

# **Cannabis Policy: Public Health and Safety Issues and Recommendations**

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A REPORT

BY THE

UNITED STATES SENATE CAUCUS  
ON  
INTERNATIONAL NARCOTICS CONTROL

ONE HUNDRED SEVENTEENTH CONGRESS  
FIRST SESSION

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## LETTER OF TRANSMITTAL

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### UNITED STATES SENATE CAUCUS ON INTERNATIONAL NARCOTICS CONTROL

Washington, D.C.  
March 2, 2021

DEAR COLLEAGUE:

The attached report represents the findings gathered by Caucus members and staff through hearings, briefings, interviews, and the review of documents from government and non-government subject matter experts. It builds largely on the topics raised during the Senate Caucus on International Narcotics Control Hearing on October 23, 2019, entitled “Marijuana and America’s Health: Questions and Issues for Policy Makers.” It outlines some of the most pressing research and public health issues related to cannabis and provides recommendations to address them.

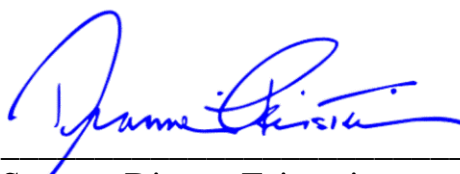
We look forward to working with you to implement these recommendations.

Sincerely,



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Senator John Cornyn  
Chairman



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Senator Dianne Feinstein  
Co-Chairman

## FINDINGS AND RECOMMENDATIONS

*More must be done to accelerate research related to cannabis, the findings of which can be used to mitigate public health consequences and guide the development of future medications, policy, and legislation. The Senate Caucus on International Narcotics Control (the Caucus) offers the following recommendations to do so.*

### REMOVING BARRIERS TO RESEARCH

1. **Finding:** Approximately 9,500 people per day, 3,700 of whom were between the ages of 12 and 17, tried cannabis for the first time in 2019.<sup>i</sup> Yet, the public health impacts of cannabis use – including those associated with the developing brain, cannabis impaired driving, and increasing THC levels, among others – are not well understood, and research is severely lacking. Similarly, while components of cannabis have shown promise in treating serious medical conditions, the barriers associated with obtaining a schedule I registration to further study cannabis can serve as disincentive; the process associated with obtaining the schedule I research registration can take more than a year.<sup>ii</sup>

**Recommendation:** Given the need to better understand the public health impacts associated with cannabis use and its potential to treat serious medical conditions, the Caucus strongly supports efforts to reduce research barriers.

During the 116<sup>th</sup> Congress, Senators Feinstein and Grassley introduced S.2032, the Cannabidiol and Marihuana Research Expansion Act, which was passed by Unanimous Consent in the Senate, but was not considered in the House. This bill would remove barriers to researching cannabis without sacrificing the necessary oversight to ensure public health and safety. Moreover, if the science shows it is effective, the legislation creates a pathway for cannabis-derived medications to be approved by the Food and Drug Administration (FDA), using strains of cannabis and cannabidiol (CBD) that are grown and produced by researchers.

Senators Feinstein and Grassley reintroduced the bill during the 117<sup>th</sup> Congress (S.253), and the Caucus urges its swift passage.

## STUDYING THE IMPACTS OF INCREASING THC LEVELS

2. **Finding:** Between 1999 and 2017, tetrahydrocannabinol (THC) concentrations, or cannabis potency, more than quadrupled.<sup>iii</sup> Today, the average potency of THC in cannabis products sold in dispensaries is between 18 and 23 percent.<sup>iv</sup> The potency of concentrated cannabis products can be up to four times stronger, reaching as high as 80 percent.<sup>v</sup>

Risks of physical dependence and unpredictable or adverse reactions, resulting in calls to poison control centers, acute intoxication, cyclical vomiting, emergency room visits, and anxiety may increase as potency increases. Moreover, the potential for these effects to become more prevalent rises as the number of cannabis users increases.

**Recommendation:** The Caucus urges the National Institutes of Health (NIH) to intensify its research on the short-and long-term impacts associated with high potency cannabis and to make a recommendation, jointly with the Food and Drug Administration (FDA), as to whether states should cap the potency of products that may be sold.

## THE IMPACT OF CANNABIS USE ON THE DEVELOPING BRAIN

3. **Finding:** More research is necessary to understand the full scope and duration of the impacts associated with cannabis use on the developing brain and the extent to which age of first use and frequency of use affect these impacts. However, available evidence indicates that THC that enters the bloodstream of pregnant women can result in adverse effects on the baby, including low birth weight and impacts on fetal brain development. Moreover, research also shows that cannabis use in adolescence can negatively impact brain development and function, which may result in decreased cognitive abilities, loss of IQ, and lower educational attainment, among other effects. Taken together, this research prompted the immediate past Surgeon General to issue an advisory, warning that no amount of cannabis is safe for adolescents or pregnant women.

**Recommendation:** Public health officials at the federal, state, and local levels should amplify the immediate past Surgeon General's warning through the implementation of effective prevention and awareness programs to ensure that adolescents and pregnant women are aware of cannabis' potential impacts on the developing brain and fetus.

## UNREGULATED PRODUCTS

4. **Finding:** The Food and Drug Administration (FDA) has recognized the significant interest in the development of therapies and other consumer products that are derived from cannabis, including cannabidiol (CBD). There has been a massive proliferation of these products since the enactment of the *Agriculture Improvement Act of 2018*, which removed hemp from the *Controlled Substances Act*. Companies have marketed these products in ways that violate the *Federal Food, Drug, and Cosmetic Act* putting consumers and patients at risk. In many cases, the FDA and the Federal Trade Commission (FTC) have found these products to be contaminated with dangerous and illicit substances or to not even contain the marketed ingredients.

**Recommendation:** The Caucus urges the FDA, in conjunction with any other relevant federal departments and agencies, to continue exercising its enforcement authorities with respect to cannabis and its derivatives, including CBD. The FDA, along with the FTC, should also continue working to ensure consumers know which businesses are selling false goods, especially those products with expressed therapeutic efficacy.

## EXPANDING LAW ENFORCEMENT TRAINING, FORENSIC LAB CAPACITY AND RESEARCH TO BETTER DETECT CANNABIS IMPAIRED DRIVING

5. **Finding:** Cannabis impaired driving threatens public safety. States have implemented a variety of laws to address this issue. However, a universal standard to detect cannabis impaired driving does not exist, largely because THC presence in the bloodstream, alone, does not indicate impairment.

Given the difficulties and expense involved in establishing cannabis or other drug related impairment, 47 out of 50 states do not differentiate between alcohol and other drugs in such cases or stack the charges. This serves as a deterrent for law enforcement to test for cannabis impairment specifically, which may skew available data on the prevalence of cannabis impaired driving.

To augment the shortcomings related to testing, the National Highway Traffic Safety Administration (NHTSA) supports research related to reliable roadside tests and supports training for law enforcement through the Drug

Recognition Expert (DRE) and Advanced Roadside Impaired Driving Enforcement (ARIDE) programs. Yet, the DRE program only trains just over one percent of law enforcement officials nationwide, and the ARIDE program only trains approximately eight percent.<sup>vi, vii</sup>

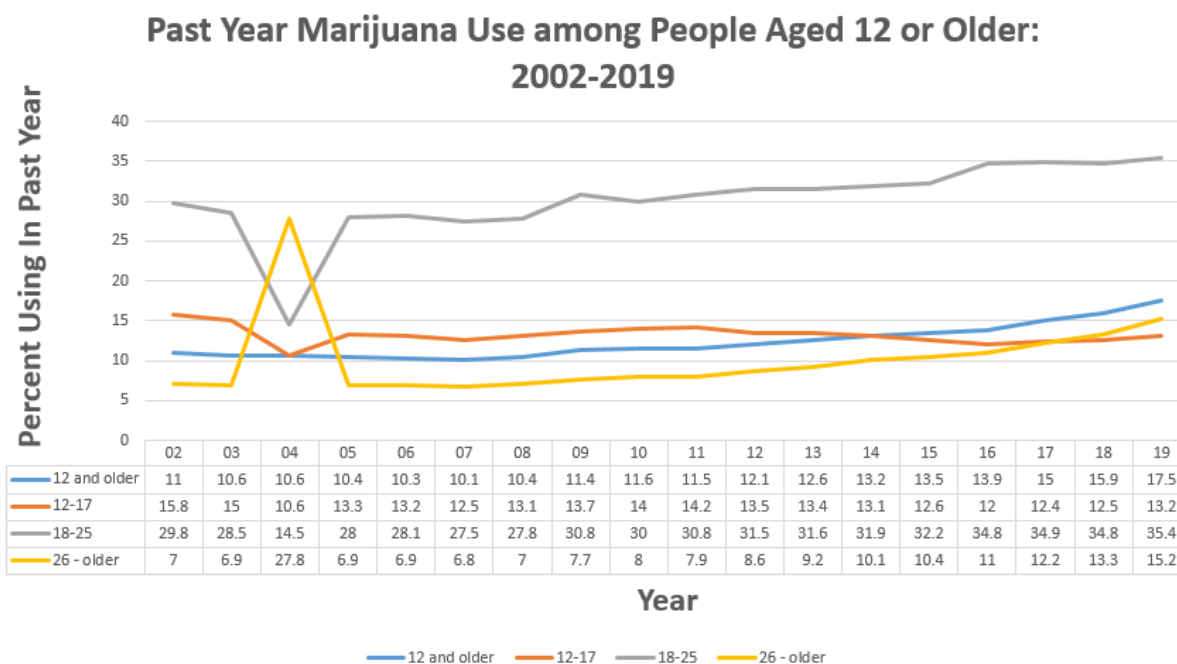
***Recommendation:*** The Caucus strongly urges the federal government to accelerate research regarding the detection of cannabis impaired driving, including the development of standardized field testing. Moreover, given their success, but limited reach, the Caucus urges NHTSA to increase funding for the DRE and ARIDE programs so that the maximum number of law enforcement and other personnel can be trained on how best to detect cannabis impaired driving. The Caucus further urges Congress to increase federal funding for state forensic and toxicology labs to ensure that testing for cannabis impaired driving is expanded and required, so that available data more accurately reflects the scope of the problem, and to expand innovative and effective programs, such as DUI/DWI courts.

## SCOPE OF THE PROBLEM

As of February 1, 2020, 36 states, as well as Puerto Rico, Guam, the U.S. Virgin Islands, and the District of Columbia, allow for the comprehensive medical use of cannabis while an additional 11 states allow for low-tetrahydrocannabinol (THC) cannabis. Fifteen states, the District of Columbia, Guam, and the Northern Mariana Islands allow for recreational use of cannabis.<sup>viii</sup>

Despite its increasing popularity – 91 percent of Americans believe cannabis should be legalized for either medical or recreational purposes – cannabis remains illegal at the federal level.<sup>ix</sup> Nonetheless, the U.S. cannabis industry is thriving. Cultivation and sales have largely shifted from Mexican cartels to U.S.-based businesses operating in licit, state markets (though a sizeable black market remains). Experts estimate the licit cannabis market employs more than 200,000 individuals and will produce as much as \$24 billion in profits 2025, nearly \$9 billion of which will be from medical cannabis sales.<sup>x,xi</sup>

The increases in market profitability coincide with increases in cannabis use in the United States. According to the National Survey on Drug Use and Health (NSDUH), in 2019, the latest year for which data is available more Americans used cannabis than in any single year since 2002.<sup>xii</sup>



Source: Results from the 2019 National Survey on Drug Use and Health



Moreover, approximately 9,500 people per day, 3,700 of whom were between the ages of 12 and 17, tried cannabis for the first time in 2019.<sup>xiii</sup>

The high rates of use and new initiates coupled with the fact that one in six of those under the age of 18 may become addicted make it imperative to better understand the potential public health impacts related to cannabis use.<sup>xiv, xv</sup>

Unfortunately, scientific research related to cannabis is lacking, and the limited research that is available highlights the complexities associated with its use. For instance, cannabis is comprised of hundreds of components beyond THC, which produces psychoactivity, or “the high,” and cannabidiol (CBD), a non-psychoactive component. Each of the individual components acts differently, both in isolation and in combination with other components, and have the potential to produce both positive and negative effects.

According to the National Academy of Sciences, there are varying degrees of evidence that certain components of cannabis may effectively treat conditions like intractable epilepsy, chemotherapy induced nausea and vomiting, muscle spasticity, chronic pain, and short-term sleep disturbances.<sup>xvi</sup>

The Food and Drug Administration (FDA) has approved one cannabis-derived drug and three cannabis-related drugs to treat specific diseases or conditions.<sup>xvii</sup> The most recent approval was for Epidiolex, an oral CBD solution used to treat seizures associated with three types of conditions.<sup>xviii</sup>

Despite its potential medical promise, existing research also shows that cannabis can have a negative impact on the developing brain, including decreased cognitive abilities, loss of IQ, and increased risk of psychosis. The full scope and duration of these impacts, and the degree to which various THC levels and frequency of use may affect these outcomes, is not yet well understood.

Available research also demonstrates that cannabis use impacts judgement and coordination, two functions that are critical to driving. Yet, a universal standard to detect cannabis impaired driving does not exist, which may jeopardize public safety.

Also concerning is the fact that THC can enter the bloodstream of pregnant women, which may result in adverse effects on the baby, including low birth weight and impacts on fetal brain development.<sup>xix</sup>

Taken together, this research prompted the immediate past Surgeon General to issue an advisory, warning that no amount of cannabis is safe for adolescents or pregnant women.

### *Intent of This Report*

Available, but limited research demonstrates that cannabis may hold both promise and peril. With this in mind, the Caucus strongly believes that it is imperative to increase the research base associated with cannabis, and that this research should be used to guide future policy so that appropriate regulations can be put in place to mitigate any negative public health consequences.

## BARRIERS TO RESEARCHING CANNABIS

### *Overview*

Cannabis is a schedule I substance pursuant to the *Controlled Substances Act* (CSA). According to the Drug Enforcement Administration (DEA), schedule I substances have no currently accepted medical use, a high potential for abuse, and a lack of accepted safety for use under medical supervision.<sup>xx</sup> As such, these substances are subject to strict control and stringent regulations, even for research purposes.

Multiple agencies play a role in ensuring the safety and quality of cannabis research. Therefore, researchers who wish to study cannabis must adhere to regulations issued by all of these agencies.

Although each of the involved agencies publicly supports expanding cannabis-related research, and federal funding has increased in recent years, the agencies have only taken modest steps to reduce regulatory hurdles associated with doing so.<sup>xxi</sup>

Given the potential for cannabis to treat serious medical conditions and the need to better understand the public health impacts associated with its use, the Caucus strongly believes that research barriers should be reduced, and that this can be achieved without sacrificing the necessary oversight to protect public health and safety.

### *Regulations Associated with Researching Cannabis in the United States*

The Department of Justice (DOJ), acting through the DEA, and the Department of Health and Human Services (HHS), acting through the Food and Drug Administration (FDA), each have statutory responsibilities associated with regulating research on schedule I substances, which are delineated by the CSA and the *Federal Food, Drug, and Cosmetics (FD&C) Act*, respectively.<sup>xxii</sup>

All proposed research involving cannabis must be reviewed by the FDA before a researcher is granted a schedule I registration by the DEA.

When a researcher submits a completed application for a schedule I registration, the DEA reviews it and is required to forward the application, including the protocol and an administrative letter of authorization from the

National Institute on Drug Abuse (NIDA) to the FDA within seven days.<sup>xxiii</sup> In order to obtain a letter of authorization from NIDA, the researcher must submit his or her protocol to the agency along with a justification for the amounts of cannabis requested.<sup>xxiv</sup> The FDA is required to review and comment on the scientific merit of the studies and qualifications of the investigators conducting the research and to report this information to the DEA within 21 days of receipt.<sup>xxv</sup>

If the study is clinical, the researcher must also obtain authorization from an institutional review board and from the FDA by submitting an investigational new drug (IND) application prior to submitting the application for the DEA schedule I registration.<sup>xxvi</sup> The FDA is required to review the IND within 30 days of receipt. When the FDA notifies the DEA that the researcher is qualified and the research is meritorious, the DEA then has 10 days to issue a registration.<sup>xxvii</sup>

As this process is ongoing, the DEA conducts background investigations on the researchers. The DEA also visits the sites of all locations in which the research will be conducted and cannabis will be stored to determine if the research investigator has adequate security controls to prevent its illegal diversion.

Given the deadlines listed above, the maximum amount of time that it should take a researcher to obtain a schedule I registration is 47 days. In practice, the DEA has said that the average length of time it takes to approve a “completed” application for a schedule I registration is 52 days.<sup>xxviii</sup> However, it is often the case that a researcher inadvertently submits an incomplete application, which results in delays, and in many instances, the entire application process can take more than a year.<sup>xxix</sup>

### *Cause of Delays in Obtaining Initial Schedule I Research Registration*

The causes for the delays in obtaining schedule I research registration vary, but typically are the result of one or more of the following:

*Incomplete Applications:* The DEA considers approximately 70 percent of applications as incomplete at the time of submission.<sup>xxx</sup>

While the DEA is required to forward a “complete” application to the FDA within seven days, if the DEA deems the application incomplete, the “seven day clock” does not apply, and there is no prescribed timeframe by which the DEA must notify an applicant that their application is incomplete.

Duplication of Effort: Duplication of effort by federal agencies can also cause delays in obtaining a schedule I research registration. This point was underscored in the National Institutes of Health’s fiscal year (FY) 2020 Congressional Budget Justification, which stated “the requirement for protocol review by the DEA can be redundant with the review that occurs through the FDA IND process and with federal grant review.”<sup>xxxi</sup>

Dosing for Human Trials: The regulations associated with formulations and dosages for clinical cannabis research are complicated and may also result in delays. For example, according to NIDA, in the case of cannabis extracts that need to be dissolved in alcohol or oil before they can be used, “...the DEA will not register a researcher for such work until the FDA has approved an IND for the final formulation; however, the final formulation is needed in order to complete the chemistry, manufacturing and controls section required to support an IND application. In these cases, researchers are required to apply for a registration to gain access to and formulate the materials under a preclinical protocol. Once the relevant data are collected, they can submit an IND to the FDA, and when the IND is authorized, they can apply for a registration (or a modification of their registration) to conduct the clinical work. This two-step process increases administrative burden on researchers and delays important clinical research.”<sup>xxxii</sup>

Security Reviews: While the CSA requires all cannabis to be stored in a substantially constructed safe or steel cabinet, local DEA field agents have, and often exercise, the discretion to require greater security based on a number of factors. In some cases, these discretionary requirements, which are not known in advance, have caused significant delays, and have also resulted in researchers having to obtain multiple schedule I registrations.<sup>xxxiii</sup>

With these factors in mind, the Caucus strongly urges the DEA to expeditiously issue updated guidance and regulations regarding the process involved with obtaining a schedule I research registration. The updated regulations should require the DEA to notify applicants who have incomplete applications and request supplemental information within 60 days of receipt. Moreover, the regulations should include a clear delineation of agency roles to reduce duplication of effort and better ensure a division between the DEA, the FDA, and NIDA in terms of protocol review.

## *Changes to Quantities of Cannabis and Approved Protocols*

Regulations issued pursuant to the CSA require schedule I research registrants to submit a new request to the DEA, if, after approval of the initial research protocol, the quantity of cannabis needed for the research changes. Although the regulations state that the change in quantity is approved “upon return of the receipt,” the receipt is not actually returned until after the DEA reviews the request and forwards it to the FDA, which ultimately approves or denies it. <sup>xxxiv</sup>

Existing regulations also stipulate that if the approved protocol for research changes, the registrant must submit supplemental documentation describing the new protocol, which “shall be processed and approved or denied in the same manner as the original research protocols.”<sup>xxxv</sup>

Therefore, changes to either the quantity of cannabis needed to carry out a study or to the protocol have the effect of stopping research while the researcher waits for the DEA and the FDA to re-approve their research protocol. <sup>xxxvi</sup>

Additionally, given the limited availability of cannabis through NIDA’s Drug Supply Program, it is possible that batches of cannabis that were included in the original IND application may no longer be available once the IND is approved. In these instances, the IND must be amended to reflect a new batch number, which can cause more delays.<sup>xxxvii</sup> Further, changes to protocols “may trigger additional inspections by the DEA, which can delay approval.”<sup>xxxviii</sup>

These regulations have been consistently identified by researchers and other federal agencies as presenting significant and practical problems.

## *Other Impediments to Research*

The DEA and the DOJ have long held the view that, pursuant to the *United Nations Single Convention on Narcotic Drugs* and the CSA, there can be only one source of cannabis in the United States.

This interpretation has contributed to a lack of research, which hinders our understanding of the public health effects of products available for sale in state regulated markets.

While the University of Mississippi, which contracts with NIDA to supply the country’s research grade cannabis, has begun producing a more varied array of

cannabis and cannabidiol (CBD) products, it is unable to keep pace with the variety of strains available on the commercial market. Moreover, researchers seeking to develop FDA-approved products may be hesitant to rely on cannabis obtained from NIDA, since its supply is not intended to be used for commercial production.<sup>xxxix</sup>

Dr. Nora Volkow, Director of NIDA, echoed these concerns in testimony before the Health Subcommittee of the Energy and Commerce Committee, stating that “Having only a single domestic source of research cannabis limits the diversity of products and formulations available to researchers and slows the development of cannabis-based medications.”<sup>xl</sup> She further stated that, “Under Federal law, researchers supported by NIDA and other federal agencies are unable to access marketed cannabis products through state cannabis dispensaries. There is a significant gap in our understanding of their impact on health.”<sup>xli</sup>

Notwithstanding the DEA’s own interpretation that there can only be one source of cannabis in the United States in order to maintain compliance with international treaty obligations, in 2016, the agency issued a policy statement asserting that it “fully supports expanding research into the potential medical utility of cannabis and its chemical constituents.”<sup>xlii, xliii</sup> The policy statement further indicated that “the best way to satisfy the current researcher demand for a variety of strains of cannabis and cannabinoid extracts is to increase the number of federally authorized cannabis growers. To achieve this result, the DEA, in consultation with NIDA and the FDA, has developed a new approach to allow additional cannabis growers to apply to become registered with the DEA, while upholding U.S. treaty obligations and the CSA.”<sup>xliv</sup> It also delineated a process by which individuals could apply to become bulk manufacturers of cannabis for research purposes.

The DEA did not issue a final rule related to this policy statement, which will enable it to act on the 38 pending applications, until December 2020.<sup>xlv</sup>

Pursuant to the rule, all currently pending applications will be considered at once in order to ensure effective controls against diversion. A manufacturer can only be granted a registration if the manufacturer can demonstrate that it already has a contract with a schedule I researcher who is registered with the DEA and that the manufacturer is in compliance with the DEA regulations and the CSA.

Given that any applicant who has been operating in a state that has legalized cannabis for medical or recreational purposes would likely be deemed out of

compliance with the CSA, the Caucus is concerned that the majority of pending applications will be denied, and that the available supply of legal cannabis that may be used for research will remain severely limited.

### *Congressional Response to Research Barriers*

The House and Senate Appropriations Committees acknowledged the difficulties associated with researching schedule I substances, including cannabis, in their respective reports accompanying the FY 18 Labor, Health and Human Services and Education Appropriations Act. Specifically, the Committees stated that they are “concerned that restrictions associated with schedule 1 of the CSA effectively limit the amount and type of research that can be conducted on certain schedule 1 drugs, especially cannabis or its component chemicals and certain synthetic drugs. At a time when we need as much information as possible about these drugs, we need to review lowering regulatory and other barriers to conducting this research.”<sup>xlvi</sup>

This report language was repeated in the Senate in FY 19, and in both years, the Senate Appropriations Committee directed NIDA to provide a report on the barriers associated with researching schedule I drugs.

In its FY 21 explanatory statement, the Senate Appropriations Committee again expressed concern that cannabis’ schedule I status could limit research. It also encouraged NIH to evaluate the long-term effects of consuming cannabinoids such as CBD.<sup>xlvi</sup> At the same time, the House Appropriations Committee encouraged NIDA to support research on cannabis and its components to better understand how cannabis use affects public health.<sup>xlvi</sup>

In addition to Appropriations report language, bipartisan legislation has been introduced in both chambers of Congress. The House passed H.R. 3797, the Medical Marijuana Research Act of 2019 at the end of 116<sup>th</sup> Congress, while the Senate passed S. 2032, the Cannabidiol and Marihuana Research Expansion Act.

Each of these bills streamline the overall process associated with obtaining a schedule I research registration. However, the Senate bill also includes provisions to ensure that FDA-approved drugs containing cannabis or cannabis derivatives can be quickly brought to the market by permitting researchers to grow and produce cannabis for the purpose of developing FDA-approved medications. In these ways, the Senate bill ensures the development of cannabis-derived medications are based on science, that appropriate dosing and delivery mechanisms



are tested and deemed safe by the FDA, and that any known interactions with other medications or side effects are studied and made known to the patient.

### *Conclusion*

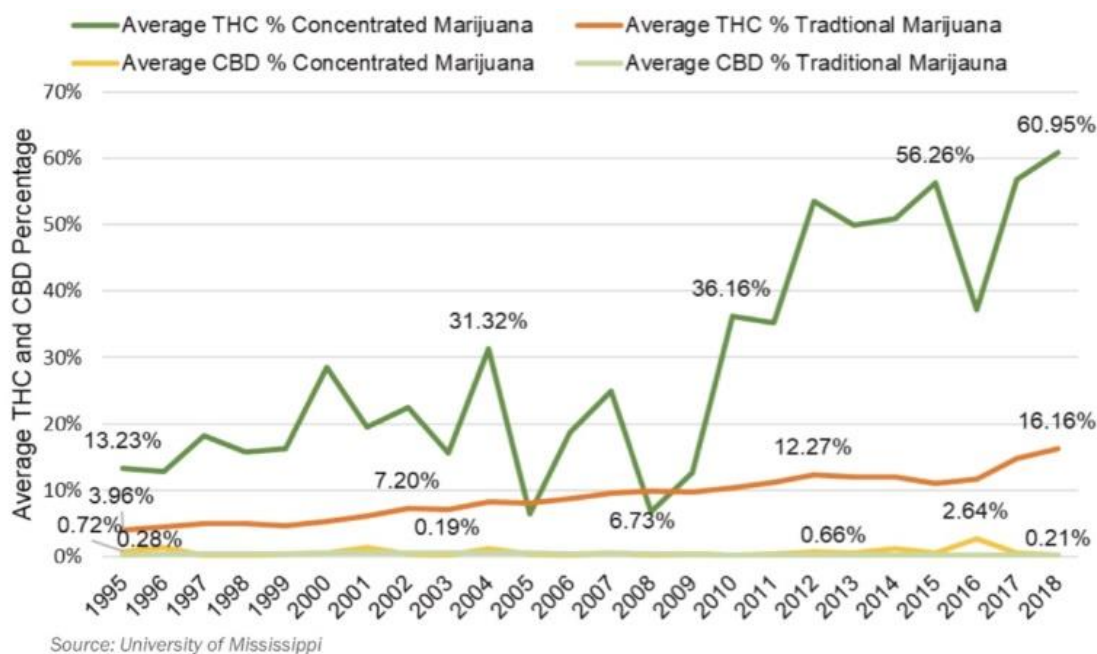
The Caucus believes that science should inform policy. Yet, existing research barriers have prevented legislators at all levels from implementing informed public health policies, and impeded the development of safe and effective cannabis-derived medications that can be approved by the FDA.

Accordingly, the Caucus urges Congress to pass S.253, the Cannabidiol and Marihuana Research Expansion Act. This bill would remove barriers to researching cannabis, without sacrificing the public health or safety, thereby enabling science to better guide policy moving forward.

## THE IMPACTS OF INCREASED CANNABIS POTENCY

### Overview

Tetrahydrocannabinol (THC) concentrations, or cannabis potency, have increased dramatically over the past three decades. According to a peer-reviewed study, in the 1990s, the average THC concentration in illicit cannabis plant material was about four percent. By 2014, that figure had tripled to about 12 percent.<sup>xliv, l</sup> Today, the average potency of THC in cannabis products sold in dispensaries in the United States is between 18 and 23 percent, and the price per serving for most product types has decreased in certain states, making it potentially more accessible.<sup>li, lii, liii, liv, lv</sup>



According to the Drug Enforcement Administration (DEA), cannabis concentrates, a highly potent form of THC that often looks like honey or butter, can be up to four times stronger than the THC found in top quality cannabis flower, and ranges from 40 to 80 percent.<sup>lvi</sup> Such concentrates are typically used in cannabis infused foods, beverages, and e-cigarettes.<sup>lvii</sup>

At the same time that potency and availability are increasing, so too is daily or near daily cannabis use. Nationally, between 2009 and 2018, among those 12 and older who reported using cannabis in the past 30 days, the percentage who used daily or almost daily increased by 18 percent.<sup>lviii</sup> By 2019, an estimated 13.8

million Americans were using cannabis daily.<sup>lix</sup> To put it simply, occasional users are becoming daily users, potentially exposing themselves to adverse health effects.<sup>lx</sup>

Also concerning is the popularity and use of potentially high potency products among youth. Nationally, according to the *Monitoring the Future Survey*, just over 12 percent of high school seniors vaped cannabis in the past month.<sup>lxi</sup> Of the high school seniors reporting that they had vaped cannabis, 2.5 percent did so daily.<sup>lxii</sup>

This is concerning not only because of the percentage of high school seniors vaping marijuana, but also because in researching the 2019-2020 outbreak of e-cigarette or vaping product use-associated injury (EVALI), which resulted in more than 2,800 suspected cases and 68 deaths, the Food and Drug Administration (FDA) found that many of the cases were linked to e-liquids containing THC and associated thickening agents (e.g., vitamin E acetate).<sup>lxiii</sup> As a result, the FDA issued a statement urging the public to “not use vaping products containing THC.”<sup>lxiv</sup> The agency further noted that while a specific compound had not been identified as causing the outbreak, the fact that “THC is present in [a majority] of the samples being tested” was concerning.<sup>lxv</sup>

Further, similar to other concentrates, the potency of cannabis used in vaping devices has also increased. In Washington State, for example, potency increased by approximately 72 percent between 2014 and 2017.<sup>lxvi</sup> Over the same time period, the number of concentrates for vaping products manufactured more than doubled, to 15 million.<sup>lxvii</sup>

While much remains to be learned, existing research indicates that the risks of physical dependence and unpredictable or adverse reactions increase as potency increases. Moreover, the potential for these effects to become more widespread increases as the number of cannabis users increases. For these reasons, the Caucus believes that the National Institutes of Health (NIH) should intensify its research on the short- and long-term impacts associated with high potency cannabis and jointly with the FDA make a recommendation as to whether states should cap the potency of products, including vaping products, that may be sold.

## *Short Term Consequences of High Concentrations of THC*

“Highly concentrated [cannabis] products raise the risks of harm from accidental ingestion, unintentional overdose, and repetitive cycles of nausea and vomiting known as cannabinoid hyperemesis syndrome.”<sup>lxviii</sup> Altogether, these effects contribute to cannabis related emergency room visits, which are estimated to cost millions of dollars.<sup>lxix</sup>

*Acute Intoxication from Unintentional Overdose:* High potency cannabis often results in adverse, unexpected reactions, including acute intoxication. Symptoms of acute intoxication include panic, fear, or depression (all related to psychosis) and, to a lesser extent, cardiovascular symptoms, like low blood pressure and increased heart rate.<sup>lxx</sup>

While all forms of cannabis can potentially cause acute intoxication, edible products are particularly concerning because they are highly concentrated and difficult to dose. Unlike smoked cannabis, which delivers THC into the bloodstream quickly, producing a relatively immediate “high” after ingestion, it takes between 30 minutes and 3 hours or 180 minutes for the THC in cannabis edibles to reach a significant blood concentration level.<sup>lxxi</sup> Because the “high” is not immediate, inexperienced users may ingest greater quantities, resulting in acute intoxication requiring emergency care. These products can also lead to more acute psychiatric emergency care visits than those arising from inhaled cannabis, as observed in one Colorado study.<sup>lxxii</sup>

*Poison Control Calls Related to Accidental Ingestion:* Edible cannabis products are frequently packaged to mimic traditional foods, such as brownies, pop tarts and candies, which appear harmless and are attractive to children. In addition to accidental ingestions, the wider availability of edibles has contributed to increased calls to poison control centers:

- In California, in 2015, there were 347 cannabis-related calls to poison control involving minors. In 2017, this number increased to 588 and around 43 percent of those calls involved children five years old and younger.<sup>lxxiii</sup> Candies and chocolate were the most commonly consumed edible in the state in the second quarter of 2017, and cannabis gummies were the most popular candy.<sup>lxxiv</sup>
- In Colorado, from 2009 to 2017, poison control calls related to cannabis and involving children younger than eight years old grew from eight to

64.<sup>lxxv</sup> In 2017, a little over 65 percent of the cannabis-related poison control calls involving children younger than eight years old were attributed to edible cannabis, an increase of nearly 29 percent from the previous two years.<sup>lxxvi</sup>

- In Oregon, less than 15 percent of cannabis-related calls to poison control centers in 2014 involved children younger than five years old. By 2017, this number increased to 20 percent.<sup>lxxvii</sup>
- In Washington State, accidental ingestions for children aged 0-5 almost tripled between 2014 and 2018.<sup>lxxviii</sup>

Lethargy, dilated pupils, loss of control of body movements, ataxia, and elevated heart rate are among the symptoms associated with accidental ingestions among children.<sup>lxxix</sup>

Recognizing the dangers associated with accidental ingestions, states have passed legislation to change the packaging requirements for cannabis-related products.

For instance, in 2017, Colorado began requiring all edibles to include labels that state “Contains Cannabis. Keep out of the reach of children.”<sup>lxxx</sup> A similar warning appears in Washington State.<sup>lxxxi</sup> Colorado also banned the words “candy” or “candies” from appearing on cannabis packaging, and requires each single serving to be clearly delineated and marked.<sup>lxxxii</sup>

However, despite the changes in packaging, not all states cap THC potency, which could reduce the effects associated with accidental ingestion. The types of caps that have been implemented are discussed later on in this report.

*Cannabinoid Hyperemesis*: Adverse health impacts related to cannabis use are not limited to edible products. Indeed, regular use of high THC concentrations found in both smoked and edible products are linked to cannabinoid hyperemesis syndrome, which may affect approximately 2.75 million Americans a year and is marked by severe cycles of nausea and vomiting.<sup>lxxxiii, lxxxiv, lxxxv, lxxxvi, lxxxvii</sup>

There is some evidence to suggest that the prevalence of cannabinoid hyperemesis may be on the rise – particularly as potency continues to rise.

For example, in Colorado, the potency in concentrates increased by approximately 21 percent between 2014 and 2017 and symptoms related to cannabinoid hyperemesis syndrome were the most frequent cause of cannabis-related emergency room visits at the UC Health University Hospital in 2017.<sup>lxxxviii, lxxxix, xc</sup>

*Emergency Room Visits:* Between 2006 and 2016, cannabis-related emergency room visits nearly quadrupled, from 17,500 to 68,703.<sup>xc</sup> Of the emergency room visits in 2016, an estimated 16,884 were due to accidental ingestions.<sup>xcii</sup> Though other factors contribute to an emergency room visit related to or caused by cannabis, given the link between increased potency and adverse reactions, potency likely played some role.

The link between increased cannabis potency and emergency room visits is also apparent at the state level. From 2011 to 2017, in Colorado, emergency room visits involving cannabis poisonings increased by 236 percent, and emergency room visits involving cannabis dependence, abuse, or use, increased by 163 percent.<sup>xciii</sup> Throughout this timeframe, the potency of concentrates increased 21 percent.<sup>xciv</sup>

*Monetary Costs Associated With Short Term Consequences of High Potency THC:* Emergency room visits associated with cannabis use come with a hefty price tag. Experts estimate that cannabis-related emergency room visits cost Washington State about \$2.5 million per year (in 2012 dollars).<sup>xcv</sup> In Colorado, a single hospital was estimated to lose \$3.7 million due to unrecuperated costs associated with treating cannabis-related admissions.<sup>xcvi</sup> As potency continues to increase, it is likely that emergency room visits and their associated costs will also increase.

### *Long Term Use Consequences*

The effects of high potency cannabis are not always acute. The risks of addiction and dependence increase as potency increases. In addition, when used frequently, high potency cannabis can increase the chances of psychosis in those that have a predisposition to the disorder.

*Addiction and Dependence:* According to the National Institute on Drug Abuse (NIDA), some studies suggest that approximately nine percent of cannabis users are dependent, and “30 percent of those that use cannabis may have some degree of a cannabis use disorder.”<sup>xcvii, xcvi, xcix</sup>

Cannabis use disorder symptom onset in new users during their first year of use increased significantly, from 1.88 times as likely at 4.9 percent potency, to 4.85 times as likely at 12.43 percent potency.<sup>c</sup>

The association between high potency cannabis and dependence is even more evident in those who use THC concentrates, such as butane hash oil. In a study of college students, those who used butane hash oil had a greater dependence on the drug, even after controlling for confounding variables like the frequency of use and the age of cannabis use onset.<sup>ci</sup>

The Caucus is concerned that more Americans may develop a cannabis use disorder as cannabis use and potency increases. The latest national data already shows concerning trends. For instance, in 2019:

- 31.6 million people used cannabis in the past month.<sup>cii</sup>
- Of these, 827,000 received some kind of treatment for cannabis use, while over 4.8 million reported having a cannabis use disorder.<sup>ciii,civ</sup>

Although State data lags in comparison to national data, it also reflects concerning trends. For example, between 2014 and 2017, California, Colorado, Oregon and Washington State, all had annual average prevalence rates of cannabis use disorder that were higher than the rest of the nation.<sup>cv</sup>

With more Americans using more potent cannabis, addiction and dependence could become increasingly widespread.<sup>cvi</sup>

*Psychosis:* While the exact connection between cannabis and psychosis is still being studied, family history of psychotic disorders and other genetic factors could play a role.<sup>cvii, cviii</sup> In addition, daily use of cannabis that contains 10 percent or more of THC, can increase the chances of developing psychosis by almost five times compared to nonusers, as found in a study using data from 11 sites across Europe and Brazil.<sup>cix</sup> Moreover, researchers have hypothesized that if cannabis potency was capped, the incidence of psychosis could be reduced.<sup>cx</sup>

## *International and Domestic Caps on THC*

In light of the public health concerns related to high potency cannabis, some countries and states within the United States have implemented or attempted to implement THC caps. The results have been mixed.

*International Caps:* While recreational cannabis is legal in the Netherlands, the THC in medical cannabis products does not exceed 22 percent, and the government has considered capping recreational products at 15 percent.<sup>cxv</sup> The Czech Republic caps THC potency in medical cannabis products at 21 percent and Uruguay at nine percent, while products in Israel do not exceed 12 percent.<sup>cxii, cxiii, cxiv</sup>

Canada has taken yet another approach. Rather than capping the THC potency, it caps the THC milligrams per serving size of cannabis products.<sup>cxv, cxvi</sup> It is important to note, however, that limiting milligrams of THC per serving or per package is not the same as limiting the potency of the product. For instance, a package containing 1,000mg of THC with a THC potency of one percent is not nearly as potent as a package with a 1,000mg of THC with a THC potency of 10 percent. As such, simply limiting the THC milligrams per serving may not mitigate the public health effects associated with high potency cannabis.

*Caps in the United States:* Several states, including Colorado and Florida have considered capping THC levels, but these efforts have largely failed.

In Colorado, many lawmakers expressed concern about children ingesting the drug, but others argued that caps could motivate users to try to make chemically volatile cannabis concentrations themselves, potentially leading to unintentional injuries.<sup>cxvii</sup>

In Florida, opponents argued that a 10 percent cap on medical cannabis would limit the drug's effectiveness.<sup>cxviii</sup> Yet, proponents of a cap pointed to studies that indicate that cannabis may lose some of its medicinal properties or even exacerbate the perception of pain at potencies that exceed 10 percent.<sup>cxix, cxx</sup>

Other states have opted to cap the serving sizes of cannabis products, rather than potency, similar to Canada. In California, for example, edibles are limited to 10mg of THC (at any concentration) per serving and 100mg of



THC per package.<sup>cxxi</sup> Non-edibles, including concentrates and topicals are limited to 1,000-mg of THC (at any concentration) per package for recreational use and 2,000mg per package for medical use.<sup>cxxii</sup> Oregon also limits the milligrams per serving for recreational cannabis.<sup>cxxiii</sup>

Despite these efforts, opposition to THC caps remains strong, with opponents arguing that caps will fuel the black market, cut into tax revenue generated by cannabis sales, and ultimately affect jobs.<sup>cxxiv</sup>

### *Conclusion*

Given the increasing number of individuals using high potency cannabis in the United States and the potential adverse public health effects associated with its use, the Caucus believes that the NIH should intensify its research on the short- and long-term impacts associated with high potency cannabis. The Caucus further believes that NIH and the FDA should make a public recommendation as to whether states should cap the potency of products that may be sold in order to mitigate the public health consequences associated with high potency cannabis.

## THE IMPACTS OF CANNABIS USE ON THE DEVELOPING BRAIN

### *Overview*

Studies demonstrate that tetrahydrocannabinol (THC) can enter the fetal brain from the mother's bloodstream and disrupt the endocannabinoid system, which is important for fetal brain development.<sup>cxxv</sup> Moreover, the human brain continues to develop until a person reaches their mid-20s.<sup>cxxvi</sup> Furthermore, some studies have shown that marijuana use can affect brain development and function.<sup>cxxvii, cxxviii, cxxix</sup> Combined, these impacts may result in decreased cognitive abilities, loss of IQ, lower educational attainment, and an increased risk of psychosis.

While more research is necessary to better understand the impact of cannabis use on the fetus and developing brain, available evidence prompted the immediate past Surgeon General to issue an advisory warning that cannabis use is not safe for pregnant women or adolescents.<sup>cxxx</sup>

The Caucus recommends that state and federal public health agencies amplify this warning and implement effective messaging and prevention campaigns regarding the potential dangers of cannabis use in adolescence and among pregnant women.

### *Cannabis Use During Pregnancy*

An estimated seven percent of women use cannabis during pregnancy.<sup>cxxxi</sup> Put another way, women use cannabis more than any other illicit drug when they are pregnant. This level of use may be attributable to dispensaries recommending cannabis use to treat symptoms including morning sickness. In Colorado, for example, 69 percent of surveyed dispensaries recommended using cannabis to treat morning sickness.<sup>cxxxii</sup>

Such recommendations appear to be contrary to existing research which has found that cannabis use by pregnant women may adversely impact the child.<sup>cxxxiii</sup> In fact, the American Academy of Pediatrics has stated cannabis should not be used at any point during pregnancy.<sup>cxxxiv</sup>

Similarly, the American College of Obstetricians and Gynecologists has advised, “[w]omen who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana use.”<sup>cxxxv</sup>

The effects of cannabis use are not limited to fetal development. THC can also be found in breast milk, which may result in newborn hyperactivity, poor cognitive function, and other long-term consequences.<sup>cxxxvi</sup>

For these reasons, many in the medical profession, including the immediate past Surgeon General, have cautioned against using cannabis during pregnancy.

### *Cognitive Function*

Early, heavy cannabis use impacts cognitive functioning, memory, problem solving skills, judgement, and learning.<sup>cxxxvii</sup> The permanency and degree to which these abilities are impaired depends on the age that a person began using, and how much or how long the person used.<sup>cxxxviii</sup> In some cases, as some studies suggest, these impairments do not disappear, even when cannabis use stops.<sup>cxxxix, cxi</sup>

*Memory:* Youth who are dependent on cannabis show short-term memory deficits and delayed recall of visual and verbal information. One study found that even after not using for four weeks, 16 to 18-year-old heavy cannabis users – defined as smoking four to five times per week – did not experience significant improvement in neurocognitive functioning, such as verbal memory.<sup>cxli</sup> Moreover, young adults who reported past use of cannabis had worse verbal memory in middle age than their peers, although processing speed and executive function did not appear to be affected.<sup>cxlii</sup>

*Problem Solving:* Early, heavy cannabis users (defined as those that began cannabis use before age 15) performed worse on abstract thinking and executive functioning tests than non-users and heavy users who began using later in life.<sup>cxliii</sup> Although studies regarding the length of impairment are ongoing, researchers hypothesize that impairments are due to reduced information processing skills in heavy cannabis users.<sup>cxliv, cxlv, cxlvi, cxlvii</sup>

*Judgement:* One study found that heavy cannabis users – those that consumed cannabis 5-7 days a week for the prior two years and who smoked a minimum of 500 joints in their lifetime – may experience impaired judgement when it comes to identifying their own mistakes, monitoring their performance, and making decisions.<sup>cxlviii</sup>

*Learning:* Impairments in memory, problem solving, and judgement can lead to an inability to retain and process new information, jeopardizing the ability to learn.<sup>cxlix</sup> Depending on age of onset and frequency of use, cannabis users

show poor ability to learn new words and complete psychomotor tasks that require executive functioning, particularly those who used during adolescence.<sup>cl</sup>

### *Cannabis and IQ*

Heavy cannabis use is one of many factors that could produce long lasting declines in IQ, yet more research is necessary to determine whether cannabis is *the* causal factor in these declines.

A longitudinal study in New Zealand, which followed a cohort of over 1,000 youth for a period of 25 years, found that early, persistent cannabis use (defined in this case as using cannabis three or more times per week) by teens can result in a drop of up to eight IQ points later in life that may not be recoverable.<sup>cli</sup> A drop of eight IQ points could move someone into the bottom third of the intelligence range.<sup>clii</sup> These findings held true even when researchers controlled for socioeconomic status or personality differences.<sup>cliii, cliv</sup>

Two prospective longitudinal twin studies also found that those who used cannabis could lose up to four IQ points in verbal abilities, and in general knowledge in preteen years (before use) and in adolescence/young adulthood (ages 17-20). However, those involved in these studies who later used cannabis had lower scores on these measures at the outset, and “no predictable difference was found between the twins when one used marijuana and one did not.”<sup>clv</sup> Thus, the declines may be due to genetics or family environment, and may not be solely attributable to cannabis use.

It is important to note, however, that the longitudinal twin studies differ from the New Zealand study in that they did not explore the impact of the dose of cannabis or development of cannabis use disorder. As such, related effects may have been masked.<sup>clvi</sup>

Clearly, more research is needed to determine whether cannabis is the causal factor in declines in IQ. Nonetheless, it is clear that “regular marijuana use in adolescence is part of a cluster of behaviors that can produce enduring detrimental effects and alter the trajectory of a young person’s life—thwarting his or her potential.”<sup>clvii</sup>

## *Performance in School and Life Outcomes*

Adolescent marijuana use is linked to lower educational performance and a higher likelihood of dropping out of school.<sup>clviii, clix, clx, clxi</sup> These risks increase for those who begin using cannabis at an early age. Studies of three Australasian cohorts found early use of cannabis could “contribute up to 17 percent of the rate of failure to obtain the educational milestones of high school completion, university enrollment and degree attainment.”<sup>clxii</sup>

Given that economic stability is often predicated on academic achievement – that is, those with college degrees tend to be employed at higher rates than those without college degrees – cannabis use at an early age can impact future earnings potential.<sup>clxiii</sup>

In a study of long term cannabis users, defined as those who used an average of 18,000 times in their life, and who are now in their 30s, 40s, and 50s, participants reported lower salaries, lower educational attainment and less financial stability, even when controlling for other factors, such as mental health disorders.<sup>clxiv</sup> Researchers found that even when heavy users came from families with similar educational and income backgrounds as study participants who abstained from cannabis use, the heavy users were less likely to complete college and more likely to have incomes of less than \$30,000.<sup>clxv</sup>

## *Psychosis*

While the link between cannabis use and psychosis has been consistent, questions remain about causality—whether cannabis use causes psychosis, or whether those who are already predisposed to psychosis gravitate toward cannabis use, potentially to self-medicate.<sup>clxvi</sup>

Psychosis is defined as “abnormalities in one or more of the following five domains: delusions, hallucinations, disorganized thinking (speech), grossly disorganized or abnormal motor behavior (including catatonia), and negative symptoms.”<sup>clxvii</sup> Schizophrenia on the other hand is “... a severe and disabling chronic mental disorder characterized by deficits in the thought process, perception, and emotional responsiveness.”<sup>clxviii</sup> Heavy cannabis use can exacerbate symptoms in individuals who already have these conditions and can accelerate their onset in those who are predisposed to these conditions.<sup>clxix, clxx</sup>

The association between cannabis use and psychosis/schizophrenia is strengthened when use starts earlier. For example, teens who used cannabis three times or more before the age of 15 were four times more likely to develop symptoms similar to schizophrenia in adulthood than those who had used it two times or less at age 15 and age 18.<sup>clxxi</sup> Research also shows that the likelihood someone develops psychosis later in life may be related to how much cannabis they used at a young age.<sup>clxxii</sup>

### *Federally Funded Research to Better Understand the Long-Term Impacts of Cannabis Use on the Developing Brain*

More research is needed to better understand the scope and duration of impacts that cannabis has on the developing brain. To help address this question, the National Institutes of Health established the Adolescent Brain Cognitive Development (ABCD) Study in 2015.

This study will follow over 10,000 youths, nationwide, for a period of ten years and analyze a wide variety of factors that may affect the developing brain, including drug use. As it relates to cannabis, the study will examine the impacts of occasional use versus regular use of the drug; higher THC levels on the developing brain; and substance use on academic achievement and cognitive skills. It will also examine whether or not the use of one substance leads to use of another.

The Caucus strongly supports this research.

### *The Need for Prevention*

According to the Centers for Disease Control and Prevention (CDC), one out of six adolescents who begin using cannabis before the age of 18 may become addicted.<sup>clxxiii</sup> For this reason, effective prevention programs that implement policies, practices and strategies to delay the age of onset and or reduce the use of cannabis use are critical and can reduce the number of individuals who become addicted. For instance, the federally funded Drug Free Communities program contributed to reductions of 12 percent, 36 percent, and eight percent, among middle school students for alcohol, tobacco, and marijuana, respectively. Similarly, among high school seniors, the program contributed to declines of 24 percent, 39 percent, seven percent and 30 percent, for alcohol, tobacco marijuana and prescription drugs, respectively.<sup>clxxiv</sup>

Moreover, such prevention programs are cost effective: Every dollar invested in prevention can save between \$2 and \$20 depending on how costs are calculated, the outcomes included, and methodologies used.<sup>clxxv</sup>

### *Conclusion*

Early cannabis use negatively affects brain development, which may result in decreased cognitive abilities, loss of IQ, lower educational attainment, and the development of psychosis. The extent to which these changes are permanent largely depends on age of onset and frequency of use.

For these reasons, the Caucus strongly supports the immediate past Surgeon General's warning that no amount of cannabis use is safe during adolescence, and encourages federal, state, and local efforts to amplify this warning through the implementation of effective prevention and awareness programs to ensure that adolescents, pregnant, and nursing women are aware of cannabis's potential impacts on the developing brain and fetus.

## UNREGULATED PRODUCTS

### *Overview*

The Food and Drug Administration (FDA) plays a critical role in regulating cannabis products that fall within the agency's jurisdiction and is responsible for assessing their safety, quality, and in the case of drugs, their effectiveness. The proliferation of products containing cannabis or cannabis-derived ingredients, including cannabidiol (CBD) necessitates that the FDA and other federal agencies be more engaged.

Until the enactment of the *Agriculture Improvement Act of 2018*, commonly referred to as the *Farm Bill*, the *Controlled Substances Act (CSA)* did not differentiate between cannabis, hemp, or CBD. Upon its enactment, a new and distinct definition was established for hemp, and hemp was removed from the list of controlled substances.

As a result of its removal, the hemp industry has begun to more aggressively market an array of hemp-derived products, including dietary supplements, foods, and the like. The FDA has found that many of these products are marketed using false medical claims and many are inaccurately labeled, which could lead to adverse consequences for an unsuspecting user.<sup>clxxvi</sup> Given that the *Farm Bill* expressly preserved the FDA's role in regulating hemp-derived products, including CBD, the agency should utilize this authority.

Similarly, the Federal Trade Commission (FTC) prohibits unfair and deceptive advertising under Sections 5(a) and 12 of the *Federal Trade Commission Act of 1914*. Specifically, "it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made." Unfair or deceptive advertising includes express or implied statements made by third party endorsers. FTC should continue working to ensure consumers know which businesses are selling false goods, especially those products with expressed therapeutic efficacy.



## *Changes in the Regulation of Hemp*

The *Farm Bill* defined hemp as “the cannabis plant, or any part thereof, including its extracts and cannabinoids, having a tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.” The *Farm Bill* ensured that any cannabinoid that is derived from hemp will be legal if the hemp is produced consistent with the statute, associated state and federal regulations, and by a licensed grower. Any CBD products produced outside of those circumstances would remain a schedule I drug, with the exception of pharmaceutical-grade CBD products that have been approved by the FDA.<sup>clxxvii</sup>

In order to meet the definition of hemp, and qualify for the exemption from schedule I, the derivative must not exceed the 0.3 percent THC limit. The Drug Enforcement Administration retains its authority of products that exceed that limit and have promulgated regulations that outline their role.<sup>clxxviii</sup>

### *CBD as an Active Pharmaceutical Ingredient*

Prior to the enactment of the *Farm Bill*, the FDA granted an investigational new drug (IND) application for CBD to GW Pharmaceuticals. The company then tested CBD in clinical trials to develop Epidiolex.

The FDA ultimately approved Epidiolex, whose active ingredient is CBD, to treat two types of intractable epilepsy, and later approved a third condition for which the drug may be used.<sup>clxxix</sup> While initially placed in schedule V, Epidiolex was ultimately removed from the list of controlled substances.<sup>clxxx</sup>

### *CBD as a Supplement*

The *Federal Food Drug and Cosmetics Act* (FD&C Act) states that if a substance has been authorized for use in an IND or is an active ingredient in an approved drug, it cannot subsequently be marketed as a dietary supplement.<sup>clxxxi</sup> Likewise, the FD&C Act also prohibits any substance from being sold in a food product if that substance “is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.”<sup>clxxxii</sup>

In other words, the FDA has determined that because CBD was not marketed as a dietary supplement or conventional food prior to GW Pharmaceuticals being granted an IND and gaining the FDA’s approval of Epidiolex, CBD cannot currently be legally marketed as a dietary supplement or included in food products.

Per the FDA, “when a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the *FD&C* Act, the exclusion applies unless FDA, in the agency’s discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the *FD&C* Act. To date, no such regulation has been issued for any substance.”<sup>clxxxiii</sup>

Despite this, the FDA appears to be leaving the door open to potentially issuing regulations related to CBD in the future, and is seeking additional information to “obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds.”<sup>clxxxiv</sup> In particular, the FDA is seeking additional information on topics related to CBD’s impacts, including but not limited to its impacts on the following:

- The liver;
- The eyes;
- The use of CBD in combination with other medicines, alcohol, dietary supplements, tobacco products, and herbal products;
- Neurological development, including on learning, cognition, and behavior;
- The ability to drive and operate heavy machinery;
- Vulnerable populations, including on children, the elderly, and women who are pregnant or breastfeeding

### *False Marketing and Mislabeling*

The *FD&C* Act notwithstanding, companies continue to market CBD products as dietary supplements and in various food products. By 2022, the CBD market is expected to top \$2 billion.<sup>clxxxv</sup>

Many companies market their products using unsubstantiated medical claims, including that they can treat Alzheimer’s disease or stop cancer cell growth.<sup>clxxxvi</sup> Moreover, many products that are on the market do not contain the level of CBD claimed in the labeling.<sup>clxxxvii</sup>

In both 2019 and 2020, the FDA tested a sample of CBD products. The FDA has acknowledged that its sample size was small and not necessarily representative, and has since developed a methodology to create a more representative, random sample of the current CBD market place. Nonetheless, even the small sample size demonstrates that more industry accountability is needed.

For example, in 2019, the FDA identified 34 CBD products for testing, of which 31 were subsequently tested for cannabinoids. Of these 31 products, 21 products claimed to have a specific amount of CBD, but only a third of these came within 20 percent of the levels of CBD contained on the label.<sup>clxxxviii</sup> Moreover, of the 31 products tested for cannabinoids, 48 percent contained THC. Similarly, in 2020, of the 102 products that the FDA tested and which claimed to have a specific amount of CBD, 18 contained less than 80 percent of the amount of CBD indicated, 46 contained CBD within 20 percent of the amount indicated and 38 contained more than 120 percent of the amount of CBD indicated.<sup>clxxxix</sup>

### *Impacts of False Marketing and Mislabeling*

There have been several notable public health investigations tied to mislabeled CBD products. In 2017, 52 individuals in Utah suffered from acute poisoning from a synthetic cannabinoid that was marketed as CBD.<sup>cx</sup> Individuals experienced adverse reactions, including altered mental status, seizures, confusion, loss of consciousness, and hallucinations.

In response, state and federal law enforcement officials established a task force to identify the source product. The task force identified nine product samples that were labeled as CBD oil, but were found to contain a synthetic cannabinoid, 4-cyano CUMYL-BUTINACA (4-CCB) instead. Eight of those products were branded as, “Yolo CBD oil” and had no information about the manufacturer or ingredients. Blood samples from the hospitalized individuals were positive for 4-CCB. In total, 33 of the 52 patients had used the Yolo CBD product and 31 had emergency room visits.

In 2019, the Associated Press conducted an investigation on CBD vaping products that were suspected in causing the hospitalization of a man in Lexington, South Carolina with acute respiratory failure and associated with at least 11 deaths in Europe. The investigation uncovered several products that were marketed as CBD, but were instead found to have synthetic cannabis known as MMB-FUBINACA.<sup>cxci</sup>

Another synthetic cannabinoid led to the hospitalization of an eight-year-old boy in Washington State in 2019. His parents had purchased CBD oil online to treat his seizures. The product was found to contain AB-FUBINACA which induced delirium and a rapid heart rate.<sup>cxcii</sup>

Mislabeled products continue to put consumers and patients at risk while manufacturers find new ways to market and sell these false or contaminated goods.

### *Warning Letters*

Pursuant to the *Farm Bill*, the FDA maintained its authority to regulate hemp-derived products, including hemp-derived CBD. Yet, the FDA has not broadly exercised this authority. Instead, although the FDA has acknowledged that it is “aware that some companies appear to be marketing products containing cannabis and cannabis-derived compounds in ways that violate the law,”<sup>cxci</sup> the agency has prioritized enforcement against companies and products that pose the greatest risk to consumers. Most often, this enforcement has taken the form of a warning letter.

Since the enactment of the *Farm Bill*, the FDA has issued at least 30 warning letters to companies related to the sale or marketing of CBD products.<sup>cxci</sup>

### *Recent Enforcement Actions*

In December 2020, the FTC announced the first law enforcement crackdown on deceptive claims by manufacturers of CBD products. The FTC took action against six sellers of CBD products for making a wide range of unsupported claims about their ability to treat serious health conditions including cancer, heart disease, hypertension, and Alzheimer’s disease. These manufacturers are required to halt making any unsupported health claims and some faced monetary judgements.<sup>cxci</sup>

These actions were taken as part of FTC’s ongoing effort to protect consumers from false and misleading health claims, many of which are made in online advertisements and through social media.

## *Policy of Enforcement Discretion*

Given the removal of hemp and hemp-derived CBD from the CSA, Congress has pushed the FDA to implement a policy of enforcement discretion; that is, to outline the circumstances under which the FDA will not take action against companies manufacturing or selling products, including dietary supplements containing hemp-derived CBD. Specifically, the explanatory statement associated with *the Further Consolidated Appropriations Act, 2020* directed the FDA to provide, within 60 days of enactment, “a report regarding the agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in products.”<sup>cxv</sup>

In its report, the FDA stated that it is “currently evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding factors the agency intends to take into account in prioritizing enforcement decisions. Any enforcement policy would need to further the goals of protecting the public and providing more clarity to industry and the public regarding the FDA’s enforcement priorities while we take potential steps to establish a clear regulatory pathway.”<sup>cxvii</sup>

## *Conclusion*

Given that the FDA is currently seeking additional scientific information related to the potential impacts that CBD may have on everything from the liver, to driving abilities to the developing brain, the Caucus urges the FDA, in conjunction with any other relevant federal departments and agencies, to continue exercising its enforcement authorities with respect to hemp and its derivatives, including CBD. The FTC should also continue working to ensure consumers know which businesses are selling false goods, especially those products with expressed therapeutic efficacy. Americans must have peace of mind that CBD and cannabis-derived products purchased through a legal and legitimate marketplace are safe and all effects are known.

## CANNABIS IMPAIRED DRIVING

### *Overview*

Cannabis use impacts judgement and coordination, two functions that are critical to driving.<sup>cxviii</sup> Moreover, cannabis use slows the reaction time of drivers, which can increase the risk of motor vehicle accidents.

Nationally, between 2013 and 2016, the percentage of drivers involved in fatal crashes who tested positive for cannabis increased by an average of 10 percent, a concerning rise.<sup>cxix</sup> However, since the mere presence of cannabis in the bloodstream is not indicative of impairment, “the role played by marijuana [cannabis] in crashes is often unclear because it can be detected in body fluids for days or even weeks after intoxication.”<sup>cc</sup> For this reason, more research is needed on the best ways to determine and detect impairment.

A universal standard to detect cannabis impaired driving does not exist, resulting in a patchwork of state laws. To better protect motorists from the potential dangers associated with cannabis impaired driving, it is important to fund and train drug recognition experts to perform field sobriety tests; support robust funding for data collection; and expand toxicology and forensic lab testing so that the full extent to which cannabis impairment involved in fatal and nonfatal car accidents can be determined.

### *State-Level Cannabis Impaired Driving Laws*

For alcohol, it is well established that a blood alcohol concentration (BAC) of .08 or more means a driver is impaired. In recognition of this, the *Department of Transportation's 2001 Appropriations Act*, conditioned a portion of federal highway construction funds for states on whether a state had enacted legislation making it illegal to drive with a BAC that exceeded .08 by 2004.<sup>cci</sup>

Given its status as a schedule I substance, and the difficulties associated with using blood and other tests to determine impairment, similar federal legislation does not exist for cannabis. All states have laws that make it illegal to drive while impaired by either alcohol or other drugs. Under these laws, “the State must prove that the drug caused the impaired driving.”<sup>ccii</sup> In addition 19 states have implemented one of three basic types of laws that are specific to cannabis: 1) zero-tolerance laws, which make it illegal to drive with any detectable amount of cannabis, or in some cases, cannabis metabolites, in the body; 2) per se laws which

limit the number of nanograms per milliliter of cannabis that individuals can have in their bloodstream and still be permitted to drive; or 3) reasonable inference laws, which assume drivers are impaired if they have five or more nanograms per milliliter of blood in their body.<sup>cciii</sup>

### *Cannabis Use Is Increasing Among Drivers in the United States*

While some states have seen decreases in cannabis-related driving incidents and accidents, these decreases are not universal. Additionally, unlike alcohol impaired driving, which primarily occurs on nights and weekends, cannabis impaired driving occurs throughout the day.<sup>cciv, ccv, ccvi</sup> This makes targeted enforcement efforts, like DUI checkpoints, difficult, regardless of a state's law.

An increasing number of states are finding that cannabis is the most commonly detected drug in impaired drivers: between 1999 and 2010, cannabis was the most frequently detected drug among drivers in six states. Moreover, the prevalence of cannabis in these drivers increased at a rate of 190 percent, from 4.2 percent to 12.2 percent.<sup>ccvii</sup>

The statistics below reflect more recent data, and also highlight a troubling trend of polysubstance use among drivers:

- In nine counties in California, there was a 69 percent increase in arrests made for driving under the influence of cannabis between 2017 and 2018. During this same timeframe, there was also a 171 percent increase in motor vehicle crashes directly involving cannabis.<sup>ccviii</sup>
- In Colorado, between 2013 and 2017, the number of drivers involved in fatal car accidents who tested positive for either cannabinoids-only or cannabinoids-in-combination with other substances increased by 183 percent.<sup>ccix</sup>
- In Massachusetts, 31 percent of fatally injured drivers between 2013 and 2017 tested positive for cannabis, making it the most prevalent drug detected.<sup>ccx</sup>
- In Michigan, crash-involved drivers testing positive for delta-9-THC or other cannabinoids increased by 120 percent between 2013 and 2017. Of these drivers, 11 percent also had blood alcohol levels that exceeded the legal limit of .08.<sup>ccxi</sup>

These statistics, particularly those involving fatal crashes, are likely under-reported, as medical examiners and coroners do not always test victims of crashes for the presence of cannabis.<sup>ccxii</sup>

### *Limitations of the Data*

The number of drivers testing positive for cannabis use throughout the country is concerning. Yet, the limitations of the data make drawing definitive conclusions difficult, and underscore the need for better training for law enforcement officers, uniform testing, increased forensic or toxicology lab capacity, and uniform reporting. The limitations described below exist at the local, state, and federal levels.

*THC Presence and Duration in the Blood:* THC is fat-soluble, which means it can remain in the bloodstream for up to 30 days. As a result, presence of THC in the blood does not equate to impairment. Therefore, tests akin to those used to determine blood alcohol concentrations are not well suited to determine cannabis-related impairment.<sup>ccxiii</sup>

*Testing:* Not all states test for cannabis impairment in a uniform manner. Some use drug recognition experts to conduct field sobriety tests, while others use blood draws or oral fluid samples. Moreover, the rates of testing at the state level are often inconsistent and unreliable.<sup>ccxiv</sup>

For states that use laboratory tests, best practices are generally lacking, and the cut-off levels to determine impairment often vary between and among jurisdictions and states. This is problematic because “different cut-offs lead to different interpretations of results, producing inconsistencies between jurisdictions. Lower concentrations may result in drivers testing positive in one area of the country, whereas the same driver may test negative in another jurisdiction. Of concern, cut-off values that are too high can result in impaired drivers avoiding detection. These variations across lab protocols make it difficult to draw conclusions regarding the number of drivers under the influence of drugs, and whether they are in fact impaired.”<sup>ccxv</sup>

*Disincentives to Test:* Forty-seven out of 50 states do not stack the penalties for driving under the influence.<sup>ccxvi</sup> That is: whether a person is driving under the influence of alcohol alone or alcohol in addition to cannabis or another substance, the penalty is the same. Thus, it is a disincentive for law



enforcement to test for cannabis specifically, in addition to alcohol, if the penalty does not change.

*Forensic and Toxicology Lab Capacity:* In many instances, the tests, equipment, and personnel needed by forensic and toxicology labs to conduct discrete tests for cannabis, alcohol, and other drugs are cost prohibitive. This limits the capacity of such labs, and can result in not all labs being able to test specifically for cannabis use.

*Lack of Standardized Reporting:* Taken together, the lack of funds for forensic and toxicology labs and the disincentives for law enforcement to collect samples that can be tested by those labs in the first place severely limits the accuracy of data (through under reporting) that local, state, and federal governments have with respect to cannabis. This inhibits the ability of individuals at any level of government to determine an effective policy to protect the public health and safety of drivers and others on the road from cannabis impaired drivers.

Moving forward, the Caucus supports more standardized testing and data collection and sharing of information between and among jurisdictions, states and federal agencies to ensure more consistent and reliable data to inform public policy.

### *Research to Better Determine Impairment*

Research is currently underway to determine if tests other than blood, are reliable indicators of impairment.

*Oral Fluids:* While the detection window for cannabis in oral fluid is similar to that for detection in a blood draw, oral fluid testing is generally preferable because it is easy to administer, cheaper, and samples can be more easily obtained at the time law enforcement stops an individual for suspected impaired driving.<sup>ccxvii</sup>

One survey of toxicology laboratories in the United States and Canada found one percent of labs reported the use of oral fluid tests.<sup>ccxviii</sup> These tests, while promising, only provide law enforcement officers with probable cause for arrest, and are not admissible as proof of impairment in court.<sup>ccxix</sup>

Sweat: To date, researchers have been unable to draw conclusions as to whether a specific cut-off level for metabolites found in sweat is a reliable indicator of impairment, or the degree to which contaminants cause false positives.<sup>ccxx, ccxxi, ccxxii</sup>

Breathalyzers for Cannabis: Several companies are developing breathalyzer tests designed to detect cannabis impairment. However, the admissibility of these tests as proof of impairment in a courtroom has been challenged because the guidelines regarding the ratio of consumption to impairment are still unknown.

In addition to privately funded research, the National Highway Traffic Safety Administration (NHTSA) supports research on testing mechanisms to better detect cannabis impaired driving, specifically in the following areas:

Standardized Field Tests: NHTSA has conducted a literature review on tests used to detect impairment, including tests of cognitive ability, behavioral tests, tests of physical capability, physiological tests, and driving skills tests.

It is currently using laboratory tests “...to assess the accuracy, feasibility, and utility of individual tests, and potential combinations of tests, to work towards the development of a standardized battery to determine whether a person has recently used [cannabis].”<sup>ccxxiii</sup>

The Effects of Inhaled Cannabis on Driving Performance: NHTSA is also studying the impacts of inhaled cannabis and alcohol in combination with inhaled cannabis on driving performance, decision-making, psychomotor control, risk-taking, and divided attention tasks through the use of a human motor vehicle driver simulator.<sup>ccxxiv</sup>

Evaluating Oral Fluid Drug Screening: Additionally, NHTSA is researching the effectiveness of five oral fluid screening tests that are currently available.<sup>ccxxv</sup>

## *Drug Recognition Expert and Advanced Roadside Impaired Driving Enforcement Programs*

In the absence of a universal standard to detect cannabis impaired driving, law enforcement typically relies on field sobriety tests, which can be used to establish probable cause that a driver is impaired.<sup>ccxxvi</sup>

*Drug Recognition Experts (DRE):* DREs are law enforcement officers who receive extensive training on conducting field sobriety tests to determine impairment. While there are approximately 9,900 DREs nationwide, this represents just over one percent of all law enforcement officers in the country.<sup>ccxxvii, ccxxviii, ccxxix</sup>

In order to become a certified DRE, officers are required to complete 72 hours of training related to physiology, vital sign detection, and administering field sobriety tests; complete 40 to 60 hours of field work; and pass 12 evaluations.<sup>ccxxx, ccxxxi</sup> DREs must pass a re-certification test every two years, and every state has a DRE coordinator who is responsible for ensuring that DREs throughout the state comply with the international standards of drug evaluation.<sup>ccxxxii</sup>

*Advanced Roadside Impaired Driving Enforcement (ARIDE) Program:* The ARIDE program ensures law enforcement officers, prosecutors and toxicologists have baseline training on how to properly determine impairment. Much less intensive than the DRE program, the ARIDE program trains participants on seven drug categories, assessing signs of impairment, pre- and post-arrest procedures, writing reports, and providing courtroom testimony.<sup>ccxxxiii, ccxxxiv</sup> In 2018, approximately 14,000 individuals received ARIDE training.<sup>ccxxxv</sup>

Both the DRE and ARIDE programs are managed by professional law enforcement associations such as the International Association of Chiefs of Police (IACP) and the National Sheriffs' Association using funding and technical assistance from NHTSA as well as state grants. In FY20, NHTSA provided roughly \$1 million to IACP through a cooperative agreement for DRE and ARIDE training. IACP used this funding to make DRE/ARIDE training grants to nine law enforcement agencies across the country.

Although some have criticized the DRE program as being subjective, evidence shows that, when confirmed by laboratory tests, most DRE programs have accuracy rates of 90 percent.<sup>ccxxxvi</sup>

### *Innovative Ways to Address Cannabis Impaired Driving*

Recognizing the dangers associated with impaired driving, states have begun implementing specialized Driving Under the Influence (DUI)/Driving While Intoxicated (DWI) courts, which provide treatment, supervision and accountability for repeat DUI/DWI offenders, including those impaired by cannabis.<sup>ccxxxvii</sup> There are currently 726 DUI/DWI courts nationwide.<sup>ccxxxviii</sup> These courts have reduced recidivism rates, in some cases, by as much as 60 percent.<sup>ccxxxix</sup> DWI courts are also cost effective. Every dollar invested in DWI courts results in a savings of \$3.19.<sup>ccxli</sup>

Innovative programs, like DUI/DWI courts should be replicated.<sup>ccxli</sup>

### *Conclusion*

Cannabis affects a driver's judgement and coordination, which threatens public safety. In light of this, the Caucus urges the Department of Transportation, through NHTSA, to accelerate research regarding the development of an accurate standard to detect cannabis-impaired driving.

The Caucus further recommends that forensic and toxicology labs be funded at the highest possible level, and that such labs be required to conduct test specific to cannabis use.

Moreover, the Caucus urges NHTSA to work with states and localities to establish a uniform reporting system to collect information on cannabis-related driving incidents nationwide.

Finally, the Caucus strongly supports funding the DRE and ARIDE programs at the highest possible levels to ensure that the maximum number of law enforcement officers and other court personnel are trained on recognizing signs of cannabis and other drug impaired driving and supports the expansion of innovative, effective models such as DUI/DWI courts.

## CONCLUSION

Cannabis-related research has largely been stymied in the United States due to overly burdensome regulations. This has inhibited our understanding of its potential medical utility as well as its public health impacts. Moving forward, it is important that Congress, federal agencies, and other policy makers consider evidence-based policies related to cannabis and its derivatives, including cannabidiol (CBD).

In order to better understand the health effects of cannabis and cannabis-derived products, the Caucus urges Congress to pass legislation to reduce the barriers associated with researching cannabis and CBD. Absent more robust research, policy makers have little information or evidence upon which to base future decisions related to cannabis.

While more research will help to better understand cannabis's larger impacts on brain cognition and long-term health consequences, currently available research demonstrates that there are potential risks associated with its use. For this reason, the Caucus encourages the Food and Drug Administration (FDA), U.S. Surgeon General, the National Institute on Drug Abuse, and other federal partners in public health to update the American public on these potential risks, especially for pregnant mothers, children and young adults and any person with an underlying mental health condition.

The Caucus also takes seriously the false claims and misleading practices undertaken by some manufacturers to market their products as therapeutics without scientifically supported evidence. The Caucus supports the FDA and the Federal Trade Commission in their efforts to combat these unfair and deceptive practices and encourages them to exercise their full enforcement authorities against unscrupulous actors. The Caucus also expects the FDA to ensure Americans know all the risks associated with any CBD-derived product. Americans must have the peace of mind knowing what they are buying is what the vendor actually says it is selling, not some cheap imitation or false sense of hope.

Lastly, more research is needed for accurate detection of cannabis-impaired driving and for the development of a standard field test. Law enforcement officers are not receiving sufficient training on detecting cannabis-impaired drivers. It is vital that more resources are allocated towards forensic and toxicology labs to ensure that testing for cannabis-impaired driving is expanded and so data can be collected to accurately account for the scope of the problem.

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