Submission to the Commonwealth Legal and Constitutional Affairs Legislation Committee.

David Gillespie
Agricultural Microbes Pty Ltd

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Preface

I currently hold a Queensland industrial hemp Category 2 license number R2-003/15 and have been breeding industrial hemp for thirteen years and registered five very low Δ^9-Tetrahydrocannabinol (THC) varieties some less than 0.05% THC with IP Australia for Agri Fibre Industries Pty Ltd. In 2004 I developed a very cheap screening technique for (THC) and cannabidiol (CBD) where I had control over male and female plants for levels of these two cannabinoids that are simply genetically inherited.

I also developed a Thin-layer chromatography (TLC) technique to clarify if progeny had suitable levels of these compounds and not Δ^9-Tetrahydrocannabivarin (THCV) and cannabidivaran (CBDV).

Because of the lack of access to standards under current law I could only use a sub-set of plant samples collected by Queensland Bio-Security officers (QDAFF) that were analysed by gas-chromatography and mass spectrophotometry by Queensland Health as my standards. Using sub-set plant samples as approximate standards for THC that related to the samples done by the Government analysis I also developed a spectrophotometry test that gave an approximate curve for THC samples that was more accurate than my colour-metric method.

Regulators should register breeders who have the necessary skills to produce medical cannabis for pharmaceutical use. A suitable breeding standard could be a person with technical level skills in horticulture or agriculture who has had many years breeding experience with other scientists or qualified scientists who have some breeding experience in breeding cannabis or other dioecious or monoecious crops. Standards of THC and CBD for laboratory use should be allowed for breeders who have had a criminal history check and possess a license to breed medical cannabis. Pharmaceutical companies should be allowed to have lawful possession of standards to calibrate instruments for samples and batches.

There is no reason to allow recreational cannabis use as there is no way a person can tell if their illicit supply is a dangerous drug. For example some illegal strains of cannabis can contain up to 45% THC and at this level it is definitely a dangerous drug. There is plenty of medical evidence that young children or teenagers who smoke high levels of THC in illicit cannabis may cause serious brain damage in the longer term. Smoking cannabis is not necessary for pain relief in terminally ill patients as metered sprays by mouth or creams applied to the tongue can give the same response without the side effect of smoking.

However, there is a place for medically supervised medicinal cannabis. People under medical supervision should be allowed an exemption under law from prosecution. Some low THC strains that contain up to 18% CBD that can help some conditions. CBD is a non psycho-active ingredient. For pain relief where opiates do not suit a patient higher levels of THC taken orally can be beneficial. Expert medical opinion is needed to define a clear maximum level of THC that is safe for such patients. There is some evidence that low levels of THC have immunological properties and high levels of THC are counter productive.

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Regulatory issues

Currently, the committee for the Senate have produced a good initial plan for legislation of medicinal cannabis for regulation, however, there are still quite a few deficiencies in that document. Listed here are a few points that need consideration.

1. T**here are no defined standards for medicinal cannabis in the draft. The paper by Geiwitz (2001) makes a good point in that THC at a low level may have immunological benefits but at too high a dose it can be counter productive.** For pain relief, however, a higher dose is required for terminally ill patients that do not respond very well to conventional medication. The Netherlands Government has very high THC levels in some of their pharmaceutical products that they control, some as high as 22% THC and I think that is far too high given that lower doses in the literature suggest that too high a level of THC has toxic effects while low levels of THC have positive immunological effects (Amar 2006), (Geiwitz 2001).
2. When the law is written **it is imperative that patients under medical supervision under new legislation are immune from prosecution from law enforcement authorities**. I believe that law enforcement agencies should continue to prosecute people for illicit cannabis where the person does not have a licence to possess it but the exemption should be for patients under medical supervision and supplied a prescribed known level of cannabinoids from their doctor. In the new legislation metered doses provided by pharmaceutical companies that have a licence to obtain medical cannabis from licensed growers and the medications conforming to the Commonwealth standards, should be exempt from prosecution. In higher doses of THC of medicinal cannabis the patients should have to surrender their driving licences so that law enforcement agencies can prosecute those who do not pass their drug tests.
3. Licensed breeders and pharmaceutical companies will need access to small quantities of official standards to standardise and calibrate their instruments. There will still be a need to have Government or NATA accredited laboratory analyses to confirm batches from growers, processors and pharmaceutical companies.
4. The Netherlands Government has a monopoly control over medicinal cannabis in their country but I think Australia should have a National Government body (Regulator) and work together with the States and Territories for licensed breeders, licensed producer growers and

licensed pharmaceutical companies. Depending on the THC level accepted by the Commonwealth the medical cannabis may have to be produced in locked glass houses. Low level THC medical cannabis could be thought of as industrial hemp if the THC level is below 0.05% or lower in inflorescences or below 10 parts per million in seed oil products for medical use. The Netherlands through its Government run monopoly abides by international covenants by controlling medical cannabis to defined standards.

5. The method of administration of suppliers of medical cannabis is not clearly defined.

6. **There is no reason to provide medical cannabis for smoking**. This may seem a bold statement but metered doses applied orally or taken like hot "tea" or in pill or cream form or medicinal biscuits can be equally effective as smoking without the side effects smoking causes (Amar 2003). With biscuits the response time may be slower but it is equally effective and patients can modify their behaviour to take small biscuits at regular intervals. The dose rate and frequency need to be clearly labelled on the packaging. In medical cannabis oil preparations or creams the patient takes a metered dose on the tongue morning and evening. Quality of life is the issue with medicinal cannabis where conventional medications are ineffective for particular conditions or for patients that do not respond well to conventional medications. The label should clearly state the dose of a particular cannabinoid preparation and frequency of use. Limited supplies by script would be recommended so doctors can assess the patient for benefits or the doctor might try a different formulation if necessary.

7. There is some confusion in the literature about the use of the acid form of THC or CBD, When heated these natural acid forms turn into THC and CBD. There is also the problem that the analyst normally uses gas-chromatography to analyse a batch of industrial or medical cannabis. The temperature conditions of gas-chromatography convert the acid form to the psycho-active form of THC. High pressure liquid chromatography (HPLC) is an alternative analysis technique to gas-chromatography and can measure these natural acid forms of cannabinoid. Expert medical advise is needed to assess the pharmaceutical benefit of the acid form compared to the heated forms of these cannabinoids.

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Known conditions where medicinal cannabis has been helpful where traditional medicine fails

(Amar 2006) lists a number of conditions patients obtain benefits from THC alone:

1. appetite stimulants in debilitating cancers and AIDS sufferers
2. analgesics replacement
3. multiple sclerosis
4. spinal cord injuries
5. Tourette's syndrome
6. glaucoma

Low THC and high CBD medications have been helpful in patients with Tuberous Sclerosis. There is growing evidence that CBD has anti psychotic properties by blocking a particular receptor in the brain (several articles in PUBMED).

Breeding systems

There are a number of breeding systems that can be used in industrial or medicinal cannabis. Control over the level of CBD and THC can be carried out before male plants shed pollen and at half seed fill of female plants. A number of cycles of selection are required to achieve distinct, uniform and stable varieties. Inbreeding is also required to fix characteristics such as a given THC and CBD level in the plant. On final selection female plants can be vegetatively propagated to achieve the desired uniform level of particular cannabinoids. Several medicinal varieties need to be bred here to standards set by the regulator. The reason why several medicinal varieties are needed is that different patients' conditions require different ratios of cannabinoids dependent on the medical condition. Reserve seed of these lines must be retained by the breeder in case there is a catastrophic failure in locked glasshouses for higher THC lines such as irrigation or cooling failure.

Great care is required to produce lines from Asian varieties as the pure varieties contain the recessive genes (2) that produce THCV and CBDV (Hillig, 2005) and (de Meijer et al 2003).

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Access to standards

Breeders need to possess a cheap screening technique for these compounds as they cannot breed cannabis varieties that are stable for THC and CBD content without having control of these levels in individual plants. Analytical methods currently in place are too expensive for individual plant analysis. There is a cheap colour-metric test that is semi quantitative and also a spectrophotometry method that is quantitative but less expensive than Government analyst equipment. Currently plant breeders have no legal access to accurate THC standards. Despite this lack of conventional standards I have bred 5 industrial hemp varieties that are lower in THC content than those produced by other breeders in this country. The varieties I produced are comparable to newly developed Canadian varieties that are less than 0.05% THC. Other firms have had to rely on imported lines to meet industrial hemp regulatory standards because they have not developed a cheap test that I have. Yet others have used unstable varieties that in a few generations will not pass regulatory standards.

It is necessary for the breeder to maintain their lines to supply reliably bred varieties to avoid such failures beyond the breeders' control. It also allows regulators to honour international covenants for medicinal cannabis to produce medicinal cannabis under regulation and have the reliance of locally bred varieties thus preventing the need to import medical cannabis.

Isolation

Isolation is extremely important in developing both industrial and medicinal cannabis so contamination of varieties is avoided. Isolation can be in partitioned glass houses that allow no pollen transfer between chambers, or a distance of 5 km in open fields for industrial cannabis. Medicinal cannabis except low THC lines should be grown locked glasshouses. The other isolation technique is time. That is sufficient time between sowings as to avoid pollination of a crop grown closer than 5 km away.

Botanical status of Cannabis

While the international community at regulatory level only recognise one genus of cannabis that being Cannabis sativa L. the scientific community are divided on the issue and recognise other species or subspecies of cannabis (Hillig 2005). The recognition of varying location of origin of cannabis is recognised by forensic DNA analysis of both industrial and medicinal cannabis (Datwyler et al 2006). There is also another technique for plant breeders for molecular markers in diverse array technology that was used in NSW rice breeding programs (Reinke, 2006). With the

advance in DNA genome screening techniques, I have not covered all methods but have listed a promising one and one that will stand up in court please review the paper by (Datwyler et al 2006). The reason that (Datwyler et al 2006) states that courts will accept the evidence is that the method he used is highly accurate and highly reproducible.

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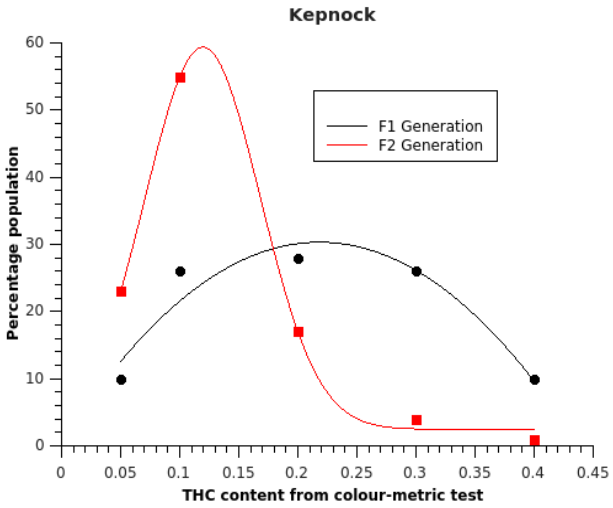
Selection for THC in two early generations of Kepnock a registered industrial hemp cultivar



The graph information produced here is from my own breeding work for very low THC industrial hemp varieties suitable for growing in sub-tropical regions. This variety of industrial hemp at the registration stage by Government analyst was on average 0.105 % THC content at a later generation stage.

So in one cycle of selection it was possible to halve the THC content. For medical cannabis it is possible to positively select for higher THC content and higher CBD content or lower THC content and raise CBD content. What I am alluding to here is that it is necessary to develop a range of THC and CBD levels for various medical conditions. For chronic pain relief a higher THC level is required than for some other conditions of patients where a low dose of THC and high CBD would be required. Regulators should seek expert medical and pharmaceutical advice as to what combinations of these cannabinoids are needed for the industry. It is quite feasible for a competent plant breeder with access to suitable testing techniques, such as I used in my industrial hemp breeding program, to produce medicinal cannabis varieties to meet regulatory standards regarding THC and CBD levels as required for the medical profession.

In later generations prior to registration THC levels of BundyGem and FibreGem analysed by the Government analyst averaged 0.0395% THC and 0.0475% THC respectively and I attach the Government analytical report before the reference section.

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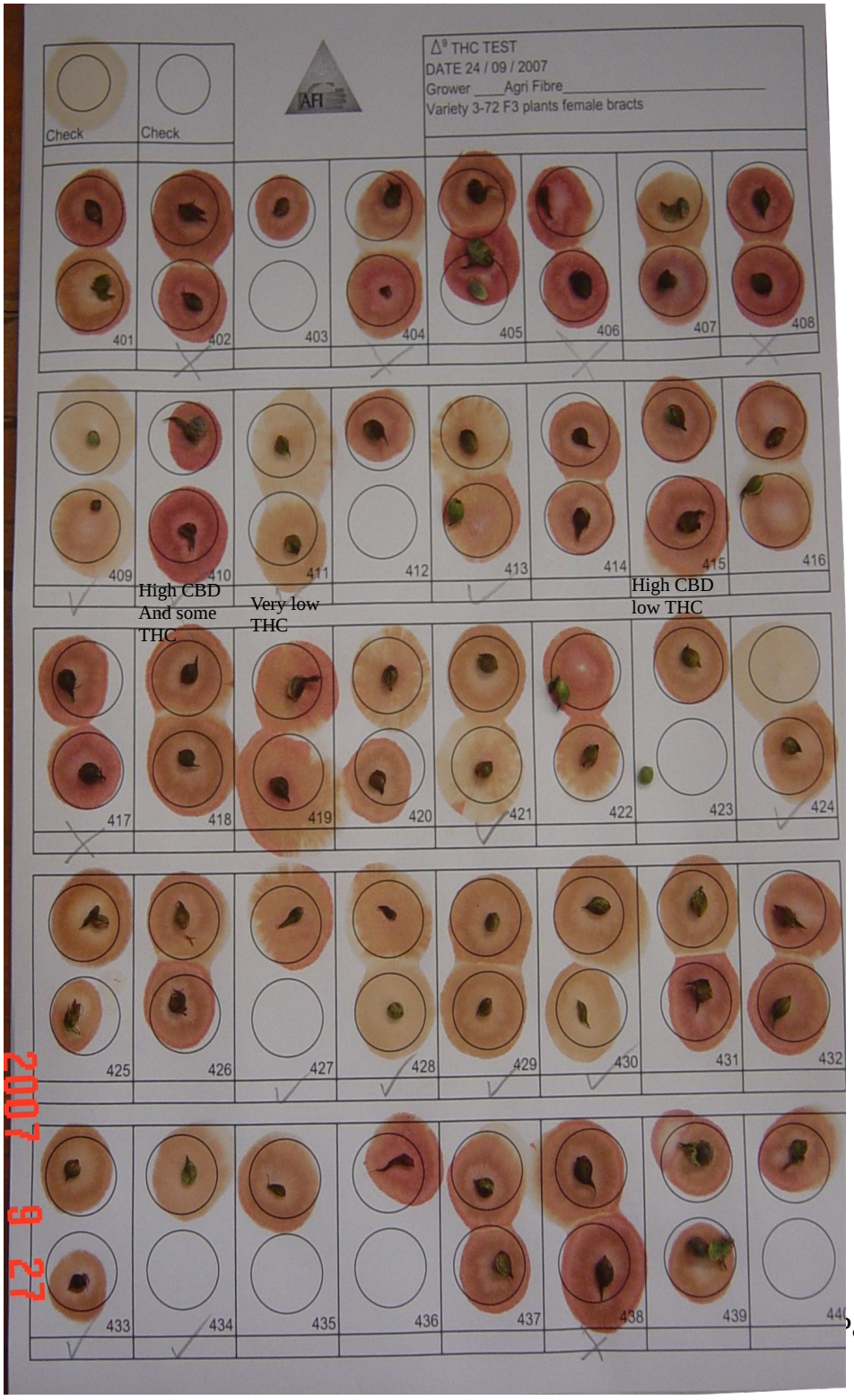
Colour-metric example



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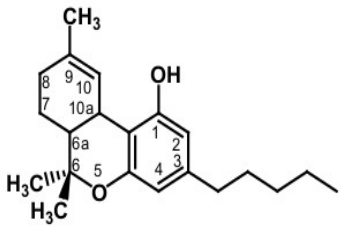
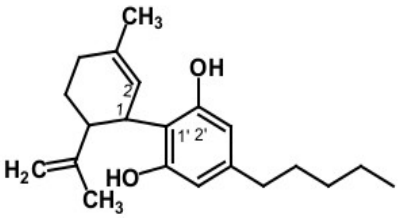
The major cannabinoids are:

(-)-Δ^9-trans-Tetrahydrocannabinol
Tetrahydrocannabinol, THC



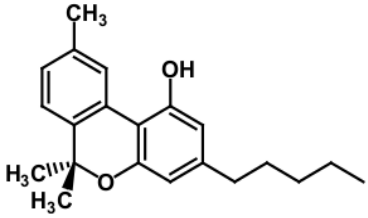
Main pharmacological characteristics:
- Euphoriant - Anti-inflammatory
- Analgesic - Anti-emetic

Cannabidiol
CBD



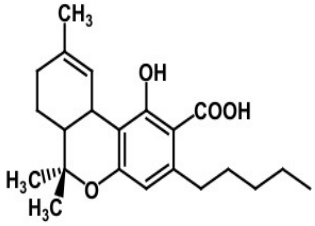
Main pharmacological characteristics:
- Anxiolytic - Anti-inflammatory
- Antipsychotic - Antispasmodic
- Analgesic

Cannabinol
CBN



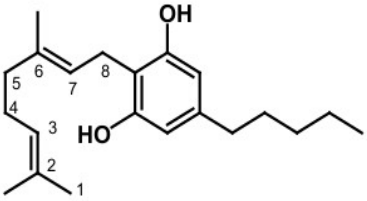
Main pharmacological characteristics:
- Sedative - Anticonvulsant
- Antibiotic - Anti-inflammatory

(-)-Δ^9-trans-Tetrahydrocannabinolic Acid
THCA



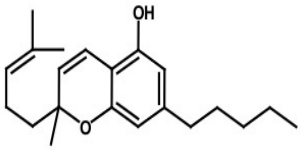
Main pharmacological characteristics:
- Antibacterial
- Antibiotic

Cannabigerol
CBG



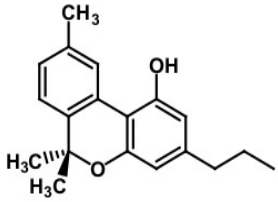
Main pharmacological characteristics:
- Antibiotic - Anti-inflammatory
- Antifungal - Analgesic

Cannabichromene
CBC



Main pharmacological characteristics:
- Anti-inflammatory - Antifungal
- Antibiotic - Analgesic

Cannabivarin
CBV



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Copies of Queensland Health analytical results for BundyGem

Queensland Government
Queensland Health

FORENSIC AND SCIENTIFIC SERVICES

Enquiries to: B. Lind
Telephone: (07) 3274 9105
Fax: (07) 3274 9123
Our Reference: 08PM60
Client Reference: 2091

February 26, 2009

TO: Paul Garland,
DPI Bundaberg,
16-32 Enterprise Street,
Bundaberg QLD, 4670

LABORATORY REPORT

Date Received : 15th January, 2009
Sample Description : Labeled bag containing hemp plant material.
Reason for Submission : Concentration of available THC.
Methods : Gas chromatography-mass spectrometry (GC-MS).
Date Commenced : 15th January, 2009

RESULT OF ANALYSIS

Please refer to Table 1 on the next page for results.

- 5 MAR 2009

OFFICE: 39 Kessels Road COOPERS PLAINS QLD 4108 AUSTRALIA
POSTAL: PO Box 594 ARCHERFIELD QLD 4108 AUSTRALIA
TELEPHONE: (07) 3274 9021 INTERNATIONAL CODE 61
FAX: (07) 3274 9123

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Table 1. Sample details and results.

DPI sample number	2091
Seal Number	088001
Client Contact	Plant Breeder: David Gillespie, AGRI Fibre Industries Pty Ltd
Inspector	Paul Garland
Variety	Bundy Gem
Tetrahydrocannabinol (%)	0.039% in dry powder

If you require further testing, please contact me.

Bronwyn Lind
A/Snr Chemist

END OF REPORT

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Agricultural Microbes Pty Ltd

Enquiries to : Graham King
Telephone: (07) 3274 9105
Fax: (07) 3274 9123
Our Reference: 10PM58
Your Reference: 00124 Tag No.088008

Queensland Government

Queensland **Health**
FORENSIC and SCIENTIFIC SERVICES

ATTENTION: GEOFF COWLES BIOSECURITY (Fax 07 3211 3293)

December 21, 2010

TO: Geoff Cowles,
Senior Registration Officer and Industrial Hemp Regulatory Officer,
Biosecurity Queensland,
Primary Industries and Fisheries,
Floor 3, 80 Ann Street,
Brisbane. Qld. 4000.

LABORATORY REPORT

Date Received : 18th November, 2010

Sample Description : One (1) sample of Bundy Gem variety hemp plant material

Reason for Submission : Concentration of available tetrahydrocannabinol (THC).

Methods : Gas Chromatography Mass Spectrometry (GCMS), QIS Method No.12863.

Date Commenced : 23rd November, 2010

RESULT OF ANALYSIS

Sample details:

Sample number	00124
Seal number	Tag No. 088008
Client contact	135 St. Johns Road, Bundaberg. QLD 4670
Inspector	Paul Garland
Variety	Bundy Gem
Tetrahydrocannabinol (%)	0.04% in dry powder

Graham King
Chief Chemist
E-mail: Graham_King@health.qld.gov.au

----------END OF REPORT ----------

OFFICE: 39 Kessels Road COOPERS PLAINS QLD 4108 AUSTRALIA
POSTAL: PO Box 594 ARCHERFIELD QLD 4108 AUSTRALIA
TELEPHONE: (07) 3274 9105 INTERNATIONAL CODE 61
FAX: (07) 3274 9123

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Yours faithfully,

David Gillespie
Director Agricultural Microbes Pty Ltd