (quoted in Syvret, 2014) asserts that "Legalising marijuana use is a step in the right direction"

## 5.2. Problem statement

Although there are real and perceived problems with Cannabis usage, esp. in the recreational area, there are also many opportunities relating to the Cannabis plant.

Regarding the fears that they may be dealing with wicked problems, Lawrence in Head & Crowley (forthcoming) observes that:

'Community sensitivities and fears and the deliberate exploitation of those concerns play a pivotal role in determining which ideas are translated into policy. In turn, the climate of opinion which influences these selections is powerfully influenced by media construction of the issues.'

It is important that at all stages of policy development, but especially at the analysis, consultation and implementation stages that that education on the subject is a priority. Usually seen as an implementation instrument, there is a lot of misinformation and anecdotal hubris that pervades and ambushes a sensible discussion on the subject of Cannabis.

As it is known as an illicit drug, that context is often the argument put in place by ignorant actors or interest groups, and that bias will be apparent in the attempts to set the broader agenda and define the problem. Medical Cannabis is not the same as recreational Cannabis, yet the two are very often confused, to the detriment of effective policy development.

### Regulation models

The issues that this enquiry is seeking to address are not unique, and there are a number of jurisdictions who are going through the same motions and wrestling with the same issue concurrently. Activists and other interested parties in Australia are well aware of the situation in many other countries. Some of these countries are more advanced and have fully implemented Medical Cannabis programs, others, such as Canada, are at similar stages to Australia. In a recent ruling, Ontario Superior Court Justice Timothy Ray dismissed an eight-year legal battle over the constitutionality of Canada's marijuana laws in a ruling that the anti-pot arguments belong in Parliament and not the courtroom. (Cobb 2014)

There are a growing number of Australians who are being charged with possession of Cannabis and legitimately claiming medical use. These are the test cases that are frustrating the courts, and there are no clear precedents being set upon which other rulings can be based. It is irresponsible of any jurisdiction to continue to allow such a grey area in the legal response, and it is imperative that there is a clear, top down response to these situations. The control through prohibition and criminal punishment is a failed exercise. Control of production, processing and regulated sales and tax will be under the control of the one agency model with a networked governance model across agencies and departments.

### Policy Analysis

Initial analysis may tend towards recommending an incremental approach (Kraft & Furlong 2010), but a rational-comprehensive approach is required (ibid) – basically, revisit the issues and policy responses with an open mind, scientific evidence and fresh set of eyes- such an approach will clearly define the problem in a 21st century and geographical context, acknowledge the broader set objectives, and consider a range of alternative proposals as possible solutions that will remain workable at the implementations stage.

### A. Economic framework

Medical Cannabis offers huge potential in employment, education and research, medical tourism (including ancillary services such as transport and accommodation etc), direct and indirect investment, as a base for taxation to increase government revenue, and in savings attributable to various agencies by treating Cannabis as a health issue, rather than solely a law problem. Shanahan & Ritter (2014) summarise their economic analysis of a Cannabis industry such that 'The net social benefit (the difference between the benefits and the costs) was positive.'

There will, no doubt, be a number of other submissions to this enquiry that will make note of other jurisdictions, esp. Colorado (Miles 2014), Arizona (Wallace 2013), Washington State and California, as examples of the both the economic activity to be gained from production and supply side, and also direct revenue from licences and taxation that is gained for local and state authorities.

These are compelling examples (Walsh 2014) to study, especially in the economic situation that Tasmania finds itself in, with the downturn in traditional Tasmanian industries such as forestry, and the recent closure of other industries such as mining in the North West. Such losses to the economy of Tasmania, cannot, quite frankly, be replaced by tourism and cultural events alone. The Tasmanian government needs to nurture opportunities such as industrial Hemp and Medical Cannabis, both of which, in isolation, offer significant potential (Syvret 2014), and together, really stand out as the industries of the future, and ones that are both accessible and productive if based in Tasmania.

## **B. Social context and community impact**

The number of Medline-indexed publications that reference Cannabis compounds has doubled each decade, from about 400 in 1990 to about 1600 in 2010. (Mather, et al. 2013). The peer-reviewed scientific evidence is mounting that there are real opportunities to change the paradigms of treatment with the use of Cannabinoids. There are dozens of jurisdictions who have implemented a successful policy response to accommodate a Medical Cannabis program within existing legislative or political eco-systems.

A whole of government response can build on the work in other jurisdictions and further integrate the program in the Health systems and hospitals of the State. This unified approach to the service delivery creates not only the best outcomes for patients, but positive paybacks for the health department, with a streamlining of disparate programs (such as drug education and rehabilitation), and importantly, creates a source of significant revenue.

If we look to the conventional theories of Cause and Effect, we can see that past constructs have strongly suggested that 'society' is the victim because of Cannabis use. The users, the dealers, the growers have all at various times in various combinations, been blamed for the issues that regulation has tried to minimise. This construct is based on a moral imperative and 'law and order' response heavily biased in favour of regulatory and punitive instruments.

It is a justifiable assertion that such instruments have created victims because of their implementation. Further victims in society have been created because of the current policy responses. These victims are the unintended consequence of the attempt to control and regulate, to be seen to be taking responsibility for the problem through intervention. These newest victims are the sick people who would benefit from the availability of Medical Cannabis, but, through the law-biased intervention of the government, do not have easy or legal access to therapeutic Cannabis preparations.

It is time for evidence-based science to redefine the causal relationship, and even in a preliminary analysis of the problem from a scientific perspective, it can be seen that the government itself is causing harm to society, indeed is creating victims, based purely on a moral framework that is out of touch with reality and the broader electorate. The government of the day is charged with minimising harm to society, not at any cost, but on a 'reasonable' basis.

There are a disparate group of victims who are, united by growing evidence, who are only suffering short and long-term problems because of current policies. It is therefore important that policy is changed to one that allows those victimised by prohibition and other punitive measures to escape the harm caused by the actions they choose (for whatever reason) to take.

## **C. In an environmental framework**

Industrial hemp presents the most dramatic case for environmental credentials of the three sectors of Cannabis. However, medicinal Cannabis also benefits from relatively low input of water and fertiliser into the growing cycle, the same soil conditioning benefits as its industrial cousin and a market for every part of the plant – as raw material or with further value adding opportunities in industrial or medicinal sectors.

#### **D. Within a legal framework**

The victimisation of Cannabis users, both medical and recreational, is a failed policy that causes more harm, and greater cost burdens to society than the actual product usage does in isolation. The current policies of prohibition arise from 80 years in the past, when a moral and political agenda that has now faded into the history books was implemented. The foundations of the prohibition of Cannabis is racism and a white supremacist attitude, as well as corporate manipulation of the media and the United State government of the day to enact policies that had never been applied to Cannabis before, not in the thousands of years of worldwide usage.

Society never had a big problem with Cannabis until the agenda setters of the period created a problem, using morality and law and order to construct the causes (since debunked and proven false) that are still actively informing Cannabis policy today. The most obvious response at the time, and re-jigged by Nixon over 40 years ago, is the 'war on drugs'.

In developing new policies, it is important to consider that 'Doctors and pharmacists will require further education about medicinal Cannabis and how to instruct patients in its use. Criteria for patient selection will need development.' (Mather, et al. 2013) There are examples and models in other jurisdictions that offer a solid basis to build an Tasmanian model upon.

Also, other agencies that currently deal with Cannabis, such as Police, the Court system, Customs and Border protection, will need to both be involved in the on-going formulation of workable policy, and implicit in implementation success. Again, there are successful models that can be transferred so that Tasmania does not have to spend time and money reinventing that particular wheel. The cultural change will need to be managed, and should be adequately resourced to ensure a successful change in those agencies.

There will always be checks and balances against the exploitation of the new policies, and it is important to note that scarce resources can be redirected away from Cannabis offenders and put to use in breaking the organised crime and illegal trade in large quantities of unlicensed Cannabis, and the much more dangerous drugs such as Amphetamines and their derivatives like Ice and meth, heroin, and synthetic compounds that pose a real risk to society.

#### **E. Political implications and potential benefits**

Managed carefully, a great amount of political capital can be gained from the positive outcomes of a successful implementation of a Medical Cannabis policy. The return for government would be apparent within a single election cycle, and constitutes a real opportunity for the government of the day to be able to increase the revenue base, improve health outcomes for citizens and to distinguish themselves as forward thinkers with an understanding of the where the future of Tasmania may be built from.

A well- informed policy development cycle that considers the comprehensive possibilities of both the Industrial Hemp and Medical Cannabis industries is necessary, and would certainly be mandated if a state election was held anytime soon. The electorate are increasingly aware of the potential, both for jobs, and for better healthcare outcomes. The media has provided relatively impartial coverage of the situations of those who benefit from it most, and such knowledge has seen many start to firstly question why Cannabis is still prohibited, and secondly, why the government of the day is not acting, in societies best interests, on these issues.

## 5.3. Policy options

### **Incremental change or paradigm shift?**

As was remarked earlier, the policies in place that attempt to deal with Cannabis, in any form or for any use, are recognised as having failed. There is little that would be gained from an incremental change to any of the policies, and therefore, a paradigm shift is required. Policy entrepreneurship is required in order to develop a whole new way of thinking about Cannabis, and the responses to it by governments and their agencies.

A paradigm shift in approach to Cannabis policy, including an evidence-based analysis (Kent & Furlong 2010) will help to 'propose new values or new ways of thinking about a problem' (ibid)

### **Policy transfer from other jurisdictions**

Rather than re-invent the wheel, we should be aiming to create a better mousetrap. We can consider the concept of policy transfer defined by Doliwitz & March (1996), and quoted in Evans & Davies (1999) as 'a process in which knowledge about policies, administrative arrangements, institutions etc. in one time and/or place is used in the development of policies, administrative arrangements and institutions in another time and/or place'.

There is an increasing amount of model material from other jurisdictions such as Colorado, Washington State and the Netherlands that we can draw from as the basis for a Tasmanian implementation. We can discover methodologies and theories used to define the issue. In regard to proposed instruments, we can study already implemented legislation; and we can also observe data and actual outcomes to help to include the most relevant policy options, and to undertake an informed consultation process.

Despite the potential for incomplete, hybridised or synthesised (Evans & Davies 1999) degrees of transfer, it must be recognised that political, cultural and institutional conditions which will condition the emergence of a policy idea. A rigorous transfer of policy knowledge can help to successfully contextualise the policies for Tasmania and outcome prioritising.

### **Governance and Regulatory models**

Presumption is made to developing a functional case-managed interface and relationship with government. This avoids the duplication of back-end bureaucracy and a reduction in transactional load. This central agency managed approach forms a more direct link into a responsive back-end of Tasmanian State Government Agencies, clearer reporting lines, between agencies, and allows an arms-length operating distance for Government regarding ownership and function of external agency operations.

This is where a best practice model for Tasmania would see the setup of a peak body that deals with all Cannabis related issues, Industrial Hemp. Medical and also recreational policies in unison, taking into account the interlinked nature of the Cannabis plant, the commercial and policy realities that are attached to each sector, and that deals with the interagency issues in a timely and efficient manner.

It is suggested that a Cannabis Commission be attached to the Department of Premier and Cabinet, considering that the policy and implementation required span a number of key and line agencies such as Health, Police, Infrastructure, treasury, tourism etc. and that access to the highest levels of the bureaucracy and the cabinet Ministers will be required to manage the programs and in a timely and direct manner.

In a model that sees the growing, processing, and supply chain responsibilities taken on by the GBE as outlined earlier in this document in Section 2 (Growing, processing and supply), there are a number of financial advantages to be realised. The commission and staff would be self-funded from their 10% share in the GBE. The 49% share directly owned by the Government would direct the moneys, (after expenses, program implementations costs and administration costs) back into specific or general revenue accounts. It is suggested that the moneys are spent on social service outcomes such as health and education, rather



than other business. This can be clarified as the idea progresses and other stakeholders and experts are brought into the development of the idea.

As noted in Section 2 (Growing, processing and supply) beside the income from the operation of the wholesale supply chain, the taxation of the product at the retail or dispensation level is a recommended step. A reasonable rate in other jurisdictions starts at 10%, and this is not a GST, but a specific taxation on the product like Alcohol or Tobacco, and this tax revenue can be used to fund direct programs that deal with issues arising from the wider usage of Cannabis, including an ongoing education program aimed at various identified targets audiences. Some of these program will have a health message, others a behavioural message.

It is the one-stop shop approach and the networked governance model that will facilitate the effective implementation and analysis of such instruments of policy. There is an opportunity for Tasmania to lead the way in this still-grey area, both in Australia, and overseas, if we get it right, and do it soon.

## 5.4. Consultation

The burden of proof concerns who bears the responsibility for making a case: those who make a claim of adverse health effects of Cannabis, or those who doubt it. If the burden falls on those who claim that it is safe, uncertainty will be resolved by assuming that it is unsafe until proved otherwise; conversely, if the burden falls on those who claim that the drug is unsafe, then it will be assumed to be safe until proven otherwise.

### **Supporting democratic values**

Medical Cannabis, especially if it is initially confused with recreational use Cannabis, is a contentious subject to a number of individuals and groups. To fully support the democratic and transparent nature of the consultation process, it must be given sufficient resources to both consult widely, allowing time and opportunity to include those who would self-identify (Althaus 2007); and to be able to discern when an agenda setting actor or non-legitimate representative of a group (ibid) are introducing bias into the input process. Weighting public participation must be tempered at times for such bias.

### **Building consensus and political support/capital**

Seeking a viewpoint from those affected by a policy decision is sometimes a legal requirement. (Bridgman & Davis 2004) In regard to supposed wicked policy areas, then it is fundamental in both supporting the policy as it moves through the cycles, and in

### **Improving regulatory quality through information collection**

The policy proposals for Medical Cannabis include a large degree of implementation (beyond legislation and monetary instruments, the remit of central agencies in the bureaucracy) by external agencies. If we look at the overall business planning that informs the policy options proposed, then we can see that there are a number of actors who already have the experience and systems in place to effectively report and consolidate information to the government. An example of this is the research that will be undertaken by the University of Tasmania on a fee-for-service basis. The University operates at a high level, and both research and results will be built on the professional foundation and academic accountability of that institution.

### **Reducing regulatory costs on bureaucracy, business and citizens**

The networked approach to governance in this sector would rely on a high degree of interagency cooperation. For each of these agencies, there may be a paradigm shift in culture or delivery priorities that will need to be worked out well in advance, in order to successfully execute the policy instruments adopted. It is important to consult with agencies and individuals to create the best solutions, mindful of bureaucratic overheads and burdening individuals with on-going compliance or unreasonable costs.

### **Increasing responsiveness**

Althaus et al. (2007) state that 'open forums... enable diverse groups to express and learn from alternative views, and' 'respond to the perspectives of others' (Cameron & Grant 2005, quoted in ibid). It is this initial airing of divergent views and an educational effort to separate uncovered myth from the focus of factual evidence that will result in subsequent stages of the consultation being more productive and Inclusive.

### **Carry out strategic agendas**

Concentrating on medical usage, we then fall into the most difficult of all regulatory regimes, medical use on humans. This is a policy area that requires a novel approach to which the partner organisations such as University of Tasmania and The Menzies Institute, plus the Tasmanian Health Department trial sites, are expected to contribute greatly – a working group of process specialists will be formed as the connections move closer together in interworking relationships.

## 5.5. Implementation recommendations

Implementation is an aspect of the policy cycle that needs to be considered in actioning a policy transfer from other jurisdictions in order to compensate, adapt or contextualise policy for the preferred Tasmanian model of a Medical Cannabis sector.

### **Policy Instruments**

How a policy will be implemented is an important consideration as to the success or failure of any proposal. The instruments that the author recommends will be based on a combination of discrete and overt options that will address the problems in a comprehensive and coordinated way.

### **Advocacy and education**

As stated previously, the biggest initial policy instrument will be to educate people. This is an area that is open to external expertise, but delivered by central agencies such as Health or police services, in conjunction with existing networks (such as GP clinics, libraries and Service Tasmania outlets); and existing pathways and modes e.g. Print & broadcast media, brochures and websites.

### **Network relationships (internal and external)**

In order to successfully achieve the desired policy outcomes, careful management and proper resourcing of disparate actors is required. Many policies have failed due to dysfunctional communication, or lack of resources. It is to be made clear in the policy and subsequent implementation planning what will be required and how the results will be benchmarked for success.

### **Monetary instruments**

The business proposal offers more details on the monetary instruments required by the external agency to develop and grow the service delivery on behalf of the government, and also models costs and fees to growers, processors, sales outlets and the end users. Taxation and product pricing models exist both more generally here in Tasmania and more specifically in other jurisdictions from which we may transfer elements of policy.

### **Direct government action**

There will be issues that only direct central agency intervention can manage. One example will be if a registered patient is found to be on-selling his medicinal Cannabis into the recreational user black market. This will require the intervention of Police, courts and diversion programs, including counsellors. As has been suggested, a thorough review and mature approach to recreational usage would be the easiest way to prevent most of these flaws-in-waiting from becoming reality. With the pricing of product and the regulated sales of attractively (compared to black market operators) priced, quality controlled product, there will be little incentive for criminals to operate in this sphere.

The legislative review will need to incorporate clauses for such conditions (perhaps more harshly than they currently are), but market forces will eventually dictate that the black market for Cannabis will diminish over a short period of time. This will allow the police service resources to be directed against harder drugs such as heroin, methamphetamine, and other schedule I substances.

### **Legislation instruments**

With the careful study of other jurisdiction's implementations, we can develop legislation that will cover most contingencies, allow latitude in interpretation and be the basis for an iterative or incremental policy review within agreed timeframes.

### **Coordination Options**

In addressing the policy issues of coordination, we can make recommendations from amongst the commonly available models. We can choose from a lead agency model, a committee model, a board model, a one-stop-shop model or a case management model. Whilst all of these different models of interaction with

the government have their own positives and negatives, in the case of this proposal, a case management model would be the preferred and most efficient model, not requiring much more than inter-agency network governance linkages between the various departments, and interfacing with the industry through a simplified connection that channels administrative traffic into and out of government, directly to the industry.

### **Evaluation Recommendations**

As the policy development process is cyclical in nature, the iterations of subsequent policy in this area is important. No-one is going to get it right first time... It is important to build in mechanisms and recognition of the value of post implementation analysis and collection of data to help inform any fine-tuning and additive elements to this original policy proposal. It can also be shown that the developments in other jurisdictions, and on-going research, are important to the evaluation phase in order to expand and re-evaluate the potential and practices of the Medical Cannabis sector.

Without any industry, or current policy, in Tasmania, there is a requirement to jump straight on at the issue identification stage, but what informs us in this relatively new area of policy is the evaluation of other examples, especially those where the models have been tested in all areas such as politically, in legislation, and in implementation. Colorado is probably the most advanced state in the US as far as recreational, but both Washington State and California have long histories with medical usage, dispensary and the regulatory regimes of licensing and distribution to call upon in defining the policy objectives and desired outcomes contained in this proposal.

## 5.6. Summary of Policy Deliverables

The main deliverables and indicators of systemic changes that will be required for successful implementation include, but are not limited to:

- I. Liaison with all stakeholders, and memorandum of understanding with Partner entities.
- II. Establishment of Cannabis Commissioner position in a networked agency arrangement in DPaC.
- III. Cannabis Commission to develop best-practice and model-process paradigms and fit-for-purpose methodologies in conjunction with Partner organisations and third parties.
- IV. Non-contested rewrite of current legislation, with due consideration to future policy requirements.
- V. Establishment of Peak Body with stakeholder input and governance.
- VI. Establishment of GBE, for production, processing and distribution purposes.
- VII. Adjustments made in interagency relationships and implementation matters.
- VIII. Clearly worded education program run by Cannabis Commission to manage the initial electorate responses when policy is announced.
- IX. Policy wording used to answer all the questions asked by media and community groups at policy announcement and launch phases.
- X. Issue licences with due diligence for growing, processing, research, testing and distribution.
- XI. Manage governance via agent model embedded in other central & line agencies, and bureaucracy.
- XII. Monitor and review Policy implementation and production reports at agreed temporal points. – eg. six months, twelve months, eighteen months, two years, and annually thereafter.
- XIII. Open dialogue on future Industrial and recreational issues to enmesh with the work already done with Medical Cannabinoids.
- XIV. Further amendments to required outcomes or other deliverables that may become known after wider consultation as agreed by all parties.

## 7. References

There are many hundred of online and bibliographic references that can be supplied upon request. The author realise that the Committee will not follow all those links or read all the papers, and that the scope of the enquiry limits the amongst of information that can be presented. If the committee has specific questions or seeks specific information on any topic or area of concern, then the author is willing to attend any public hearings to expand on the summary information in this submission, or to attend private meetings to help to build a comprehensive body of knowledge on all aspects that can be used to confidently make recommendations and that will allow action to be taken to develop a Medical cannabis industry in a timely manner.

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### **Links to other jurisdictions – Policy Transfer**

**Colorado State:** <https://www.colorado.gov/pacific/cdphe/categories/services-and-information/marijuana>

**Minnesota State:** <http://www.health.state.mn.us/topics/cannabis/faq.html>

**Netherlands:** <http://www.cannabisbureau.nl/en/>

**Portugal:** <http://www.cato.org/publications/white-paper/drug-decriminalization-portugal-lessons-creating-fair-successful-drug-policies>