CANNABIS

Recreational Marijuana (RMJ)

The Changing Legal Status of Cannabis and its Potential Effects on Ridgefield Connecticut

COMMENT:

The material in the Executive Summary section was largely assembled from various sources without citation.

The material in the Discussion section was authored.

FIRST DRAFT

11/12/2021

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The Changing Legal Status of Cannabis and its Potential Effects on Ridgefield Connecticut

RMJ EXCUTIVE SUMMARY

1. **Why is RMJ being de-criminalized?**
   a. Because of the risk/benefit profile of RMJ. (See attached **Document A**)
   b. Because of the history of the evils of prejudiced policing.
2. **What is the difference between de-criminalization and legalization?**
   a. Money. Big Money. A huge opportunity for big business. Legalization will result in the eventual concentration of capital into a few industry giants that make enormous profits and will be largely beyond the reach of political control. (De-criminalization does not produce this result]
   b. Decriminalization means that a state repealed or amended its laws to make certain acts criminal, but no longer subject to prosecution. In the marijuana context, this means individuals caught with small amounts of marijuana for personal consumption won't be prosecuted and won't subsequently receive a criminal record or a jail sentence.
   c. In many states, possession of small amounts of marijuana is treated like a minor traffic violation. A growing number of states have decriminalized marijuana.
   d. Even in states that have decriminalized the herb, possessing larger quantities or selling marijuana has significant potential penalties. Therefore, it is essential to be aware of the criminal laws in your state or in any state you travel through.
3. **Status of federal decriminalization**
   a. Basically, Federal marijuana decriminalization means **you can't be arrested, ticketed, or convicted for using marijuana if you follow the state laws as to age, place, and amount for consumption.** If the state law criminalizes RMJ, Federal law overrides it.
   b. The MORE Act is under active consideration in Congress. Its removes marijuana from the list of scheduled substances under the Controlled Substances Act and eliminates criminal penalties for an individual who manufactures, distributes, or possesses marijuana.The bill also makes other changes, including the following:
      i. replaces statutory references to *marijuana* and *marihuana* with *cannabis*,
      ii. requires the Bureau of Labor Statistics to regularly publish demographic data on cannabis business owners and employees,

iii. establishes a trust fund to support various programs and services for individuals and businesses in communities impacted by the war on drugs,

iv. imposes an excise tax on cannabis products produced in or imported into the United States and an occupational tax on cannabis production facilities and export warehouses,

v. makes Small Business Administration loans and services available to entities that are cannabis-related legitimate businesses or service providers,

vi. prohibits the denial of federal public benefits to a person on the basis of certain cannabis-related conduct or convictions,

vii. prohibits the denial of benefits and protections under immigration laws on the basis of a cannabis-related event (e.g., conduct or a conviction),

viii. establishes a process to expunge convictions and conduct sentencing review hearings related to federal cannabis offenses, and

ix. directs the Government Accountability Office to study the societal impact of cannabis legalization.

4. *Status of state implementations*

a. Federal law supercedes state law. However, a number of states have moved ahead of the Federal government and others are in opposition and lag behind. The situation will likely go to the Supreme Court.

b. RMJ has been fully legalized for recreational use in 18 states, starting with Colorado and Washington in 2012. A total of 37 states have approved medical marijuana. In California, cannabis has been legal for medical use since 1996 and for recreational use since late 2016.

c. Legislation is under consideration in Connecticut. (See attached *Document B* for a detailed summary of its provisions and an accompanying discussion. It is too lengthy to include here.)

5. *Key provisions of CT RMJ proposed legislation that affect local governments:*

(for full text see attached *Document C)*

a. Towns are required to put to a referendum the question of permitting RMJ stores to open and operate if petitioned by 10% of the electorate. (For Ridgefield, this requires 2500 signatures. As discussed below, it is estimated that 1500 regular users of RMJ live in Ridgefield. That number is less than 2500 by a significant margin. The actual number, however, may be much higher than 1500.)

b. Regulation of Smoking and Cannabis Use: Existing law allows municipalities to regulate activities deemed harmful to public health, including tobacco smoking, on municipally-owned property. The bill broadens this to include property that a municipality controls but does not own. For the purposes of this section, property that a municipality controls includes, but not limited to, sidewalks, parks, beaches, municipal land and buildings, etc. It specifies that this regulatory

authority applies to (1) smoked or vaped tobacco or cannabis, and (2) other types of cannabis use or consumption.

    c. Municipalities are permitted to ban cannabis smoking and vaping at outdoor sections of restaurants. Through regulations, municipalities may set fines for violations of up to $1,000 for businesses who allow cannabis smoking or vaping contrary to the regulation of the municipality.

    d. Allows municipalities to amend their zoning regulations or local ordinances to take the following actions regarding cannabis establishments:

        i. prohibit them from opening;

        ii. reasonably restrict their hours and signage;

        iii. restrict their proximity to religious institutions, schools, charitable institutions, hospitals, veterans' homes, or certain military establishments.

    e. Municipalities are prohibited from granting zoning approval for more retailers or micro-cultivators than a number that would allow for one retailer and one microcultivator for every 25,000 municipal residents. For Ridgefield that means one store.

An example of what one town has done: Although Maine has legalized RMJ, Bowden Maine, a college town, does not have a store selling RMJ. Students have to drive to another town 25 minutes away.

6. *Status of scientific research*

    a. A 486 page study titled "The Health Effects of Cannabis and Cannabinoids: The Current State of the Evidence" was conducted by The National Academies of Science, Engineering and Medicine and published in 2017. (See attached ***Document D*** for the table of contents and the Summary of Conclusions).

    b. The study identified a large number of research gaps where basic knowledge does not exist. (See attached ***Document E*** for a discussion of the barriers to research).

    c. A bill called "Medical Marijuana Research Act " is under consideration in Congress to permit RMJ research (See attached ***Document F***)

COMMENT:

It is essential to understand that 'absence of evidence' does not equate to 'evidence of absence'. The conclusions of this study, by the researchers own admission, are not based on an adequate body of experimental data.

Reading the conclusions one is led to ask, "If this drug is this useless, then why are so many people using it?" More research will answer that question or, one assumes, will provide a basis for people to decide to stop using it and use alternative practices or medications.

Curiously, the study did not address the 'recreational' dimension. Specifically, "Feeling Good" was not considered a health benefit by the study. This is a serious omission if the goal is to determine the complete story.

It is unlikely that there would be data about 'Feeling Good'. People do not seek treatment from the medical establishment because they are feeling good. As a consequence they generate no data which would in turn, explain why no data along this line would show up in a study such as this one.

What it seems one can conclude from the study is that for significant health disorders, RMJ was not a cure or even an effective therapy for most of those considered. On the contrary it seemed to make some of them worse.

This raises the question of why medical marijuana has been approved in so many states.

Clearly, the state of research on this entire subject is completely inadequate. This is a conclusion that the authors of the study would agree with.

DISCUSSION:

The question that comes to the forefront regarding RMJ is this:

> *How can it be ethical to unleash yet another health scourge onto the body politic when there is a choice about whether to do so or not?*

The short and simple answer is this:

> *There is no choice not to do so because the ethical consequences and cost of continuing to make its use illegal substantially outweigh the ethical consequences and costs of de=criminalizing it.*
>
> *It is a choice between the least bad of two undesirable things.*

If one charges all over the landscape of considerations that can be debated about this matter, the endless wrangling all comes down to what is summarized above.

THEREFORE: DE-CRIMINALIZATION FOLLOWED BY *LEGALIZATION IS COMING. IT IS ESSENTIAL TO UNDERSTAND AND PREPARE FOR THE CHALLENGES THAT WILL RESULT*

COMMENT:

> *There is a scale that can be applied to complex socially divisive issues where the range goes from active opposition, even criminalization, on the negative end to active enthusiasm, even celebration, on the positive end. The mid-point on that scale is Tolerance. De-criminalization of RMJ is, for the purposes of this analysis, equivalent to Tolerance. Tolerance does not imply enthusiasm in any form. It simply means that there will not be active opposition.*

The new questions raised by accepting the above conclusion are these:

- *What of positive value can be achieved by the situation where cannabis use is de-criminalized or legal?*
- *What are the negative consequences that are virtually certain to occur?*
- *How do these positive and negative consequences interact?*
- *Which of these will impact the decisions and actions and consequences at the local level of the town of Ridgefield?*
- *What actions can be taken by the managers of Ridgefield to reduce the damage of those negative consequences?*

SHORT VERSION OF THE ANSWERS TO THE QUESTIONS:

- *What of positive value can be achieved by the situation where cannabis use is legal?*

Research into the effects of cannabis on the body and mind of humans will no longer be illegal. We will no longer have to add ignorance to the complications of an already complicated subject.

We will no longer criminalize and imprison people for its use, a result that is far more destructive both to individuals and to society than the use itself.

Given the challenges that result from all the bad and tragic things that can occur in people's lives,

- Many people will prefer self-medication with RMJ to obtaining a prescription for a mood-altering drug from a psychiatrist even though the prescribed drug may very well be more effective.
- Prescribed drugs are not benign.
- Many people do not have medical coverage that provides mental health benefits
- Many people think there is a stigma associated with seeing a psychiatrist.

Many individuals will have some residual benefit from 'thinking outside the box' of their daily routine which is one of the effects of cannabis.

Many individuals will have some relaxing moments at a lower health cost than accomplishing the same with alcohol or other drugs.

- ***What are the negative consequences that are virtually certain to occur?***

There will be an initial surge of use and public display of use which will, in the immediate short term, significantly degrade the perceived quality of life in the community.

There will be a percentage of users that become addicted which will have severe effects on the involved family and the consequences of that will directly affect the local community where that family lives.

- In a population of 25,000, assuming half are adults, studies show that 12% will use RMJ regularly yielding 1500 users in Ridgefield.
- 7% of those users will become psychologically dependent. That means that 105 affected families in Ridgefield.
- That number will only go up as the percentage of use goes up.
- Exploratory usage has reached 49% in America, up from 20% in 1977.

Young children will be exposed to second-hand smoke and become intoxicated whether they know it or not and whether they like it or not. They are then set up to be biased for future use. Potentially they will be going to school partially stoned.

There will be a significant and unavoidable rise in perceived hypocrisy in the community. "Do as I say and not as I do."

Initially its use will not replace alcohol or tobacco but will be added to it making both of those health hazards worse.

Legalization will create (already is creating) yet another megacorporation which acts for its own benefit at the expense of the public good.

There will be young people that fail to achieve their positive potential because the use of cannabis creates the illusion of success without the need to expend the required effort. While the use of alcohol is potentially more damaging to health, this delusional thinking is not one of its effects. Alcohol is, in a way, a puritanical drug because overuse produces a hangover which is no fun at all.

There will be consequences that affect society as a whole e.g. 72,000 truck drivers cannot drive trucks due to failure to pass drug and alcohol tests. This is occurring in the middle of a supply chain crisis that is causing inflation in prices that affect the whole of society.

https://nypost.com/2021/11/07/supply-chain-stalled-by-72000-truckers-who-failed-drug-tests/

- **How do these positive and negative consequences interact?**

"A modestly self-aware user of RMJ will recognize that while usage helps in dealing with stress and is less damaging than alternatives, RMJ is also what is undermining the ability to deal with the underlying problems causing the stress. This is because RMJ saps energy and dilutes focus and artificially creates a temporary state of comfort. The user is trapped into a kind of immobility between these two competing considerations." (comments by a RMJ user.)

- **Which of these will impact the decisions, actions, and consequences at the local level of the town of Ridgefield?**

All of them.

- **What actions can be taken to reduce the damage of those negative consequences?**

ON THE ONE HAND:

  NIMBY (Not in my back yard). In keeping with the comment above about Tolerance, the town of Ridgefield is under no obligation to do more than simply stop criminalizing RMJ use. There is no further obligation. One approach is to simply leave it to other towns to provide access to RMJ if they wish but not to do so in Ridgefield. Given all the negative consequences listed above there is good reason for considering this approach.

ON THE OTHER HAND:

  It is essential to remember that some people think they need RMJ to get through their week, perhaps a minimum of 1500 in Ridgefield ranging to possibly twice or three times

that number. This need is sufficiently compelling that they are willing to risk having a criminal record to meet that need. Those that don't should be careful not to be guilty of 'If they are out of bread then let them eat cake!" kind of thinking made notorious by Marie Antoinette. Not everyone has a gold-plated medical plan with full psychological benefits coverage.

Strategies for action can be roughly grouped as follows:

- Leader
- Fast Follower
- Middle of the Roader
- Laggard
- Non-participant

Not surprisingly, California took the role of Leader in the nation in de-criminalization and legalization of RMJ. Given Ridgefield's demographics, Middle of the Roader is the most realistic approach. Given proper research, it is likely that a reasonable basis for not becoming a laggard or a non-participant will become apparent.

- More research is required. Ridgefield should take an active role in participating in and potentially sponsoring that research with Yale or other Connecticut academic and medical institutions. That has practical as well as symbolic value. **The need for further research can serve as the basis for NIMBY, certainly for the short term.**
- Anything more than very casual use of cannabis involves non-zero risk to mental and physical well-being and these risks are poorly understood at present. For example:
    - The human body contains a complex and comprehensive internal set of cannabis receptors on almost every cell in the body. This system is called the Endocannabinoid System. This system, on present understanding, seems to have the job of modulating, i.e. balancing out, the function of other systems. For example, when the adrenalin 'fight of flight' system is engaged, the response of the body to outside stress is raised to a very high energy level. After the danger is passed the body has to 'calm back down.' This recovery process seems to be modulated by the Endocannabinoid System.
    - The use of RMJ interferes with and changes the function of the Endocannabinoid System in the user. It appears, on present understanding, that these changes are reversible. Knowledge is very inadequate on these questions.
    - The use of RMJ is known to have a significant and negative effect on the functions of short-term memory. Whether these changes are fully reversible is not well understood.
- Rather than unleash an uncontrolled 'science experiment' on the public through widespread availability, delay that action until more fundamental understanding of the scientific facts involved is developed.

- Taking a leadership role in sponsoring research makes a very important statement about the perception of Ridgefield as a place willing to provide insightful and intelligent leadership in the broader community. This goes to the 'brand management' point reiterated below.
- Education and carefully designed publicity and public relations actions. To avoid hypocrisy, both the potential benefits as well as the potential dangers must be honestly represented.
- Carefully designed regulatory actions aimed primarily at symbolic educational significance and community 'brand management' more than actual attempts at control of use.
- Because functional addiction to RMJ seems to come in the form of psychological dependence rather than biochemical cellular level addiction, publicly funded support resources, probably in the form of an expansion of the Ridgefield Youth Counseling Services are the appropriate support strategy for vulnerable younger members of the community.
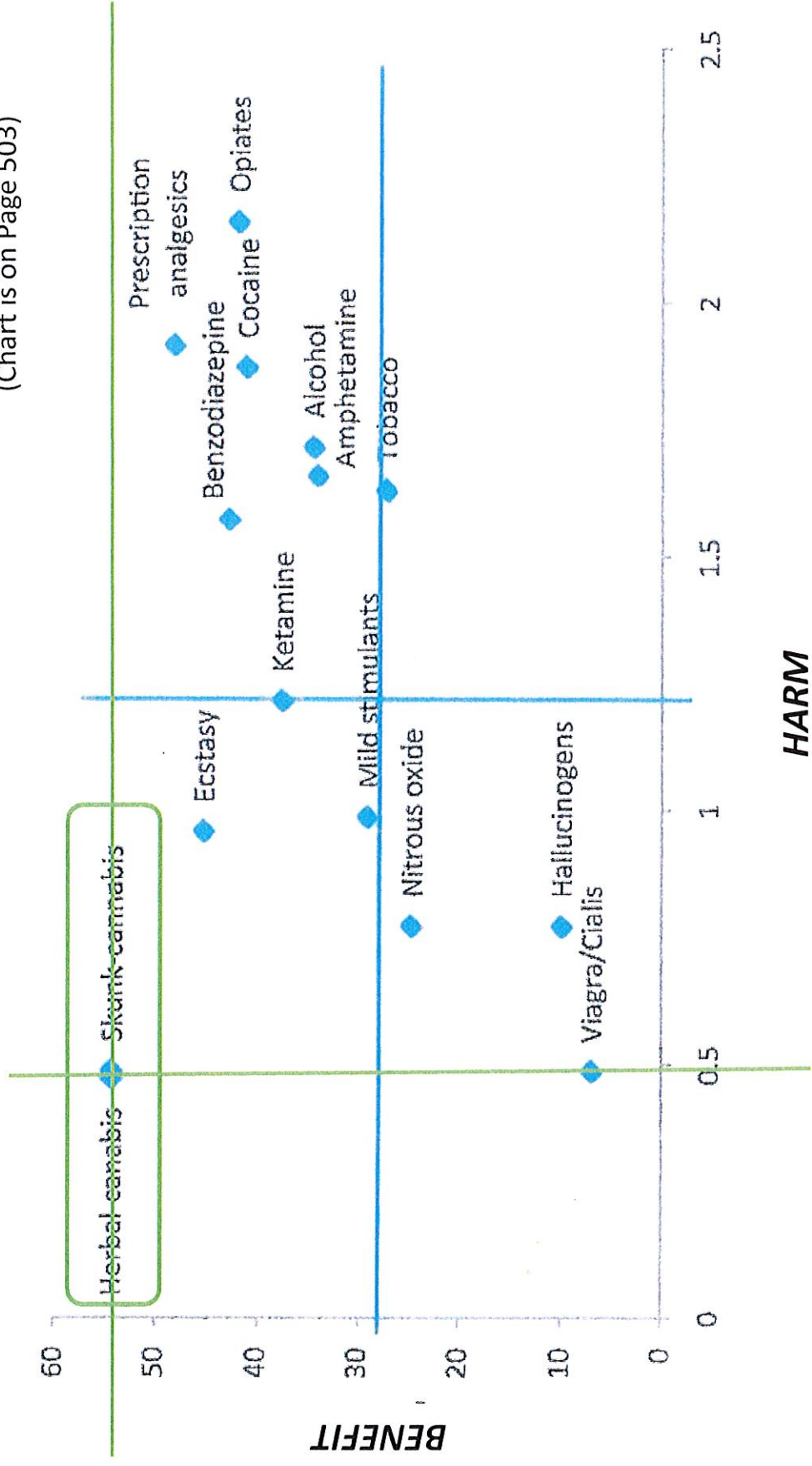- Similar support for adult members of the community is a further option to consider.

DOCUMENT A:

WHY RMJ IS BEING LEGALIZED

Harms and Benefits Associated With Psychoactive Drugs

Findings of an International Survey of Active Drug Users

WHY RMJ IS BEING LEGALIZED

INTERNATIONAL STUDY OF DRUG USERS: 5971 USERS FROM 40 COUNTRIES
(Chart is on Page 503)

categories of harm: 'physical', 'dependence-related' and 'social', each with three sub-levels, allowing currently used and new psychoactive substances to be more objectively compared on the basis of experts' ratings. Nutt et al.'s findings showed no relationship with the rank ordering by experts and categorisation of drugs under the UK Misuse of Drugs Act, and caused considerable controversy within the government and media.

Subsequently we used the same harm matrix to survey over 1500 UK drug users and found significant correlations between their harm rankings and those of Nutt et al.'s experts, but none between users' rankings and the current classification of drugs under the UK Misuse of Drugs Act (Morgan et al., 2010b). These findings were then replicated in the Netherlands, where a two-class classification systems is employed (van Amsterdam et al., 2010), and a recent web-based survey of drug users (predominantly mephedrone users) which provided a very similar profile of rankings to the studies outlined above based on harm ratings of 13 psychoactive substances (Carhart-Harris, 2011). Once again alcohol and tobacco were rated to be highly harmful whilst cannabis, ecstasy and magic mushrooms were rated as relatively safe. In response to doubts raised about the differential weighting and choice of criteria used, Nutt et al. (2010) used 'multicriteria decision analysis' to develop a weighted model, based again on ratings by experts. Their results supported their previous findings – again, there was no correlation between rated harms and UK ABC classification.

A debate has ensued, with some disputing whether it is logically possible to rank drugs on any single dimension of harm (Caulkins et al., 2011; Cohen, 2010). It is argued that no model would ever be perfect because ratings of harm to others and harms to self are neither objective nor measureable, as they will always be influenced by expertise and personal biases; indeed, Nutt et al. used a small number of experts with uncertain knowledge of drug-related harms outside of their area of expertise (Coulson and Caulkins, 2012). Furthermore, the principle of combining individual and aggregate harm measures to create a weighted total 'harm score' may be flawed, in that the relationship between these two types of harm may not be additive. The latter authors further suggested that even perfect calculation of harm scores cannot determine how a new drug should be scheduled. Scheduling systems are interrelated with some drugs being precursors to others, and thus it is difficult for them to be considered on a drug-by-drug basis. In addition the consequences of scheduling, changes depend on context of use of the drug; for example, alcohol is highly harmful to use whilst driving. Nutt et al. (2010) also did not take into account either differential availability of illegal substances or poly drug use. Caulkins et al. (2011) proposed alternative 'harm matrices' which would take into account the context of drug use, so each substance in each context would be associated with harm-type ratings. However, although this process would be an interesting one to explore, it was deemed too lengthy and complex for an internet survey, and thus we adopted the Nutt et al. framework, for parsimony and ease of use.

Whilst drug harms may not be sufficient to determine policy (Kalant, 2010) the belief that policies informed by science are better than those with no scientific basis at all has been expressed by several researchers (e.g. Fischer and Kendall, 2011; Obot, 2011; Room and Lubman, 2010). The value of informing policy makers of the relative harm of drugs is not opposed even by critics (Caulkins et al., 2011). As well as harms, however, recreational

drugs have perceived benefits, otherwise they would not be used. There are a variety of historical and emerging beneficial uses of various compounds that are illicit substances; for example cannabis, once used as a sedative and anti-convulsant in the UK and US (Walton, 1938), has recently been explored in its organic form and components as an analgesic, anti-emetic and appetite stimulant. Renewed efforts have also been made to demonstrate the efficacy of illicit drugs as adjuncts to psychotherapy, either as psycholytics or psychedelics, with promising results (see Sessa, 2005 for a review). For example, in two small studies, MDMA has been found to be effective as an adjunct to exposure therapy for post-traumatic stress disorder (PTSD) and therapy-resistant anxiety disorders (Johansen and Krebs, 2009; Mithoefer, 2006; Sessa, 2007). In addiction treatment with single dose of LSD, in the context of alcohol treatment programmes in the 1960s and 1970s, is associated with a decrease in alcohol misuse (Krebs and Johansen, 2012), whilst ketamine has improved rates of abstinence in the treatment of heroin addicts (Krupitsky et al., 2002).

A wide literature has detailed the benefits of recreational drugs to users (e.g. Griffiths et al., 2006, 2008, 2011; Móró and Noreika, 2011; Müller and Schumann, 2011; Tart 1971). However, only two studies to date have compared the potential benefits of illicit drugs to the harms (Carhart-Harris and Nutt, 2010; Morgan et al., 2010b). The latter assessed the perceived acute and long-term benefits of 21 substances in over 1500 drug users whilst the former compared the benefits of four types of substances in 626 users. Users presumably make a complex cost/benefit judgement when taking recreational drugs. Understanding both the harms and benefits of taking drugs for users is important for the uptake of health education, and therefore it is important to collect accurate and up-to-date data on regular users' perspectives of the benefits of taking drugs.

The current study aimed to provide a more comprehensive account of the perceived benefits as well as harms of 18 psychoactive substances (11 illicit and seven legal). As previous surveys have been limited to UK or the Netherlands, it also aimed to obtain an international sample of users with diverse cultural and legal approaches to psychoactive substances.

Methods

A website was designed using Web II software and was distributed internationally via a link on Erowid in three optional languages (English, Spanish and French). Participants were required to provide informed consent and confirm they were over 18 before entering the survey. Withdrawal from the survey was permitted at any time using a button at the bottom of the page, and participants were informed that in this instance their data would not be saved.

Psychoactive substance use was recorded first to establish which of the 18 drugs each participant would then be able to rate. The following drugs were grouped into three classes once data on substance use had been entered; Hallucinogens: 2-CB/ 2-CI, ayahuasca, DMT, GHB, LSD, Mescaline/ Peyote, mushrooms, salvia divinorum; Amphetamines: amphetamine/methamphetamine, prescribed stimulants (e.g. Dexedrine, Ritalin); Opiates: heroin, methadone, opium (prescription analgesics were kept in their own separate group).

Only participants who regularly used the drugs went on to rate their benefits and harms, except in the case of hallucinogens

Harms and benefits associated with psychoactive drugs: findings of an international survey of active drug users

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Abstract

There have been several recent efforts in the UK and the Netherlands to describe the harms of psychoactive substances based on ratings of either experts or drug users. This study aimed to assess the perceived benefits as well as harms of widely used recreational drugs, both licit and illicit, in an international sample of drug users. The survey was hosted at https://www.internationaldrugsurvey.org/ and was available in three languages. Residents reported their experience of 15 commonly used drugs or drug classes; regular users then rated their harms and benefits. In all, 5791 individuals from over 40 countries completed the survey, although the majority were from English speaking countries. Rankings of drugs differed across 10 categories of perceived benefits. Skunk and herbal cannabis were ranked consistently beneficial, whilst alcohol and tobacco fell below many classified drugs. There was no correlation at all between users' harm ranking of drugs and their classification in schedules of the USA or ABC system in the UK. Prescription analgesics, alcohol and tobacco were ranked within the top 10 most harmful drugs. These findings suggest that neither the UK nor US classification systems act to inform users of the harms of psychoactive substances. It is hoped the results might inform health professionals and educators of what are considered to be both the harms and benefits of psychoactive substances to young people.

Keywords

Alcohol, benefits, cannabis, drug abuse, ecstasy, harms, legal status

Introduction

Worldwide alcohol causes 2.5 million deaths per year (World Health Organisation, 2011) whilst tobacco is implicated in twice this number (Mackay et al., 2006), collectively accounting for 12% of all deaths. The health costs of tobacco smoking total $96 billion per year in the USA and £2.25 billion in the UK (Mackay et al., 2006). The cost of alcohol is an accumulation of health, social and crime-related spending and can total up to £20 billion in the UK and $200 billion in the USA (Global Status Report on Alcohol and Health, 2011). Recently, there has been an increase in non-medical use of prescription analgesics (or painkillers), with a growing trend of 'pill mills' and 'doctor shopping'. In the USA, the non-medical use of these drugs by 12 million people made them the second most common form of illicit drug use after cannabis in 2010 (Substance Abuse and Mental Health Services Administration, 2011). Deaths from prescription analgesics in the USA are greater than those from heroin and cocaine combined, with rates tripling in the last 10 years (Centre for Disease Control and Prevention, 2011), which is perhaps unsurprising given their much larger number of consumers.

Illicit drugs are only used by a minority of the world's population, with between 3.5% and 5.7% having used an illicit substance at least once (United Nations Office on Drugs and Crime, 2010). Around 10–15% of these are classed as 'problematic users'. Cannabis has the highest prevalence of use followed by amphetamine, cocaine and heroin. In the UK, problem drug use of Class A substances costs society £15.4 billion a year, of which £13.9 billion is attributable to criminal offences. The US Department of Justice National Drugs Intelligence Centre (2011) reported that the total impact of illicit substances on society amounted to over $193 billion, with crime and incarceration accounting for over $100 billion of these costs.

Current approaches aimed at reducing illicit drug use include prohibition of supply, education and treatment. Most countries and international agencies (such as the United Nations and World Health Organisation), classify drugs according to how dangerous or harmful they are. For example, under the UK Misuse of Drugs Act 1971, drugs are segregated into three classes (A, B and C) which are meant to (i) reflect their relative harms and (ii) determine the penalties for possessing and trafficking each drug. In the USA drugs are classified into five schedules reflecting their 'potential for abuse'. It has been argued that these systems have evolved in an unsystematic way according to social, political and historical concerns rather than being based on any scientific evidence.

Recently, attempts have been made to develop a 'rational' scale to assess and compare the overall harms of psychoactive drugs (Nutt et al., 2007). Their 'harm matrix' included three

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where all those reporting any prior use of the drugs were included on the assumption that few people would take hallucinogens 'regularly'. This was an unfortunate practical consideration to limit the length of the survey for respondents. Because of very low numbers of users (less than 0.7% of the total sample), three drugs (crack, anabolic steroids, solvents: aromatic and aliphatic hydrocarbons, ketones and haloalkanes such as benzene, m-xylene, ethylbenzene, propylbenzene, 1,1,1-trichlorethane (TCE) and nitrites e.g. Poppers) were not included in the analyses.

Measures (for the full survey see supplementary online material)

Harms

Participants were asked to rate the harms associated with each drug on the basis of seven risk factors;

1. **Short-term physical risk:** Participants were asked to think about how much short-term physical risk they thought was associated with taking a single dose of a drug. They were instructed that a 'single dose' meant one bottle of beer, one ecstasy tablet or one line of coke. They were then asked 'when someone is under the effects of a drug how likely are they to cause themselves some physical damage. For example, if someone is likely to die from an overdose this would be considered 'extreme risk', or if someone is likely to have an accident this would be 'moderate risk'.'
2. **Long-term physical risk:** Participants were asked to rate how much long-term physical risk they thought would be associated with regular use each of the drugs.
3. **Risk of injecting:** Participants were asked, 'how likely do you think people are to inject the following drugs?' Although injection is not a harm in itself, it is an indicator of a higher likelihood of dependence, due to the rapid onset of effects and is also associated with risk of a range of serious secondary health outcomes, for example hepatitis C and HIV transmission.
4. **Risk of physical dependence:** this was assessed by asking the question 'If someone takes the drugs below on a regular basis, what is the risk that they will become physically reliant on them and experience physical side effects if they stop?'.
5. **Risk of psychological dependence:** This was assessed by the question 'what is the risk if someone takes the drugs below on a regular basis that they will develop cravings?'.
6. **Risk to society:** Participants were told that some drugs are seen to have a negative impact on society by damaging family relationships, damage to property, or through the cost of policing. They were then asked to rate the level of risk to society which they thought each drug posed.
7. **Risk of bingeing:** Participants were asked to rate the likelihood of bingeing. Bingeing means the tendency to repeatedly dose with a substance, and is an indicator of the dependence-forming properties of a drug, hence it presence as an indicator of harm .When a person takes an excessive amount of a drug, for example more than 10 units of alcohol in a single session, this is considered 'bingeing'.

Participants were asked to score each substance on a four-point scale, with 0 no risk, 1 some risk; 2 moderate risk and 3 extreme risk. The scores for these seven factors were averaged to give a mean harm score.

Benefits

Participants rated 10 benefits, defined below. Five benefits comprised multiple items. The number of participants who rated a drug as having a particular benefit was calculated as a proportion of the total number of participants who rated that drug.

1. **Sociability** (4 items; Lose inhibitions/ be more sociable, Feel more confident, Feel closer to people/ more empathy, Feel part of a social group)
2. **Enjoyment** (5 items; Enhance activities, Enhance sense of fun/humour, Help with creativity/ abstract thinking, Increase sexual function/ enjoyment, Feel elated/ euphoric)
3. **State of mind** (6 items; Open up to new experiences, Altered senses, Increase existential awareness, Find meaning in the self and the world, Help alter consciousness, To get out of my head/ escapism)
4. **Pain** (2 items; Relieve symptoms of disease/ illness, Relieve physical pain)
5. **Relieve anxiety/ depression** (1 item)
6. **Feel more relaxed/ relieve stress** (1 item)
7. **Change appearance of body (bulk up/ lose weight)** (1 item)
8. **Help wake up/ have more energy** (1 item)
9. **Help to get to sleep** (1 item)
10. **Improve attention, memory and concentration** (1 item)

Participants were also asked to report their first and second preference for drugs.

Finally, participants were asked to assess their own dependence using four binomial yes/no questions taken from the CAGE-AID ('Cut-Down, Annoyed, Guilty, Eye-Opener' Adapted to Include Drugs) dependence scale (Brown and Rounds, 1995) The CAGE-AID was developed as a time-saving screening tool for clinicians in primary care and whilst it cannot indicate dependence, it can reflect a likelihood of abuse or dependence, warranting further screening.

The survey was launched on Erowid on the 7 March 2011 and all data up until 17.30 on 5 December 2011 were included in this report.

Statistical analyses

Spearman's rank correlation coefficient was used to analyse the relationship between UK classifications and US scheduling of illicit substances and the perceived harms of psychoactive drug as rated by users in the UK and US.

Results

Demographics

A total of 5691 individuals, worldwide, completed the online survey. Their demographic data are displayed in Table 1.

Table 1. Demographic data for the sample: percentage in each category.

Gender

Male	Female	No reply
76.2	23.5	0.4

Age

18–24	25–30	31–40	41–50	51–60	61–65	66–110	No reply
61.53	14.40	10.53	6.75	4.87	1.00	0.43	0.48

Education

Early leaver	Secondary	Undergraduate	Post-graduate	No reply
6.04	35.73	42.95	14.28	1.00

Employment

Retired	Unemployed	Carer/homemaker	studying	Employed	No reply
2.19	13.33	2.38	39.39	41.94	0.76

Ethnicity

White	African	Indian	East Asian	Mixed Race	Other	No Reply
88.36	0.64	1.33	0.35	5.61	3.16	0.55

Sexual Orientation

Heterosexual	Homosexual	Bisexual	No Reply
83.60	3.70	11.74	0.97

Religion

Christian	Hindu	Muslim	Buddhist	Jewish	Agnostic/Atheist	Sikh	Other	No reply
17.42	0.50	0.47	3.61	1.54	50.15	0.02	22.41	3.89

Country

USA	UK	Europe	Canada	Australia/ New Zealand	South/ Central America	Other	No Reply
54.31	15.25	11.10	7.53	4.54	2.09	4. 59	0.59

Number of participants who rated themselves as regular users of a drug and therefore rated their associated harms and benefits are reported in Table 2.

Harms

Table 3 presents mean harm ratings of drugs on the seven risk factors. Data for the overall mean harm ratings are presented in Figure 1. They are displayed in terms of the drug's classification under (a) US schedules and (b) UK Misuse of Drugs Act as they represented the largest number of respondents. Amphetamines and prescription analgesics were excluded from the UK interpretation and opiates/heroin were excluded from the US interpretation, as substances falling within these drug categories had different classifications or scheduling. US ratings of harms were not correlated with their status under the Controlled Substances Act schedule (Spearman's rank correlation -0.240; p=0.41).

UK ratings also did not correlate with the legal classifications under the Misuse of Drugs Act, as evidenced in the lack of correlation between ranking of harms by users (Spearman's rank correlation 0.095; p=0.76).

Benefits

Percentages of participants reporting each of the 10 benefits are shown in Table 4 ranked from highest to lowest percentage. Skunk and herbal cannabis/resin were considered overall to be the most beneficial drugs, followed by prescription analgesics, cocaine and opiates. Sildenafil (Viagra) / Tadalafil (Cialis) and hallucinogens were rated to be least beneficial on these scales. The mean percentage of participants rating each drug as a benefit compared with the mean harm rating of that substance is displayed in Figure 2.

Drug of choice

Drug preferences of regular users as evidenced by first and second 'drug of choice' are displayed in Figure 3. First and second preference profiles for drugs were very different. Skunk, prescription

Table 2. Participants' experience of drugs.

	Regular users	Occasional users	Ex users	Have tried it	Know someone who has used it	No direct experience /Not heard of it	Total able to rate harms
Alcohol	2341	2472	475	388	54	61	**2341**
Amphetamines	634	1236	778	2653	2794	3477	**634**
Benzodiazepines	335	792	294	1281	1155	1929	**335**
Cannabis: herbal	2863	1302	576	639	243	162	**2863**
Cannabis: skunk	2810	1154	518	570	262	472	**2810**
Cocaine	99	789	506	1617	1853	927	**99**
Ecstasy	336	1353	423	1332	1577	765	**336**
Hallucinogens	1058	5202	1018	7898	11606	25316	**14587**
Ketamine	106	357	106	842	1739	2641	**106**
Nitrous oxide	126	711	173	1592	1016	2168	**12619**
Mild stimulants	3187	1524	153	538	113	271	**3187**
Opiates	202	441	428	2168	4369	9764	**202**
Prescription analgesics	354	952	316	1783	1054	1327	**354**
Tobacco	2107	987	968	1058	526	145	**2107**
Viagra/Cialis	43	125	9	412	1071	4126	**43**

'Mild Stimulants' = caffeine, khat.
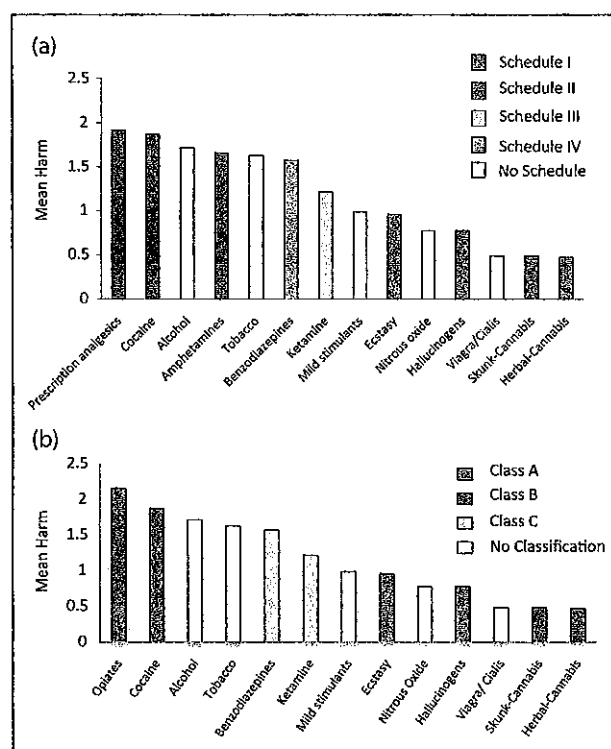
Figure 1. Mean harm ratings of drugs against a) US Schedules under the Controlled Substances Act b) UK legal classifications under the Misuse of Drugs Act.

analgesics and opiates were rated highly as first-preference drugs, but were rated relatively low as second preferences. Alcohol, herbal cannabis and benzodiazepines showed the opposite pattern and were rated highly as second preference drugs but not as first preferences. Ecstasy showed consistently high ratings across first and second preferences, whilst tobacco, nitrous oxide (N$_2$O), and hallucinogens were consistently ranked in the bottom 10 drugs.

Personal use and abuse of drugs

Tobacco consistently had the highest percentage of participants who rated themselves as showing likelihood for abuse or dependence on the CAGE-AID (Table 5).

Discussion

In terms of harms, there was a lack of any correlation between the rankings of nearly 6000 individuals and the rankings of drugs within either the US Schedules or the UK Misuse of Drugs Act. The findings in terms of UK rankings concur with previous literature (Nutt et al., 2007, 2010; Morgan et al., 2010b) and in terms of the USA scheduling system are consistent with UK findings yet novel in this context. Over 50% of respondents were from the US, with the majority of users being young (18–24), white, educated and currently either employed or studying.

Harms

Under US scheduling, the drugs rated as most harmful were either classed as Schedule II or not classified, whilst several of the drugs rated as least harmful are currently Schedule I. Similarly in the UK, two currently unclassified drugs – alcohol and tobacco – were rated in the top 10 most harmful drugs, whilst ecstasy and hallucinogens (both Class A drugs) were both rated relatively low on harms. Both strains of cannabis were rated as the least harmful drugs despite their Class B status. High harm ratings appeared to be driven by perceived long-term physical risks, risk of bingeing and craving. As expected, alcohol was perceived as a particularly high risk to society and had the highest perceived risk of bingeing, whilst risk of injecting was associated predominantly with opiate use, perhaps unsurprisingly.

Benefits

Whilst cocaine, ecstasy, mild stimulants and amphetamines were linked to 'help waking up' and 'improving attention and memory', benzodiazepines, prescription analgesics and both types of cannabis were associated with relaxation, decreased depression/anxiety and relief from pain and illness. Although our division is somewhat arbitrary, overall, herbal and skunk cannabis, ecstasy and ketamine were rated as having low harms but high benefits, and tobacco was rated high on harms and low on benefits. Opiates, prescription analgesics and cocaine showed particularly high harms and benefits. Viagra/ Cialis and hallucinogens were rated to be of relatively little benefit.

High benefits, low harms

Herbal cannabis and skunk were consistently placed in the top five drugs across the majority of benefits (except for 'improving attention,

memory and concentration', 'help waking up/ have more energy' and 'changing appearance of body'). In addition, both strains had the highest percentage of participants reporting benefits of 'enjoyment' and 'relief of physical pain/ symptoms of illness or disease', with skunk showing a slightly higher percentage in both instances. The two strains of cannabis were rated similarly for benefits, both with a primary benefit of relaxation/stress relief followed by their ability to aid sleep and enjoyment. There was little difference between skunk and other forms of cannabis, which is surprising given recent debates about increased harms of high-THC/low-cannabidiol varieties (di Forti et al., 2009; Morgan et al., 2010a,c). Ecstasy was also rated highly across all benefits (except for relaxation, relief from anxiety/ depression, relief of pain and help sleeping). MDMA was the highest ranked drug in the sociability category, with 'feeling closer to people/empathy' being the most often reported aspect of sociability. In contrast with both UK and USA classification systems, skunk and herbal cannabis were rated as

Table 3. Mean harm ratings of drugs on each of the seven risk factors.

	Short-term physical risk	Long-term physical risk	Risk of injecting	Risk to society	Risk of bingeing	Risk of reliance	Risk of craving
Opiates	1.3	2.1	2.4	1.8	2.3	2.5	2.7
Prescription analgesics	1.1	2.0	1.6	1.5	2.3	2.4	2.5
Cocaine	1.1	2.2	1.4	1.8	2.5	1.6	2.5
Alcohol	1.0	2.1	0.2	2.3	2.6	1.8	2.0
Amphetamines	1.0	1.9	1.2	1.5	2.2	1.7	2.1
Tobacco	0.9	2.4	0.1	1.1	2.0	2.3	2.6
Benzodiazepines	0.9	1.9	0.7	1.1	2.1	2.2	2.1
Ketamine	0.9	1.5	1.4	0.8	1.6	0.8	1.5
Mild stimulants	0.5	1.1	0.5	0.5	1.3	1.4	1.6
Ecstasy	0.8	1.4	0.4	0.6	1.7	0.6	1.2
Nitrous oxide	0.7	1.1	0.1	0.4	1.5	0.4	1.2
Hallucinogens	1.0	1.2	0.5	0.7	1.1	0.3	0.6
Viagra/ Cialis	0.3	0.6	0.3	0.3	0.9	0.6	0.4
Skunk cannabis	0.3	0.7	0.1	0.3	0.6	0.3	1.1
Herbal cannabis	0.3	0.7	0.1	0.3	0.6	0.3	1.0

Table 4. Ranked percentages of participant reporting each of 10 benefits.

Sociability		Enjoyment		State of mind		Relieve pain/ illness		Relieve anxiety/ depression	
Ecstasy	70.6	Skunk.C	77.5	Ketamine	74.1	Skunk.C	71.4	Benzos	91.6
Alcohol	59.3	Herbal.C	77.2	Ecstasy	71.2	Herbal.C	70.7	Skunk.C	74.8
Cocaine	51.8	Ecstasy	77.0	Skunk.C	62.7	PPK	66.8	Herbal.C	74.8
Herbal.C	40.4	Cocaine	60.0	Herbal.C	62.4	Opiates	62.4	PPK	70.6
Skunk.C	40.3	Ketamine	54.0	N₂0	53.8	Ketamine	40.1	Opiates	64.9
PPK	39.1	N₂0	50.2	PPK	36.0	Benzos	34.0	Ketamine	61.3
Benzo	36.2	Alcohol	46.1	Cocaine	36.2	N₂0	24.6	Ecstasy	60.0
Opiates	36.0	PPK	45.1	Opiates	34.2	Alcohol	24.1	Alcohol	49.2
Amphet	31.8	Amphet	41.9	Benzos	30.3	Ecstasy	21.4	Tobacco	45.7
Ketamine	28.8	Opiates	39.1	Alcohol	28.3	Cocaine	19.2	Cocaine	45.5
Mild stim	23.1	Viagra	34.0	Hallucin	27.6	Amphet	15.8	Amphet	36.6
Viagra	20.9	Mild stim	31.4	Amphet	22.9	Viagra	10.8	N₂0	29.4
Tobacco	19.6	Benzos	26.5	Mild stim	13.9	Mild stim	8.3	Mild stim	22.4
N₂0	15.1	Hallucin	22.5	Viagra	12.0	Tobacco	7.0	Hallucin	11.0
Hallucin	10.9	Tobacco	11.2	Tobacco	7.1	Hallucin	3.7	Viagra	9.3

Table 4. (Continued)

Feel more relaxed/ relieve stress		Help to get to sleep		Help wake up/ have more energy		Improve attention, memory and concentration		Change appearance of body (bulk up/ lose weight)	
Benzos	95.8	Benzos	90.2	Cocaine	84.9	Amphet	66.7	Cocaine	36.4
Herbal.C	92.5	Skunk.C	78.2	Mild stim	83.7	Mild stim	63.4	Amphet	34.7
Skunk.C	91.7	Herbal.C	77.5	Amphet	67.7	Cocaine	51.5	Ecstasy	22.3
PPK	86.1	PPK	61.3	Ecstasy	53.3	Tobacco	31.9	Opiates	19.8
Tobacco	82.2	Opiates	50.5	Tobacco	39.0	PPK	28.8	PPK	17.5
Alcohol	81.5	Alcohol	43.6	PPK	31.9	Herbal.C	24.6	Tobacco	16.0
Opiates	67.3	Ketamine	17.9	Opiates	25.7	Skunk.C	23.8	Mild stim	14.8
Ketamine	66.0	N_2O	16.7	Ketamine	17.0	Opiates	21.3	Viagra	11.6
Ecstasy	59.5	Tobacco	14.2	Herbal.C	14.3	Ecstasy	16.7	Herbal.C	9.2
N_2O	51.6	Viagra	4.7	Skunk.C	14.0	Benzos	14.0	Ketamine	9.4
Mild stim	29.2	Amphet	3.2	Viagra	9.3	Viagra	9.3	Skunk.C	8.7
Viagra	27.9	Cocaine	2.0	Alcohol	7.3	Ketamine	8.5	Alcohol	6.2
Cocaine	25.3	Mild stim	2.0	Benzos	6.3	Hallucin	5.1	Benzos	4.8
Amphet	21.1	Hallucin	1.8	N_2O	4.8	Alcohol	1.4	Hallucin	1.3
Hallucin	11.6	Ecstasy	1.5	Hallucin	4.3	N_2O	0.8	N_2O	1.2

Herbal.C: herbal cannabis; Skunk.C: skunk cannabis; PPK: prescription painkillers (prescription analgesics); Benzo: benzodiazepines; Amphet: amphetamine; Mild stim: mild stimulants; N_2O: nitrous oxide; Hallucin: hallucinogens.
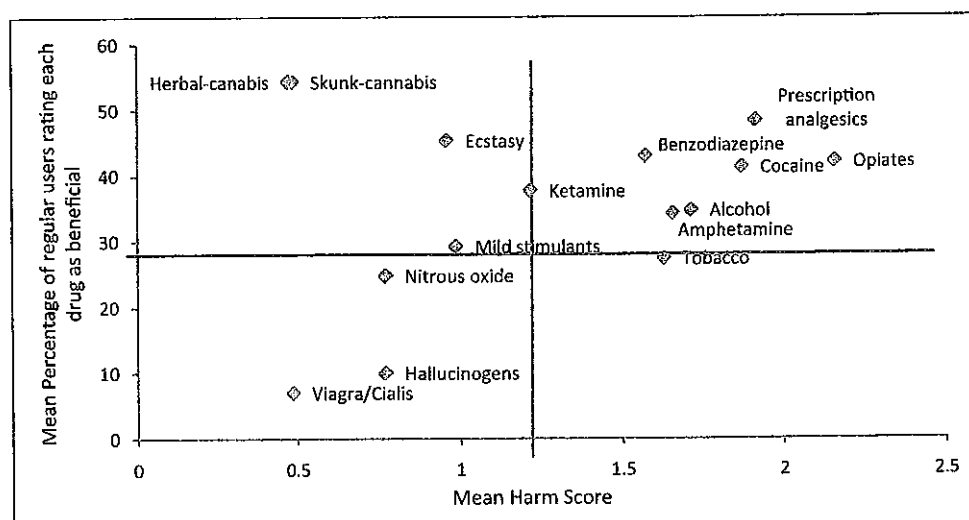
Figure 2. Comparison between mean percentage of participants rating each drug as a benefit and mean harm of drugs.

the least harmful drugs whilst ecstasy was rated as sixth least harmful. These low harm scores were driven by particularly low perceived risk of dependence, risk to society and risk of injecting.

Ketamine was ranked fifth as a drug of choice, and was ranked high on benefits for an individual's state of mind, enjoyment and pain relief. Ketamine was ranked eighth overall in terms of harms, higher than the two types of cannabis and ecstasy, which appears to be a result of higher ratings on measures of craving, bingeing and long-term physical risk, concurrent with recent reports of dependence on ketamine (Morgan and Curran, 2011).

High benefits, high harms

Cocaine showed consistently high rankings across all benefits but was rated as the third most harmful drug due to high perceived risk of bingeing, dependence and craving as well as long-term physical risk. Prescription analgesics were also ranked in the top 10 drugs across every benefit except 'help waking up', and were ranked in the top four in terms of relief from anxiety/ depression, stress and physical pain. As with cocaine, perceived overall harm of prescription analgesics was also extremely high (second most harmful). Opiates were rated as the most harmful drug, but were perceived to be highly beneficial for pain relief, alleviation of anxiety/ depression and stress. Whilst these drugs shared some of the benefits and harms of prescription analgesics, they were less likely to be a drug of choice, which may be due to the higher risk of injecting and craving associated with this group.

Benzodiazepines had the benefits of sedative and anti-depressant/anxiolytic effects and showed similar rankings as opiates in terms of sociability and state of mind. Benzodiazepines
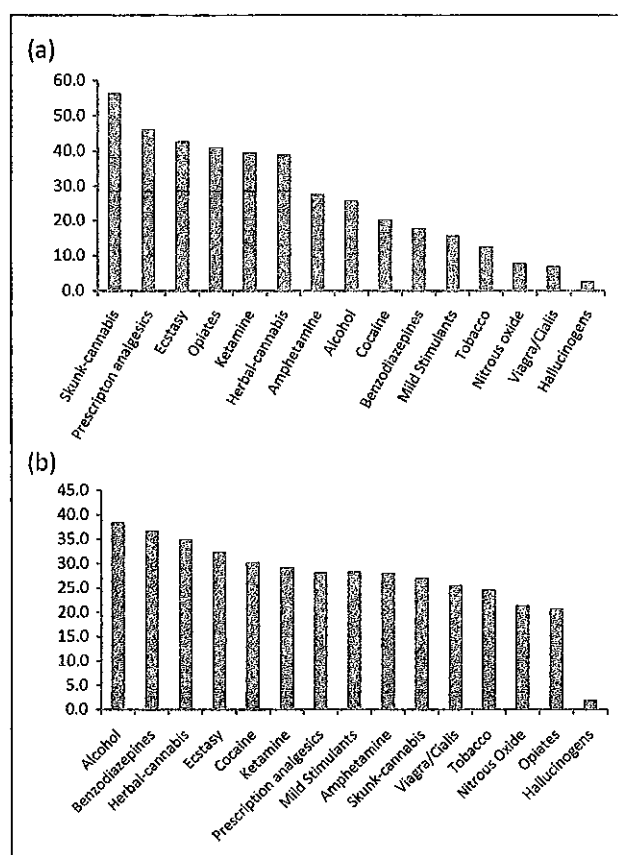
Figure 3. Percentage of participants reporting each drug as a) first preference b) second preference.

Table 5. Ranked percentage of participants using each substance who responded 'yes' to two or more CAGE questions.

	CAGE score ≥2 (%)
Tobacco	93.2
Prescribed analgesics	75.7
Cocaine	69.7
Opiates	63.4
Cannabis- skunk	63.3
Alcohol	61.7
Cannabis - herbal/resin	61.1
Benzodiazepines	57.9
Ketamine	52.8
Mild stimulant	43.6
Amphetamines	43.2
Ecstasy	42.0
Nitrous oxide	21.0
Viagra/ Cialis	17.1
Hallucinogens	6.9

were rated as considerably less harmful than opiates; in this respect, the perceptions of these drugs concurs with their legal status. The high preference for prescription analgesics and benzodiazepines by regular users is a profile that has not been

reported in any other study and may indicate a relatively unusual sample, or may reflect the recent trend towards prescription drug use in the US.

Low benefits, high harms

Tobacco was consistently ranked in the bottom three drugs in terms of benefits, with the exception of relieving anxiety/ depression or feeling more relaxed/ relieving stress. Whilst tobacco was ranked seventh in overall harms, this drug was unsurprisingly associated with high long-term physical risk and risk of reliance. Tobacco had the highest proportion of likely dependent users as classified by the CAGE.

Amphetamines and alcohol were rated to be of medium benefit. Both were rated as drugs with high risk of bingeing and craving, but amphetamines scored highly on benefits of stimulant effects such as waking up/ having more energy, changing appearance of the body and were ranked as the most beneficial drugs in terms of improving attention, memory and concentration. Alcohol was thought to be highly beneficial for sociability. It was ranked fifth in terms of harms, with particularly high risk to society and risk of bingeing.

Low benefits, low harms

Drugs that were rated as having low harms and low benefits were Viagra, hallucinogens, nitrous oxide and mild stimulants. The low beneficial rating of hallucinogens contradicts the findings of our prior UK drug survey (Morgan et al., 2010b). where hallucinogens were rated as one of the drugs with greatest long-term benefits. Hallucinogens were the least preferred drug, which may reflect the inclusion of a wider group of users compared with all other substances, and along with Viagra/cialis were ranked in the bottom five on all benefits. This is perhaps surprising given the use of Viagra/Cialis as a medicine and previous reports of the positively beneficial effects of hallucinogens (e.g. Griffiths et al., 2006, 2008); this may, however, reflect the very specific benefits of these substances which are not reflected in a mean overall benefits rating on the scale used in this study.

Abuse and dependence

The USA scheduling system is based on the potential for abuse of each substance, hence one might expect it to be mirrored in the proportion of individuals scoring in the abuse range of the CAGE-AID for the different drugs included in this survey. However, in the present study tobacco had the highest proportion of regular users showing possible abuse or dependence, followed by opiates, prescription analgesics, cocaine and alcohol. Thus three drugs in the UK and two in the US which are currently unclassified produce the greatest likelihood of abuse or dependence, albeit on a crude scale. Indeed, in the case of prescription analgesics, opiates, cocaine and alcohol, the overall high harm ratings obtained tended to result from high risks of reliance and craving, whilst tobacco scored particularly high in terms of reliance. Furthermore, ecstasy and hallucinogens, currently Class A and Schedule I, were scored low in the proportion of regular users showing possible abuse on the CAGE-AID.

Limitations

As an internet survey, it was not possible to verify that each respondent was unique, and the sample was inevitably self-selecting. Of the nearly 6000 individuals who completed the survey, the majority were well educated, white, employed or studying. The survey was only translated into English, Spanish and French, and this may have reduced the number of respondents from many countries where other languages predominate. At the same time, this is the first multi-language survey of drug users to date with the largest number of respondents who were spread across 61 countries worldwide.

A further limitation of the current study is that the harms and benefits of polysubstance use, which is becoming the norm amongst the vast majority of drug users, were not addressed. This was beyond the scope of this study and it would be have been a complex task for drug users to rate the effects of multiple substances. Further, research suggests that drug users are aware of the key effects of the drugs they take, even novel compounds such as mephedrone (Carhart-Harris, 2011), despite being taken in combination with other substances. However, future work should aim to explore this interesting issue. Similarly, the study could not assess the context dependence of the benefits or harms or the benefits of the drug effects versus drug culture, for example the benefits of the sociable dance music culture that can occur around ecstasy use. This study also did not distinguish between what were benefits of acute drug effects and longer-term benefits (although we attempted this in our previous UK drug survey, Morgan et al., 2010b). In future work, we would aim to compare harms and benefits on similar scales, and take into account context effects.

Another limitation was that the number of users rating on hallucinogens was much greater than for other substances because, as there are no 'regular' users, this included people who had ever tried any of a wide range of hallucinogens. For all other drugs, harms and benefits could only be rated by those who judged themselves regular users and so data for hallucinogens were comparatively skewed. Thirdly, there were low numbers rating some drugs (e.g. crack) and we did not explore the use of different drugs in combination, mainly to restrict the length of the survey so as to increase completion rates. Only regular users of each drug were allowed to rate its benefits and harms in the current study, thus drug benefits may be perceived to be greater than if a sample of ex- or non-users were used. Regular users may downplay risks in their continued use of these substances, much as a car driver plays down the risk of road traffic accidents. Therefore it could be argued that users are not the best people to rate on harms. However, in our previous study of drug users' views of harms (Morgan et al., 2010b) we found a very high correlation between 'expert' and user ratings of harm, therefore it would seem that even if users downplay the risks in their own behaviour, or simply weight the benefits greater than the potential costs, this would not appear to substantially diminish their awareness of the severity of the harms. Further, this sample is unique in its ability to provide extensive knowledge of drug effects, particularly benefits, across a range of psychoactive substances. Given that the literature on drug use has been dominated by research into harms, taking into account the views of these users – even if they might be skewed towards more positive perceptions of recreational drugs – is important if we are to converge on a more balanced position on illicit substance use.

Implications

Our survey expanded upon that of Nutt et al. (2007, 2010) by including a detailed assessment of the perceived benefits of drugs. A full scientific understanding of the relative harms and benefits of recreational drugs is important. In understanding the perceived benefits of illicit substances we may learn about the motivation behind their use, which can prove useful in developing treatment programmes. The lack of correlation between the users' ranked harms and drug classifications in the UK and USA suggest that current drug policy is not serving to inform those who take drugs of the harms of these substances. Furthermore, the prevalence of use of each substance within this sample suggests that current policy does not influence whether people choose to use the drug. For example, herbal cannabis and skunk, currently Class B in the UK and Schedule I in the USA, were respectively the second and third most regularly used drugs.

The high benefits and low harms of skunk, herbal cannabis and ecstasy do not correspond with their current legal classifications. Further, alcohol and several prescription analgesic drugs are currently not classified in the UK, e.g. Tramadol, but were rated high in harm, whereas in the USA all prescription analgesics have been classified as Schedule II. Whilst these results might be taken to imply that prescription analgesic drugs should be placed in the highest class or schedule, these drugs were also rated as having a wide variety of benefits. Although a system based entirely on drug harms has been suggested to be unworkable (Caulkins et al., 2011), it would seem prudent to produce a full assessment of the relative harms and benefits of psychoactive substances – which perhaps this preliminary study may in some way inform – so that policy makers may more accurately take into account the relative harms and benefits when deciding how to control these substances. Whilst these data, which are simply the opinions of drug users, may not serve to inform policy, they can inform us of the views of drug users on the perceived benefits and harms of psychoactive substances, which may be important for effective drugs education and treatment.

Conclusion

In summary, there are very marked disparities between the rated harms of different drugs by nearly 6000 users and the rankings of these drugs in both UK and USA classification systems. In particular the classification of skunk, herbal cannabis/resin and ecstasy appears arbitrary not only in terms of rated harms but also ranked benefits, preference and dependence. Currently unclassified drugs (alcohol and prescription analgesics (UK)) had high ratings of harms but also relatively high ranking of benefits and high preference. It is therefore important to consider both the perceived consequences and motivations for drug use to better inform both policy and educational programmes.

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Conflict of interest

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DOCUMENT B

CURRENT DRAFT OF

CONNECTICUT RMJ LAW

CT SSB 1118:

An Act Concerning Responsible and Equitable Regulation of Adult-Use Cannabis

(with accompanying discussion)

Summary of Connecticut's S.B. 1118 — An Act Concerning Responsible and Equitable Regulation of Adult-Use Cannabis

S.B. 1118 — An Act Concerning Responsible and Equitable Regulation of Adult-Use Cannabis — would legalize possession and cultivation of cannabis for adults 21 and older and expunge thousands of past records. It replaces the unregulated illicit market with a taxed and regulated system of licensed cultivators, retailers, manufacturers, and delivery services and invests the bulk of tax revenues into disproportionately impacted communities. Half of new cannabis business licenses would be issued to social equity applicants, who could receive technical assistance, start-up funding, assistance from an accelerator program, and workforce training. S.B. 1118 also includes strong protections for public safety and deterrents for underage use.

The bill is sponsored by Sen. President Martin Looney and Speaker of the House Matt Ritter. It incorporates ideas from Gov. Ned Lamont's S.B. 888, along with concepts from Rep. Robyn Porter's H.B. 6377 (related to labor and equity) and input from lawmakers and advocates.

On June 7, the Senate approved the bill 19-17. It now heads to the House.

Personal Liberty and Possession Limits

- Beginning on July 1, 2021, allows adults 21 and over to:
    - possess up to 1.5 ounces of cannabis or an equivalent amount of cannabis products or concentrates; and
    - possess up to five ounces of cannabis or an equivalent amount in a locked container in the person's residence, the person's locked glove box, or their vehicle's trunk.
    - Equivalency: One ounce of cannabis is considered equivalent to five grams of cannabis concentrate or any other cannabis product with up to 500 milligrams of THC.
- Decriminalizes possession of fewer than five ounces on one's person and fewer than eight ounces in their vehicle's trunk or locked glove box, imposing a civil fine instead of possible jail time.
- Decriminalizes first-offense possession of more than five ounces on one's person and more than eight ounces in one's locked glove box or trunk, imposing a $500 fine for a first offense. A second offense is a class D misdemeanor, which has a maximum sentence of up to 30 days in jail and/or a fine of up to $250.
- Allows adults 21 and over to gift cannabis, within legal limits, to each other.
- Starting October 1, 2021, allows qualifying medical marijuana patients who are at least 18 to securely cultivate up to three mature and three immature plants in their homes.
- Starting July 1, 2023, allows all adults 21 and older to securely cultivate up to three mature and three immature plants in their homes. Includes a household cap of 12 plants.
    - Before that date, decriminalizes cultivating up to three mature and three immature plants. A first offense results in a written warning. A second offense carries a fine of up to

$500, and a subsequent offense is a class D misdemeanor. Evidence for illegal home cultivation of that amount cannot be admitted if it was found in the context of any other investigation that was not specific to cannabis.
  - DCP will issues written recommendations to the legislature no later than January 1, 2023 on whether to continue to allow home cultivation, along with precautions to secure cannabis, how states are handling home cultivation, and other relevant public safety or regulatory issues.
- Legalizes possession and use of cannabis paraphernalia.
- Decriminalizes first offense of illegally manufacturing, selling, or possessing with intent to sell up to eight ounces.
- Eliminates odor of cannabis or burnt cannabis as a basis to stop or search.
- Eliminates suspected possession or possession of up to five ounces as a basis to stop or search.
- Prohibits prosecution for sale or possession when seeking medical assistance.
- Prohibits smoking, inhaling, or ingesting marijuana while driving or riding in a motor vehicle. Specifies that a motor vehicle cannot be stopped solely on that basis, which is important to prevent pretextual and otherwise unjustified stops based on smoking a cigarette or nicotine vape.

Redresses Harms Caused by Prohibition and Unequal Enforcement

- Beginning July 1, 2021, prohibits state-legal cannabis possession or use from being grounds for revoking parole, special parole, or probation except in cases where there is an individualized basis for finding that the person's cannabis use would pose a danger.
- The Department of Consumer Protection (DCP) must return seized paraphernalia and drugs that do not violate the law.
- Beginning July 1, 2022, individuals can petition for erasure of prior convictions for possession, drug paraphernalia, and sale and manufacture of four or fewer ounces or six or fewer plants. If the petition is in order, it must be granted. No fee may be charged.
- Beginning January 1, 2023, provides for automatic erasures of convictions from January 1, 2000 through September 15, 2015 for possession of fewer than four ounces.
- Any person whose record has been erased can represent that the arrest or conviction did not occur.
- Prohibits landlords and property managers from:
  - refusing to rent to, or otherwise discriminating against, an existing or prospective tenant based on a past conviction in Connecticut for possessing specified amounts of cannabis, or in another jurisdiction for possessing four or fewer ounces of cannabis;
  - requiring tenants to submit to a drug test; and
  - banning non-inhaled use of cannabis at one's rental home.
- Institutions of higher education may not deny individuals financial aid, student loans, or expel a student solely for possessing four or fewer ounces of cannabis.
- Starting on January 1, 2022, schools may not impose harsher discipline for students using, possessing, or selling, cannabis than they would impose for alcohol.
- Prevents state entities from denying professional licensing based on the legal use of cannabis, a conviction for no more than four ounces of cannabis, or work for a cannabis establishment.
- Prohibits all state agencies and political subdivisions from relying on a violation of federal law to take adverse action against a person.
- Prevents the following actions based on an individual testing positive for cannabis metabolites:

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- a person being denied organ transplants or other medical care, unless there is an evidence-based reason;
- adverse action being taken by the Department of Children and Families, absent a risk of harm to the child; or
- failing to give students educational opportunities, absent a federal requirement.
- Establishes a new impaired driving intervention program and a pretrial drug intervention and community service program.

Protections to Prevent Underage Use

- Prohibits cannabis-related advertising in ways that target those under age 21.
- Imposes penalties on cannabis retailers or hybrid retailers who allow underage individuals to loiter or enter certain parts of the establishment.
- Makes it a class A misdemeanor for a person who is 23 or older to sell or give cannabis to a person who they know or should know is under 21.
- Cannabis establishment licensees who sell or deliver cannabis or cannabis products to people under age 21 are guilty of class A misdemeanors are punishable by up to one year in prison, a fine of up to $2,000, or both.
- By January 1, 2023, requires the Alcohol and Drug Policy Council to make recommendations to the governor and legislature on efforts to promote public health and science-based harm reduction, mitigate misuse and the risk of cannabis addiction, and effectively treat cannabis addiction with a particular focus on individuals under age 21.
- Makes it a class A misdemeanor for someone in control of a home or private property to allow someone under age 21 to possess cannabis there.

Penalties for Underage Possession

Individuals age 18 to 20:

- First offense possession of less than five ounces or its equivalent: $50 fine, except the fine is waived if the individual attests to his or her indigence.
- Second offense or subsequent possession of less than five ounces: $150 fine, or as an alternative, the individual may perform six hours of community service for a private, nonprofit charity or other nonprofit organization (if the individual chooses community service, he or she must attest to completing that service and present confirming documentation).
- Possession of five ounces or its equivalent or more: First offense: $500 civil fine, except the fine is waived if the individual attests to his or her indigence. Subsequent offense: Class D misdemeanor (carries up to 30 days in jail and/or a fine of up to $250).
- All possession offenses: View and sign a statement acknowledging the health effects of cannabis on young people.
- Sixty-day suspension of the driver's license or nonresident operating privilege for anyone under age 21 convicted of possessing any amount of cannabis.

Individuals under age 18:

- First offense possession of less than five ounces or its equivalent: a written warning and

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possible referral to a youth services bureau or other appropriate services.
- Second offense: mandatory referral to a youth services bureau or other appropriate services.
- Third or subsequent offense or possession of five ounces of more or its equivalent: adjudicated as delinquent in juvenile court.
- Does not allow arrests for minors in possession of cannabis.
- Sixty-day suspension of the driver's license or nonresident operating privilege for anyone under age 21 convicted of possessing any amount of cannabis.

Local Controls

- Prohibits host community agreements by municipalities, which have been detrimental to equity in Massachusetts.
- Allows municipalities to prohibit cannabis establishments from opening within their jurisdiction.
- Prohibits municipalities from banning cannabis delivery.
- Allows local referendum on whether or not to allow the sale of marijuana for adult use. To qualify for the ballot, 10% of voters must sign a petition.
- Allows municipalities to reasonably restrict cannabis establishments' hours and signage.
- Allows municipalities to reasonably restrict cannabis establishments' number or density. Until June 30, 2024, sets a maximum of one retailer and one cannabis micro-cultivator (which can sell at retail) per 25,000 residents, as determined by the most recent census. Beginning July 1, 2024, the DCP will set a new limit.
- Allows municipalities to restrict cannabis establishments' proximity to religious institutions, schools, charitable institutions, hospitals, veterans' homes, or certain military establishments.
- Allows municipalities, for the first 30 days after cannabis retailers or hybrid retailers open, to charge up to $50,000 for reasonable municipal costs for public safety services related to the opening (such as for directing traffic).
- Allows municipalities to establish fines of up to $50 for use of cannabis on under control of the municipality. Allows for fines of up to $1,000 for businesses violating a local public use ordinance.

Public Health and Safety

Clean Indoor Air:

- Adds cannabis and hemp smoking and vaping to the areas where tobacco is restricted under the Clean Indoor Air Act.
- Expands the Clean Indoor Air Act's ban on smoking and using e-cigarettes to include "any area" of a facility, building, or establishment, including outside areas that are within 25 feet of a doorway, operable window, or air intake vent, in addition to the premise's interior, and "any area" of a retail establishment accessed by the public.
- Bans smoking and e-cigarette use in workplaces, regardless of the number of employees.

Road Safety:

- Requires Police Officer Standards and Training Council (POST) and Department of Transportation (DOT) to increase the number of officers to be trained in advanced roadside

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impaired driving enforcement (ARIDE).
- Increases access to ARIDE training and drug recognition expert (DRE) training for police officers and law enforcement units.

Public Health:

- Beginning in the fiscal year starting on July 1, 2023, 25% of cannabis excise tax revenue will be dedicated to the Prevention and Recovery Services Fund for substance abuse prevention, treatment and recovery services, and collection and analysis of data regarding substance use.
- Establishes a program within the Department of Public Health to collect information on cannabis-associated adverse events, injuries, and cannabis use poisoning.
- Caps the potency of cannabis that can be sold in the state, capping flower at 30% THC and all other products except pre-filled vape cartridges at 60%; these caps can be adjusted by regulators.
- Directs the Commissioner of the Department of Consumer Protection to craft health, safety, and security requirements, including:
    - prohibiting products designed to appeal to children;
    - restricting advertising, including banning ads with an audience that is more than 10% under the age of 21;
    - limiting servings to five mg of THC (other than medical cannabis) and requiring individual servings to be separate or demarcated;
    - requiring retailers to provide access to low-THC and high-CBD products;
    - prohibiting certain manufacturing methods, the addition of any additive with nicotine, and — unless approved by the department — added flavoring, terpenes or other additives; they may include pamphlets, packaging inserts, signage, online and printed advertisements and advisories and printed health materials;
    - requiring, in consultation with the Department of Mental Health and Addiction Services, that consumer health materials be posted or disseminated at retail locations;
    - labeling and packaging requirements, including a universal symbol and child-resistant packaging;
    - mandating lab testing and product tracking;
    - developing storage and transportation requirements and training and employment requirements;
    - giving DCP the authority to restrict forms of cannabis products and delivery systems for public health and consumer safety; and
    - requiring registration of cannabis brand names, which cannot be confusingly similar to the name of another product, obscene, associated with minors, or be an unfair or deceptive trade practice.

Taxation

- The bill imposes an excise tax based on potency at the point of retail sale and exempts medical cannabis. The rate is:
    - $0.00625 per milligram of THC in raw, flower cannabis;
    - $0.0275 per milligram of THC in edibles; and
    - $0.009 per milligram of THC in other cannabis products.
- Until June 30, 2023, 100% of the excise tax would be directed to the General Fund. (Beginning

on June 10, 2021, up to $50 million in bonds may be issued to fund start-up capital for social equity applicants, the cannabis business accelerator program, and workforce training developed by the Social Equity Council.)
- Starting on July 1, 2023 and thereafter, 25% of the excise tax would go to the Prevention and Recovery Services Fund.
- From July 1, 2023 until June 30, 2026, 60% of the excise tax would go to the Social Equity and Innovation Fund. On July 1, 2026, that would increase to 65%. Beginning on July 1, 2028, it would increase again, and would remain at 75%.
- The remainder of the tax — ranging from 15% in the last half of 2023 to 0% starting on July 1, 2028 — would go to the General Fund.
- The state's standard 6.35% sales tax would also apply to cannabis sales.
- The bill imposes a 3% municipal gross receipts tax on the sale of cannabis and cannabis products. Municipal sales tax revenue must be used for one or more of the following:

> 1. Streetscape improvements and other neighborhood developments in communities where cannabis or hybrid retailers or micro-cultivators are located
> 2. Youth employment and training programs in these municipalities
> 3. Services for individuals living in these municipalities who were released from DOC custody, probation, or parole
> 4. Mental health or addiction services
> 5. Youth services bureaus
> 6. Community civic engagement efforts

License and Regulatory Structure

The Department of Consumer Protection would be charged with licensing and regulating cannabis businesses.

License Types and Numbers

No later than 30 days after the Social Equity Council identifies criteria and supporting documentation for social equity applicants, it may begin accepting applications from the following types of licenses:

> 1. retailer
> 2. hybrid retailer (which sells both adult-use and medical cannabis)
> 3. cultivator (which cultivate 15,000 square feet or more)
> 4. micro-cultivator (which start between 2,000 and 10,000 square feet)
> 5. product manufacturer
> 6. food and beverage manufacturer
> 7. product packager
> 8. delivery service
> 9. transporter

Before accepting applications, DCP will determine the maximum number of licenses of each type and post it on its website. Fifty percent of each license type are reserved for social equity applicants.

The department will establish the maximum grow space permitted by a cultivator and micro-

cultivator. In doing so, it will seek to ensure an adequate supply.

On-site consumption is not initially allowed. By January 1, 2023, DCP will made recommendation on whether to authorize on-site consumption or events that allow cannabis usage.

License Fees

Existing Dispensaries

DCP will begin accepting applications from dispensaries to covert to also serve adult-use starting on September 1, 2021. To become a "hybrid retailer," a dispensary must:

- Submit a detailed medical preservation plan on how it will prioritize medical cannabis access, including consumer traffic, supply shortages, staffing, and delivery.
- Pay a fee of $1 million, which can be reduced to $500,000 if they create at least one "equity joint venture." "Equity joint ventures" must be at least 50% owned by a social equity applicant.

Existing Producers (Grower/Processors)

Sometime after July 1, 2021, DCP can authorize producers to also produce cannabis for adult use. To convert to also serve adult use, producers must:

- Pay a fee of $3 million, which can be reduced to $1.5 million if they create at least two "equity joint ventures," which cannot be cultivators.
    - Equity joint ventures must be at least 50% owned by individuals from disproportionately impacted areas that are below the income thresholds. They are not subject to the lottery.
    - Producers may not own more than 50% of the equity joint venture for the first seven years.
    - If they fail to create at least two equity joint ventures, the producers must pay the full $3 million.
- Pay a fee of $500,000 to the social equity account or provide 5% of their grow space to a social equity applicant, mentor that business for five years, cover all necessary business costs for the social equity applicant, and require 100% of the profits be directed to the social equity applicant.
- Implement a DCP-approved medical cannabis preservation plan.
- Implement a Social Equity Council-approved workforce development plan.

Licensing Fees — Social Equity

Fees paid by social equity applicants who enter the lottery are 50% lower than the open licensing fees. They are:

> 1. A retailer or hybrid retailer fee to enter the lottery is $250, the fee for a provisional license is $2,500, and the fee for a final license or renewal is $12,500;
> 2. A cultivator fee to enter the lottery is $500, the fee for a provisional license is $12,500, and the fee for a final license or renewal is $37,500;
> 3. A micro-cultivator fee to enter the lottery is $125, the fee for a provisional license is $250, and the fee for a final license or renewal is $500;
> 4. A product manufacturer fee to enter the lottery is $375, the fee for a provisional license

is $2,500, and the fee for a final license or renewal is $12,500;

5. A food and beverage manufacturer fee or delivery service fee to enter the lottery is $125, the fee for a provisional license is $500, and the fee for a final license or renewal is $2,500; and

6. A product packager fee to enter the lottery is $250, the fee for a provisional license is $2,500, and the fee for a final license or renewal is $12,500.

Licensing Fees — Open Licensing

Fees paid by other cannabis applicants and licensees are:

1. A retailer or hybrid retailer fee to enter the lottery is $500, the fee for a provisional license is $5,000, and the fee for a final license or renewal is $25,000;

2. A cultivator fee to enter the lottery is $1,000, the fee for a provisional license is $25,000, and the fee for a final license or renewal is $75,000;

3. A micro-cultivator fee to enter the lottery is $250, the fee for a provisional license is $500, and the fee for a final license or renewal is $1,000;

4. A product manufacturer fee to enter the lottery is $750, the fee for a provisional license is $5,000, and the fee for a final license or renewal is $25,000;

5. A food and beverage manufacturer, delivery service, or transporter fee to enter the lottery is $250, the fee for a provisional license is $1,000, and the fee for a final license or renewal is $5,000; and

6. A product packager fee to enter the lottery is $500, the fee for a provisional license is $5,000, and the fee for a final license or renewal is $25,000.

Licensing Fees — Staff and Backer

The license fee for a backer or key employee is $100; employee registrations for others are $50.

Licensing Qualifications

Individuals are disqualified from owning a cannabis establishment if they have a conviction within the last 10 years for money laundering, vendor fraud, insurance fraud, forgery, filing a false record, bribery, witness tampering, perjury, false statement on a certified payroll, bribery of a labor official, bribery of commercial bribe, receiving kickbacks, paying kickbacks, rigging, telephone fraud, identity theft, or willful tax evasion in any state.

Licensure Process

Licensing By Lotteries, With Social Equity First

If the application period for a license type closes and DCP received more than the maximum number of applications, a third-party lottery operator must conduct a lottery to select applications for DCP review.

The vast majority of new licenses will be issued by lottery. This provides an equal chance to all qualified applicants and avoids requiring unsuccessful applicants to spend large sums of money to apply. The lottery may include multiple separate geographic lotteries.

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The lottery for social equity applicants is first. At least 50% of each new license type will be issued to social equity applicants. After that, a second lottery will include both unsuccessful social equity applicants and any other applicant.

In the lottery, every entrant will get a numerical ranking, including those who are not initially selected. After the lottery selects applicants, the Social Equity Council will verify that the winners qualify as a social equity applicant — without having any identifying information. If an applicant does not qualify, they will be entered into the open lottery provided they pay the other half of the lottery fee. For any applicant that does not qualify, the lottery operator will identify the next-ranked applicant who will then be reviewed.

The bill requires that all applicants selected in the lottery and not disqualified be provided a provisional license application.

Applicants must complete their applications within 60 days after they receive it, and the right to apply for a provisional license is nontransferable.

A provisional license expires after 14 months and is not renewable. A provisional licensee may apply for a final license during the initial application period. Final license application requires:

> 1. A contract with an approved seed-to-sale vendor in accordance with the bill's provisions;
> 2. A right to occupy the location where the cannabis establishment will be located;
> 3. Any necessary local zoning approval for the cannabis establishment;
> 4. A social equity plan;
> 5. A workforce development plan;
> 6. Written policies for preventing diversion and misuse of cannabis and sales to underage persons;
> 7. All other security requirements set forth by the department based on the specific license type;
> 8. A labor peace agreement entered into between the cannabis establishment and a bona fide labor organization; and
> 9. A certification that they are using a project labor agreement for construction projects of $5 million or more.

Only cannabis establishments with approved final licenses can begin operations.

Social equity licenses cannot change ownership to non-social equity applicants until three years after final licensure, except in specific cases such as death or illness.

Additional Cultivation License(s)

- The Social Equity Council will use funds from producers to assist social equity applicants in opening no more than two micro-cultivator licenses total, which producers shall provide mentorship for. It will select applicants without a lottery or request for proposals.
- Thirty days after the Social Equity Council posts criteria for social equity applicants, the department will open a three-month application period for social equity applicants to apply for

provisional cultivator licenses in a disproportionately impacted area. These applicants shall be granted a license if the applicant pays a $3 million fee to the Social Equity and Innovation Fund. (This problematic provision is in Sec. 149.)
- Micro-cultivators can apply to expand their grow space by 5,000 square feet per year. The maximum size for a micro-cultivator is 25,000 square feet. At that point, they may apply for a cultivator license, without undergoing a lottery process.

Social Equity and Industry Inclusion

- DCP must reserve 50% of the maximum number of applications that must be considered for eligible license types for social equity applicants.
- Social equity applicants receive a 50% reduction in license fees for the first three renewal cycles.
- A "social equity applicant" is defined as an applicant for a cannabis establishment license that is either at least 65% owned *and* controlled by one or more individual who lived in a disproportionately impacted area for either at least five of the past 10 years of nine of their first 17 years of life.
    - A disproportionately impacted area is a census tract that has either an unemployment rate of over 10% or that has a high rate of drug arrests over the past 40 years.
    - Social equity applicants must also have a median income for the last three years that was no more than triple the state's median income.
    - The Social Equity Council can add additional criteria to the definition.
- Creates $50 million in bonding for initial funding for start-up capital for social equity applicants, the cannabis business accelerator program, and workforce training developed by the Social Equity Council.
- Beginning on July 1, 2023, directs from 60% to 75% of the cannabis excise tax revenue will be directed to the Social Equity and Innovation Fund. Those funds can be used to promote social equity in relation to access to capital for businesses, funding workforce education, and funding for community investments.

Within 45 days after bill passage, the Social Equity Council must establish criteria for proposals for an independent third party to conduct a study addressing the following issues, in relation to Connecticut:

> 1. Historical and current social, economic, and familial consequences of cannabis prohibition, the criminalization and stigmatization of cannabis use, and related public policies;
> 2. Historical and current structures, patterns, causes, and consequences of intentional and unintentional racial discrimination and disparities in the development, application, and enforcement of this prohibition and related public policies;
> 3. Foreseeable long-term social, economic, and familial consequences of unremedied past racial discrimination and disparities arising from past and continued cannabis prohibition, stigmatization, and criminalization;
> 4. Existing patterns of racial discrimination and disparities in access to entrepreneurship, employment, and other economic benefits arising in the state's medical marijuana sector; and
> 5. Any other matters that the council deems relevant and feasible to study for making reasonable and practical recommendations for establishing an equitable and lawful adult-

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use cannabis business sector.

By January 1, 2022, taking into account the study's results, the Social Equity Council must make recommendations to the governor and the General Law, Judiciary, and Finance, Revenue and Bonding committees for legislation to implement these social equity provisions. The recommendations must address:

> 1. Creating programs to ensure that individuals from disproportionately harmed communities have equal access to cannabis establishment licenses;
> 2. Specifying additional qualifications for social equity applicants;
> 3. Providing for expedited or priority license processing for social equity applicants for retailer, hybrid retailer, cultivator, micro- cultivator, product manufacturer, food and beverage manufacturer, product packager, and delivery service licenses;
> 4. Establishing minimum criteria for cannabis establishments licensed on or after January 1, 2022 that are not owned by a social equity applicant to comply with an approved plan to reinvest or provide jobs and training opportunities for individuals in disproportionately affected communities;
> 5. Establishing a social equity plan for any cannabis business licensed on or after January 1, 2022;
> 6. Recruiting individuals from these communities to the workforce training program established under the bill;
> 7. Potential uses for revenue generated under the bill to further equity;
> 8. Encouraging participation by investors, cannabis establishments, and entrepreneurs in the cannabis business accelerator program established under the bill;
> 9. Establishing a process to best ensure that social equity applicants have access to the capital and training needed to own and operate cannabis establishments; and
> 10. Developing a vendor list of women- and minority-owned businesses that cannabis establishments may contract with for necessary services, such as office supplies, information technology infrastructure, and cleaning services.

The Social Equity Council, by October 1, 2023, is required to report to the governor and Judiciary Committee on arrest and conviction data for cannabis possession, including a breakdown by town, race, gender, and age.

- Expands the Angel Investor Tax Credit to allow investors to claim a 40% income tax credit for credit-eligible investments in these businesses, imposes a $15 million per fiscal year cap on these credits.
- Establishes a Cannabis Business Accelerator program to provide technical assistance to accelerator licensees by partnering social equity licensees who wish to participate with a cannabis establishment. It may partner with a unit of a state college or university to create the program.
- Requires the Social Equity Council to partner with regional workforce development boards to develop workforce training boards, partner with training providers, and create apprenticeship programs across the state.

Tribal Governments

- The governor may enter into cannabis-related agreements or compacts with the Mashantucket Pequot Tribe and/or the Mohegan Tribe of Indians.

Protecting Medical Cannabis Patients

- Beginning on October 1, 2021, allows medical marijuana patients who are at least 18 to securely grow up to three mature and three immature cannabis plants in their homes.
- Allows patients and caregivers to possess up to five ounces of marijuana.
- Allows DCP to add qualifying medical conditions without further legislative approval or delay.
- Prohibits hybrid retailers (that serve adults and medical patients) from converting to serve adult-use patients only outside of lottery process.
- Starting September 1, 2021, the bill permits dispensary facilities and hybrid retailers to apply to DCP to provide delivery services to qualifying patients and caregivers (1) using their own employees or an available delivery service, and (2) delivering marijuana only from their own inventory.
- Starting October 1, 2021, the bill eliminates current law's requirement that qualifying patients (or parents or guardians of patients who are minors) designate a dispensary facility or hybrid retailer as their exclusive location to purchase medical marijuana.
- Before June 30, 2022, prohibits the department from approving a dispensary relocation that is further than 10 miles from the current location.
- Until June 30, 2023, allows DCP to deny a change of location for a dispensary facility or hybrid retailer because of patient needs.
- Requires hybrid retailers (medical dispensaries that can also serve adult-use consumers) to (1) maintain a licensed pharmacist on-site when the retail location is open to the public or to qualifying patients and caregivers, (2) include a space for pharmacists to hold private consultations with qualifying patients and caregivers, (3) provide an approved medical cannabis preservation plan to ensure against supply shortages of medical marijuana product, and (4) accommodate an expedited entry method that allows priority entrance for qualifying patients and caregivers.

Discussion of CT bill under consideration:

The bulk of the nearly 300-page bill, however, resembles the version passed last week by the Senate. It would legalize personal possession and use of cannabis by adults 21 and older and eventually launch a regulated commercial cannabis market.

The Department of Consumer Protection (DCP) would be in charge of licensing and regulating cannabis businesses, with legal sales expected to begin in mid-2022.

Half of all business licenses would need to be issued to social equity applicants, defined as people with who have lived in geographic areas disproportionately impacted by the war on drugs as well as those with past cannabis arrests or convictions. A second amendment from Winfield, approved prior to the full floor vote, expanded an income limit for social equity applicants to clarify that no individual who makes more than three times the state's median income would be eligible for the status.

Equity applicants could also qualify for technical assistance, workforce training and funding to cover startup costs. Much of the revenue from the new commercial market would be reinvested back into communities hit hardest by the drug war.

For residents who don't want to buy cannabis commercially, home cultivation would also be allowed under the bill—first for medical patients, then eventually for all adults 21 and older.

Here are some key details about the Senate-approved legislation:
- It would allow adults 21 and older to possess up to 1.5 ounces of cannabis starting on July 1, and it would establish a retail market. Legislative leaders anticipate sales to launch in May 2022, though the bill includes no official start date.
- Regulators with the Department of Consumer Protection (DCP) would be responsible for issuing licenses for growers, retailers, manufacturers and delivery services. Social equity applicants would be entitled to half of those licenses.
- A significant amount of tax revenue from cannabis sales would go toward community reinvestment.
- Home cultivation would be permitted—first to medical marijuana patients and then later to adult-use consumers.
- Criminal convictions for possession of less than four ounces of cannabis would be automatically expunged beginning in 2023. Expungement would

apply to possession convictions from January 1, 2000 through September 15, 2015.

- Beginning July 1, 2022, individuals could petition to have other cannabis convictions erased, such as for possession of marijuana paraphernalia or the sale of small amounts of cannabis.
- The smell of cannabis alone would no longer be a legal basis for law enforcement to stop and search individuals, nor would suspected possession of up to five ounces of marijuana.
- Absent federal restrictions, employers would not be able to take adverse actions against workers merely for testing positive for cannabis metabolites.
- Rental tenants, students at institutions of higher learning, and professionals in licensed occupations would be protected from certain types of discrimination around legal cannabis use. People who test positive for cannabis metabolites, which suggest past use, could not be denied organ transplants or other medical care, educational opportunities or have action taken against them by the Department of Children and Families without another evidence-based reason for the action.
- Cannabis-related advertising could not target people under 21, and businesses that allow minors on their premises would be penalized. Licensees who sell to minors would be guilty of a Class A misdemeanor, punishable by up to a year in prison and a $2,000 fine. People in charge of households or private properties who allow minors to possess cannabis there would also face a Class A misdemeanor.
- Adults 18 to 20 years old who are caught with small amounts cannabis would be subject to a $50 civil fine, although subsequent violations could carry a $150 fine and/or mandatory community service. All possession offenses would require individuals to sign a statement acknowledging the health risks of cannabis to young people.
- Minors under 18 could not be arrested for cannabis possession. A first offense would carry a written warning and possible referral to youth services, while a third or subsequent offense, or possession of more than five ounces of marijuana, would send the individual to juvenile court.
- Local governments could prohibit cannabis businesses or ban cannabis delivery within their jurisdictions. Municipalities could also set reasonable limits on the number of licensed businesses, their locations, operating hours and signage.
- Until June 30, 2024, the number of licensed cannabis retailers could not exceed one per 25,000 residents. After that, state regulators will set a new maximum.

- Cannabis products would be capped at 30 percent THC by weight for cannabis flower and all other products except pre-filled vape cartridges at 60 percent THC, though those limits could be further adjusted by regulators. Medical marijuana products would be exempt from the potency caps. Retailers would also need to provide access to low-THC and high-CBD products.
- Products designed to appeal to children would be forbidden.
- The state's general sales tax of 6.35 percent would apply to cannabis, and an additional excise tax based on THC content would be imposed. The bill also authorizes a 3 percent municipal tax, which must be used for community reinvestment.
- Existing medical marijuana dispensaries could become "hybrid retailers" to also serve adult-use consumers. Regulators would begin accepting applications for hybrid permits in September 2021, and applicants would need to submit a conversion plan and pay a $1 million fee. That fee could be cut in half if they create a so-called equity joint venture, which would need to be majority owned by a social equity applicant. Medical marijuana growers could also begin cultivating adult-use cannabis in the second half this year, though they would need to pay a fee of up to $3 million.
- Licensing fees for social equity applicants would be 50 percent of open licensing fees. Applicants would need to pay a small fee to enter a lottery, then a larger fee if they're granted a license. Social equity licensees would also receive a 50 percent discount on license fees for the first three years of renewals.
- The state would be allowed to enter into cannabis-related agreements with tribal governments, such as the Mashantucket Pequot Tribe and the Mohegan Tribe of Indians.

The latest bill also includes changes adopted as an amendment in the Senate last week. Among other revisions, it deleted a section that would have allowed backers of marijuana producers to obtain cultivation licenses without being subject to a lottery and clarifies that a higher percentage of equity joint-venture owners be from disproportionately impacted areas. It also expanded equity provisions of the bill so that 100 percent of profits with joint ventures with existing businesses go to equity partners, rather than the 5 percent in the original bill, and exempted medical marijuana from potency limits that apply to adult-use products.

A fiscal note for the legislation projects that taxes and fees for marijuana would bring in an estimated $4.1 million in additional revenue for the state and municipalities in

fiscal year 2022, which would grow over time to a projected annual haul of $73.4 million by fiscal year 2026.

Lamont, who introduced his own legalization bill earlier this year, urged the legislature to adopt the policy change during a press briefing late last week. "I have a strong point of view to do whatever it takes to get this over the finish line," he said. "Around the country, we have red states and blue states that are passing this and doing it in a very careful, regulated way—and I think we're ready to do the same."

Some advocates initially criticized an early version of the new bill for failing to include a provision aimed at redressing individual harm caused by the criminal drug war, which disproportionately affected Black and brown people.

A provision that was in the governor's original bill, SB 888, as well as separate legalization legislation by Rep. Robyn Porter (D), would have granted social equity status to cannabis business license applicants if they or a parent, spouse or child had been arrested or convicted of a past cannabis crime. That criterion was left out of the legislation the Senate passed last week and the new bill when it was introduced on Monday, but Winfield's striking amendment added it in. Other qualifications for social equity status include residency in low-income or high-unemployment areas or those that have seen disproportionate policing under prohibition.

Jason Ortiz, executive director of Students for Sensible Drug Policy, posted to Facebook on Monday that the initial omission of the clause meant "that the people most impacted by over policing will be will be intentionally taken out of the cannabis equity program."

"The laws that made my and my community into 'criminals' were put there for racist and political reasons," he wrote. "People have profited from our suffering and our imprisonment. And now they won't even admit that the people who were locked up deserve a shot at a license."

"Imagine having multiple years to study one basic concept and on gameday not understanding the foundational concept of social equity," added Ortiz, who served as a member of the governor's legalization working group that issued recommendations on social equity late last year.

Ortiz included an image of what appears to be a friends-only Facebook post by Porter, whose own legalization proposal prioritized social equity and reinvestment into communities hit hardest by the drug war. That bill, which was favored by many

advocates for its focus on equity, <u>passed the House Labor and Public Employees Committee</u> in March but did not proceed further.

"So, the cannabis bill running tomorrow in the Senate doesn't have the following language, which is the most CRITICAL component of the 'social equity applicant definition,'" the post says, referencing the provision about past cannabis records making applicants eligible for social equity status. "We've gone from being INTENTIONALLY TARGETED to INTENTIONALLY EXCLUDED. Now, where is the EQUITY in that?"

Those concerns were apparently heard by legislative leaders, however, and the conviction qualifying criteria was added in Winfield's large-scale amendment that the Senate adopted.

"The notion that those people might not be included in the [social equity] definition—while I don't believe that's what the definition did—was problematic for many people that I've had conversation with," Winfield said during floor debate.

Legalization advocates at Marijuana Policy Project cheered the amended bill's passage.

"I'm grateful that today the Senate reaffirmed their commitment to ending the failed policies of cannabis prohibition," DeVaughn Ward, senior legislative counsel for the group, told Marijuana Moment in an email. "Legislative leaders, the governor and advocates should be applauded for their efforts as this bill contains some of the strongest equity provisions in the country. I'm hopeful the House will follow the Senate's lead tomorrow and end the devastating war on marijuana in Connecticut."

The bill passed by senators on Tuesday is the result of a compromise between legislative Democrats and the governor's office, and proponents have said it includes elements of both Porter's HB 6377 and Lamont's SB 888, which <u>moved through two committees</u> during the regular session.

If a legalization measure isn't enacted this year, Lamont said last month that the issue could ultimately go before voters.

"Marijuana is sort of interesting to me. When it goes to a vote of the people through some sort of a referendum, it passes overwhelmingly. When it goes through a legislature and a lot of telephone calls are made, it's slim or doesn't pass," the governor said. "We're trying to do it through the legislature. Folks are elected to make a decision, and we'll see where it goes. If it doesn't, we'll probably end up in a referendum."

Ritter said late last month that he feels there's a 57-43 chance that the legislation is approved, whereas he previously gave it a 50-50 chance.

He last year that if the legislature isn't able to pass a legalization bill, he will move to put a question on the state's 2022 ballot that would leave the matter to voters.

According to recent polling, if legalization did go before voters, it would pass. Sixty-four percent of residents in the state favor legalizing cannabis for adult use, according to a survey from Sacred Heart University released last month.

The legislature has considered legalization proposals on several occasions in recent years, including a bill that Democrats introduced last year on the governor's behalf. Those bills stalled, however.

Lamont reiterated his support for legalizing marijuana during his annual State of the State address in January, stating that he would be working with the legislature to advance the reform this session.

The governor has compared the need for regional coordination on marijuana policy to the coronavirus response, stating that officials have "got to think regionally when it comes to how we deal with the pandemic—and I think we have to think regionally when it comes to marijuana, as well."

Meanwhile in neighboring Rhode Island, a legislative committee on Monday approved a marijuana legalization bill that's being championed by Senate leadership in that state.

DOCUMENT C

CURRENT DRAFT OF

CONNECTICUT RMJ LAW

CT SSB 1201:

MUNICIPAL AUTHORITY

IMPACT OVERVIEW

SB 1201 – AN ACT CONCERNING RESPONSIBLE AND EQUITABLE REGULATION OF ADULT-USE CANNABIS

www.ct.gov/cannabis

MUNICIPAL AUTHORITY - IMPACT OVERVIEW

Sec. 83 – effective July 1, 2021: Addresses various issues on municipalities' authority to regulate cannabis, such as (1) requiring them, upon petition of 10% of their voters, to hold a local referendum on whether to allow the recreational sale of marijuana or whether to allow certain types of cannabis businesses within the municipality; (2) barring them from prohibiting the delivery of cannabis by authorized persons; and (3) allowing them to charge retailers, hybrid retailers, and micro-cultivators for certain initial public safety expenses.

Local Referendum: A municipality must hold a referendum on whether to allow certain cannabis sales if at least 10% of its electors' petition for such a vote at least 60 days before a regular election.

Specifically, these votes may determine whether to allow (1) the sale of adult-use marijuana in the municipality or (2) the sale of adult-use marijuana in one or more of the cannabis establishment license types.

The ballot designations are as follows: "Shall the sale of recreational marijuana be allowed in …. (Name of municipality)?" or "Shall the sale of cannabis under (Specified license or Licenses) be allowed in …. (Name of municipality)?" or "Shall the sale of recreational marijuana be prohibited (No Licenses) in …. (Name of municipality)?"

The referendum and ballot designations conform to existing procedures. The results take effect on the first Monday of the month after the election and stay in effect until another vote is taken. The bill allows a vote to occur at a special election, following existing procedures, if at least one year has passed since the previous vote. Existing laws on absentee voting at referenda apply to these votes. These referenda do not affect any class of cannabis establishments already allowed in a municipality and do not affect any class of cannabis establishments that do not sell adult-use cannabis, including a medical dispensary and establishments that grow cannabis products.

Delivery and Transport: Municipalities cannot prohibit the delivery of cannabis to (1) consumers or (2) qualifying medical marijuana patients or their caregivers, if the delivery is made by someone authorized to do so under the bill (e.g., delivery services). It also bars municipalities from prohibiting the transport of cannabis to, from, or through the municipality by anyone licensed or registered to do so.

Ban on Certain Actions and Local Host Agreements: The bill prohibits municipalities or local officials from conditioning any official action on, or accepting any donations from, any cannabis establishment or applicants for cannabis establishment licenses in the municipality. The bill also bars municipalities from negotiating or entering into a local host agreement with a cannabis establishment or license applicant.

Charge for Initial Public Safety Costs: The bill allows municipalities, for the first 30 days after cannabis retailers or hybrid retailers open, to charge them up to $50,000 for any necessary and reasonable municipal costs for public safety services related to the opening (such as for directing traffic).

Sec. 84 - effective October 1, 2021: Allows municipalities to prohibit consumption of cannabis in public areas and to establish fines for use of cannabis in such areas.

Existing law in place through September 30, 2021 – Allows a municipality to regulate, on any property owned by the municipality, any activity deemed to be deleterious to public health, including the lighting or carrying of a lighted cigarette, cigar, pipe or similar device. This provides sufficient authority to regulate the consumption of cannabis of any form in the interim.

Regulation of Smoking and Cannabis Use: Existing law allows municipalities to regulate activities deemed harmful to public health, including tobacco smoking, on municipally-owned property. The bill broadens this to include property that a municipality controls but does not own. For the purposes of this section, property that a municipality controls includes, but not limited to, sidewalks, parks, beaches, municipal land and buildings, etc. It specifies that this regulatory authority applies to (1) smoked or vaped tobacco or cannabis, and (2) other types of cannabis use or consumption.

For municipalities with more than 50,000 people, if they regulate the public use cannabis, the regulations must designate a location in the municipality where public consumption is allowed. This section does not require that such municipalities provide for a location where any or all forms of cannabis can be consumed, but only some forms of cannabis can be consumed. The most common forms of cannabis consumption are smoking, vaping, and edibles. Through regulations, municipalities may set fines for violations by individuals regarding outdoor consumption of cannabis of up to $50.

Municipalities are permitted to ban cannabis smoking and vaping at outdoor sections of restaurants. Through regulations, municipalities may set fines for violations of up to $1,000 for businesses who allow cannabis smoking or vaping contrary to the regulation of the municipality.

Sec. 126 – effective July 1, 2021: Imposes a 3% municipal sales tax on the sale of cannabis that applies in addition to the state's 6.35% sales tax and the state cannabis tax established under the bill; specifies the purposes for which municipalities may use the tax revenue. The 3% municipal sales tax will be administered through DRS, though each municipality will be responsible for collecting the appropriate amounts as identified by DRS.

Municipal Designee: The bill requires each municipality in which a cannabis retailer, hybrid retailer or micro-cultivator is located to submit to the DRS commissioner, at least annually, the name and contact information of the individual designated by the municipality to receive notifications regarding the tax. The DRS commissioner must notify these designated individuals of the tax amount reported due from each cannabis retailer, hybrid retailer and micro-cultivator located in their respective. Such municipalities are then responsible for collecting the tax payments from each payor.

Municipal Uses of Funds: The amounts remitted become a part of the municipality's general revenue and may only be used for the following purposes:
1. streetscape improvements and other neighborhood developments in communities where cannabis retailers, hybrid retailers or micro-cultivators are located;
2. education programs or youth employment and training programs in the municipality;
3. services for individuals living in the municipality who were released from DOC custody, probation, or parole;
4. mental health or addiction services;
5. youth service bureaus and municipal juvenile review boards; and
6. community civic engagement efforts.

Sec. 148 – effective July 1, 2021: Authorizes municipalities to enact certain zoning regulations or ordinances for cannabis establishments; temporarily prohibits municipalities from granting zoning approval for more retailers or micro-cultivators than a number that would allow for one of each for every 25,000 residents; and allows the DCP commissioner to set a population-based cap for number of retailers or micro-cultivators in the future.

General Zoning Authority and Restrictions: Allows municipalities to amend their zoning regulations or local ordinances to take the following actions regarding cannabis establishments:

1. prohibit them from opening;
2. reasonably restrict their hours and signage; or
3. restrict their proximity to religious institutions, schools, charitable institutions, hospitals, veterans' homes, or certain military establishments.

Municipal chief zoning officials are required to report these zoning changes to the OPM Secretary and DCP. They must report in writing within 14 days after adopting the change.

Affirmative Zoning Approval for Retailers and Micro-Cultivators: Until June 30, 2024, municipalities are prohibited from granting zoning approval for more retailers or micro-cultivators than a number that would allow for one retailer and one micro-cultivator for every 25,000 municipal residents, as determined by the most recent decennial census. Beginning July 1, 2024, the DCP commissioner may post on the department's web site a specific number of residents such that no municipality shall grant zoning approval for more retailers or micro-cultivators than would result in one retailer and one micro-cultivator for every such specific number of residents, as determined by the commissioner.

In order to ensure compliance, the bill requires a special permit or other affirmative approval for any retailer or micro-cultivator seeking to be located within a municipality. A municipality must not grant the special permit or approval for any applicant if an approval would result in exceeding the density cap set by the bill or DCP Commissioner. The purpose of the special permit or other affirmative approval is not to require a public meeting or any other steps or procedures than would otherwise be required under a municipality's zoning ordinance, but rather to ensure that no more retailers or micro-cultivators are granted zoning approval than the number allowable under the legislation.

DOCUMENT D

STATUS OF RMJ RESEARCH

Table of Contents and

Summary of Conclusions from the following study:

The Health Effects of Cannabis an Cannabinoids

The Current State of the Evidence

And

Recommendations for Research

Study by the

National Academies of

Sciences, Engineering & Medicine

The Health Effects of Cannabis and Cannabinoids

THE CURRENT STATE OF EVIDENCE AND
RECOMMENDATIONS FOR RESEARCH

Committee on the Health Effects of Marijuana:
An Evidence Review and Research Agenda

Board on Population Health and Public Health Practice

Health and Medicine Division

A Report of

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

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COMMITTEE ON THE HEALTH EFFECTS OF MARIJUANA: AN EVIDENCE REVIEW AND RESEARCH AGENDA

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

Eric Bass, Johns Hopkins University
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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Eric B. Larson,** Group Health Research Institute, and **Bobbie A. Berkowitz,** Columbia University Medical Center. They were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Contents

Summary

Over the past 20 years there have been substantial changes to the cannabis policy landscape. To date, 28 states and the District of Columbia have legalized cannabis for the treatment of medical conditions (NCSL, 2016). Eight of these states and the District of Columbia have also legalized cannabis for recreational use. These landmark changes in policy have markedly changed cannabis use patterns and perceived levels of risk. Based on a recent nationwide survey, 22.2 million Americans (12 years of age and older) reported using cannabis in the past 30 days, and between 2002 and 2015 the percentage of past month cannabis users in this age range has steadily increased (CBHSQ, 2016).

Despite the extensive changes in policy at the state level and the rapid rise in the use of cannabis both for medical purposes and for recreational use, conclusive evidence regarding the short- and long-term health effects (harms and benefits) of cannabis use remains elusive. A lack of scientific research has resulted in a lack of information on the health implications of cannabis use, which is a significant public health concern for vulnerable populations such as pregnant women and adolescents. Unlike other substances whose use may confer risk, such as alcohol or tobacco, no accepted standards exist to help guide individuals as they make choices regarding the issues of if, when, where, and how to use cannabis safely and, in regard to therapeutic uses, effectively.

Within this context, in March 2016, the Health and Medicine Division

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BOX S-1
Statement of Task

The National Academies of Sciences, Engineering, and Medicine (the National Academies) will appoint an ad hoc committee to develop a comprehensive, in-depth review of existing evidence regarding the health effects of using marijuana and/or its constituents.

The committee will develop a consensus report with two primary sections: (1) a section of the report will summarize what can be determined about the health effects of marijuana use and, (2) a section of the report will summarize potential therapeutic uses of marijuana. The report will also provide a background overview of the cannabinoid/endocannabinoid system, history of use in the United States, and the regulation and policy landscape. In addition, the report will outline and make recommendations regarding a research agenda identifying the most critical research questions regarding the association of marijuana use with health outcomes (both risks and therapeutic) that can be answered in the short term (i.e., within a 3-year time frame) as well as any steps that should be taken in the short term to ensure that sufficient data are being gathered to answer long-term questions (e.g., appropriate questions on large population surveillance surveys, clinical data collection or other data capture, and resolution of barriers to linkage between survey data and death/morbidity registries to enable population-level morbidity and mortality effects estimates). The committee should focus on questions and consequences with the potential for the greatest public health impact, while shedding light on the characteristics of marijuana use that impact both short- and long-term health.

In conducting its work, the committee will conduct a comprehensive review of the evidence, using accepted approaches of literature search, evidence review, grading, and synthesis. Studies reviewed regarding health risks should be as broad as possible, including but not limited to epidemiology and clinical studies, and toxicology and animal studies when determined appropriate by the committee. The committee will provide summary determinations regarding causality based on strength of evidence. Both U.S. and international studies may be reviewed based upon relevance and methodological rigor.

(formerly the Institute of Medicine [IOM][1]) of the National Academies of Sciences, Engineering, and Medicine (the National Academies) was asked to convene a committee of experts to conduct a comprehensive review of the literature regarding the health effects of using cannabis and/or its constituents that had appeared since the publication of the 1999 IOM report

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[1] As of March 2016, the Health and Medicine Division continues the consensus studies and convening activities previously carried out by the Institute of Medicine (IOM).

Marijuana and Medicine. The resulting Committee on the Health Effects of Marijuana consisted of 16 experts in the areas of marijuana, addiction, oncology, cardiology, neurodevelopment, respiratory disease, pediatric and adolescent health, immunology, toxicology, preclinical research, epidemiology, systematic review, and public health. The sponsors of this report include federal, state, philanthropic, and nongovernmental organizations, including the Alaska Mental Health Trust Authority; Arizona Department of Health Services; California Department of Public Health; CDC Foundation; Centers for Disease Control and Prevention (CDC); The Colorado Health Foundation; Mat-Su Health Foundation; National Highway Traffic Safety Administration; National Institutes of Health/National Cancer Institute; National Institutes of Health/National Institute on Drug Abuse; Oregon Health Authority; the Robert W. Woodruff Foundation; Truth Initiative; U.S. Food and Drug Administration; and Washington State Department of Health.

In its statement of task, the committee was asked to make recommendations for a research agenda that will identify the most critical research questions regarding the association of cannabis use with health outcomes (both harms and benefits) that can be answered in the short term (i.e., within a 3-year time frame), as well as steps that should be taken in the short term to ensure that sufficient data are being gathered to answer long-term questions. Of note, throughout the report the committee has attempted to highlight research conclusions that affect certain populations (e.g., pregnant women, adolescents) that may be more vulnerable to potential harmful effects of cannabis use. The committee's full statement of task is presented in Box S-1.

STUDY CONTEXT AND APPROACH

Over the past 20 years the IOM published several consensus reports that focused on the health effects of marijuana or addressed marijuana within the context of other drug or substance abuse topics.[2] The two IOM reports that most prominently informed the committee's work were *Marijuana and Health,* published in 1982, and the 1999 report *Marijuana and Medicine: Assessing the Science Base.* Although these reports differed in scope, they were useful in providing a comprehensive body of evidence upon which the current committee could build.

The scientific literature on cannabis use has grown substantially since the 1999 publication of *Marijuana and Medicine.* The committee conducted an extensive search of relevant databases, including Medline, Embase,

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[2] See https://www.nap.edu/search/?year=1995&rpp=20&ft=1&term=marijuana (accessed January 5, 2017).

BOX S-2
Health Topics and Prioritized Health Endpoints
(listed in the order in which they appear in the report)

Therapeutic effects

- Chronic pain; cancer, chemotherapy-induced nausea/vomiting; anorexia and weight loss; irritable bowel syndrome; epilepsy; spasticity related to multiple sclerosis or spinal cord injury; Tourette syndrome; amyotrophic lateral sclerosis; Huntington's disease; Parkinson's disease; dystonia; dementia; glaucoma; traumatic brain injury; addiction; anxiety; depression; sleep disorders; posttraumatic stress disorder; schizophrenia and other psychoses

Cancer

- Lung cancer; head and neck cancer; testicular cancer; esophageal cancer; other cancer

Cardiometabolic risk

- Acute myocardial infarction; stroke; metabolic dysregulation, metabolic syndrome, prediabetes, and diabetes mellitus

Respiratory disease

- Pulmonary function; chronic obstructive pulmonary disorder; respiratory symptoms (including chronic bronchitis); asthma

Immunity

- Immune function; infectious disease

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the Cochrane Database of Systematic Reviews, and PsycINFO, and they initially retrieved more than 24,000 abstracts that could have potentially been relevant to this study. These abstracts were reduced by limiting articles to those published in English and removing case reports, editorials, studies by "anonymous" authors, conference abstracts, and commentaries. In the end, the committee considered more than 10,700 abstracts for their relevance to this report.

Given the large scientific literature on cannabis, the breadth of the statement of task, and the time constraints of the study, the committee developed an approach that resulted in giving primacy to recently published systematic reviews (since 2011) and high-quality primary research for 11 groups of health endpoints (see Box S-2). For each health endpoint,

Injury and death

- All-cause mortality; occupational injury; motor vehicle crash; overdose injury and death

Prenatal, perinatal, and postnatal exposure to cannabis

- Pregnancy complications for the mother; fetal growth and development; neonatal conditions; later outcomes for the infant

Psychosocial

- Cognition (learning, memory, attention, intelligence); academic achievement and educational outcomes; employment and income; social relationships and other social roles

Mental health

- Schizophrenia and other psychoses; bipolar disorders, depression; suicide; anxiety; posttraumatic stress disorder

Problem cannabis use

- Cannabis use disorder

Cannabis use and abuse of other substances

- Abuse of other substances

systematic reviews were identified and assessed for quality using published criteria; only fair- and good-quality reviews were considered by the committee. The committee's conclusions are based on the findings from the most recently published systematic review and all relevant fair- and good-quality primary research published after the systematic review. Where no systematic review existed, the committee reviewed all relevant primary research published between January 1, 1999, and August 1, 2016. Primary research was assessed using standard approaches (e.g., Cochrane Quality Assessment, Newcastle–Ontario scale) as a guide.

The search strategies and processes described above were developed and adopted by the committee in order to adequately address a broad statement of task in a limited time frame while adhering to the National

Academies' high standards for the quality and rigor of committee reports. Readers of this report should recognize two important points. First, the committee was not tasked to conduct multiple systematic reviews, which would have required a lengthy and robust series of processes. The committee did, however, adopt key features of that process: a comprehensive literature search; assessments by more than one person of the quality (risk of bias) of key literature and the conclusions; prespecification of the questions of interest before conclusions were formulated; standard language to allow comparisons between conclusions; and declarations of conflict of interest via the National Academies conflict-of-interest policies. Second, there is a possibility that some literature was missed because of the practical steps taken to narrow a very large literature to one that was manageable within the time frame available to the committee. Furthermore, very good research may not be reflected in this report because it did not directly address the health endpoint research questions that were prioritized by the committee.

This report is organized into four parts and 16 chapters. Part I: Introduction and Background, Part II: Therapeutic Effects (Therapeutic Effects of Cannabis and Cannabinoids), Part III: Other Health Effects, and Part IV: Research Barriers and Recommendations. In Part II, most of the evidence reviewed in Chapter 4 derives from clinical and basic science research conducted for the specific purpose of answering an a priori question of whether cannabis and/or cannabinoids are an effective treatment for a specific disease or health condition. The evidence reviewed in Part III derives from epidemiological research that primarily reviews the effects of smoked cannabis. It is of note that several of the prioritized health endpoints discussed in Part III are also reviewed in Part II, albeit from the perspective of effects associated with using cannabis for primarily recreational, as opposed to therapeutic, purposes.

Several health endpoints are discussed in multiple chapters of the report (e.g., cancer, schizophrenia); however, it is important to note that the research conclusions regarding potential harms and benefits discussed in these chapters may differ. This is, in part, due to differences in the study design of the reviewed evidence, differences in characteristics of cannabis or cannabinoid exposure (e.g., form, dose, frequency of use), and the populations studied. As such, it is important that the reader is aware that this report was not designed to reconcile the proposed harms and benefits of cannabis or cannabinoid use across the report's chapters. In drafting the report's conclusions, the committee made an effort to be as specific as possible about the type and/or duration of cannabis or cannabinoid exposure and, where relevant, cross-referenced findings from other report chapters.

REPORT CONCLUSIONS ON THE ASSOCIATION
BETWEEN CANNABIS USE AND HEALTH

From their review, the committee arrived at nearly 100 different research conclusions related to cannabis or cannabinoid use and health. Informed by the reports of previous IOM committees,[3] the committee developed standard language to categorize the weight of evidence regarding whether cannabis or cannabinoid use (for therapeutic purposes) is an effective or ineffective treatment for the prioritized health endpoints of interest, or whether cannabis or cannabinoid use (primarily for recreational purposes) is statistically associated with the prioritized health

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[3] *Adverse Effects of Vaccines: Evidence and Causality* (IOM, 2012); *Treatment of Posttraumatic Stress Disorder: An Assessment of the Evidence* (IOM, 2008); *Veterans and Agent Orange: Update 2014* (NASEM, 2016).

BOX S-3
Weight-of-Evidence Categories

CONCLUSIVE EVIDENCE

For therapeutic effects: There is strong evidence from randomized controlled trials to support the conclusion that cannabis or cannabinoids are an effective or ineffective treatment for the health endpoint of interest.

For other health effects: There is strong evidence from randomized controlled trials to support or refute a statistical association between cannabis or cannabinoid use and the health endpoint of interest.

For this level of evidence, there are many supportive findings from good-quality studies with no credible opposing findings. A firm conclusion can be made, and the limitations to the evidence, including chance, bias, and confounding factors, can be ruled out with reasonable confidence.

SUBSTANTIAL EVIDENCE

For therapeutic effects: There is strong evidence to support the conclusion that cannabis or cannabinoids are an effective or ineffective treatment for the health endpoint of interest.

For other health effects: There is strong evidence to support or refute a statistical association between cannabis or cannabinoid use and the health endpoint of interest.

For this level of evidence, there are several supportive findings from good-quality studies with very few or no credible opposing findings. A firm conclusion can be made, but minor limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.

BOX S-3 Continued

MODERATE EVIDENCE

For therapeutic effects: There is some evidence to support the conclusion that cannabis or cannabinoids are an effective or ineffective treatment for the health endpoint of interest.

For other health effects: There is some evidence to support or refute a statistical association between cannabis or cannabinoid use and the health endpoint of interest.

For this level of evidence, there are several supportive findings from good- to fair-quality studies with very few or no credible opposing findings. A general conclusion can be made, but limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.

LIMITED EVIDENCE

For therapeutic effects: There is weak evidence to support the conclusion that cannabis or cannabinoids are an effective or ineffective treatment for the health endpoint of interest.

For other health effects: There is weak evidence to support or refute a statistical association between cannabis or cannabinoid use and the health endpoint of interest.

For this level of evidence, there are supportive findings from fair-quality studies or mixed findings with most favoring one conclusion. A conclusion can be made, but there is significant uncertainty due to chance, bias, and confounding factors.

NO OR INSUFFICIENT EVIDENCE TO SUPPORT THE ASSOCIATION

For therapeutic effects: There is no or insufficient evidence to support the conclusion that cannabis or cannabinoids are an effective or ineffective treatment for the health endpoint of interest.

For other health effects: There is no or insufficient evidence to support or refute a statistical association between cannabis or cannabinoid use and the health endpoint of interest.

For this level of evidence, there are mixed findings, a single poor study, or health endpoint has not been studied at all. No conclusion can be made because of substantial uncertainty due to chance, bias, and confounding factors.

endpoints of interest. Box S-3 describes these categories and the general parameters for the types of evidence supporting each category. For a full listing of the committee's conclusions, please see this chapter's annex.

REPORT RECOMMENDATIONS

This is a pivotal time in the world of cannabis policy and research. Shifting public sentiment, conflicting and impeded scientific research, and legislative battles have fueled the debate about what, if any, harms or benefits can be attributed to the use of cannabis or its derivatives. The committee has put forth a substantial number of research conclusions on the health effects of cannabis and cannabinoids. Based on their research conclusions, the committee members formulated four recommendations to address research gaps, improve research quality, improve surveillance capacity, and address research barriers. The report's full recommendations are described below.

Address Research Gaps

Recommendation 1: **To develop a comprehensive evidence base on the short- and long-term health effects of cannabis use (both beneficial and harmful effects), public agencies,[4] philanthropic and professional organizations, private companies, and clinical and public health research groups should provide funding and support for a national cannabis research agenda that addresses key gaps in the evidence base. Prioritized research streams and objectives should include, but need not be limited to:**

Clinical and Observational Research

- Examine the health effects of cannabis use in at-risk or under-researched populations, such as children and youth (often described as less than 18 years of age) and older populations (generally over 50 years of age), pregnant and breastfeeding women, and heavy cannabis users.
- Investigate the pharmacokinetic and pharmacodynamic properties of cannabis, modes of delivery, different concentrations, in various populations, including the dose–response relationships of cannabis and THC or other cannabinoids.
- Determine the harms and benefits associated with understudied cannabis products, such as edibles, concentrates, and topicals.
- Conduct well-controlled trials on the potential beneficial and harmful health effects of using different forms of cannabis, such

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[4] Agencies may include the CDC, relevant agencies of the National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA).

as inhaled (smoked or vaporized) whole cannabis plant and oral cannabis.
- Characterize the health effects of cannabis on unstudied and understudied health endpoints, such as epilepsy in pediatric populations; symptoms of posttraumatic stress disorder; childhood and adult cancers; cannabis-related overdoses and poisonings; and other high-priority health endpoints.

Health Policy and Health Economics Research

- Identify models, including existing state cannabis policy models, for sustainable funding of national, state, and local public health surveillance systems.
- Investigate the economic impact of recreational and medical cannabis use on national and state public health and health care systems, health insurance providers, and patients.

Public Health and Public Safety Research

- Identify gaps in the cannabis-related knowledge and skills of health care and public health professionals, and assess the need for, and performance of, continuing education programs that address these gaps.
- Characterize public safety concerns related to recreational cannabis use and evaluate existing quality assurance, safety, and packaging standards for recreational cannabis products.

Improve Research Quality

Recommendation 2: **To promote the development of conclusive evidence on the short- and long-term health effects of cannabis use (both beneficial and harmful effects), agencies of the U.S. Department of Health and Human Services, including the National Institutes of Health and the Centers for Disease Control and Prevention, should jointly fund a workshop to develop a set of research standards and benchmarks to guide and ensure the production of high-quality cannabis research. Workshop objectives should include, but need not be limited to:**

- The development of a minimum dataset for observational and clinical studies, standards for research methods and design, and guidelines for data collection methods.

- Adaptation of existing research-reporting standards to the needs of cannabis research.
- The development of uniform terminology for clinical and epidemiological cannabis research.
- The development of standardized and evidence-based question banks for clinical research and public health surveillance tools.

Improve Surveillance Capacity

Recommendation 3: **To ensure that sufficient data are available to inform research on the short- and long-term health effects of cannabis use (both beneficial and harmful effects), the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, the Association of State and Territorial Health Officials, National Association of County and City Health Officials, the Association of Public Health Laboratories, and state and local public health departments should fund and support improvements to federal public health surveillance systems and state-based public health surveillance efforts. Potential efforts should include, but need not be limited to:**

- The development of question banks on the beneficial and harmful health effects of therapeutic and recreational cannabis use and their incorporation into major public health surveys, including the National Health and Nutrition Examination Survey, National Health Interview Survey, Behavioral Risk Factor Surveillance System, National Survey on Drug Use and Health, Youth Risk Behavior Surveillance System, National Vital Statistics System, Medical Expenditure Panel Survey, and the National Survey of Family Growth.
- Determining the capacity to collect and reliably interpret data from diagnostic classification codes in administrative data (e.g., *International Classification of Diseases-10*).
- The establishment and utilization of state-based testing facilities to analyze the chemical composition of cannabis and products containing cannabis, cannabinoids, or THC.
- The development of novel diagnostic technologies that allow for rapid, accurate, and noninvasive assessment of cannabis exposure and impairment.
- Strategies for surveillance of harmful effects of cannabis for therapeutic use.

Address Research Barriers

Recommendation 4: **The Centers for Disease Control and Prevention, National Institutes of Health, U.S. Food and Drug Administration, industry groups, and nongovernmental organizations should fund the convening of a committee of experts tasked to produce an objective and evidence-based report that fully characterizes the impacts of regulatory barriers to cannabis research and that proposes strategies for supporting development of the resources and infrastructure necessary to conduct a comprehensive cannabis research agenda. Committee objectives should include, but need not be limited to:**

- Proposing strategies for expanding access to research-grade marijuana, through the creation and approval of new facilities for growing and storing cannabis.
- Identifying nontraditional funding sources and mechanisms to support a comprehensive national cannabis research agenda.
- Investigating strategies for improving the quality, diversity, and external validity of research-grade cannabis products.

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ANNEX

Report Conclusions[5]

Chapter 4 Conclusions—Therapeutic Effects of Cannabis and Cannabinoids

There is conclusive or substantial evidence that cannabis or cannabinoids are effective:

- For the treatment of chronic pain in adults (cannabis) (4-1)
- As antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids) (4-3)
- For improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids) (4-7a)

There is moderate evidence that cannabis or cannabinoids are effective for:

- Improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis (cannabinoids, primarily nabiximols) (4-19)

There is limited evidence that cannabis or cannabinoids are effective for:

- Increasing appetite and decreasing weight loss associated with HIV/AIDS (cannabis and oral cannabinoids) (4-4a)
- Improving clinician-measured multiple sclerosis spasticity symptoms (oral cannabinoids) (4-7a)
- Improving symptoms of Tourette syndrome (THC capsules) (4-8)
- Improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders (cannabidiol) (4-17)
- Improving symptoms of posttraumatic stress disorder (nabilone; a single, small fair-quality trial) (4-20)

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[5] Numbers in parentheses correspond to chapter conclusion numbers.

There is limited evidence of a statistical association between cannabinoids and:

- Better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage (4-15)

There is limited evidence that cannabis or cannabinoids are *ineffective* for:

- Improving symptoms associated with dementia (cannabinoids) (4-13)
- Improving intraocular pressure associated with glaucoma (cannabinoids) (4-14)
- Reducing depressive symptoms in individuals with chronic pain or multiple sclerosis (nabiximols, dronabinol, and nabilone) (4-18)

There is no or insufficient evidence to support or refute the conclusion that cannabis or cannabinoids are an effective treatment for:

- Cancers, including glioma (cannabinoids) (4-2)
- Cancer-associated anorexia cachexia syndrome and anorexia nervosa (cannabinoids) (4-4b)
- Symptoms of irritable bowel syndrome (dronabinol) (4-5)
- Epilepsy (cannabinoids) (4-6)
- Spasticity in patients with paralysis due to spinal cord injury (cannabinoids) (4-7b)
- Symptoms associated with amyotrophic lateral sclerosis (cannabinoids) (4-9)
- Chorea and certain neuropsychiatric symptoms associated with Huntington's disease (oral cannabinoids) (4-10)
- Motor system symptoms associated with Parkinson's disease or the levodopa-induced dyskinesia (cannabinoids) (4-11)
- Dystonia (nabilone and dronabinol) (4-12)
- Achieving abstinence in the use of addictive substances (cannabinoids) (4-16)
- Mental health outcomes in individuals with schizophrenia or schizophreniform psychosis (cannabidiol) (4-21)

Chapter 5 Conclusions—Cancer

There is moderate evidence of *no* statistical association between cannabis use and:

- Incidence of lung cancer (cannabis smoking) (5-1)
- Incidence of head and neck cancers (5-2)

There is limited evidence of a statistical association between cannabis smoking and:

- Non-seminoma-type testicular germ cell tumors (current, frequent, or chronic cannabis smoking) (5-3)

There is no or insufficient evidence to support or refute a statistical association between cannabis use and:

- Incidence of esophageal cancer (cannabis smoking) (5-4)
- Incidence of prostate cancer, cervical cancer, malignant gliomas, non-Hodgkin lymphoma, penile cancer, anal cancer, Kaposi's sarcoma, or bladder cancer (5-5)
- Subsequent risk of developing acute myeloid leukemia/ acute non-lymphoblastic leukemia, acute lymphoblastic leukemia, rhabdomyosarcoma, astrocytoma, or neuroblastoma in offspring (parental cannabis use) (5-6)

Chapter 6 Conclusions—Cardiometabolic Risk

There is limited evidence of a statistical association between cannabis use and:

- The triggering of acute myocardial infarction (cannabis smoking) (6-1a)
- Ischemic stroke or subarachnoid hemorrhage (6-2)
- Decreased risk of metabolic syndrome and diabetes (6-3a)
- Increased risk of prediabetes (6-3b)

There is no evidence to support or refute a statistical association between *chronic effects* of cannabis use and:

- The increased risk of acute myocardial infarction (6-1b)

Chapter 7 Conclusions—Respiratory Disease

There is substantial evidence of a statistical association between cannabis smoking and:

- Worse respiratory symptoms and more frequent chronic bronchitis episodes (long-term cannabis smoking) (7-3a)

There is moderate evidence of a statistical association between cannabis smoking and:

- Improved airway dynamics with acute use, but not with chronic use (7-1a)
- Higher forced vital capacity (FVC) (7-1b)

There is moderate evidence of a statistical association between *the cessation* of cannabis smoking and:

- Improvements in respiratory symptoms (7-3b)

There is limited evidence of a statistical association between cannabis smoking and:

- An increased risk of developing chronic obstructive pulmonary disease (COPD) when controlled for tobacco use (occasional cannabis smoking) (7-2a)

There is no or insufficient evidence to support or refute a statistical association between cannabis smoking and:

- Hospital admissions for COPD (7-2b)
- Asthma development or asthma exacerbation (7-4)

Chapter 8 Conclusions—Immunity

There is limited evidence of a statistical association between cannabis smoking and:

- A decrease in the production of several inflammatory cytokines in healthy individuals (8-1a)

There is limited evidence of *no* statistical association between cannabis use and:

- The progression of liver fibrosis or hepatic disease in individuals with viral hepatitis C (HCV) (daily cannabis use) (8-3)

There is no or insufficient evidence to support or refute a statistical association between cannabis use and:

- Other adverse immune cell responses in healthy individuals (cannabis smoking) (8-1b)
- Adverse effects on immune status in individuals with HIV (cannabis or dronabinol use) (8-2)
- Increased incidence of oral human papilloma virus (HPV) (regular cannabis use) (8-4)

Chapter 9 Conclusions—Injury and Death

There is substantial evidence of a statistical association between cannabis use and:

- Increased risk of motor vehicle crashes (9-3)

There is moderate evidence of a statistical association between cannabis use and:

- Increased risk of overdose injuries, including respiratory distress, among pediatric populations in U.S. states where cannabis is legal (9-4b)

There is no or insufficient evidence to support or refute a statistical association between cannabis use and:

- All-cause mortality (self-reported cannabis use) (9-1)
- Occupational accidents or injuries (general, nonmedical cannabis use) (9-2)
- Death due to cannabis overdose (9-4a)

Chapter 10 Conclusions—Prenatal, Perinatal, and Neonatal Exposure

There is substantial evidence of a statistical association between maternal cannabis smoking and:

- Lower birth weight of the offspring (10-2)

There is limited evidence of a statistical association between maternal cannabis smoking and:

- Pregnancy complications for the mother (10-1)
- Admission of the infant to the neonatal intensive care unit (NICU) (10-3)

There is insufficient evidence to support or refute a statistical association between maternal cannabis smoking and:

- Later outcomes in the offspring (e.g., sudden infant death syndrome, cognition/academic achievement, and later substance use) (10-4)

Chapter 11 Conclusions—Psychosocial

There is moderate evidence of a statistical association between cannabis use and:

- The impairment in the cognitive domains of learning, memory, and attention (acute cannabis use) (11-1a)

There is limited evidence of a statistical association between cannabis use and:

- Impaired academic achievement and education outcomes (11-2)
- Increased rates of unemployment and/or low income (11-3)
- Impaired social functioning or engagement in developmentally appropriate social roles (11-4)

There is limited evidence of a statistical association between *sustained abstinence from* cannabis use and:

- Impairments in the cognitive domains of learning, memory, and attention (11-1b)

Chapter 12 Conclusions—Mental Health

There is substantial evidence of a statistical association between cannabis use and:

- The development of schizophrenia or other psychoses, with the highest risk among the most frequent users (12-1)

There is moderate evidence of a statistical association between cannabis use and:

- Better cognitive performance among individuals with psychotic disorders and a history of cannabis use (12-2a)
- Increased symptoms of mania and hypomania in individuals diagnosed with bipolar disorders (regular cannabis use) (12-4)
- A small increased risk for the development of depressive disorders (12-5)
- Increased incidence of suicidal ideation and suicide attempts with a higher incidence among heavier users (12-7a)
- Increased incidence of suicide completion (12-7b)
- Increased incidence of social anxiety disorder (regular cannabis use) (12-8b)

There is moderate evidence of *no* statistical association between cannabis use and:

- Worsening of negative symptoms of schizophrenia (e.g., blunted affect) among individuals with psychotic disorders (12-2c)

There is limited evidence of a statistical association between cannabis use and:

- An increase in positive symptoms of schizophrenia (e.g., hallucinations) among individuals with psychotic disorders (12-2b)
- The likelihood of developing bipolar disorder, particularly among regular or daily users (12-3)
- The development of any type of anxiety disorder, except social anxiety disorder (12-8a)
- Increased symptoms of anxiety (near daily cannabis use) (12-9)

- Increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder (12-11)

There is no evidence to support or refute a statistical association between cannabis use and:

- Changes in the course or symptoms of depressive disorders (12-6)
- The development of posttraumatic stress disorder (12-10)

Chapter 13 Conclusions—Problem Cannabis Use

There is substantial evidence that:

- Stimulant treatment of attention deficit hyperactivity disorder (ADHD) during adolescence is *not* a risk factor for the development of problem cannabis use (13-2e)
- Being male and smoking cigarettes are risk factors for the progression of cannabis use to problem cannabis use (13-2i)
- Initiating cannabis use at an earlier age is a risk factor for the development of problem cannabis use (13-2j)

There is substantial evidence of a statistical association between:

- Increases in cannabis use frequency and the progression to developing problem cannabis use (13-1)
- Being male and the severity of problem cannabis use, but the recurrence of problem cannabis use does not differ between males and females (13-3b)

There is moderate evidence that:

- Anxiety, personality disorders, and bipolar disorders are *not* risk factors for the development of problem cannabis use (13-2b)
- Major depressive disorder is a risk factor for the development of problem cannabis use (13-2c)
- Adolescent ADHD is *not* a risk factor for the development of problem cannabis use (13-2d)

- Being male is a risk factor for the development of problem cannabis use (13-2f)
- Exposure to the combined use of abused drugs is a risk factor for the development of problem cannabis use (13-2g)
- Neither alcohol nor nicotine dependence alone are risk factors for the progression from cannabis use to problem cannabis use (13-2h)
- During adolescence the frequency of cannabis use, oppositional behaviors, a younger age of first alcohol use, nicotine use, parental substance use, poor school performance, antisocial behaviors, and childhood sexual abuse are risk factors for the development of problem cannabis use (13-2k)

There is moderate evidence of a statistical association between:

- A persistence of problem cannabis use and a history of psychiatric treatment (13-3a)
- Problem cannabis use and increased severity of posttraumatic stress disorder symptoms (13-3c)

There is limited evidence that:

- Childhood anxiety and childhood depression are risk factors for the development of problem cannabis use (13-2a)

Chapter 14 Conclusions—Cannaabis Use and the Abuse of Other Substances

There is moderate evidence of a statistical association between cannabis use and:

- The development of substance dependence and/or a substance abuse disorder for substances, including alcohol, tobacco, and other illicit drugs (14-3)

There is limited evidence of a statistical association between cannabis use and:

- The initiation of tobacco use (14-1)
- Changes in the rates and use patterns of other licit and illicit substances (14-2)

DOCUMENT E

BARRIERS TO RMJ RESEARCH

CHAPTER 15

OF THE

NATIONAL ACADEMIES STUDY

Chapter 15 Conclusions—Challenges and Barriers in Conducting Cannabis Research

There are several challenges and barriers in conducting cannabis and cannabinoid research, including

- There are specific regulatory barriers, including the classification of cannabis as a Schedule I substance, that impede the advancement of cannabis and cannabinoid research (15-1)
- It is often difficult for researchers to gain access to the quantity, quality, and type of cannabis product necessary to address specific research questions on the health effects of cannabis use (15-2)
- A diverse network of funders is needed to support cannabis and cannabinoid research that explores the beneficial and harmful health effects of cannabis use (15-3)
- To develop conclusive evidence for the effects of cannabis use on short- and long-term health outcomes, improvements and standardization in research methodology (including those used in controlled trials and observational studies) are needed (15-4)

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Challenges and Barriers in Conducting Cannabis Research

Several states have legalized cannabis for medical or recreational use since the release of the 1999 Institute of Medicine (IOM)[1] report *Marijuana and Medicine: Assessing the Science Base* (IOM, 1999). As of October 2016, 25 states and the District of Columbia had legalized the medical use of cannabis, while 4 states and the District of Columbia had also legalized recreational cannabis use (NCSL, 2016; NORML, 2016a).[2] In November 2016, voters in California, Maine, Massachusetts, and Nevada approved ballot initiatives to legalize recreational cannabis, while voters in Arkansas, Florida, Montana, and North Dakota approved ballot initiatives to permit or expand the use of cannabis for medical purposes (NORML, 2016b).

Policy changes are associated with marked changes in patterns of cannabis use. In recent years, the number of U.S. adolescents and adults ages 12 and older who reported using cannabis increased by 35.0 percent and 20.0 percent for use in the past month and in the past year, respectively (Azofeifa et al., 2016). Revenue from the sale and taxation of cannabis can serve as a proxy measure for cannabis use and suggests that the scope of cannabis use in the United States is considerable. For example, the total estimated value of legal cannabis sales in the United States was $5.7 bil-

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[1] As of March 2016, the Health and Medicine Division continues the task of producing consensus studies and convening activities previously undertaken by the Institute of Medicine (IOM).

[2] The count of states where cannabis is legalized for medical use includes Ohio and Pennsylvania, where medical cannabis laws were not operational as of October 2016 (NCSL, 2016).

lion in 2015 and $7.1 billion in 2016 (Arcview Market Research and New Frontier Data, 2016). At the state level, the Colorado Department of Revenue reported that sales and excise taxes on recreational and medical cannabis sales totaled $88,239,323 in fiscal year 2015 (CDOR, 2016a, p. 29),[3] and in Washington, state and local sales taxes and state business and occupation taxes on recreational and medical cannabis totaled $53,410,661 in fiscal year 2016 (WDOR, 2016a,b).[4]

Despite these changes in state policy and the increasing prevalence of cannabis use and its implications for population health, the federal government has not legalized cannabis and continues to enforce restrictive policies and regulations on research into the health harms or benefits of cannabis products that are available to consumers in a majority of states. As a result, research on the health effects of cannabis and cannabinoids has been limited in the United States, leaving patients, health care professionals, and policy makers without the evidence they need to make sound decisions regarding the use of cannabis and cannabinoids. This lack of evidence-based information on the health effects of cannabis and cannabinoids poses a public health risk.

In order to promote research on cannabis and cannabinoids, the barriers to such research must first be identified and addressed. The committee identified several barriers to conducting basic, clinical, and population health research on cannabis and cannabinoids, including regulations and policies that restrict access to the cannabis products that are used by an increasing number of consumers and patients in state-regulated markets, funding limitations, and numerous methodological challenges. The following sections discuss these barriers in detail.

REGULATORY AND SUPPLY BARRIERS

Regulatory Barriers

Investigators seeking to conduct research on cannabis or cannabinoids must navigate a series of review processes that may involve the National Institute on Drug Abuse (NIDA), the U.S. Food and Drug Administration (FDA), the U.S. Drug Enforcement Administration (DEA), institutional review boards, offices or departments in state government, state boards

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[3] $22,225,750 (Marijuana Sales Tax [2.9%]) + $42,017,798 (Retail Marijuana Sales Tax [10%]) + $23,995,775 (Retail Marijuana Excise Tax [15%]) = $88,239,323.

[4] Medical Cannabis: $5,236,536 (State Retail Sales Tax) + $792,906 (State Business and Occupation Tax) + $ 2,084,323 (Local Retail Sales Tax) = $8,113,765. Recreational Cannabis: $30,017,823 (State Retail Sales Tax) + $4,050,212 (State Business & Occupation Tax) + $11,228,861 (Local Retail Sales Tax) = $45,296,896. $8,113,765 (Total Medical Cannabis Taxes) + $45,296,896 (Total Recreational Cannabis Taxes) = $53,410,661.

of medical examiners, the researcher's home institution, and potential funders. A brief overview of some of these review processes is discussed.

Researchers conducting clinical research on biological products such as cannabis must submit an investigational new drug (IND) application to the FDA. As a next step, the investigator may contact NIDA, an important source of research-grade cannabis, to obtain an administrative letter of authorization (LOA). An LOA describes the manufacturer's facilities, as well as the availability and pertinent characteristics of the desired cannabis product (e.g., strains, quality, strength, pharmacology, toxicology). To safeguard against the acquisition of cannabis or cannabinoids for non-research purposes, investigators must also apply for a DEA registration and site licensure before conducting studies involving cannabis or any of its cannabinoid constituents, irrespective of their pharmacologic activity.[5] The investigator must submit the IND and LOA to the FDA and the DEA for review (FDA, 2015).

After submitting an IND application, researchers must wait at least 30 days before initiating research, during which period the FDA reviews the application to ensure that research participants will not be exposed to unreasonable risk (FDA, 2016a). If the FDA determines that the proposed research would expose study participants to unreasonable risk or that the IND application is in some other way deficient, a clinical hold postponing the research may be imposed. This hold is not lifted until and unless the sponsoring researchers have resolved the deficiencies (FDA, 2016b).

It is important to note that the Controlled Substances Act of 1970 classified cannabis as a Schedule I substance, the highest level of drug restriction.[6] As defined by the Act, Schedule I substances are those that (1) have a high potential for abuse; (2) have no currently accepted medical use in treatment in the United States; and (3) have a lack of accepted safety for their use under medical supervision.[7] Other substances classified in Schedule I include heroin, LSD, mescaline, hallucinogenic amphetamine derivatives, fentanyl derivatives (synthetic opioid analgesics), and gammahydroxybutyrate (GHB).[8] By contrast, Schedule II substances—though they also have a high potential for abuse and may lead to severe psychological or physical dependence—are defined as having a currently

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[5] Code of Federal Regulations, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Title 21, § 1301.11 and Code of Federal Regulations, Schedules of Controlled Substances, Title 21, § 1308.11.

[6] Code of Federal Regulations, Schedules of Controlled Substances, Title 21, § 1308.11; United States Code, Schedules of Controlled Substances, Title 21, § 812.

[7] United States Code, Schedules of Controlled Substances, Title 21, § 812(b)(1).

[8] Code of Federal Regulations, Schedules of Controlled Substances, Title 21, § 1308.11.

BOX 15-1
Illustrative Examples of the Current Research
Barriers to Colorado Researchers

As a concrete example of the impact of the divide between federal and state policy, cannabis concentrate sales doubled in Colorado from 2015 to 2016, reaching $60.5 million in the first quarter of 2016 (Marijuana Business Daily Staff, 2016), and yet current federal law prevents chemists from examining the composition of those products as it may relate to safety, neuroscientists from testing the effects of those products on the brain or physiology in animal models, and clinical scientists from conducting research on how these products may help or harm patients. And while between 498,170 and 721,599 units of medical and recreational cannabis edibles were sold per month in Colorado in 2015 (CDOR, 2016b, p. 12), federal law also prohibits scientists from testing those products for contaminants, understanding the effects of these products in animal models, or investigating the effects in patient populations.

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accepted medical use and can be prescribed with a controlled substance prescription (DEA, 2006).[9]

In some states, researchers conducting clinical research on cannabis or cannabinoid products must also apply for and receive a controlled substance certificate from a state board of medical examiners or a controlled substance registration from a department of the state government in order to conduct clinical trials or any other activity involving Schedule I substances (Alabama Board of Medical Examiners, 2013; MDHSS, n.d.). Some state governments require additional approvals. For example, California requires that all trials involving Schedule I or II controlled substances be registered with and approved by the Research Advisory Panel of California (CADOJ/OAG, 2016). When the necessary approvals are secured, only then can the investigator apply for a DEA registration and site licensure to conduct research on a Schedule I controlled substance (see Box 15-1 for examples of research barriers).

Researchers conducting trials of Schedule I substances must additionally submit a research protocol to the DEA that includes details regarding the security provisions for storing and dispensing the substance.[10] Previously, nonfederally funded studies on cannabis were also required to undergo an additional review process conducted by the Public Health

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[9] United States Code, Schedules of Controlled Substances, Title 21, § 812(b)(2).

[10] Code of Federal Regulations, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Title 21, § 1301.18.

Service. This review process was determined to unnecessarily duplicate the FDA's IND application process in several ways and, as of June 2015, is no longer required.[11]

To ensure that controlled substances obtained for research purposes will be stored and accessed in accordance with DEA security requirements, local DEA officials may perform a preregistration inspection of the facility where the proposed research will take place (University of Colorado, 2016). DEA security requirements include storing cannabis in a safe, a steel cabinet, or a vault, and limiting access to the storage facility to "an absolute minimum number of specifically authorized employees.[12] The extent of the security measures required by DEA varies with the amount of cannabis being stored,[13] and among local DEA jurisdictions (Woodworth, 2011). Funders must bear the costs of meeting the necessary security requirements.

Additionally, as with any human clinical trial, approval from an institutional review board must be sought.[14] Obtaining this approval confirms that an appropriate plan to protect the rights and welfare of human research subjects has been outlined in the proposed research efforts. If a study is being conducted in a clinical research center, a separate review may be required by this entity's medical or research advisory committee.

In summary, basic and clinical researchers seeking to obtain cannabis or cannabinoids from NIDA for research purposes—including efforts to determine the value of cannabis or cannabinoids for treating a medical condition or achieving a therapeutic end need—must obtain a number of approvals from a range of federal, state, or local agencies, institutions, or organizations. This process can be a daunting experience for researchers. The substantial layers of bureaucracy that emerge from cannabis's Schedule I categorization is reported to have discouraged a number of cannabis researchers from applying for grant funding or pursuing additional research efforts (Nutt et al., 2013). Given the many gaps in the research of the health effects of cannabis and cannabinoids, there is a need to address these regulatory barriers so that researchers will be

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[11] Office of the Secretary, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services. Notice. "Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999," *Federal Register*, 80, no. 120 (June 23, 2015): 35960, https://www.gpo.gov/fdsys/pkg/FR-2015-06-23/pdf/2015-15479.pdf (accessed November 25, 2016).

[12] Code of Federal Regulations, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Title 21, § 1301.72 (a) and (d).

[13] Code of Federal Regulations, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Title 21, § 1301.71 (c).

[14] Code of Federal Regulations, Institutional Review Boards, Title 21, § 56.103.

better able to address key public health questions about the therapeutic and adverse effects of cannabis and cannabinoid use.

> **CONCLUSION 15-1 There are specific regulatory barriers, including the classification of cannabis as a Schedule I substance, that impede the advancement of cannabis and cannabinoid research.**[15]

Barriers to Cannabis Supply

In the United States, cannabis for research purposes is available only through the NIDA Drug Supply Program (NIDA, 2016a). The mission of NIDA is to "advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health," rather than to pursue or support research into the potential therapeutic uses of cannabis or any other drugs (NIDA, 2016b). As a result of this emphasis, less than one-fifth of cannabinoid research funded by NIDA in fiscal year 2015 concerns the therapeutic properties of cannabinoids (NIDA, 2016c).[16] Because NIDA funded the majority of all the National Institutes of Health (NIH)-sponsored cannabinoid research in fiscal year 2015 (NIDA, 2016c),[17] its focus on the consequences of drug use and addiction constitutes an impediment to research on the potential beneficial health effects of cannabis and cannabinoids.

All of the cannabis that NIDA provides to investigators is sourced from the University of Mississippi, which is currently the sole cultivator of the plant material and has been since 1968 (NIDA, 1998, 2016a).[18] In the past, the varieties of cannabis that were available to investigators through NIDA were limited in scope and were not of comparable potency to what patients could obtain at their dispensaries (Stith and Vigil, 2016). Because

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[15] The committee was specifically directed in its statement of task not to comment on cannabis policy issues, such as regulatory options for legalization, taxation, or distribution. While the committee has identified the Schedule 1 classification of cannabis as posing a significant barrier to the conduct of scientific research on the health effects of cannabis, the committee is aware that any decision on the regulation of cannabis involves many factors far outside the committee's remit and expertise. Specifically, the committee did not comment on the abuse or dependency liability or accepted medical use of cannabis compared to other scheduled drugs.

[16] In fiscal year 2015, NIDA's investment in cannabinoid research totaled $66,078,314, of which $10,923,472 was allocated for therapeutic cannabinoid research (NIDA, 2016c).

[17] In fiscal year 2015, NIH's investment in cannabinoid research totaled $ $111,275,219, of which $66,078,314 was allocated to NIDA (NIDA, 2016c).

[18] NIDA contracts with the University of Mississippi through an open solicitation process. Although the University of Mississippi is currently NIDA's only supplier of research-grade cannabis, other groups can compete for the contract (NIDA, 2015, 2016a).

of restrictions on production and vicissitudes in supply and demand, federally produced cannabis may have been harvested years earlier, is stored in a freezer (a process that may affect the quality of the product) (Taschwer and Schmid, 2015; Thomas and Pollard, 2016), and often has a lower potency than cannabis sold in state-regulated markets (Reardon, 2015; Stith and Vigil, 2016). In addition, many products available in state-regulated markets (e.g., edibles, concentrates, oils, wax, topicals) are not commonly available through federal sources (NIDA, 2016d). Since the products available through the federal system do not sufficiently reflect the variety of products used by consumers, research conducted using cannabis provided by NIDA may lack external validity. In July 2016, NIDA posted a formal request for information on the varieties of cannabis and cannabis products of interest to researchers (NIDA, 2016e). Reflecting the perceived shortcomings of cannabis and cannabis products currently provided by NIDA, a summary of the comments received in response to this request states that "the most consistent recommendation was to provide marijuana strains and products that reflect the diversity of products available in state dispensaries" (NIDA, 2016e).

Naturally, it is difficult for a single facility at the University of Mississippi to replicate the array and potency of products available in dispensaries across the country. It is worth noting, however, that NIDA has been increasingly responsive to the needs of clinical investigators. For example, NIDA has contracted with the University of Mississippi to produce cannabis strains with varying concentrations of Δ^9-tetrahydrocannabinol (THC) and cannabidiol (CBD) (NIDA, 2016d), and NIDA has previously authorized development of cannabis extracts, tinctures, and other dosage formulations for research purposes (Thomas and Pollard, 2016). As mentioned above, NIDA has sought public comment on the needs of cannabis researchers in order to inform efforts to "expand access to diverse marijuana strains and products for research purposes" (NIDA, 2016e). In addition, cannabis is made available to research investigators funded by NIH at no cost.[19] Finally, the DEA has adopted a new policy that increases the number of entities that may be registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States.[20] Under this new policy, the DEA will facilitate cannabis research by increasing the number of private

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[19] In December 2016, cannabis provided by NIDA was generally free for NIH-sponsored research. For research not funded by the federal government, the cost of non-placebo cannabis was $10.96 per cigarette and $1,133 per pound ($2,497 per kilogram) (NIDA, 2016d).

[20] DEA, U.S. Department of Justice. Policy Statement. "Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States," *Federal Register*, 81, no. 156 (August 12, 2016): 53846, https://www.gpo.gov/fdsys/pkg/FR-2016-08-12/pdf/2016-17955.pdf (accessed January 7, 2017).

entities allowed to cultivate and distribute research-grade cannabis. As of December 2016, the University of Mississippi remains the sole cultivator of cannabis provided to researchers by NIDA (NIDA, 2016a).

Although new plans are being made to provide a wider array of more clinically relevant cannabis products for research, at present this issue is still a significant barrier for conducting comprehensive research on the health effects of cannabis use. How the proposed changes will affect cannabis research in the future remains to be seen.

> **CONCLUSION 15-2 It is often difficult for researchers to gain access to the quantity, quality, and type of cannabis product necessary to address specific research questions on the health effects of cannabis use.**

Funding Limitations

Funding for research is another key barrier; without adequate financial support, cannabis research will be unable to inform health care or public health practice or to keep pace with changes in cannabis policy and patterns of cannabis use. NIH is responsible for funding research across a number of health domains. In 2015, NIH spending on all cannabinoid research totaled $111,275,219 (NIDA, 2016c). NIDA, a member institute of NIH, has as its mission to study factors related to substance abuse and dependence and conducts research on the negative health effects and behavioral consequences associated with the abuse of cannabis and other drugs (NIDA, 2016b). Because cannabis was historically perceived to have only negative effects, the majority of cannabis research has been conducted under the auspices of NIDA.

In fiscal year 2015, studies supported by NIDA accounted for 59.3 percent ($66,078,314) of all NIH spending on cannabinoid research; however, only 16.5 percent ($10,923,472) of NIDA's spending on cannabinoid research supported studies investigating therapeutic properties of cannabinoids (NIDA, 2016c).[21,22] As demonstrated in Chapter 4 of this report, a growing body of evidence suggests that cannabis and cannabinoids also have therapeutic health effects. In light of these findings, a comprehen-

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[21] $66,078,314 (Total NIDA spending on cannabinoid research in fiscal year 2015)/ $111,275,219 (Total NIH spending on cannabinoid research in fiscal year 2015) = 0.593. $10,923,472 (Total NIDA spending on therapeutic cannabinoid research in fiscal year 2015)/ $66,078,314 (Total NIDA spending on cannabinoid research in fiscal year 2015) = 0.165.

[22] By contrast, NIH spending on tobacco research totaled $300 million in 2015, and spending on research related to the harms and benefits of alcohol use totaled $473 million in 2015 (NIH, 2016).

sive research agenda that investigates both the potential adverse and the potential therapeutic health effects of cannabis use is needed.

However, it may be unrealistic to expect NIDA to have the resources or interest to fund this broader research agenda, which could involve investigating the health effects of cannabis use on a diverse range of conditions (e.g., metabolic syndrome, cardiovascular disease, cancer, obesity and sedentary behavior, Alzheimer's disease) that are targeted by other institutes and centers of NIH. While it is not clear how these studies might be funded, almost assuredly the changing norms and the changing legal status of cannabis will have an impact on conditions that are targeted by institutes other than NIDA, and it will become increasingly important to have a funding mechanism to better understand the comprehensive health effects of cannabis so that consumers and policy makers can respond to changing trends accordingly.

CONCLUSION 15-3 A diverse network of funders is needed to support cannabis and cannabinoid research that explores the harmful and beneficial health effects of cannabis use.

METHODOLOGICAL CHALLENGES

Drug Delivery Challenges

Another challenge in investigating the potential health effects of cannabis and cannabinoids is the identification of a method of administering the drug that is accepted by study participants, that can be performed at most research sites, and that ensures standardized dosing. Smoking as a route of administration is particularly challenging, as some study participants may not view it as an acceptable method of drug administration, and academic medical centers or other locations where cannabis or cannabinoid research takes place may lack facilities where study participants can smoke under controlled conditions. Furthermore, variations among individuals in terms of their cannabis smoking techniques make it difficult to ensure that study participants reliably receive the targeted dose of the drug. Devices for providing a metered dose of cannabis via inhalation exist (Eisenberg et al., 2014), but the FDA has not approved such devices for use. Standardized smoking techniques have also been developed (Foltin et al., 1988) but can be difficult to perform correctly. These difficulties are due, in part, to differences among individuals in their tolerance of the potential psychoactive effects of the drug (D'Souza et al., 2008; Ramaekers et al., 2009), which may prevent the receipt of equal doses by all study participants.

Researchers have also explored vaporization as a method for adminis-

tering cannabis (Abrams et al., 2007). Cannabinoids vaporize at lower temperatures than the temperature at which pyrolytic toxic compounds are created through combustion; as a result, levels of some carcinogenic compounds are lower in cannabis vapor than in cannabis smoke (Eisenberg et al., 2014). However, there is a paucity of research on the effectiveness of these devices as a mode of drug administration. For example, data on the plasma concentrations of cannabinoids achieved through use of vaporizers exists, but they are limited (Abrams et al., 2007; Zuurman et al., 2008). In addition, even less is known about the long-term pulmonary effects of inhaling a vaporized liquid than about the effect of inhaling plant material. As vaporizing devices proliferate and evolve, researchers may benefit from advances in their portability and usability, but they will also have to account for clinically relevant differences in the functioning and the effectiveness of an increasingly wide range of models.

To circumvent the practical and methodological challenges involved in administration of cannabis through smoking or vaporization, investigators may choose to study the health effects of orally administered dronabinol or nabilone, which offer a more controlled method of drug delivery. However, the effects generated by these isolated cannabinoids might, at least in part, be different from those produced by the use of the whole cannabis plant, which also contains CBD and other cannabinoids, as well as terpenoids and flavonoids. As a result, extrapolating from the observed health effects associated with use of an isolated cannabinoid such as dronabinol or nabilone in order to predict the health effects associated with the use of cannabis may lead to erroneous conclusions.

The Placebo Issue

The gold standard of drug development is the prospective, randomized, double-blind, placebo-controlled clinical trial. Placebo cannabis produced by solvent extraction is available from NIDA and has a potency of 0.002 percent THC by weight and 0.001 percent CBD by weight (NIDA, 2016d).[23] The extraction process seems to retain the terpenoids and flavonoids so that the combusted placebo material smells similar to the true cannabis, thus helping to preserve the blinding to some extent. However, the psychoactive and vasoactive effects of cannabis pose a considerable challenge for effective blinding, since study participants who feel such

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[23] In December 2016, placebo cannabis provided by NIDA was generally free for NIH-sponsored research. For research not funded by the federal government, the cost of placebo cannabis was $13.94 per cigarette and $1,133 per pound ($2,497 per kilogram) (NIDA, 2016d).

effects will surmise that they are receiving cannabis or cannabinoids, and not a placebo.

Strategies to promote the effectiveness of blinding exist. For example, if the cannabis being studied has a very low THC content, study participants—especially those who, through regular use of more potent cannabis strains, are inured to the psychoactive effects of cannabis with low THC content—may not notice the psychoactive effects of the cannabis and therefore be unable to reliably determine whether they are using cannabis or a placebo. There is also a possibility that cannabis products with a lower ratio of the concentration of THC to the concentration of CBD may have less psychoactivity than products with a comparatively higher ratio of the concentration of THC to the concentration of CBD (Hindocha et al., 2015; Jacobs et al., 2016). Using these strains with diminished psychoactive effects could promote more effective blinding. Researchers may also try treating both study arms in a placebo-controlled cannabis trial with a mildly psychoactive or sedating drug, the effects of which may help to ensure that study participants are unable to determine whether they are receiving a placebo or cannabis. However, by introducing another active agent, the investigators risk obfuscating the results of their study.

A potential method for assessing the effectiveness of blinding in a cannabis trial is to ask study participants to guess whether they are receiving true cannabis or a placebo. If most or all of the participants correctly guess their assignment, it can be inferred that the blinding was ineffective. Whether or not such methods are employed, investigators risk undermining their study results. On the one hand, conducting the test carries the risk of discovering that attempts at blinding were ineffective, thereby rendering the study results invalid. On the other hand, not conducting the test may lead journal reviewers aware of the challenges of blinding in cannabis trials to assume that blinding was ineffective and to discount the study results accordingly. Thus, research to address the challenge of achieving reliably effective blinding in a cannabis trial is of marked importance.

Exposure Assessment

In order to arrive at valid and meaningful results, population studies on the health effects of cannabis require as detailed an ascertainment of exposure to cannabis as possible. However, obtaining such a detailed exposure history can be difficult. This is especially true for recreational cannabis use due to the lack of a standardized dose and the existence of diverse routes of administration, including multiple modes of inhalation (Schauer et al., 2016). In addition, known pharmacological biomarkers of cannabis use may be unreliable in some circumstances, while population

studies to identify novel pharmacological biomarkers of cannabis exposure are limited (Hartman et al., 2016; Schwope et al., 2011). Furthermore, the wide variety of different cannabis strains developed through a long and ongoing process of cultivation and the associated variation in the concentration of active substances in cannabis further complicate the characterization of cannabis exposure (ElSohly and Gul, 2014; Elsohly et al., 2016; Mehmedic et al., 2010). Finally, recreational cannabis may contain chemical contaminants or adulterants (Busse et al., 2008). Cannabis users may be unaware of the presence of these chemicals, making it unlikely that such chemicals would be identified through toxicological evaluation unless the user became involved in a forensic investigation.

Most observational studies, particularly case-control and cohort studies, depend on self-report in order to assess cannabis exposure. These reports may be incomplete, inaccurate, or imprecise due to failure on the part of investigators to ask cannabis users detailed questions about their cannabis exposure history, including the source of their cannabis exposure (e.g., smoking, edibles, vaping), or because users themselves may have limited knowledge of some aspects of their exposure or may be resistant to reporting some information. Personal recall of substance use may also be affected by other factors. For example, memory problems have been identified as a cause of inaccuracies in reporting drug use (Johnson and Fendrich, 2005; Pedersen, 1990). In other cases, study participants may not report illicit substance use in an attempt to conform to perceived social norms (Johnson and Fendrich, 2005). Similarly, individuals with substance dependency syndromes may have psychiatric comorbidity that affects the accuracy of reporting.

Finally, important information often missing from cannabis exposure histories is the extent of other substance use. As noted in Chapter 14, there is limited evidence that cannabis use is associated with the use of other licit or illicit substances. Despite this association and the confounding effect of polysubstance use on evaluations of the health effects of cannabis use, surveys used to characterize cannabis exposure histories do not always assess for the presence of other substance use. Since secondhand exposure to cannabis smoke can have minor health effects, there may also be value in assessing for such exposure as part of larger assessments of cannabis exposure (Herrmann et al., 2015).

Cannabis-Related Study Designs

In researching the health outcomes of cannabis use, the committee identified a number of studies, particularly cohort studies, of general health outcomes such as all-cause mortality or important chronic illnesses such as cancers or cardiovascular diseases. For both cohort and

case-control studies, a better assessment of cannabis use would offer more valuable information, such as years of use and age at first use. Particularly for cohort studies, this would offer better ascertainment of the duration and net burden of use as well as more insight into period and age effects. As discussed in the proceeding health outcomes chapters of the report, in many of the existing cohort studies cannabis use was often queried only at baseline, and thus there was little information on interval use over time or on the variation or cessation in that use. There was also very limited information on interval health events as the cohorts progressed, impeding a summarization of long-term use and the consequent health effects. Attention to these issues will likely improve the precision of study findings.

CONCLUSION 15-4 To develop conclusive evidence for the effects of cannabis use on short- and long-term health outcomes, improvements and standardization in research methodology (including those used in controlled trials and observational studies) are needed.

BOX 15-2
Summary of Chapter Conclusions*

There are several challenges and barriers in conducting cannabis and cannabinoid research, including

- There are specific regulatory barriers, including the classification of cannabis as a Schedule I substance, that impede the advancement of cannabis and cannabinoid research (15-1)
- It is often difficult for researchers to gain access to the quantity, quality, and type of cannabis product necessary to address specific research questions on the health effects of cannabis use (15-2)
- A diverse network of funders is needed to support cannabis and cannabinoid research that explores the harmful and beneficial health effects of cannabis use (15-3)
- To develop conclusive evidence for the effects of cannabis use on short- and long-term health outcomes, improvements and standardization in research methodology (including those used in controlled trials and observational studies) are needed (15-4)

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* Numbers in parentheses correspond to chapter conclusion numbers.

SUMMARY

The methodological challenges and the regulatory, financial, and access barriers described above markedly affect the ability to conduct comprehensive basic, clinical, and public health research on the health effects of cannabis use, with further consequences for the many potential beneficiaries of such research. In the absence of an appropriately funded and supported cannabis research agenda, patients may be unaware of viable treatment options, providers may be unable to prescribe effective treatments, policy makers may be hindered from developing evidence-based policies, and health care organizations and insurance providers lack a basis on which to revise their care and coverage policies. In short, such barriers represent a public health problem. See Box 15-2 for a summary of the chapter conclusions.

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DOCUMENT F

REMOVING BARRIERS TO RMJ RESEARCH

STATUS OF THE

MEDICAL MARIJUANA RESEARCH ACT

Could This Be the First Big Step Towards Marijuana Legalization?

More research is needed on marijuana in the country, and the Medical Marijuana Research Act could make it easier for scientists to study the drug.

David Jagielski
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Nov 2, 2021 at 6:33AM
Author Bio

Key Points

- A lack of hard data on the health benefits of marijuana is a big reason it remains a Schedule I substance.
- Making research easier would go a long way in creating much-needed evidence for the industry to prove that marijuana isn't all bad.
- Marijuana legalization likely won't happen within the next year or two, so investors will need to remain patient with any pot stocks they own.

A big obstacle in marijuana legalization is that some lawmakers remain skeptical about the health benefits of cannabis. While there is plenty of anecdotal evidence out there, cold hard facts are hard to come by. And that's why news of a recent bipartisan bill in Congress has me optimistic that it could lead to legalization down the road.

Any kind of reform would be welcome news for the sector, at this point. And once the ball starts rolling, it could pave the way for even more changes in the industry.

Bill would allow researchers to use products from dispensaries

The Medical Marijuana Research Act, if it becomes law, would make cannabis research easier in the country. In an interview with Marijuana Moment, Congressman Earl Blumenauer, who helped make the bill a reality, said, "because cannabis is a Schedule I substance, researchers must jump through hoops and comply with onerous requirements just to do basic research on the medical potential of the plant."

Under this bill, the process would be simplified and researchers would be provided with high-quality, real-world products to study. The bill would also benefit marijuana dispensaries operating in the U.S., creating demand for their products in the process.

Why there's hope for bills like this to finally become law

There have been many marijuana bills over the years and yet, there's been little to show for them. But under the Biden Administration, there's reason to believe that there could finally be some movement on marijuana reform. Although he isn't a staunch supporter of the full legalization of cannabis, he is in favor of decriminalization, stating, "getting caught for smoking marijuana shouldn't deny you a good-paying job and career, a loan, or ability to rent an apartment."

And there has already been a noticeable change in the government's approach to marijuana. In May, the Drug Enforcement Administration (a federal agency) announced that it would open the door to allow multiple companies to provide the government with marijuana that can be used for research. That's a big change from just the one source for cannabis (the University of Mississippi) that researchers have been relying on for decades.

Odds are the marijuana legalization process will still take a while

Although advancing a research bill may seem like a nominal step for the industry, it would still be an important one. By being able to do more research and provide more hard data behind the effects of marijuana use, it will be easier to show any medical benefits from the drug's use. That can lead to moving the substance out of Schedule I and eventually to full legalization.

While Canadian cannabis producers like **Canopy Growth** (NASDAQ:CGC) may be optimistic that they will be operating in the U.S. pot market within a year, the reality is it will probably take some time before that happens. Senate Majority Leader Chuck Schumer does have a bill in place (the Cannabis Administration and Opportunity Act) that would end the federal ban on marijuana, but even he admits that the votes aren't there to pass it right now.

Attitudes are changing on marijuana and public support for legalization has never been higher than it is now. But lawmakers, especially conservative ones who still support the War on Drugs, will need convincing before there is widespread and bipartisan support for marijuana legalization.