

- From : [REDACTED] . 20 May 2020.

RE :Consultation: Proposed amendments to the Poisons Standard - Joint ACMS/ACCS meetings, June 2020

https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-joint-acmsaccs-meetings-june-2020?fbclid=IwAR1EPO2vjQL-rfdpSh10nDn82coZwH3em1YrROe8z-5Uo9G1GhRreT4GuxA#.XsHEAE_Cdtuk.facebook

Suggested amendment.

CBD to be moved from schedule 4 to 3 of the Poison's Schedule , with some provisions, on strength, quantity, and limits of other cannabinoids.

Reasoning

Lack of affinity for CB1 and CB2 limits psychoactivity.

The age limit of over 18 is due to lack of safety evidence in under 18.

My Response.

CBD should be removed from the poisons schedule, as in this proposal document there is an admission that there has not been a single report of an adverse reaction to DAEN.

- As of 1 April 2020, there were no reports of adverse events for products containing cannabidiol as an active ingredient on the Database of Adverse Event Notifications (DAEN).[8]

And even psychoactive forms of cannabis, have been deemed to be the Safest Therapeutic Substance known.

DEA JUDGE'S 'FRESH' VIEW ON LEGAL MARIJUANA USE

By **Michael Isikoff**

September 19, 1988

...Perhaps nothing illustrates Young's "fresh" approach more than a controversial passage of his opinion in which he analyzes the relative dangers of marijuana, noting that -- unlike virtually every other drug, including household aspirin -- **there is no known dosage that is considered lethal.**

Young calls this "remarkable," noting that in the 5,000 years that human beings are believed to have been smoking the drug, "there are simply no credible medical reports to suggest that consuming marijuana has caused a single death."

Medical researchers have failed in their efforts to kill laboratory animals by

feeding them enormous amounts of marijuana, Young said.

"In strict medical terms, marijuana is far safer than many foods we commonly consume," Young concluded. "For example, eating 10 raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death. Marijuana in its natural form is one of the safest therapeutically active substances known to man."

<https://www.washingtonpost.com/archive/politics/1988/09/19/dea-judges-fresh-view-on-legal-marijuana-use/2055d246-9003-403d-94a6-69fb9b469a3e/>

Since then we have seen legalization via removal from controlled drugs schedules occurring especially in north america.

A position also under consideration by UN /WHO on recommendation from UNGASS.

The United Nations Commission on Narcotic Drugs (CND) has decided to delay until December a vote due to take place this week on the potential global rescheduling of cannabis. The CND—which is meeting in Vienna, Austria from March 2-6—was due to vote on a set of recommendations from the World Health Organization (WHO) to loosen restrictions on cannabis and related substances like CBD and THC.

This is the second time the CND has refused to vote on the recommendations, which the WHO first presented in January 2019.

<https://idpc.net/alerts/2020/03/un-commission-on-narcotic-drugs-once-again-postpones-key-cannabis-vote>

And indeed I agree with the European / UK position mentioned in the proposal.

- The European Union guides all member states that hemp should not exceed a THC limit of 0.2%. In January 2019, European Union's Novel Food regime, led to the classification of all extracted cannabinoids as "novel". Novel Food is defined as food that had not been used for human consumption to a significant degree in the European Union before 15th May 1997. According to this new classification, CBD products require pre-market authorisation
- In the United Kingdom (U.K), CBD in its pure form is not classed as a controlled drug. The limit on THC content is set at 1mg of THC per container limit. The UK Food Standards Agency has set a deadline on 21 March 2021 for companies marketing CBD extracts as foods or foods supplements, to submit Novel Food approval applications.

Indeed given the safety as above and efficacy as mentioned below, any poisons and/or dangerous drugs scheduling would be actually harming sick people by creating difficulty in accessing medical therapy.

This would be / is a contravention of human Rights and indeed to Convention on the Rights of Disabled People, Article 28A, which implores government to enable access to healthcare.

Article 28 – Adequate standard of living and social protection

1. States Parties recognize the right of persons with disabilities to an adequate standard of living for themselves and their families, including adequate food, clothing and housing, and to the continuous improvement of living conditions, and shall take appropriate steps to safeguard and promote

the realization of this right without discrimination on the basis of disability.

2. States Parties recognize the right of persons with disabilities to social protection and to the enjoyment of that right without discrimination on the basis of disability, and shall take appropriate steps to safeguard and promote the realization of this right, including measures:

a) To ensure equal access by persons with disabilities to clean water services, and to ensure access to appropriate and affordable services, devices and other assistance for disability-related needs;

<https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-28-adequate-standard-of-living-and-social-protection.html>

Sadly for people like men with PTSD, Anxiety, depression, and other forms of so called mental illness, the only forms of subsidized medicines for our conditions are psychiatric medications.

Explanation of Cannabis for PTSD by Dr T Mikuriya, who founded Society of Cannabis Clinicians.

<https://beyondthc.com/wp-content/uploads/2013/04/THMCannabisPTSD.pdf>

In addition the Article above on DEA Judge Francis Young, cites Harvard Psychiatrist Dr. L Grinspoon, also endorsing the use of Cannabis.

<https://www.washingtonpost.com/archive/politics/1988/09/19/dea-judges-fresh-view-on-legal-marijuana-use/2055d246-9003-403d-94a6-69fb9b469a3e/>

And more recently,

Benzodiazepines are prescription medications commonly used for anxiety and neurological conditions. These sedative medicines commonly have side effects. In an observational study of 146 patients who used medical cannabis, 45% of them successfully discontinued their pre-existing benzodiazepine therapy.

<https://www.liebertpub.com/doi/10.1089/can.2018.0020>

Mary Ann Liebert, Inc., publishers

Article 25. CRPD

b. Provide those health services needed by persons with disabilities specifically because of their disabilities, including early identification and intervention as appropriate, and services designed to minimize and prevent further disabilities, including among children and older persons;

<https://www.humanrights.gov.au/our-work/rights-and-freedoms/right-health>

For example I can get Valium on PBS, but PBAC can't seem to recognize cannabis, so I have to pay \$30 a gram which is \$450 a fortnight, that is unaffordable to most on a disability pension.

Forcing those who do not want to break the law and can't get compassionate access (I've tried), to take drugs like valium which are well known to be much more dangerous, and indeed are a greater cause of OD, especially in combination with opiates.

According to the report, the number of Australians who died from unintentional overdoses has increased by almost 38% in 10 years, from 1171

fatalities to 1612.

Opioids – both pharmaceuticals and in illicit forms – continue to be the primary drug group associated with unintentional drug-related deaths. However, for the first time since 2003, heroin was involved in more unintentional overdose deaths than the next highest opioid group (oxycodone/morphine/codeine).

Benzodiazepines was the second most common group of drugs linked to unintentional overdoses, followed by stimulants such as methamphetamine or ice.

‘It’s very important to note that this is not, and never has been, only a crisis of illicit drugs,’ Mr Ryan said in a statement.

<https://www1.racgp.org.au/news/clinical/australia-s-overdose-crisis-is-getting-worse>

And

Accidental drug overdose deaths up almost 40 per cent in a ...

www.abc.net.au › news › health › accidental-drug-over...

Aug 26, 2019 - More than 1,600 Australians died from an accidental drug overdose in 2017 ... health organisation the **Penington** Institute, which commissioned the report. ... involving heroin; Accidental deaths involving benzodiazepines have ...

Drug overdoses kill one Australian every five hours | Australia ...

www.theguardian.com › australia-news › aug › drug-o...

Aug 26, 2019 - The **overdose** report by the **Penington** Institute, released on Tuesday, ... linked to unintentional **overdoses** was **benzodiazepines**,

Sadly I still see people in social media groups asking for access to blackmarket oil because their Doctor / GP is refusing to provide them with a prescription for cannabis.

An obvious ignorance noted in recommendations of recent Senate Inquiry into Medical Cannabis Access, which included improved Medical Education, which sadly seems to still be failing the sick and vulnerable, as is the call for compassionate access from industry.

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Medicinalcannabis/Report/section?id=committees%2freportsen%2f024403%2f72688#s72688rec19

It is worth noting while current scheduling keeps cannabis inaccessible to most vulnerable in Australia, in USA, cannabis has been deemed an essential medicine.

Medical Marijuana Deemed “Essential” During COVID-19 Pandemic
Tuesday, March 24, 2020

Notwithstanding numerous restrictions limiting access to many resources during the ongoing coronavirus (COVID-19) pandemic, marijuana users in states where medicinal and adult use is legal may still have access to cannabinoid supplies. Even as states, counties, and municipalities increasingly restrict or shut down business activities to stem the spread of the virus, many jurisdictions will keep medical marijuana dispensaries open as “essential” businesses like pharmacies and grocery stores.

<https://www.natlawreview.com/article/medical-marijuana-deemed-essential-during-covid-19-pandemic>

It is also of note that there is pandemic related stress and increases in suicide.

<https://abcnews.go.com/Politics/calls-us-helpline-jump-891-white-house-warne>
<https://abcnews.go.com/Health/unemployment-isolation-covid-19s-mental-healt>
[h-impact/story?id=69939700](https://abcnews.go.com/Health/unemployment-isolation-covid-19s-mental-healt)

And

<https://abcnews.go.com/Health/unemployment-isolation-covid-19s-mental-healt>
[h-impact/story?id=69939700](https://abcnews.go.com/Health/unemployment-isolation-covid-19s-mental-healt)

And as far as I know Cannabis is the only therapy which seems to reduce suicidality in PTSD.

The below study shows rates of major depression with PTSD is 7 times higher than average, and suicidal ideation 4x higher than generally for people who don't use Cannabis, but not those who do.

In multivariable analyses, post-traumatic stress disorder was significantly associated with recent major depressive episode (adjusted odds ratio = 7.18, 95% confidence interval: 4.32–11.91) and suicidal ideation (adjusted odds ratio = 4.76, 95% confidence interval: 2.39–9.47) among cannabis non-users. post-traumatic stress disorder was not associated with either outcome among cannabis-using respondents (both $p > 0.05$).

Conclusions:

This study provides preliminary epidemiological evidence that cannabis use may contribute to reducing the association between post-traumatic stress disorder and severe depressive and suicidal states. There is an emerging need for high-quality experimental investigation of the efficacy of cannabis/cannabinoids for the treatment of post-traumatic stress disorder.

Does cannabis use modify the effect of post-traumatic stress disorder on severe depression and suicidal ideation? Evidence from a population-based cross-sectional study of Canadians

<https://journals.sagepub.com/doi/full/10.1177/0269881119882806>

But here we have stories like these.

https://www.abc.net.au/news/2020-04-25/the-former-drug-cop-hunting-cannabis-for-army-veteran-sons-ptsd/12181306?utm_medium=spredfast&utm_content=sf233188938&utm_campaign=fb_abc_news&utm_source=m.facebook.com&sf233188938=1

“It’s understandable. Americans have grown increasingly anxious as they’ve seen this global pandemic upend their lives within a very short time. This analysis, showing that many Americans are turning to medications for relief, demonstrates the serious impact COVID-19 may be having on our nation’s mental health.

The greatest increase was in prescriptions for anti-anxiety medications, which rose 34.1% from mid-February to mid-March, including a week-over-week spike of nearly 18% during the week ending March 15. The number of prescriptions filled for antidepressants and sleep disorders increased 18.6% and 14.8%, respectively, from February 16 to March 15.

We also observed that:

- More than three quarters (78%) of all antidepressant, antianxiety and anti-insomnia prescriptions filled during the week ending March 15th (the peak week) were for new prescriptions.
- The percent increase in the number of new prescriptions between the week of February 16 and week ending March 15 for the all three categories was 25.4%
- The percent increase in the number of new prescriptions between the week of February 16 and week ending March 15 for anti-anxiety medications was 37.7%

<https://www.express-scripts.com/corporate/americas-state-of-mind-report?fbclid=id=IwAR2D2TvkNC1x1exUdQM9vdHFLz81W3Oa11mEi4kPLK15INtr7EuqpDHLF5s>

More Reasoning.

It is proposed that down-scheduling to Schedule 3 is more appropriate than Schedule 2, as pharmacist advice is necessary to mitigate safety risks associated with CBD's high potential for drug-drug interactions when used concomitantly with many other commonly prescribed drugs that are metabolised via CYP pathways.

Broccoli, brussel sprouts, grapefruit and char grilled meat also affects cytochrome metabolism.

<https://drug-interactions.medicine.iu.edu/MainTable.aspx>

Note problems in trials was with isolate, that is without other synergistic cannabinoids, and so a very high dose is given, ie 20mg/kg/day when some suggest daily adult dose may be just 10mg, ie significantly less than 1 mg/kg/day

While all three trials reported a significantly greater than 50% convulsive seizure reduction in participants on CBD when compared to those on placebo, there were also more adverse events described in participants on 20 mg/kg/day of CBD (about 90%) than on placebo (approximately 72%) [74,75,76]

Cheung KAK, Peiris H, Wallace G, Holland OJ, Mitchell MD. The Interplay between the Endocannabinoid System, Epilepsy and Cannabinoids. *Int J Mol Sci.* 2019;20(23):6079. Published 2019 Dec 2. doi:10.3390/ijms20236079

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6929011/>

It is interesting to see Dr G Wallace ref to 3 CBD trials ref 74, 75, 76, none of which were his, that is in Dec 2019, he co-authors a paper but doesn't cite any GW study from LCCH announced in 2016, which seems unusual, given other trials were just 14 weeks, so should have been completed a considerable time ago.

I also wonder at a 70% adverse affect rate in placebo arm and the consumption of AEDs which were real issue with raised liver enzymes and needs to be considered in such case by prescriber vs demand all consumers buy through pharmacy, based on this evidence.

\$6 million investment in medicinal cannabis research in ...

[statements.qld.gov.au](#) › Statement › 6-million-investme...

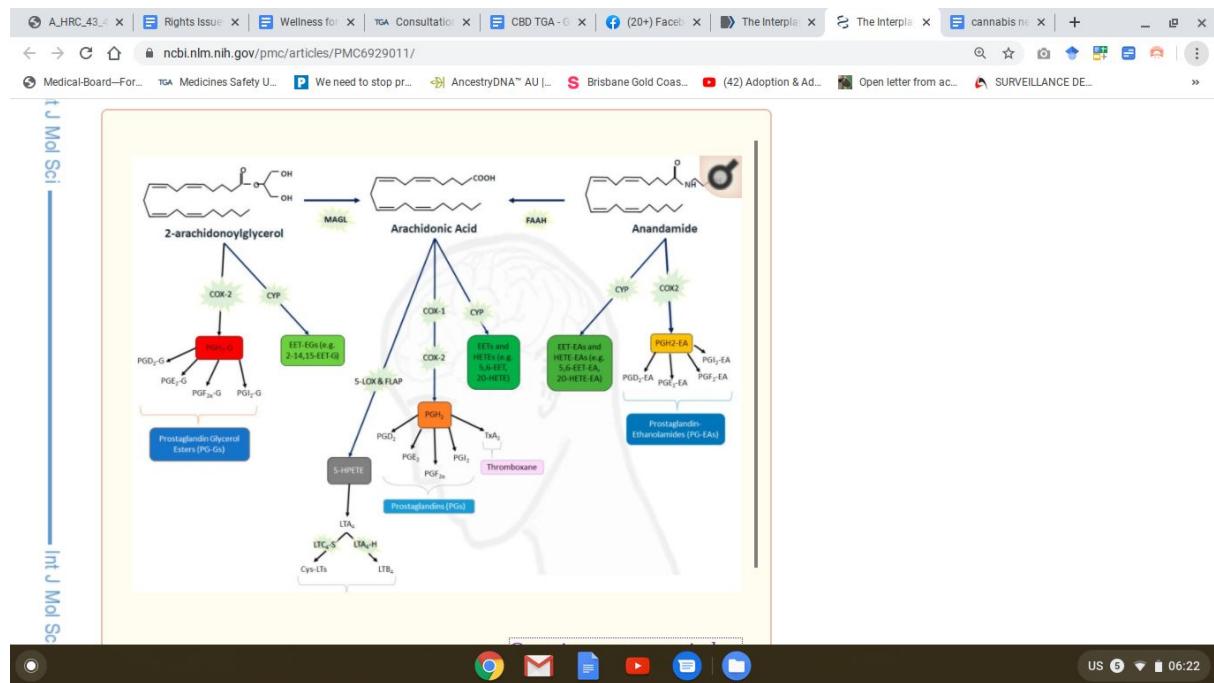
Jul 27, 2016 - Parents of Queensland children with severe drug-resistant **epilepsy** can now ... This project will be led by **Lady Cilento Children's Hospital** Director of ... a total **\$6 million** over three years to medicinal cannabis **trials** and the ...

Medicinal cannabis trial available for Queensland children ...

[www.abc.net.au](#) › news › medicinal-cannabis-qld-childr...

Jul 27, 2016 - Queensland children with severe drug-resistant **epilepsy** can apply to take part in ... The research team from the **Lady Cilento Children's Hospital** in **Brisbane** ... It is part of a **\$6 million** State Government spend that will include ...

I do note however there was important information mentioned in the CBD study.



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6929011/>

That is the integral role endocannabinoids, and indeed cannabinoids play in the inflammatory response, right down to cell membrane integrity.

I believe it is this factor, that make cannabinoids more suitable to be classed as a food rather than a drug.

This also fits with the variability which makes all but isolates difficult to fit into the traditional chemical drug approval system and PBAC.

Sadly by removing the other cannabinoids you lose synergy, and various antioxidants.

This is obvious when you see children in CBD isolate trials given 20mg/kg, while adults may have a dose of just 10 or 20 mg, or less than 1mg/kilo.

Keeping this plant product on the poisons schedule also prevents access to fresh herb, and enables the prosecution of people who are sick and poor and just seeking some relief from pain, anxiety, insomnia, and other conditions.

Cannabis is also a far safer antiinflammatory than those preferential pushed by prescribers, such as NSAIDS, COXI or corticosteroids.

The patented neuroprotective effects of cannabis, especially in head injury, also suggestive they may have a preventive role which is not technically covered by medicare or PBS, which are designed to treat disease, which make cannabis different to other chemical medical therapies.

Additional Consideration.

In places where cannabis has been removed from the schedule as a pharmaceutical drug, it is often sold in licensed dispensaries, this allows for specialist knowledge, a range of choice of herbs, and other forms, from oils to edibles, which are very different to products in a pharmacy, and often more like a health food store.

Given that many consumers are from the social margins, and have problems like PTSD, and so called mental illness, there is also a psychological benefit from a more casual, less clinical , more social model of delivery, hence the popularity.

In Conclusion.

Cannabis should be removed from the poisons schedule.

If any cannabinoid type product should be controlled by schedule 3, it should be synthetics and isolates like CBD. given it's relative inefficacy means it needed to be given in very large doses, which, are also thus unlikely to be affordable.

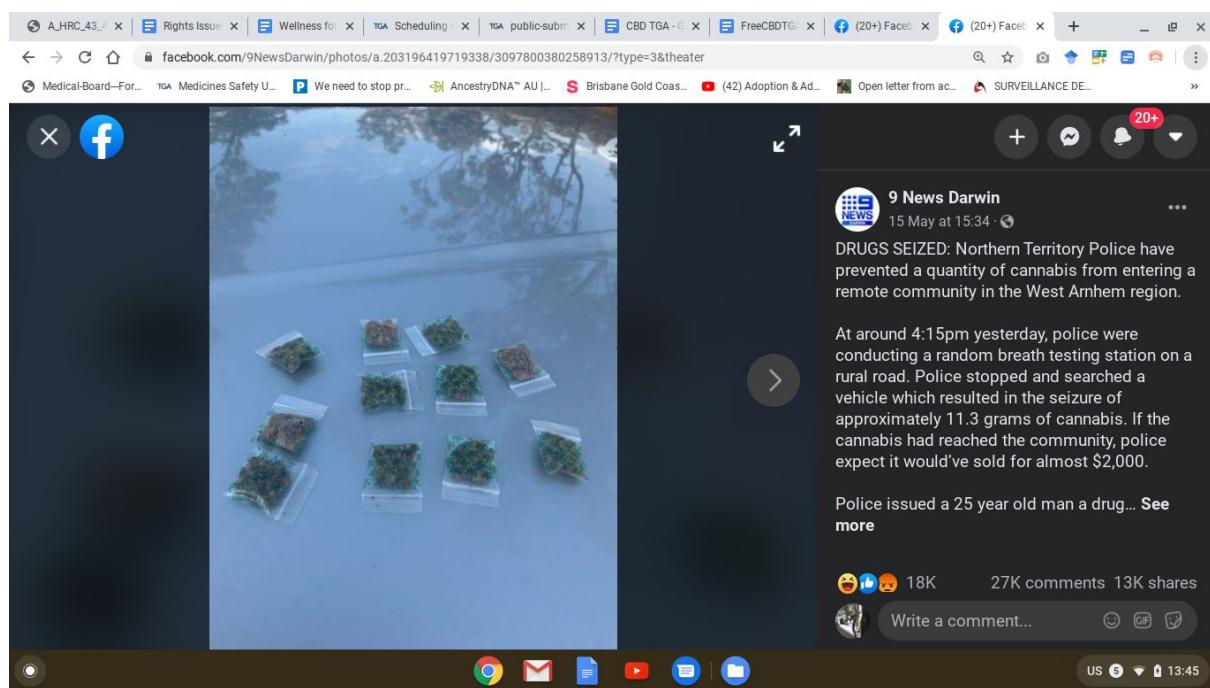
With no affordable options for many on Disability Pensions , and a failure of states to create compassionate access scheme, it is time to stop prosecuting

people for attempts at some gardening to gain self sufficiency, especially from the criminal type of drug dealer.

Additional benefits of decriminalizing cannabis include, less social damage due to imprisoning of people for non violent drug possession, which is a large proportion of the prison population, especially indigenous people who face disproportionate prosecution. This can aggravate trauma, be a gateway to harder drugs and blood born diseases, and a high cost to community in subsequent care and repeat offending.

The image below shows how bad it has gotten with Police suggesting 11g of cannabis would cost the remote community \$2000, or \$200 a gram.

Note 27 000 comments, I read some, much outrage.



Lets not forget first nations people have major issues with intergenerational trauma, and social disadvantage which is an unpleasant feeling, hence the use of alcohol, drugs and other substances, like any with PTSD.

Sadly such scheduling will always mean Police are expected to find and confiscate this safe and effective herbal remedy, and there is no hope of a

pharmacy for over the counter or a Doctor in the NT willing to prescribe cannabis for Indigenous PTSD..

That means because of the TGA in Canberra, Mothers, Fathers, and others are locked up and further damaged just for trying to feel a bit better.

The antioxidant, nutritional benefits also cannot be under estimated in malnourished communities at high risk of diseases of oxidative stress such as cardiovascular disease, dementia, renal failure and other conditions which are often very inflammatory.

Financial.

Limiting this herbal remedy to a schedule which allows access only via a Doctor / pharmacy, is hardly a real safety issue.

That is if 20mg/kg/day of CBD isolate in? Carrier (GW), interacts with epileptic medication metabolism, cannabis can be added to all the other medications which also interact with such medications, as a warning on that medication, and is not a general problem or one which cannot be managed with usual dispensing advice with AEDs and other affected medications.

The real reason cannabis is to be doctor only (prescription drug), or pharmacy only, Schedule 3, in Australia, is Money. CBD is a food, and healthfood preparation in Europe and there is no poor outcome which genuinely justifies such restrictions.

I think given that so many economic opportunities have been lost during COVID-19, with Doctors and Pharmacists perhaps among the least affected, most likely to benefit with billion dollar additional benefits, it's about time this duopoly accepted that other people have the right to cannabis without prejudice, especially as they fail to make great moves from complete ignorance on the topic, while compassionate carers are treated as criminals if they find the

benefits themselves and want to help others, as we see with the prosecution of Jenny Hallam.

This peer support is particularly important and preferred in mental illness, where a person who can relate to real struggles can offer acceptance and empathy, which is far more healing than the medical model, where a psychiatrist sits on a elevated position and denounces a person's sanity, calls them names which carry serious stigma and indeed more prejudice, while pushing chemicals now known to be addictive, brain damaging, and hardly even suitable for the problem, which may be social isolation,

Joanna Moncrieff - The Myth of the Chemical Cure: The Politics of Psychiatric Drug Treatment (At UNE).

<https://www.youtube.com/watch?v=IV1S5zw096U&t=3100s>

I genuinely hope that the TGA sees that it's current position is an abuse of Human Rights, impairs CRDP, is dangerous, anticompetitive, and entrenches social injustice, rising rates of deaths from OD, prevents proper treatment of inflammatory diseases, and may even block people with cancer's last hope.

Cannabinoids, Endocannabinoids and Cancer - NCBI

[www.ncbi.nlm.nih.gov › pmc › articles › PMC3366283](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3366283)

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Yours Sincerely,

Melissa Costin MBBS.