

# **Rescheduling of CBD from TGA 4 to 3: Over the Counter Cannabidiol**

Dalgarno Institute Submission

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# Rescheduling of CBD from TGA 4 to 3: Over the Counter Cannabidiol

Dear Committee,

The Dalgarno Institute sincerely appreciates the opportunity to offer a submission on this important and emerging topic of CBD reclassification.

The institute is a long-standing not-for-profit organisation that seeks to assist governments, schools and communities to rediscover proactive and protective options of best-practice prevention models in the alcohol and drug arena.

## Introduction

CBD has been a topic of much interest particularly since the legalisation of new novel forms of medical marijuana (as opposed to existing fully vetted and TGA approved medicinal therapies derived from cannabis). Various studies are still ongoing and show some positive signs in treatment within specific health conditions including MS<sup>1</sup> and specific seizure disorders.<sup>2</sup>

However, it also needs underscoring that at present CBD treatments are limited to medically approved products<sup>3</sup> as research remains sparse regarding many other hyped health claims.<sup>4</sup> Something even pro CBD organisations admit.<sup>5</sup>

Nonetheless, on the back of medical marijuana legalisation in Australia and recreational marijuana legalisation in the US, the lobbying and marketing proliferation by big corporation marijuana ensures that unclear and unproven health claims are kept firmly in public view ensuring CBDs almost ubiquitous presence.<sup>6</sup> For example, Constellation Brands that also fund a therapeutic division with purported health benefits of CBD oil has been instrumental in driving the growth of the US market. And companies now have their sights set on a potential burgeoning Australian market dubbed as “the next Canada”.<sup>7</sup>

CBD is extracted from the cannabis sativa plant found in hemp and marijuana. The latter is the most consumed drug worldwide and despite much scientific evidence to the contrary<sup>8</sup>, is widely perceived as ‘harmless’. Therefore, a proposed down scheduling requires particular care as public perception not scientific evidence is often a key driver for consumer demand.<sup>9</sup>

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<sup>1</sup> [https://link.springer.com/article/10.1007/s10072-020-04413-6?error=cookies\\_not\\_supported&error=cookies\\_not\\_supported&code=9872e6f2-5cf3-4152-88db-b91caf71efb9](https://link.springer.com/article/10.1007/s10072-020-04413-6?error=cookies_not_supported&error=cookies_not_supported&code=9872e6f2-5cf3-4152-88db-b91caf71efb9)

Mary Biles wrote in *Project CBD*, “A new wave of research and mounting anecdotal evidence points toward cannabinoids having an adaptive, immunomodulating effect, rather than just suppressing immune activity.” In other words, it’s possible that cannabinoids like CBD may keep inflammation at bay when healthy, but increase inflammation when getting sick.”

<sup>2</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>

<sup>3</sup> For CBD marketed as an over-the-counter medication proper non industry approved trials are required, as to date many are drawn from skewed surveys, anecdote and small-scale CBD studies. Compare these with Epidiolex’s effectiveness that was studied in three randomized, double-blind, placebo-controlled clinical trials involving 516 patients with either Lennox-Gastaut syndrome or Dravet syndrome. Epidiolex, taken along with other medications, was shown to be effective in reducing the frequency of seizures when compared with placebo.

<sup>4</sup> <https://www.cbsnews.com/news/charlottes-web-marijuana-a-hope-for-kids-with-seizures-despite-unproven-medical-benefits/>

<sup>5</sup> <https://weedmaps.com/news/2020/04/setting-the-record-straight-about-cbd-and-coronavirus/>

<sup>6</sup> <https://www.nytimes.com/2018/10/27/style/cbd-benefits.html>

<https://themarijuanareport.org/medical-marijuana-inc-announces-prominent-coverage-on-mexican-news-station-about-benefits-of-cbd-and-global-cbd-policy/>

An [early and oft-reported survey](#) of children on Charlotte’s Web found that 80 percent who tried it eliminated at least three of every four of their seizures. Now, even one of the specialists involved in that study questions whether it was overly optimistic. Subsequent studies [have suggested](#) the response rate might be closer to 30 percent or, perhaps, even lower.

<sup>7</sup> <https://www.businessnewsaus.com.au/articles/australia-s-top-20-cannabis-companies.html>

<sup>8</sup> <https://cosmosmagazine.com/biology/the-bad-science-of-medical-cannabis>

<https://thenationalmarijuananeews.com/bad-science-behind-medical-cannabis/>

<sup>9</sup> <https://www.studyfinds.org/cbd-interest-among-americans-surpass-nearly-all-other-health-products/>

Given CBDs already heightened public interest, a situation that directly compares with the recent pre-legalisation of medical marijuana, this current attempt to down schedule may be a sign of the industry's first attempts to loosen restrictions on medical marijuana prescriptions. This is anticipated to yield a significant boost to marijuana companies waiting to cash in on increased sales with projected distribution channels implemented across retail pharmacies, e-commerce websites, marijuana medical dispensaries and hospital pharmacies.<sup>10</sup>

Essentially, to achieve down scheduling CBD from level four to three requires:

- Evidence of level of risk not as great as originally perceived
- Potential health benefits outweigh potential increases in risk

These are each addressed in turn as well as supplementary relevant information often overlooked that may assist with current deliberations.

## 1. Australian TGA Review

In December 2019, the TGA completed its review on low dose CBD. From the outset it was noted that there was a “**paucity (scarcity or smallness) of high-quality published trials** (meta-analyses and RCTs) with the **majority of the literature for analysis being lower quality explorative studies or case series with no placebo control**. Thus, no clear conclusions can be drawn on efficacy of CBD at low doses as larger phase III and conclusive efficacy trials have not been conducted.”<sup>11</sup>

Therefore, the only data available was sourced from case studies ranging from 72 to and single patient.<sup>12</sup>

Both Brown and Winterstein and later Iffland and Grotenhermen noted the, “**general** previously described favourable safety profile of CBD use in humans was confirmed and that CBD did not lead to serious adverse effects,” but **was limited to** “the treatment of epilepsy and psychotic disorders.”<sup>13</sup>

### 1.1 Health Benefits

#### 1.1.1 Children

“There is **limited evidence** about the use of low dose CBD (**single case study**) in children and therefore evidence for and knowledge of the safety of CBD in children is **extremely limited**. Consideration should be given to whether when considering down scheduling that low dose CBD, i.e. 60mg/day should be limited to management of conditions in adults (i.e. those over 18 years of age).”<sup>14</sup>

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<sup>10</sup> <https://www.marketresearchfuture.com/reports/cbd-oil-market-7355>

<sup>11</sup> <https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf>

Pg. 9, Safety of low dose cannabidiol, version 1.0, April 2020

<sup>12</sup> Ibid. Pg. 11

<sup>13</sup> The Epilepsy Foundation documents the narrow (gold standard) research involving CBD and the successful treatment of specific and rare forms of epilepsy <https://www.epilepsy.com/learn/treating-seizures-and-epilepsy/other-treatment-approaches/medical-marijuana-and-epilepsy>

<sup>14</sup> <https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf>, Pg. 10, Safety of low dose cannabidiol, version 1.0, April 2020

Furthermore, advocates for CBD often point to the popular documentary *Weed*, featuring five-year-old Charlotte Figi, who experienced 50 seizures per day. Charlotte became the face of medical marijuana and the name's sake for the cultivation of the CBD oil, Charlotte's Web. However, what is often left out is Charlotte's treatment did **not involve low-dose CBD oil** but a **high CBD/THC ratio**.

As other researchers have pointed out, increased media publicity has resulted in high expectations of cannabinoids<sup>15</sup>, particularly from families with children who have intractable epilepsy. The heightened prospect for the efficacy CBD contributes to a **significant placebo effect** and prompted many families to move to states like Colorado.<sup>16</sup> This factor alone seems to explain why this demographic were three times more likely to report improved seizures with cannabis compared with those who already resided in Colorado. Highly suggesting that the level of personal investment in receiving cannabinoid treatment contributes to perceived improvement.<sup>17</sup>

### 1.1.2 Adults

The TGA noted that available CBD adult related studies are also restricted to the “recommended daily dose based on weight and therefore is **limited to evidence about the safety profile for low dose CBD** in essentially an adult population (that is people of at least 60kg).”<sup>18</sup>

## 1.2 Health Risks

### 1.2.1 Drug interaction

Most notably, the report cited significant reservations in the use of CBD due to a **lack of critical evaluation on its interactions** with other **commonly prescribed drugs**. This should then serve as a significant qualifying factor before any decision to down schedule CBD as, “**further study was needed** on the action of CBD on hepatic enzymes, drug transporters and interactions with other drugs.

The data for drug interaction is not only scant but the degree of adverse risk remains substantial. The TGA observing a “**high potential for drug-drug interactions when used concomitantly with many other commonly prescribed drugs** that are metabolised via CYP pathways, currently there is **insufficient evidence as to whether these would not occur with the use of low dose CBD**.”<sup>19</sup>

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<sup>15</sup> <https://www.liebertpub.com/doi/10.1089/acm.2019.0428>

<sup>16</sup> <https://extras.denverpost.com/stateofhope/#part1> “An [early and oft-reported survey](#) of children on Charlotte's Web found that 80 percent who tried it eliminated at least three of every four of their seizures. Now, even one of the specialists involved in that study questions whether it was overly optimistic. Subsequent studies [have suggested](#) the response rate might be closer to 30 percent or, perhaps, even lower.

It's not just that parents are taking a gamble by moving to Colorado. It's that they don't even know the odds.

“When these kids come, we hear a lot about it,” said Dr. Larry Wolk, head of the Colorado health department and a skeptic of the treatment's success. “They get their CBD oil or their Charlotte's Web. And if they respond, we continue to hear about it. If they don't, they quickly disappear...”

“The migration to Colorado by families of sick children seeking medical marijuana is fueled by hope, not science. Little is known about the treatment's effects, and researchers suggest that some parents see progress because they're desperate to see it.”

<sup>17</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/dmcn.14087>

<sup>18</sup> <https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf>

Pg.10, Safety of low dose cannabidiol, version 1.0, April 2020

<sup>19</sup> Consumers seek CBD as a specific therapy for multiple diverse medical conditions—particularly pain, anxiety, depression, and sleep disorders. These data provide a compelling rationale for further research to better understand the therapeutic potential of CBD.

<https://www.liebertpub.com/doi/10.1089/can.2018.0006>

As CBD is most sought after for treating common ailments such as sleep, pain and depression disorders, a suspension on down scheduling should be considered. Particularly as many prescription medications for these conditions are readily available and come with their own set of idiosyncratic risks. A deeper assessment is needed to ascertain how they may interact with CBD.<sup>20</sup>

## 2. U.S. Review

Arguably some of the most compelling information and commentary regarding CBD is sourced from the American experience that began with California legalising medical marijuana in 1996.

Since then many other states have followed suit and as touched upon earlier has led to an influx of CBD infused products. The FDA lists the most popular.

“We’re seeing CBD being marketed in a number of different products, such as oil drops, capsules, syrups, food products, such as chocolate bars and teas, cosmetics and other topical lotions and creams, as well as products marketed for pets and other animals – and we understand consumers are seeking out these novel products for a variety of perceived health-related or other reasons.”<sup>21</sup>

### 2.1 Health Risks

CBD product proliferation has prompted a slew of **FDA warnings**<sup>22</sup> not dissimilar to those identified within the TGA review.

“As the agency has stated before, we are concerned that some people wrongly think that the myriad of CBD products on the market have been evaluated by the FDA and determined to be safe, or that using CBD ‘can’t hurt.’ Aside from one prescription drug approved to treat two rare, severe paediatric epilepsy disorders, no other CBD products have been evaluated or approved by the FDA. We remain focused on educating the public about the number of questions that remain regarding CBD’s safety. There may be risks that need to be considered before using CBD products outside of the monitored setting of a prescription from your health care provider.”

The FDA identified **health risks** arising from significant CBD knowledge gaps that include:

- potential liver injury,
- interactions with other drugs
- male reproductive toxicity
- drowsiness
- potential effects of sustained and/or cumulative use of CBD

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<sup>20</sup> Brown and Winterstein noted that the range of potential medicines that could be affected was **wide ranging** including immunosuppressants, antidepressants, opioids, statins, fungal treatments, antiepileptics, cimetidine and sartans. And may in factacerbate the very symptoms seeking relief, “therefore, some adverse effects such as somnolence, insomnia and sleep disturbances are likely to occur with sporadic and acute exposure, other effects such as liver function test abnormalities and weight loss would require prolonged exposure.”

<sup>21</sup> <https://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-public-health-providing-market>

<sup>22</sup> <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>

- co-administration with other medicines
- risks to vulnerable populations, for example -
  - o children,
  - o pregnant and lactating women,
  - o elderly,
  - o unborn children
  - o certain animal populations

While the marijuana industry remains incensed over the FDAs cautious approach doctors and drug professionals are issuing similar precautions.

In 2012, Colorado legalised both medical and recreational marijuana use. Since then, a considerable body of literature on the public health outcomes has become available.

Dr Karen Randall specialises in Emergency Medicine at Pueblo Colorado and is *Certified in Cannabis Science and Medicine*. In February this year she visited several Australian states speaking at public forums and with politicians cautioning against lobbying groups and commercial industry pushing to expand marijuana.

Initially ambivalent towards pro-marijuana legalisation efforts<sup>23</sup> she has since actively spoken out of her first-hand accounts on the wide-ranging devastating impacts of medicinal and recreational marijuana including CBD to the community. These insights are broken into specific health risks/concerns.

### 2.1.1 Abundant THC and Vaping

“CBD products [are] often not what they say on the bottle. Many indicate THC free but that is clearly not the case. Unless synthetic, there is THC in all the industry products.<sup>24</sup> There is minimal regulation on the content of these products. They are typically made in a process of extraction - butane or propane being the most common solvent. Here in the US, each state has its own set of laws regarding production of marijuana products. The Colorado state law, last I checked, did not have a limit on the amount of butane/propane that can remain in the final product. Since these are potent solvents, they obviously carry medical harms. There is minimal oversight on the contents of the products.”<sup>25</sup>

Lynn Riemer is the director of *ACT on Drugs*.<sup>26</sup> She joined Dr Randall in Australia. Lynn is an experienced chemist (DEA), former member of the North Metro Drug

<sup>23</sup> <https://www.youtube.com/watch?v=rUmiUWzjs1M>

<sup>24</sup> In a 2017 article Dr Randall states, “The industry has been irresponsible in ramping up the concentration of THC (the psychoactive portion of marijuana) in all products. The literature is clear that growing and developing brains are adversely affected by marijuana (and these studies were done with low potency marijuana). The medical community has no idea what high dose dabs, shatter, etc. will actually do to a developing brain. I have seen numerous elderly patients in the ED with acute psychosis, acute nausea and vomiting, and accidental overdose secondary to the high dose edibles. I have seen a tremendous increase in emergency room visits for nausea and vomiting associated with cannabis. The marijuana industry has claims that it will cure everything from Parkinson’s to insomnia, to pregnancy-induced vomiting (and more, you simply have to do a Google search to see what marijuana “cures or treats”). None of those claims have been supported with peer-reviewed research. The medical community has no idea what the long-term benefits or consequences from marijuana will be. Studies are ongoing, but it is anyone’s guess at this time. Most likely, most of the medical benefits will come from CBD (the non-psychoactive portion of marijuana) rather than THC. I have a friend who runs a large substance abuse program at the state hospital. She tells us that her methamphetamine addicts won’t use the marijuana here because it is too strong.”

<https://vtdigger.org/2017/06/20/karen-randall-marijuana-legalization-colorado-community-member/>

<sup>25</sup> see attachment to submission: Dr Karen Randall re CBD (1)

<sup>26</sup> <https://actondrugs.org/>

Task Force in Colorado and speaks regularly with students, community child advocacy groups, industrial and professional groups, and employees of local and State governmental agencies.

In recent correspondence asking specifically on observations surrounding CBD, she stated that the **risks associated with high THC-CBD were very real.**

“What I know is CBD and THC always go together unless they are synthetically made. If the CBD product is from a plant extract THC is always there. So, the potential to fail a drug test is real. You will find multiple cannabinoids in these products if tested - CBN, CBG, CBD, THC, etc. The problem is how much THC is in these products? From tests that have been run on the CBD products, **they are usually high in THC and little to no CBD.** If they are made from hemp seed oil, they have no CBD or cannabinoids in them. CBD is produced from the plant, not the seed. You might as well rub vegetable oil all over you. The majority of products claiming to contain CBD are fraudulent, containing no CBD and over 600 samples tested in Colorado showed most were THC-rich with no CBD and those containing CBD had on average 0.1%.”<sup>27</sup>

Furthermore, Reimer explains that the concerning high uptake of teen vaping extends to the use of CBD. “CBD is just another product to vape. They can vape any drug, but they do promote CBD and THC a lot! They have preloaded cartridges for many of the vapes. They sell CBD cartridges in gas stations/convenient stores here and they don't have CBD in them! They have ‘bath salts’ the dangerous designer drug with same base molecule as Meth and Ecstasy. Problem is there are often other compounds in these products as well and none are tested. I guarantee you the kids know all about all the drugs they can vape and buy in cartridges! If they aren't vaping marijuana cannabinoids now, they will be soon.”<sup>28</sup>

These insights when connected with the overwhelming research on the dangers of THC to developing brains particularly on the unborn<sup>29</sup>with the trend toward CBD use by pregnant mothers,<sup>30</sup>and earlier references to the already high use of marijuana among youth, all lean heavily towards deterring CBD down scheduling.

### 2.1.2 Contaminants

Dr Randall list many dangerous incidental chemicals used in product development. “There is minimal regulation on the content of these products. They are typically

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<sup>27</sup> See attachment to submission: Lynn Reimer email re CBD (1)

<sup>28</sup> See attachment to submission: Lynn Reimer re CBD (2)

Vaping is the fastest growing substance habit among youth. [https://www.youtube.com/watch?time\\_continue=7&v=G739xd-ncpl&feature=emb\\_logo](https://www.youtube.com/watch?time_continue=7&v=G739xd-ncpl&feature=emb_logo)

<https://www.health.harvard.edu/blog/can-vaping-damage-your-lungs-what-we-do-and-dont-know-2019090417734>

While THC from cannabis is the main substance used, there's almost no research on the side effects of vaping CBD (see:

<https://www.marijuanabreak.com/cbd/101/dangers-of-vape-pen-cbd-oil/>).

However, some reported side effects of [using CBD oil](#) include:

- fatigue,
- irritability,
- nausea.

These side effects tend to be mild. Marijuana and CBD e-liquids usually contain other chemicals, such as base liquids or flavouring agents. They may cause side effects similar to those of nicotine-free e-cigarettes.

<sup>29</sup> <https://neurosciencenews.com/thc-cbd-fetal-development-15169/>

<sup>30</sup> <https://hightimes.com/health/mothers-labor-using-cannabis-manage-pain-during-birth/>

<https://www.parents.com/pregnancy/everything-pregnancy/cbd-oil-for-pregnancy-how-moms-are-using-it/>



made...in a process of extraction - butane or propane being the most common solvent. Here in the US, each state has its own set of laws regarding production of marijuana products. The Colorado state law, last I checked, did not have a limit on the amount of butane/propane that can remain in the final product. Since these are potent solvents, they obviously carry medical harms. There is minimal oversight on the contents of the products.

Additionally, the products are not produced in sterile or sanitary conditions. There are so many products that have been shown to have contamination - heavy metals, bacteria, fungi, chemicals, pesticides, etc. In the process of concentrating the CBD (during the extraction process), all the bad things are concentrated as well.”<sup>31</sup>

### 2.1.3 Drug Interaction

As with the TGA, Dr Randall outlines her concerns of drug interactions. “CBD is metabolized by the P450 cytochrome system in the liver. Many drugs are. So, there is exceptional potential for drug-drug interactions when CBD is used. Some of the drugs included is warfarin (also known as coumadin - a potent blood thinner), seizure medications, HIV medications, etc. The list is long. There are now many reports of drug interactions with CBD.”<sup>32</sup>

CBD can also increase the level in your blood of the blood thinner coumadin, and it can raise levels of certain other medications in your blood by the exact same mechanism that grapefruit juice does.<sup>33</sup>

### 2.1.4 Dosing schedule

Broad public perception and industry narratives presenting CBD as benign, healthy, natural and organic alternatives seem to have fuelled an environment of little accountability or concerns surrounding dosing, prompting the FDA to issue numerous company warnings.<sup>34</sup> As Dr Randall puts it, “Since CBD is billed as being safe, healthy, beneficial, harmless, and there is no dosing schedule, **people are using CBD to excess**. Some of the **worst rashes that I have seen in the recent years** are from people who have applied CBD topically.”<sup>35</sup>

Nevertheless, dosing is purported as an attainable obstacle overcome through the use of full spectrum CBD products therefore benefiting the consumer from what is referred to as entourage effects<sup>36</sup>, but this supposed benefit has **been a topic of dispute among scientists** as discussed in the TGA review.<sup>37</sup>

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<sup>31</sup> Alice P. Mead, *Finding the Medicine in Marijuana*, Oct 1, 2015, GW Pharmaceuticals.

<http://www.nbcnews.com/storyline/legal-pot/legal-weed-surprisingly-strong-dirty-tests-find-n327811>

See attachment to submission: Dr Karen Randall re CBD (1)

<sup>32</sup> See attachment to submission: Dr Karen Randall re CBD (1)

<sup>33</sup> <https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476>

<sup>34</sup> <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>

<sup>35</sup> See attachment to submission: Dr Karen Randall re CBD (1)

<sup>36</sup> An extract from <https://www.health.com/condition/pain/what-is-cbd> explains:

“When thinking about dosing, also consider whether your CBD is full-spectrum or isolate: Full-spectrum could include other cannabinoids like cannabidivarin or cannabigerol (this is important, since ‘there’s something called the “entourage effect” when all together, they’re more effective than any one of them alone,’ Roth explains), while isolate is 100% CBD. ‘Some people might only need 10 milligrams of full-spectrum CBD, but with isolate, even taking 80 or 100 milligrams might not have the same effect,’ he says.”

<sup>37</sup> “Some researchers have claimed that the endocannabinoid system demonstrates an ‘entourage effect’, whereby ‘inactive’ metabolites and closely related molecules increased the activity of the endogenous cannabinoids, however the existence of an entourage effect remains disputed...Vast differences in bioavailability based on dosage forms and route of administration is feasible.”



And as already mentioned earlier from Dr Randall’s observations, **liver damage from high dosage** was ascertained in a study from the University of Arkansas for Medical Sciences, finding high doses of CBD brought about liver damage in mice within 24 hours. Many of the animals died or were close to death within three or four days. Countering the findings of this study, critics have argued that the dosage used was extreme. But again, this fails to take into account that the highest dosage used (615mg/kg for 10 days) was the **“the allometrically scaled mouse equivalent... of the maximum recommended human maintenance dose...”**

Put another way, “These doses were the allometrically scaled mouse equivalent doses (MED) of the **maximum recommended human maintenance dose of CBD in EPIDIOLEX® (20 mg/kg).**”<sup>38</sup>

Harvard University also cites dosing inconsistencies as considerably problematic. “A significant safety concern with CBD is that it is primarily marketed and sold as a supplement, not a medication. Currently, the FDA does not regulate the safety and purity of dietary supplements. So, you cannot know for sure that the product you buy has active ingredients at the dose listed on the label. In addition, the product may contain other (unknown) elements. We also don’t know the most effective therapeutic dose of CBD for any particular medical condition.”<sup>39</sup>

### 2.1.5 Other possible health risks from under or over labelling

Both Dr Randall and Lynn Reimer allude to this issue that finds corroboration in a 2017 study. Marcel Bonn-Miller, an adjunct assistant professor in the psychiatry department at the *University of Pennsylvania’s Perelman School of Medicine*, found that nearly 70 percent of CBD products they analysed were mislabelled.<sup>40</sup>

Approximately 40 per cent of the 84 items were “under-labeled,” meaning they had significantly more CBD than indicated and another quarter were “over-labeled,” meaning consumers were not getting a large enough dose to achieve any potential therapeutic benefit. Even more troubling, Bonn-Miller says, some CBD products may contain THC in amounts sufficient to intoxicate or impair.

This has ramifications for users inadvertently driving under the influence, testing positive on a workplace drug screen or experiencing what Bonn-Miller calls “a number of negative consequences, ranging from addiction to cognitive impairment, anxiety — particularly at high doses — and risk of psychosis.”

Moreover, with the range of edibles arising from increasing hemp food production, the FDA warns that many safety concerns are still left unanswered.

“To support CBDs broader use in FDA-regulated products, including in foods and dietary supplements, has resulted in unique complexities for its regulation, including many unanswered questions related to its safety.

For example, how much CBD is safe to consume in a day? What if someone applies a topical CBD lotion, consumes a CBD beverage or candy, and also consumes some

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TGA Safety of low dose cannabidiol, V1.0 April 2020, pg. 12-13.

<sup>38</sup> <https://www.mdpi.com/1420-3049/24/9/1694>

<sup>39</sup> <https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476>

<sup>40</sup> <https://jamanetwork.com/journals/jama/fullarticle/2661569>

CBD oil? How much is too much? How will it interact with other drugs the person might be taking? What if she's pregnant? What if children access CBD products like gummy edibles? What happens when someone chronically uses CBD for prolonged periods? These and many other questions represent important and significant gaps in our knowledge.”<sup>41</sup>

## 2.2 Health Benefits

While there is interest and potential in ongoing CBD trials, currently the available scientific evidence remains limited to medically approved CBD drugs for the treatment of rare medical conditions such as Dravet syndrome and Lennox-Gastaut syndrome.

Dr Randall reiterates what many outside the vested interests of marijuana lobby groups and industry have consistently stated, “CBD is mostly junk. There are minimal studies that are “real” studies that show CBD - as it is marketed now, has healing, curative or treating potential. The first CBD medication was “Charlotte’s Web”. This was an extract of CBD/THC and is used to treat paediatric seizures. The problem is that the true seizure disorders that this is indicated for are very limited. There is now a pharmaceutical grade medication - Epidiolex that can be purchased for seizures. There is a real dosing schedule as opposed to CBD bought in the store, over the counter.”<sup>42</sup>

Lynn Riemer also comes to the same conclusion, “I am big on science and even our Surgeon General came out said there is no science proving CBD treats anything these companies claims it treats. These are quotes from the release from FDA and SG. The FDA has not approved any CBD products other than one prescription human drug product to treat rare, severe forms of epilepsy (Epidiolex).”

*The Epilepsy Foundation* backs up such statements.<sup>43</sup> Outside of these limited medically approved drugs, “there is very limited information for marketed CBD products, which differ in composition from the FDA-approved product and have not been evaluated for potential adverse effects on the body.”

With both the “FDA, FTC warn[ing] companies marketing unapproved cannabidiol (CBD) products with unsubstantiated claims to treat teething and ear pain in infants, autism, ADHD, Parkinson’s and Alzheimer’s disease.”

This brings into focus another less discussed demographic negatively impacted from unsubstantiated or outright false CBD health benefits, **the elderly**. “CBD is being heavily marketed to the elderly population. Many seniors are not going to be convinced to use THC/hallucinogenic products, but many are looking for the “magic cure” for their ailments and can be duped into spending a lot of money on these products with no proven benefits,” says Dr Randall.

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<sup>41</sup> <https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-sharpless-fda-public-hearing-scientific-data-and-information-about-products-containing>

<sup>42</sup> [https://www.sciencedaily.com/releases/2020/02/2020227160545.htm?utm\\_source=feedburner&utm\\_medium=email&utm\\_campaign=Feed%3A+sciencedaily%2Fmind\\_brain%2Fmarijuana+%28Marijuana+News+--+ScienceDaily%29](https://www.sciencedaily.com/releases/2020/02/2020227160545.htm?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+sciencedaily%2Fmind_brain%2Fmarijuana+%28Marijuana+News+--+ScienceDaily%29)

<sup>43</sup> <https://www.epilepsy.com/article/2017/5/new-england-journal-medicine-publishes-data-purified-cbd-epidiolex-people-dravet>

Particularly as the health burden of an aging population and rates of Alzheimer's rise. "Ultimately, I think that there may be some benefits seen medically for parts of the cannabis plants. There is some anti-inflammatory properties. It does cross over into the brain, so there is a thought/theory that it may help with Alzheimer's. The industry has already made unfounded and incorrect conclusions based on this and already advertise that it treats Alzheimer's. Again, in the present form, it does NOT treat, cure or even alter Alzheimer's. There is a statement from the Alzheimer's society.<sup>44</sup> You can look it up. Basically, the conclusion is that it may help with some of the symptoms of Alzheimer's but its worsened confusion and other symptoms, making it potentially too risky to use. It is not recommended by the American Alzheimer's society," asserts Dr Randall.

A view also mirrored in the 2017 findings of *the National Academies of Sciences, Engineering and Medicine* convened a panel of experts to review the health effects of cannabis and cannabinoids. Examining more than 10,000 studies, most of which examined marijuana, **not CBD**, found evidence that some cannabinoids — not including CBD — are effective for pain, nausea from chemotherapy and muscle spasms in multiple sclerosis.<sup>45</sup>

In fact, in 2018 the TGA approved **Sativex for treatment of MS**<sup>46</sup> and other cannabis derived drugs are approved overseas but not registered in Australia, these include **Marinol, Cesamet and Epidiolex**.<sup>47</sup>

**With respect to CBD**, the panel found only a few small randomized clinical trials, and concluded that there was **insufficient evidence that CBD was effective** in treating conditions like insomnia, addiction to cigarettes and Parkinson's disease, and limited evidence in its ability to treat anxiety.<sup>48</sup>

Although even those currently against the dubious CBD health claims are not entirely dismissive that the future may show great potential for CBD health benefits. Dr Randall expresses the environment so far, "There are so many aspects to the harms of CBD with limited true benefits. Certainly, the benefits of CBD as a true 'medication' will not come from marijuana dispensary stores with little regulatory oversight.

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<sup>44</sup> <https://alz.org/news/2020/cannabis-helpful-or-harmful> "The availability of cannabis and cannabis-derived products — in natural and synthetic forms, such as oils, lotions, beverages, food and even dog treats — has sparked a lucrative industry, with some companies asserting dubious claims about their health benefits. Currently, there's a lack of research on the use of cannabis and cannabis-derived products to treat Alzheimer's and other dementias, and results from the small group of existing studies have been inconclusive."

<sup>45</sup> <https://www.forbes.com/sites/mikeadams/2019/07/07/fda-says-beware-of-cbd-for-these-reasons/#5b679efc300d>

"Some CBD manufacturers have come under government scrutiny for wild, indefensible claims, such that CBD is a cure-all for cancer, which it is not. We need more research, but CBD may be prove to be an option for managing anxiety, insomnia, and chronic pain. Without sufficient high-quality evidence in human studies we can't pinpoint effective doses, and because CBD is currently is mostly available as an unregulated supplement, it's difficult to know exactly what you are getting. If you decide to try CBD, talk with your doctor — if for no other reason than to make sure it won't affect other medications you are taking."

<sup>46</sup> <http://www.emergehealth.com.au/news/media-release-sativex-nabiximols-now-available-in-australia-for-ms-spasticity>

<sup>47</sup> Other cannabis medicines that have been registered by regulators outside of Australia, but are not registered in Australia, include:  
Marinol® (dronabinol) synthetically manufactured, and registered in the US by the Food and Drug Administration (FDA) for the treatment of anorexia in patients with AIDS, and for the management of chemotherapy-induced nausea and vomiting where standard anti-nausea treatments have failed.  
Cesamet® (nabilone) synthetically manufactured, and registered in the US by the FDA for the management of chemotherapy-induced nausea and vomiting.  
Epidiolex® (cannabidiol) plant-derived, and registered in the US by the FDA for the management of Dravet and Lennox-Gastaut syndromes.

<sup>48</sup> <https://www.nap.edu/read/24625/chapter/4#53>

And Lynn Reimer states, “I have friends using CBD products who swear by them. I think CBD has some medical properties, **but science should guide it not the marijuana industry.**”

This is not a unique view. By far this is the main concern that surrounds marijuana industry driven CBD “research” dominating the push for down scheduling based on unverifiable health benefits.<sup>49</sup> The billion-dollar marijuana industry has taken advantage of politicians through campaign contributions using federal spending bills to gain legitimacy, attract investment, and spend millions of dollars to legalise marijuana in other states. This is reminiscent of Big Tobacco for good reason. **The marijuana industry even boasts about soliciting money from Big Tobacco** in exchange for writing the laws favorably for tobacco companies.<sup>50</sup>

Spurious claims and currying political favour is something that even some insiders are warning against as this may ultimately turn public opinion.<sup>51</sup>

A *New York Times* editorial puts it most emphatically, “Don’t go chugging a shot of CBD oil just yet, though. Dr. Blessing said that much of the research is in its infancy, and the purity and dosage of some CBD consumer products may not be reliable. And, she noted, CBD can have negative interactions with many medications, so potential users should talk to their doctors before taking it.’

The frothy claims about CBD ‘sets up some false expectations that the molecule will never be able to live up to,’ Mr. DeLand said. ‘Not only are questionable claims an invitation for government regulation, but they risk making even legitimate applications seem dubious,’ he said.

‘In isolation, CBD obviously does have some benefits, but it’s certainly not a catchall for all the world’s health problems, he said. ‘We are at the tip of the iceberg on what its therapeutic applications are, and how to make those applications repeatable.’

‘The future of this industry, Mr. DeLand added, is going to be based on fact, not fiction.’<sup>52</sup>

De Land’s view is **supported far more widely** than the general public is led to believe from mainstream media.

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<sup>49</sup> <https://medicalxpress.com/news/2020-03-industry-wider-access-medical-cannabis.html>

<sup>50</sup> <https://www.bmj.com/content/368/bmj.m1044>

<https://cqcengage.com/learnaboutsam/home>

<sup>51</sup> <https://www.alternet.org/2019/07/cannabis-wont-solve-the-opioid-crisis-despite-what-norml-says-heres-why-thats-okay/>

<https://www.foxnews.com/opinion/cbd-oil-is-the-new-rage-among-millennials-but-as-a-doctor-heres-what-i-worry-about> “Let’s remember that when cigarettes first emerged on the market people used them to treat lung conditions and encouraged smoking. And we can’t forget the crisis that the once-promised long-acting, “less-addicting” opioids produced. Although the limited and short-term data on CBD oil is promising, I reserve caution until the long-term data proves it is more than a fad.”

<sup>52</sup> <https://www.nytimes.com/2018/10/27/style/cbd-benefits.html?auth=login-email&login=email&searchResultPosition=1>

### 3. UK Review

In April this year a study of over the counter CBD was conducted in the UK.

The results on health risks associated with under and over labelling correspond with both Australian and US findings suggesting this issue is endemic within the CBD industry.

The researchers summarised their findings: “Based on the knowledge that the quality of over-the-counter CBD products has often been found to be substandard in other countries, coupled with the large increase in consumer use of over-the-counter CBD products, we undertook an independent blinded analysis of 29 CBD oil products available in the United Kingdom. Our **results are similar to those that have been reported elsewhere**, that is, the **majority of products did not contain the amount of CBD advertised on the labeling**; the variation from the advertised CBD content ranged from 0 to 155%. Additionally, **more than half of the products contained the controlled substances THC and CBN**. These data add to the accumulating evidence that there **needs to be increased regulation of CBD products** to protect consumers.

In conclusion, our data add to the accumulating evidence that over-the-counter CBD products are often mislabelled with respect to the total CBD content and contain many phytocannabinoids that are not always labelled, including controlled drugs. This has significant implications on vulnerable consumers using these products with respect to efficacy, side effects, and drug testing.”<sup>53</sup>

#### 3.1 Health Risks

##### 3.1.1 Under and Over Labelling

The majority of products did not contain the amount of CBD advertised on the labelling. CBD content ranged from 0 to 155%. Consistent with studies in other countries, including Italy, Netherlands and the US, the quality of over-the-counter CBD products in the UK was overall substandard, particularly with regard to CBD content, and often contains levels of controlled substances.

Ultimately, this may lead to “negative experiences with CBD products will also lead to a reduced public perception of the usefulness of CBD products.”

##### 3.1.2 Dosing

The risks for incorrect dosing follow from this fact that so many available CBD products do not contain the advertised amount of CBD means that vulnerable consumers will not be receiving the “dose” of CBD that they think they are getting, probably leading to reduced or even no efficacy of the products.

Although not addressed in the report it may also have ramifications for overdosing as more of the product could be consumed in an attempt to relieve symptoms.

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<sup>53</sup> Mary Ann Liebert, Inc., publishers, April 1, 2020, Jonathan Paul Liebling, Nicholas James Clarkson, Blair William Gibbs, Andrew Stephen Yates, and Saoirse Elizabeth O'Sullivan. Cannabis and Cannabinoid Research. <http://doi.org/10.1089/can.2019.0078>

### 3.1.3 THC

More than half of the products contained the controlled substances THC and CBN. The study showed that 55% of products had measurable levels of THC or CBN. This was compared to the US that detected THC in 21% of CBD products and in most products in Italy. The health risks for consumers included intoxicating effects of THC or side effects that are attributable to THC, such as loss of memory, hallucinations, or paranoia. However, this is unlikely given the very low levels of THC in these products. Conversely, the presence of THC in CBD products could cause a consumer to test positively for cannabis use (which is based on THC metabolites), which could have significant consequences for professionals, particularly those with sports careers (CBD is increasing being used as an aid to recovery in sports).

### 3.1.4 Contaminants

Various contaminants at relatively small amounts were found including: n-pentane ethanol, ethyl acetate, isopropanol, heptane, cyclohexane, lead and arsenic. The researchers concluding that, “the percentage of solvents and heavy metals in all products was below the permitted daily dose levels in pharmaceutical products according to the International Council for Harmonisation guidelines, although above food limit safety levels. Thus, our data suggest that the range of solvents and heavy metals tested are not of concern in these UK products, at least of those tested in this analysis.”

## 3.2 Health Benefits

The aforementioned UK study makes no mention of the efficacy of CBD in treatment of symptoms but with the low degree of CBD detected, “patients are increasingly turning to over-the-counter cannabis-based products for relief for self-treatable symptoms. However, over-the-counter CBD is also used for relief from more life-threatening disorders such as childhood epilepsy because of the current inability to access CBD easily through the NHS. This is particularly important considering that the doses in over-the-counter products are already lower than used in CBD products being developed as registered medicines, and because of the poor bioavailability of CBD. Negative experiences with CBD products will also lead to a reduced public perception of the usefulness of CBD products... These data add to the accumulating evidence that there needs to be **increased regulation of CBD products to protect consumers.**”

Given CBDs popularity for treating brain related diseases like the US Alzheimer’s Foundation the UK also followed up with a disclaimer on the efficacy of CBD. It too concluded that there was currently limited value for CBD and overall, “there are **no research studies** that prove cannabis, or products such as cannabis oil (CBD oil), can stop, slow, reverse or prevent the diseases that cause dementia.”<sup>54</sup>

Sleep disorders represent one of the most sought after uses for CBD. One study assessed both these issues using CBD but was limited due to the study being only, “naturalistic...all patients were receiving open-label treatment, and there was no

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<sup>54</sup> <https://www.alzheimers.org.uk/about-dementia/treatments/alternative-therapies/cannabis-cbd-oil-and-dementia>



comparison group. Concurrent psychiatric medications were employed as in routine clinical care... Other researchers have noted that the large societal notoriety about cannabis and medical marijuana probably contributes to a larger-than-normal placebo effect.”

Overall researchers conclude that “presently cannabidiol **may hold benefit** for anxiety-related disorders [but] **controlled clinical studies are needed.**”<sup>55</sup>

#### 4. Supplementary Issues Concerning CBD

With proper rigorous research CBD may ultimately prove to have immense potential in relieving various illnesses and symptoms. But until then the most comprehensive studies show there is not sufficient evidence to support its hype as a new wonder drug<sup>56</sup> nor its down scheduling from a class four to three.

This is reminiscent of the sensationalism and the many unsubstantiated claims surrounding medical marijuana and its long strategic campaigning history.<sup>57</sup> Former director of NORML, Keith Stroup, in an interview with the *Emory Wheel* on February 6<sup>th</sup>, 1979 that he later disputed the inferred meaning, stated, “We are trying to get marijuana reclassified medically. If we do that...[we’ll] be using the issue as a red herring to give marijuana a good name. That’s our way of getting to them indirectly, just like the paraphernalia laws are their way at getting to us.”<sup>58</sup>

The cannabis industry remains at the forefront of the current CBD push as this potentially represents another enormous revenue stream with April 2020 forecasted to bring billions in sales. It therefore seeks to keep expanding its product diversification and distribution into new markets.<sup>59</sup>

For this reason, the TGA needs to consider both the overseas evidence for CBD health risks and benefits impacting consumer welfare above commercial interests. It is a far more difficult task to prosecute and curb products once a product becomes widely available and public perceptions become fixed, as the US is finding out.

Earlier reference was made to the FDA prosecuting false CBD claims including the treatment of opioid addiction and more recently to treat, prevent or cure COVID-19 and cancer.<sup>60</sup>

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<sup>55</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6326553/>

<sup>56</sup> <https://www.ontrackdiabetes.com/author/10060/harrar>

<https://www.nbcnews.com/think/opinion/cbd-oil-products-promise-miracle-creases-does-science-support-hype-ncna984216>

<sup>57</sup> <https://sciencebasedmedicine.org/marijuana-beliefs-outstrip-evidence/>

<https://cosmosmagazine.com/biology/the-bad-science-of-medical-cannabis>

<https://thenationalmarijuananeews.com/bad-science-behind-medical-cannabis/>

<sup>58</sup> <https://hitchensblog.mailonsunday.co.uk/2011/07/denying-reality-the-red-herring-of-medical-cannabis-and-the-long-goodbye-of-mr-f.html>

<https://www.nationalfamilies.org/legalization/redherring.html#herring>

<sup>59</sup> <https://www.denverpost.com/2018/05/14/marijuana-growers-cbd-extracts/>

<https://www.investopedia.com/biggest-challenges-for-the-cannabis-industry-in-2019-4583874>

<https://www.medicalmarijuanainc.com/marijuana-industry-overview/>

<sup>60</sup> <https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-cbd-products-treat-medical-conditions-opioid-addiction>

<https://www.law360.com/articles/1268780>



## 4.1 Organised Crime

But there are other concerns that are well documented within the marijuana industry including the longstanding dominance of organised criminal cartels in western markets.<sup>61</sup>

The legalisation of medical marijuana of which CBD forms one basis has, possibly unwittingly, made law enforcement and prosecution of marijuana trafficking extremely complex as illicit activities are masked behind legal operations.<sup>62</sup>

Added to this, marijuana legalisation has caused prices to fall that is in turn incentivising the manufacture of new product ranges such as CBD.<sup>63</sup> As a consequence both legal and illegal CBD markets are flourishing.<sup>64</sup>

There is no reason to assume that this pattern would not find replication in Australia. The traditional source of illicit drug profits, cannabis cultivation and distribution, still constitutes an estimated 80 to 90 per cent of the market and remains in the firm grip of organised criminals. Findings affirmed through multiple criminal intelligence reports and consistently supported by several royal commissions.<sup>65</sup>

## Conclusion

While there is much enthusiasm and promise for the eventual use of further CBD medications, the necessary proven clinical studies<sup>66</sup> to support the efficacy of low dose CBD are yet to materialise but so too there are many associated risks as an over the counter product, as this is in part attributable to its production and revenue appeal both within legal and illegal marijuana markets.

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<sup>61</sup> In the U.S., the vastly outnumbered Californian Fish and Game Wardens are fighting the forced takeover of local and state federal parks (often adjacent to suburban homes) and wildlands against Mexican drug cartel-sponsored marijuana farmers that are well armed and unafraid of protecting themselves and their lucrative product with firepower and booby traps.

“Above the quiet, calm, and affluent community of Saratoga, today’s mission would take us into another steep canyon, this time on Midpeninsula Open Space property. Alarming close to a wooded community of owners of custom-built houses, this grow site was just like the day before—perfectly positioned and well-hidden with an excellent year-round water source. And like so many other grow sites we found throughout the Santa Clara County foothills; it was insidiously located right under the nose of so many people.”

John Nores Jr.; James A. Swan. *War in the Woods: Combating the Marijuana Cartels on America’s Public Lands*, Kindle edition (Kindle Location: 1017-1020).

<https://www.nbcnews.com/news/us-news/foreign-cartels-embrace-home-grown-marijuana-pot-legal-states-n875666>

<sup>62</sup> <https://cannabisnow.com/hemp-makes-marijuana-crimes-difficult-to-prosecute/>

<https://www.hudson.org/research/6095-up-in-smoke>

<https://www.marketwatch.com/story/federal-prosecutors-investigate-california-marijuana-companies-in-wide-ranging-probe-2020-03-02>

<https://mjbizdaily.com/wp-content/uploads/2020/04/US-Attorney-letter-to-Ghost-Management.pdf>

<sup>63</sup> <https://www.denverpost.com/2018/05/14/marijuana-growers-cbd-extracts/>

<sup>64</sup> <https://www.nbcnews.com/news/us-news/foreign-cartels-embrace-home-grown-marijuana-pot-legal-states-n875666>

<https://www.cbsnews.com/news/mexico-cartels-landscape-rising-violence-el-chapo-sons-el-mencho-sinaloa-jalisco-new-generation/>

“Stratfor also noted an **increase in 2019 in production of concentrated cannabis oil**. Often smuggled in buckets, it’s more compact and easier to move across the border than the huge marijuana bales of old and can be used to make edibles and other products.”

<https://themazatlanpost.com/2019/02/20/mexican-companies-prepare-to-be-the-giants-of-medical-marijuana/>

<https://wtkr.com/2020/01/08/drug-cartels-caught-carrying-new-form-of-marijuana-across-border/>

<sup>65</sup> Small, C and Gilling T, *Evil Life: The true story of the Calabrian mafia in Australia*, Allen & Unwin, NSW. 2016, p.145 & pp.222-223.

In Australia, this has meant positioning drug manufacture activities on the most fertile land such as the Riverina and abundant water supply regions including the Murrumbidgee Irrigation Area the major tributary of the Murray River (area so desperately contested for competing water rights), spread across thousands of hectares found in every state using crown land and farmers often indebted and exploited to leasing land for cash. But the waste it is also seen from the chemical waste and drug toxicity detected in waterways.

<sup>66</sup> Clinically, CBD is still being investigated in phase 2 and 3 trials in diverse areas including schizophrenia, drug dependency, tumour reduction, pain conditions, and post-traumatic stress disorder.



It bears mentioning once again that wide scale CBD marketing efforts exerted today cannot be entirely separated from earlier marijuana campaigns including that of tobacco companies. There are too many similarities to ignore.<sup>67</sup>

Therefore, at this stage, Dalgarno Institute does not support any down scheduling but submits that CBD remain as a medicine requiring a medical prescription to authorise supply.

In the process we also encourage TGA approved CBD to become easier for patients to access so as not to motivate seeking untested CBD products.

Once again, on behalf of the Dalgarno Institute we thank you for the opportunity to offer our research perspective and welcome any enquiries.

Your faithfully,

  
The Dalgarno Institute 

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<sup>67</sup> A mere cursory glance at the persistence of advertising agencies and company marketing budgets reveals their belief on the power of persuasion. What is now known due to decades of fighting corporations (in 1998 tobacco companies spent nearly \$7 billion, more than \$18 million a day, to advertise and promote cigarettes — CDC) and the courage of industry whistle-blowers, is that tobacco firms and vested interest groups actively obscured, lied and denied cigarette harms and made concerted marketing efforts to target the young. Doctors joined ranks with tobacco companies offering their expert opinion on the safety of cigarette smoking. See: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1470496/> and <https://med.stanford.edu/news/all-news/2015/07/physicians-testified-for-tobacco-companies-against-plaintiffs.html>

## Appendix/Attachments

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*Alice P. Mead; Finding the Medicine in Marijuana; Oct 1, 2015; GW  
Pharmaceuticals <http://www.nbcnews.com/storyline/legal-pot/legal-weed-surprisingly-strong-dirty-tests-find-n327811>*

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<https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>

<https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>

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