



Promoting Illicit Drug Prevention Initiatives Nationally

16 January 2023

Proposed reforms to the regulation of nicotine vaping products

Therapeutic Goods Administration

PO Box 100

WODEN ACT 2606

Drug Free Australia responses to proposed reforms

Drug Free Australia works towards the prevention of use of substances that cause unacceptable individual and societal harm.

Nevertheless we are libertarian in our socio-political policy – where we believe a population should have the liberty to freely trade and use those things which do not harm others. Like libertarian John Stuart Mill, we recognise that many drugs of addiction incur unacceptable harms to others as well as to the individual user, and for that reason we seek to educate members of Parliament in the science concerning these harms as it comes to light and also seek the regulation or prohibition of such substances.

1. Do you support restricting or prohibiting the inclusion of flavours in NVPs? If so, which flavours would you like to see restricted? Should all flavours be prohibited or should tobacco flavour still be permitted?

Because Drug Free Australia takes a libertarian position where those things which do not cause unacceptable harms to the individual and the rest of society should be freely permitted, we support vaping products of any flavour, other than tobacco flavour, that are certified free of nicotine.

As per a later question, we urge the TGA to take control of importation of ALL vaping products coming into the country, only allowing non-disposable products for prescription users AND disposable vaping products for importation which cannot be repurposed for the vaping of other harmful substances. This would require disposable vape products to be produced in such a way that they cannot be opened to introduce any other liquid once spent. This would put the onus on manufacturers who want to access the Australian market to design their product to meet Australian regulations.

Tobacco flavour must not be permitted because it is likely to predispose an individual to trying tobacco in some other form by getting a taste for the substance – the very thing the Australian community seeks to discourage.

2. Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients? Why?

Our position is that any ingredients that are identified as causing unacceptable physical harm should be excluded. If the science ultimately concludes that vaping solutions will not work without such harms, then TGA approval for such products should cease.

We have considerable concerns about the recreational use of cannabis, given that the scientific understanding of its physiological harms to the user and their children and grandchildren – where in vitro and animal studies had established very considerable harms decades ago - have now been confirmed in 2021 and 2022 medical journal studies at the population level. Such population studies have analysed the full US disease burden, as well as 27 European countries as it relates to the relative use in states or countries, and the agreement between both these vast populations gives considerable confidence regarding those harms. Such harms, newly confirmed, are that cannabis is likely causal in:

- 33 cancer types (as against 14 for tobacco)
- 70% of pediatric cancers
- 89 of 95 birth defects
- Accelerated aging by 30% in users

We have appended full documentation on these new findings, which apply even moreso, in many cases, to Cannabidiol (CBT) as compared to any other cannabinoid.

We note that any pharmaceutical drug brought to market with this kind of risk profile would be immediately banned by the TGA.

Therefore it is of utmost importance that any product be as closely monitored for cannabis as much as for nicotine. We incidentally note that medicinal use of cannabis will be threatened by the medical journal study results.

3. Do you support introducing plain packaging requirements for NVPs? If so, should this entail packaging similar to other prescription only medicines, or should additional measures be considered?

In our view, plain packaging is mandatory because of diversion to minors as well as those who have never previously used nicotine. The packaging should follow the existing guidelines for cigarette packaging.

4. Do you support introducing additional warning statements for NVPs? If so, which warning statements should be included? How would this align with the treatment of NVPs as prescription-only medicines?

We support standards for NVPs being the same as for cigarette packaging, with additional warnings appropriate to the harms of the NVP mode of delivery.

5. Do you support restricting nicotine concentrations in NVPs to 20mg/mL (or base form equivalent concentration for nicotine salt products)? If not, what alternative do you support?

100 mg/mL is too high. We support the concentration that provides the least nicotine harm (heart issues, blood pressure etc) while providing adequate nicotine to satisfy a smoker's demand for nicotine – recognising that dosing demand is as much driven by habit rather than by craving. This may require more research.

6. Do you support limiting the maximum volume of liquid NVPs? If so, what maximum volume should be specified?

If the TGA centrally controls the importation of all NVPs and regulates to suppress the black market, we do not have an opinion on volume.

7. Do you support preventing access to disposable NVPs?

As per our response to Question 1 - we would support disposable NVPs if they are designed to be unusable once spent. This would put the onus on manufacturers wanting to access Australian markets to design such a product if they wanted to get TGA approval.

8. Would any of these options have an impact on you? How?

Drug Free Australia has no conflicts of interest. There would be no impact on our organisation.

9. If new restrictions were to be introduced how much time would you require, if any, to become familiar with the reforms, and to organise procurement of compliant products as necessary, before the reforms come into effect?

Drug Free Australia is a drug prevention entity, not a provider of products.

10. Are there any other potential minimum requirements for unregistered NVPs that the TGA should consider including in TGO 110?


Drug Free Australia supports the removal of importation rights for individual prescription, where the TGA should rather regulate importers and the products they wish to import and then on-sell. Regulation should monitor importation and national distribution in such a way as to be able to identify those suppliers who are likely to be feeding a black-market, where TGA monitoring of sales to individuals with a prescription can be centrally monitored.

In this scenario there would be no unregistered NVPs. Customs would still need to monitor for NVPs in novel forms.

We also support the TGA monitoring vaping products for nicotine where the product claims no nicotine, with a 'one strike and you're out' proviso for manufacturers. This would require a monitoring of imports to ascertain the specific manufacturer for each product imported, which would no doubt require more documentation and constant vigilance.

We trust that you find our responses helpful.

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A background image of cannabis leaves, with a central dark green panel containing text. The leaves are shown in various shades of green, from light to dark, and are arranged in a way that suggests a growing plant. The central panel is bordered by thin orange lines.

The current science . . . how can cannabis possibly remain legal?

**Massive population studies
published in 2021 and 2022 for the
US and Europe are confirming what
in vitro and animal studies
had shown decades ago
- that cannabis causes many
cancers, more than twice as many
as tobacco, contributes to most birth
defects, and accelerates
aging by 30%.**

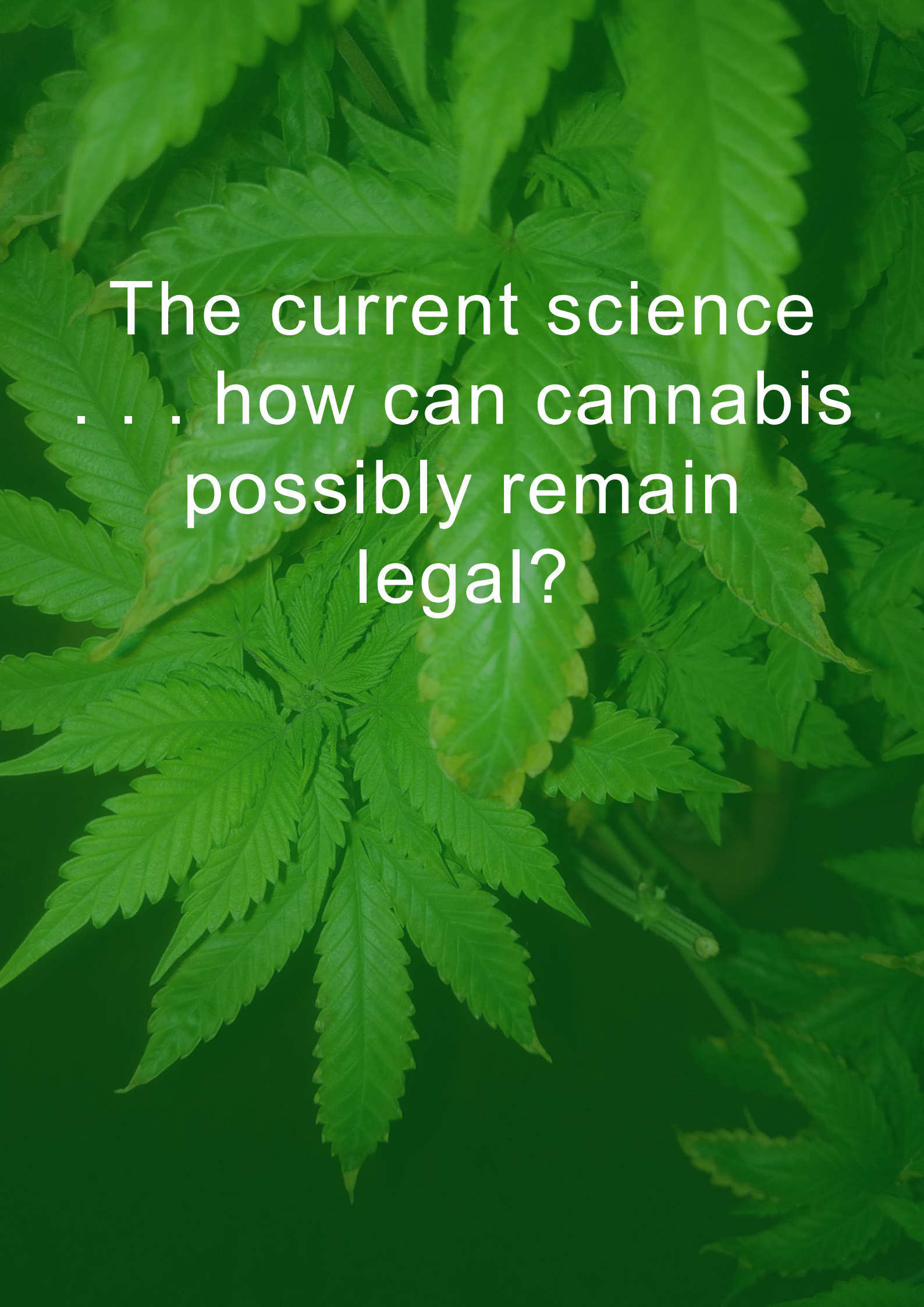
Cannabidiol (CBD) is not exempt.

**DRUG
FREE
AUSTRALIA**

This document presents with URL links to the abundant science showing that cannabis delivers more death and damage than other illegal drugs such as heroin, speed, ice and cocaine, with the added deficit of deleteriously affecting any cannabis user's children and multiple generations to come.

It's medicinal benefits have been, perhaps purposely, over-hyped, and are far outweighed by its risks.

Legislators must act now.



The current science
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Executive Summary

1. Research has established over a period of **50 years** that cannabis is genotoxic, mutagenic, oncogenic and teratogenic, meaning that **cannabis destroys genetic information in the cell, causing mutations which then cause cancers and birth defects.**
2. In 2021 and 2022, vast population studies for the entire US and also for 27 countries in Europe have demonstrated what in vitro and animal study research had already demonstrated, **that cancers, including childhood cancers, and birth defects had strongly elevated levels in those US States or European countries which have high cannabis use due to cannabis legalisation/liberalisation regimes.**
3. **Cannabis is causal in 33 cancers as compared to tobacco which causes 14.** Regulatory agencies would withdraw pharmaceutical drugs with this profile, and medicinal cannabis needs to be withdrawn, perhaps excepting children with epileptic-like seizures.
4. The **methodology** for these studies has been recorded in one of the world's top scientific journals, **Nature - Scientific Reports.**
5. Recent population studies have demonstrated that **cannabis is contributing significantly to the autism epidemic.**
6. The studies demonstrate that birth defects are caused by the parental use of cannabis by both mother and father. This is due to **cannabis use literally shattering chromosomes**, where the body's DNA repair mechanisms sometimes fail, causing mutations. These mutations are passed on to future generations, with cannabis significantly degrading the human genome.
7. A recent phenomenon, which reprises the **Thalidomide** birth defects of 50 years ago, where babies are **born without limbs**, correlates strongly to areas where cannabis has been fed to farm animals and become part of the human food chain. This again establishes the teratogenic nature of cannabis.
8. Research in 2022 also demonstrated that cannabis **prematurely ages** users by an accelerated 30%.
9. Older research has demonstrated that cannabis causes **30% of new psychosis/schizophrenia diagnoses in London, and 50% in Amsterdam.** It has also been shown to be causal in violence and homicide.
10. Despite public misunderstanding, medicinal cannabis carries all of the harms of recreational cannabis use - cancers, birth defects, aging, psychosis etc.
11. **Cannabidiol (CBD) is the most cancer-causing** of the cannabinoids in cannabis, **causing 12 of 27 cancers** identified in an early population study. It is also the major cannabinoid that is causal for autism and some other birth defects.
12. CBD can be converted in laboratories **into Delta-8-THC**, which is as psychactive and as dangerous as Delta-9-THC.
13. CBD can still contain small quantities of THC which due to the long half-life of the substance, can accumulate in the body. **CBD thereby does not exempt users from the dangers of THC.**
14. **Hemp seed food ingredients** also will have small quantities of THC which, because of the amounts consumed, **can deliver THC amounts in excess of limits set by specific US States.**

The latest science on cannabis and cannabinoids

Genotoxic nature of cannabis known for decades

For more than 50 years via *in vitro* and animal studies cannabis research has overwhelmingly demonstrated the genotoxic nature of cannabis.

The conclusion of an extensive 2009 review of 5,198 studies on cannabis concluded, "Chronic cannabis use is associated with psychiatric, respiratory, cardiovascular, and bone effects. It also has oncogenic, teratogenic, and mutagenic effects all of which depend upon dose and duration of use."

Thus there should be no surprises concerning what the latest vast population studies are demonstrating.

Population studies now confirm the research

2016 marked the year when the mechanisms behind the oncogenic, teratogenic and mutagenic nature of cannabis have been fully confirmed, and only since late 2021 and early 2022 that nationwide studies have been completed and published in medical journals which allow the full impact of cannabis use to be gauged at the population level.

Methodology published in top science journal

The various geospatial-temporal studies on the population impacts of cannabis have now been published in more than a dozen medical and scientific journals, with one of these studies with a clear explication of methodology, published in one of the world's top science journals, Nature - Scientific Reports.

For the first time geospatial-temporal programming has allowed previously unmanageable amounts of population

data - specific nationwide diseases, differing cannabis use statistics by state or country, specific cannabinoids found in drug control seizures by jurisdiction, confounding other drug use, socio-economic confounders - to be combined to reveal cannabis health impacts. This has been combined with a whole range of tools - mixed effects, panel, robust and spatiotemporal regression modeling, inverse probability weighting and expected values (E-values) to make causal inferences, where E-values higher than 9 are considered high.

Immense populations studied

A strength of these population studies is the very large populations of the US and multiple European countries studied, as well as the very significant numbers of cancer or birth defect incidence in any given year. For instance, the US expects more than 1.8 million new cancer diagnoses in a given year (2020) while these population studies typically work with 15 years of cumulative cancer or birth defect data.

Future generations adversely affected

Significant within these studies is the commentary on the epigenomic effects of cannabis indicating that the genotoxic damage of cannabis is passed epigenetically to future generations, raising ethical and moral concerns about its use either medically or recreationally given that its damages do not only affect the individual user. With 1,754 megabases of the 3,000 megabases of the total human genome liable to damage, 59% of the human genome is affected.

Research further shows that it is a mistake to believe that only the mother using cannabis while pregnant is responsible for intergenerational birth defects or pediatric cancers, as alterations to the father's sperm are also implicated.

Cannabis not fit for human consumption

Thus, the very recent science, which confirms what has been known for decades, now gives a clear understanding of the negative physical implications of any cannabis use, quite apart from the psychological damages. **It renders cannabis no longer acceptable for any kind of human consumption.** Perhaps the only defensible use remaining is for children with epileptic-like seizures where the benefits for the 40% that respond might arguably outweigh the risks.

It is crucial that legislators, media and regulators recognise that if smoking tobacco was recommended to alleviate any long-term medical condition it would never be treated seriously given the relationship between smoking and cancers. With cannabis, whether smoked or ingested, the relationship with cancers, birth defects and premature aging all persist.

The latest science

We will here cite summary text of the current science deriving from the many geospatial-temporal studies:

More than twice as many cancers as for tobacco

"These cancers have been causally associated with cannabinoids in studies based in the United States and Europe:

United States (25/28 cancers):

All cancer, acute lymphoid leukemia, acute myeloid leukemia, bladder, brain, breast, chronic myeloid leukemia, chronic lymphoid leukemia, colorectal, Kaposi, kidney, liver, lung, melanoma, myeloma, Hodgkins and non-Hodgkins lymphoma, esophagus, oropharynx, ovary, pancreas, prostate, stomach, testis, and thyroid;

Europe (33/40 cancers):

Acute lymphoid leukemia, acute myeloid leukemia, bladder, breast, chronic myeloid leukemia, chronic lymphoid leukemia, colorectal, hepatocellular, Kaposi, kidney, liver, lung, myeloma, melanoma, Hodgkins and non-Hodgkins lymphoma, esophagus, oropharynx, ovarian dysgerminoma germ cell tumor, pancreas, prostate, stomach, testis, non-seminoma of testis, and thyroid. In addition to those identified in the United States: Anus, penis, corpus uteri, gall bladder, larynx, mesothelioma, testis seminoma, and vulva."

There are 14 cancers historically tied to the use of tobacco, which these studies likewise find and thus confirm. However, with a total of 33 cancers likely caused by cannabis, there is more than a doubling of cancer risk presented by cannabis use as opposed to tobacco.

Cannabidiol (CBD) most implicated in cancers

Of the specific cancers related to cannabis as identified in these recent causal-inference studies, it is notable that all of the cannabinoids tracked within the studies contribute to cancer incidence. However, Cannabidiol (CBD), which is largely promoted as benign, is likely causal in twice as many cancer types than the psychoactive THC. This presents major

risks to medicinal cannabis users who are moving more and more towards CBD preparations particularly as an adjunct to opiates for chronic pain.

Cannabis likely causal in pediatric cancer increases

A study published in the medical journal BMC Cancer in February 2021 demonstrated that rising rates of childhood cancers, which have increased by 49% since 1975 throughout the United States, are closely related to increased cannabis use in US States that have decriminalised or legalised cannabis for medical and recreational use. A causal relationship of cannabis to these cancers is demonstrated, indicating that cannabis particularly should not be used by women during pregnancy.

Data from the US Centers for Disease Control and Prevention (CDC) indicates that cancers such as leukemias, neuroblastoma, soft tissue sarcoma, lymphoma, testicular cancer and cancers of the brain and nervous system in under-20 year olds have all increased. These comprise 60-70% of all pediatric cancers, with previous studies linking many of them to parental cannabis use.

Pediatric cancers are conceptually important as they represent transgenerational and likely multigenerational transmission of heritable genotoxicity and epigenotoxicity.

Likely causal in 89 Of 95 birth defects

Most birth defects have now been linked to cannabis use. Again we cite the summary text of the current science.

"These systems and congenital anomalies have been causally associated with cannabinoids:

Systems found to be particularly affected in both the United States and Europe: Central nervous system, cardiovascular, chromosomal, orofacial, limb, gastrointestinal, uro-nephrological, body wall, and general;

Congenital anomalies found to be particularly affected in the United States: 46 of 62 anomalies;

Congenital anomalies and systems found to be particularly affected in Europe: 90 of 95 anomalies and systems:

Forty shared anomalies: anotia/microtia, interrupted aortic arch, aortic valve stenosis, atrial septal defect, atrioventricular septal defect, bilateral renal agenesis, bladder extrophy, choanal atresia, chromosomal anomalies, cleft lip and cleft palate, cleft palate alone, club foot, coarctation of the aorta, congenital cataract, diaphragmatic hernia, double-outlet right ventricle, Down syndrome (trisomy 21), Edward syndrome (trisomy 18), encephalocele, deletion 22q11.2, congenital hip dislocation, Hirschsprung's disease (congenital megacolon), holoprosencephaly, hypoplastic left heart, hypospadias, large intestinal/ rectal/anorectal atresia/stenosis, limb reduction anomalies, microphthalmos/anophthalmos, esophageal atresia/stenosis (+ tracheoesophageal fistula), omphalocele, Patau syndrome (trisomy 13), congenital posterior urethral valve, pulmonary valve atresia, single ventricle, small intestinal stenosis or atresia, spina bifida

(without anencephalus), tetralogy of Fallot, total anomalous pulmonary venous return, Turner syndrome (female XO), and ventricular septal defect.”

Limbless babies from cannabis in food chain

The latest research is uncovering the congenital anomaly effects of cannabis as it relates to the substance entering the food chain as feed for animals, where the animal products - meat, milk, cheese, eggs - are then consumed by humans. Of most concern is that food-chain cannabis is acting as the new Thalidomide, causing limbleness in human babies. A study published in the International Journal of Environmental Research & Public Health in September 2022 records,

Particularly concerning in this regard is the well documented exponential dose response of cannabis genotoxicity [12 – 18]. It might be reasonably expected that a marked jump in community cannabinoid exposure could be expressed as a switch like mechanism in epidemiological patterns of disease as indeed appears to have occurred recently in north-eastern France where both calves and human babies are suddenly being born without limbs at greatly elevated rates 60-times those of background [19–21]. There are indications that in these areas large crops of cannabis are being cultivated and food chain contamination seems likely. Since epidemiological studies have confirmed that the exponentiation of cannabinoid genotoxicity seen in the laboratory is also reflected in patterns of congenital anomaly incidence [1,3,4,8,22–25] a relatively abrupt rise in community cannabinoid exposure would be expected to be associated with a relatively sudden and abrupt step-wise rise in congenital anomaly rates. This issue seems to not be well understood in the public health community.

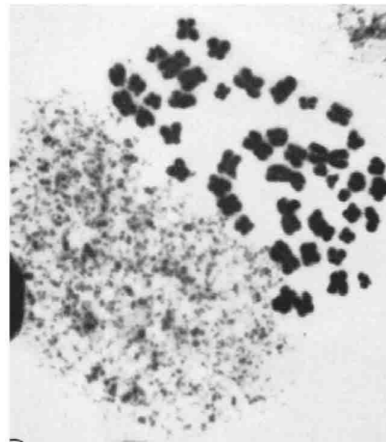


Fig. 1. Chromosomal Pulverization. Original Report of Chromosomal Pulverization. Figure 7 . Kato H., Sandberg AA (1967). "Chromosome Pulverization in Human Binucleate Cells. Following Colcemid Treatment." J. Cell Biol. 34 (1): 35–45. Re-used by permission.

Cannabinoids act directly on chromosomes, literally shattering or pulverising them. This process of 'chromothripsis', first discovered in 1967, should be able to be reversed by the body's DNA repair capabilities, which normally have sophisticated verification mechanisms with an error or mutation rate of 10^{-8} . In germ cells the rate is 100 times lower. Chromothripsis explains "the high rate of micronuclei, chromosomal fragments and abnormal chromosomes (truncated arms, chain and ring chromosomes and double minute circles) which are frequently seen in malignant tissues."

Chromothripsis, combined with epigenetic mechanisms which entail mutations being passed to future generations, well explains the mutagenic nature of cannabis, as well as the many congenital abnormalities associated with its use.

Causes 50% of new psychosis in Amsterdam

At the Geneva Drug Convention deliberations in 1925 cannabis was first made illegal with the advice of Mr El Guindy from the Egyptian delegation being part of the evidence. El Guindy reported that cannabis could produce a delirium which "takes a violent form in persons of violent character" and also that "the addict very frequently becomes neurasthenic and, eventually, insane."

While the pro-cannabis lobby habitually ridiculed this evidence, saying it was as concocted as the 1930's movie *Reefer Madness*, scientific research has established that the original advice was correct.

The research link between cannabis and psychosis was first suggested in a 1987 Swedish study which found a 6 times elevated risk of schizophrenia for those who had used cannabis 50 times or more. Follow-up studies from

the Netherlands by Van OS in 2002 and many since have now been verified in five major reviews.

The 2017 US National Academies of Science review of reviews found that,

The association between cannabis use and the development of a psychotic disorder is supported by data synthesized in several good-quality systematic reviews. The magnitude of this association is moderate to large and appears to be dose-dependent, and it may be moderated by genetic factors. Factors contributing to the strength of the evidence derived from the cited systematic reviews include large sample sizes, the relative homogeneity of the findings, the presence of relationships between the dose/ exposure and the risk, the studies having been controlled for confounders, and the systematic reviews having assessed for publication bias. The primary literature reviewed by the committee confirms the conclusions of the systematic reviews, including the association between cannabis use and psychotic outcome and the dose-dependency of the

effects, further bolstering the overall strength of evidence for our conclusions.

In a 2019 Lancet study by Kings College of London, Di Forti et al. determined that 30% of new psychoses/schizophrenia diagnoses in London, and 50% in Amsterdam were caused by high-THC forms of cannabis such as skunk.

Cannabis causal in bipolar development

The aforementioned 2017 review of reviews by the US National Academies of Science also concluded that,

There is limited evidence of a statistical association between cannabis use and the likelihood of developing bipolar disorder, particularly among regular or daily users.

Cannabis causal in violence

The anecdotal evidence coming from women's refuges, where staff report a strong representation of cannabis-induced violence from partners, albeit often from temporary cannabis withdrawal, has been demonstrated from research which has sought to exclude confounders such as alcohol use, antisocial personality syndromes and relationship satisfaction factors.

Other research into correlations between cannabis and violence has included longitudinal studies which look at the development of violent behaviours as they relate to cannabis use. Yet other studies examine the linkages between cannabis use and criminal behaviour.

Cannabis use and violent homicide

As a correlation that can only be examined after the fact, the evidence necessarily derives from court proceedings, most often tracked in newspaper articles. Extensive evidence for this correlation is found in the book by the former New York Times reporter Alex Berenson in his book "Tell you Children." One example amongst the dozens of reports and studies recorded in the book is that of Raina Thaiday, an Australian woman from Cairns, Queensland, responsible for murdering eight children, seven her own and one niece all at the one time. The court judgment stated that Thaiday,

"was suffering from a mental illness, paranoid schizophrenia, and that she had no capacity to know what she was doing was wrong."

and

"Thaiday gave a history of the use of cannabis since she was in grade 9 . . . All the psychiatrists thought that it is likely that it is this long-term use of cannabis that caused the mental illness schizophrenia to emerge."

The linkage between psychosis/schizophrenia and homicide is as uncontroversial as that between cannabis and psychosis/schizophrenia. Thus court judgments that make the step of linking cannabis to homicide is founded on a weight of evidence.

The linkage between mass murders in the US and long-term cannabis use is controversial, but is currently being tracked for future study.

What we already knew about cannabis

Decades of research on cannabis have indicated a long list of harms.

- Cannabis is an established gateway to other dangerous drugs, adding an additional gateway beyond the two existing legal drugs
- Cannabis users are 50% more likely to develop alcohol use disorder
- Cannabis is associated with Amotivational Syndrome
- Cannabis use is associated with a 3 fold risk of suicidal ideation
- Brain Function
 - Verbal learning is adversely affected
 - Organisational skills are adversely affected
 - Cannabis causes loss of coordination
 - Associated memory loss can become permanent
 - Cannabis is associated with attention problems
- Drivers are 16 times more likely to hit obstacles
- Miscarriage is elevated with cannabis use
- Fertility is adversely affected
- Newborns are adversely affected with appearance, weight, size, hormonal function, cognition and motor function adversely affected through to adulthood
- Cannabis use causes bronchitis
- Testicular cancer is associated with cannabis use
- Cannabis is also associated with cardio-vascular stroke and heart attack, with chance of myocardial infarction 5 times higher after one joint

According to the most authoritative 2017 review on cannabis by the US National Academies of Medicine, medicinal cannabis had scientific support for the treatment of only the following:

- Chronic pain – modest effect only
- Nausea – with most other available options more effective
- Multiple Sclerosis (MS) – modest effect only
- AIDS wasting – with many other better options available
- Tourette Syndrome
- Post Traumatic Stress Disorder (PTSD)
- Traumatic brain injury, intracranial haemorrhage

Treatment of childhood epilepsy-like syndromes via the use of CBD-based Epidiolex was demonstrated after 2017.

Medicinal cannabis carries all the harms

For all the harms of cannabis that have come to light through careful research, the persistent perception amongst the public is that any harms to recreational users do not in any way accrue to medicinal cannabis patients.

Nothing could be further from the truth. Excluding preparations high in CBD, most medicinal cannabis products have elevated THC, the psychoactive cannabinoid considered most likely to cause psychoses. At the same time, all the other cannabinoids which cause the conditions laid out in this document are present and active, again in more concentrated forms than in cannabis that was smoked in the 1960s.

Accidental ingestion by children

In a study of children hospitalised for cannabis exposure - between 2008 and 2019 there were 1,898,432 adolescent hospitalisations in 18 states and Washington, DC, with 37,562 (2%) of those hospitalisations having a cannabis-related diagnosis - 8,457 (23%) in states with no legal use, 20,444 (54%) in medical use only states, and 8,661 (23%) in states (NMCL) where recreational cannabis use had been legalised. The conclusion of the study was that,

Conclusions: Cannabis-related adolescent hospitalizations at children's hospitals are increasing, with a disproportionate increase postlegalization in states with NMCLs. Interventions are warranted to increase cannabis use identification and treatment among at-risk adolescents in the hospital-based setting.

The reason for the many hospitalisations is that THC edibles "can be easily mistaken for commonly consumed foods such as breakfast cereal, candy, and cookies, and accidentally ingested," says the US FDA. (quoted from FDA Powerpoint presentation 27/10/2022 - "Understanding FDA's Approach to Cannabis Science, Policy, and Regulation). The FDA further blames cannabis products with logos that appear similar to regular foods, causing children to ingest often in error.

Adverse events include hallucinations, elevated heart rate and vomiting.

Medicinal cannabis often poorly regulated

A problem reported from the US which appears to be a likely issue in other countries like Australia with reduced regulatory commitment is that independently tested medicinal cannabis products are frequently tainted with mould and other toxins such as pesticides.

A report from California cites 80% of medicinal cannabis products being tainted when tested by Anresco Laboratories at a Hempcon event in the Bay area.

Because cannabis appears to be given a pass that no other medicinal product is ever given - without being tested for strength, purity and dose or testing via clinical trials - there are unknowns as to the long-term health deficits of these unregulated products.

It also raises serious questions as to why cannabis is getting such an easy pass from regulatory agencies which only a few years back were rigid in any requirements concerning any drug or food additive.

Regulatory agencies not doing their job

The latest science clearly shows that cannabis is not fit for human consumption. It is mutagenic, oncogenic and teratogenic, with mechanisms that also prematurely age users. It is also clear that the physiological impacts of cannabis are not rare side-effects, but harming very significant numbers of users as well as future generations.

Any regulatory agency that is faced with this level of inflicted harm, particularly as it relates to a medicinal product, would either issue black box warnings or would withdraw the

product from the market.

The fact is that there is significant investment, and influential investors in cannabis would never in the past have been allowed any easy pass. Today our regulatory agencies appear to be captured by monied interests, unwilling to do anything because there is a simple lack of public scrutiny.

Media not doing its job

The lack of media attention to the science which is continually advancing on cannabis, with results that would alarm the public if properly reported, is leading to a situation where many lives are being put at risk for the sake of monied interests. The media has traditionally had a role of reporting the news dispassionately, but more often makes reports on the harms of cannabis and cannabinoids as insignificant as possible.

Alternate pathways needed for publicity

If the media is not going to do its job, drug prevention organisations are forced to use alternate media pathways to disseminate the science on cannabis harm.

To this end an Australian Taskforce of drug prevention agencies is seeking crowdfunding to ensure that the public can be exposed to the current science.

The latest science on Cannabidiol (CBD)

The largely unevidenced promotion of CBD

Cannabidiol (CBD) has been aggressively promoted to the public as a substance with miraculous properties. Even those articles that claim scientific support use mostly very limited studies which lack the rigour of random control trials. For instance, Forbes magazine listed the scientifically-verified conditions alleviated by CBD use as anxiety and depression, childhood epilepsy-like conditions, PTSD, opioid addiction, ALS, unmanageable pain, diabetic complications, protection against neurological diseases and arthritis. This list is conservatively short as compared to its advertised benefits on internet advertising services, where every malady seemingly finds its answer in this wonder drug - even as a cure to cancer.

The common experience with claims about cannabis has been that when rigorous clinical trials are conducted, the claims evaporate. This is best evidenced by the 2017 National Academies of Medicine review of cannabis, led by a committee of 16 professors and epidemiologists and 15 reviewers of similar qualification. Very few claims for cannabis were found to have rigorous research support. And on the contrary, when it comes to scientific rigour, CBD is generally the most lethal of the cannabinoids.

Genotoxicity of CBD uncontroversial

Dr Stuart Reece, a Professor at the University of Western Australia and possibly the world's most authoritative source on cannabis physiology and biochemistry, has confirmed that the genotoxicity of CBD is uncontroversial. Dr Reece, along with Dr Gary Hulse, is well-published in areas such as cannabis genotoxicity, teratology and epigenetics.

In e-mail communication with Drug Free Australia dated 27 June 2019 Dr Reece confirmed that the CBD effect on mitochondria is highly significant, well recognised and

uncontroversial. He further stated that it is now accepted that mitochondrial toxicity can become reflected in genotoxicity also through the balance mechanisms between mitochondria and nucleus, which is likewise uncontroversial.

Notably, the genotoxicity of CBD is admitted in authorised prescribing information with the US FDA and with the European Medicines Agency. It even appears on the labels of hemp oil marketed by Woolworths in Australia.

CBD the most carcinogenic cannabinoid

In the first run of data on US cancer rates as they relate to cannabis use across the various state drug policy regimes, CBD was found to be the most carcinogenic of the cannabinoids selected for inclusion in the study, with CBD likely causal in 12 of the 27 cancers there confirmed as compared to 7 for THC.

As is the case with tobacco, which was likewise verified in the study to be causal in 14 cancer types, any health authority would not allow it to be marketed as the cure for numerous maladies given the risks it presents.

Precisely the same should be the case with CBD products, where Australia's regulatory body was informed in 2021 of the carcinogenic nature of CBD, but nevertheless moved shortly thereafter to remove regulatory strictures on its availability, leading to serious questions about the TGA's current philosophy on safety.

CBD implicated in autism epidemic

The often-voiced claim that CBD is benign, presenting no significant harms to a patient, needs to be reassessed in the light of an evolving science on CBD.

In a recent letter to the New England Medical Journal, Dr Stuart Reece and his research colleague Dr Gary Hulse wrote the following,

. . . CBD was found to be the most carcinogenic of the cannabinoids selected for inclusion in the study, with CBD likely causal in 12 of the 27 cancers as compared to 7 for THC.

As one of the major cannabinoids and a high-dose ligand at CB1R's cannabidiol is implicated in the close spatial (northeast USA), temporal (recent years) and demographic (young adults) association between cannabis use and mental illness chronicled by SAMHSA and the nationwide surge in autism recently linked to cannabidiol.

CBD is more strongly implicated in autism prevalence than THC, and cannabis moreso than opiates according to this study. This has been established by waste-water data which establishes the strength of THC and various other cannabinoids in cities across the US correlated against increases in autism in those US States that have legalised access to recreational and medicinal cannabis.

CBD more causal in certain birth defects

Reece and Hulse, in their aforementioned letter to the New England Journal of Medicine assert the following:

Cannabidiol is a known chromosomal clastogen, epigenotoxin and mitochondrial toxin and was linked to the 29% surge in Colorado birth defects, led by cardiovascular defects, just as in Canada; and the pattern of rise of Downs syndrome, anotia and absent arms in Alaska and Oregon; and parts of France after it was added to the food supply; or the emergence of new cannabis-related defects like atrial septal defect in Colorado, Alaska, Oregon, Kentucky and Hawaii.

While cannabis is implicated in growing rates of gastroschisis (a birth defect where babies are born with their intestines outside the body) in States and countries which are legalising cannabis for medical and recreational use, it is CBD moreso than THC that appears causal in these population studies.

In e-mail communication dated 21 January 2019 between Drug Free Australia and Dr Stuart Reece who was one of the researchers that uncovered the association between cannabis and gastroschisis, Reece stated that,

The order of potency for both gastroschisis and autism is CBD>THC>Opioids.

This statistical finding alone suggests more study needs to be done on CBD's relationship to birth defects, given the known DNA damage it has been demonstrated to cause.

CBD symptoms similar to THC

Research published in the journal Cannabis and Cannabinoid Research shows that more than 40% of children with epilepsy who were given CBD orally had adverse events that included THC like symptoms. The research challenged the widely accepted premise that CBD is not intoxicating. There is evidence that CBD is biotransformed to metabolites that have similar effects as THC.

Notably, the FDA-listed Adverse Reactions for CBD include THC-like symptoms such as suicidal ideation, depression and anxiety. Their advice is as follows:

Antiepileptic drugs (AEDs), including EPIDIOLEX, increase the risk of suicidal thoughts or behavior in patients taking

these drugs for any indication. Patients treated with an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27863 AED-treated patients was 0.43%, compared to 0.24% among 16029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as 1 week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

More studies needed - CBD/THC metabolism

Concerning the transformation of orally-ingested CBD into THC, even the US Hemp Connoisseur magazine recognizes that more study is needed. They write:

Much research has involved the administration of THC and CBD to patients for symptoms such as fibromyalgia, Crohn's disease and insomnia, but researchers have been circumspect in declaring their results and have called for further testing. Watanabe's research, though conducted on mice, may hold true for humans – but that must be the subject of future studies. As Georgetown University Medical School's Dr. Robert du Pont pointed out, there are an estimated 400 components in the cannabis plant, making it difficult to determine exactly which component is providing relief when cannabis is ingested for medical reasons.³

Could anomalies in results have resulted from the way gastric juices break down CBD within the human body? In a 2016 study published in Cannabis and Cannabinoid Research, by John Merrick and associates, it was noted that, "In recent epilepsy research, pediatric subjects receiving orally administered CBD showed a relatively high incidence of adverse events (≤44%), with somnolence (≤21%) and fatigue (≤17%) among the most common."⁴ This led the researchers to more closely investigate the accepted premise that CBD is non-psychoactive. They came to the conclusion that, "Gastric fluid without enzymes converts CBD into the psychoactive components Δ9-THC and Δ8-THC, which suggests that the oral route of administration may increase the potential for psychomimetic adverse effects from CBD.

THC in CBD hemp accumulates in the body

It is important to recognise that CBD, a product of low THC hemp where THC cannot exceed 0.3%, nevertheless will most likely have these low quantities of THC present. A Health Canada study recognises the issues around THC accumulation in the body thus,

According to Canada's national health department, Health Canada, "In theory the ripened seeds of Cannabis contain no detectable quantity of THC. However, because of the nature of the material it is almost impossible to obtain the seeds free from extraneous THC in the form of residues arising from other parts of the plant which are in close proximity to the seeds. Although it is required for the seeds to be cleaned before any subsequent use, the resinous nature of some of the material makes complete cleaning extremely difficult."

Since THC and the over 60 other cannabinoids are fat-soluble, i.e., store themselves in the fatty tissues of the brain and body, even a very small amount may be damaging, especially if ingested regularly. Fat-soluble substances accumulate in the body.

THC has a half-life of about seven days, meaning that one-half of the THC ingested or inhaled stays in the brain and body tissue for seven days. Traces can stay in body tissues for a month or more. The only important substance that exceeds THC in fat solubility is DDT.

A risk assessment done for Health Canada states that, "New food products and cosmetics made from hemp – the marijuana plant – pose an unacceptable risk to the health of consumers. It also says that hemp products may not be safe because even small amounts of THC may cause developmental problems. "Those most at risk," the study says, "are children exposed in the womb or through breast milk, or teen-agers whose reproductive systems are developing."

"Hazards associated with exposure to THC include acute neurological effects and long-term effects on brain development, the reproductive system and the immune system," the study says. "Overall, the data considered for this assessment support the conclusions that inadequate margins of safety exist between potential exposure and adverse effect levels for cannabinoids (the bio-active ingredients) in cosmetics, food and nutraceutical products made from hemp."

Hemp THC ingestion beyond health limits

Quite apart from accumulations of THC in body fats and the health risks presented by it, there is another issue of large quantities of hemp ingredients being used in hemp edibles. The following demonstrates that a serving of hemp seed flour chips can have, despite being 0.3% THC, 8 times as much THC allowable for a typical serving. Add to this the accumulation of cannabinoids as described at our previous heading, and there is real cause for concern about hemp edibles opening up the consumer to various dangers caused by THC.

Using what I call "Farm Bill Math", the definition for hemp in the 2018 Farm Bill allows for 3 milligrams (mg) of THC

per gram (same as 1,000 milligrams) by product weight. At face value, this may not seem like a big deal, until one realizes the weight of many food products that we and our children consume. For example, a bag of Tostitos Corn Chips specifies that one serving size is 7 chips, which has a listed weigh of 28 grams. Thus, each chip would weigh about 4 grams (28 grams divided by 7 chips). Assuming that these chips could be made from hemp seed flour, one chip could legally contain up to 12 mg of THC (4 grams X 3 mg/gram). Also consider the 28 grams serving size, or 7 chips, noted on the Tostitos bag. This serving size could contain up to 84 mg of THC (28 grams X 3 mg THC/gram)! Corn chips also contain very little moisture in the form of water (low dry weight); it is only about 1% to 2.5%, so likely hemp-based chips would be very similar.

It is important to keep in mind that in Colorado, a product that contains THC is limited to 10 mg per serving for public health and safety reasons. Therefore, in Colorado, only one hemp-based corn chip (containing 0.3% THC by dry weight) would be roughly equivalent to the legal serving size of THC.

CBD can be readily converted to Delta-8-THC

From the University of Connecticut, commenting on Δ8-THC, which is equally as psychoactive as Δ9-THC, being produced from hemp, and the differing legalities across US states. This is just another way that unregulated CBD can produce an illicit recreational product.

Newswise — One is an illegal drug found in marijuana while the other is marketed as a safe herbal alternative. But the claimed differences between them aren't backed by science, a group of UConn researchers report on Nov. 1 in Drug and Alcohol Dependence.

Tetrahydrocannabinol, or THC, is the psychoactive compound produced by cannabis plants. The federal government lists Δ9-THC (pronounced delta-9-THC) on the Schedule 1 list of dangerous drugs with no accepted medical use. But other versions of THC that differ only by the location of a double bond, such as Δ8-THC, remain quietly quasi-legal on the federal level.

The legality differences between the various versions of THC are causing conflict between the hemp and cannabis industries. There is also potential for harm to consumers. Although Δ8-THC is viewed as an herbal extract of hemp, many manufacturers use solvents and chemical processes that can leave harmful residues in the product, and there are no standards for purity or safety. Because there are no limits, some products contain ridiculously high levels of Δ8 and other THC variants that could potentially cause harm due to the sheer dosage. And states do not agree on its safety or legality. Some states, such as Connecticut, have made Δ8-THC as controlled as Δ9-THC, while in others it remains legal. Cannabis producers allege the distinction is giving rise to unfair competition between the hemp and marijuana markets.

If regulating Δ9-THC as an illegal drug is based on the fact that it has physical and psychoactive effects, then the first step to rational regulation of Δ8-THC would look at

whether it, too, has those effects. And people who have experience with both say it does; most agree the effects of Δ8 are similar to Δ9.

CBD no better than placebo for pain


Given that CBD is increasingly being marketed as a safe and effective substance for pain relief, there is an increasing amount of research coming to hand demonstrating that CBD is ineffective. A JAMA review of 20 studies found that CBD is no more effective than placebo. Other related studies are determining no benefit for CBD with final stage cancer patients as it relates to the alleviation of pain, depression, anxiety and quality of life.

When it is considered that 62% of Australians use cannabis for chronic pain relief, the role being given to a substance such as CBD with its many physiological dangers is inordinately great, and alarming.

US FDA CBD bans due to lack of safety

The US Food and Drug Administration (FDA) has been continuing to monitor the safety of CBD and lists the current concerns below. It must be noted that there is still extensive research to be done to establish the real harms or otherwise of many of their concerns, which, it must be noted, have not reckoned with the most recent science on CBD as reported in this document. Adverse event reports follow.

We posted scientific questions about CBD safety related to:



- The risk of liver injury
- Toxicities of active metabolites, e.g. 7-COOH-CBD
- Impact on the male reproductive system
- Effect of co-administration with other substances
- Impact on neurological development
- Sedative effects, including effects on driving and operating heavy machinery
- Transdermal penetration and pharmacokinetics
- Long-term (chronic) repeated dose toxicity studies
- Effect of different routes of administration (e.g., oral, topical, inhaled)
- Effect on pets and food-producing animals
- The potential for bioaccumulation of CBD
- Effect on the eye

Figure 1. Number of exposure calls involving cannabidiol to U.S. Poison Control Centers by year: National Poison Data System 2014-2019

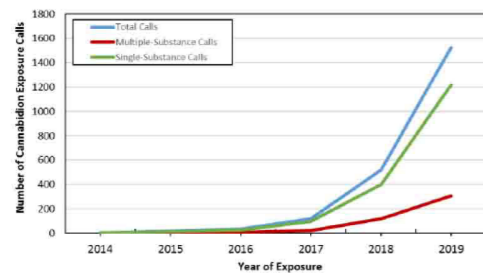


Figure 2. Exposure calls involving cannabidiol to U.S. Poison Control Centers by sex and age category: National Poison Data System 2014-2019

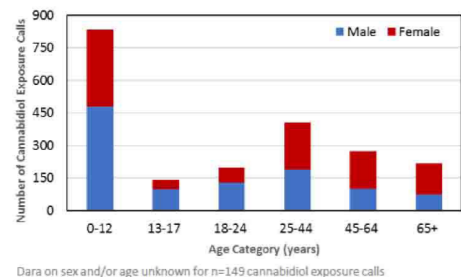


Figure 3. Formulation in exposure calls involving cannabidiol to U.S. Poison Control Centers: National Poison Data System 2014-2019

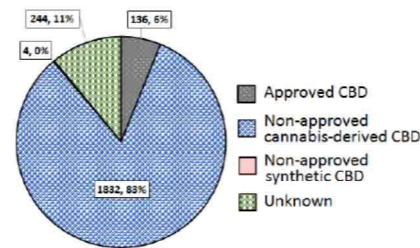
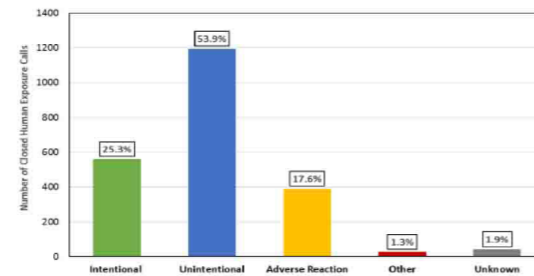


Figure 4. Reasons for exposure among U.S. Poison Control Center calls involving cannabidiol: National Poison Data System 2014-2019



Animal products transfer CBD dangers

As previously recorded in this document, cannabinoids entering the food chain with hemp being introduced as animal feed, presents genuine risks to humans. This may not only be through the Thalidomide-like phenomenon of human babies being born without limbs, but may have other manifestations given the accumulation of cannabinoids in the body. The US FDA has ruled that hemp feed and CBD 'medication' cannot be used with animals that are part of the human food chain.

The U.S. Food and Drug Administration (FDA) has issued warning letters to four companies illegally selling unapproved animal drugs containing cannabidiol (CBD) that are intended for use in food-producing animals. The companies include Haniel Concepts dba Free State Oils, Hope Botanicals, Plantacea LLC dba Kahm CBD and Kingdom Harvest. While the FDA does not know the current extent of CBD use in food-producing animals, the agency is taking steps regarding these unapproved and potentially unsafe products now to help protect animals and the safety of the food supply.

Unapproved drugs like these CBD products have not been evaluated by the FDA to determine whether they are effective for their intended use, what the proper dosage might be, how the products could interact with FDA-approved drugs, or whether they have dangerous side effects or other safety concerns.

The FDA is concerned about these CBD products for food-producing animals not only because CBD could pose a safety risk for the animals themselves, but also because of lack of data about the safety of the human food products (meat, milk and eggs) from the animals that have consumed these CBD products.

Regulatory agencies not doing their job

The latest science clearly shows that hemp and CBD is not fit for human consumption. It is mutagenic, oncogenic

and teratogenic, and is a contributor to the premature aging processes likely caused by cannabis. It is also clear that the physiological impacts of cannabis are not rare side-effects, but harming very significant numbers of users as well as future generations.

Any regulatory agency that is faced with this level of inflicted harm, particularly as it relates to a medicinal product, would either issue black box warnings or would withdraw the product from the market.

The fact that there is significant investment, and influential investors in cannabis would never in the past have allowed cannabis a pass. Today our regulatory agencies appear to be captured by monied interests, unwilling to do anything because of a lack of public scrutiny.

Media not doing its job

The lack of media attention to the science which is continually advancing on hemp and CBD, with results that would alarm the public if properly reported, is leading to a situation where many lives are being put at risk for the sake of rich investors. The media has a role of reporting the news dispassionately, but more often makes reports on the harms of cannabis and cannabinoids as insignificant as possible.

Alternate pathways needed for publicity

If the media is not going to do its job, drug prevention organisations are forced to use alternate media pathways to disseminate the science on cannabis harm.

To this end an Australian Taskforce of drug prevention agencies is seeking crowdfunding to ensure that the public can be exposed to the current science.